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A sign for the U.S. Food and Drug Administration outside of the headquarters in White Oak, Md., on July 20, 2020. (Sarah Silbiger/Getty Images)

PREMIUM **AMERICA**

FDA Says Telling People Not to Take Ivermectin for COVID-19 Was Just a Recommendation

By Zachary Stieber | November 19, 2022 Updated: November 19, 2022 A A Print

The U.S. Food and Drug Administration (FDA) telling people to "stop" taking ivermectin for COVID-19 was informal and just a recommendation, government lawyers argued during a recent hearing.

“The cited statements were not directives. They were not mandatory. They were recommendations. They said what parties should do. They said, for example, why you should not take ivermectin to treat COVID-19. They did not say you may not do it, you must not do it. They did not say it’s prohibited or it’s unlawful. They also did not say that doctors may not prescribe ivermectin,” Isaac Belfer, one of the lawyers, told the court during the Nov. 1 hearing in federal court in Texas.

“They use informal language, that is true,” he also said, adding that, “it’s conversational but not mandatory.”

The hearing was held in a case brought by three doctors who say the FDA illegally interfered with their ability to prescribe medicine to their patients when it issued statements on ivermectin, an anti-parasitic that has shown positive results in some trials against COVID-19.

Ivermectin is approved by the FDA but not for COVID-19. Drugs are commonly used for non-approved purposes in the United States; the practice is known as off-label treatment.

The FDA created a webpage in 2021 titled “Why You Should Not Use Ivermectin to Treat or Prevent COVID-19” and later posted a link to the page on Twitter while writing: “You are not a horse. You are not a cow. Seriously, y’all. Stop it.” A second post stated: “Hold your horses, y’all. Ivermectin may be trending, but it still isn’t authorized or approved to treat COVID-19.”

In a separate page, the FDA said: “Q: Should I take ivermectin to prevent or treat COVID-19? A: No.”

Those actions interfered with the doctors’ practice of medicine, violating the laws including the Federal Food, Drug, and Cosmetic Act, the lawsuit alleges.

It asked the court to rule the actions unlawful and bar the FDA from directing or opining as to whether ivermectin should be used to treat COVID-19.

Jared Kelson, an attorney representing the plaintiffs, told the court during the hearing that that informal claim “doesn’t explain the language they actually used: ‘Stop it. Stop it with the ivermectin.'”

The FDA's actions "clearly convey that this is not an acceptable way to treat these patients," he argued.

Plaintiffs in the case include Dr. Paul Marik, who began utilizing ivermectin in his COVID-19 treatment protocol in 2020 while he was chief of pulmonary and critical care medicine at Eastern Virginia Medical School and director of the intensive care unit at Sentara Norfolk General Hospital.

After the FDA's statements, Marik was told to remove the protocol from the school's servers while Sentara issued a memorandum to hospitals telling them to stop using ivermectin against COVID-19, with a citation to the FDA.

Marik was forced to resign from his positions because he couldn't prescribe ivermectin due to the FDA's statements, the suit alleges.

The government has moved to dismiss the complaint, asserting plaintiffs lack standing because the injuries cannot be traced back to the FDA.

Dr. Paul Marik in Kissimmee, Fla. on Oct. 14, 2022. (The Epoch Times)

More From the Hearing

During the recent hearing, which was on the motion to dismiss, the government said the FDA could not be blamed for the injuries.

“Plaintiffs have also not shown that any of their claimed injuries are fairly traceable to defendants’ statements because their injuries were caused by independent third-party conduct that was not a predictable response to those statements,” Belfer, the government lawyer, said.

Belfer noted that the FDA’s pages say people can use ivermectin if their health care provider prescribes it, argued the statements “did not bind the public or FDA, did not interpret any substantive rules, and did not set agency policy,” and said the FDA’s position could change in the future if new data become available.

“They also do not have legal consequences for anyone but simply provide nonbinding recommendations to consumers,” he said.

Kelson disagreed.

“If the government is going to label ivermectin a horse medicine or a horse dewormer and promulgate the idea that it is only for animals, then the natural correlation is that doctors who prescribe it are horse doctors or quack doctors, which has played out,” he said. “That is enough of a harm to get into court,” or have the motion to dismiss rejected, he said.

Ivermectin is used on animals in addition to humans. The FDA used a picture of a horse in its Twitter posts and on one of its pages.

“The government engaged in a singularly effective campaign here to malign a common drug that has been used for a very long time and has been dispensed in billions of doses. It’s one of the most famously safe drugs in the history of human medicine. And when people did exactly what the FDA said to ‘Stop it. Stop it with the ivermectin,’ I don’t understand how that would not be traceable back to the FDA,” Kelson said.

U.S. District Judge Jeffrey Brown, a Trump appointee overseeing the case, said that he was most concerned about the social media statements because they did not include any qualifiers.

Belfer argued the statements were aimed at consumers and that the Twitter posts linked to one of the pages, which does include the qualifier.

“So it was predictable that if you include the link to the article, people will click on the link and will see the full article, which includes that disclaimer that if your doctor writes you a prescription, you should fill it exactly as prescribed,” he said.

“The plaintiffs, by their own admission, have continued to prescribe ivermectin. So they always had the authority. It may be that patients were not able to fill prescriptions, but the doctors themselves always had the authority,” he added later.

Brown said he appreciated the briefing from the parties and that he would rule “as quickly as we can for ya’ll.” As of Nov. 19, he has not issued a ruling.