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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, welcome virus scientist entrepreneur and president of Access Health International, Dr. William Haseltine, who's been writing extensively on the COVID pandemic for Forbes, and a series of online books that are updated when new science emerges. His warning that the rapidly changing landscape of SARS-coV-2 the COVID 19 pandemic is shape shifting with Omicron presenting a real threat much more contagious, and a bigger threat than we yet understand.

Lori Robertson also checks in, Managing Editor of FactCheck.org. She 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 wellbeing and everyday life. If you have comments, please email us at chcradio@chc1.com or find us on Facebook, Twitter, or wherever you listen to podcast. You can also hear us by asking Alexa to play the program. Now stay tuned for our interview with Dr. William Haseltine here on Conversations on Health Care.

Mark Masselli: Pills to treat COVID-19, they sound like an important part of the solution to dealing with the pandemic. But a warning from our guest is attracting a lot of attention and controversy. You'll hear him explain in his own words why he's concerned about a new drug which could, and I emphasize could, have led to the Omicron variant.

Margaret Flinter: Dr. William Haseltine is at the forefront of medical research and application, he's taught at Harvard Medical School. He designed the strategy to develop the first treatment for HIV/AIDS. He's well known for his groundbreaking work on cancer, he led the team that pioneered the development of new drugs based on the human genome information and now serves as President of Access Health International, that's a nonprofit think tank and advisory group dedicated to improving access to high quality, affordable care. Dr. Haseltine we can't think of a better person to have with us today for the show. Thank you so much.

Dr. William Haseltine: You're welcome, and thank you for that.

Mark Masselli: Yeah, and really welcome back to Conversations on Health Care. You know the FDA has yet to authorize use of Merck's Molnupiravir, an antiviral medication for COVID patients. You have some pointed thoughts about that. I'm wondering if you could share that with our

listeners.

Dr. William Haseltine: Well, the first thing is, we do need drugs both to prevent and to treat COVID. Now that we know that there are variants of blast through almost all vaccines including people who have been infected and then vaccinated, it's looking a little bit more like HIV, which is very hard to vaccinate against, at least permanently. Now there is of course, the hope that the vaccines will protect you at least for some time from serious disease or death. That's really good news. Even if you get the virus, maybe it won't be as bad for you, and it's a very good reason to get vaccinated. But we have to add new tools to our armamentarium.

Just as we realized, once we knew that it would be hard to vaccinate against HIV, we developed a whole series of drugs. Now, this virus is a little bit different in the sense that when you get HIV, you have many years to treat before somebody has manifest. Here, once you feel the first symptoms, you may have three days to treat. That's the window for the Pfizer jar. Now you've asked me about another drug called Molnupiravir that Merck has pushed as a treatment. I have very grave concerns that have been shared for many years about this drug. This is not a new drug. It's been around since the 80s. A lot of people have looked at it and dropped it because it has some unfortunate potentials.

How does this drug work? It actually causes the virus to mutate itself to death. What it does, it's a mutagen (inaudible 00:04:10) it creates mutations. It doesn't sound just on the surface of it. You want to speed up these viruses ability to make mutations. It sounds like a really bad idea. When you look at what happens in tissue culture with other coronaviruses, including the MERS it just look the viruses that come out of treatment of Molnupiravir are highly mutated. Sometimes they have over 100 mutations in them. It makes --- and so we know that if you treat somebody with Molnupiravir for a few days they shed virus, those viruses are going to be mutant. I am very worried that that drug not only is not particularly effective about 30% effective at this point, if you take it early, but has potential to significantly accelerate the rate of variation of this virus, and therefore the pandemic, that's not 100% certain.

France is taking these cautions, its lack of good efficacy, the fact that it may cause mutations that are very difficult for especially pregnant women and others, and the possibility that it could make the pandemic worse to not allow the drug to be used. So far as I know the only country that’s not approved it for us even canceled their order. This, as I say, this drug was considered to be too dangerous to use for biopreparedness is not a good idea, in my opinion. I hope that the US FDA reaches the same conclusions.

Margaret Flinter: Yeah. Dr. Haseltine, clarify for me, we've been following this because

as you probably know this is one medication that's being made available throughout the country on a preliminary basis anyway for use. We've all certainly been excited to think that there have been opportunities to identify people at risk who are positive early on, treat to reduce the burden of symptoms and hopefully prevent progression to hospitalization, or even death. This is an incredibly important issue. My understanding, and I think you may have just said this, but I want to make sure I heard it correctly, that we have not yet gotten emergency use authorization for this drug in the United States. Am I correct on that?

Dr. William Haseltine: You're correct. The FDA is --- and the committee was divided, that's unusual, I think, 13 to 10 decision. Some of the scientists that were on that voice exactly the same concerns I have just given you, they have concerns as well. I think it's --- you can turn it down on efficacy, you can turn it down on danger to mutagenesis, but I am very concerned about exacerbating an already bad situation. We now know we're not the end of virus variation, Omicron has put the end to those hoax, and we don't want any more mutations than we have to put up with

Mark Masselli: This is more about the drug itself less about where the clinical trial was held, which is South Africa, they had a couple of other locations I was doing it. It's the drug, not the location or was there anything about the patient population that --- or any data that you looked at that might have also stirred your concern, because it sounds like you have a historic concern on this drug, but anything that you saw in their documentation that gave rise to additional concern?

Dr. William Haseltine: Well, first of all, is tested around the world like you have to do if you want to move quickly. South Africa was one of the places.

Mark Masselli: Yeah.

Dr. William Haseltine: It's not even sure Omicron had originated in South Africa, it was first found there. But by the time it's found there, we found in lot of other places that we didn't find it. But let me say there is one additional concern and that is that in their initial trial, going way back to October 2020, where they tried to use the drug to treat people who are already ill, not within the little window from symptom, that three to five day window, they failed the trial, but they did a dose escalation. They use a low dose, that doesn't really work so well. The viruses that come out are going to keep coming, and they're going to be mutated. They use a low dose, a higher dose and finally this dose.\

Now for a drug, you've got to use those escalation. But others who looked at this drug for biopreparedness decided it was too dangerous to use. Others who created research programs are private companies dropped the drug because they feared it was too dangerous to use. Why it has been put forward as a drug to treat perhaps 10s or more

millions of people is beyond my understanding.

Margaret Flinter: You know, Dr. Haseltine I think the public and even those of us who would consider ourselves reasonably well-informed, not experts like yourself, but reasonably well-informed, I think are getting a little whiplash about what is just really the --- maybe the normal evaluation as knowledge becomes available, right. This week, I think we heard about Janssen right that Janssen probably ought to be moved out of the list of vaccines for COVID. We haven't seen anything official yet, but certainly there are some good evidence about both complications and efficacy.

Politico, I think, raised in its reporting this week that the Biden Administration is really frustrated about doctors and scientists going on Twitter and cable to criticize their moves and thinking that that is confusing to the public. But it seems to me this goes exactly to what our experts have been saying is that we need to get all the opinions out there so that people can hear the information, although we worry at the same time about misinformation, this is really hard for the public. (Crosstalk)

Dr. William Haseltine: This is a very difficult situation for everybody, and I sympathize with the people in the Biden Administration. They're very good people. They have the best intentions. But, you know what I'm really sad about is we had a president who called this a hoax. We have a president who takes this really seriously (inaudible 00:10:34) a good portion of his time, and has an excellent people around it, and we still can't seem to make the progress, not because of the leadership but because of our people. We are divided. We have all sorts of reasons. The moment you politicize a health issue, you've done something that can be deadly dangerous to the population.

It’s not even necessarily completely political. It is a very complicated situation. I think that Ed Young in The Atlantic, today or yesterday wrote a very, very good article. We're not prepared for this as a people as a country and until --- he's --- actually something I've been saying now for some time. Until we realize that we are our brother's keeper, that what I do to protect myself and my family is to protect me and it's to protect you, and you've got to do the same thing. We're in deep trouble, and we're nowhere near there. Right now, we're facing, even as I speak today, a virus over the next few days that Omicron is likely to double, and double after that. If you keep doubling 2, 4, 8, 16 ,32 it takes you a week to 10 days to get everybody, and by the way, that's what's happened in Africa and it's what's happening in the UK right now, and it's what's happening right now.

I just got a note from a friend on Twitter who said, I woke up and everybody I know that (inaudible 00:11:59) was COVID. That sounds

funny, but it's not so funny because it's happened to me, too. All of a sudden, people I know are calling me up and say, Will, I just had a positive COVID test, and these are vaccinated, sometimes triple vaccinated people. This is a situation which is rapidly evolving.

Let me take one message that has been given which I have a question about why it came out of the White House, which is, oh this is a more mild infection. I was suspicious of that. I looked at this virus, I couldn't --- the sequence and its behavior, I couldn't see anything that suggested that it was more mild. The recent papers that have just come out of the UK say we can't see any difference either. When we look at our patient population, although it's very tiny right now, it looks just the same or worse than Delta, so I wouldn't be reassured.

I think that it's really difficult that I understand the difficulties of trying to give a coherent public message in a rapidly evolving situation. But just remember when the same group well meaning to get people vaccinated says the vaccine will absolutely protect you. Well, it doesn't. Some of us said, let's be careful about that statement. Okay, are we to be put in the doghouse because we raised an important issue, because it doesn't conform to public health message? It's true, maybe it does confuse the public. But this is a confusing situation for all us.

Mark Masselli: You raise an interesting point that I do want to get into a little later about the sort of the battle that's going on in the private science community with the governmental science and what's happening there. But I do want to sort of pick up on your point, there's been spontaneous combustion because we've all had the same experience that everybody we know is all of a sudden calling us up and saying, hey, we've gotten this, which sort of goes to the question about Omicron and its effectiveness with the vaccines. When are we going to know whether or not the third shot, booster third shot whatever is working, and whether Moderna or Pfizer is the best to take for that? I think people are really sort of lost and then just how Omicron evades vaccine neutralization would be helpful. But talk a little bit about your sense of when we'll have some definitive word on what might be the best pathway for people in terms of vaccine protection.

Dr. William Haseltine: Well, let me say with respect to the third shot, we know the answer. It doesn't protect you for very long, maybe only three months, the third shot. If you've been infected, and had two doses of the Moderna or the Pfizer vaccine, it doesn't protect you longer than three months either. Maybe four months and, Mark, Moderna maybe a shed shade better, that's sort of I'd say three and a half instead of three months. But when you look at the data that I've just seen, you don't --- you get very little protection.

When Pfizer says something like, well, this three shots is significantly

protective, it means it's tenfold less If you look at the data, protective, than it was against Delta. It also, or I guess, it also says after three months you'll have virtually no protection, a few people may, but most people don't. The answer is what to do? The answer is, which is test yourself very frequently so you know if you're infected. Get yourself a pulse oximeter so you know whether or not you have to go to the hospital. If your oxygen level drops you know you're in trouble. Hopefully it doesn't. Avoid crowds. Don't go to your Christmas parties. Don't travel. Stay home. That's hard to say after all we've been through. But I would strongly advise against bars, restaurants, theaters, and parties.

Going to give you an example of a friends. I was --- I went to my last party about three days ago. I said, everybody this is --- I'm not going to anymore until Omicron is gone. I wish I hope you will listen to me. One of my friends just wrote me, said, Will, I wish I had listened. I went out and somebody I was with had Omicron. Now I'm isolated, and I hope I don't get it. That's what I would recommend. It's hard to say, I know it's hard for people to do that. It's hard for businesses. This is a time when you fill up your money back for the end of the year and get some cash that it ties you over for January and February, which is a terrible month for retail. But it's pretty dangerous right now, really dangerous.

Margaret Flinter: Well, it is sobering to put it mildly. I guess the question is, and after living through this year, right, and this was the year when we had the vaccine so we were very optimistic. We gave 800,000 vaccines across the state of Connecticut. We got very optimistic that this was going to stop it. It feels like we're going to be back to what was very inflammatory in our society, which was lockdowns and mandatory quarantines and maybe school closings.

What is your sense? Are you having an opportunity to weigh in with the policy people about whether these measures which really come back to local people, right, governors and mayors and superintendents of the Board of Education to impose. What's your sense of what's going to happen with those decisions? Are they necessary? Are they the right thing to do right now, you know, if you can't go to a bar, you probably shouldn't be going to your second grade class either.

Dr. William Haseltine: Well, let me just say we have a model work hours, this is a UK, which is not exactly like us, but close enough. They decided they would try to tough it out, and boy do they have problems, and every day it gets worse. In the past, our experience in most parts of our country --- the UK experience has not been a happy one. It doesn't look like to me we're going to do the things we need because we don't have the consensus that we need in our population. I'm writing a new book

now on multimodal COVID control. The first thing I'm saying that we need is a consensus society. If you don't have that, it doesn't matter how good you are at everything else. We're the best in the world at communications and drug development, vaccine development, and this hasn't done us any good. We have more people dead from this than anybody else in the world, more Americans, and we're only 5% countries that are 5, 10 times bigger than us. Maybe India rivals us. Okay, we're right there in the same boat with India. It is not a happy circumstance.

We think our health systems are better than India's, but the results aren't better. But what can we say? We can only hope that we wise up at --- I'm always projecting for it. How many years decades or centuries is it going to take for us to get to a consensus society? How many more disasters? Well, the coming infections lure like Omicron bring us closer together or push us further apart.

Mark Masselli: I want to pick up on that thread about the consensus society. I'm wondering within the scientific community and I alluded to it earlier. These are your friends at CDC, at the White House, at NIH that you know, and yet we seem to have some difference of opinion going on, or their recommendations are not being listened to. What do you think is at the heart of simply the CDC not coming out and saying the third dose, the booster whatever, should be mandated. Where's the disconnect that's happening?

Dr. William Haseltine: I think it's a political disconnect, because one of the things this is teaching us which it's teaching us again, is that leaders cannot lead where they know we have to go. They can only lead where people will follow. FDR as a great example, I read a lot about FDR before World War II, by the late 30s, he knew we were going to be in that war. But the American people resisted just dug it in their heels. You watch how he struggled and maneuvers and tried, he was a great leader of people, and he did everything he can. But until Pearl Harbor, he couldn't do very much, that change things.

Omicron I don't think it's going to be our Pearl Harbor for this. There may be one which allows leaders to lead, a leadership wants them but if you look behind you, and nobody's there, you're in trouble. I think that's the lesson between the two presidents. One of them calls it a hoax one who takes it really seriously, and the results were about this.

Margaret Flinter: Well, that is a good note. That is a good note, Dr. Haseltine for us to wrap up on. We know you have a time deadline. We've been speaking with Dr. William Haseltine of virologist, the author of two books about COVID. As you just heard somebody with a strong and clear message about COVID variants, antiviral drugs and what we might expect going into the new year. You can learn more about him at www.williamhaseltine.com. Dr. Haseltine thank you so much for

joining us again on Conversations on Health Care.

Dr. William Haseltine: Thank you very much. I appreciate it.

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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 health care 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 US politics. Lori, what have you got for us this week?

Lori Robertson: With the release of its pediatric COVID-19 vaccine, Pfizer switched the buffer used in its formulation to increase the stability of the product. This allowed the vaccine to remain at refrigerator temperatures for longer. The Food and Drug Administration okayed the change and the changes also been made to some doses for teens and adults. Social media post however have misleadingly suggested that the ingredient swap is dangerous or was added to prevent heart attacks in children. There's no evidence to support that.

The ingredient in question is Tris or Rrimethylamine, which is used as a buffer in the children's vaccine and will soon be available in some adult and teen formulations as well. A buffer keeps doses at the correct pH, neither too acidic or too basic. The original iteration of the Pfizer BioNTech vaccine used phosphate buffered saline or PBS. Pfizer and the FDA have said the switch was made to improve the stability of its mRNA vaccine, which previously had to be kept ultra cold for long term storage and lasted a month in a refrigerator ones thought. The newer version can last in the fridge for up to 10 weeks. Other experts back that up.

Tris has safely been used in other vaccines and other products. Less stringent cold chain requirements are especially helpful for the pediatric vaccine, which is being administered more in doctor’s offices. As for social media post claims about Tris being dangerous or a drug for heart attacks, in large quantities Tris can be used as a drug, but here as in other vaccines and medicines the compound is present in only a very small amount as an inactive ingredient to keep the vaccine stable.

Dr. Kawsar Talaat an infectious disease physician and vaccine scientist at the Johns Hopkins Bloomberg School of Public Health told us the infinitesimal amount of Tris in vaccines has absolutely nothing to do with the much larger volumes and higher concentrations of Tris being given to people who are having heart attacks. The Pfizer BioNTech COVID-19 vaccine is not known to increase the risk of a heart attack in any population. Instead, the cardiac concern that has been identified

for the two mRNA vaccines is an increased risk of Myocarditis or inflammation of the heart muscle and Pericarditis an inflammation of the lining surrounding the heart particularly in young men. But these adverse events are rare and as a buffer Tris would not be expected to modify the risk in either direction. That's my fat check for this week. I'm Lori Robertson, Managing Editor of FactCheck.org.

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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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Mark Masselli: Each week Conversations highlights a bright idea about how to make wellness a part of our communities and everyday lives. Fitness trackers have become all the rage, especially among upwardly mobile fitness conscious people seeking to monitor their own health and fitness goals. But another trend has emerged in the age of wearable devices. After a few months, about a third of users simply stop using them, leaving a lot of costly devices sitting on the shelf and not in use. The reality captured the imagination of Tufts University School of Medicine, Professor, Dr. Lisa Gualtieri.

Dr. Lisa Gualtieri: I had read about the abandonment rates and I thought what if you could take all of these abandoned trackers and give them to the people who could benefit most from them.

Mark Masselli: She thought what if we could get disinterested owners to donate their used fitness trackers and wearable devices to be repurposed and donated to underserved populations.

Dr. Lisa Gualtieri: A lot of the work that we've been doing has been with older adults, racial and ethnic minorities. For a lot of people, they're quite interested in owning one of these devices to help them increase their fitness. For a lot of people, the cost is prohibitive, so I think that that's a barrier for a lot of people.

Mark Masselli: In 2015, she launched her nonprofit enterprise Recycle Health, an online social media campaign to raise awareness for her program which seeks donated wearable devices no longer in use, to provide these expensive devices for free to those in need. She partnered with organizations working with low income adults in wellness programs and those with mental health issues, seniors in fall prevention programs, minorities and veterans as well. Her goal is to start collecting vital data on the deployment of these devices and the

impact they may be having on behavior change in vulnerable populations.

Dr. Lisa Gualtieri: What we do is talk to people about how active, how sedentary they are, to helping them to see it as an educational process where they might start off with 2000, 3000 steps as their goal to make that higher when they're ready to.

Mark Masselli: She's hoping to scale that number up significantly in the future, and to expand their data collection on health outcomes for vulnerable populations who gain access to these wearables. Recycle Health, a simple repurposing of personalized wearables providing these tools for free to vulnerable populations, empowering them to engage in activities that can improve their own health, provide useful data on using these devices to improve population health. 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.

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.