

**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)

**UNOPPOSED MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF OF
THE ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS**

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By analogy with the FED. R. APP. PROC. 29, the Association of American Physicians and Surgeons respectfully requests leave to file their accompanying *amicus curiae* brief in support of plaintiffs here. Plaintiffs have consented to this motion while defendants have indicated that they do not oppose it.

I. IDENTITY AND INTEREST OF *AMICUS CURIAE*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*

¹ The undersigned counsel certifies that counsel for the *Amicus* authored this motion and accompanying brief in whole; no counsel for a party authored this motion and brief in any respect; and no person or entity – other than *Amicus*, its members, and its counsel – contributed monetarily to this motion and brief’s preparation or submission.

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)

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

II. AUTHORITY TO FILE THE *AMICUS CURIAE* BRIEF OF AAPS.

As now-Justice Samuel Alito observed while serving on the U.S. Court of Appeals for the Third Circuit, “I think that our court would be well advised to grant motions for leave to file *amicus* briefs unless it is obvious that the proposed briefs do not meet Rule 29’s criteria as broadly interpreted. I believe that this is consistent with the predominant practice in the courts of appeals.” *Neonatology Assocs., P.A. v. Comm’r*, 293 F.3d 128, 133 (3d Cir. 2002) (citing Michael E. Tigar and Jane B. Tigar, *Federal Appeals – Jurisdiction and Practice* 181 (3d ed. 1999) and Robert L. Stern, *Appellate Practice in the United States* 306, 307-08 (2d ed. 1989)). Then-Judge Alito quoted the Tigar treatise for the statement that “[e]ven when the other side refuses to consent to an *amicus* filing, most courts of appeals freely grant leave to file, provided the brief is timely and well-reasoned.” 293 F.3d at 133.

This motion for leave to file an *amicus* brief is timely because it is filed (along with the accompanying brief) within seven days of the filing of the brief that *Amicus* supports, as filed by plaintiffs on September 23, 2022.

III. REASONS WHY THIS *AMICUS CURIAE* BRIEF IS DESIRABLE AND WHY THE MATTERS ASSERTED ARE RELEVANT TO THE DISPOSITION OF THIS CASE.

The accompanying *amicus curiae* brief by AAPS will be beneficial to this Court's resolution of the issues raised for the following reasons, as more fully explained in the accompanying brief:

A. 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).

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.

B. 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, as explained in the accompanying *amicus* brief.

C. 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.

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.

WHEREFORE, *Amicus* AAPS respectfully requests that its unopposed motion for leave to file its accompanying *amicus curiae* brief be granted.

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 1,005 words as indicated by Microsoft Word, and that its page length is no more than 5 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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