IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF TEXAS

GALVESTON DIVISION

No. 3:22-cv-184

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

AMICUS CURIAE BRIEF OF AMERICA'S FRONTLINE DOCTORS

Respectfully Submitted,

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SUMMARY OF ARGUMENT

In 2021 the Food and Drug Administration ("FDA") illegally launched an anti-ivermecin propaganda campaign, in direct violation of federal law, 21 U.S.C. §396, and 21 C.F.R. § 312.2(d). Accordingly, this lawsuit, filed by three very distinguished plaintiff physicians, is well founded and should not be dismissed, because these blatantly illegal governmental actions must be curtailed. The plaintiff physicians have alleged multiple serious harms to their medical practices, and to their livelihoods, sufficient to justify standing.

As plaintiffs critically point out in their Complaint, Paras 57-60:

> " 57. Courts have consistently cited [21U.S.C.] § 396 as applying to the prescription or administration of drugs as well. *See Markland v. Insys Therapeutics, Inc.*, 758 F. App'x 777, 780 (11th Cir. 2018); *U.S. ex rel King v. Solvay Pharms., Inc.*, 871 F.3d 318, 328 (5th Cir. 2017); *U.S. ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 454 n.2 (4th Cir. 2013); *United States v. Caronia*, 703 F.3d 149, 167 (2d Cir. 2012); *United States v. Muoghalu*, 662 F.3d 908, 911 (7th Cir. 2011); *Smith v. C.R. Bard, Inc.*, 730 F. Supp. 2d 783, 803 (M.D. Tenn. 2010).
> 58. The FDA thus cannot interfere with "the practice of medicine, which is the exclusive realm of individual states." *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d. 502, 505 (6th Cir. 2006); *see Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 350 (2001).
> 60. FDA regulations recognize that the agency cannot interfere with the practice of medicine or off-label use of approved drugs. 21 C.F.R. § 312.2(d) ("This part does not apply to the use in the practice of medicine for an unlabeled indication of a new drug product approved under part 314 or of a licensed biological product.")."

The statutes, regulations and jurisprudence cited above are totally determinative of the indisputable fact that the Food and Drug Administration crossed the legal red line in this case.

The FDA's blatantly illegal public pressure campaign to discourage or prohibit ivermectin use, is to the extent of our knowledge, singularly unprecedented in the history of the agency. Any FDA statements have an outsized influence in healthcare. Even non-binding advisory opinions severely interfere with the practice of medicine in general and with the plaintiffs' practice of medicine in particular.

Finally, ivermectin is one of the safest drugs on the market. It has been used hundreds of millions of times. There is significant evidence that ivermectin is effective at treating COVID-19, which evidence directly refutes the illegal propaganda campaign being waged against ivermectin by the Food and Drug Administration.

ARGUMENT

A. The FDA's public pressure campaign to discourage or prohibit ivermectin use is blatantly illegal. To the extent of our knowledge, this is singularly unprecedented in the history of the agency, and infringes on physician free speech rights.

The statutes, regulations, and jurisprudence cited above prove conclusively

that the Food and Drug Administration violated federal law by illegally intruding upon the protected doctor/patient relationship, when it launched its inaccurate and ill-advised propaganda campaign against the use of ivermectin to treat COVID-19. Please see 21 U.S.C. §396, 21 C.F.R. § 312.2(d), *Markland v. Insys Therapeutics, Inc.*, 758 F. App'x 777, 780 (11th Cir. 2018); *U.S. ex rel King v. Solvay Pharms., Inc.*, 871 F.3d 318, 328 (5th Cir. 2017); *U.S. ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 454 n.2 (4th Cir. 2013); *United States v. Caronia*, 703 F.3d 149, 167 (2d Cir. 2012); *United States v. Muoghalu*, 662 F.3d 908, 911 (7th Cir. 2011); *Smith v. C.R. Bard, Inc.*, 730 F. Supp. 2d 783, 803 (M.D. Tenn. 2010); *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d. 502, 505 (6th Cir. 2006); and *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 350 (2001).

The defendants acknowledge on page 1 of their motion to dismiss that, in addition to concerns about the human use of animal-grade ivermectin, the FDA's pressure campaign also cautioned against the human use of human-grade ivermectin, a decision strictly reserved to the medical profession. This admission establishes a *per se* legal violation. Further, on pages 11-15 of the plaintiff physicians' opposition to the motion to dismiss, plaintiff physicians enumerate numerous serious harms that they have directly suffered as a result of the illegal Food and Drug Administration pressure campaign, amply conferring standing

upon plaintiffs. Indeed, the harms inflicted upon the plaintiff physicians were major and significant. The Food and Drug Administration is not permitted by law to interfere with the plaintiff physicians' relationships with their patients, their medical boards, their insurance companies, and their very livelihoods.

The FDA was formed on June 30, 1906, as a federal agency under the aegis of the U.S. Department of Health and Human Services ("DHH"). The FDA is charged with the purported responsibility of "protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products."[1]

However, throughout its 116-year existence, the FDA has never prohibited physicians from using drugs – including the common and well-established medical practice of prescribing off-label drugs.[2]

In fact, it is common medical practice to prescribe off-label drugs. One in

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[1]https://en.wikipedia.org/wiki/Food_and_Drug_Administration

[2]https://www.fda.gov/files/drugs/published/A-History-of-the-FDA-and-Drug-Regulation-in-the-United-States.pdf

five prescriptions today are prescribed for off-label use.[3]

Doctors do not forfeit their constitutional rights when they earn their medical degrees. On the contrary, like the physician plaintiffs herein, they are well-trained professionals who can deliver considered professional opinions based on their experience, research, and clinical practices with numerous patients. Other doctors may have different considered professional opinions. Professional opinions, of course, sometimes differ. We are all familiar with the "battle of the experts" in the context of lawsuits.

There is no basis in American law or society for a government agency such as the FDA, other than the fact-finding judge or jury assigned to a particular case with competing experts, to declare one expert or the other to be the government-approved version of the truth. And there is certainly no basis to threaten or attempt to silence experts -- including U.S. doctors, for not supporting a government-approved version of the "truth."

This is not the first time protected free speech and privacy rights of doctors in the doctor/patient relationship were attacked by American government officials who disagreed with those opinions. In fact, one of the most famous free speech

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[3]https://www.ahrq.gov/patients-consumers/patient-involvement/off-label-drug-usage.html#:~:text=Off%2Dlabel%20prescribing%20is%20when,are%20for%20off%2Dlabel%20use.

and privacy cases of modern times, *Griswold, et. al. v. Connecticut*, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed.2d 510 (1965), was just such a case.

In *Griswold*, a doctor was criminally convicted under a Connecticut statute for counseling a married couple regarding contraception. In reversing the doctor's conviction, the Supreme Court found that the doctor's treatments, associations and doctor/patient privacy rights were protected by the penumbras emanating from the First, Fourth, and Ninth Amendments, affirming the principle that the concept of liberty protects personal fundamental human rights.

More recently, the United States Supreme Court decided the important case of *National Institute of Family and Life Advocates, dba NIFLA, et. al. v. Becerra, Attorney General of California, et. al.*, 585 U.S. ___, 138 S. Ct. 2361, 201 L. Ed. 2d 835 (2018). The California Reproductive Freedom, Accountability, Comprehensive Care, and Transparency Act ("FACT Act") similarly attempted to impose analogous "content moderation" (i.e., mandatory medical speech) upon health care providers. The FACT Act required pro-life health care clinics to inform patients that free or low-cost abortions were available in California and required the clinics to give the patients a telephone number to call for those services. The United States Supreme Court held that this law was likely an unconstitutional violation of the First Amendment. The *NIFLA* Court noted that content-based laws

targeting speech based on its communicative content, which compel speakers to speak a particular message, are presumptively unconstitutional.

Many state Attorneys General have joined the United States Supreme Court in its support of medical freedom, medical privacy, and freedom of speech. A survey of state Attorneys General around the country reveals that the Attorneys General and Surgeons General from many states, including Nebraska, Missouri, Louisiana, Kansas, New Hampshire, Florida, Oklahoma, and South Carolina, all share similar views.

Last September 2021, for example, Louisiana Attorney General Jeff Landry became the first attorney general to publicly endorse his support for ivermectin (and hydroxychloroquine) prescriptions. In a letter to the Louisiana Board of Pharmacy, with a copy to the Louisiana State Medical Board, he cautioned them both on preventing the use of ivermectin. Attorney General Landry wrote, "I find nothing that would allow the Board to second guess the sound medical judgment of a doctor when it comes to prescribing legal drugs to their patients."[4]

The same logic applies to the FDA.

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[4] *Letter To Pharmacy Board On Preventing The Use Of Ivermectin* https://agjefflandry.com/Files/Shared/Documents/Pharmacyboardletter9.7.21.pdf

The Oklahoma Attorney General also supports ivermectin prescriptions[5], as does the Nebraska Attorney General[6] and the South Carolina Attorney General.[7]

The FDA's unprecedented anti-ivermectin propaganda campaign unlawfully interferes with the doctor/patient relationship.

B. Any FDA statements have an outsized influence in healthcare, and even nonbinding advisory opinions severely interfere with the practice of medicine.

As a federal agency, the FDA cannot create or enforce laws. However, the FDA has an undue influence on most physicians. One study concluded as many as 80% of physicians favorably view the FDA's drug approval regulations agreeing that its approval process helps "protect the public from ineffective or dangerous drugs."[8]

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[5]*Oklahoma AG OKs prescribing ivermectin, hydroxychloroquine*" https://www.usnews.com/news/best-states/oklahoma/articles/2022-02-08/oklahoma-ag-oks-prescribing-ivermectin-hydroxychloroquine

[6]*Nebraska AG issues opinion on Ivermectin and Hydroxychloroquine* https://www.ketv.com/article/nebraska-ag-issues-opinion-on-ivermectin-and-hydroxychloroquine-as-covid-19-treatments/37973809#

[7]*The Scotfree | South Carolina Attorney General Confirms Support of Ivermectin Bill*: https://www.scag.gov/about-the-office/news/attorney-general-alan-wilson-issues-opinion-on-the-legality-of-doctors-prescribing-alternative-drugs-to-treat-covid

[8]*Kesselheim AS, Woloshin S, Lu Z, Tessema FA, Ross KM, Schwartz LM. Physicians' Perspectives on FDA Approval Standards and Off-label Drug*

The famous Stanley Milgram experiments of the early 1960s disclose that most people unquestionably obey perceived figures in authority figures, especially ones in white lab coats.[9]

As plaintiff Dr. Apter notes in Para.18 of his Complaint: "Dr. Apter has been referred to the Washington Medical Commission and Arizona Medical Board for disciplinary proceedings for prescribing ivermectin to treat COVID-19. *Id.* The referrals include copies of the FDA's publications directing against the use of ivermectin to treat COVID-19. *Id.* He explains that state regulatory boards rely heavily on pronouncements from the FDA. *Id.* at 3."

Also, as Dr. Breggin, a psychiatrist who possesses decades of experience, is the author of multiple books on psychiatric topic and drugs, and is an expert witness in several high-profile pharmaceutical lawsuits, notes, "The worldwide suppression of hydroxychloroquine and now ivermectin, even at the direct cost of lives, is so inexplicable that before describing the situation further, it may help to answer the question, 'Why is it so necessary for the establishment to suppress

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Marketing. JAMA Intern Med. 2019 May 2019
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6503563/

[9]https://www.ukessays.com/essays/psychology/implications-of-stanley-milgrams-1963-study-on-obedience-on-the-clinical-environment.php
https://www.simplypsychology.org/milgram.html

inexpensive, easily available treatments for COVID-19? The answer is this: If effective treatments are already available, the FDA cannot issue Emergency Use Authorizations (EUAs), allowing the FDA to skip its usual safety and effectiveness studies to push expensive, highly remunerative drugs and vaccines down the pipeline as experiments to be inflicted on the population."[10]

C. Ivermectin is one of the safest drugs on the market. It has been used hundreds of millions of times, and there is significant evidence that ivermectin is effective at treating COVID-19.

The discovery of ivermectin and its enormously beneficial medicinal properties cannot be overstated. The unique and extraordinary microorganism that produces the avermectins (from which ivermectin is derived) was discovered in 1973 in Japanese soil by biochemist Satoshi Ōmura, who won the Nobel Prize for the discovery of ivermectin.[11] Together with another Nobel-Prize-awarded Irish biologist, William Campbell, who worked at the Merck Institute for Therapeutic

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[10] See *Peter R Breggin MD, Ginger Ross Breggin, COVID-19 and the Global Predators: We are the Prey* 147 (2021).
The Emergency Use Authorization is part of Federal Food, Drug, and Cosmetic Act, Pub.L.No. 75-717 (as amended at 21 U.S.C. §§ 301-399f). It is interpreted and applied by the FDA.

[11] Crump, A. *Ivermectin: enigmatic multifaceted 'wonder' drug continues to surprise and exceed expectations*. J Antibiot 70, 495–505 (2017). https://www.nature.com/articles/ja201711#citeas

Research, they discovered the soil-based bacteria could cure mice infected with roundworm.[12] Ivermectin was thus originally recognized as an anti-parasitic and veterinary drug. However, it soon gained worldwide popularity as a miraculous drug that could treat and cure a vast array of human diseases. Human distribution began in the late 1980s, and has since helped cure millions from Onchocerciasis (or River Blindness) and Lymphatic filariasis (or Elephantiasis).[13] It's hard to overstate the immeasurable beneficial impact on the lives of millions of people throughout the world due to the discovery of ivermectin. It has been rightfully described by many clinicians as a "wonder drug".[14] Ivermectin contains antimicrobial, antiviral, anti-inflammatory, and anti-cancer properties. To that end, it has recently been proven to be a powerful prophylaxis and treatment for

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[12] P. Kory et. al. *Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectnig in the Prophylaxis and Treatment of COVID-19* American Journal of Therapueutics: amy/June 2021 – volume 28 – Issue 3 -https://journals.lww.com/americantherapeutics/fulltext/2021/06000/review_of_the_emerging_evidence_demonstrating_the.4.aspx

[13] Crump A, Ōmura S. *Ivermectin, 'wonder drug' from Japan: the human use perspective.* Proc Jpn Acad Ser B Phys Biol Sci. 2011;87(2):13-28. doi: 10.2183/pjab.87.13. PMID: 21321478; PMCID: PMC3043740. https://pubmed.ncbi.nlm.nih.gov/21321478/

[14]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3043740

COVID-19.[15] There is an abundance of irrefutable scientific evidence to support the defense of ivermectin as a legally approved treatment which has been proven safe and effective.[16]

Therefore, the FDA propaganda campaign against ivermectin was not only illegal, it was also completely incorrect and dangerous from a medical standpoint.

In addition to the papers footnoted in this *amicus curiae* brief, a plethora of prestigious scientific resources support ivermectin in treating COVID-19:

1. Caly L, Druce JD, Catton MG, Jans DA, Wagstaff KM. *The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro*. Antiviral Res. 2020 Jun;178:104787. doi: 10.1016/j.antiviral.2020.104787. Epub 2020 Apr 3. PMID: 32251768; PMCID: PMC7129059. https://pubmed.ncbi.nlm.nih.gov/32251768/

2. MERCK. *35 Years: The Mectizan Donation Program*. January 6, 2021. https://www.merck.com/stories/mectizan/

3. The Nobel Prize. PRESS RELEASE. 2015-10-05. https://www.nobelprize.org/prizes/medicine/2015/press-release/

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[15] Heidary, F., Gharebaghi, R. *Ivermectin: a systematic review from antiviral effects to COVID-19 complementary regimen*. J Antibiot 73, 593–602 (2020). https://www.nature.com/articles/s41429-020-0336-z#citeas

[16]https://journals.lww.com/americantherapeutics/Fulltext/2021/06000/Review_of_the_Emerging_Evidence_Demonstrating_the.4.aspx

4. Veeresham C. *Natural products derived from plants as a source of drugs*. J Adv Pharm Technol Res. 2012 Oct;3(4):200-1. doi: 10.4103/2231-4040.104709. PMID: 23378939; PMCID: PMC3560124. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3560124/

5. Rajter JC, Sherman MS, Fatteh N, Vogel F, Sacks J, Rajter JJ. *Use of Ivermectin Is Associated With Lower Mortality in Hospitalized Patients With Coronavirus Disease 2019: The Ivermectin in COVID Nineteen Study*. Chest. 2021 Jan;159(1):85-92. doi: 10.1016/j.chest.2020.10.009. Epub 2020 Oct 13. PMID: 33065103; PMCID: PMC7550891. https://pubmed.ncbi.nlm.nih.gov/33065103/

6. FLCCC ALLIANCE. *One Page Summary of the Clinical Trials Evidence for Ivermectin in COVID-19 as of January 11, 2021*. https://covid19criticalcare.com/wp-content/uploads/2020/12/One-Page-Summary-of-the-Clinical-Trials-Evidence-for-Ivermectin-in-COVID-19.pdf

CONCLUSION

The brave plaintiff physicians are on the right side of history. The FDA should never illegally cross the line and overreach into the practice of medicine again. This disrupts the protected doctor/patient relationship, endangers patients, and causes significant harms. The FDA pressure campaign was illegal, medically dangerous, and caused major enumerated harms. The defendants' motion to dismiss should be denied.

Respectfully Submitted,

s/ David A. Dalia
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Certificate of Compliance

I hereby certify that the foregoing *amicus curiae* brief contains 3255 words as measured by Microsoft Word, and that its page length is no more than fourteen (14) pages. I further certify that this motion is in 14-point Times New Roman type.

s/ David A. Dalia
David A. Dalia

Certificate of Service

I hereby certify that on the 6th day of October, 2022, a copy of the foregoing Consent Motion was filed electronically with the Clerk of Court using the CM/ECF system, and notice of this filing was sent electronically to all counsel of record using the CM/ECF system.

s/ *David A. Dalia*
David A. Dalia