Dr. Paul Offit

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Moderator: 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. Paul Offit, renowned vaccine expert and member of the FDA's COVID-19 Vaccine Advisory Panel. He talks about the dramatic impact of vaccine deployment in the U.S. bringing down cases significantly. He also talks about the mRNA Science, decades in the making and the statistical impossibility that the technology will "alter your DNA."

FactCheck.org's Lori Robertson checks in, Managing Editor looks at misstatements spoken about health policy spoken in the public domain, separating the fake from the facts. And 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. And you can also hear us by asking Alexa to play the program. Now stay tuned for our interview with Dr. Paul Offit here on Conversations on Health Care.

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Mark Masselli: We're speaking today with Dr. Paul Offit, Director of the Vaccine Education Center, and Professor of Pediatrics in the Division of Infectious Disease at the Children's Hospital of Philadelphia. He is a member of the FDA's Vaccine Advisory Committee on COVID-19 and of the National Institute of Health's working group on vaccines.

Margaret Flinter: Dr. Offit is a founding advisory board member of the Autism Science Foundation and the Foundation for Vaccine Research. And he is the editor of the publication, Vaccines. Dr. Offit, we really want to welcome you back to Conversations on Health Care, today.

Dr. Paul Offit: Thank you, happy to be here.

Mark Masselli: Yeah. You know the G7 Nations meeting President Biden announced that he was donating 500 million doses of the vaccine to developing nations. But we also learned that our death total in 2021 eclipsed 2020 and yet here in the United States I think people feel, we've turned the corner. What say you about where we stand on the trajectory of the global pandemic?

Dr. Paul Offit: Well, on the global pandemic, you've a 195 countries out there and there are many of them whom have not given a single dose of vaccines. So I think the global pandemic is going to be with us for a

while. In the United States things are certainly better for three reasons, one is its summer and this is basically a winter virus, you can see that last summer when the cases came down on before the winter hit. We've obviously about the at least or close to 60% of the adult population that's now fully vaccinated, and natural infection also protects. And we've probably looking at antibody surveillance studies about a 100 million people in this country who have already been naturally infected.

So you're probably at sort of herd immunity rates of around close to 65% to 70%. That may not be enough, you know these variants that are circulating now, we're now like moving to variant #3. The first virus that came into this country was variant #1, the second one that started to takeover was the, what was called what at one point UK variant that's now called the Alpha variant. And now there is a third variant that's coming up that's more contagious, the so called Delta variant which was [inaudible 00:03:21] in India. If that's true and these viruses are more contagious, you need a higher percentage of the population to be immune. So we're not there yet. We'll see what happens over the winter, but I suspect you will see a spike again this coming winter.

Margaret Flinter: Well Dr. Offit, you know sometimes it seems like every day is a COVID day, right and it's been here for years and sometimes just the speed of which we've moved through this pandemic, really astonishes me. And one of those sign post is, how scarce vaccine supply was, just a few short months ago, and now many places in United States are really sitting with an excessive vaccine in their freezers and refrigerators that may expire before they can actually give it to people. And we see all sorts of incentives being used to get people to come out and get the vaccine.

And you've said that vaccine resistance, the resistance of people to get the vaccine is what really scares you. Information is out there, strategies are out there, but still we've an enormous chunk of people who just are saying they are not going to get the vaccine. What do you say to people at this point about that?

Dr. Paul Offit: Well, if it's a matter of education we can educate. If it's a matter of access we can provide access. If it's a matter of sort of inertia and people just needed nudge, then incentives work. What worries me is the fourth group. This is a group that is just not going to get vaccinated. They believe that vaccines are more harmful than helpful. They are cynical about the information that they hear. And so what do you do then? What do you do then if there is a critical percentage of the population that's choosing not to vaccinate, so much so that it causes the virus to continue to spread, to mutate, to create variants. What do you do?

I mean people will say, look it's a personal choice, well it's not a personal choice. Because it's a choice you're making for other people, people with whom you come in contact with. So what do you do then? And I think that's what you're seeing down on the private sectors which is mandates, certain businesses will say if you want to come back to work, get vaccinated.

Mark Masselli: Well, let's pull away some of those and just pointing on the thread of the question, pull away some of those glaring rumors, because we see there are still people who are waiting. There are as you said a group of individuals who said "No, I'm not getting this vaccine whatever you say." But maybe just respond to a couple of these rumors that are out there of vaccines weren't fully vetted, they were made too quickly.

Dr. Paul Offit: Well they certainly were made quickly, I mean this was a vaccine really do is we'd this virus in hand that sequenced in January of 2020. And there were two large clinical trials that we're performing within the 11 months, I mean that's remarkable. But I think people have this misconception that critical timelines were skipped or worse that safety guidelines were ignored, that's not true. Those trials, those original trials of 30,000 to 40,000 people were the size of any typical pediatric or adult vaccine trials. Similarly there was, the other thing that wasn't a different, was the safety follow-up. I mean any severe safety issue that's coming up with vaccines has come up within six weeks of the vaccine. So the safety, follow up had to be two months after the last dose.

The real difference was length of follow-up for efficacy. So when we approved those say, two mRNA vaccines in December, we could say that they were effective for a few months. But we didn't know that whether they were effective for a year or two years or three years, but you're not going to do a three or four years studies when 500,000 people just died that year to see whether it remained effective. And I am sure it's going to be you know effective for probably a few years. That was really the only difference.

Mark Masselli: Well, speaking of the mRNA, also we've heard that vaccines alter your DNA, particularly those two, the Pfizer and the Moderna one.

Dr. Paul Offit: Yeah I'm not sure why people think that when their DNA is altered it's always for the worst, you know why can't you develop x-ray vision, for example if you're getting a vaccine. Right, it's not possible. So it's understandable how people could think this. Because it's really, these are our first genetic vaccines, meaning you're not being given the SARS-CoV-2 to spike protein, you're being given the gene that codes for the spike protein and so your body makes the spike protein, and then antibodies that protein.

But what happens when messenger RNA enters your cells and now as

part of the other 200,000 copies of messenger RNA that are also in your cells making proteins and enzymes, is it will make that protein for a couple of days, but the mRNA in order to alter your DNA would have to get into nucleus, which means it would require a nuclear access signal which it doesn't have. Also it's mRNA, it's not DNA, so it would have to be converted DNA which requires an enzyme called reverse transcriptase which it also doesn't have. And then even if it was converted into DNA which it can't be, it still has to be integrated into DNA which requires an enzyme called Integrase, which it also doesn't have. So the chances of it altering your DNA aren't small, they are zero. You know you have a better chance of becoming Spiderman if you're getting these vaccines -- altering your DNA.

Margaret Flinter: I think maybe we should have neurology as a required course in high school, going forward since we're going to be dealing with these things for a while. But on a very serious note, Dr. Offit as happy as we are about some of the progress with vaccines, here in the United States, in the northeast where we're based, the rest of the world certainly is lagging so far behind in vaccinations. Sub-Saharan Africa, I think people are saying not even 1% in many countries and I think I've heard in Haiti, really for all of the volunteer organizations we've and the health organizations, nothing has been delivered yet.

So good news that's the Biden administration is giving 500 million doses to the global effort. But what's the strategy for global vaccination? I don't recall anything like this ever in our lifetimes as we think about it, is it COVAX is at the volunteerism of countries, what's the strategy for really getting vaccines across the globe, particularly in countries that we know have to depend on other people to get it to them.

Dr. Paul Offit: Right, I mean, I think there is going to have to be, you should know sort of an international strategy to try and do, because we can't do it. I mean there is no doubt that you can make enough vaccine. I mean say something like the mRNA vaccines, remember those are given at microgram doses, that's a million for the gram, you can make kilograms of mRNA which is thousands of grams, that's a 9 log difference, that's a billion fold difference. So you can make billions of doses of mRNA vaccine. But that's not the hard part. I think the hard part is going to be getting it into people's arms and that's expensive and difficult and there is also not an infrastructure at all for that in the developing world. It took also a while in this country to put into place an infrastructure for mass vaccination in adults.

It's going to take a lot of money and a tremendous effort to do that. But it is, I mean you know we can argue that it's an altruistic thing for us to do to give vaccines to the developing world, it's really not. We need the world to be vaccinated. Remember, we, every year in the

United States children get a polio vaccine, why we haven't had polio in this country since the 1970s. The reason we give it is because polio still exists in the world. And therefore because international travel is common, we're always at-risk. So we need to get the world vaccinated. We're going to have to have a highly vaccinated population in the United States until we get control of this virus in the world and that's going to be years if not decades.

Mark Masselli: We're speaking today with Dr. Paul Offit, the member of the FDA's COVID Vaccine Advisory Committee and Director of the Vaccine Education Center at the Children's Hospital of Philadelphia. You know just pulling the thread on where we have to get a lot of people or the vast majority of people vaccinated, young people are now eligible, 12 and up for the vaccine, but only 15% of kids of that age group have gotten vaccinated. And you know just trying to understand how important this is and I'm sure parents worry about their children getting vaccinated. When might we see that we move away from the EUA status to sort of a permanent status?

I'm wondering also about the likelihood of a booster shot being required. You know a booster shot if it's going to be acquired a year out, and you said earlier, you thought it had a longer shelf life than a year, but the logistics on that are going to be complicated. We're going to be in December when we're one year out, where health workers got vaccinated that's usually a time where people think, they get, annually get an additional shot. So maybe on both of those young people in terms of what's happening there and then maybe on the EUA and the booster as well

Dr. Paul Offit: So I think we need a vaccine for children. It's estimated that about four million children have been infected with this virus, about 40,000 had been hospitalized, at least 300 have died, this particular inflammatory syndrome, multisystem inflammatory disease in children is pretty frightening. I mean it's a multisystem vasculitis, I mean that's one of the heinous nature of this virus is it causes you to react you on blood vessel.

So we need a vaccine for children out, the numbers are all going down now. So I think people are taking you know it's good. Now I think the benefits really are much less than they would have been, you know I've been hearing things about you know side effects that are worrisome and so maybe I don't need a vaccine. I think that's false thinking, you're going to see this how well we're doing once winter hits. And I think that when winter hits you're going to see a spike again, and you're going to continue to see spikes in the winter until we get on top of this pandemic.

In terms of children not getting the vaccine they need, I think you know it's understandable, we ask parents to inject or ask them to

allow for injection of a biological into their children -- don't really understand very well, and right now we're not seeing a lot of the disease. So they are thinking you know what, I'll just take a pass, but in terms of when you'll see the EUA being converted to a Licensure, the FDA is looking for six months of follow-up, so that could really happen by the end of Augus,t by you know at least for those over 18 years of age. And so the Pfizer product really over 16 --

Margaret Flinter: Dr. Offit, look back on these last six months and you talked about, how yeah you've learned to get the vaccine out there after you know sort of trial and errors in the beginning. But it's pretty impressive across the country, what happened in terms of mass vaccine clinics, unlike anything else, if you put your full attention to, they got pretty smooth, after a while where you're able to see lots of people pretty satisfying.

Now we're talking about dismantling all of them. And I've to ask from a public health perspective, is this a good idea, not just for COVID, but here is what I think we learned. We learned that when you make something that is necessary for the public health available at no cost to people, without having to produce an insurance card, without having to look at your co-insurance rate, without having to produce evidence that you're a citizen of the United States or you're here legally, you can actually get the job done. And my question to you'd be from a public health perspective, shouldn't we believe some of this infrastructure and place and shouldn't this be the new normal if we need to do a public health intervention across the country rather than dismantling it all and having to relearn this all over again?

Dr. Paul Offit: No, I think that's right and in many ways that comes to boosters especially for adults. I mean there really is an infrastructure for vaccinating children which is the pediatrician's office. For adults not so much, so adults don't go to doctor, you can't be actually among that crowd, but so how do you do that? You have to have it in the way we've it now, pharmacies etc. And I mean it's really going to come down to how, whether we need booster doses and if so, how frequently. I do think that if you look at for example the cellular immune response after the second dose of mRNA vaccines, you have a really high frequency of cells like memory B cells you know which are the cells that make antibodies or memory T helper cells which are the cells that help these cells make antibodies, that usually predicts fairly longer lived immunity.

If I had to make a guess on this I shouldn't since I see you recording this. But if I had to make a guess, I would say that, we would probably need a booster every few years for this, assuming that a variant is not created that's completely resistant to immunity from natural infection and mutation, in which case then you really are not talking about a

booster, you're talking about a second vaccine. But you're right, I think we need an infrastructure in place for adults to vaccinate. We're going to be dealing with this virus for a while. I think we're certainly going to need boosters at some point. And so to dismantle it we do that at our own peril.

Mark Masselli: Dr. Offit, you're advising the FDA on the COVID vaccine but they recently got a lot of attention for another breaking health new story, the approval of the first Alzheimer drug in two decades, turned out it's quite expensive, it's controversial, it produced some lack luster results, but obviously not enough to dissuade the FDA to move forward, tell us about the process, how it was orchestrated at the FDA and what you expect to see from this green light grant the company making the product Biogen, and others who are in the pipeline developing similar types of medications.

Dr. Paul Offit: Some I'm on the vaccine, not the drugs. So I can comment comfortably on the vaccines where you know these products are held through high standard because they are given the healthy, for the most part to healthy children or healthy people. The drug side is different, I don't, I know what you know from reading in the newspaper that that approval was a surprise for the Alzheimer's drug, like it certainly was what the advisory panel had recommended. But I think three people in that panel, actually just resigned because they disagree with that decision, but again this is not my --

Margaret Flinter: Well, we appreciate your clarity about that. Maybe I can just ask you sort of the million dollar question I guess. This is your area, is there likely to be, we think there is perhaps pandemics in our future, not COVID pandemics, but pandemics that we can't yet imagine. What should the preparation be and I'm reminded of this because I was recently in an emergency preparedness meeting and looking at our plan which was all written during anthrax, right 2002, 2003 and everything that we put in place.

Again from your sort of broad perspective and we'll just say about the United States for now, recommendations for what we do to be prepared for the next pandemic, mass vaccine clinics aside, we're seeing investments in public health and like, you're in a teaching organization, there is training issues. If you've a few thoughts to share with us, as a country how do we prepare for whatever is coming next in the form of pandemics?

Dr. Paul Offit: Well I think it's safe to say there will be another pandemic and likely in our lifetime. And you had a, you know the SARS1 raised its head in 2003, you've had MERS in 2012, this is the third now pandemic raised its head in 2019. We live in close association with animals, I mean a bat virus became essentially a human virus. A Influenza was a bird virus, that became a human virus. HIV, Human Immunodeficiency

Virus was a simian virus it became a human virus. So you can assume there is going to be mutations that allow these viruses to again enter the human population.

I think what we, if we haven't learned our lessons from this pandemic, we'll never learn the lesson. I mean this pandemic brought the world economically to its knees. And I think at the very least, the first thing that has to happen is there has to be an international consortium with all countries participating that the minute that a virus like this raises its head, that you know about it. You know we shouldn't have had to be dependent on a whistleblower in Wuhan to tell us that there was a virus that was circulating there, that was killing people. I mean I think the Chinese government is culpable in that regard.

And so that is like step 1, and then once you know that, you can have an international team of scientists that you know quickly identify the virus, sequence the virus, come up with strategies for how to make a vaccine, do the research in place and the researcher is [inaudible 00:19:05] vast international research infrastructure. It's the mass production infrastructure that's not in place. The hardest part of making vaccines as they say, is making vaccines, I mean mass production isn't easy, mass administration isn't easy and that's what we need to learn, I think from this pandemic.

Mark Masselli: Did we see any silver linings in the pandemic in terms of the changes in the delivery system, certainly the advent of Telehealth, really was a force multiplier in terms of spreading that and hopefully getting access to many more people. But anything else that from your vantage point that you saw that helped improve the overall delivery system?

Dr. Paul Offit: Well just for my vantage point, I think we've entered a new era of vaccinology. I mean previously you know we gave the protein or attenuated form of the virus or killed form of the virus. Now we give the gene that codes virus, or in the case would be vector virus is you gave a replication to effective virus which carries in the gene that you are interested in. That's interesting to see to what extent that will apply then to other diseases for which we've had difficulty making a vaccine like HIV or universal flu vaccine, or malaria vaccine so that's number one.

Number two, and this is more of a personal thing. I think you know normally when you do trials as was done for the mRNA vaccines, they often aren't done in pregnant women which is too bad because pregnant women obviously are more likely to be hospitalized and mechanically ventilated if they gets SARS-CoV-2 infection than a women of the same age who is not pregnant, so they benefit from this vaccine. What the CDC did initially was instead of doing what they always do, which is to say, this vaccine is contraindicated for pregnant

women because you know they don't have data, they said a pregnant women could reasonably choose to get the vaccine and then tens of thousands of women did do that. And you had clear data now that as compared to women who were pregnant, that didn't get the vaccine, there is no difference in maternal or fetal outcome, so that's good. And so I think that now you've a tremendous safety portfolio with this vaccine in pregnant women and for other vaccines that will be in the future for pregnant women like [inaudible 00:21:07]vaccine, or Strep vaccine, or meningococcal vaccine. So I think that's one advantage here.

Margaret Flinter: Well that's great and that's actually positive news, we're happy to share through the show. We've been speaking today with Dr. Paul Offit, he is a member of the FDA's COVID Vaccine Advisory Committee, and Director of the Vaccine Education Center at the Children's Hospital at Philadelphia. Learning more about his important work by going to www.paul-offit.com or follow him on Twitter @DrPaulOffit. Dr. Offit, thank you as always for your clear, concise voice on science, on vaccine science specifically, for your career long contributions to this field and for joining us today on Conversations on Health Care.

Dr. Paul Offit: Thank 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: Let's take a look at the COVID-19 variants and vaccination. So far COVID-19 vaccines have been effective against variants of the coronavirus. Scientists are monitoring the situation carefully with updated or new vaccines a possibility in the future, if need be. The fact that variants of the original SARS-CoV-2 virus have emerged is not surprising, viruses mutate randomly as they replicate and make errors as the genome is copied again and again.

A variant is a distinct virus typically with several mutations. Most mutations don't change the virus's biology or how the body's immune system responds. But sometimes mutations can result in a competitive advantage for the virus and its ability to replicate or transmit for instance, or in how effectively immunity from a previous infection or a vaccine is able to fight the virus. The good news is that so far the authorized vaccines in the U.S. have been largely effective against the variants that have most concerned scientists.

The Centers for Disease Control and Prevention is using three classifications for variants. There are five variants of concern that's CDC is middle level for variants for which there is evidence of increased transmissibility, more severe disease, or reduced effectiveness of treatment or vaccines. There are no variants in the CDC's top classification level, a variant of high consequence. While the authorized COVID-19 vaccines in the United States from Pfizer BioNTech, Moderna and Johnson & Johnson were designed to protect against the original SARS-CoV-2 virus that's not the virus the vaccines ultimately have confronted. Still they worked extremely well as shown in the clinical trials. In real world studies have shown they continue to work well against those variants of concern.

For instance in Qatar, researchers used national databases on vaccinations, testing and clinical characteristics to estimate the Pfizer vaccine effectiveness against any infection of the B117 variant at 89.5% that's the variant that first emerged in the United Kingdom and is the most common variant in the U.S. according to the CDC. Effectiveness against any infection of the B1351 variant, first identified in South Africa was 75%. But effectiveness against severe critical or fatal disease from any variant was an estimated 97.4%.

The Johnson & Johnson vaccine's clinical trial data also give an indication of its effectiveness against variants of concern, since it included study sites in South Africa and Brazil where such variants were identified. While the vaccines efficacy in preventing moderate to severe disease was lower in those countries than in the United States in the trial, the effectiveness against severe or critical COVID-19 was more than 80% in all three locations. And 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. Healthcare providers are forever on the lookout for that magic elixir that can cure a host of chronic ills in one step. And in the case of obesity, depression, anxiety, and stress, that elixir could be turns out, a number of steps, as in taking a hike. A large study conducted by several institutions, including the University of Michigan and Edgehill University in the UK, looked at the medicinal benefits derived from regular group hikes conducted in nature.

Dr. Sara Warber: This study had enough people in it and following them overtime. That we could see that these two different types of health for our mental well-being, they are operating independently, that means that if we go out in nature for a walk, we're getting an additional boost to our mental well-being.

Margaret Flinter: Researchers evaluated some 2,000 participants in a program called Walking for Health in England, which sponsored some 3,000 walks per week across the country.

Dr. Sara Warber: Well this is a national study in the UK, there was investment in these walking groups, in training leaders to take people on walks, finding trails that were good for people to do even if they had health problems.

Margaret Flinter: Dr. Sara Warber, professor of Family Medicine at the University of Michigan School of Medicine said the study showed a dramatic improvement in the mental well-being of participants, especially those who had recently experienced something stressful like the loss of a loved one or a serious illness.

Dr. Sara Warber: Depression was reduced, perceived stress was reduced, and it certainly relates to most of our lives. And that people had, they experienced more positive feelings, or positive emotions. And there has been really lovely research that's shown that when we have positive emotions, we actually have better health in the long run. And we have less negative emotions when we're out in nature and when we're out in nature in a group.

So we did have controls and that's another thing that makes a study powerful, is that our control group were people who, at one time, intended to be part of walking groups, agreed to be followed, but they never took up the practice. And so, we were able to match our walking group participants with people who were just basically just like them, but who didn't walk-in groups, and so we could see how they differed over time.

Margaret Flinter: The participants almost universally reported reduced stress and depression, after participating in group nature heights and the effect was cumulative over time. Dr. Warber says it seems to be the combination of breathing in fresh air surrounded by nature during moderate exercise and the group dynamic adds a social benefit. Other studies have shown a link between mood and exercise, but Dr. Warber says this is the first study that revealed the added benefits of group hikes in nature and significant mitigation of depression.

Dr. Sara Warber: Because we were really interested in whether, if you are more stressed, would you get some better benefits from being in nature. And in fact, that did pan out. So, if you're going through stress, if

you're having a hard time, getting out in nature, getting out in nature with a group or with others, has real benefit in reducing your stress.

Margaret Flinter: Walk for Health, a simple guided group nature hike program which incentivizes folks suffering from depression and anxiety to step into the fresh air with others, to talk out their thoughts while taking a hike, improving their mood, reducing their depression, increasing their overall health at the same time, 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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Moderator: 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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