Gerald Harmon, MD, on what to know about COVID-19 therapeutics

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In today's COVID-19 Update, AMA Chief Experience Officer Todd Unger is joined by the AMA's president, Gerald Harmon, MD, a family medicine specialist in Pawleys Island, South Carolina, who shares new information and big takeaways about therapeutics for COVID-19 after his recent conversation with three physician leaders from the FDA.

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Speaker

- Gerald Harmon, MD, president, AMA

Transcript

Unger: Hello, this is the American Medical Association's COVID-19 Update video and podcast. Today I'm joined by AMA's president, Dr. Gerald Harmon, a family medicine specialist in Pawleys Island, South Carolina. He's going to talk about what he learned about therapeutics for COVID-19 in his recent conversation with three physician leaders from the FDA. I'm Todd Unger, AMA's chief experience officer in Chicago. Dr. Harmon, thanks so much for joining us. After this webinar that you had this week, you can understand why there's probably a lot of confusion around therapeutics. We've gone from a period of time when we were very focused on reducing the severe risk of COVID or preventing it through the vaccines. We've had new EUAs come through for antivirals at the same
time, that some monoclonal antibody treatments have taken out of the mix because of their ineffectiveness against the Omicron variant. Why don’t we just start by talking about as a frontline physician, how are you treating your patients with COVID? How do you use therapeutics in your practice and which patients seem to benefit the most from it?

Dr. Harmon: Great question Todd, and I, as you know, I learned a lot and had a plethora of information provided for me on frontline therapeutics options now for COVID-19 pandemic. But what I really do, and I bet most doctors do this too, we ask this consideration, I consider each case as an individual. That's where the doctor-patient relationship is critical. And so I consider each individual with their risk factors. If they have an acute COVID infection, they ... I’ve had a couple call me already today about being positive. What therapeutics have we exercised? And so we try to make an isolated judgment for each one appropriately, okay. And we do have risk factors and considerations, whether they’re vaccinated fully, whether they’re under vaccinated, unvaccinated at all. They're comorbid conditions, age, obesity, chronic disease, things like that, immune compromise.

So I really have a very candid conversation with the patient and we discuss whether it's an oral agent, an IV agent, whether it's a need for further evaluation with testing, maybe a hospital or emergency into visit or acute office visit. And I have a candid conversation but it really comes down to me giving them advice. I don't want to burden them with making the sole decision. I have shared decision-making but I tell them here's ... And they were asking me, "What do you advise Dr. Harmon?" So here's my advice. And based upon their individual risk factors, availability of the treatment options, I'll make a recommendation. I know that's a roundabout way but I'll decide whether they need a prescription for an oral agent, whether they need to go get an IV monoclonal antibody, whether they need to go get remdesivir in the emergency department at the hospital over a three-day course. All those are in my armamentarium now. And again, the question might be, and we'll answer later in this conversation, the availability of either any of those options.

Unger: Well, I think we're going to focus on one of the words that you just said in that, which is availability. You go through that decision-making process that you talked about and then it comes down to we’re in a serious short supply situation with some of these treatments. So now how do you deal with that situation?
Dr. Harmon: Well, you nailed it is, again, and I alluded to it in my comments. It depends on what's available, which is interesting. Among the therapeutic options that are available right now, my tightest local issue right now is with IV monoclonal antibody, sotrovimab. I'm really having a little more trouble getting sotrovimab for my eligible patients than I am for some of the, believe it or not, the oral agents are the IV remdesivir right now. So the sotrovimab is probably my biggest challenge. I'll tell you what's interesting too as far as availability, I've had a couple of local pharmacies in our counties here have the oral agents, molnupiravir and Paxlovid, have been available, limited quantities. So I've been very pleasantly surprised on their availability.

Unger: That's good news. I'm assuming but let's talk about the longer term outlook for supply of these particular treatments. What's the word from the FDA?

Dr. Harmon: Well, it was interesting. When we heard Dr. Farley and his colleague from the FDA in our recent webinar with them, they suggested that they know that it's been a difficult winner, they know, they recognize there's been supply chain issues for therapeutics, no question. And we do know that the Omicron variant had some resistance to previous treatments and was able to allude some antibody, responsiveness, no question. They told us, and I heard this loud and clear from them, they're working to improve the supply of the monoclonal antibody sotrovimab. They're working to improve the supply of Paxlovid and molnupiravir. And they mentioned as earlier as the spring, and I'm thinking, well, gee, that's pretty far in the future. But if you think about spring is ...

Unger: That's a couple months away.

Dr. Harmon: We're only month or so away from it, so it's not as grim or as dark, as you might think about it. And there's one other treatment option that's in there. And he mentioned it too. I believe, and that's remdesivir, is now an ambulatory treatment option too, when before, it was inpatient only. So there's some supply chain issues but the future's looking better, I have to say that.

Unger: Well, one of the issues that you discussed it's around this kind of timeframe when physicians needed to prescribe many of these treatments. I know just anecdotally, when I talk to people, who've had COVID, they spend the first couple days blaming on allergies or something else like that. And that's precious time that goes by because you need to really move in that early course of the illness. Can you address how you deal with that situation, what advice you would have for other physicians.

Dr. Harmon: Todd, you nailed that too. I mean, clearly you've been involved with this well as a journalist and an experienced chief experience officer, you've experienced this and heard it from other doctors. You're right. The oral agents, the antivirals have a five-day window when they're most effective. And then once you diagnose that window, once you make the diagnosis with it, symptom onset and then positive test indicating that you've got the disease and allows us to prescribe it, you've got five days of treatment that you begin too. So there's a very brief window for that anti-COVID
treatment. Then there's a little longer treatment window for the monoclonal antibodies. You have 10 days from either symptom onset or the date of the positive test. So that gives us a 10-day window. And then we don't really have a definite window for remdesivir, which is the IV ambulatory treatment that's now given over three days.

However, all those numbers can kind of fly around in the primary care physician's head. And the treating doctor's head already got five days here, then I've got seven days of treatment or seven days, I could use it in 10 days. And it has changed. Originally the remdesivir was a 10-day course, and it was shortened to a seven or a five-day inpatient course. Now it's only a three day outpatient course. Then if you get the five day, one of the treat oral antivirals, molnupiravir and Paxlovid, then you have got a five-day treatment on top of a five-day diagnostic window.

It can get a little confusing and you have to kind of think it through. So what I find myself doing when I deal with my patients and forgive me if it may sound kind of dull and boring but I have an oral conversation, I have a kind of a thinking out loud conversation with a patient and we use that. So it can be a little informed of what might be available. And I kind of talk it through in a thought experiment, what would be the most available, most appropriate, all those options, however, are beneficial. So that's a good sign or a good thing for me.

Unger: I like that idea of kind of enrolling the patient along with you in that kind of decision-making process. Obviously, you're equipped with a lot more data and they did go into a great level of detail. And I encourage everybody out there to check out this webinar on our YouTube channel. But let's talk about that because we won't go into detail about the data they shared on the therapeutics but what do you learn and how does that affect how you think about using these therapeutics with your patients?

Dr. Harmon: Yeah, it does. And you're right, Todd. Again, I've found that the therapeutic options, I can get a little comfortable with but they're so varied and they are dynamic as it were. They're not changing just for the sake of confusion, they're changing because the data indicates the treatment options might be improved. So that's what we do. We wind up and that's why my thought experiment each time with each individual case allows me to discuss it, the logistics of access. Does the patient have a right to get the monoclonal antibodies? Because I can't just call that in to the pharmacy. They're going to have to be scheduled for the sotrovimab if we have it in stock. Will their insurance, believe it or not, cover the oral agent because not all oral agents might cover it. You have to make sure I'll be covered by the particular insurance plan.

Do they need to go to the emergency model? They're a little bit higher risk where I'm really worried, not so much about the oral agent. And so I think perhaps in this sicker patient population, I have experience with remdesivir and now that we can do that in an ambulatory setting, I might suggest that, if they can have an opportunity to get logistically to there. A huge variety of treatment options available and logistics are probably best handled by the local provider.
Unger: Anything about benefits and risks that you learned from the conversation?

Dr. Harmon: I really did. I learned that in all cases, the benefit is far by beating all these treatments, just like getting the vaccines, the benefit is far better to get the available prevention and/or treatment than it is to get the disease and be subjected to the whims of the virus and what part of its organ system it attacks, what the long COVID virus syndrome might entail. So in every situation, the benefit of treatment and/or vaccination will outweigh the risk. So that's not a concern there too. And I have personal experience having been a frontline provider now for almost two years. I know that the side effects for these treatments are very negligible. The IV monoclonals before sotrovimab were well-received, well-effective and had a high effective rate against prevention of advanced disease and particularly hospitalization or death. Also know that the remdesivir, the IV antiviral that we're using in the hospital for the better part of the treatment, the last two years has been very safe and effective. And I'm getting to get some confidence now. Clearly I have less experience with the oral antivirals. All right. I don't know how they're going to work. I get the data from the experts. They explain that they are very safe with a little bit of drug interactions you have to concern to yourself with but I have pretty good confidence in all of it.

Unger: Dr. Harmon, I'm curious when you're talking with your patients about these treatments, is there less resistance than say they might have had to vaccines?

Dr. Harmon: Well, it's interesting you bring that up. I find it fascinating that there seem to be much more receptive of treatments tied. In my personal experience to my vaccines, then they had some hesitation perhaps for vaccines. It's interesting. When they call me up, they say, "Hey, I've just tested positive with a home test or I've gone to the local urgent care center," or maybe even one of the other ambulatory practices in our practice says this, I'm positive. So what do I want to do? And they're anxious to receive a treatment. It's fascinating how there is lower resistance and a better acceptance of the various antivirals, even though they're relatively new surely versus the resistance sometimes to get the vaccination, which has been very effective, been around for over a year now. So yeah, it is a little bit of a change in approach.

Unger: Someday we'll be able to unlock the mysteries of the mind and the interpretation of these various alternatives but we're still learning. Peaking of learning. Anything else that you found particularly surprising from your conversation with these folks from the FDA?

Dr. Harmon: What I found surprising is they were pretty confident that they're moving in the right direction. They have good confidence in their processes, their research their development. And they struck me as being, not just trying to answer in a matter of fact but in a very positive way, they're very comfortable. Their science, their development process is making available very effective therapeutic options. And I like, y'all know, I like their optimism. I like their engagement and I like their candor when
they discussed the safety, the viability and the efficacy of their treatment options. So I don't know that I was surprised but I was encouraged by the positivity and the expertise that my colleagues at the FDA manifest in our webinar.

**Unger:** That's good because we need optimism and good news. I think where we are right now in this. And speaking of which, I thought you closed on something I found personally very inspiring. And you talked about the power of science and medicine, and you thanked all your physician colleagues for the many roles that they've played throughout this pandemic. How do you think history is going to look at this pandemic in terms of medical innovation and advancement?

**Dr. Harmon:** Well Todd, I'll tell you, one of my biggest takeaways for the entire meeting was that we have great therapeutic options. But one of my biggest takeaways, and if we look back in history, is that all these treatment options are like we're looking for silver bullets still. Okay. A lot of my patients, you mentioned they're resistant or they have lower resistance to taking these treatments. They're hoping these things are silver bullets so they can shoot the monster, the coronavirus monster. What I think is the best protection shows that we don't need to wait on silver bullets. We need to protect ourselves from being attacked by the monster. So we need vaccinations, that's what I would tell you. So my biggest takeaway is even those are great therapeutic options, highly effective, they're still not silver bullets.

We need to get vaccinated, need to build our prevention together. I think history's going to say that science of medicine power and this COVID pandemic is going to be reinforced. We're going to have some unprecedented innovation now, as a result, the silver linings using another analogy to the cloud, we're going to have silver linings. We have now developed new immunotherapies. We developed new vaccine development technology using messenger RNA and other new innovative virus, vaccine delivery mechanisms. We have an expanded use of messenger RNA and antivirals for other disease states. We are going to use telehealth, telemedicine, digital medicine. We're going to improve our public health infrastructure. We're going to be better as a nation, not only for this pandemic, for the next pandemic.

And one of the other things that I can talk about with some confidence here is although we had preexisting health care disparities and we knew there were health care disparities, now we have really seen the need for that and emphasized the need for addressing health disparities. And I think that's going to be much improved and seriously addressed in the future. So I think the history will look back on the AMA, on organized medicine on the, the public health infrastructure is being critically needed, critically innovative and very energized going forward to address the next pandemic.

**Unger:** And resilient. Under two years of trauma. So thank you, Dr. Harmon for being here today and to all your colleagues and a huge and heartfelt shout out to the folks at the FDA. They joined us in all of their colleagues for the work that they continue to do to bring this pandemic to a close. Now, we covered a lot of material in the webinar. If you didn't have a chance to visit it, you can still find that by
looking at the information in this video or checking out the AMA YouTube site and finding this, What Physicians Need to Know series of webinars. We’ll be back soon with another COVID-19 Update. Thanks for joining us today and please take care.

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