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Marianne O'Hare: Welcome to Conversations on Health Care with Mark Masselli and Margaret Flinter, a show where we speak to the top thought leaders in health innovation, health policy, care delivery, and the great minds who are shaping the healthcare of the future.

This week Mark and Margaret speak with Dr. Eric Topol, Founder and Director of the Scripps Translational Research Institute, a renowned cardiologist with multiple patents to his name. He's become a leading advocate in promoting personalized genomic space medicine. Since the pandemic Dr. Topol has focused on galvanizing input from the digital health community to promote better national surveillance of the path of COVID-19.

Lori Robertson also checks in, the Managing Editor of FactCheck.org and looks at misstatements spoken about health policy in the public domain, separating the fake from the facts. We end with a bright idea that's improving health and well being in everyday lives.

If you have comments, please e-mail us at chcradio@chc1.com or find us on Facebook, Twitter, or wherever you listen to podcasts. You can also hear us by asking Alexa to play the program. Now stay tuned for our interview with Dr. Eric Topol here on Conversations on Health Care.

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Mark Masselli: We're speaking today with Dr. Eric Topol, Founder and Director of the Scripps Research Translational Institute. He's the Executive Vice President of Molecular Medicine at Scripps Research.

Margaret Flinter: Dr. Topol has published more than 1200 peer reviewed papers, multiple bestsellers, and is the Editor-in-chief of the health industry publication Medscape. Dr. Topol, we welcome you back to Conversations on Healthcare.

Dr. Eric Topol: Thanks, good to be with you both.

Mark Masselli: You know vaccine distribution has been accelerating with Pfizer, Moderna, and Johnson vaccines, all receiving swift emergency authorization, but there are concerns about AstraZeneca's vaccine and possible cherry picking of safety data that they supply to the federal regulators and some possible side effects that we've all been reading about in Europe. I wonder if you could just address the AstraZeneca controversy and whether it might fuel distrust or mistrust around other vaccines.

Dr. Eric Topol: Right. Well, this is a very significant issue with respect to the cherry picking of data. So what we understand and we're awaiting the final

data is that the Data and Safety Monitoring Board, which is the same one for all the vaccines, except for Pfizer, so called Operation Warp Speed working with NIH, they were in constant communication with AstraZeneca through the course of their United States trial. During that trial, as it came to the end in March, the Data and Safety Monitoring Board saw the final data set and they said, that's what you should be disseminating. But rather, instead AstraZeneca decided to use the data from February 17, which is not the final data, it was an interim analysis. It was incomplete. Based on the communications that we know of now, the efficacy is not 79%, as was broadcasted by AstraZeneca on Monday this week, and what we don't know is the real number.

Now, the vaccine is, I'm sure, is going to be efficacious. We know that. But why would the company not give the right data. And this is unprecedented in my career as far as experiencing clinical trials. It's very disturbing and it undermines trust. So it's very likely that the EUA will be granted in the weeks ahead by the FDA for this vaccine but this was unnecessary. This was a kind of self-inflicted damage, unfortunately, and it's not the first time this company has done that. There are issues that are beyond that. The one you mentioned with respect to these rare clotting events that occurred in multiple European countries and stirred a lot of concern last week, Germany, Norway, Spain and others. These are rare likely vaccine induced exceedingly rare. They are young, healthy people that get this very low platelet count and then develop clotting that's quite diffuse multi organ.

Now, this can occur with all the vaccines, any vaccine. It sets off an immune response. The thing that is disturbing here is it looks like it has slightly increased risk with this vaccine. And again, lack of transparency, that's the theme. Instead of giving us a full disclosure of all the cases and what happened so the medical community will have complete confidence they didn't do that. They just said it's not related to the vaccine or it's very rare. I'm sure it is exceedingly rare, but the way to diffuse this is to provide the data and be transparent. So this has been a problem with this particular vaccine manufacturer from the inception of the program for COVID.

Margaret Flinter: Well, I think you're absolutely right, that transparency is what's critical and in order for us to be able to communicate that to the people that we're trying to get vaccinated, we have to have confidence in the data so that we can give them assurance that that confidence is there. So thank you for being so clear about that. One of the big concerns that we are hearing about, reading about, and that people are talking about now, in our part of the country and I think nationally and really across the world is the issue of the variants---the UK variant now the dominant strain in the US, certainly reading about what's happening

in Brazil, cases across Europe spiking. What's most concerning to you about the impact of variants in this phase of the pandemic? I dare I say, we thought we had just climbed a little bit towards the top of the hill and it looks like the hill just moved ahead of us.

Dr. Eric Topol: Right. Well, this is the main topic of the day for the pandemic in the United States, for sure, is what about these variants. The one that is most concerning is this UK B117. The reason for that is, it's so highly infectious. It has a higher lethality and it is, as you say, going to become the dominant strain throughout the world and in certain parts of this country it already has reached at greater than 50% a cause of infection. Now, the good thing is, we maybe able to fend this off because the US has done a very good job with vaccinations, maybe not perfect by any means but we have some 86 million people who had at least one dose, which is more than one in every four Americans. We have over 70% of the high risk group age greater than 65, who've had at least one dose. So we've done pretty darn well in these months since late December. If we do fend off the B117 as far as in not causing a big surge in cases, it'll be because of that, because on the other hand we've relaxed mitigation and many states have opened up and the wrong thing to do at this juncture.

The good thing about that variant is it's highly responsive to vaccines. The vaccines that are being used should or against it and that's kind of the picture with the UK variant. The other variant, particularly the South African variant and the Brazil, they are different. Their main property is so called immune evasion. That is the vaccines won't work quite as well, particularly the South African one is more in that line. But the transmission or infectiousness doesn't appear, at least at this juncture to be as problematic. Now there are reports in Brazil, it could be 250% or more. But that doesn't really make sense because we know the transmission for the UK variant is about 50% increased, if it was 250% increase for the Brazil variant, we would know it by now around the world. So their main issue is re-infection for people who've already had COVID. But they're not going to be outrun by B117. That's the strain that's going to take over the world.

The one that can transmit the best is the one that's most fit and so that's what we're going to see in the in the next few months. Now, what about the New York variant? What about other new variants? The New York variant appears to be more like the Brazil and South African with this immune evasion property, not so much the high transmissibility. We may see other variants because we still don't have this virus in check. Remember, this is a worldwide story. We're seeing big surges in central Eastern Europe, and also in South America, and even in Western Europe, in places like Italy and other countries. So we're not over with this pandemic, the only thing that we can do now is not relax mitigation and keep up with the aggressive

vaccination and maybe we'll get through this. We're going to get through it the question is when, and I'm still optimistic that by end of June, we'll be in very good shape.

Margaret Flinter: Great.

Mark Masselli: Well, that's good news. And really speaking of those variants, and there have been a few recent studies that have been published, they've shown a number of vaccinated patients are testing positive, small numbers. I'm wondering that could be connected to this growing number of variants, you're talking about the B1526 the New York one and obviously the bigger one the B117 from England. I guess perhaps it's just another reminder that even if you get the vaccine, it's important to be vigilant with the public health protocols, as you were saying, while vaccination efforts continue to scale.

Dr. Eric Topol: This so called breakthrough when you've had a vaccine and you get COVID, so far it's actually remarkable that it hasn't been associated with symptoms. It's like the chance of you getting sick after the vaccine. It's just remarkable. I take this moment just to point out a paper that we wrote, Dennis Burton and I, Super Human Vaccines. That's what this is. We're so lucky. I mean, I just can't even emphasize this enough now that we have these vaccines with extraordinary efficacy that are better than our immune system. Better, far better. So the point is, if you just had COVID, you could get a re-infection. But if you've had the vaccine, the chances of you getting an infection, just so symptomatic it so incredibly low. Now, you could harbor the virus in your nasal mucosa and you could potentially not low likely, but you could potentially be a carrier. But the chance you getting sick is it's not nil but it's very low, very, very low. So these vaccines are just one of the greatest triumphs of biomedicine in history.

Margaret Flinter: Well, I really appreciate the absolute enthusiasm you have about that. I think it's so true and I'm not sure that message has been broadcast out there as loudly as it should. So thank you for that. Along with that certainly we need to celebrate what the President has said, science is bad back under President Biden, and we're seeing this with the CDC and the way they're coming forth with their information. Certainly there was some erosion of confidence and trust in some of our vital public institutions over the last year. What are you seeing coming up in terms of how this administration is going to use the lessons from last year to build a more robust public health infrastructure in the country and to restore trust in science and in public health?

Dr. Eric Topol: Well, you know, it hasn't been all that long since January 20th to now and we've seen remarkable strides. The thing that I think about every day is if we had the current administration a year ago, what kind of different footing we'd be on right now, and we wouldn't have lost over 530,000 Americans. So I see the restoration of trust is happening

quickly and the funding for both the shunting of $200 million from the government to the CDC for genomic surveillance, in addition to the a good portion of the 1.9 trillion in the rescue package, these are things that are going to help restore the public health ability to execute, to support opening in schools, to support rapid testing, to support all the things that we shouldn't have been doing a year ago. So I do think, and the vaccination obviously, we've been relying on just tens of thousands of volunteers throughout the country. But if we had that better support, we could do better and go faster. So these are all the things that we need to really take control of the pandemic, contain the virus, and put it behind us, which we will, but fortunately we're on the right path now.

Mark Masselli: We're speaking today with Dr. Eric Topol, Director of the Scripps Research Translational Institute and editor of Medscape. His twitter feed has become a trusted daily digest of scientific analysis around COVID-19. I'm wondering Dr. Topol, the pandemic has really accelerated the pace of life science research. It often takes decades to just a very short window. I'm wondering if you could just talk about some of the remarkable scientific achievements that have been realized. Certainly, you just were talking about the vaccine, but monoclonal antibodies, digital surveillance, telehealth. Has this cross walked over into any other disease state or laid the foundation for some promising research?

Dr. Eric Topol: Right Mark, well, I did write a short essay recently at Wall Street Journal on that. I think what the points I was trying to get across or just what you're alluding to. We've never seen a vaccine just get developed in 10 months from the identity of the pathogen. Usually that's average for the successful vaccines, eight years, and usually the review by the FDA is a year, not three weeks, and everything has gone into a lightning speed, likes of which we've never seen in the history of biomedicine. Now, the exciting part of this is that it not only sets new standards or how fast we can move, but also like, for example, the mRNA platform used for the vaccines can be used and is being used to develop cancer vaccines, to develop autoimmune disease interventions, and even nerve degenerative intervention.

So we have now a whole new biotechnology that's been validated now used in hundreds of millions of people, which we didn't have before. So the spinouts here, it's kind of like remember how the NASA program we learned all these things in space that ultimately changed medicine like holter monitors and everything, it's kind of the same thing. We learned from the pandemic. We are deriving so many vital advances and speed, which used to be until now the average time from an innovation to clinical practice use was 17 years, and we've done that in less than a year. I mean, it's astounding. As a student of medicine for over three decades I'm stunned by this every day and

that's what really gets me enthralled about how the progress has been made.

Margaret Flinter: Well, that's incredibly exciting. I will say that the pandemic has maybe overshadowed, I think, a little bit of the incredible work that has been done over the last several years, and a project that you've been guiding the All of Us Precision Medicine Initiative at the NIH, which we've been proud to participate in and to learn from and to share with people around the country. It seems to me that that project, leveraging genomics and biometric data and AI, really focusing on engaging people who have not, and communities have not always been well represented in research, maybe had a lot to teach us in this pandemic, as well, about how we engage people, how we gain their trust, how we bring people in for a service or care or participation where they might have been left out. I'm really curious, since you sit in so many positions of leadership across these communities, have the lessons of the All of Us program informed some of the recommendations about how we address the pandemic and also vice versa, we've learned things in this pandemic, that will be helpful in the All of Us program, which for listeners who may not be as familiar is a long term project that Dr. Topol leads.

Dr. Eric Topol: Well, the All of Us is most ambitious medical research program in American history, pushing 400,000 participants to be followed for decades ahead. What's interesting here is more than half are underrepresented minorities and the real, I think, goal is getting every one of these people to become citizen scientists, if they weren't already. Now, during the pandemic, we've seen that again with people with long COVID. They form peer groups, they are citizen scientists. They're participating not just in surveys but now with sensors and testing whether or not vaccines will help them get out of long COVID. So we're seeing a citizen science movement, which it annotated all of us, but it's getting amplified now. It's really terrific to see because we can engage with all these people remotely through their phone, and we can get their data back to them. And we are all basically democratizing medical information trying to help each other. So we learn from it not just overall, but at the individual level, I think that's really gratifying.

Mark Masselli: I want to pull the thread on a couple of things that we've talked about, and you said, and certainly, we're in a different world than we were last year. With the new administration, you've talked about their commitment to science. Obviously, they're backing that up with financial resources and more to come. Talk just a little bit now about making sure that the BIPOC population, diverse population, our country are represented in all the work that we do with the clinical trials, spilling this sense of confidence and then just a few minutes ago, you and I were chatting about sort of a vision for the future and

healthcare. I wonder if you could just expand a little more on it. What might that average citizen be looking at over the next three or four years or be hopeful about as you think about this confluence? You've been certainly a promoter of telemedicine, telehealth, but talk about how this inflection point that we're at now, how it might translate, and it won't be that slow [inaudible 00:19:52] 17 years, but we might see some rapid adoption. Paint that picture a little more for us.

Dr. Eric Topol: Well, I think the conduit is a smartphone and for people who don't have a smartphone or don't have broadband internet, we should be giving people a smartphone and data plans, because the phone and years of data plans is cheaper than one night in the hospital or one visit to an emergency room, which are average $5,000 to $2,000, respectively. So we have to think smarter about using the technology we have in Moore's Law that got us to this point. No one's really doing that yet, but we should be doing it. And so what I envision is that, mobile phones aren't going away, they're just going to get even more center stage for healthcare, and apps to help people manage their condition or prevent their conditions. And so that's where we're headed is.

We have to reach out to people that don't have technology, so that every single American, if we're talking about the US, is on a level footing with respect to access. That's how we reach them and that's how we can get them vaccinated if they are willing. There's so much we can do once we use that Synapse and we know that people who have these smartphones are totally relying on them for it's about food and water in terms of necessity, we just have to get them to everybody and we haven't done that. We still, maybe 15 20% of our population doesn't have this technology.

Mark Masselli: Well, just note the FCC has launched a $3.2 billion for low income people to get broadband, which is going to be, we'll tell our listeners more about it later, but in April it opens up, which should go at the heart of what you're saying, which is leveling this playing field so everybody has that access.

Dr. Eric Topol: Yeah, this technology is never going to go away. It's just going to get better with 5G and just faster and more data flow. I think it's time now that we get everybody who if there's a problem of affordability, we fix it. But these are small investments. When we're spending $2 trillion this is a tiny line item. It just befuddles me that we haven't done this, when you think about the cost of American health care, which is astounding. So I hope we'll see that come along.

Mark Masselli: But I dare ask the question. What publication are you are you working on right now that might hit?

Dr. Eric Topol: Well, we have a long COVID one coming out hopefully soon about,

people that develop a very fast heart rates for months. They go from 70 to 100 and so in addition to their symptoms, they have physiologic objective signs that are---we're going to learn a lot more about long COVID. It's a big residual of our inadequate efforts last year. The cases of long COVID it may be 10% of the 30 million confirmed cases, at least.

Mark Masselli: What's your sense just about the pediatric, the need for pediatric vaccines?

Dr., Eric Topol: I think it's essential, even though they don't get sick very often, they're still carriers and there's still some who do get sick and get that MISC, horrendous condition, even though it's exceedingly rare. So we have to get everybody across the board hopefully kids' vaccine work will get done pretty quickly.

Margaret Flinter: We've been speaking today with Dr. Eric Topol, Director of the Scripps Research Translational Institute, the editor of Medscape, author of several bestsellers including The Patient Will See You Now. Follow his work by going to drerictopol.com or follow him on Twitter @EricTopol. Dr. Topol, we want to thank you for being a lighthouse in this pandemic storm for being a voice of trust of reason and science, and for fostering collaboration across the global scientific community. And thanks for joining us once again on Conversations on Health Care.

Dr. Eric Topol: Thanks very much Margaret and Mark, great to be with you.

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Mark Masselli: At Conversations on Health Care we want our audience to be truly in the know when it comes to the facts about healthcare reform and policy. Lori Robertson is an award winning journalist and Managing Editor of FactCheck.org, a nonpartisan, nonprofit consumer advocate for voters that aim to reduce the level of deception in U.S. Politics. Lori, what have you got for us this week?

Lori Robertson: A Food and Drug Administration presentation on monitoring the safety of COVID-19 vaccines listed possible adverse events the agency might track. But an Instagram post misrepresents the document, falsely claiming it shows the vaccines are known to cause harmful side effects including death. It's just one example of misinformation about the COVID-19 vaccines that is circulating on social media. The popular Instagram post cites a government document to falsely claim that federal officials know that the COVID-19 vaccines cause death and other dangerous side effects. But the post is wrong. The FDA presentation on its sites, which is publicly available doesn't say that and there is no evidence that the COVID-19 vaccines have caused any deaths.

The FDA presentation was given at an October 30 meeting of a CDC

Advisory Committee. The presentation outlined a variety of ways that FDA's Center for Biologics Evaluation and Research would monitor vaccine safety once COVID-19 vaccines were available. One slide in the presentation showed a "working list of possible adverse event outcomes". These are outcomes the FDA could possibly monitor once a vaccine was authorized. Daniel Salmon, Director of the Institute for Vaccine Safety at Johns Hopkins University told us, officials develop a list of adverse events to monitor in order to proactively ensure the vaccine rollout is safe. And there's a difference between a report of an adverse event following immunization and an adverse event caused by the vaccine, he said.

Anyone can submit a report of an adverse event that occurred after immunization through the vaccine adverse event reporting system. With more than 109 million doses of COVID-19 vaccines administered in the US as of March 15, the CDC received 1913 reports of deaths that took place after someone received the vaccine. On March 15, the CDC said that none were linked to the vaccination. "A review of available clinical information including death certificates, autopsy and medical records revealed no evidence that vaccination contributed to patient deaths".

That's my fact check for this week. I'm Lori Robertson, Managing Editor of FactCheck.org.

Margaret Flinter: FactCheck.org is committed to factual accuracy from the country's major political players and is a project of the Annenberg Public Policy Center at the University of Pennsylvania. If you have a fact that you'd like checked e-mail us at www.chcradio.com, we'll have FactCheck.org's Lori Robertson check it out for you here on Conversations on Health Care.

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Margaret Flinter: Each week Conversations highlights a bright idea about how to make wellness a part of our communities and everyday lives. When venture capitalist and Shark Tank co-host Mark Cuban decides to sink a couple of hundred thousands of dollars into your business idea, you're probably onto something. That's what happened to Olivier Noel, a medical student and young geneticist at the University of Pennsylvania, when he appeared on the popular ABC show. Noel learned that no matter how many resources a clinical study has, it is still extremely difficult to get a large sample of participants to join in studies, especially ethnic diversity. So he thought, what if you could eliminate the barriers to research participation and build up a rich DNA database for future research all at the same time, and he created DNAsimple.

Olivier Noel: I think the idea came about right on my second year of my PhD. I was

sequencing ability, there was enough funding for a really amazing research projects, but ended up being a little bit of a chasing game, where we couldn't build strong enough codes at first. Some of the patients we were looking for, it was taking a very long time for them to come. And so I ended up going to a genetics conference and the keynote speaker there was alluding to a similar problem. One of the ways they were able to contact patients was through Facebook. So, the joke at the time at the conference was that, Facebook is the new way of doing genetics. So I wanted to sort of leverage the Internet and particularly leverage social media to be able to build a national database where somebody did not need to be a patient to be able to participate in this research study.

Margaret Flinter: All the participants have to do is to take a simple swab of the inside of the mouth, send it in and wait to see if your specific DNA is of interest to researchers. Noel says that the company will make their DNA and disease data available to researchers studying specific diseases, offering those researchers a much broader spectrum of study participants.

Olivier Noel: So one of the things we really wanted to do with DNAsimple is to allow for the possibility of doing longitudinal study so that you keep continue keeping contact anonymously, obviously with a particular donor. If you're doing a study for example, and you have the ability to collect samples now, collect samples in three months and see how that varies, which is very difficult to do if you are going to be in contact with a patient once.

Margaret Flinter: The study participants themselves receive an extra something for choosing to participate a cash stipend for offering up their DNA to research.

Olivier Noel: So we ultimately provide a minimum of $50 every time somebody provides a saliva sample.

Margaret Flinter: DNAsimple a vetted database linking researchers with a broad array of participants to enhance lab research by eliminating the barriers to finding participants, now that's a bright idea..

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Mark Masselli: You've been listening to Conversations on Health Care. I'm Mark Masselli.

Margaret Flinter: And I'm Margaret Flinter.

Mark Masselli: Peace and Health

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Marianne O'Hare: Conversations on Health Care is recorded at WESU at Wesleyan

University, streaming live at www.chcradio.com, iTunes, or wherever you listen to podcasts. If you have comments, please e-mail us at www.chcradio@chc1.com or find us on Facebook or Twitter. We love hearing from you. This show is brought to you by the Community Health Center.

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