

Conservative judges revive case on FDA's "you are not a horse" ivermectin posts

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A panel of conservative judges has revived a lawsuit over the Food and Drug Administration's statements about the anti-parasitic and de-worming drug ivermectin—statements meant to clarify that the drug is not effective against COVID-19 and that formulations for animals, including livestock, are not safe for use in humans.

After the FDA received reports of people being hospitalized from taking livestock ivermectin, one of the agency's particularly viral posts began: "You are not a horse."

The lawsuit over the posts comes from three doctors, all of whom have faced charges and/or discipline from their respective state medical boards and employers over their ivermectin prescribing. The disgraced trio argue that the FDA's statements interfered with their ability to prescribe the antiparasitic drug to COVID-19 patients—including some patients the doctors had never actually examined, according to allegations by state medical boards.

In December, US District Judge Jeffrey Vincent Brown dismissed the lawsuit, arguing that the doctors' arguments didn't overcome the FDA's "sovereign immunity," which generally

protects the government from civil lawsuits.

In an attempt to overcome the FDA's immunity, the doctors argued that the agency's ivermectin-related statements (including a consumer update and social media posts) were outside the agency's authority—and even the legal standard of a “colorable basis for authority.” Specifically, they argued that while the FDA's posts seemed targeted to people trying to use the animal versions of ivermectin for COVID-19, the information also advised against using human versions, which are approved for some conditions, though not COVID-19. Thus, use of the human version for COVID-19 would be an off-label use—and off-label use of an approved human drug is common and generally at a doctor's discretion. The lawsuit argued that the FDA doesn't have express authority to advise against using an approved drug for off-label uses, and therefore, it exceeded its authority.

Brown, who was appointed by former President Donald Trump, rejected this argument, saying there is no statute that limits the FDA's actions in the context of the drugs it regulates.

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“Although the FDA could have, and perhaps should have, been more prudent in their communications, they had at least a colorable basis in authority—and there is no statute saying otherwise,” Brown wrote in his decision to dismiss the suit.

The doctors also argued that the FDA's online postings met the legal hurdle of being a “final agency action” that set up “legal consequences” that ended up harming the doctors. All three listed harms they say were linked to their ivermectin prescribing and, by extension, the FDA's postings. Plaintiff Robert L. Apter was referred to two state medical boards and has pending enforcement actions against him in the state of

Washington; plaintiff Mary Talley Bowden, an anti-vaccine advocate, lost her admitting privileges at a Texas hospital; and plaintiff Paul E. Marik lost his positions at a medical school and a hospital, both in Virginia, following several scandals.

Brown likewise rejected the additional arguments, saying that some postings from the agency do not constitute “final agency action” and that its consumer update and social media posts didn’t set any legal standard that caused them harm. In all, Brown determined the doctors had no standing and dismissed the lawsuit.

When the trio appealed, a conservative panel of three judges at the 5th U.S. Circuit Court of Appeal in New Orleans sided with Brown on some of the points—specifically, that the FDA’s posts aren’t “final” agency actions and they didn’t cause the doctors any legal harm.

But, in their decision, filed September 1, the three judges—judges Don Willett, a Trump appointee, Jennifer Walker Elrod, and Edith Brown Clement, both appointed by George W. Bush—reversed Brown’s earlier opinion on the FDA’s authority. The judges argued that the FDA’s recommendation against off-label use of ivermectin constitutes medical advice, and the agency failed to identify any authority it had to provide medical advice.

“FDA is not a physician. It has authority to inform, announce, and apprise—but not to endorse, denounce, or advise,” Willett wrote for the panel in its decision. “The Doctors have plausibly alleged that FDA’s Posts fell on the wrong side of the line between telling about and telling to. ... Even tweet-sized doses of personalized medical advice are beyond FDA’s statutory authority.”

The panel reversed Brown’s dismissal, and the doctors can now proceed with their legal claims.

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