IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

ROBERT L. APTER, M.D., FACEP; MARY TALLEY BOWDEN, M.D.; and PAUL E. MARIK, MBBCh, M.MED, FCCM, FCCP, *Plaintiffs*, v. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; FOOD AND DRUG ADMINISTRATION; and ROBERT M. CALIFF, M.D., MACC, in his official capacity as Commissioner of Food and Drugs, *Defendants*.	)	Case No. 3:22-cv-184 (JVB)

AMICUS CURIAE BRIEF OF THE ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS

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IDENTITY, INTEREST AND AUTHORITY TO FILE[1]

Amicus curiae Association of American Physicians and Surgeons ("AAPS") is a national association of physicians. Founded in 1943, AAPS has been dedicated to the highest ethical standards of the Oath of Hippocrates and to preserving the sanctity of the patient-physician relationship. AAPS has been a litigant in federal courts. *See, e.g., Cheney v. United States Dist. Court*, 542 U.S. 367, 374 (2004) (citing *Ass'n of American Physicians & Surgeons v. Clinton*, 997 F.2d 898 (D.C. Cir. 1993)); *Ass'n of American Physicians & Surgeons v. Mathews*, 423 U.S. 975 (1975). In addition, the U.S. Supreme Court has expressly made use of *amicus* briefs submitted by AAPS in high-profile cases. *See, e.g., Stenberg v. Carhart*, 530 U.S. 914, 933 (2000); *id.* at 959, 963 (Kennedy, J., dissenting); *District of Columbia v. Heller*, 554 U.S. 570, 704 (2008) (Breyer, J., dissenting). Over the span of more than a decade, the Fifth and Third Circuits have expressly cited an *amicus* brief by AAPS in the first paragraph of one of its decisions. *See Texas v. United States*, 945 F.3d 355, 369 (5th Cir. 2019); *Springer v. Henry*, 435 F.3d 268, 271 (3d Cir. 2006). AAPS was the plaintiff in a decision relied upon by the government here in its pending motion, which reinforces AAPS's interest in this case. (Govt Mot. 13)

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[1] The undersigned counsel certifies that counsel for the *Amicus* authored this brief in whole; no counsel for a party authored this brief in any respect; and no person or entity – other than *Amicus*, its members, and its counsel – contributed monetarily to this brief's preparation or submission. *Amicus* files an accompanying motion for leave to file this brief, and all the parties have stated that they do not oppose this motion.

Amicus AAPS members have direct and vital interests in the issues here, particularly the interference by the FDA with the practice of medicine.

SUMMARY OF ARGUMENT

Defendant FDA has improperly exploited misunderstandings about the legality and prevalence of off-label uses of medication, in order to mislead courts, state medical boards, and the public into thinking there is anything improper about off-label prescribing. Not only is off-label prescribing fully proper, legal, and commonplace, but it is also absolutely necessary in order to give effective care to patients. It has never been proper for the FDA to interfere with that essential part of the practice of medicine, and the FDA knows it. Yet it has engaged in a campaign of interference with the proper use by physicians of ivermectin, which has long been approved as fully safe for human use.

Multiple courts have been misled by the FDA's improper campaign against this medication that was approved as safe for humans decades ago, and the FDA has made no attempt to retract its prior approval. In ruling against patients seeking access to ivermectin to treat Covid-19, as recommended by their physicians, multiple courts have relied on the misinformation and improper interference by the FDA as a basis for denying access now.

Defendant FDA lacks both the authority and the expertise to practice medicine, interfere with the practice of medicine, guide the practice of medicine, or advise about the practice of medicine. Federal law is clear about this, and common sense reinforces it. FDA employees are not practicing physicians, and are not treating patients. FDA employees, for the most part, are not even licensed physicians.

States confer the sole authority on licensed physicians to decide whether to prescribe an already-approved safe medication for a new off-label use, as is widely done. When confronted with a new illness as Covid-19 has been, off-label use of available medications is a necessary approach to effective treatment of that novel virus.

The injury caused by the FDA's interference with the practice of medicine is to many physicians, including members of *Amicus* AAPS and to plaintiffs here, who have standing to object to the FDA's harmful overreach. Reputations are harmed by falsely disparaging physicians for proper prescriptions that coincidentally have veterinary uses, as many drugs do. Nothing would be gained and much would be lost by barring this meritorious claim at the courthouse steps without ever adjudicating it substantively.

ARGUMENT

I. Off-Label Prescribing Is Necessary to Effective Medical Treatment, and the FDA's Interference Is Illegal.

As expressly recognized by the Supreme Court, "courts, several States, and the 'FDA itself recognize the value and propriety of off-label use.'" *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (quoting Beck & Azari, "FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions," 53 Food & Drug L. J. 71, 76-77 (1998)). The Supreme Court added that "'[o]ff-label use is widespread in the medical community and often ***is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize***.'" *Buckman*, 531 U.S. at 351 n.5 (quoting Beck & Azari, 53 Food & Drug L. J. at 72, emphasis added).

It follows, from the recognition by the Supreme Court that off-label uses are ethically required, that it is wholly improper for the FDA to interfere with such off-label practices. Ivermectin has long been a medication fully approved as safe for humans. That is where the FDA's authority begins and ends. Beyond that, it is exclusively a matter of state law in authorizing physicians to prescribe approved-as-safe medications for the benefit of their patients. When a physician is fully licensed by a state to practice medicine, then he has the authority without interference by the FDA to prescribe an approved-as-safe medication such as ivermectin to treat Covid-19 or any other illness.

As observed by the Sixth Circuit, "the Federal Food, Drug, and Cosmetic Act … does not bar doctors from prescribing an approved drug (like hydroxychloroquine) for an off-label use (like COVID-19)." *Ass'n of Am. Physicians & Surgs v. United States FDA*, 13 F.4th 531, 544 (6th Cir. 2021). The same, of course, is true about ivermectin: the FDA is without authority to interfere with prescriptions by physicians of this approved-as-safe medication for treating Covid-19 or any other condition.

An article published in the peer-reviewed AAPS medical journal, by attorney and physician Marilyn Singleton, M.D., J.D., explained in detail how essential off-label prescribing is to the practice of effective medicine:

> Prescribing a medication for a medical condition other than its FDA-approved purpose is called "off-label" prescribing. According to the Congressional Research Service (CRS) 56 percent of oncology and 12 to 38 percent of prescriptions overall are written for uses not listed on the FDA-approved labeling.[2] Off label prescribing

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[2] Congressional Research Service, "Off-Label Use of Prescription Drugs," (Feb. 23, 2021). https://sgp.fas.org/crs/misc/R45792.pdf (viewed Sept. 27, 2022).

> is left to the judgment of the physician and is not only legal but ethical.[3] G. Caleb Alexander, MD, MS, a medical ethics advocate and assistant professor of medicine at the University of Chicago Medical Center noted, "[o]ff-label use is so common, that virtually every drug is used off-label in some circumstances. ... Doctors are free to prescribe a drug for any [reason they think is medically appropriate]."[4]
>
> Off-label prescribing allows patients to benefit from a drug without waiting years for FDA approval. The CRS notes that off-label prescribing can reflect cutting-edge clinical expertise or a new treatment approach when other options have failed. …
>
> Some examples of off-label use are (1) tamoxifen approved for breast cancer and used off label to treat infertility; (2) spironolactone, a diuretic used off label for acne vulgaris; (3) beta blockers approved for treating high blood pressure, arrhythmias, coronary artery disease, migraines, and glaucoma used off label for anxiety; and (4) statins approved to lower cholesterol and used off-label to prevent heart attacks in people with diabetes.
>
> It could not be more clear that off-label use of approved medications is an accepted and beneficial component of medical practice. Until COVID-19, off-label prescribing had not faced particular scrutiny. Unfortunately for patients, two low-cost repurposed medications that have been prescribed for years without incident and are on the World Health Organization's list of essential medications are being blackballed.[5] The truth is, numerous studies show that when started early, hydroxychloroquine and ivermectin significantly reduce symptoms and prevent hospitalizations and deaths.

Marilyn M. Singleton, M.D., J.D., "Dear AMA: The Oath of Hippocrates Is Enough," 26

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[3] Federal Drug Administration, "Understanding Unapproved Use of Approved Drugs 'Off Label,'" (Feb. 5, 2018). https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label (viewed Sept. 27, 2022).

[4] K. Miller, "Off-Label Drug Use: What You Need to Know," WedMD (2009). https://www.webmd.com/a-to-z-guides/features/off-label-drug-use-what-you-need-to-know (viewed Sept. 27, 2022).

[5] WHO, "Model List of Essential Medicines" (22nd list, 2021) https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02 (viewed Sept. 27, 2022).

Journal of American Physicians and Surgeons 109, 111 (Winter 2021).[6]

Despite the clarity of federal law and common practice on this issue of off-label prescribing, the FDA continues to illegally interfere with it as explained more fully in plaintiffs' Amended Complaint and brief in opposition to Defendants' motion to dismiss. *See also* Exh. 6 to plaintiffs' Amended Complaint (FDA: "You are not a horse. Stop it with the #ivermectin. It's not authorized for treating #COVID."). That statement by the FDA of "not authorized" is misinformation of the worst kind. The FDA does not specifically authorize the use of approved-as-safe medication for virtually any new use deemed effective by physicians licensed to practice by their state medical boards.

II. FDA's Unjustified Overreach Has Propagated into Court Decisions and State Medical Board Actions.

The FDA's unauthorized and unjustified disparagement of physicians prescribing ivermectin has wrongfully influenced multiple courts and state medical boards.

"Although a number of physicians across the country have prescribed ivermectin to treat COVID-19, the Food and Drug Administration (FDA) has not approved ivermectin for use in treating COVID-19 …." *Frey v. Trinity Health-Michigan*, No. 359446, 2021 Mich. App. LEXIS 6988, at *2 (Ct. App. Dec. 10, 2021). Yet once the FDA approves a drug as being safe, there is no reason for it to approve the drug again for every new use of it, and neither the FDA nor drug manufacturers incur that senseless additional expense. The drug is safe. It is solely within the authority of physicians to

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[6] https://www.jpands.org/vol26no4/singleton.pdf (viewed Sept. 27, 2022).

prescribe approved-as-safe drugs for new uses.

FDA officials know but disregard this. They insisted and continue to insist on interfering with the prescription of this safe medication by physicians in treating Covid-19. The FDA's illegal public stance became part of court decisions, disciplinary actions, public confusion, refusal by pharmacists to fill valid prescriptions, and countless deaths of Covid-19 patients due to denial of this early treatment.

"Throughout the October 12 hearing, the circuit court repeatedly questioned the parties to elicit additional information and greater detail. For example, the circuit court asked questions regarding the Food and Drug Administration's (FDA) position regarding ivermectin as a COVID-19 treatment." *Gahl v. Aurora Health Care, Inc.*, 977 N.W.2d 756, 782 (Wis. Ct. App. 2022).

One of the state courts misled by the FDA was in litigation involving a plaintiff in this case, Dr. Mary Bowden. The court ruled against her attempt to treat a patient with ivermectin because:

> while … Ivermectin has already been approved by the FDA for unrelated illnesses, and that it may have an effective off-label use in the treatment of COVID-19, using a drug off-label is not the same thing as using it after a phase-one clinical trial while FDA approval is pending.

Tex. Health Huguley, Inc. v. Jones, 637 S.W.3d 202, 219-20 (Tex. App. 2021). In this same case the Texas state court observed:

> The doctor explained that he had not prescribed Ivermectin while treating Mr. Jones's COVID-19 ***because the Food and Drug Administration (FDA) had issued a warning that the drug should not be used for COVID-19 treatment***, and because, ***likely for the same reason***, the drug was not part of Huguley's COVID-19 protocol.

Tex. Health Huguley, 637 S.W.3d at 209 n.12 (emphasis added). This is undeniable reliance on the FDA's unjustified overreach in its authority.

The FDA's bizarre photo of a woman dressed as a physician standing next to a horse, which remains posted on the FDA website[7] and is complained about in plaintiffs' pleading here, was slick and improper. *See also* Exh. 6 to plaintiffs' Amended Complaint (quoted above). The FDA further interfered by writing to the Federation of State Medical Boards and the National Association of Boards of Pharmacy. (Govt Mot. 9) Despite being biased misinformation as the FDA well knows, it is cited as an authority on this by courts, medical boards, other parts of the federal government, and confused members of the public. Ironically, while the FDA was interfering with the practice of informed physicians in treating patients, the Biden Administration has been demanding that social media take down postings that the Biden disliked, perhaps because it contradicted him: "I make a special appeal to social media companies and media outlets: Please deal with the misinformation and disinformation that's on your shows. ***It has to stop***."[8]

State medical boards have been unjustifiably investigating physicians for prescribing off-label uses of ivermectin for Covid-19 patients, which newspapers and others pejoratively describe as a "deworming" medication based on the misinformation

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[7] https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19 (viewed Sept. 27, 2022).

[8] Remarks by President Biden at Virtual Meeting on Military Deployments Supporting Hospitals for the COVID-19 Response, The White House (January 13, 2022, emphasis added), https://tinyurl.com/45ezsejt (viewed Sept. 28, 2022).

put out by the FDA. "A Kansas physician-legislator who has acknowledged that he is under investigation by the state medical board after supporting the deworming drug ivermectin is instructing doctors on COVID-19 treatment in a letter." Associated Press, "KS Sen. Mark Steffen sends letters to physicians on COVID-19" (Apr. 6, 2022). That Associated Press article, which is typical of media recitation of the FDA's misinformation, concludes that "[t]he FDA has tried to debunk claims that animal-strength versions of ivermectin can help fight COVID-19." *Id.*

III. Legal Standing Exists to Challenge Devastating, Unauthorized Falsehoods by Government.

The government seeks to avert substantive review here by challenging the legal standing of plaintiffs. (Govt Mot. 11-17) But AAPS, as an association of physicians many of whom having been treated Covid-19 patients since early 2020, can attest that the impact of defendants' actions beyond their authority has been causing real harm to practicing physicians, including plaintiffs.

In addition to the precedents for standing cited by plaintiffs in their brief, *see, e.g.*, *Block v. Meese*, 793 F.2d 1303 (1986) (Scalia, J.), several more decisions support standing here. *See, e.g.*, *Cmty. for Creative Non-Violence v. Pierce*, 814 F.2d 663 (D.C. Cir. 1987). There the D.C. Circuit found that homeless men had standing to challenge a report issued by the Department of Housing and Urban Development ("HUD"), based on the likelihood of being turned away from a homeless shelter due to it. *Id.* at 667-68. The D.C. Circuit pointed out that it "is sufficient to provide standing that the ultimate harm alleged is a threatened harm rather than an accomplished fact." *Id.* at 667 (citing *Los*

Angeles v. Lyons, 461 U.S. 95, 101-02 (1983); *United States v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669, 688-89 (1973)).

Likewise, state medical boards and even court decisions as cited above have been relying on the unauthorized and false pronouncements by defendants, to the detriment of plaintiffs. While not homeless as a result, plaintiffs face interference with their professional careers and thus their likelihood. They face public disgrace as a result of defendants' improper actions. This suffices to establish standing by plaintiffs here.

A decision concerning the upgrade of dioxin to be categorized as a "known" carcinogen by HHS, which found standing by a private manufacturer to challenge that redesignation, is analogous to the existence of standing by plaintiffs here. *See Tozzi v. HHS*, 271 F.3d 301 (D.C. Cir. 2001). There the D.C. Circuit held that:

> Even if the Department's claims were true, we disagree that Brevet has failed to show that its injury is fairly traceable to the dioxin upgrade. … Where, as here, the alleged injury flows not directly from the challenged agency action, but rather from independent actions of third parties, we have required only a showing that "the agency action is at least a substantial factor motivating the third parties' actions." *Cmty. for Creative Non-Violence v. Pierce*, 259 U.S. App. D.C. 134, 814 F.2d 663, 669 (D.C. Cir. 1987). …
>
> Applying this standard to the facts of this case, we have little doubt that the dioxin upgrade will represent a "substantial factor" in the decisions of state and local agencies to regulate products containing dioxin or of healthcare companies to reduce or end purchases of PVC plastics. …
>
> An additional factor reinforces our conclusions regarding both injury and causation: When the government attaches an inherently pejorative and damaging term such as "carcinogen" to a product, the probability of economic harm increases exponentially. The Department's reliance on *Block*, in which the government's label of "propaganda" was not inherently pejorative, is therefore misplaced. It is not too speculative to conclude that the Report will injure Brevet economically, even with the presence of other causal factors. *See, e.g., Mountain States Legal Found. v.*

> *Glickman*, 320 U.S. App. D.C. 87, 92 F.3d 1228, 1234-35 (D.C. Cir. 1996) (holding incremental risk of forest fires from Forest Service's challenged decision sufficient to support Article III standing, despite existence of other causal factors for forest fires).

Tozzi v. HHS, 271 F.3d at 308-09 (citations omitted).

Standing was also found by the Supreme Court in *Meese v. Keene*, in recognizing standing there despite an objection to it by the Department of Justice:

> Because the alleged injury stems from the Department of Justice's enforcement of a statute that employs the term "political propaganda," we conclude that the risk of injury to appellee's reputation "fairly can be traced" to the defendant's conduct. *Simon v. Eastern Kentucky Welfare Rights Organization*, 426 U.S. 26, 41 (1976).
>
> Moreover, enjoining the application of the words "political propaganda" to the films would at least partially redress the reputational injury of which appellee complains. The Attorney General argues that an injunction would not provide the relief sought, because appellee's constituents and others may continue to react negatively to his exhibition of films once they have been labeled as "political propaganda." However, appellee's alleged harm occurs because the Department of Justice has placed the legitimate force of its criminal enforcement powers behind the label of "political propaganda." A judgment declaring the Act unconstitutional would eliminate the need to choose between exhibiting the films and incurring … reputation[al harm].

Meese v. Keene, 481 U.S. 465, 476-77 (1987).

Similarly, the strong disparagement by the FDA of using ivermectin to treat Covid-19 is sufficient to justify standing by plaintiffs here, as treating physicians, to object to that unauthorized disparagement. Standing exists regardless of how the ultimate merits of this case may be resolved.

CONCLUSION

For the foregoing reasons and those set forth by plaintiffs in their brief, *Amicus* AAPS respectfully requests that the pending motion to dismiss by defendants be denied in its entirety.

Dated: September 29, 2022

Respectfully submitted,

/s/ Andrew L. Schlafly

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CERTIFICATE OF WORD AND PAGE COUNTS

I hereby certify that the total number of words in this document, exclusive of sections properly omitted from this count, is 3,139 words as indicated by Microsoft Word, and that its page length is 12 pages. I further certify that this document is in size 13 Times New Roman font.

/s/ Andrew L. Schlafly
Andrew L. Schlafly

CERTIFICATE OF SERVICE

I hereby certify that on this September 29, 2022, I caused service of all the parties of the foregoing document through operation of the Court's CM/ECF system.

/s/ Andrew L. Schlafly
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