Written by **Bob Adelmann** on September 4, 2023

Appeals Court Upholds Lawsuit Claiming FDA Overreached in Condemning Ivermectin

The Fifth Circuit Court of Appeals <u>reversed a</u> <u>lower court's ruling on Friday</u>, sending the case back "for further proceedings." At issue is the overreach by the Food and Drug Administration (FDA) when it excoriated the legitimate use of ivermectin in treating Covid-19 during the pandemic.

Rather than just issuing "information" about ivermectin (and hydroxychloroquine), it strongly advocated against their usage and, by implication, the preferred use of the experimental and highly profitable alternatives developed by the industry that long ago captured the agency.



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Physicians who favored the usage of ivermectin and hydroxychloroquine were heavily personally and professionally damaged when the media took the faulty message to the public and institutions bought the lie. Three of those physicians — Robert Apter, M.D.; Mary Talley Bowden, M.D.; and Paul Marik, M.D. — claimed in their lawsuit that the FDA and the compliant media "interfered with their individual 'ability to exercise professional medical judgment in practicing medicine.'"

Dr. Apter said he was "referred to [two state medical boards] ... for prescribing ivermectin to treat Covid-19," and that "the referrals include[d] copies of the FDA's [posts]. Drs. Apter and Bowden said that pharmacies have refused to fill ivermectin prescriptions for the patients because of those posts. Dr. Bowden lost her admitting privileges at a hospital after "tweeting about using ivermectin to treat patients with Covid-19." Dr. Marik lost his positions at a medical school and at a hospital "for promoting the use of ivermectin."

The posts referred to were these, which the FDA issued between August 2021 and April 2022:

Q: Should I take ivermectin to prevent or treat Covid-19?

A: No.

You are not a horse. You are not a cow. Seriously, y'all. Stop it.

You are not a horse. Stop it with #ivermectin. It's not authorized for treating Covid-19.

"Hold your horses, y'all. Ivermectin may be trending [gaining traction as a legitimate treatment for Covid-19], but it still isn't authorized or approved to treat Covid-19."

Each post featured an image of a horse. The mainstream media loved it and bought the lie, promoting the canard using the horse image. From the lawsuit:

The strategy worked well, and media outlets nationwide ran headlines and stories emphasizing FDA's "horse" image. Medical organizations also took note of the Posts, as did



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pharmacy boards and hospitals.

Federal and state courts, too, began citing the Posts in cases involved ivermectin.

All told, the Posts ... saw citations in newspapers, magazines, digital media outlets, medical and professional advisories, legal complaints, and judicial opinions across the Nation.

When the three physicians sued the FDA, the district court tossed it using the argument that the FDA officials promoting the lie were somehow "immune": "The district court held that sovereign immunity protects the Agenc[y] and the Officials [including Xavier Becerra, Secretary of Health and Human Services, and Robert Califf, Commissioner of the FDA], and it dismissed the suit. We disagree."

The three plaintiffs claimed overreach by the FDA - *ultra vires* - which is the exception to the immunity claimed when actions go beyond or exceed the bounds of an agency's legal authority.

One of the plaintiffs provided the most persuasive argument:

- 1. The FDA cannot act without express statutory authority;
- 2. The FDA does not have express authority to recommend against off-label uses of drugs approved for human use;
- 3. The posts recommend against ivermectin; so therefore
- 4. The posts are beyond FDA's authority.

Friday's ruling to remand the lawsuit back to the lower court concluded:

In sum, while FDA cites plenty of statutory authority allowing it to issue *information*, it never identifies ... authority allowing it to make medical *recommendations*.... The Doctors can therefore use the *ultra vires* exception to sue the Agenc[y] and the Officials. [Emphasis in original.]

It added:

FDA is not a physician. It has authority to inform, announce, and apprise — but not to endorse, denounce, or advise.

The Doctors have plausibly alleged that FDA's Posts fell on the wrong side of the line between telling *about* and telling *to*.

As such, the Doctors can ... assert their *ultra vires* claims against the Agenc[y] and the Officials.

Even tweet-sized doses of personalized medical advice are beyond FDA's statutory authority.

We REVERSE the district court's judgment of dismissal, and REMAND for further proceedings. [All emphasis in original.]

As a side note: When the "horse image" post hit the mainstream media, FDA staffers noted that the canard was "the most popular post we've had on Twitter," and that they were "pleased with the response and the results."

That the agency is merely a public-relations mouthpiece for the pharmaceutical industry was further





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revealed when FDA staffers described the posts as part of a "new recommended approach" comprising an "ambitious effort to counter much of the [negative] vaccine information out there."



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