Gerald Harmon, MD, on FDA's full approval of Pfizer vaccine

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In today’s COVID-19 Update, AMA President and family medicine specialist, Gerald Harmon, MD, dives into the details about the FDA’s full approval of the Pfizer vaccine—and what it means for physicians and patients.

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Speaker

- Gerald Harmon, MD, family medicine specialist; president, AMA

Transcript

**Unger:** Hello, this is the American Medical Association's COVID-19 Update. Today we're talking with Dr. Gerald Harmon, AMA President and a family medicine specialist in Pawleys Island, South Carolina, about the FDA’s full approval of the Pfizer vaccine and what it means for physicians and patients. I'm Todd Unger, AMA's chief experience officer in Chicago.

Dr. Harmon, thanks so much for joining us today. I know you're very busy. You called FDA's full approval of the Pfizer vaccine "a milestone in our long battle against COVID-19" in the release that went out from the AMA yesterday. Why is this approval so significant in our overall efforts to defeat the virus?

**Dr. Harmon:** Todd, this is an incredibly safe, well-researched highly effective vaccine. This removes, I would hope, some barriers that might exist in the vaccine-hesitant, unvaccinated population and reassures them that this is a very safe, fully accredited vaccine by the FDA's very rigorous standards. It gives us the most effective weapon we can have. Prevention by vaccination is so much better than
having to treat this highly virulent, highly contagious disease that we’re still in the midst of.

**Unger:** You were just talking before the segment about what you're seeing in your own hospital system down there. You're seeing that vaccinated/unvaccinated situation playing out?

**Dr. Harmon:** Oh, we are. I was commenting offline and I'll do this in some interviews and other times, just among my colleagues. Six weeks ago, we had two to three inpatients in a COVID positive situation in our small hospital system here in rural South Carolina. And one day we even had zero patients, which is remarkable in the end of June.

And now about six weeks later, we're running 50 to 60 patients, inpatient-wide, among our hospital system with positive COVID diagnoses. And of those of those 50 or 60 patients, we have about 10 in the ICU and about five on ventilators. And all of those in the ICU and on ventilators are unvaccinated patients, 90% of what we're admitting and seeing in the hospital and putting in the ICU and putting on ventilators are unvaccinated folks.

So it's a very effective vaccine. If you get vaccinated, you have a very low risk of becoming sick enough to go to the doctor, to get hospitalized, placed in the ICU, to be ventilated and then to die. This is a very effective weapon.

**Unger:** Well with full approval, hopefully one of those obstacles to those that are remaining unvaccinated will be removed. What do you tell physicians in order to help them reassure their patients that no corners were cut either with the EUA or in full approval?

**Dr. Harmon:** This is, again, even some of our doctors, without reading through, or really, they're so busy taking care of patients maybe they haven't had time to do it. No corners were cut. Peter Marks and I'll quote him. He's the FDA's top vaccine regulatory authority, Dr. Peter Marks. "The public and the medical community can be confident that although we approved this vaccine as expeditiously, it was fully in keeping with very rigorous, existing high standards for vaccines in the U.S."

The only expedition was in the funding. It wasn't in any of the rigorous scientific processes. There were adequate trials, very well-studied, held to very rigorous standards and it was in emergency use authorization for now six full months after being implemented in an EUA. So it's met fully our FDA approval standards for vaccines.

**Unger:** That's really important, Dr. Harmon, because when we did talk to Dr. Marks, what he made very clear was no corners were cut, like you said. But expediting around, just cutting out red tape and wasted time. It's so important in a pandemic that we're in right now. And I think one of the additional things is just ongoing safety monitoring. Can you talk about what will be occurring as time goes by?

**Dr. Harmon:** Well, consistent with FDA standards and previous vaccines and previous FDA releases of other types of vaccines and treatments, there will remain some monitoring. Forever, there will be
monitoring. In particular, these three vaccines that we have now, the two messenger RNA and the antiviral vector vaccine from Johnson & Johnson, there'll be some ongoing monitoring of very rare cases of myocarditis or pericarditis. And those were actually there in the safety warnings now that are approved by the fully-approved FDA vaccine. It was also in the EUA vaccinations.

They'll be monitored and there'll be follow on just in case there's a longterm effect for many other vaccine side effects but that's standard. And that really is still, because we've had so many vaccines given, the 300 plus million doses, we know this is a very, very low side effect and a potential complication.

Unger: Now with the full authorization decision, there's an expectation that it might kick off a number of vaccine mandates. Can you talk about the AMA's position on that?

Dr. Harmon: We just released a message from the AMA encouraging every employer, in fact, recommending employers, organizations, to require and mandate vaccinations for their staff, their employees as a safety measure to mitigate the spread of this highly virulent, highly contagious coronavirus that's paralyzing economically and health care wise, many of our industries and economies in the country. We're supportive of this. AMA, as you know, recommended vaccination for health care providers at its last meeting, and we've been excited about encouraging others by example to do this. So, yeah, we're very much in support of it.

Unger: And other statement that was out there just with AHA and the ANA supporting the FDA's approval as well. Any comment on that?

Dr. Harmon: Yeah. We jointly combined with the AHA, the American Hospital Association, the ANA, the American Nurses Association, to issue a joint statement supporting and applauding the full FDA approval. And what we're trying to demonstrate here is that we're united across health care. All of us who are on the front lines, either providing the care as an institution, supporting the care as front line workers—both nurses and doctors—we're all in this together. So our joint effort and our joint applause for the FDA I hope delivers a message that we have full confidence in its safety and efficacy going forward.

Unger: I really liked what you said in your statement, which is, to paraphrase it, "If you've been waiting for a full approval, that time's now and it's time to get your vaccine." You've had a lot of practice in talking to patients who are not vaccinated. Do you have any advice for physicians about what they should be telling patients in regard to this as just another piece of data?

Dr. Harmon: You know what I would tell people and you've heard me say this before, and I do it even now in my local community, we're good ambassadors. People trust their doctors. They trust their doctors almost before they'll trust anyone else. They trust us with the most precious items in their lives, their possessions, their health, the health of their loved ones, the lives of their loved ones. And they really trust us now to give them the science, the proof that this is the right thing to do for their
families, for them to protect them with their loved ones.

So, yeah, this is the message we need to be delivering from doctor to patient. Even sometimes soliciting. Be proactive. Don't necessarily wait for your patient to ask you. So I find a lot of times when I'm dealing with my folks in the community, not just in the practice setting, I'll see them in their natural habitat, as it were. I might be working with them at their jobs or seeing them, and they're doing some service work. I'll say, "Hey, how you doing?" "Fine. We're fine, doc, how are you?"

I say, "By the way, have you gotten your COVID vaccine?" And if they give me a little head, "Well..." They look away and say, "Well..." I said, "Listen. I can give it tomorrow in my office, no charge. I'm looking for you about two o'clock tomorrow. I'll tell my nurse you're coming." So I'm very proactive. And I think all of us can take those steps to do it. And then we give a message. Not only if we're supportive but action ... actively improving the vaccination rate.

**Unger:** One of those actions is really leading by example, like you talked about before. So important for physicians. What are your thoughts there?

**Dr. Harmon:** Yeah. One of the things we've done to doctors, fortunately, we're among the first to receive or have an opportunity to get the vaccine. So we stepped up. Health care providers across the nation, even as early as December of 2020 when it was approved, when the vaccine became available. I've got some in my right arm. I think my first shot was on the right arm. The second messenger RNA vaccine weeks later was on the left. I've just rotated for sake of giving the nurses more practice, I suppose.

They love sticking a needle in me, by the way, Todd. We tend to poke each other, we would tend to literally do it on rare occasion. We figured we'd do it often. But yeah, doctors stepped up and front line workers did. And that gives us a message too. Our statistics from the AMA tell us that over 97% of physicians have taken advantage of this vaccine effort; they've received their vaccines.

So they're telling our patients, they're telling our family members, they're telling the public in general, that we're very confident that these vaccines not only work but that they're safe and they make us safe when we go back home to our family members, when we work in our communities, and when we're delivering care and to those folks that aren't active at COVID right now, they're still ... I know we're making a very big deal of COVID, but a lot of our health care, you've heard me comment coming on this too, health care doesn't stop. Chronic disease goes on.

Don't socially distance from your doctor. Continue to get there. You know your doctors protected, you know your doctor and that work environment for that physician and your health care environment is a safe environment to be in, especially as we improve the percentages of fully vaccinated individuals.

**Unger:** Dr. Harmon that is so important to know that physicians are protected and don't socially distance from your doctor. I love that statement. Please see your doctor and get treated for those...
chronic conditions that are so important. And Dr. Harmon, thanks to you and all of your colleagues for the strong support you continue to give in encouraging folks to get vaccinated right now.

That's it for the COVID-19 Update. We'll be back with another segment soon. In the meantime, for resources on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us. Please take care.

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