No. 22-40802

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

Robert L. Apter, Medical Doctor, FACEP; Mary Talley Bowden, Medical Doctor; Paul E. Marik, MD, M.MED, FCCM, FCCP,

Plaintiffs-Appellants,

v.

Department of Health & Human Services; Xavier Becerra, in his official capacity as Secretary of Health and Human Services; Food & Drug Administration; Robert M. Califf, in his official capacity as Commissioner of Food and Drugs,
Defendants-Appellees.

On Appeal from the U.S. District Court
for the Southern District of Texas

BRIEF OF FRONT LINE COVID-19 CRITICAL CARE ALLIANCE AS NON-PARTY *AMICUS CURIAE* IN SUPPORT OF REVERSAL

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CERTIFICATE OF INTERESTED PERSONS

Apter et al. v. Dep't of Health & Human Services et al.
No. 22-40802

The undersigned counsel certifies that the following listed persons and entities as described in Fifth Circuit Local Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

Amicus Curie

The Front Line COVID-19 Critical Care Alliance (FLCCC) is a non-stock 501(c)(3) organization with no parent corporation.[*]

Counsel

Alan Dumoff, Law Office of Alan Dumoff is counsel for amicus.

Dated: February 13, 2023

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[*] Co-plaintiff Paul E. Marik, MD is a co-founder of FLCCC. Dr. Marik has been rigorously excluded from all aspects of this filing and had no participation in the FLCCC decision to file this amicus brief and did not draft, discuss, review, participate in, financially support or otherwise involve himself in this filing. FLCCC, an organization with approximately 4,700 professional members, represents its own, independent organizational interest in informing the Court based upon FLCCC's knowledge about the impacts of the FDA Campaign on its members and on physicians and patients generally.

RULE 29(4)(E) CERTIFICATION

The undersigned hereby certifies that I, as the amicus' counsel, authored this brief, no party contributed money to the preparation of this brief, the funding of this brief came from the general funds of the organization (FLCCC) and no other person contributed money that was intended to fund preparing or submitting this brief.

Dated: February 13, 2023

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STATEMENT OF INTEREST

The Front Line COVID-19 Critical Care Alliance (FLCCC) is a 501(c)(3) organization founded by leaders in critical care medicine. FLCCC has extensively researched and published meta-studies on the use of ivermectin to treat COVID-19. FLCCC physicians have led large ICUs and boast nearly 2,000 published peer reviewed publications. With a membership of approximately 4,700 physicians, pharmacists, nurse practitioners and scientists, it continually develops consensus-based standards supported by global academic physicians and researchers.

The FLCCC has been an active part of this controversy as it publishes guidelines that include the use of ivermectin[1] and is thus directly involved in and aware of the impacts of the FDA Campaign as part of its organizational mission.[2]

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[1] The FLCCC publishes an on-line protocol for the treatment of hospitalized COVID patients, which includes the use of ivermectin, at https://covid19criticalcare.com/treatment-protocols/

[2] While not before the Court, and the Court need not address the merits of ivermectin's use in COVID-19, it would be helpful for the Court to be aware that there has been an inaccurate narrative maintaining the objectively false statement that there is no evidence to support the use of ivermectin in COVID-19. While there can be disagreement over whether the totality of evidence favors use, there is a substantial body of evidence–larger than that ordinarily required to obtain new drug approval– supporting this indication. The oft-repeated drumbeat that "there are no scientific studies that show that ivermectin is safe or effective in the treatment of COVID-19" is contradicted by a substantial body of completed research including peer-reviewed meta-analyses. Presently, there are over 95 trials including at least 43 randomized controlled trials, which cumulatively show both safety and significant benefit. These studies are summarized at an extensive repository listed at https://c19ivm.org and a meta-analysis found at https://c19ivm.org/meta.html (constantly updated).

The FLCCC has testified before Congress and state legislatures, submitted an amicus before the Wisconsin Supreme Court on appeal from *Gahl v. Aurora Health Care, Inc.*, 403 Wis. 2d 539 (Wis. Ct. App. 2022) and played a role in numerous legal cases in which governmental authorities and medical insurers have directly cited the US Food and Drug Administration ("FDA" or "Agency") anti-ivermectin campaign ("Campaign") as a finding that physicians should not prescribe ivermectin for COVID-19. FLCCC writes to inform the Court of the pervasive use by courts, state authorities, public health agencies and others of the FDA Campaign to aggressively deter such prescribing contrary to FDA's representation or authority. Further, we write to support the legal basis for granting the parties' request for reversal. FLCCC has a strong interest in ensuring patient access to reasonable therapies recommended by their physicians without unfounded interference by a governmental agency.

SUMMARY OF ARGUMENT

The FDA position before the District Court was that the Campaign against ivermectin's use in COVID-19[3] was not intended to tell physicians they could not write such prescriptions, arguing that "[t]hese statements included non-binding

[3] https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19.

recommendations to consumers who could purchase animal-use ivermectin over the counter not to take ivermectin to treat COVID-19, but the statements did not say that doctors could not prescribe ivermectin to treat COVID-19 or that consumers could not take ivermectin for that purpose." (emphasis added.) ROA. 1675.

This representation is entirely disingenuous; without question, the FDA Campaign has been recognized and acted upon in every arena of health care for what it is, an FDA position against such prescribing. Numerous courts have cited directly to the FDA Campaign as an advisory against physicians prescribing ivermectin for COVID-19. While the Agency argues it expressed no opinion about physician prescribing, in cases seeking in hospital access to ivermectin, the judiciary has widely and universally read the Campaign with that very meaning. Widespread governmental and institutional actors have expressly cited the FDA Campaign as such a bar, including a New York Attorney General's order to physicians to cease and desist such use, a health plan order to participating doctors not to engage in such prescribing, medical board disciplinary actions against physicians, major medical organizations citations to the FDA Campaign calling for physicians to stop and news media reporting that clearly understood and cited to the FDA as unequivocally stating that physicians were not to prescribe ivermectin

for COVID-19 and should be disciplined for doing so.

This was clearly the FDA's intended effect. The warning about use of animal drugs was entirely appropriate, but the precise message the FDA attempts to disclaim here has been echoed through every layer of medicine with the knowledge and design of the Agency. The FDA denial is understandable because the Agency does not have the jurisdiction to dictate the use of an approved medication. The District Court plainly erred in holding that restrictions on FDA imposition on standards of medical practice are limited to medical devices, a holding contrary to significant judicial, administrative and legislative precedent and express administrative requirements.

To the extent that the FDA is statutorily allowed to warn about post-market drug dangers, the FDA completely ignored and failed to follow those procedures. The complex process of determining appropriate indications for drugs was also entirely bypassed, as the Agency believed it could make the proclamation as a consumer alert without the bothersome fetters of any deliberative process. The Agency in fact took overt steps to mislead the public into thinking that it had studied this indication, thought it had not. We support Appellant's view that the FDA's action were harmful and in excess of statutory authority and thus ultra vires, arbitrary and capricious and not in accordance with law.

ARGUMENT

I. The FDA Campaign Has Been Universally Understood to be an Agency Position that Physicians Should Not Prescribe Ivermectin for COVID-19.

A. The FDA Message Has Been Understood by Legal and Health Authorities for What it Is: Opposition to Physician Ivermectin Prescribing.

The FDA argued in its Motion to Dismiss that "assuming the third parties that allegedly injured Plaintiffs read the cited FDA statements, they would likely have concluded that FDA wanted consumers to be aware of the agency's concerns about using ivermectin to prevent or treat COVID-19, but that doctors have discretion to prescribe ivermectin for that use." ROA. 1458. (MTD at 17.) Yet in all corners of the health care world, courts and other authorities have understood the FDA Campaign that "you should not take ivermectin to prevent or treat COVID-19" for exactly what it seems; an Agency finding that under no circumstances should ivermectin be used for COVID-19, including by prescription. A representative sampling:

1) The Judiciary's Understands the FDA Campaign as Against Physician Prescribing in Cases Addressing Hospital Denial of Patient Access.

There have been a large number of injunctive relief attempts in response to hospital refusals to provide ivermectin for their COVID-19 patients. The FDA

Campaign is frequently cited by courts as a basis for denying relief. This body of cases not only shows that the FDA Campaign has had real world impacts, as argued by Appellants, Appellants Brief at 19-20, 47-48, but establishes that the judiciary disagrees with the FDA argument that a fair reader would not find opposition to physician prescribing. These trial and state appellate courts cite the FDA Campaign (sometimes referred to as an "advisory") as a primary consideration in not requiring hospitals to allow patients access to ivermectin. *See for e.g. Gahl v. Aurora Health Care, Inc.*, 403 Wis. 2d 539, 578 n. 30, 977 N.W.2d 756 (Ct. App. 2022); *Pisano v. Mayo Clinic Fla.*, 333 So. 3d 782, 787 (Fla. Dist. Ct. App. 2022) (the FDA is "opposed" to physician prescribing); *DeMarco v. Christiana Care Health Servs*., 263 A.3d 423, 422, 432 (Del. Del. Ch. 2021) ("the FDA [has] issued advisories indicating that ivermectin is not authorized or approved for the prevention or treatment of COVID-19"); *Shoemaker v. UPMC Pinnacle Hosps*., 2022 PA Super 163, 283 A.3d 885 (FDA ... warns of the drug's potential risks, and concludes that "[c]urrently available data do not show ivermectin is effective against COVID-19," expressly citing the FDA Campaign at 1 note 2); *Abbinanti v. Presence Cent. & Suburban Hosps. Network*, 2021 IL App (2d) 210763, 455 Ill. Dec. 557, 557, 191 N.E.3d 1265 (citing directly to the FDA Campaign); *Salier v. Walmart, Inc.*, No. 22-CV-0082 (PJS/ECW), 2022 U.S. Dist.

LEXIS 148684 (D. Minn. Aug. 19, 2022) (Slip Op. at 11, note 4; "FDA...has criticized the use"); *Smith v. W. Chester Hosp., LLC*, No. CV 2021 08 1206, 2021 Ohio Misc. LEXIS 103, Slip Op. at 5 (Ct. Com. Pl. Sep. 6, 2021) (Citing that FDA issued an advisory "against the use of ivermectin.")

The FDA Campaign has been extensively relied upon by courts to rule against access to ivermectin. These cases demonstrate not only that the Campaign has had profound legal consequences, but that judges read the FDA Campaign exactly as Appellants, and not the FDA, represent its intended meaning.

2) State Regulatory Authorities Clearly Acted to Restrict Physician Prescribing Based Upon in Significant Part on the FDA Campaign.

Regulators unequivocally understood the FDA's Campaign to be a finding that physicians should not prescribe ivermectin for COVID-19 and acted on that finding:

New York Attorney General Letitia James took an unprecedented step in November of 2021and sent letters to physicians who were listed in an FLCCC directory as willing to consider ivermectin for COVID-19 and instructed them to cease and desist. FLCCC Exhibits, attached (hereinafter "Exh.") at 1. (Addressee redacted for confidentiality). In her letter, she not only refers to the lack of FDA approval for COVID-19 as an indication, which is simply an off-label use, but

twice cites to the FDA Campaign "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19") (Exh. at 1, 2 notes 2 and 4.)

Numerous medical boards have investigated or taken disciplinary action against physicians for using ivermectin to treat COVID-19, relying in significant part on the FDA Campaign. A Maryland delegate, for example, also a physician, was investigated for prescribing ivermectin. The reporting about Andy Harris, M.D. noted the investigation occurred because the FDA "has not approved the use of ivermectin to treat COVID. 'Using the Drug ivermectin to treat COVID-19 can be dangerous and even lethal.[4] The FDA has not approved the drug for that purpose,' the FDA said. 'You are not a horse. You are not a cow. Seriously, y'all.

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[4] The claim of lethality for one of the safest drugs known is solely a matter of media hysteria. The media reports about deaths due to ivermectin turned out to be faked, https://rescue.substack.com/p/a-myth-is-born-how-cdc-fda-and-media as did the story about clogged emergency rooms, https://www.usatoday.com/story/news/factcheck/2021/09/15/fact-check-oklahoma-hospitals-not-backed-up-ivermectin-cases/8271014002/ and the two incidents cited on the CDC report, *see* footnote 11, were particularly egregious cases of misuse that can occur with any medication, in these cases drinking an injectable form prepared for use in cattle and a case of unknown strength purchased on the Internet.

The Poison Control Center ivermectin calls reported by CDC cite 1,140 cases between January 1 and September 21 of 2021. As 70% of these were consumers of the animal drug, note 11, in that eight-month period there were about 11 calls per week about prescribed ivermectin. According to the CDC health alert, there were approximately 39,000 prescriptions per week at the beginning of 2021 and rising.

There has not a confirmed death from prescribed ivermectin. During a January to September 2021 time frame, when over one million scripts were written, adverse events were reported in roughly 0.019% of cases according to the FDA Adverse Event Reporting System. Of those, the majority would be from animal forms, leaving an estimate of moderate to severe events with human drugs in the range of 1 in 40,000 prescriptions. This is a remarkable safety record.

Stop it.' the FDA said in a tweet."[5]

There have been numerous news reports describing and editorials calling for disciplinary action against physicians for prescribing ivermectin. While many of these Board investigations generally have either found errors in the method of prescribing rather than expressly charge on ivermectin or dismiss the matter outright, physicians not only have to navigate the risks and costs of an intrusive medical board matter for deciding to follow the evidence, particularly important during a novel and developing pandemic with limited options, but these highly publicized cases substantially chill physician willingness to prescribe, which is the FDA's intended effect.

A few examples tell this story; for a board investigation, a letter from the Washington Medical Commission to a physician investigating him for prescribing ivermectin. (Exh. at 3, name redacted for confidentiality); a sample news report, "The Arkansas Medical Board is investigating after a doctor said he prescribed an anti-parasitic drug "thousands" of times for treatment of Covid-19, including to inmates in an Arkansas jail. The FDA has been warning against the use of

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[5] https://foxbaltimore.com/news/connect-to-congress/maryland-congressman-andy-harris-compliant-filed-against-him-medical-license-prescribing-ivermectin-livestock-dewormer-treat-covid-19

ivermectin for treatment of Covid-19 since March."[6]; samples of the outcries to discipline doctors include a Seattle Times editorial entitled, over an image of an ivermectin box, "Discipline doctors who prescribe quack COVID-19 cures" [7] and The Tampa Bay Times, in an August, 2021 article stated "Doctor advising DeSantis promoted ivermectin to treat COVID-19 despite FDA warnings: 'Any physician that espouses this should be reported to the state medical association,' one medical expert said."[8] [9]

Boards of Pharmacies have also been sending out their own statements to pharmacists cautioning them not to fill ivermectin scripts for COVID-19 based in significant part on the FDA Campaign. Utah Pharmacy Association, Exh. at 6; Maine Board of Pharmacy Statement, linking to FDA Campaign, Exh. at 7. The impact, if not the origin, of these notices was exposure of pharmacists to potential state disciplinary sanctions[10] that was enhanced by the FDA pronouncement.

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[6] https://www.cnn.com/2021/08/26/us/covid-ivermectin-arkansas-doctor/index.html; https://www.cbsnews.com/colorado/news/scott-eric-rollins-ivermectin-colorado-doctor-unprofessional-conduct-covid-19-patients/

[7] https://www.seattletimes.com/opinion/editorials/discipline-doctors-who-prescribe-quack-covid-19-cures/

[8] https://www.tampabay.com/news/florida-politics/2021/08/28/doctor-advising-desantis-promoted-ivermectin-to-treat-covid-19-despite-fda-warnings/

[9] *See also for e.g.,* https://midmichigannow.com/news/state/west-michigan-doctor-promoted-ivermectin-as-covid-19-treatment-despite-fda-cdc-warnings .

[10] For example, a pharmacist under Texas law can be sanctioned by the State Board of Pharmacy for "the dispensing of a prescription drug order not issued for a legitimate medical purpose or in the usual course of professional practice shall include the following: (i) dispensing

3) Medical Insurers Have Taken Actions Against Physician Prescribing Based in Significant Part on the FDA Campaign.

Insurance companies have ordered their participating physicians not to prescribe and, in at least one case, terminated a physician who refused to follow that practice restriction. Independence Blue Cross of Pennsylvania ("IBC") issued a strong statement in November of 2021 "Do not prescribe ivermectin for COVID-19." Exh. at 8. (Name Redacted). In that letter, it cited, *inter alia,* that FDA "[has] strongly warned against prescribing ivermectin for the prevention or treatment of COVID-19 infection" citing the FDA Campaign. IBC terminated the participation agreement of a physician who refused to comply. In correspondence leading to the termination, Exh. at 10, IBC again expressly grounded their decision in part on the fact that the FDA had, despite the Agency's protestations to the contrary, "unequivocally stated that ivermectin should not be prescribed for the prevention or treatment of COVID-19."[11]

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controlled substances or dangerous drugs to an individual or individuals in quantities, dosages, or for periods of time which grossly exceed standards of practice, approved labeling of the federal Food and Drug Administration, or the guidelines published in professional literature..." 22 Tex. Admin. Code § 281.7 (a)(2)(A). (Emphasis added.)

[11] Note that regulatory and insurance actions also cite CDC and NIH policy as a basis. The CDC posted a Health Alert citing a five-fold increase in Poison Control Center calls; 70% of these calls regarded veterinary forms. https://www.npr.org/sections/coronavirus-live-updates/2021/09/04/1034217306/ivermectin-overdose-exposure-cases-poison-control-centers. *See also* Exh. at 12. This increase in calls arose not only as a result of the unfortunate, widespread use of veterinary forms (that occurred in part because of difficulty accessing ivermectin through physicians), but also a 24-fold increase in

As another example, AdventHealth sent an advisory that their guidelines do not allow for this prescribing, Exh. at 14, including a reference to the FDA Campaign, as well as to a Becker Hospital Review article that was itself largely based on the Campaign.[12]

4) Medical Organizational Efforts Opposing Physician Prescribing Were Based in Significant Part on the FDA Campaign.

Major medical organizations understood the message FDA was disseminating and used the Campaign to funnel that clearly intended message. The American Medical Association (AMA), American Pharmacists Association (APhA), and American Society of Health-System Pharmacists (ASHP),[13] for example, issued a joint press release to "strongly oppose the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical

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physician prescribing. That such profound increases in use only led to a five-fold increase does not demonstrate a safety signal. Unlike the FDA Campaign, the CDC did not issue headlines that blared that ivermectin should never be used. https://emergency.cdc.gov/newsletters/coca/020122.htm. In the absence of the FDA Campaign it was unlikely to have been taken as a bar to physician prescribing. The safety of ivermectin is f by FLCCC at https://covid19criticalcare.com/safety-of-ivermectin/. The NIH position is addressed *infra* at ___.

[12] https://www.beckershospitalreview.com/pharmacy/physicians-prescribing-ivermectin-for-covid-19-despite-fda-warning.html

[13] While the government cites these organizations as independent third-party actors, these are professional associations whose function is to represent their memberships and are not independent standard-setting bodies. They merely echo the messages of authorities. While also citing to NIH and CDC, the AMA, APhA and ASHP all clearly understood that the FDA was telling physicians not to prescribe.

trial."[14] Exh. at 15. That Press Release hyperlinks directly to the FDA Campaign.

5) News Media Reporting about the Campaign Reported it as FDA Informing Physicians Not to Prescribe Ivermectin for COVID-19.

The FDA posture that physicians should not prescribe ivermectin for COVID-19 was widely reported in the media, with frequent calls that medical boards should take action against physicians who prescribed ivermectin. For example:

The Wall Street Journal, in an editorial dated July 8, 2021 entitled "Why is the FDA attacking a Safe, Effective Drug? Ivermectin is a promising Covid treatment and prophylaxis, but the Agency is denigrating it."[15] That article, briefly noting the numerous studies in support of ivermectin effectiveness as well as safety, criticized the FDA for its position. The Wall Street Journal understood the Campaign to be an attack on physician prescribing.

The New York Times began an article bluntly stating that "Ivermectin, an anti-parasitic drug commonly used for livestock, should not be taken to treat or prevent Covid-19, the Food and Drug Administration said on Saturday."[16]

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[14] https://www.ama-assn.org/delivering-care/public-health/what-fda-wants-doctors-tell-patients-asking-ivermectin

[15] https://www.wsj.com/articles/fda-ivermectin-covid-19-coronavirus-masks-anti-science-11627482393

[16] https://www.nytimes.com/2021/08/21/world/ivermectin-fda-covid-19-treatment.html

Forbes Magazine, commenting on the public debate around Joe Rogan after he had contracted Covid-19 and taken ivermectin, reported that "the Food and Drug Administration advocates against as a treatment for Covid-19."[17]

The New York Post reported that "the Food and Drug administration has warned people to stop ingesting the animal and human version of the drug to fight COVID-19."[18] (Emphasis added.)

ABC News reported that concern about a physicians prescribing despite "FDA and CDC's warning that people should not be taking ivermectin at all for COVID-19 treatment outside of a clinical trial.[19]

Newsweek stated in an article about an FLCCC founding physician's prescribing of ivermectin that "the Food and Drug Administration (FDA) has stated the drug should not be used for treatment of COVID-19."[20]

That the media widely and consistently quoted FDA as opposed to ivermectin use in COVID-19 in any form, including physician prescribing, is clear

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[17] www.forbes.com/sites/masonbissada/2022/02/17/joe-rogans-spotify-deal-allegedly-worth-200-million-doubling-initial-report/?sh=4e2604a42c39clear

[18] https://nypost.com/2021/11/05/aaron-rodgers-called-joe-rogan-for-covid-19-treatments/ *See also* https://www.thecrimson.com/article/2022/2/7/neil-young-joe-rogan-spotify-vaccine-misinformation-joni-mitchell/ which includes links to the FDA Campaign

[19] https://abcnews.go.com/US/group-physicians-combats-misinformation-unproven-covid-19-treatments/story?id=83097330

[20] https://www.newsweek.com/doctor-claims-he-used-ivermectin-thousands-covid-patients-despite-fda-warnings-1623441

evidence that this was in fact the message FDA was communicating in stark contrast to FDA's claims about what a reader "would likely have concluded."

B. The FDA Message That Physicians Should Not Prescribe Ivermectin for COVID-19 was Intentional.

The government representation that it only intended to stop consumer use is entirely disingenuous; the FDA initiated and actively invited, if not instructed, organizations such as the FSMB, NABP, AMA, APhA and ASHP to join its efforts to restrict physician prescribing. As Appellant's note in their brief at 2, 16, 49 and 58, the FDA escalated its anti-ivermectin campaign by writing to the Federation of State Medical Boards ("FSMB") and the National Association of Boards of Pharmacy ("NABP") calling attention to its views that it should not be used for COVID-19. Exh. at 16.

The Appellant's address this conduct and timeline in some detail in their brief at 12-19. An additional observation may help make this even clearer. The FDA posted its Campaign on or about March 5, 2021. Exh. at 18. The NIH had just recently rescinded its opposition to ivermectin,[21] which though later reversed

[21] "NIH Revises Treatment Guidelines for Ivermectin for the Treatment of COVID-19: Ivermectin is Now a Therapeutic Option for Doctors & Prescribers, 15 January 2021. https://www.newswise.com/coronavirus/nih-revises-treatment-guidelines-for-ivermectin-for-the-treatment-of-covid-19.

given additional data[22] (under dispute by FLCCC[23]) is consistent with changing medical judgment in the midst of an ongoing novel pandemic.[24]

The FDA launched its Campaign about two months after NIH maintained it could be a reasonable choice and then led the echo chamber in its opposition to physician prescribing. Were the FDA's representations at oral argument true that this was not its intent, it could have publicly stated that it was in fact not recommending against physician prescribing. The Agency has tacitly, if not overtly, endorsed this interpretation of its Campaign. It is not remotely plausible that it was unaware of the regulatory activity its Campaign was generating against physicians. It not only persisted but accelerated its campaign with letters to national organizations and social media postings.

What the Agency did, however, is even worse. From its power center in the national debate over ivermectin it misrepresented that it had conducted an evaluation of the evidence. Its Campaign website made it appear as if it had conducted such a process. The website declared that:

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22 https://www.covid19treatmentguidelines.nih.gov/therapies/miscellaneous-drugs/ivermectin/

23 https://covid19criticalcare.com/flccc-alliance-response-to-the-nih-guideline-committee-recommendation-on-ivermectin-use-in-covid-19-dated-january-14th-2021/

24 NIH clearly states its guidelines are just that and "should not be considered mandates. The choice of what to do or not to do for an individual patient is ultimately decided by the patient and their provider." https://www.covid19treatmentguidelines.nih.gov/about-the-guidelines/guidelines-development/?utm_source=site&utm_medium=home&utm_Campaign=highlights

> The FDA's job is to carefully evaluate the scientific data on a drug to be sure that it is both safe and effective for a particular use, and then to decide whether or not to approve it. Using any treatment for COVID-19 that's not approved or authorized by the FDA, unless part of a clinical trial, can cause serious harm.
> Exh. at 18.

This is a caution against off-label use, already in excess of FDA's authority as set forth in the Appellants' Brief at 1,5, 8-10. *See also* note 25. When the FDA initially launched their Campaign, it at least included this acknowledgment:

> The FDA has not reviewed data to support use of ivermectin in COVID-19 patients to treat or to prevent COVID-19...
> Exh. at 19.

In the fall of 2021, the FDA removed this acknowledgment and left only its misleading statement that its job was to review the evidence, and presumably had, yet, as discussed *infra* at ___, no review has ever been done.

The FDA not only intentionally created a sweeping pronouncement against any use of ivermectin for COVID-19, including by prescription, but it intentionally mislead whether it had ever reviewed the evidence to support its position.

II. The District Court Failed to Recognize that FDA Cannot Set Medical Standards, Exceeded its Authority by Violating Statutes Governing Adverse Drug Warnings and Indications and is thus Ultra Vires.

The FDA Campaign, in its direct language that ivermectin should not be used in COVID-19 cases, and as it has been widely understood and encouraged by

the Agency as a bar against physician prescribing, is an act outside the scope of its authorization.

A. The FDA Does Not Have Jurisdiction Over the Practice of Medicine and Acted in Excess of its Authority in Explicit Violations of its Own Governing Statute.

The Appellant properly sets forth the statutory and long-recognized limitations on FDA's ability to determine off-label indications and its prohibitions against interfering with the practice of medicine.[25] *See* Appellant Brief at 25-39. To that analysis we add statutory detail that makes even clearer that the Agency action here is unprecedented, beyond its authority, in violation of its own enabling statute and unsupported by any Agency deliberation.

1) The FDA Has Explicit Requirements for Issuing Drug Alerts That it Failed to Follow.

One of the FDA's missions is to monitor adverse drug reports and issue regular alerts to inform consumers and physicians of potential risks. This was arguably an element of the FDA Campaign, but even that narrower mission would

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[25] *See also, for e.g.* the extensive discussion in *Amarin Pharma, Inc. v. United States FDA*, 119 F. Supp. 3d 196, 200-01 (S.D.N.Y. 2015). A brief excerpt: "Significant here, however, the FDA does not regulate doctors. After a drug has been approved by the FDA, a doctor may lawfully prescribe it for both FDA-approved and non-FDA approved ("off-label") uses. *See* [*United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012)] 703 F.3d at 153 *(citing Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001); *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989); John E. Osborn, Can I Tell You the Truth? A Comparative Perspective on Regulating Off-Label Scientific and Medical Information, 10 Yale J. Health Pol'y L. & Ethics 299, 303 (2010) ("Physicians may their medical judgment."))

have had to follow the detailed procedure and criteria pursuant to 21 U.S.C. § 355(k)(3)(C).[26] That was not done here. The FDA instead allowed the Consumer Affairs Office to conduct the Campaign without the Agency having made any findings or followed any process whatsoever.

When safety signals suggested serious risk of heart attack and stroke for COX-2 inhibitors, leading to the voluntary withdrawal of Vioxx (rofecoxib) by Merck,[27] the FDA undertook an investigation required by law and issued a black box warning. Even then it never issued a statement that remotely stated "Why you should not take Vioxx to treat arthritis pain." In the distinction between that hypothetical and the facts here lie the essence of Drs. Apter, Bowen and Marik's valid complaint against the FDA.

2) The FDA Has Explicit Mechanisms for Approving or Disproving a New Indication for a Drug, Yet Did Not Have Before it a New Drug Application Allowing for Such Consideration.

Even had the FDA followed the criteria and procedures necessary to issue a

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[26] Such warnings are subject by statute to a requirement that FDA develop criteria about the publication of adverse events, 21 U.S.C. § 355(k)(5) and a detailed internal expert review process for scientific expert review, 21 U.S.C. § 355(n), among other detailed regulations that prescribe how the Agency should make such determinations and public announcements. The FDA sought to circumvent this by calling it merely sharing "information." ROA. 1450. (MTD at 1.) "Information" as used here is apparently a euphemism for a point of view.

[27] Antman, E.M. et al. Use of Nonsteroidal Antiinflammatory Drugs, An Update for Clinicians: A Scientific Statement From the American Heart Association (2007;115:1634–1642) doi.org/10.1161/CIRCULATIONAHA.106.181424

safety alert, which it did not, the decision about whether a drug should be prescribed always remains with the physician. The FDA not only does not have the authority, it does not have the mechanisms necessary to weigh risks and benefits and dictate medical standards. The overreach here was even more serious, as it was not simply a risk advisory that failed to follow administrative procedure, it was a judgment about use for a specific indication. One of the reasons that the FDA is not permitted to opine about off-label uses, solely within the province of state-regulated medical practice as correctly argued in Appellant's brief at 3-5, 8-12, is that it has no statutory mechanism to review a new indication for a drug other than of an extensive New Drug Application ("NDA") filed pursuant to a detailed statute, 21 U.S.C. § 355. The current pharmaceutical user fee of $3,242,026 to have an NDA reviewed gives one quick measure of the substantial nature of that process.[28]

Against the detailed Congressionally authorized mechanisms to weigh and simply warn about specific risks, and the extensive regulatory framework about

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[28] This also explains why COVID-19 as an indication for ivermectin, an inexpensive generic drug, has never been filed with the Agency; it was financially impossible without a sponsor, which requires a patentable interest. The FDA, Merck, also making pronouncements against this use of ivermectin, were focused on competitive new drug development. https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments. The FDA receives 45% of its budget from these user fees, a concerning conflict of interest. http://www.businessinsider.com/fda-user-fees-from-pharmaceutical-companies-2016-8.

how the Agency may review whether a drug indication is appropriate, the District Court rested its finding that FDA had authority by turning to the general mission statement of the Agency, found its purpose of "protecting public health and ensuring that regulated medical products are safe and effective," citing to the broadly generic authority of the FDA under 21 U.S.C. 393(b)(1) and (b)(2)(B), and found the FDA has colorable authority. ROA. 1652. This analysis would justify any action regardless of the complex statute that governs FDA authority. It proves far too much, is entirely inadequate and inaccurate. It is not sensible that Congress put detailed guardrails around the procedures needed to monitor and simply warn physicians about a drug's adverse effects, or even more so the years of effort required to review an indication yet intended that the Agency could bypass these requirements and simply make pronouncements about medical decisions without any required process whatsoever.

The FDA in fact engaged in no deliberative process regarding physician prescribing that would support its statement that ivermectin should not be used to prevent or treat COVID-19. In contrast to either safety alerts or NDA review, the FDA never held any inquiry, consulted any federal advisory group, issued any proposal for notice and comment or evidenced any other deliberative process that could have led them to make a finding regarding the safety or efficacy of

ivermectin to treat COVID-19. The Agency could not meaningfully or lawfully issue such a statement given the complete lack of any administrative process.

The simple fact that FDA issued a statement that ivermectin should not be used for the indication of COVID-19, without first conducting any administrative process, alone requires reversal. That it intentionally mislead the nation about whether it had actually studied the matter makes reversal particularly acute. Whether measured by the limitations on its Congressional authorization, the contrast with its requirements for safety warnings or ruling on new indications, basic requirements under the APA or plain common sense, such agency failures cannot be sustained.

3) Acting Under the Guise of a Consumer Alert Does Not Insulate the FDA From Redress.

While a warning for consumers not to self-medicate may indeed fall within the Agency's general mission had proper procedures been followed, the statement that ivermectin should not be used to prevent or treat COVID-19 is expressly outside the FDA's authority. The FDA tacitly admitted this at oral argument when it did not defend its authority but instead attempted to deny it meant to communicate that message. The FDA argues that this was simply a consumer warning. Yet no statute authorizes the FDA Office of External Affairs the ability to

bypass Agency administrative requirements and offer public comment about whether a disease can be treated with an off-label medication. To hold otherwise is to allow federal agencies to avoid the administrative responsibilities by simply passing matters to their consumer affairs division.

B. The FDA Action is Ultra Vires.

When an Agency acts without Congressional authorization its action is ultra vires. *D&G Holdings, LLC v. Burwell*, 156 F. Supp. 3d 798, 816 (W.D. La. 2016) ("In the agency context, an *ultra vires* act is one where the agency has exceeded its statutory or constitutional power to act. *See City of Arlington v. FCC*, 569 U.S. 290, 297, 133 S.Ct. 1863, 185 L.Ed.2d 941 (2013) ("Both an agency's power to act and how agencies are to act is authoritatively prescribed by Congress, so that when they act improperly, no less than when they act beyond their jurisdiction, what they do is *ultra vires*.") When an agency acts in a manner not authorized by statute, its action is ultra vires and a violation of the APA. *See* 5 U.S.C. § 706(2)(C).

Because the FDA does not have the statutory authority to dictate how doctors can practice medicine, even regarding off-label use of drugs, and failed to follow its own regulatory scheme before issuing either a drug warning or ruling on a new indication, its effort to do so was without authority. "An ultra vires action

through which the FDA "exceeded the authority granted to it by Congress, and its . . . action cannot stand." *Citing Brown & Williamson Tobacco Corp. v. FDA,* 153 F.3d 155, 176 (4th Cir. 1998). *Am. Acad. of Pediatrics v. FDA,* 379 F. Supp. 3d 461, 492 (D. Md. 2019).

C. The FDA Action is Arbitrary, Capricious and an Abuse of Discretion.

The Agency action was thus arbitrary, capricious, and an abuse of discretion. The APA allows courts to set such actions aside. *See* 5 U.S.C. § 706(2)(A). An agency runs afoul of this standard "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Sacal-Micha v. Longoria*, 449 F. Supp. 3d 656, 666 (S.D. Tex. 2020) citing *Tex. Oil & Gas Ass'n v. U.S. E.P.A.* , 161 F.3d 923, 933 (5th Cir. 1998) *(quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983)). The agency must "examine the relevant data and articulate a satisfactory explanation for its action." *Motor Vehicle Mfrs. Assn.*, 463 U.S. at 43.

The Agency has no administrative record developed in which the limits of its authority, the basis for its views and the impacts upon the critical national

enforcement of health policy could be weighed. In light of the actors who took FDA as intending the imposition of restrictions on physicians, the lack of any process shows the Agency actions are arbitrary and capricious. Framing its message as a consumer one does not allows the Agency's failures to be brushed aside as consumer "information."[29]

Instead of offering an explanation, the Agency hopes to back away and claim that its statement that ivermectin should not be used somehow exempted physician prescribing. That is not how anyone else saw it. When viewed through the lenses of all the activity the Campaign generated, the FDA's actions are arbitrary, capricious and an abuse of discretion.

IV. The Actions of Third-parties Does Not Insulate the FDA from the Requested Relief; the Harms Are Fairly Traceable to the FDA.

The FDA has played an active role in leading other organizations to oppose ivermectin prescribing, and now tries to insulate itself by pointing to that and other third-party conduct. In addition to the well-constructed argument of Appellants in their brief at 56-61, we note that FDA speculation that third party viewpoints alone might have led to the same injuries offers the government no defense.

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[29] These administrative arguments support Appellants' view that the FDA does not have sovereign immunity; as that has been ably argued in their brief at 39-49, we do not address that here.

This should not be heard, in part, because the FDA actively sought to elicit their participation. More critically, third-party conduct does not excuse ultra vires actions or those taken without any deliberative process. Where judges, medical boards, insurance companies and others cite the FDA Campaign, causation is direct. The fact that other organizations like NIH and CDC are also cited for their opinions does not undo FDA responsibility; expressing an ultra vires opinion cited with consequence cannot be defended by calling injury speculative merely because others were involved, whatever the origin of their positions. The concept of traceability does not require resolving the FDA's speculation. "A plaintiff is not limited to only challenging the most plausible source of the plaintiff's injury; a plaintiff has standing to challenge any plausible source of the plaintiff's injury. *(Citing Barilla v. City of Hous*., 13 F.4th 427 (5th Cir. 2021). Any concrete injury furnishes standing when it is 'fairly traceable' to the Government's actions and redressable in court." *(*Emphasis added*.) Tex. Gen. Land Office v. Biden,* No. 7:21-cv-00272, 2022 U.S. Dist. LEXIS 145737 at 14 (S.D. Tex. Aug. 3, 2022).

V. The FDA Posture is an Ongoing, Redressable Injury.

Many of the examples offered in this brief are a widespread, on-going problem; the *Gahl* matter is currently pending before the Wisconsin Supreme

Court. There are numerous medical board proceedings and other actions brought on an ongoing basis. A retraction/clarification now about the reach of FDA's jurisdiction and a correction about its ivermectin warning would allow third-parties to more responsibly weigh appropriate standards without falsely believing that the FDA has weighed and pronounced on the issue. There is a "substantial likelihood" that relief would change the landscape for plaintiffs and medicine nationally. *See Duke Power Co. v. Carolina Environmental Study Group*, 438 U.S 59, 75 n. 20, 98 S. Ct. at 2631 n. 20, 57 L. Ed. 2d at 612 n. 20 (1978); *Cutler v. Kennedy*, 475 F. Supp. 838, 850 (D.D.C. 1979).

VI. The FDA Campaign Materially Misrepresented the Scope of its Authority and Support for its Findings; Allowing the District Court Ruling to Stand Would Upend FDA Regulation and Allow the Imposition of Federal Control over State Medical and Public Health Decision-making.

One of the real harms of the Campaign is the public perception intentionally created by the Agency that it had conducted fact-finding to determine if the use of ivermectin in COVID-19 patients is safe or effective. It had not.

Numerous public health and professional organizations, courts, an attorney general, medical insurers and others have cited and acted upon the FDA Campaign as a statement by the Agency that it had conducted an inquiry into this matter. It encouraged that false perception.

Allowing this to stand would be a license for the Agency to do what it is not otherwise authorized to accomplish by allowing their public relations departments to issue proclamations and then demur legal responsibility for them. It would wreak havoc on the boundaries around the FDA's limited authority and call into question the administrative constraints on federal authority over state regulated conduct. It would allow agencies to bypass their regulatory obligations and step over boundaries, invading state authority by framing their actions as simply "consumer information."

CONCLUSION

The rejection of relief by the District Court is grounded in misunderstanding of the facts on the ground and well-established limitations and requirements upon FDA's authority to opine about standards of medicine. We respectfully ask the Court reverse and remand with instructions consistent with the law, which would allow diverse opinions to be addressed within medicine, especially critical as we continue to face this novel pandemic, without being squelched by unsupported governmental intervention.

Respectfully submitted this 14th day of February, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on February 14, 2023, I electronically filed the foregoing document with the Clerk of this Court by using the CM/ECF system, which will serve all parties automatically.

February 13, 2023

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitations of Fifth Circuit Rule 29.3 and Federal Rules of Appellate Procedure 29(a)(5) and 32(7)(B) because it contains 6,474 words measured by Microsoft Word, excluding the portions exempted by Rule 32(f). This brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure Rule 32(a)(5)–(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times Roman 14 point font.

Dated this 13th day of February, 2023

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