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, MBBCh, 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

OPENING BRIEF FOR APPELLANTS

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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 of record certifies that the following listed persons and entities as described in the fourth sentence of 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.

Appellants

1. Robert L. Apter
2. Mary Talley Bowden
3. Paul E. Marik

Appellees

4. Department of Health and Human Services
5. Xavier Becerra
6. Food and Drug Administration
7. Robert M. Califf

Counsel

8. Boyden Gray & Associates: C. Boyden Gray, R. Trent McCotter, Jonathan Berry, Michael Buschbacher, and Jared M. Kelson are counsel for Appellants.

9. U.S. Department of Justice: Ashley Cheung Honold, Oliver McDonald, Daniel Bentele Hahs Tenny, Isaac Belfer, and Oliver McDonald are counsel for Appellees.

Dated: February 7, 2023

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REQUEST FOR ORAL ARGUMENT

Pursuant to Federal Rule of Appellate Procedure 34(a) and (f) and Fifth Circuit Rule 28.2.3, Appellants respectfully request oral argument. This case involves important issues of statutory interpretation and sovereign immunity. Oral argument would substantially aid the Court in its resolution of the case.

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JURISDICTIONAL STATEMENT

This District Court had jurisdiction under 5 U.S.C. §§ 701–706 and 28 U.S.C. §§ 1331, 1346, 1361, 2201, the U.S. Constitution, and pursuant to the equitable powers of this Court. The District Court granted Appellees' motion to dismiss on December 6, 2022. Appellants timely filed a notice of appeal with this Court three days later, on December 9, 2022. *See* Fed. R. App. P. 4(a)(1)(B). This Court has appellate jurisdiction under 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUES

Whether sovereign immunity shields the FDA from suit for equitable relief regarding a series of publications the agency issued and maintains about the use of ivermectin to treat or prevent COVID-19.

INTRODUCTION

The U.S. Food and Drug Administration ("FDA") is a gatekeeper with authority to "approve" when a drug can be introduced to the market in the United States and what labeling it can use. But "the FDA does not restrict physicians from prescribing an otherwise FDA-approved drug for an off-label use," meaning use for a purpose or in a dosage that differs from the FDA-approved labelling. *U.S. ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 328 (5th Cir. 2017). Off-label use is not only "common," but—as this Court has observed—it may "in many cases … represent the standard of care in the industry." *Id.* (cleaned up).

Consistent with this, the FDA also cannot advise whether or for what purpose a doctor should prescribe, or a patient should take, an approved drug. Those decisions fall within the scope of the doctor-patient relationship. Attempts by the FDA to influence or intervene in the doctor-patient relationship constitute interference with the practice of medicine, the regulation of which is—and always has been—reserved to states. In fact, the Federal Food, Drug, and Cosmetic Act ("FDCA") is explicit that it does not in any way authorize the FDA to "limit or interfere" with the practice of medicine, codified at 21 U.S.C. § 396.

The FDA breached this critical boundary between federal and state authority by repeatedly directing the public—including health professionals, professional organizations, and patients—not to use ivermectin for COVID-19, even though the drug remains fully approved for human use. This includes formal, unequivocal, and conclusory actions to prohibit or otherwise interfere with the off-label use of ivermectin for COVID-19, including a publication titled, "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," ROA.972, to which the FDA linked in a letter to the Federation of State Medical Boards and which on its face seeks to interfere with a decision that is preserved for the doctor-patient relationship. Other public directives are even more blunt, stating: "Q: Should I take ivermectin to prevent or treat COVID-19? A: No," ROA.976; ROA.979; and "You are not a horse. You are not a cow. Seriously, y'all. Stop it," ROA.981; and "You are not a horse. Stop it with the #ivermectin. It's not authorized for treating #COVID," ROA.988. These directives have remained active on official FDA platforms, some for almost two years.

Appellants in this case—Dr. Robert L. Apter, Dr. Mary Talley Bowden, and Dr. Paul E. Marik, who is a critical care specialist and one

of the world's leading experts on sepsis—have successfully treated thousands of patients for COVID-19 since the earliest days of the pandemic. But they have also been and continue to be harmed in their efforts by the FDA's unlawful interference in the practice of medicine. Specifically, they have been pressured in the exercise of their professional judgment, hindered in their ability to timely treat patients according to their professional judgment, forced to resign privileges and positions, and threatened with or subjected to professional disciplinary proceedings. This has further resulted in both reputational and monetary harm. ROA.960; *see also* ROA.992–94; ROA.1005–06; ROA.1010–12.

Common sense confirms that the only reason the FDA would issue and maintain its ivermectin publications in the first place is because of the predictable and intended effects they would have on health professionals, regulatory boards, hospitals, patients, and the broader public to stop the use of ivermectin to treat COVID-19—precipitating the very harms caused to Appellants. The FDA plainly desired these effects, or the entire endeavor would have been pointless. The FDA cannot use unlawful means to accomplish exactly what it intended, then seek to wash its hands of the consequences.

Accordingly, Appellants sued the FDA[1] for non-monetary equitable relief, alleging its actions were ultra vires and violated the Administrative Procedure Act ("APA"). The District Court held that the FDA is shielded from suit because, "[a]lthough the FDA could have, and perhaps should have, been more prudent in their communications, they had at least a colorable basis in authority," and thus the actions were not ultra vires. ROA.1653. Accordingly, the ultra vires exception to sovereign immunity did not apply. *Id.* The District Court also concluded that the FDA's actions weren't "final" because they did not "determine rights, obligations, or legal consequences," and thus the APA waiver of sovereign immunity for APA claims did not apply either. ROA.1655; ROA.1660.

The District Court was wrong on both points. Sovereign immunity does not bar this suit, for several reasons. *First*, this Court previously issued a binding decision demarcating the FDA's authority in this area—"the FDA does not restrict physicians from prescribing an otherwise FDA-approved drug for an off-label use." *King*, 871 F.3d at 328. The FDA violated that limitation here, and thus its actions were ultra vires. But

[1] Appellants sued the FDA, the Department of Health and Human Services, the Secretary of Health and Human Services, and the Commissioner of Food and Drugs (collectively, "the FDA").

the District Court declined to follow that decision because this Court's opinion used a "*see*" signal when citing § 396, the FDCA provision that expressly prohibits the FDA from interfering in the practice of medicine. ROA.1651. Regardless of which Bluebook signal this Court used, or whether it cited a statute at all, *King* established that the FDA cannot interfere with the off-label use of approved drugs within the doctor-patient relationship, and so the FDA's decision to do so here was ultra vires. This limitation on the FDA has been understood since the FDCA was first passed in 1938 and reflected in case law ever since, which necessarily means under longstanding precedent that sovereign immunity does not apply.

The District Court also reasoned that "[a]s there is no statute limiting the FDA's actions here, it cannot have acted outside of any statutory limitations." ROA.1652. That is backwards. "[A]gencies, as mere creatures of statute, must point to explicit Congressional authority justifying their decisions." *Clean Water Action v. EPA*, 936 F.3d 308, 313 (5th Cir. 2019). Without it—and the FDA cannot identify any authority here—the agency acted outside of its statutory limitations.

The District Court then relied on the FDA's mission statement in 21 U.S.C. § 393(b)(1), (2), which the court summarized as "protecting public health and ensuring that regulated medical products are safe and effective, among other things." ROA.1652–53. The court presumed the FDA has "authority, generally, to make public statements in-line with these purposes." ROA.1653. But "statements of purpose … cannot override a statute's operative language," *Sturgeon v. Frost*, 139 S. Ct. 1066, 1086 (2019), and the FDA wasn't ensuring that any product was safe and effective, anyway, which is how the mission statement directs the FDA to promote public health. The agency was instead playing doctor and telling physicians and patients what already-approved medications should be used and for what purpose. That transgressed a bright line the FDA was not authorized to cross.

Second, the District Court failed to recognize that the APA waives sovereign immunity not merely for APA claims but also for *all non-statutory claims* (including ultra vires actions) that seek equitable relief in response to agency action, as recognized by this Court and argued by Appellants below. Appellants certainly satisfied those minimal

requirements for their ultra vires claim, and thus the APA independently provided a waiver of sovereign immunity.

Third, the FDA's actions were final, so the APA waived sovereign immunity for Appellants' separate APA claims. The FDA's unequivocal publications have remained in place and been reiterated for almost two years. They have significantly interfered with Appellants' practice of medicine and, most notably, been relied on by courts in legal proceedings to determine the appropriate standard of care. This is more than sufficient to show these actions were "not … of a merely tentative or interlocutory nature," and determined "rights or obligations." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (cleaned up).

This case is not about whether ivermectin is an effective treatment for COVID-19. It's about who determines the appropriate treatment for each unique patient and whether the FDA can interfere with that process. It cannot. If the FDA is not limited to its statutory lane, its unlawful actions will no doubt persist and be repeated, damaging the carefully constructed statutory wall between federal and state regulatory powers, and between the FDA and the professional judgment of health professionals.

This Court should reverse and remand for further proceedings.

STATEMENT OF THE CASE

I. BACKGROUND

A. FEDERAL FOOD, DRUG, AND COSMETIC ACT

The FDA has authority under the FDCA to approve a drug "for introduction into interstate commerce" if the agency determines it is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," and there is "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(a), (d); *see* 21 C.F.R. § 201.57. Once approved, doctors are free to prescribe these drugs for "off-label" purposes.

Off-label prescriptions are "common, and can be a source of innovation, and in some settings may represent the standard of care." Donna T. Chen et al., *U.S. Physician Knowledge of the FDA-Approved Indications and Evidence Base for Commonly Prescribed Drugs: Results of a National Survey*, 18 Pharmacoepidemiology & Drug Safety 1094, 1094 (2009) (footnotes omitted). One study found that 21% of all

prescriptions were for off-label use, and that number jumps to 36.2% in intensive care units. Christopher M. Wittich et al., *Ten Common Questions (and Their Answers) About Off-label Drug Use*, 87 Mayo Clinic Proc. 982 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538391. The National Ambulatory Medical Care Survey similarly observed that 38.3% of prescriptions are for off-label uses. W. David Bradford et al., *Off-Label Use of Pharmaceuticals: A Detection Controlled Estimation Approach*, 66 J. Indus. Econ. 866, 866 (2019); *see also* Stephanie Greene, *False Claims Act Liability for Off-Label Promotion of Pharmaceutical Products*, 110 Penn. St. L. Rev. 41, 46 (2005) ("Off-label prescription of drugs is common, with as many as forty percent of all prescriptions issued involving off-label use."). Regarding off-label prescriptions, the FDA has even acknowledged that "[g]ood medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment." *"Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices*, FDA (May 6, 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-

documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices.

Generally, the FDA cannot prohibit, direct, or advise against off-label uses of approved human drugs. Nothing in the FDCA gives the agency that authority. *Ass'n of Am. Physicians & Surgeons* (*"AAPS"*) *v. FDA*, 13 F.4th 531, 534 (6th Cir. 2021) ("Although the [FDCA] regulates a manufacturer's distribution of drugs, it does not go further by regulating a doctor's practice of medicine.... It instead leaves the regulation of doctors to the states."); *Judge Rotenberg Educ. Ctr., Inc. v. FDA*, 3 F.4th 390, 400 (D.C. Cir. 2021) ("Choosing what treatments are or are not appropriate for a particular condition is at the heart of the practice of medicine."). When Congress has authorized the FDA to limit particular uses of an approved drug, it has done so explicitly. *E.g.*, 21 U.S.C. § 333(e) (restricting off-label use of "human growth hormone"). It is undisputed that Congress has not done so here.

Moreover, the FDCA is explicit in 21 U.S.C. § 396 that nothing in the statute "shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device for any condition or disease within a legitimate health care

practitioner-patient relationship." At least six circuits, including this Court, and multiple district courts have consistently interpreted this prohibition as applying to the prescription or administration of *drugs*. *See* Part I.B, *infra*. The provision was added to the FDCA specifically to "emphasize that the FDA should not interfere in the practice of medicine." H.R. Rep. No. 105-399, at 97 (1997).

The FDA thus cannot take actions, including pressure campaigns and jawboning, that "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 also, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 350 (2001) ("[T]he FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals."); *AAPS*, 13 F.4th at 534; *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 400.

Once a drug has been approved by the FDA for human use, appropriate health professionals can prescribe or dispense the drug off-label when done for a medical purpose within the scope of a doctor-patient relationship. *See, e.g.*, *In re Schering Plough Corp. Intron/Temodar*

Consumer Class Action, 678 F.3d 235, 240 (3d Cir. 2012) ("Because the FDCA does not regulate the practice of medicine, physicians may lawfully prescribe drugs for off-label uses."); *Planned Parenthood Cincinnati Region*, 444 F.3d at 505 ("Absent state regulation, once a drug has been approved by FDA, doctors may prescribe it for indications and in dosages other than those expressly approved by the FDA.... Off-label use does not violate federal law or FDA regulations[.]"); *Wash. Legal Found. v. Henney,* 202 F.3d 331, 333 (D.C. Cir. 2000) ("A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA.").

Doctors, of course, do not have *carte blanche*, since the standard of care for writing prescriptions is set and enforced by the relevant state authorities. But the FDA cannot wade into the debate over whether certain drugs can or should be used for specific purposes. Its role is a gatekeeper, not regulator of the practice of medicine.

B. THE FDA CAMPAIGN AGAINST IVERMECTIN

Despite this well-established division of authority, the FDA embarked on a "new engagement strategy" on March 5, 2021, and

published "Why You Should Not Take Ivermectin to Treat or Prevent COVID-19" on its website. ROA.1238; ROA.1242. The title of the publication states an official FDA position that ivermectin should not be used for the treatment or prevention of COVID-19. *Id.* Nowhere did this publication acknowledge that doctors can lawfully prescribe ivermectin for that use, instead stating only that "[i]f you have a prescription for ivermectin *for an FDA-approved use*, get it from a legitimate source and take it exactly as prescribed." ROA.1239 (emphasis added). This incorrectly conveyed that ivermectin can only be prescribed and used for FDA-approved purposes. Ironically, the FDA took this action notwithstanding a simultaneous admission that the agency "ha[d] not reviewed data to support use of ivermectin in COVID-19 patients to treat or to prevent COVID-19." *Id.*

The FDA later amended "Why You Should Not Take Ivermectin to Treat or Prevent COVID-19" to state that "[i]f your health care provider writes you an ivermectin prescription, fill it through a legitimate source such as a pharmacy, and take it *exactly* as prescribed," thus removing "for an FDA-approved use." ROA.973. But that pseudo-concession is buried in the middle of the document, and the FDA did not change the

title, which still unequivocally discourages the use of ivermectin to treat or prevent COVID-19. *Id.*

The FDA has also published an Ivermectin FAQ, entitled "COVID-19 and Ivermectin Intended for Animals." ROA.976. The Ivermectin FAQ begins with, "Q: Should I take ivermectin to prevent or treat COVID-19?" and flatly answers that question, "A: No." *Id.* It continues that "[w]hile there are approved uses for ivermectin in people and animals, it is not approved for the prevention or treatment of COVID-19. You should not take any medicine to treat or prevent COVID-19 unless it has been prescribed to you by your health care provider and acquired from a legitimate source." *Id.* None of this changes the FDA's unequivocal direction that ivermectin should not be used to treat COVID-19 and clear message that doctors should not (and possibly cannot) prescribe it for that use.

The FDA also maintains a COVID-19 FAQ that similarly asks, "Q: Should I take ivermectin to prevent or treat COVID-19?" and answers that question, "A: No." ROA.979. The COVID-19 FAQ continues that "[w]hile there are approved uses for ivermectin in people and animals, it is not approved for the prevention or treatment of COVID-19," and "[r]ead

more about why you should not use ivermectin to treat or prevent COVID-19." The answer also includes a link to "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." *Id.* Beyond unequivocally stating that ivermectin should not be used in this context, by citing lack of FDA-approval the COVID-19 FAQ misleadingly suggests that drugs should only be used for FDA-approved purposes.

On August 21, 2021, the FDA tweeted, "You are not a horse. You are not a cow. Seriously, y'all. Stop it." ROA.981. The tweet displayed the title of FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" and linked to that publication. The FDA posted the same image and message on LinkedIn and Facebook. ROA.984. All three publications unequivocally direct the public not to use ivermectin for COVID-19.

The tweet was viewed by over 24 million people in two days—not including the millions more who saw the tweet reproduced on other platforms or in mainstream media—quickly becoming the most viewed tweet in FDA history. ROA.1242.

Also on August 21, 2021, the FDA posted on Instagram a picture of a horse with the caption, "You are not a horse. Stop it with the

#ivermectin. It's not authorized for treating #COVID." ROA.988. The post misleadingly depicts ivermectin as a horse medication not approved for human use and unequivocally directs the public not to use it for COVID-19.

The FDA celebrated the August 21, 2021 tweet and posts as part of a "new engagement strategy" to influence the public. ROA.1242. Erica Jefferson, Associate Commissioner for External Affairs, explained that the agency saw this as an "opportunity to remind the public" of the FDA's position on ivermectin, creating "a unique viral moment" where the FDA could "reach the 'everyday' American …. in a time of incredible misinformation." ROA.1248–49. She similarly expressed her satisfaction about the number of people who viewed the tweet: "The numbers are racking up and I laughed out loud." ROA.1247.

Unsatisfied with direct efforts, the FDA then sent a letter to the Federation of State Medical Boards and National Association of Boards of Pharmacy to further influence medical practice. It warned against using ivermectin for COVID-19 and included a link to "Why You Should Not Take Ivermectin to Treat or Prevent COVID-19." ROA.1256.

The FDA's "new engagement strategy" resulted in its foreseeable and intended effect of maligning ivermectin and stopping doctors from using it to treat COVID-19. The FDA was delighted to see media outlets parrot its message, referring to ivermectin as "horse dewormer" and "horse paste."[2] As intended, others pushed the narrative with headlines like "Say 'Neigh' to Ivermectin" and "You Are Not a Horse."[3]

Consistent with the FDA's attempts to frame ivermectin as only an animal drug, NPR reported that popular commentator Joe Rogan had taken "ivermectin, a deworming veterinary drug that is formulated for use in cows and horses." Vanessa Romo, *Joe Rogan Says He Has COVID-19 and Has Taken the Drug Ivermectin*, NPR (Sept. 1, 2021), https://www.npr.org/2021/09/01/1033485152/joe-rogan-covid-ivermectin. Rogan confirmed he took ivermectin intended for human use, as prescribed by his doctor. Caleb Ecarma, *Joe Rogan and CNN Are Butting*

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[2] *See, e.g.*, Mike Snider, "*You Are Not a Horse." FDA Warns Against Use of Ivermectin as a Treatment for COVID-19*, USA Today (Aug. 23, 2021), https://www.usatoday.com/story/news/health/2021/08/23/covid-warning-treatment-ivermectin-fda-mississippi/8244302002/; Martin Pengelly, *"You Are Not a Horse": FDA Tells Americans Stop Taking Dewormer for Covid*, Guardian (Aug. 23, 2021), https://www.theguardian.com/us-news/2021/aug/23/fda-horse-message-ivermectin-covid-coronavirus.

[3] *See, e.g.*, Joe Fisher, *FDA, Poison Control Say "Neigh" to Ivermectin*, Times-Republican (Sep. 9, 2021), https://www.timesrepublican.com/uncategorized/2021/09/fda-poison-control-sayneigh-to-ivermectin/.

Heads Over "Horse Dewormer" COVID Cure, Vanity Fair (Oct. 22, 2021), https://www.vanityfair.com/news/2021/10/joe-rogan-cnnhorse-dewormer-covid.

Individual health professionals even joined the refrain, with some referencing the FDA and publicly labeling health professionals who prescribe ivermectin, including one of Appellants, as quack doctors practicing veterinary medicine on humans. *See, e.g.*, ROA.1259; ROA.1261.

Again, following the FDA's lead, the American Medical Association, American Pharmacists Association, and American Society of Health-System Pharmacists all quickly issued a joint statement "strongly oppos[ing] the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial," and pointing to the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" as part of their justification. ROA.1264. This joint statement was issued a mere 11 days after the FDA's "Stop it with the #ivermectin" post. State pharmacy boards likewise issued statements on dispensing ivermectin, which directly linked to the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." *See, e.g.*, ROA.1271. And

hospitals also started relying on the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" and August 21, 2021, tweet—even reproducing the tweet in court filings—to justify prohibiting the use of ivermectin to treat patients regardless of whether the drug was prescribed by a doctor. ROA.1149; ROA.1280–81; ROA.1293; ROA.1296–97.

Even courts have relied on the FDA's actions to decide cases involving ivermectin, including as persuasive evidence about the effectiveness of the drug and appropriate standard of care. *See, e.g.*, *Shoemaker v. UPMC Pinnacle Hosps.*, 283 A.3d 885, 895 (2022); *Smith v. West Chester Hosp.*, 2021 WL 4129083, at *1, 2, 4 (Ohio Com. Pl. Sept. 6, 2021); *DeMarco v. Christiana Care Health Servs., Inc.*, 263 A.3d 423, 435 (Del. Ch. 2021); *Abbinanti v. Presence Cent. & Suburb. Hosps. Network*, 2021 IL App (2d) 210763, ¶ 10; *see also Gahl v. Aurora Health Care, Inc.*, 977 N.W.2d 756, 762–63 (Ct. App. 2022) (expert relying on FDA statements against using ivermectin to treat COVID-19). Indeed, courts have looked to the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" to determine "deviation from accepted medical practices," which "is an essential element of medical malpractice." *D.J.C.*

for D.A.C. v. Staten Island Univ. Hosp.-Northwell Health, 157 N.Y.S.3d 667, 673 (N.Y. Sup. Ct. 2021).

On April 26, 2022, the FDA continued its relentless campaign, again pushing its narrative that ivermectin is only for animal use. The tweet reads: "Hold your horses, y'all. Ivermectin may be trending, but it still isn't authorized or approved to treat COVID-19." ROA.990. The tweet again displays the title of "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" and links to that publication. *Id.*

C. DISTRICT COURT PROCEEDINGS

Appellants filed suit in the Southern District of Texas on June 2, 2022, and amended their complaint on August 8, 2022, alleging the FDA acted ultra vires and violated the APA. On August 26, 2022, the FDA filed a motion to dismiss under Federal Rule of Procedure 12(b)(1), invoking sovereign immunity and claiming Appellants lacked constitutional standing to pursue their claims, and under Rule 12(b)(6), arguing Appellants failed to exhaust administrative remedies.

Appellants responded that sovereign immunity does not bar a suit alleging that "a Federal officer act[ed] in excess of his authority or under authority not validly conferred." *Larson v. Domestic & Foreign Com.*

Corp., 337 U.S. 682, 690–91 (1949) (quoting *Phila. Co. v. Stimson*, 223 U.S. 605, 620 (1912)). Appellants further argued that Congress expressly waived sovereign immunity in the APA, 5 U.S.C. § 702, for *both* ultra vires *and* APA claims. *See Ala.-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484, 489 (5th Cir. 2014). Appellants also explained their standing and that there were no administrative remedies to exhaust in this case.

On December 6, 2022, the District Court granted the motion to dismiss on grounds of sovereign immunity. The court reasoned that "[a]lthough the FDA could have, and perhaps should have, been more prudent in their communications, they had at least a colorable basis in authority," and thus the actions were not ultra vires and that exception to sovereign immunity did not apply. RAO.1653.

The District Court dismissed this Court's precedent in *King* that "the FDA does not restrict physicians from prescribing an otherwise FDA-approved drug for an off-label use," 871 F.3d at 328, because the opinion used a "*see*" signal when citing § 396, the FDCA provision limiting the FDA's authority. ROA.1651. Reviewing that provision, which

expressly prohibits interference in the practice of medicine, the District Court concluded that it was limited to devices, not drugs like ivermectin.

The District Court then reasoned that "there is no statute limiting the FDA's actions here" so "it cannot have acted outside of any statutory limitations." ROA.1652. And, citing the general mission of the FDA in 21 U.S.C. § 393(b) about "protecting public health and ensuring that regulated medical products are safe and effective, among other things," the court presumed the FDA has "authority, generally, to make public statements in-line with these purposes." ROA.1652–53.

The District Court further acknowledged that whether sovereign immunity barred Appellants' ultra vires claim "could be analyzed under either the non-statutory claim standard of the APA or the *ultra vires* doctrine," and that "APA and *ultra vires* jurisprudence … are two distinct waivers of sovereign immunity." ROA.1649. But the court failed to consider that separate waiver of sovereign immunity in the APA for the ultra vires claim.

The District Court next held that the FDA's actions weren't "final" under the APA, and therefore the APA waiver of sovereign immunity did not apply to the APA claims. The court reasoned that none of the FDA's

statements "determine rights, obligations, or legal consequences," and thus the waiver of sovereign immunity for general claims under the APA did not apply either. ROA.1655; ROA.1660.

The District Court did not resolve any other issues.

SUMMARY OF THE ARGUMENT

Sovereign immunity does not bar suit for equitable relief when government officials act outside the bounds of their authority. The FDA does not have, and has never had, authority to direct or even recommend usage of any previously approved drugs. Moreover, § 396 provides a clear prohibition against the FDA "interfer[ing]" in the practice of medicine. At least six circuit courts, including this Court, and multiple district courts have interpreted that provision as applying to the use of drugs, and thus to ivermectin. The District Court was wrong to conclude otherwise.

The District Court also failed to address the waiver of sovereign immunity in the APA for all "non-statutory" actions seeking equitable relief, including ultra vires actions. This Court has held that sovereign immunity does not apply to suits for injunctive relief against unlawful "agency action" of any kind. *Ala.-Coushatta Tribe of Tex.*, 757 F.3d at 489. Binding precedent from this Court makes clear that the agency acted

here, and in an unlawful manner. *King*, 871 F.3d at 328. That alone is sufficient for the waiver of immunity in the APA for non-APA claims.

Similarly, sovereign immunity does not apply because the APA also waives sovereign immunity for APA challenges to final agency action. The FDA's actions here were official agency positions, some maintained now for almost two years, with devastating effects for Appellants and doctors across the country. That renders them "final" action under the "flexible" and "pragmatic" approach to APA finality. *Qureshi v. Holder*, 663 F.3d 778, 781 (5th Cir. 2011) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149–50 (1967)).

Finally, this Court need not reach the issue, but the District Court was correct not to dismiss this case for lack of standing. Appellants have suffered interference with their practice of medicine and reputational harm for almost two years, which clearly traces to the FDA's campaign against ivermectin and would be remedied by equitable relief. This is more than sufficient to demonstrate standing.

STANDARD OF REVIEW

This Court reviews sovereign immunity de novo. *Tex. All. for Retired Ams. v. Scott*, 28 F.4th 669, 671 (5th Cir. 2022).

ARGUMENT

I. SOVEREIGN IMMUNITY DOES NOT APPLY BECAUSE FDA OFFICIALS ACTED IN CLEAR EXCESS OF THEIR STATUTORY AUTHORITY

The District Court erred by concluding that Appellants had not alleged an ultra vires claim and thus demonstrated that sovereign immunity does not apply. By declining to move to dismiss the ultra vires claim on its merits under Rule 12(b)(6), the FDA effectively conceded below that Appellants had alleged a plausible ultra vires claim premised on the FDA's interference in the practice of medicine. That alone should have resolved whether Appellants had pleaded an ultra vires claim, and thus whether sovereign immunity barred the suit.

In any event, the court's analysis was erroneous because the FDA has never had authority to interfere in the practice of medicine, and in fact the FDCA expressly forbids it.

A. THE FDA HAS NEVER HAD AUTHORITY TO INTERFERE WITH THE PRACTICE OF MEDICINE

"All the officers of the government, from the highest to the lowest, are creatures of the law and are bound to obey it." *United States v. Lee*, 106 U.S. 196, 220 (1882). And federal courts have long recognized that sovereign immunity does not bar a suit alleging that "a Federal officer

act[ed] in excess of his authority or under authority not validly conferred." *Larson*, 337 U.S. at 690–91; *see also id.* ("[I]n case of an injury threatened by his illegal action, the officer cannot claim immunity from injunction process.") (quoting *Phila. Co.*, 223 U.S. at 620). Ultra vires actions "may be made the object of specific relief," especially when the remedy is "merely ordering the cessation of the conduct complained of," not "affirmative action by the sovereign or the disposition of unquestionably sovereign property." *Id.* at 689, 691 n.11; *see also, e.g.*, *Universal Life Church Monastery Storehouse v. Nabors*, 35 F.4th 1021, 1041 (6th Cir. 2022); *Strickland v. United States*, 32 F.4th 311, 363 (4th Cir. 2022); *Danos v. Jones*, 721 F. Supp. 2d 491, 496 (E.D. La. 2010)*, aff'd,* 652 F.3d 577 (5th Cir. 2011).

"[A]gencies, as mere creatures of statute, must point to explicit Congressional authority justifying their decisions." *Clean Water Action*, 936 F.3d at 313. "[A]n agency literally has no power to act … unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986). The FDCA does not, and never has, authorized the FDA to interfere in the practice of medicine. The agency can approve a drug "for introduction into interstate commerce" if the agency

determines it is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," and there is "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d); *see* 21 C.F.R. § 201.57. The FDA can also collect information on adverse events resulting from use of approved drugs, 21 U.S.C. § 355(k), request changes to drug labeling, *id.* § 355(o)(4), impose risk evaluation and mitigation strategies like mandatory patient monitoring, *id.* § 355-1, communicate the risks of using approved drugs, *id.* § 360bbb-6, and even withdraw approval of a drug entirely under certain circumstances, *id.* § 355(e).

None of these general provisions authorizes the FDA to prohibit, direct, or advise against off-label uses of drugs approved for human use. Accordingly, on the rare occasion when Congress *has* authorized the FDA to limit particular uses of an approved drug, it has done so specifically and explicitly. *E.g.*, *id.* § 333(e) (restricting off-label use of "human growth hormone"). But Congress has not done so for ivermectin or for prescription drugs generally.

This limitation on the FDA has been understood for nearly a century, since the inception of the FDCA. From the very beginning, Congress established federal drug regulation on the basis that it would not extend to the practice of medicine. *See Chaney v. Heckler*, 718 F.2d 1174, 1179 (D.C. Cir. 1983) ("FDCA's legislative history expresses a specific intent to prohibit FDA from regulating physicians' practice of medicine."), *rev'd on other grounds,* 470 U.S. 821 (1985); Wendy Teo, *FDA and the Practice of Medicine: Looking at Off-Label Drugs*, 41 Seton Hall. Leg. J. 305, 308 (2016) ("[T]he legislative debates preceding the enactment of the [1938 FDCA] demonstrated that Congress had never intended for FDA to regulate the practice of medicine.").

Amending the FDCA in 1962, Pub. L. No. 87-781, 76 Stat. 780, Congress once again affirmed that the FDCA "should not interfere with the professional function of the physician" because while "FDA clearance would assure physicians that a drug effectively produces certain physiological actions, … the physician, not the FDA, would determine whether these specific physiological effects would be useful or beneficial with respect to particular patients." S. Rep. No. 87-1552, at 1998 (1962).

In the Food and Drug Administration Modernization Act of 1997, Congress further stipulated, under the heading "Practice of Medicine," that "nothing in [the FDCA] shall be construed to limit or interfere with the authority of a healthcare practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." Pub. L. No. 105-115, § 214, 111 Stat. 2296, 2348 (codified at 21 U.S.C. § 396). Congress again affirmed this practice-of-medicine limitation in the Food and Drug Administration Amendments Act of 2007, which provides that "nothing in this section shall be construed to restrict, in any manner, the prescribing of antibiotics by physicians, or to limit the practice of medicine." Pub. L. No. 110-85, § 1111(d), 121 Stat. 823, 976.

Principles of federalism confirm that the FDA has no authority to interfere with the practice of medicine. "States, not the federal government, traditionally have regulated the practice of medicine." *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 400 (citing *Gonzales v. Oregon*, 546 U.S. 243, 275 (2006)). The FDCA leaves that role in "the exclusive realm of individual states." *Planned Parenthood Cincinnati Region*, 444 F.3d at 505; *see Buckman,* 531 U.S. at 350; *AAPS*, 13 F.4th

at 534; *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 399–400. And Congress must use "exceedingly clear language if it wishes to significantly alter the balance between federal and state power." *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021) (quoting *U.S. Forest Serv. v. Cowpasture River Pres. Ass'n*, 140 S. Ct. 1837, 1850 (2020)). Congress has not done so here—on the contrary, as explained below, it has explicitly directed the agency to respect the traditional realm of state regulation of the practice of medicine. The FDA's authority thus does not extend beyond the plain terms of the FDCA, lest it interfere with an area that is within the exclusive realm of the states. *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 399–400.

Rather than point to any specific statute authorizing the FDA's actions here (presumably because none exists), the District Court instead cited the FDA's mission statement in 21 U.S.C. § 393(b), which the court summarized as "protecting public health and ensuring that regulated medical products are safe and effective." ROA.1652. The court in turn concluded that the FDA presumably "has authority, generally, to make public statements in-line with these purposes." ROA.1652–53.

"[S]tatements of purpose … cannot override a statute's operative language." *Sturgeon*, 139 S. Ct. at 1086; *see District of Columbia v. Heller*, 554 U.S. 570, 578 (2008) ("[A] prefatory clause does not limit or expand the scope of the operative clause."). Furthermore, generic goals listed in "ancillary" and precatory mission statements, *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001), are hardly the type of specific and clear statutes needed to overcome federalism concerns and grant the FDA authority to play doctor and issue public directives about when and how drugs should be used, *see Ala. Ass'n of Realtors*, 141 S. Ct. at 2489. Indeed, elevating "purpose" language above the statute's text and background principles of constitutional federalism "frustrates rather than effectuates legislative intent," because the lines drawn in the statute about the scope of an agency's authority to pursue those goals represent "the very essence of legislative choice." *Rodriguez v. United States*, 480 U.S. 522, 525–26 (1987). The District Court erred by finding this authority provided a colorable basis for issuing public directives on the use of ivermectin and interfering with the practice of medicine.

Moreover, as demonstrated next, such a reading of the FDA's authority is expressly contradicted by another provision prohibiting the FDA from interfering in the practice of medicine.

B. SECTION 396 CLEARLY PROHIBITS THE FDA FROM INTERFERING WITH THE PRACTICE OF MEDICINE

The FDA also acted in excess of its authority under § 396, which appears under the heading "Practice of Medicine," Pub. L. No. 105-115, § 214, 11 Stat. at 2348, and provides that "[n]othing in [the FDCA] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396. This provision independently confirms the FDA acted ultra vires here.

Section 396's scope is relevant in two ways. *First*, by prohibiting the FDA not just from "limit[ing]" but also from "interfer[ing]" with the doctor-patient relationship, Congress not only barred direct regulation but also barred even *indirect* influence. While "limit" denotes establishing "the final or furthest confines, bounds, or restriction of something," *Am. Heritage Dict. of the Eng. Language* 758 (William Morris ed., 1969) (def. 1), the word "interfere" extends beyond legal restraint and

means "to be a hinderance or obstacle," or to "intervene or intrude in the affairs of others," *Am. Heritage Dict. of the Eng. Language* 683 (defs. 1, 3); *see also* 7 *Oxford Eng. Dict.* 1102 (2d ed. 1989) (def. 4(b)) ("To meddle with; to interpose and take part in something, esp. without having the right to do so[.]").

Thus, as the Supreme Court has recognized, § 396 encompasses attempts by the FDA to hinder or even "intrud[e] upon decisions statutorily committed to the discretion of health care professionals," including anything that would "*deter* off-label use." *Buckman,* 531 U.S. at 350 (emphasis added).

Second, although § 396 uses the word "device," courts have consistently held that this encompasses drugs. Especially relevant here, this Court has like cited § 396 in holding that the "FDA does not restrict physicians from prescribing an otherwise FDA-approved *drug* for an off-label use." *King*, 871 F.3d at 328 (emphasis added). At least five other circuits and multiple district courts have likewise held that § 396 bars the FDA from interfering with the rights of doctors to prescribe approved drugs off-label. *See Med. Mut. of Ohio v. AbbVie Inc.*, 784 F. App'x 457, 457 (7th Cir. 2019); *Markland v. Insys Therapeutics, Inc.*, 758 F. App'x

777, 780 (11th Cir. 2018); *U.S. ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 615 (2d Cir. 2016); *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); *In re Gilead Sci. Sec. Litig.*, 536 F.3d 1049, 1051 & n.2 (9th Cir. 2008); *In re Actiq Sales & Mktg. Pracs. Litig.*, 307 F.R.D. 150, 170 (E.D. Pa. 2015); *Smith v. C.R. Bard, Inc.*, 730 F. Supp. 2d 783, 803 (M.D. Tenn. 2010); *Miller v. Pfizer Inc. (Roerig Div.)*, 196 F. Supp. 2d 1095, 1105 & n.39 (D. Kan. 2002), *aff'd sub nom. Miller v. Pfizer, Inc.*, 356 F.3d 1326 (10th Cir. 2004); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 263 (E.D.N.Y. 1999).[4] Indeed, § 396 refers to "prescribing" and "administering," which is standard terminology when referring to prescription drugs. *See* 21 U.S.C. § 353(d)(1)(A) ("prescribe such drug").

Even the FDA has agreed, citing § 396, that "the practice of medicine exception permits physicians to prescribe or administer a legally marketed *drug* or device to their patients for any use they consider

[4] *See also, e.g.*, *Inchen Huang v. Higgins*, 2019 WL 1245136, at *1 (N.D. Cal. Mar. 18, 2019); *U.S. ex rel. Palmieri v. Alpharma, Inc.*, 2016 WL 7324629, at *3 (D. Md. Dec. 16, 2016); *Whitener v. PLIVA, Inc.*, 2011 WL 6056546, at *4 (E.D. La. Dec. 6, 2011); *S. Ill. Laborers' & Emps. Health & Welfare Fund v. Pfizer Inc.*, 2009 WL 3151807, at *2 n.5 (S.D.N.Y. Sept. 30, 2009).

appropriate in the exercise of their medical judgment." Letter from Leslie Kux, Assistant Commissioner for Policy, FDA, to Alan Mertz, American Clinical Laboratory Association, *Re: Docket No. FDA-2013-P-0667*, at 5–6 (July 31, 2014), *available at* https://www.regulations.gov/document/FDA-2013-P-0667-0008.

As explained by the Supreme Court, "the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals," again, including anything that would "deter off-label use." *Buckman,* 531 U.S. at 350. Section 396 and the long line of cases interpreting it make explicit that the FDA is affirmatively prohibited from intruding on the rights of doctors to recommend and prescribe approved drugs, even for off-label uses. "Choosing what treatments are or are not appropriate for a particular condition is at the heart of the practice of medicine" as protected by § 396. *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 400.

The District Court, however, dismissed all of these cases on the theory that, because this Court introduced its citation to § 396 in *King* with a "*see*" signal, that case "does not stand for the proposition that § 396

applies equally to drugs as it does to devices." ROA.1651. Giving more weight to The Bluebook than to this Court's decision, the District Court argued that a "*see*" signal "acknowledges that there is an "inferential step" required between the statute's plain language and the court's assertion." *Id.* (citing The Bluebook R.1.2, at 62 (21st ed. 2020)).

That reasoning is wrong for at least three reasons. *First*, this Court's "published opinion" in *King* "is this court's last statement on the matter" of the FDA's statutory authority, and thus "like all published opinions, binds the district courts in this circuit," regardless of what introductory signal *King* used—indeed, regardless of whether the Court cited any authority at all. *O'Donnell v. Salgado*, 913 F.3d 479, 482 (5th Cir. 2019).

Second, a "*see*" signal means the "[c]ited authority clearly supports the proposition." The Bluebook R.1.2, at 62 (explanation of "*see*"). And as is common knowledge in the profession, lawyers and judges routinely include a "*see*" signal before citations that directly support the proposition and could have been cited with no introductory signal at all. The Seventh Circuit omitted a signal altogether when it cited § 396 as barring interference with doctors' prescription of drugs. *See Med. Mut. of*

Ohio, 784 F. App'x at 457; *Muoghalu*, 662 F.3d at 911. And to the extent this Court puts such weight on the precise introductory Bluebook signals used, it is worth noting that if *King* had meant § 396 stood for a different, but related proposition, it would have used "*cf.*," which means "[c]ited authority supports a proposition different from the main proposition but sufficiently analogous to lend support." *Id.* (meaning of "*cf.*").

Third, even assuming the use of a "*see*" signal in *King* was truly meant to indicate some meaningful inferential step, the relevant step was *not* that § 396 applies to drugs, but rather that because the FDA statutorily *cannot* restrict off-label use, it logically follows that "the FDA *does not*" in fact restrict off-label use. *King*, 871 F.3d at 328.

Referring to the application of § 396 to drugs, the District Court continued that "[i]n some circumstances, this may be a comfortable inference for the court to make," but "[i]n the context of an ultra vires claim, however, it is too much." ROA.1651. That is wrong. The meaning of § 396 is not context specific. If it includes drugs—as this Court and numerous others have already held—then it includes drugs.

The District Court then compounded its error by reasoning that "[a]s there is no statute limiting the FDA's actions here, it cannot have

acted outside of any statutory limitations." ROA.1652. That is backwards. Again, "agencies, as mere creatures of statute, must point to explicit Congressional authority justifying their decisions." *Clean Water Action*, 936 F.3d at 313. The FDA "literally has no power to act...unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n*, 476 U.S. at 374. Without it—and the FDA cannot identify any authority here—the agency acted outside of its statutory limitations.

* * *

Because the FDCA does not grant the FDA authority to opine on the use of FDA-approved drugs or to interfere with the practice of medicine, and because § 396 expressly bars the agency from doing so, the agency acted "without any authority whatever." *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 101 n.11 (1984). Accordingly, the ultra vires claim is not barred by sovereign immunity, and this Court should remand for further proceedings on that claim.[5]

[5] As noted above, the FDA declined to move to dismiss the ultra vires claim on its merits under Rule 12(b)(6) and accordingly would be prohibited from seeking to do so on remand. *See* Fed. R. Civ. P. 12(b).

II. THE APA WAIVES SOVEREIGN IMMUNITY FOR ALL NON-STATUTORY CLAIMS SEEKING EQUITABLE RELIEF

As the FDA acknowledged below, Congress expressly waived sovereign immunity in the APA, 5 U.S.C. § 702, not just for APA claims but also for *any* non-statutory claim seeking equitable relief. *See* ROA.1469. As amended in 1976, the APA waives "the Federal Government's immunity from a suit 'seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority.'" *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 215 (2012) (quoting 5 U.S.C. § 702). The amendment's purpose was "to remove the defense of sovereign immunity as a bar to judicial review of federal administrative action otherwise subject to judicial review." H.R. Rep. No. 94-1656, at 1 (1976).

To invoke that waiver, a plaintiff need only (1) "identify some 'agency action' affecting him in a specific way"; (2) have "'suffered legal wrong because of the challenged agency action, or [be] adversely affected or aggrieved by that action within the meaning of a relevant statute'"; and (3) seek equitable relief from the Court. *Ala.-Coushatta Tribe of Tex.*, 757 F.3d at 489 (quoting *Lujan v. Nat'l Wildlife Found.,* 497

U.S. 871, 883 (1990)); *see Trudeau v. FTC*, 456 F.3d 178, 186 & n.11 (D.C. Cir. 2006) ("Section 702 of the APA waives sovereign immunity for all suits seeking equitable relief.") (cleaned up) (cited repeatedly and approvingly in *Alabama-Coushatta Tribe of Texas*).

Appellants satisfy each requirement. *First*, Appellants adequately alleged "agency action" affecting them. "There is no requirement of 'finality' for this type of waiver to apply." *Ala.-Coushatta Tribe of Tex.*, 757 F.3d at 489. The APA provides that "agency action" "includes the whole or part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act," and the use of "includes" indicates the list is not exhaustive. 5 U.S.C. § 551(13); *cf. Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 162 (2012). This Court has been clear that "[t]he APA defines the term 'rule' broadly enough to include virtually every statement an agency may make." *Avoyelles Sportsmen's League, Inc. v. Marsh*, 715 F.2d 897, 908 (5th Cir. 1983). As a result, statements of agency policy and even purely informational statements are "rules." *See id.*; *Data Mktg. P'ship, LP v. Dep't of Lab.,* 45 F.4th 846, 855 (5th Cir. 2022) (finding an informational letter was agency action); *see also South Dakota v. Ubbelohde*, 330 F.3d 1014, 1028 (8th Cir.

2003) ("Where a policy statement purports to create substantive requirements, it can be a legislative rule regardless of the agency's characterization."). Accordingly, the FDA statements here easily qualify as rules and thus agency action.

The FDA has taken an official position—maintained for two years—that ivermectin should not be used to treat or prevent COVID-19, even unequivocally directing the public not to use ivermectin for that purpose. The agency then celebrated the consequences of those actions and how they were interpreted by the public. ROA.1247–49. The agency cannot now turn around and pretend it did not even take "agency action."

Additionally, in this context, Congress has intentionally withheld authority from the FDA to interfere in the practice of medicine, going so far as to codify that limitation in § 396. It would be passing strange if an agency could issue directives or medical recommendations in excess and express violation of its statutory authority, interfering with the practice of medicine and harming Appellants, without doing anything that would rise to the minimal level of "agency action," especially when Congress expressly foresaw the possibility that the FDA would do so and sought to foreclose it.

Second, Appellants "suffered legal wrong" and are "adversely affected or aggrieved … within the meaning of a relevant statute." *Ala.-Coushatta Tribe of Tex.*, 757 F.3d at 488–89. As discussed in Part I.A, *supra*, the FDCA has always intentionally insulated the doctor-patient relationship from the FDA, and the agency's overreach harmed Appellants' ability to practice medicine. The specific limitation in § 396 confirms this a protected interest under the FDCA. Again, it is notable that the FDA did not move to dismiss this case under Rule 12(b)(6) for failure to state a plausible claim of interference in the practice of medicine, conceding that Appellants plausibly alleged such interference.

Third, Appellants seek equitable relief. *See Trudeau*, 456 F.3d at 186 & n.11. The Amended Complaint seeks no damages, only injunctive and declaratory relief for the ultra vires claim. ROA.968–69.

The District Court failed to address this waiver at all. It observed that the ultra vires claim "could be analyzed under either the non-statutory claim standard of the APA or the *ultra vires* doctrine," and that "[t]he APA and ultra vires jurisprudence … are two distinct waivers of sovereign immunity" and "it would be incorrect to use the two interchangeably." ROA.1649–50. But the court then proceeded to

consider the ultra vires doctrine *only*, ignoring the APA waiver of sovereign immunity as applied to non-statutory claims, including ultra vires. This was a particularly strange choice after the District Court correctly observed that the waiver of sovereign immunity in the APA *could* apply to the ultra vires claim. ROA.1649.

The District Court justified its decision because the complaint labels the ultra vires claim as such, and because Appellants emphasized at oral argument the District Court "should be careful to ... view the *ultra vires* claim and the APA claim separately." ROA.1650. Neither point is justification for overlooking the APA waiver of sovereign immunity for ultra vires claims. Appellants clearly argued below that there were multiple bases for finding no sovereign immunity for the ultra vires claim: (1) either the ultra vires doctrine itself, or (2) the APA's waiver of sovereign immunity for non-statutory actions seeking equitable relief. *See* ROA.1517–19; ROA.1696–98. And Appellants stressed at oral argument that the ultra vires and APA claims must be considered separately because different sovereign immunity standards apply, *not* because the waiver in the APA does not extend to the ultra vires claim at all.

This Court should correct the District Court's misunderstanding and re-affirm that the APA waives sovereign immunity for non-statutory claims seeking equitable relief, like Appellants' ultra vires action.

III. THE APA WAIVES SOVEREIGN IMMUNITY FOR APA CLAIMS CHALLENGING FINAL AGENCY ACTION

Appellants also brought claims directly alleging violations of the APA itself. ROA.963–68. As explained above, the waiver of sovereign immunity in the APA applies broadly to plaintiffs who (1) "identify some 'agency action' affecting [them] in a specific way," and (2) have "'suffered legal wrong because of the challenged agency action, or [be] adversely affected or aggrieved by that action within the meaning of a relevant statute.'" *Ala.-Coushatta Tribe of Tex.*, 757 F.3d at 489 (quoting *Lujan v. Nat'l Wildlife Found.,* 497 U.S. at 883). Unlike an ultra vires claim, however, when the APA provides the cause of action, the agency action must also be "final." *See id.*

The first two requirements—agency action, and legal wrong or adverse effect—are satisfied for the reasons stated above. *See* Part II, *supra*. The FDA's actions were also final. A final agency action (1) "must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature," and (2) "must be one

by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett*, 520 U.S. at 177–78 (cleaned up). Both requirements are satisfied here.

The Supreme Court has interpreted the "finality requirement as 'flexible' and 'pragmatic.'" *Qureshi*, 663 F.3d at 781 (quoting *Abbott Labs.*, 387 U.S. at 149–50). Courts thus reject a "hypertechnical" approach and have held that "a series of agency pronouncements" may constitute final agency action if their "cumulative effect" causes injury. *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 435 n.7 (D.C. Cir. 1986).

Appellants satisfy the first requirement of finality because publication of unqualified directives against using ivermectin to treat COVID-19 constituted the culmination of the decision-making process. The FDA has publicly and repeatedly maintained this position for almost two years without fail. This is hardly a tentative position, unless the FDA is suggesting it plans to disclaim its numerous statements about ivermectin. Nor is there anything "tentative" about statements like "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," ROA.971; and "Q: Should I take ivermectin to prevent or treat COVID-19? A: No," ROA.976; ROA.979; and "You are not a horse. You are not a

cow. Seriously, y'all. Stop it," ROA.981; and "You are not a horse. Stop it with the #ivermectin," ROA.988. The possibility that the FDA might change positions in the future does not alter the fact that the agency has taken an official position now. *Data Mktg. P'ship*, 45 F.4th at 854. As this Court repeatedly emphasized, "[w]ere it otherwise, no agency action would be final because an agency could always revisit it. And that can't be right." *Id.*

Although it made no ruling on the issue, the District Court added in passing that some of the FDA's statements included tentative language like "[c]urrently available data" and "[a]dditional testing was needed," then seemed inclined to excuse others because "no case law establishes the proposition that fleeting content on social media can mark the consummation of an agency's decisionmaking process." ROA.1655. If true, then no agency action would ever be final, since agency action is always premised on currently available data or agencies could recite that truism to avoid judicial review. Such boilerplate language does not defeat the finality of definite language elsewhere in the document. *See Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022–23 (D.C. Cir. 2000). And maintaining social media posts for two years is hardly "fleeting."

The second requirement for finality is also satisfied. Even "a 'policy statement' can nonetheless be 'final agency action' under the APA." *State v. Biden*, 10 F.4th 538, 550 (5th Cir. 2021). As this Court held in *Texas v. EEOC*, 933 F.3d 433 (5th Cir. 2019), an agency's statement or guidance document "is 'binding as a practical matter'"—and thus "final" for APA purposes—where "'private parties can rely on it as a *norm* or safe harbor by which to shape their actions.'" *Id.* at 443–44 (emphasis added). "What matters is whether the document has *practical binding effect* such that affected private parties are *reasonably led to believe* that failure to conform will bring adverse consequences." *Id.* at 442 (emphasis added).

The District Court attempted to distinguish *Texas v. EEOC* because the guidance at issue in that case "told EEOC staff what was illegal, established a framework for employers to follow to comply with law, and created safe harbors for employers to avoid liability." ROA.1657. The court reasoned that "shaping behavior around the [FDA's] statements here would not protect [Appellants], or anyone else, from liability at the hands of the FDA." ROA.1658.

But the District Court entirely overlooked that the FDA *has* created a legal standard that governing entities are regularly relying on to

establish the appropriate medical care and dictate the practice of medicine, including by courts in legal proceedings. *See, e.g.*, *See, e.g.*, *Shoemaker*, 283 A.3d at 895; *West Chester Hosp.*, 2021 WL 4129083, at *1, 2, 4; *DeMarco*, 263 A.3d at 435; *Abbinanti*, 2021 IL App (2d) 210763, ¶ 10; *see also Gahl*, 977 N.W.2d at 762–63 (expert relying on FDA statements against using ivermectin to treat COVID-19). Courts have even looked to the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" to determine "deviation from accepted medical practices," which "is an essential element of medical malpractice." *D.J.C. for D.A.C.*, 157 N.Y.S.3d at 673.

The District Court also overlooked the standard this Court actually articulated. All that "matters is whether the [agency statement] has *practical* binding effect." *EEOC*, 933 F.3d at 442 (emphasis added). The FDA's statements here certainly have a "practical binding effect" on doctors across the country. The FDA cannot flex its authority as the premier agency on drugs in the United States and then pretend no one listened.

It is also indisputable that, at the very least, the FDA's statements on ivermectin dictate a "norm" for doctors to follow. *EEOC*, 933 F.3d at

444. Presumably that is precisely why the FDA directed the Federation of State Medical Boards to "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." ROA.1256.

Reinforcing Appellants' reading of *Texas v. EEOC*, this Court in *Louisiana State v. U.S. Army Corps of Engineers* explained that "[j]udicially reviewable agency actions … *tend to expose* parties to civil or criminal liability for noncompliance with the agency's view of the law." 834 F.3d 574, 583 (5th Cir. 2016) (emphasis added). That's exactly what's happening here—the FDA's actions "tend to expose" health professionals to legal consequences for noncompliance. And the agency knows this, because it's been happening for two years, yet the agency leaves its publications in place and even reiterated its views in April 2022 to make sure that the "practical binding effect" of that "norm" stayed strong.

In any event, legally binding effects are not necessary to render agency action "final" for purposes of judicial review when the action in question is clearly outside the agency's statutory authority and further prohibited by statute. Congress recognized the unique ability of the FDA to "interfere" with the doctor-patient relationship and intentionally withheld and prohibited it. Failure to find "final" agency action here

would in many cases make this prohibition a mere suggestion that's never judicially enforceable even when it concretely harms doctors, like Appellants. When Congress has made a conscious decision to withhold authority and even expressly prohibit certain agency action, that should weigh heavily in the "flexible" and "pragmatic" interpretation of finality. *Qureshi*, 663 F.3d at 781 (quoting *Abbott Labs.*, 387 U.S. at 149–50).

For these reasons, the FDA's actions are final for purposes of judicial review, and sovereign immunity does not bar Appellants' APA claims, either.

IV. APPELLANTS HAVE STANDING

Because the District Court resolved this case solely on sovereign immunity, this Court need not address the FDA's alternative argument, raised below, that Appellants lacked standing. In any event, the District Court was correct not to dismiss this case for lack of standing, as Appellants made a strong showing of each requirement. *See also Dep't of Com. v. New York*, 139 S. Ct. 2551, 2565 (2019) ("[A]t least one plaintiff must have standing to sue.").

To establish standing to sue as required by Article III of the Constitution, Appellants need only have plausibly alleged (1) "a concrete

and particularized injury," (2) "that is fairly traceable to the challenged conduct," and (3) "is likely to be redressed by a favorable judicial decision." *Hollingsworth v. Perry*, 570 U.S. 693, 704 (2013). Standing "incorporates concepts concededly not susceptible of precise definition" and is not "a mechanical exercise." *Allen v. Wright*, 468 U.S. 737, 751 (1984).

In performing that analysis, courts "must accept as true all material allegations of the complaint and construe the complaint in favor of the complaining party." *AAPS v. Tex. Med. Bd.*, 627 F.3d 547, 550 (5th Cir. 2010) (cleaned up).

A. INJURY

In its motion to dismiss, the FDA notably did *not* flatly assert that Appellants have failed to demonstrate any cognizable Article III injury. Rather, the FDA carefully worded its briefing to contend only that "*[m]any* of [Appellants'] allegations fail to show the requisite injury in fact," ROA.1460, which tacitly acknowledged that *some* of Appellants' allegations show the requisite injury and thus are sufficient for Article III purposes, *see also id.* (arguing injuries are insufficient "*to the extent* they do not allege concrete injuries to" Appellants). And all that is needed

is *some* concrete injury—indeed, "it need not measure more than an identifiable trifle." *OCA-Greater Houston v. Texas*, 867 F.3d 604, 612 (5th Cir. 2017) (cleaned up).

Appellants alleged numerous examples of how the FDA has interfered in their practice of medicine. Pharmacists have refused to fill ivermectin prescriptions from Dr. Apter for his patients, citing the FDA's actions regarding use of the drug for COVID-19, which delays his ability to treat patients when early treatment is vital. ROA.992. In his extensive experience as a doctor, patients believe that FDA's pronouncements are authoritative and want care that complies with such pronouncements. ROA.993. Insurance companies are further refusing to pay for ivermectin to treat COVID-19, and the only observable basis for this is pronouncements and pressure from the FDA. *Id.* Dr. Apter has also been referred to the Washington Medical Commission and Arizona Medical Board by the Iowa Board of Medicine for disciplinary proceedings for prescribing ivermectin to treat COVID-19, and the referrals expressly include copies of the FDA's publications directing against that use. ROA.932–33; ROA.993. Where "a plaintiff has engaged in a course of [protected] conduct and the state has instructed him to stop or face

disciplinary action, … a plaintiff has adequately alleged a concrete and imminent harm sufficient to meet the 'injury in fact' requirement." *Kiser v. Reitz*, 765 F.3d 601, 608 (6th Cir. 2014).

Pharmacists have similarly refused to fill Dr. Bowden's prescriptions for ivermectin, citing FDA directives not to use the drug for COVID-19. ROA.1006. Her patients have also delayed seeking treatment because the FDA says not to use ivermectin for that purpose. *Id.*

Dr. Bowden was derided by Houston Methodist Hospital and forced to resign her privileges there as a result. ROA.933; ROA.1005. This has further resulted in both reputational and monetary harm, not to mention the abuse she now endures online, examples of which were included in the Amended Complaint. ROA.933; ROA.1259; ROA.1261. And Dr. Marik was forced to resign from his positions at Eastern Virginia Medical School ("EVMS") and Sentara Norfolk General Hospital—even after developing EVMS's COVID-19 treatment protocol—for continuing to promote ivermectin to treat COVID-19 after the FDA's attempts to stop use of those drugs for that purpose. ROA.938. The undeniable timing of these injuries immediately following when the FDA began in earnest its

pressure campaign against ivermectin highlights the predominant role that issue played in their forced resignations.

As noted, Appellants' patients have also been harmed by the FDA's actions, which interfere with their doctor-patient relationship and have caused them to delay seeking treatment because the FDA says not to use ivermectin for COVID-19. ROA.934–35. The Supreme Court has held that unique considerations inherent in the practice of medicine can allow "providers to invoke the rights of their actual or potential patients," *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2118 (2020), especially regarding treatments that have been heavily stigmatized, in this case by the FDA as being animal-only medicines.

Moreover, as demonstrated above, Congress has consciously withheld authority from the FDA to interfere in the practice of medicine, and § 396 further provides Appellants with a statutorily protected interest against FDA interference with their practice of medicine. *See* Part I, *supra.* It is well established that a "plaintiff suffers an 'injury in fact' when his legally protected interest has been invaded"—as has occurred here—and the resulting injury is "concrete" and "actual"—as has also occurred here, as explained above. *Kiser*, 765 F.3d at 608

(quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)). The FDA is unlawfully "intruding upon decisions statutorily committed to the discretion of health care professionals." *Buckman*, 531 U.S. at 350.

The sufficiency of Appellants' injuries is confirmed by *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190 (2021), where the Supreme Court explained that "a 'close relationship' to a harm traditionally recognized as providing a basis for a lawsuit in American courts" or "historical or common-law analogue for their asserted injury" is sufficient for purposes of standing. *Id.* at 2200, 2204 (quoting *Spokeo, Inc. v. Robins*, 578 U. S. 330, 340–341 (2016)). Even "various intangible harms including ... reputational harm" suffice. *Id.* at 2200. An "exact duplicate" is not required, thus allowing for "de facto injuries that were previously inadequate in law" and "may be difficult to prove or measure." *Id.* at 2204, 2211.

It is beyond dispute that Appellants have suffered reputational harm. Dr. Bowden in particular has been subject to vicious reputational attacks, examples of which were cited in the Amended Complaint. ROA.1259; ROA.1261. In addition, tortious interference with the doctor-patient relationship is an injury with its own cause of action. *See, e.g.*,

Liability for Interference with Physician-Patient Relationship, 87 A.L.R.4th 845 (1991) (collecting cases); *Regents of the Univ. of Cal. v. Aisen*, 2016 WL 1428072, at *6 (S.D. Cal. Apr. 12, 2016) (denying motion to dismiss claim for "tortious interference with existing physician-patient relations"); *Garcia v. Home Depot U.S.A., Inc.*, 1999 WL 362787, at *6 (N.D. Tex. June 2, 1999); *Moore & Assoc. v. Metropolitan Life Ins. Co.*, 604 S.W. 2d 487 (Tex. Civ. App. 1980). And the FDA did not dispute below that Appellants had stated a plausible claim of interference in the practice of medicine.

Appellants have thus demonstrated numerous injuries, any one of which is sufficient for purposes of standing.

B. FAIRLY TRACEABLE

Appellants injuries are also easily traceable to the FDA. "Proximate causation is not a requirement of Article III standing, which requires only that the plaintiff's injury be fairly traceable to the defendant's conduct." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 134 n.6 (2014). An injury is "fairly traceable" if it "relies … on the predictable effect of Government action on the decisions of third parties," even when those third parties' decisions are illogical or "unlawful." *Dep't of Com.*,

139 S. Ct. at 2565–66; *see also Tozzi v. U.S. Dep't of Health & Hum. Servs.*, 271 F.3d 301, 308–09 (D.C. Cir. 2001); *Cmty. for Creative Non–Violence v. Pierce,* 814 F.2d 663, 669 (D.C. Cir. 1987) (explaining traceability is satisfied if government action played a "substantial factor motivating the third parties' actions"). Traceability "requires no more than *de facto* causality," *New York*, 139 S. Ct. at 2565–66 (quoting *Block v. Meese*, 793 F.2d 1303, 1309 (D.C. Cir. 1986)).

The FDA is the common cause behind Appellants' injuries, which began only after the FDA embarked on its campaign to stop the use of ivermectin to treat COVID-19. The agency has consistently asserted itself as the authoritative voice on drugs in the United States, and now leverages its influence in an admittedly novel way to hang Damocles' sword over healthcare professionals and pressure professional and patient judgment about the use of ivermectin, thereby interfering with Appellants' practice of medicine. *See* ROA.1242 (FDA admitting to this "new engagement strategy").

Common sense dictates that there was no reason for the FDA to issue the ivermectin statements *except* to cause such reactions. The FDA told the entire country to "Stop it with the #ivermectin," with the tweet

being the most-viewed in FDA history, so the FDA cannot now insist that it is not even *plausible* that patients, pharmacists, and hospitals may have reacted by doing just that. The FDA even sent a letter about ivermectin to the Federation of State Medical Boards and the National Association of Boards of Pharmacy linking to "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19), ROA.1256. Combined with the FDA's public pressure campaign telling people to "Stop it with the #ivermectin," it was predictable and intended that those regulatory boards—who obviously want to stay in the FDA's good graces—would react by focusing their attention on doctors seeking to use ivermectin.

Traceability can also be established in retrospect. *Lujan v. Defenders of Wildlife*, 504 U.S. at 562 (1992) ("[P]laintiffs can 'adduce facts showing that [third-party] choices *have been* or will be made in such manner as to produce causation and permit redressability of injury[.]'" (emphasis added)). As explained above, the FDA's actions have been used as evidence by state regulatory boards. ROA.932–33. Pharmacists have expressly cited FDA directives in refusing to fill prescriptions for ivermectin, ROA.932; ROA.934. And patients have delayed seeking treatment because the FDA says not to use ivermectin to treat COVID-

19. ROA.935. Even courts have recognized the legal effects and implications of the FDA's actions, citing the FDA's statements as evidence about the effectiveness of ivermectin to treat COVID-19 and the appropriate standard of care. *See* Part II, *supra*.

Nor can the FDA claim, especially at this stage of the pleadings, that such reactions were not foreseeable. As the Amended Complaint demonstrates at length, health professionals, state regulatory boards, patients, and the public are heavily influenced or feel bound by the FDA's actions, regardless of their technical legal effects, which is reinforced by courts relying on those same statements and "guidance" to determine legal standards. Those involved in interfering with Appellants' practice of medicine explicitly rely on FDA directives not to use ivermectin for COVID-19. Even more importantly, if the consequences weren't foreseeable initially, their effect became immediately clear, yet the FDA still publicly maintains its official publications on official FDA platforms and even doubled down by issuing additional anti-ivermectin statements in April 2022.

Given all this, it is more than "fair" to conclude that the harm suffered by Appellants is "traceable" to the FDA. Indeed, leading health

professionals, scientists, and researchers recognize that the FDA is interfering with the practice of medicine vis-à-vis ivermectin. *See* ROA.956–58. As alleged in the Amended Complaint, for example, Peter A. McCullough, M.D., MPH—a renowned epidemiologist—explained the impetus for the effectual ban on the use of ivermectin:

> The FDA put official communications out through Twitter and through other social media, and major media. And it said, "Ivermectin is only a horse dewormer. Don't use a veterinary product to treat COVID-19." That was picked up by the major media. And it was parroted as well.

Part I: Dr. Peter McCullough—The Inexplicable Suppression of Hydroxychloroquine, Ivermectin, and Other COVID-19 Treatments, Epoch Times (Dec. 30, 2021), https://www.theepochtimes.com/dr-peter-mccullough-the-inexplicable-suppression-ofhydroxychloroquine-ivermectin-and-other-covid-19-treatments-part-1_4186432.html. He concluded, "So, there was a clear theme that was going on. At least the obvious suppression from a regulatory, immediate perspective on ... Ivermectin." *Id.*; *see* ROA.957.

In a letter to the FDA, members of Congress likewise recognized that the agency is illegally interfering with the practice of medicine, noting that the FDA has "taken steps to curtail the use of potential early

treatments," including through the FDA's "mocking of ivermectin, conflating a widely-available human drug that was the basis for Nobel prize winning research, with its veterinary version," and have "created a new industry standard that restricts doctors' abilities to prescribe certain off-label treatments for COVID-19." ROA.1414–15. The letter also cites "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." ROA.1416 n.11.

When the actions of third parties consistently cite to the same FDA directions, Appellants' injuries do not turn on "guesswork as to how independent decisionmakers will exercise their judgment." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 413 (2013). Rather, the link is at least "fair" and likely, if not undeniable. The FDA would have the Court believe that all these other actions would have occurred even absent the FDA's assault on ivermectin, but *that* view is the one that is implausible.

C. REDRESSABILITY

Appellants' injuries are redressable by vacatur, declaratory, and injunctive relief against the FDA. Critically, at this stage, Appellants "need only show that a favorable ruling could potentially lessen [their] injury," and they "need not definitively demonstrate that a victory would

completely remedy the harm." *Sanchez v. R.G.L.*, 761 F.3d 495, 506 (5th Cir. 2014) (cleaned up); *see also Friends of the Earth, Inc. v. Laidlaw Env't. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000) (holding that a plaintiff establishes redressability if it is "likely"—not certain—"that the injury will be redressed by a favorable decision").

"[C]ausal connection and redressability are two sides of the same coin." *Ctr. for Biological Diversity v. Exp.-Imp. Bank of the U.S.*, 894 F.3d 1005, 1012 n.2 (9th Cir. 2018) (cleaned up). Thus, because Appellants' harms are fairly traceable to the FDA's actions, redressability is presumed, at least as a factual and logical matter. The FDA would not have issued the challenged statements if it did not believe its actions would affect the use of ivermectin to treat COVID-19. Having succeeded in its pressure campaign, the FDA cannot now disclaim that clearly intended effect, nor contend that vacating the challenged statements would somehow have no effect. The FDA's actions have inhibited Appellants' ability to practice medicine, and thus a favorable ruling would result in at least partial relief by removing that inhibition.

Moreover, this Court has held that redressability is satisfied where the "fear of future prosecution may be alleviated" by a favorable ruling,

especially where it could "arguably" result in "third parties" "chang[ing] … the policy" that negatively affects the plaintiffs. *McClure v. Ashcroft*, 335 F.3d 404, 411 (5th Cir. 2003). Here, the judgment of other health professionals and entities in the causal chain of Appellants' injuries would be freed from this material interference. For decades, health professionals, hospitals, and state regulatory boards have supported the off-label prescription of approved drugs and would likely revert to that norm, at least in part (which is sufficient for redressability). ROA. 943–45, 961. And patients will no longer be caught between the FDA's pressure campaign and Appellants' advice, restoring the primacy of the doctor-patient relationship. ROA.943–45; ROA.961. Their patients have been unable to timely receive prescribed treatments because of the FDA's actions, which would likely be alleviated if health professionals and other entities are freed from the FDA's interference.

* * *

The FDA undertook a singularly effective campaign against ivermectin. It cannot now disclaim those intended and predictable effects by asserting that Appellants have not demonstrated standing. Appellants have provided "substantial evidence," including "declarations

and affidavits detailing specific instances," "of a causal relationship between the government policy and the third-party conduct, leaving little doubt as to causation and the likelihood of redress." *Renal Physicians Ass'n v. HHS*, 489 F.3d 1267, 1275 (D.C. Cir. 2007) (quoting *Nat'l Wrestling Coaches Ass'n v. Dep't of Educ.*, 366 F.3d 930, 941 (D.C. Cir. 2004)); *see* ROA.992–94; ROA.1005–06; ROA.1010–12. That is more than sufficient to demonstrate standing.

CONCLUSION

The Court should reverse and remand for further proceedings.

Dated: February 7, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 7, 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.

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitations of Fifth Circuit Rule 32 and Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,587 words, 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 Century Schoolbook and 14-point font.

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