No. 22-40802

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

ROBERT L. APTER, M.D., FACEP;
MARY TALLEY BOWDEN, M.D.; and
PAUL E. MARIK, MBBCh, M.MED, FCCM, FCCP,
***Plaintiffs-Appellants*,**

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-Appellees

AMICUS CURIAE BRIEF OF AMERICA'S FRONTLINE DOCTORS IN SUPPORT OF PLAINTIFFS-APPELLANTS FOR REVERSAL

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). This illegal and inaccurate misinformation campaign caused significant real world harms including many unnecessary deaths. Accordingly, this lawsuit, filed by three very distinguished plaintiff physicians, is well-founded and should not have been dismissed. 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. Additionally, *amicus* has identified many other egregious real world harms discussed below.

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).
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> 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 by attempting to offer prohibited (and inaccurate) medical advice. This was exacerbated by the FDA's promotion of inaccurate and inappropriate "advice", as evidenced by its widely-cited "advice" article entitled *"*Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," ROA.972. Again, the FDA is not allowed by law to interfere with the practice of medicine via pronouncements, recommendations, edicts, publicity campaigns, or the like.

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 and has saved many lives. This evidence directly refutes the illegal and inaccurate propaganda campaign being waged against ivermectin by the Food and Drug Administration.

ARGUMENT

A. The FDA is not entitled to sovereign immunity in order to shield its egregious *ultra vires* conduct.

Plaintiffs-Appellants are correct when they state that sovereign immunity does not bar suit for equitable relief when government officials act outside the bounds of their authority in an *ultra vires* manner. Plaintiffs-Appellants in their Complaint, Paras 57-60 (above), cite authority from 6 separate Circuits, above, including the Fifth Circuit, showing that these FDA actions in promoting its illegal propaganda campaign were clearly illegal and *ultra vires*. Further, these *ultra vires* actions were egregious, as *amicus* research shows that excess deaths in the United States were caused by these FDA's illegal actions. That these actions represent egregious misconduct is another reason to reject a sovereign immunity defense in this case.

Plaintiffs-Appellants further correctly rely upon *Ala.-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484, 489 (5th Cir. 2014), holding that there is a

waiver of sovereign immunity in the APA for all "non-statutory" actions seeking equitable relief, including *ultra vires* actions such as these egregious *ultra vires* FDA actions. The FDA's actions became "final" when its *ultra vires* and harmful publications, such as its "advice" article interfering with the practice of medicine titled *"*Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," ROA.972, and the other FDA publications complained of by Plaintiffs-Appellants, were published, and the damage was begun. *Amicus* adopts Plaintiffs-Appellants position on sovereign immunity.

B. 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-Appellees acknowledged on page 1 of their trial court 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 *per se* illegal FDA interference violation in the doctor/patient relationship. Further, on pages 51-56 of the Plaintiffs-Appellants brief, these plaintiff physicians enumerate numerous serious harms that they have directly suffered as a result of the illegal Food and Drug Administration pressure campaign, thus 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. *Amarin Pharma, Inc. v. FDA,* 119 F. Supp. 3d 196 (S.D.N.Y. 2015). *Amicus* has further identified many other egregious real world harms discussed below.

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

Doctors do not forfeit their constitutional rights when they earn their

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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

[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.

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 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.

The Oklahoma Attorney General also supports ivermectin prescriptions[5], as

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

[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

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.

C. 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]

The famous Stanley Milgram experiments of the early 1960s disclose that most people unquestionably obey perceived figures in authority figures, especially

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

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 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

[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

down the pipeline as experiments to be inflicted on the population."[10]

D. 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 and that early treatment with ivermectin prevents needless deaths.

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 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

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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

[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

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 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.

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[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

[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

Ivermectin is so safe that it is now available over the counter in Tennessee[17].

"Ivermectin: a multifacted drug of Nobel prize-honoured distinction with indicated efficacy against a new global scourge, COVID-19". A group of medical doctors / scientists from the U.S., Japan, and Australia, including the distinguished Dr. Peter McCullough, note that since March 2020, when ivermectin was first used against COVID-19, there have been more than 20 randomized clinical trials (RCTs) which tracked inpatient and outpatient treatments. Six of seven meta-analyses of ivermectin treatment RCTs reported in 2021 found notable reductions in COVID-19 fatalities, with a mean 31% relative risk of mortality vs. controls [*emphasis added*]. Also, "during mass ivermectin treatments in Peru, excess deaths fell by a mean of 74% over 30 days in its ten states with the most extensive treatments. Reductions in deaths correlated with the extent of ivermectin distributions in all 25 states with $p < 0.002$.". [*emphasis added*] The indicated biological mechanism of ivermectin, competitive binding with

[17]Ivermectin now available over-the-counter from pharmacists in Tennessee, Newswire, May 13, 2022. "The nation's first over-the-counter sale of ivermectin took place May 11, 2022 at The Compounding Lab, a family-owned pharmacy in Johnson City, TN. Senate Bill 2188 by Senator Frank Niceley and Representative Susan Lynn (companion house bill), was ratified by the Tennessee Legislature and signed by Governor Lee, becoming effective April 22, 2022. This new law allows Tennessee pharmacists to dispense safe USP grade ivermectin over-the-counter under what's known as a Collaborative Pharmacy Practice Agreement." https://www.einnews.com/pr_news/572339675/ivermectin-now-available-over-the-counter-from-pharmacists-in-tennessee

SARS-CoV-2 spike protein, is likely non-epitope specific, possibly yielding full efficacy against emerging viral mutant strains[18].

"Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines". Moderate-certainty evidence finds that large reductions in COVID-19 deaths are possible using ivermectin. Using ivermectin early in the clinical course may reduce numbers progressing to severe disease. The apparent safety and low cost suggest that ivermectin is likely to have a significant impact on the SARS-CoV-2 pandemic globally[19].

"ICON (Ivermectin in COVID Nineteen) study: Use of Ivermectin is Associated with Lower Mortality in Hospitalized Patients with COVID19". A group of Broward County, Florida scientists/medical doctors published in medRxiv: "We have shown that ivermectin administration was significantly associated with lower mortality among patients with COVID-19, particularly in patients with more severe disease. Interpretation of these findings are tempered by the limitations of the retrospective design and the possibility of confounding.

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[18]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8383101/pdf/main.pdf

[19]https://journals.lww.com/americantherapeutics/fulltext/2021/08000/ivermectin_for_prevention_and_treatment_of.7.aspx

Appropriate dosing for this indication is not known; nor are the effects of ivermectin on viral load, or in patients with milder disease. Further studies in appropriately designed randomized trials are recommended before any conclusions can be made[20]."

"Ivermectin in combination with doxycycline for treating COVID-19 symptoms: a randomized trial". 15 Indian scientists in the Dhaka Medical College and Hospital in Dhaka, Bangladesh discovered that patients with mild-to-moderate COVID-19 infection treated with ivermectin plus doxycycline recovered earlier, were less likely to progress to more serious disease, and were more likely to be COVID-19 negative by RT-PCR on day 14[21].

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/

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[20]https://www.medrxiv.org/content/10.1101/2020.06.06.20124461v2.full-text

[21]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8127799/pdf/10.1177_03000605211013550.pdf

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/

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

7. MedinCell Announces Positive Results for the SAIVE Clinical Study in Prevention of Covid-19 Infection in a Contact-Based Population: https://www.businesswire.com/news/home/20230105005896/en/MedinCell-Announces-Positive-Results-for-the-SAIVE-Clinical-Study-in-Prevention-of-Covid-19-Infection-in-a-Contact-Based-Population

8. "A five-day course of ivermectin for the treatment of COVID-19 may reduce the duration of illness" Per the abstract, "Ivermectin, a US Food and Drug Administration-approved anti-parasitic agent, was found to inhibit severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) replication in vitro. There were no severe adverse

drug events recorded in the study. A 5-day course of ivermectin was found to be safe and effective in treating adult patients with mild COVID-19. Larger trials will be needed to confirm these preliminary findings.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7709596/pdf/main.pdf

9. "A plea to allow the use of Ivermectin as Covid-19 treatment delivered to Ramaphosa's house" "Twenty countries are using Ivermectin to treat Covid-19. They include Mexico, Guatemala, Argentina, Brazil, Bolivia, Slovakia, the Czech Republic, Portugal, Nigeria, and Egypt. In South Africa doctors are allowed to prescribe Ivermectin, but it is not being rolled out everywhere and in hospitals and clinics." Also, "This article, written by eleven doctors and professors to the Department of Health, urges the Department to facilitate the use of Ivermectin in the public health sector. The article was delivered to President Cyril Ramaphosa's house by Jeremy Gordon who believes that we could end the crisis of the pandemic with the use of Ivermectin as they have in Zimbabwe."
https://www.biznews.com/health/2021/07/29/ivermectin-treatment

E. Additional examples of real world harms caused by the FDA's illegal propaganda campaign suppressing ivermectin.

The safety and efficacy of ivermectin as a treatment for COVID-19 is well established, as shown above. This proven safety and efficacy makes ivermectin treatment as a prophylaxis and as a disease treatment a preferred option chosen by many patients in consultation with their doctors. The right to choose off-label treatment by ivermectin by patients and doctors is a protected right, fundamental to the practice of medicine.

Yet, despite the protected nature of this private and fundamental right of

informed consent and patient choice, there are still significant obstacles placed in the way of medical freedom of choice by the FDA's illegal misinformation campaign, which result in many real world harms, including excess, unnecessary deaths. See footnotes 18, 19 and 20, above.

Plaintiffs-Appellants have extensively enumerated the real world harms that befell the plaintiff physicians traceable to this FDA campaign in their Appellants' Brief, pgs. 51-56.

Additionally, many other patients were actually forced to hire attorneys to sue hospitals and pharmacies to obtain access to life-saving ivermectin, after those hospitals and pharmacies refused to fill the legal prescriptions written by the patients' physicians. It is shocking that any patient would be forced to go to court to obtain their urgently needed legal medication as prescribed by their doctor. Yet this happened numerous times. This represents extreme interference with the practice of medicine, generated in large part by the FDA's stubborn demonization of ivermectin campaign, as evidenced by its widely-cited "advice" article titled *"*Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," ROA.972, and the other FDA publications complained of by Plaintiffs-Appellants.

Unfortunately, all too many patients passed away before their court proceedings were successful. A few examples of these tragic unnecessary deaths

can be found here[22].

In one particularly egregious case, the patients' attorney successfully obtained a court order for ivermectin treatment, only to have the hospital refuse to obey the court order. The patient died[23]. In other cases in which the ivermectin order was obeyed, the patient lived[24].

There were also multiple real world harms to medical professionals and to the practice of medicine. Retaliatory actions and wrongful firings were taken by hospitals and medical boards against doctors and other health care workers for simply prescribing legal ivermectin in consultation with their patients. A few

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[22]Jacksonville man with Covid-19 at center of ivermectin lawsuit against Mayo Clinic dies: https://www.jacksonville.com/story/news/2022/01/24/jacksonville-man-center-lawsuit-against-mayo-clinic-allow-ivermectin-covid-patient-has-died/9200618002/ ; Teacher whose husband sued hospital for refusing to use ivermectin dies: https://www.wptv.com/coronavirus/teacher-whose-husband-sued-palm-beach-gardens-medical-center-for-refusing-to-treat-wife-with-ivermectin-dies ; COVID-19 patient whose wife sued for ivermectin treatment dies, attorney says: https://www.fox19.com/2021/10/04/covid-19-patient-whose-wife-sued-ivermectin-treatment-dies-attorney-says/

[23]Man dies of COVID-19, family says Sugar Land hospital refused court ordered treatment of Ivermectin: https://www.fox26houston.com/news/74-year-old-veteran-prescribed-ivermectin-dies-after-houston-hospital-refused-to-administer-family

[24]'Praise the Lord' On brink of death, elderly man fully recovers after judge orders hospital to allow ivermectin: https://www1.cbn.com/cbnnews/2021/november/praise-the-lord-on-brink-of-death-elderly-man-fully-recovers-after-judge-orders-hospital-to-allow-ivermectin

examples of these wrongful firings can be found here[25]. The egregious real world harms caused by the illegal FDA propaganda campaign are undeniable.

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 including excess unnecessary deaths. The *ultra vires* FDA pressure campaign was illegal, medically dangerous, and caused major enumerated harms. The Defendants-Appellees' motion to dismiss should have been denied.

Respectfully Submitted,

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[25]Pennsylvania Doctor Accused of Prescribing Ivermectin for Covid is Fired: https://www.nytimes.com/2022/02/04/us/pennsylvania-doctor-ivermectin-fired.html ; Arkansas doctor under investigation for prescribing anti-parasitic drug thousands of times for Covid-19 despite FDA warning: https://www.cnn.com/2021/08/26/us/covid-ivermectin-arkansas-doctor/index.html ; What the FDA wants doctors to tell their patients asking for ivermectin: https://www.ama-assn.org/delivering-care/public-health/what-fda-wants-doctors-tell-patients-asking-ivermectin

CERTIFICATE OF COMPLIANCE WITH RULE 32(g)

I hereby certify that the foregoing brief complies with Fed. R. App. P. 32(a)(7)(B) and Fed. R. App. P. 29(a)(5) because it contains 4544 words, including the parts of the brief exempted by Fed. R. App. P. 32(f) and 5th Cir. R. 32-4. I further certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced font in Microsoft Word using 14-point Times New Roman.

s/ David A. Dalia
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CERTIFICATE OF SERVICE

I hereby certify that on February 14th, 2023, I electronically filed the foregoing Amicus Brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit via the Court's CM/ECF system, which will automatically serve all counsel of record via CM/ECF notice.

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