

## John Farley, MD, MPH, on not using ivermectin to prevent or treat COVID

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### Featured topic and speakers

In today's COVID-19 Update, a discussion with John Farley, MD, MPH, director of the Office of Infectious Diseases in the Center for Drug Evaluation and Research's Office of New Drugs at the FDA, about what physicians and patients really need to know about ivermectin.

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### Speaker

- John Farley, MD, MPH, director, Office of Infectious Diseases in the Center for Drug Evaluation and Research's Office of New Drugs, FDA

### Transcript

**Unger:** Hello, this is the American Medical Association's COVID-19 Update. Today we're discussing what physicians and patients need to know about ivermectin, with Dr. John Farley, director of the Office of Infectious Diseases in the Center for Drug Evaluation and Research of New Drugs at the FDA in Silver Spring, Maryland.

I'm Todd Unger, AMA's chief experience officer in Chicago. Dr. Farley, thank you so much for joining us. Obviously, we've been hearing a lot in the news about ivermectin and how people are taking it in the hopes of preventing or treating COVID. What are you hearing at the FDA?

**Dr. Farley:** Well, thanks Todd and I'm happy to be here today. So as part of our work during the

epidemic, FDA has been conducting ongoing daily surveillance for the safety of drugs, including ivermectin, that are reportedly being used in an attempt to treat or prevent COVID-19.

We've identified multiple concerning cases of patients who required medical treatment and were hospitalized after using ivermectin products to treat or prevent COVID. Some of these products were intended for animal or veterinary use and others were products intended for human use.

**Unger:** I know for instance, it's in my dewormer for, I think my dog. Obviously intended for animals, what are the dangers people face when they take a drug for veterinary use essentially?

**Dr. Farley:** Yeah. So one problem with humans taking drugs intended for animals is that those drug formulations often contain other ingredients and those ingredients would be safe for a horse or a cow but not for a human.

In the case of ivermectin, a number of the veterinary products contain much larger doses of ivermectin than is safe for humans because they're actually intended for large animals like horses and cows.

**Unger:** You know, when you think about ivermectin that is used in and for humans, are there any other kind of differences besides the size of the dosage, per se, or some of these additives that you mentioned?

**Dr. Farley:** Yeah, there are some, what we call inactive ingredients, in the tablet that are simply not safe for humans, where they would be for a large animal. So, that's one of the differences in addition to dose.

**Unger:** So, why? Obviously I think it's a little bit moot but physicians are trusted voices here. People trust their doctors. Why is it so important that physicians actively manage ivermectin use in patients?

**Dr. Farley:** Well, I think ivermectin is approved by the FDA to treat people with certain conditions caused by parasitic worms and it's a valuable drug, particularly in international settings. But it's important for physicians and everyone to understand that oral ivermectin, or ivermectin by mouth, generally it's given as a single dose treatment, which may in some cases, be repeated at recommended intervals.

We actually don't have data about the safety of taking ivermectin every day for a long period of time and some folks are doing to treat or prevent COVID.

**Unger:** What are some of the biggest concerns about patients taking this drug, specifically to prevent COVID?

**Dr. Farley:** Well, I think the first would be side effects and so it's important for physicians to think

about those. There are side effects from the drug itself and that could be worse in some patients and need to be monitored. These include stomach problems, skin rash and itching, and nervous system problems, including dizziness and tremors.

Then in fact, many of the listeners will know that last year there's a report in New England Journal, of a teenager ended up in a coma after taking the recommended dose of ivermectin for scabies. So, we had the agency are working to determine if there's more cases like that.

The physicians also know with any drug, there are potential interactions with other drugs the patient might be taking and there's some patients who require a special kind of risk-benefit consideration when considering ivermectin. For example, we have pretty limited information regarding the safety of ivermectin for women who may be pregnant or breastfeeding.

**Unger:** You mention that, that usage in a normal circumstance, the one dose thing you're talking about kind of not having data to support, even know what would happen for that kind of multiple use situation. So that's the prevention side of this. What about, we're hearing about people taking ivermectin to treat COVID. What are the concerns there?

**Dr. Farley:** Yeah. Well, first I think if you get COVID and are in a high risk group, such as older age or obesity or a chronic medical condition, you should be treated with a monoclonal antibody to reduce your risk of needing to be admitted to the hospital.

Now, there are publications of small clinical trials that report a benefit for ivermectin as a treatment for COVID-19 and that's fueled in part the increase in the use of ivermectin. But it's important for folks to know that there are also clinical trials, which show no benefit for ivermectin at all and it's also important for folks to know that many of the trials which reported benefit, were conducted in other countries without any oversight by the FDA, so we actually have no way of confirming whether the results reported in those trials are real or not.

We do have large and well-designed clinical trials going on in this country and others, which should tell us more about whether ivermectin is helpful.

**Unger:** So I'm curious, I think that starts to get to this phenomenon and you do have someone like Joe Rogan who says, threw everything at it, including monoclonal antibodies and ivermectin, this kind of just begins to perpetuate a little bit. But you know, in the beginning of this, how does a phenomenon like this happen and how do we get to a point where there's so much hype around using a drug to treat something when there's not data to support it?

**Dr. Farley:** Yeah. Well and that for me, particularly when ivermectin is being used for prevention is a real tragedy because there's not convincing data that ivermectin can prevent COVID but we have safe and effective vaccines that can keep people out of the hospital and keep folks from dying.

For many people making that choice to choose ivermectin over vaccine can be a tragic choice that can lead to them getting very sick, needing to get admitted to the hospital or even dying from COVID. I know that people want a pill to treat COVID. We all do and actually clinical trials have a number of by-mouth drugs to treat COVID are underway and that's a very high priority for the government. We need to wait for the results of those trials to know if one of those treatments shows benefit and if we do have convincing clinical trial data, we at FDA and the U.S. government are going to work as hard as we can, to make that treatment available and provide docs the information they need to use the treatment to maximize the benefit and minimize the risk.

**Unger:** So I'm sure there are many physicians out there who have patients coming to them that are asking for the drug. They've read about it. They've heard about it. What is your advice about how a physician should respond to requests like that?

**Dr. Farley:** So, as I was thinking about this, I was reading the paper this morning and there was a study just done in Maryland, interviewing people who had not yet been vaccinated. And in this group, the person they trusted the most for information about COVID was their primary care physician.

So know that if they're sitting in your exam room, even if they're pushing back and giving you a hard time, they trust your recommendations. So I would encourage them to get vaccinated for prevention. If they're infected and qualify for monoclonal antibodies, they should be treated. And if they're infected and at low risk for disease progression, insist on ivermectin, the best way for them to help everyone know if the drug helps at all, is to join a clinical trial and get treated with a safe formulation of the drug, at the right dose. They can find clinical trials available with contact information at a website, [clinicaltrials.gov](https://clinicaltrials.gov), one word, [clinicaltrials.gov](https://clinicaltrials.gov).

**Unger:** Dr. Farley, thank you so much for your perspective around this important topic. Appreciate you being here today. That's it for today's 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](https://ama-assn.org/COVID-19). Thanks for joining us. Please take care.

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