IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

No. 3:22-cv-184

ROBERT L. APTER, M.D., FACEP;

MARY TALLEY BOWDEN, M.D.; and

PAUL E. MARIK, MBBCh, M.MED, FCCM, FCCP,

Plaintiffs,

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES;

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services;

FOOD AND DRUG ADMINISTRATION; and

ROBERT M. CALIFF, M.D., MACC, in his official capacity as Commissioner of Food and Drugs,

Defendants.

COMPLAINT

FOR VACATUR, DECLARATORY, AND INJUNCTIVE RELIEF

INTRODUCTION

1. 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. The FDA generally cannot ban particular uses of human drugs once they are otherwise approved and admitted to the market, even if such use differs from the labeling—commonly referred to as "off-label" use. The FDA also cannot advise whether a patient should take an

approved drug for a particular purpose. Those decisions fall within the scope of the doctor-patient relationship. Attempts by the FDA to influence or intervene in the doctor-patient relationship amount to interference with the practice of medicine, the regulation of which is—and always has been—reserved to states.

2. The FDA breached this critical boundary between federal and state authority by directing the public, including health professionals and patients, not to use ivermectin to treat COVID-19, even though the drug remains fully approved for human use.

3. 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.

4. The FDA has unlawfully taken formal, unequivocal, and conclusory actions to prohibit or otherwise interfere with the use of ivermectin to treat COVID-19, including:

a. A publication entitled, "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." Ex. 1, *Why You Should Not Use Ivermectin to Treat or Prevent COVID-19*, FDA (Dec. 10, 2021), https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19.

b. A "Frequently Asked Questions" that begins, "Q: Should I take ivermectin to prevent or treat COVID-19? A: No. . . ." Ex. 2, *FAQ: COVID-19 and Ivermectin Intended for Animals*, FDA (Apr. 26, 2021), https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals ("Ivermectin FAQ").

c. An August 21, 2021 tweet that reads, "You are not a horse. You are not a cow. Seriously, y'all. Stop it." Ex. 3. The tweet displays the title of "Why You Should

Not Use Ivermectin to Treat or Prevent COVID-19" and includes a link to that publication. *Id.*

d. An April 26, 2022 tweet that reads: "Hold your horses, y'all. Ivermectin may be trending, but it still isn't authorized or approved to treat COVID-19." Ex. 4. The tweet again displays the title of "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" and includes a link to that publication. *Id.*

5. The FDA proceeded with knowledge and intent that these actions would interfere with the practice of medicine.

6. The FDA acted in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Administrative Procedure Act ("APA").

7. Because the FDA has unlawfully attempted to prohibit the use of ivermectin to treat COVID-19, or to otherwise interfere with the practice of medicine, this Court should hold unlawful and set aside any FDA actions that direct or opine on whether ivermectin is an appropriate treatment for COVID-19, declare such actions unlawful, and issue permanent injunctive relief enjoining the FDA from further engaging in such actions.

8. This is not the first pandemic our country has faced, nor will it be the last. And COVID-19 isn't going away. If the FDA is not limited to its statutory lane, its unlawful actions will no doubt persist and repeat themselves.

9. Moreover, if the FDA is allowed to interfere with the practice of medicine now under cover of a pandemic, this interference will metastasize to other circumstances, destroying the carefully constructed statutory wall between federal and state regulatory powers, and between the FDA and the professional judgment of health professionals.

PARTIES

10. Plaintiffs are doctors who have been harmed by the FDA's interference with the practice of medicine.

Robert L. Apter, M.D., FACEP

11. Robert L. Apter, M.D., graduated from the University of Colorado School of Medicine in 1974. Ex. 5, Declaration of Robert L. Apter, M.D., FACEP, at 1. He has over 40 years of experience in emergency medicine. *Id.*

12. Dr. Apter is licensed to practice medicine in Arizona and Washington. *Id.* He is a certified Diplomate of the American Board of Emergency Medicine and a Fellow of the American College of Emergency Physicians. *Id.*

13. Dr. Apter has completed over 6,000 patient consultations for COVID-19 through MyFreeDoctor.com, about half for prophylaxis and half for treatment, with a patient survival rate over 99.98%. *Id.* He has frequently prescribed ivermectin to these patients, finding the treatment effective. *Id.*

14. Dr. Apter asserts that statements by the FDA to stop using ivermectin to treat COVID-19 have interfered with his ability to exercise professional medical judgment in practicing medicine. *Id.* The off-label prescription of drugs is common and well-established medical practice, and often necessary for the effective treatment of each unique patient. *Id.*

15. Pharmacists have refused to fill ivermectin prescriptions for Dr. Apter's patients, citing the FDA's statements on using the drug to treat COVID-19. *Id.* This refusal delays his patients in obtaining their prescribed treatment—when early intervention is paramount—while they look for a pharmacy to fill their prescription, if they can find one at all. *Id.*

16. In Dr. Apter's professional experience, the practice of medicine is affected by FDA statements regardless of whether the FDA can legally enforce them, because the practice of medicine has become highly driven by standards and guidelines. *Id.* at 1–2. Doctors are increasingly employees of entities that look to the FDA for guidance and enforce standards accordingly. *Id.* Government pressure, largely through the FDA, has also led pharmacies—especially in large corporate chains—to refuse to fill ivermectin prescriptions for COVID-19, because that position is supported by the FDA. *Id.*

17. Dr. Apter has observed that patients believe that FDA's pronouncements are authoritative and want care that complies with such pronouncements. *Id.* at 3. Further, insurance companies are refusing to pay for ivermectin to treat COVID-19, and the only observable basis for this is pronouncements and pressure from the FDA. *Id.*

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

Mary Talley Bowden, M.D.

19. Plaintiff Mary Talley Bowden, M.D., graduated *summa cum laude* from the Medical College of Georgia in 1998. Ex. 6, Declaration of Mary Talley Bowden, M.D., at 1. She completed residency in Otolaryngology–Head and Neck Surgery at the Stanford University Medical Center in 2003. *Id.* She is certified by the American Board of Otolaryngology, and for Sleep Medicine by the American Board of Internal Medicine. *Id.*

20. Dr. Bowden is licensed to practice medicine in Texas. *Id.*

21. Dr. Bowden began recommending ivermectin to treat COVID-19 in early 2020 and found the therapy effective. *Id.* She was derided by Houston Methodist Hospital and forced to resign her privileges there as a result. *Id.*

22. Dr. Bowden is the owner of BreatheMD, where she continues to treat COVID-19 patients. *Id.* She is also a clinical advisor at the Front Line COVID-19 Critical Care Alliance. *Id.*

23. Dr. Bowden has treated more than 3,900 patients for COVID-19, with a success rate over 99.97%. *Id.* No patient who received early treatment from her required hospitalization.

Id. The only patient who did not recover was already in the late stages of the disease and needed ventilator support before seeing Dr. Bowden. *Id.*

24. The FDA's actions regarding ivermectin, specifically its directives to stop using the drug to treat COVID-19, have harmed Dr. Bowden's ability to practice medicine and treat patients. *Id.* As her attached declaration observes, health professionals, regulatory boards, and patients feel compelled to follow any directives or recommendations from the FDA, which presents itself as the authoritative source on the appropriate use of drugs. *Id.* This is especially true during a pandemic. *Id.*

25. Dr. Bowden also explains that the off-label prescription of drugs is common and well-established medical practice. *Id.* at 2. Doctors must be able to exercise their professional medical judgment in the context of each specific patient, including by prescribing drugs off-label, to effectively practice medicine. *Id.* But by inserting itself into the practice of medicine, the FDA has intentionally manipulated the ability of doctors to use ivermectin—a famously safe drug—off-label. *Id.*

26. Other doctors have referred patients to Dr. Bowden specifically because she prescribes ivermectin to treat COVID-19. *Id.*

27. Pharmacists have refused to fill ivermectin prescriptions for Dr. Bowden's patients, citing FDA directives not to use the drug to treat COVID-19, thereby interfering with her ability to treat patients in a timely manner. *Id.*

28. Pharmacists have likewise refused to fill ivermectin prescriptions for Dr. Bowden's patients because it is not FDA approved for the treatment of COVID-19, treating those off-label prescriptions in a manner categorically different from other off-label prescriptions. *Id.*

29. Patients have also delayed seeking treatment from Dr. Bowden because the FDA says not to use ivermectin to treat COVID-19, only to reverse course when other treatments don't work. Another patient similarly delayed following a course of treatment using ivermectin as recommended by Dr. Bowden—even after filling that prescription—because of the FDA, again only to reverse course when other treatment didn't work. *Id.* These delays can be devastating because early treatment of COVID-19 is key. *Id.*

Paul E. Marik, MBBCh, M.Med, FCCM, FCCP

30. Plaintiff Paul E. Marik, MBBCh, M.Med, FCCM, FCCP, is a critical care specialist who has practiced medicine for over 40 years. Ex. 7, Declaration of Paul E. Marik, MBBCh, M.Med, FCCM, FCCP, at 1.

31. Dr. Marik received his medical degree in 1981 from the University of Witwatersrand in Johannesburg, South Africa. *Id.* His academic credentials include:

- Bachelor of Medicine and Surgery (MBBCh), from the University of Witwatersrand;
- Bachelor of Science with Honors in Pharmacology, from the University of Witwatersrand;
- Master of Medicine, from the University of Witwatersrand;
- Diploma in Tropical Medicine and Hygiene (DTM&H), from the University of Witwatersrand.

Id.

32. Dr. Marik is a Fellow of the College of Physicians of South Africa, a Fellow of The Royal College of Physicians of Canada, a Fellow of the American College of Critical Care Medicine, and a Fellow of the American College of Chest Physicians. *Id.*

33. Dr. Marik is certified by the:

- American Board of Internal Medicine, for Internal Medicine and Critical Care Medicine;
- American Board of Physician Nutrition Specialists, as a Physician Nutrition Specialist;
- United Council for Neurological Subspecialities (USA), as a Neurocritical Care Specialist;
- British Medical Council, as a General Practitioner with a specialty certification in Internal Medicine;
- South African Medical and Dental Council, as a General Practitioner with a specialty certification in Internal Medicine, and a sub-specialty certification in Critical Care Medicine; and
- Canadian Medical Council, as a General Practitioner with a specialty certification in Internal Medicine, and a sub-specialty certification in Critical Care Medicine.

Id. at 1–2.

34. According to Semantic Scholar, Dr. Marik has over 750 publications and been cited more than 40,000 times, with an h-index of 95. *Id.* at 2; *P. Marik,* Semantic Scholar, https://www.semanticscholar.org/author/P.-Marik/3887524 (last accessed June 1, 2022).

35. Dr. Marik is among the top scientists across all scientific fields according to John P. A. Ioannidis et al., *A Standardized Citation Metrics Author Database Annotated for Scientific Field*, PLoS Biol. 17(8), table S1 (2019), https://doi.org/10.1371/journal.pbio.3000384.

36. Expertscape's PubMed-based algorithm ranks Dr. Marik in the top .01% of scholars worldwide on sepsis, a life-threatening condition and common result of COVID-19. Ex. 7, at 2; *Expertise in Sepsis: Paul Ellis Marik*, Expertscape, https://www.expertscape.com/au/sepsis/Marik%2C+P (last accessed June 1, 2022).

37. Dr. Marik is a founding member and Co-Chief Medical Officer at the Front Line COVID-19 Critical Care Alliance. Ex. 7, at 2.

38. Dr. Marik was a Professor of Medicine and Chief of Pulmonary and Critical Care Medicine at Eastern Virginia Medical School ("EVMS") in Norfolk, Virginia, from 2009 through 2021, with tenure starting in 2014. *Id.* He also served as a Director of the Intensive Care Unit at Sentara Norfolk General Hospital. *Id.*

39. Dr. Marik developed a protocol for EVMS for treating COVID-19. *Id.* It was called the EVMS COVID-19 Management Protocol, which included the MATH+ Protocol. *Id.* Ivermectin was added to the EVMS COVID-19 Management Protocol, including the MATH+ Protocol, after Dr. Marik and others observed that the drug was effective to treat COVID-19, especially as an early treatment. *Id.*; *see, e.g.*, Ex. 8, EVMS COVID-19 Management Protocol (Dec. 17, 2020), at 6–7, 9–10, 13, 18.

40. Dr. Marik was directed by EVMS to remove the protocol from its servers and not speak publicly about ivermectin following the FDA's August 21, 2021 tweet deriding the drug as animal medication and directing against its use to treat COVID-19. Ex. 7, at 2.

41. Sentara also issued a "Call for Immediate End to Prescribing, Dispensing, and Use of Ivermectin to Prevent or Treat COVID-19 Outside Clinical Trials" to its hospitals, citing in part the FDA. Ex. 9, Sentara Comprehensive COVID-19 Treatment Guidelines—Version 26 (Sept. 27, 2021), at 3.

42. The FDA's actions harmed Dr. Marik's ability to practice medicine. *Id.* at 2–3. He was forced to resign from his positions at EVMS and Sentara Norfolk General Hospital for promoting the use of ivermectin—as well as other safe, cheap, and effective off-label FDA-approved drugs—to treat COVID-19 following the FDA's attempts to stop use of those drugs for that purpose. *Id.*

43. Dr. Marik explains that it doesn't matter whether FDA statements are technically binding on health professionals. In his experience and observation, after the FDA's decision to interfere with the use of ivermectin to treat COVID-19, doctors have been threatened with revocation of their medical licenses and adverse disciplinary actions should they prescribe the drug contrary to the FDA's public position. Hospitals have relied on FDA publications to prohibit their pharmacies from dispensing ivermectin and have threatened doctors with revocation of their privileges if they don't comply with NIH/FDA guidelines. Many pharmacists have refused to fill prescriptions for out-patients with COVID-19 because the drug is not "FDA approved" for this purpose, even though filling off-label prescriptions is routine. Refusing to allow patients to receive effective early treatment for COVID-19 has led to innumerable hospitalizations and deaths, and caused extreme distress for patients, their families, and health professionals. *Id.* at 3.

Defendants

44. Defendants are United States governmental agencies and appointed officials of the United States government responsible for the challenged actions. The individual named defendants are all sued in their official capacities.

45. Defendant Xavier Becerra, in his official capacity as Secretary of Health and Human Services, has authority over the U.S. Department of Health and Human Services ("HHS") and its components, including the FDA.

46. Defendant Robert M. Califf, M.D., MACC, in his official capacity as Acting Commissioner of Food and Drugs, has authority over the FDA and the unlawful actions of that agency to prohibit or otherwise interfere with the use of ivermectin to treat COVID-19.

JURISDICTION AND VENUE

47. This Court has jurisdiction under 5 U.S.C. §§ 701–706, and 28 U.S.C. §§ 1331, 1346, 1361, 2201, under the U.S. Constitution, and pursuant to the equitable powers of this Court.

48. The Court is authorized to award the requested relief under 5 U.S.C. §§ 702, 706, and 28 U.S.C. §§ 1361, 2201, 2202, and pursuant to the equitable powers of this Court.

49. Venue is proper under 28 U.S.C. § 1391(e)(1)(B) because an officer of the United States in his or her official capacity, or an agency of the United States, is a Defendant, and a substantial part of the events giving rise to Plaintiffs' claims occurred in this District. Venue is also proper under 28 U.S.C. § 1391(e)(1)(C) because an officer of the United States in his or her official capacity, or an agency of the United States, is a Defendant, and Dr. Bowden resides in this District, and no real property is involved.

FACTUAL BACKGROUND

The FDA

50. The FDCA establishes the FDA as an agency within HHS. 21 U.S.C. § 393. The Secretary of Health and Human Services is responsible for executing the FDCA through the Commissioner of Food and Drugs. *Id.* § 393(d).

51. 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." *Id.* § 355(d); *see* 21 C.F.R. § 201.57.

52. 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).

53. None of these provisions authorize the FDA to prohibit, direct, or advise against off-label uses of drugs approved for human use.

54. When Congress has authorized the FDA to limit particular uses of an approved drug, it has done so explicitly. *E.g.*, *id.* § 333(e).

55. The FDA also has authority to regulate animal drugs, *id.* §§ 321(g)(1), 351(a)(1), 360(b), which includes the ability to "prohibit particular uses of an animal drug." *Id.* § 360b(a)(4)(A). No similar authority exists for the FDA to prohibit particular uses of human drugs.

56. Importantly, the FDCA further provides 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."

57. Courts have consistently cited § 396 as applying to the prescription or administration of drugs as well. *See Markland v. Insys Therapeutics, Inc.*, 758 F. App'x 777, 780 (11th Cir. 2018); *U.S. ex rel King v. Solvay Pharms., Inc.*, 871 F.3d 318, 328 (5th Cir. 2017); *U.S. ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 454 n.2 (4th Cir. 2013); *United States*

v. Caronia, 703 F.3d 149, 167 (2d Cir. 2012); *United States v. Muoghalu*, 662 F.3d 908, 911 (7th Cir. 2011); *Smith v. C.R. Bard, Inc.*, 730 F. Supp. 2d 783, 803 (M.D. Tenn. 2010).

58. The FDA thus cannot interfere with "the practice of medicine, which is the exclusive realm of individual states." *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 505 (6th Cir. 2006); *see Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 350 (2001) ("[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."); *Ass'n of Am. Physicians & Surgeons 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."); *see also 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.").

59. As a result, 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 Buckman Co.,* 531 U.S. at 350 ("'[O]ff-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."); *Judge Rotenberg Educ. Ctr., Inc.*, 3 F.4th at 395 ("Section 396 ensures that once the FDA permits a device to be marketed for one use, health care practitioners have the flexibility to draw on their expertise to prescribe or administer the device for any condition or disease, not just the use the FDA approved—in short, to practice medicine."); *Solvay Pharms., Inc.*, 871 F.3d at 328 ("[T]he FDA does not restrict

physicians from prescribing an otherwise FDA-approved drug for an off-label use."); *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."); *Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine,* FDA (June 15, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and ("FDA approved products may be prescribed by physicians for off-label uses if they determine it is appropriate for treating their patients, including during COVID.").

60. FDA regulations recognize that the agency cannot interfere with the practice of medicine or off-label use of approved drugs. 21 C.F.R. § 312.2(d) ("This part does not apply to the use in the practice of medicine for an unlabeled indication of a new drug product approved under part 314 or of a licensed biological product.").

61. Appropriate healthcare professionals can—and often do—prescribe or dispense drugs off-label precisely because they have been approved by the FDA for human use. 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/. 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).

62. One study found that 21% of all prescriptions were for off-label use. Wittich et al., *supra*. That fraction is nearly twice as high, 36.2%, in intensive care units. *Id.*

63. The National Ambulatory Medical Care Survey 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).

64. Regarding off-label prescriptions, the FDA has 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.

65. An FDA Deputy Commissioner for External Affairs likewise emphasized that "off-label drug use is often essential to good medical practice," and "it is on this edge that science and medicine move forward to benefit patients with intractable illness." Carol Scheman, *Prescription Drug Marketing and Promotion—An FDA Perspective*, Address before the PMA Public Affairs Section, Mid-Year Meeting (Apr. 15, 1992).

66. The Council on Scientific Affairs of the American Medical Association ("AMA") agrees, reporting that "[t]he prevalence and clinical importance of prescribing drugs for unlabeled uses are substantial," and "the prescribing of FDA-approved drugs for unlabeled uses is often necessary for optimal patient care." Joseph W. Cranston, et al., *Report of the Council on Scientific*

Affairs: Unlabeled Indications of Food and Drug Administration-Approved Drugs, 32 Drug Info. J., 1049, 1050–51 (1998).

The COVID-19 Pandemic

67. On January 31, 2020, the Secretary of Health and Human Services determined that COVID-19 resulted in a public health emergency under section 319 of the Public Health Service Act, Pub. L. No. 78–410, as amended.

68. On March 13, 2020, President Trump determined pursuant to the National Emergencies Act, 50 U.S.C. § 1601 et seq., that the COVID–19 outbreak in the United States constituted a national emergency that threatened national security.

69. The United States has suffered 1,004,447 deaths attributed to COVID-19 as of the week ending on May 28, 2022. *See COVID-19 Mortality Overview*, CDC, https://www.cdc.gov/nchs/covid19/mortality-overview.htm (last accessed June 1, 2022).

Ivermectin

70. Ivermectin was developed in the late 1970s and has been used successfully for over forty years to treat humans for onchocerciasis (commonly known as river blindness), worm infections, scabies, and other parasitic diseases.

71. The World Health Organization lists ivermectin as an "essential medicine." Ex. 10, *World Health Organization Model List of Essential Medicines* 6, 24 (22nd ed. 2021), https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02.

72. Alongside penicillin and aspirin, ivermectin is one of the "few drugs that can seriously lay claim to the title of 'Wonder drug' . . . . based on its versatility, safety and the beneficial impact that it has had, and continues to have, worldwide—especially on hundreds of millions of the world's poorest people." Andy Crump & Satoshi Ōmura, *Ivermectin, 'Wonder*

Drug' from Japan: The Human Use Perspective, 87 Proc. Jpn. Acad., Ser. B 13, 13 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3043740/pdf/pjab-87-013.pdf.

73. Sculptures have been erected around the world—from Atlanta to Amsterdam, from the World Bank to the World Health Organization itself—to commemorate the accomplishments of ivermectin. Derek Yach, *Health as a Cornerstone of Good Business and Sustainable Development*, 106 Am. J. Pub. Health 1758, 1759 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5024391/pdf/AJPH.2016.303387.pdf.

74. In 1996, the FDA approved ivermectin for use in humans to treat onchocerciasis and a parasitic roundworm, strongyloidiasis. Ex. 11, Center for Drug Evaluation and Research, *Approval Package for: Ivermectin* (1996), https://www.accessdata.fda.gov/drugsatfda_docs/nda/96/050742ap.pdf.

75. The FDA has also approved ivermectin for use in animals. *See, e.g.*, *ZIMECTERIN GOLD—Ivermectin and Praziquantel Paste*, FDA (Jan. 4, 2021), https://www.accessdata.fda.gov/spl/data/3553c950-dd70-413e-8d58-ee8d792bbbe3/3553c950-dd70-413e-8d58-ee8d792bbbe3.xml.

76. Ivermectin is a very safe drug. It "has been used safely in 3.7 billion doses worldwide since 1987 and is well tolerated even at much greater doses than the standard single dose of 200 μg/kg." Alessandro D. Santin et al., *Ivermectin: A Multifaceted Drug of Nobel Prize-Honoured Distinction with Indicated Efficacy Against a New Global Scourge, COVID-19*, New Microbes & New Infections 43:100924, at 2 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8383101/. In fact, Merk has now donated over 4.4 billion treatments of ivermectin, brand name Mectizan, for use in mass distribution campaigns alone. *See 35 Years: The Mectizan Donation Program*, Merck (May 25, 2022), https://www.merck.com/stories/mectizan/ ("The

program reaches more than 300 million people in the affected areas annually, with more than 4.4 billion treatments donated since 1987.").

77. A 2002 study demonstrated that ivermectin is safe even at dosages many multiples higher than the treatment initially approved by the FDA. *See* Cynthia A. Guzzo, MD, et al., *Safety, Tolerability, and Pharmacokinetics of Escalating High Doses of Ivermectin in Healthy Adult Subjects*, 42 J. Clinical Pharmacology 1122 (2002), https://accp1.onlinelibrary.wiley.com/doi/10.1177/009127002237994.

78. The World Health Organization reporting system VigiAccess shows only 25 deaths associated with ivermectin since 1992. Ex. 12.[1] The FDA Adverse Events Reporting System (FAERS) shows only 70 deaths associated with ivermectin since 1996. Ex. 13.[2] By comparison, VigiAccess lists 3,893 deaths and FAERS lists 3,918 deaths associated with acetaminophen, the active ingredient in Tylenol. Exs. 14, 15.[3]

79. Ivermectin is so safe that it's sold over-the-counter in many countries or made available free in mass distribution campaigns. It is *not* a controlled substance under the Controlled Substances Act, 21 U.S.C. § 801.

80. Ivermectin is also regularly used off-label. *See* Andy Crump, *Ivermectin: Enigmatic Multifaceted "Wonder" Drug Continues to Surprise and Exceed Expectations*, 70 J. of Antibiotics 495, app. 1 (2017), https://www.nature.com/articles/ja201711.pdf (cataloguing off-label uses); Leon H. Kircik et al., O*ver 25 Years of Clinical Experience with Ivermectin: An Overview of Safety*

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[1] VigiAccess, WHO, vigiaccess.org (last accessed May 9, 2022), vigiaccess.org (search "Ivermectin," select "Reported Potential Side Effects," "General Disorders and Administration Site Conditions," "Death").
[2] *FDA Adverse Events Reporting System (FAERS) Public Dashboard*, FDA, https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis (last accessed May 9, 2022) (search "Ivermectin," select "Cases by Reaction," "Death").
[3] VigiAccess, *supra* (search "Acetaminophen," select "Reported Potential Side Effects," "General Disorders and Administration Site Conditions," "Death"); FAERS Public Dashboard, *supra* (search "Acetaminophen," select "Cases by Reaction," "Death").

for an Increasing Number of Indications, 15 J. Drugs & Dermatology 325 (2016) ("Numerous studies report low rates of adverse events, as an oral treatment for parasitic infections, scabies and head lice. Ivermectin has been used off-label to treat diseases associated with Demodex mites, such as blepharitis and demodicidosis.").

81. Researchers have demonstrated that ivermectin may be an effective treatment for a long list of pathogens, including yellow fever virus, dengue virus, Japanese encephalitis, tick-borne encephalitis, HIV-1, chlamydia, and certain cancers. Crump, *supra*, at 500.

82. Dr. William Campbell and Dr. Satoshi Ōmura received the Nobel Prize in Physiology or Medicine in 2015 for the discovery of ivermectin and its contribution to the treatment of diseases that "have plagued humankind for millennia." *Press Release*, The Nobel Assembly (Oct. 5, 2015), https://www.nobelprize.org/prizes/medicine/2015/press-release/. The Nobel Prize in Physiology or Medicine is awarded to those doctors and scientists who have made discoveries that have "conferred the greatest benefit on mankind." *The Last Will of Alfred Nobel*, Nobel Peace Center, https://www.nobelpeacecenter.org/en/the-last-will-of-alfred-nobel (last accessed June 1, 2022).

FDA Directives Against the Use of Ivermectin to Treat COVID-19

83. On March 5, 2021, the FDA published "Why You Should Not Take Ivermectin to Treat or Prevent COVID-19" on its website. Ex. 16, FDA, *Why You Should Not Use Ivermectin to Treat or Prevent COVID-19* (Mar. 5, 2021). The title of the publication clearly states the FDA's official position that ivermectin should not be used for the treatment or prevention of COVID-19. *Id.* Nowhere did the publication acknowledge that doctors can lawfully prescribe ivermectin for that use, instead stating only that "[if] you have a prescription for ivermectin for an FDA-approved use, get it from a legitimate source and take it exactly as prescribed." *Id.* This unmistakably conveyed that ivermectin can only be prescribed and used for FDA-approved purposes.

84. The FDA published "Why You Should Not Take Ivermectin to Treat or Prevent COVID-19" notwithstanding an 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.*

85. The publication was updated after criticism that it was misleading. *See* David R. Henderson & Charles L. Hooper, *The FDA's War Against the Truth on Ivermectin*, Valley News (Nov. 5, 2021), https://myvalleynews.com/blog/2021/11/05/the-fdas-war-against-the-truth-on-ivermectin/ (cataloging changes).

86. Although the publication now states 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," that pseudo-concession is buried in the middle of the document and does not influence the effect of the title, unequivocally discouraging the use of ivermectin to treat or prevent COVID-19. Ex. 1.

87. The FDA has also published an Ivermectin FAQ, entitled "COVID-19 and Ivermectin Intended for Animals." Ex. 2. The title continues the FDA's efforts to deride ivermectin as an animal drug.

88. The Ivermectin FAQ begins with, "Q: Should I take ivermectin to prevent or treat COVID-19?" and answers that question, "A: No." *Id.*

89. The Ivermectin 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. 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 unequivocal statement 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.

90. On August 21, 2021, the FDA tweeted, "You are not a horse. You are not a cow. Seriously, y'all. Stop it." Ex. 3. 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 tweet unequivocally directs the public not to use ivermectin to treat COVID-19.

91. The FDA celebrated its successful messaging. Erica Jefferson, Associate Commissioner of Food and Drugs, explained that the agency's tweet reached 14.5 million people—"a unique viral moment" where FDA guidance can "reach the 'everyday' American . . . in a time of incredible misinformation." Ex. 17, Mary Beth Pfeiffer & Linda Bonvie, *Horse-Bleep: How 4 Calls on Animal Ivermectin Launched a False FDA-Media Attack on a Life-Saving Human Medicine*, Rescue (Oct. 16, 2021), https://rescue.substack.com/p/horse-bleep-how-4-calls-on-animal?s=r (reproducing FDA emails). She similarly expressed her satisfaction about the number of people who viewed the tweet: "The numbers are racking up and I laughed out loud." *Id.*

92. Janet Woodcock, Acting Commissioner of Food and Drugs, congratulated her media team, saying: "That was great! Even I saw it!" *Id.*

93. The FDA then sent a letter to the Federation of State Medical Boards warning against the use of ivermectin to treat COVID-19 and including a link to "Why You Should Not Take Ivermectin to Treat or Prevent COVID-19." Ex. 18, Letter from Shannon Glueck, Acting Branch Chief, U.S. Food & Drug Administration, to Humayun J. Chaudhry, President and CEO, Federation of State Medical Boards (Dec. 13, 2021), https://content.govdelivery.com/attachments/WIDHS/2021/12/22/file_attachments/2030302/Ivermectin%20Letter%20to%20FSMB%20Final%20%281%29.pdf.

94. The FDA sent the same letter to the National Association of Boards of Pharmacy. *See id.*

95. On April 26, 2022, the FDA continued its relentless campaign against ivermectin, pushing its narrative that the drug is only intended 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." Ex. 4. 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.*

96. During this same period, the FDA issued a statement on August 6, 2021, that it had "approved an abbreviated new drug application for dexamethasone sodium phosphate injection" to treat COVID-19. *Coronavirus (COVID-19) Update: August 6, 2021*, FDA, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-august-6-2021. The statement explained that "[d]examethasone injection is used to treat conditions such as arthritis, blood disorders, hormone disorders, allergic reactions, skin diseases, eye disorders, breathing problems, bowel disorders, cancer, and immune system disorders." *Id.* In stark contrast to its approach with ivermectin, the FDA omitted that dexamethasone is also a horse medication.

The Media Parrots the FDA's Message

97. Media outlets large and small parroted the FDA's message, referring to ivermectin as "horse dewormer" and "horse paste." *See* Ex. 17.

98. Others pushed the narrative with headlines like "Say 'Neigh' to Ivermectin." Joe Fisher, *FDA, Poison Control Say "Neigh" to Ivermectin*, Times-Republican (Sep. 9, 2021), https://www.timesrepublican.com/uncategorized/2021/09/fda-poison-control-say-neigh-to-ivermectin/; *see also, 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.

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

100. Individual health professionals even joined the refrain. A pharmacist named Savannah Sparks, with the TikTok handle "rx0rcist" and approximately 1 million followers on that platform, displayed the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" and berated a doctor (a Plaintiff in this case) for using ivermectin because "the FDA said nope." Ex. 19, rx0rcist, *Stop Prescribing Ivermectin*, TikTok (Apr. 3, 2021), https://www.tiktok.com/@rx0rcist/video/7082586876007288107.

The FDA's Actions Have Their Intended Effect

101. The FDA's actions resulted in their foreseeable and intended effect of stopping doctors from using ivermectin to treat COVID-19.

102. Following the FDA's lead, the AMA, American Pharmacists Association ("APhA"), and American Society of Health-System Pharmacists ("ASHP") all 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 pointed to the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" as part of their justification. Ex. 20, *AMA, APhA, ASHP*

Statement on Ending Use of Ivermectin to Treat COVID-19, Am. Med. Ass'n (Sep. 1, 2021), https://www.ama-assn.org/press-center/press-releases/ama-apha-ashp-statement-ending-use-ivermectin-treat-covid-19.

103. State pharmacy boards issued statements on dispensing ivermectin that linked to the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." *See, e.g.*, Ex. 21, Maine Board of Pharmacy Statement #01-2021 (Sept. 28, 2021).

104. Hospitals have relied 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 in their facilities, regardless of whether the drug is prescribed by a doctor. *See, e.g.*, Ex. 9, at 3; Ex. 22, Memorandum Law in Opposition to Plaintiff's Complaint for Emergency Medical Declaratory Judgment and Emergency Injunctive Relief and Objection to Injunction Relief, *Smith v. West Chester Hosp.*, No. CV 2021 08 1206 (filed Sept. 2, 2021), at 8-9, 21.

105. Courts have relied on the FDA's actions to decide cases involving ivermectin as well, including as persuasive evidence about the effectiveness of the drug and appropriate standards of care. *See, e.g.*, *Smith v. West Chester Hosp.*, No. CV 2021 08 1206, 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. & Suburban Hosps. Network*, 2021 IL App (2d) 210763, ¶ 10. 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).

106. Jeffrey Barke, M.D., has used ivermectin in the successful treatment of hundreds of patients for COVID-19. He said, "I have not seen a single adverse reaction to ivermectin. It's a safe drug. And when used early in the course of COVID-19, ivermectin . . . works." Jennifer Margulis, *Was Ivermectin Unfairly Torpedoed as Treatment for COVID-19?*, Epoch Times (April 15, 2022) (quoting Jeffrey Barke), https://www.theepochtimes.com/was-ivermectin-unfairly-torpedoed-as-treatment-for-covid-19_4394927.html. But, he continued, "It's easier for me to prescribe oxycontin than ivermectin." *Id.*

107. Peter A. McCullough, M.D., MPH—a renowned internist, cardiologist, epidemiologist, and highly published medical scientist—explained the impetus for the effectual ban on the use of ivermectin:

> The FDA picked this up. 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-of-hydroxychloroquine-ivermectin-and-other-covid-19-treatments-part-1_4186432.html ("McCullough Interview"). 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.*

108. Multiple courts have relied previously on Dr. McCullough's work. He has also testified many times before Congress, including about COVID-19 and early treatment. *See, e.g.*, *Early Outpatient Treatment: An Essential Part of a COVID-19 Solution: Hearing Before the S.*

Comm. on Homeland Sec. & Governmental Affs., 116th Cong. (2020), https://www.hsgac.senate.gov/hearings/early-outpatient-treatment-an-essential-part-of-a-covid-19-solution (statement of Peter A. McCullough).

109. Pierre Kory, M.D., MPA—a distinguished and highly published critical care specialist—has made similar observations:

> We have pharmacists across the land who are refusing, refusing to fill these [prescriptions] because they've been manipulated and brainwashed into thinking that the FDA hasn't approved the use, as if that matters. Off-label prescriptions and prescribing has been going on for decades. It's encouraged when there are no effective treatments. Yet when I try and treat my patients . . . we have pharmacists who refuse to fill some of the safest and [most] low-cost medicines known in the history of medicine.

COVID-19: A Second Opinion: Panel Convened by Sen. Ron Johnson, 117th Cong. (2022), https://rumble.com/vt62y6-covid-19-a-second-opinion.html, at 3:15:40 (testimony of Pierre Kory) ("Kory Testimony").

Members of Congress Express Concern that FDA and HHS, Among Other Agencies, Are Interfering with the Practice of Medicine

110. Members of Congress have recognized that the FDA is illegally interfering with the practice of medicine by denouncing and directing against the use of ivermectin to treat COVID-19.

111. On October 6, 2021, Senator Ron Johnson and twenty-one other Members of Congress wrote to the FDA and HHS, among other agencies, stating that they "at times seem to have participated in an aggressive campaign against the use of specific early treatment options." *See* Ex. 23, Letter from Ron Johnson, U.S. Senator, et al. to Xavier Becerra, Secretary of Health and Human Services et al. (Oct. 5, 2021), https://www.ronjohnson.senate.gov/2021/10/sen-

johnson-leads-colleagues-in-pressing-biden-administration-on-their-failure-to-make-early-treatment-options-available-to-the-american-people, at 1.

112. The letter continues that the agencies "have overtly discouraged the use of cheap and widely-available early treatments like ivermectin in favor of expensive new drugs like Remdesivir (which costs more than $3,000 per treatment)," and that 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, has cast doubt over the integrity of [ivermectin research]." *Id.* at 1–2.

113. Specifically, the letter cites the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," makes clear that the agencies "have also taken steps to curtail the use of potential early treatments," and emphasizes that their "actions have created a new industry standard that restricts doctors' abilities to prescribe certain off-label treatments for COVID-19." *Id.* at 3 & n.11.

114. The letter is explicit that the agencies are engaging in a "campaign of misdirection" and fomenting a "strong bias against generic drugs [that] has prevented early treatments from being widely adopted and has cost an untold number of lives." *Id.* at 3.

STANDING

115. To establish standing under *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560–61 (1992), Plaintiffs must show (1) injury in fact, (2) causation, and (3) redressability. A plaintiff "need only show that a favorable ruling could potentially lessen its injury; it 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) (internal quotation marks omitted); *see Bennett v. Donovan*, 703 F.3d 582, 589

(D.C. Cir. 2013) ("The relevant question for standing, however, is not whether relief is *certain*, but only whether it is *likely*, as opposed to merely speculative.").

116. Plaintiffs have each been harmed in their ability to practice medicine. Plaintiffs have been pressured, unable to prescribe medication, and threatened with or subjected to professional discipline. This has further resulted in both reputational and monetary harm.

117. Plaintiffs' injuries are fairly traceable to the FDA. The agency asserts itself as the authoritative voice on appropriate and permissible drug use, and intentionally exerts severe pressure on Plaintiffs' professional judgment. In addition, health professionals and state regulatory boards are heavily influenced or feel bound by FDA statements and "guidance," regardless of their technical legal effects, which is reinforced by courts relying on those same statements and "guidance" to establish legal standards and liability. The state regulatory boards, professional associations, hospitals, pharmacies, and others involved in the causal chain interfering with Plaintiffs' practice of medicine explicitly rely on FDA directives not to use ivermectin to treat COVID-19.

118. Leading health professionals, scientists, and researchers, and Members of Congress confirm that the FDA is interfering with the practice of medicine, which has caused Plaintiffs' injuries. *See, e.g.*, McCullough Interview, *supra*; Kory Testimony, *supra*; Ex. 23.

119. Plaintiffs' injuries are likewise redressable by vacatur, declaratory, and injunctive relief against the FDA. Plaintiffs' professional judgment would no longer be subject to pressure from the FDA. The independent professional judgement of other health professionals and entities in the causal chain of Plaintiffs' injuries would also be freed from this material interference. Health professionals and state regulatory boards have traditionally supported the off-label prescription of approved drugs and will revert to that norm. And patients will no longer be caught between the

FDA's seemingly authoritative directives and Plaintiffs' advice, restoring the primacy of the doctor-patient relationship.

120. Doctors can further "invoke the rights of their actual or potential patients" to establish standing. *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2118 (2020). As Plaintiffs' have explained, their patients have been unable to timely receive prescribed treatments because of the FDA's actions, which would be alleviated if health professionals and other entities are freed from the FDA's material interference.

121. If the FDA did not believe its actions would affect the use of ivermectin to treat COVID-19, it would not have done anything. Publicly vacating, declaring unlawful, and enjoining those actions will remove that interference with the practice of medicine.

122. Plaintiffs' standing thus does not require "guesswork as to how independent decisionmakers will exercise their judgment." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 413 (2013). Health professionals and state regulatory boards understandably hesitate to contravene FDA directives that carry the imprimatur of governmental authority and are enforced by courts, even if it's an authority the FDA does not have. Patients are likewise reluctant to transgress seemingly authoritative statements from agencies that wield sovereign power. As Justice Thurgood Marshall presciently explained, "the value of a sword of Damocles is that it hangs—not that it drops. For every employee who risks his job by testing the limits of the [government's action], many more will choose the cautious path." *Arnett v. Kennedy*, 416 U.S. 134, 231 (1974) (Marshall, J., dissenting).

123. In sum, Plaintiffs offer "substantial evidence 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)). And Plaintiffs submit "declarations and affidavits detailing specific instances" in support. *Renal Physicians Ass'n*, 489 F.3d at 1275. All roads lead to the FDA.

CLAIMS FOR RELIEF

COUNT ONE

(Ultra Vires Acts)

124. The allegations in each of the preceding paragraphs are expressly incorporated herein as if restated in full.

125. A plaintiff may "institute a non-statutory review action" against an agency head "for allegedly exceeding his statutory authority." *Chamber of Com. of U.S. v. Reich*, 74 F.3d 1322, 1327–28 (D.C. Cir. 1996).

126. The FDA cannot "limit or interfere with the authority of a health care practitioner to prescribe or administer" drugs approved for human use "for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396. The FDA has violated this prohibition by directing against the use of ivermectin to treat COVID-19, thereby limiting its off-label use and interfering with the practice of medicine.

COUNT TWO

(APA Violation: Arbitrary or Capricious)

127. The allegations in each of the preceding paragraphs are expressly incorporated herein as if restated in full.

128. The APA authorizes judicial review of "final" agency actions, 5 U.S.C. § 704, and requires courts to "hold unlawful and set aside any "action, findings, and conclusions found to be . . . arbitrary" or "capricious." 5 U.S.C. § 706(2)(A).

129. Statements by federal agencies can qualify as actions subject to review under the APA. *Avoyelles Sportsmen's League, Inc. v. Marsh*, 715 F.2d 897, 908 (5th Cir. 1983). The APA authorizes review even when there is no written policy or where its precise terms are unclear. *Texas v. EEOC*, 933 F.3d 433, 441–42 (5th Cir. 2019); *Venetian Casino Resort, L.L.C. v. EEOC*, 530 F.3d 925, 930–31 (D.C. Cir. 2008).

130. A final agency action "must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature," and "must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (cleaned up).

131. The Supreme Court has interpreted the "finality requirement as 'flexible' and 'pragmatic.'" *Qureshi v. Holder*, 663 F.3d 778, 781 (5th Cir. 2011) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149–50 (1967)).

132. The publication of unqualified and non-tentative statements against using ivermectin to treat COVID-19 constitutes the culmination of the decisionmaking process. The FDA has publicly maintained this position for over a year. 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.

133. Statements with the false imprimatur of authority, intended to stop non-conforming practice and be interpreted by the public as authoritative, have the effect of determining rights and obligations, or otherwise resulting in legal consequences. These statements are regularly relied on to establish the appropriate standard of care and dictate the practice of medicine, including by courts in legal proceedings. Unequivocal statements to "[s]top it" also don't purport to be guidance, but convey a directive to the public.

134. In addition, legally binding effects are not necessary to render an agency action "final" for purposes of judicial review when the action in question is prohibited by statute regardless of such effects. The FDA cannot "limit or interfere with the authority of a health care practitioner to prescribe or administer" drugs approved for human use "for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396. Interfering with the practice of medicine is the action prohibited by the FDCA.

135. The FDA's actions to prohibit or otherwise interfere with the use of ivermectin to treat COVID-19 thus constitute final agency action reviewable under the APA.

136. Agency actions are "arbitrary" or "capricious" under the APA if the agency fails to engage in "reasoned decisionmaking." *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998) (internal quotation omitted).

137. This necessarily means that "[n]ot only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational." *Id.* More specifically, "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

138. The FDA did not provide adequate justification for taking official positions on the use of ivermectin to treat COVID-19, failing to address or respond to *any* of the scientific evidence showing that ivermectin is an effective prophylactic or acute treatment for COVID-19. At one point, the FDA even admitted it was acting without considering the relevant evidence. *See* Ex. 16 ("The FDA has not reviewed data to support use of ivermectin in COVID-19 patients to treat or to prevent COVID-19.").

139. The FDA thus did not engage in reasoned decision making when it acted in a formal, conclusory, and unequivocal manner to prevent or otherwise interfere with the use of ivermectin to treat COVID-19. Those actions are therefore both arbitrary and capricious.

COUNT THREE

(APA Violation: Not in Accordance with Law)

140. The allegations in each of the preceding paragraphs are expressly incorporated herein as if restated in full.

141. Under the APA, courts must "hold unlawful and set aside agency action" that is "not in accordance with law." 5 U.S.C. § 706(2)(A).

142. The FDCA prohibits the FDA from "limit[ing] or interfer[ing] with the authority of a health care practitioner to prescribe or administer" drugs approved for human use. 21 U.S.C. § 396.

143. By directing against the use of ivermectin to treat COVID-19, the FDA has deliberately interfered with the practice of medicine and the authority of health care practitioners to prescribe approved drugs in bona fide practitioner-patient relationships, in violation of the FDCA.

COUNT FOUR

(APA Violation: In Excess of Statutory Authority)

144. The allegations in each of the preceding paragraphs are expressly incorporated herein as if restated in full.

145. Under the APA, courts must "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

146. The FDA has authority to ensure that drugs are "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," 21 U.S.C. § 355(d), to require "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," *id.*, to collect information on adverse events resulting from use of the drug, *id.* § 355(k), to request changes to drug labeling, *id.* § 355(o)(4), to impose risk evaluation and mitigation strategies like mandatory patient monitoring, *id.* § 355-1, to communicate the risks of using approved drugs, *id.* § 360bbb-6, and to withdraw approval of a drug entirely under certain circumstances, *id.* § 355(e).

147. But the FDA cannot limit—directly or indirectly—the off-label use of a drug otherwise approved for human use without specific statutory authority to do so. Congress has not given the FDA that power here.

148. The FDA's lack of general authority to prohibit the off-label use of drugs otherwise approved for human use, such as ivermectin, is reinforced by the agency's explicit power to limit the off-label use of specific drugs like human growth hormone and drugs approved for animal use. *See id.* §§ 333(e), 360b(a)(4)(A).

149. The FDA also cannot give medical advice about how approved drugs should be used off-label without specific statutory authority to do so. Congress has not given the FDA that power, reinforced by an explicit prohibition on "limit[ing] or interfer[ing] with the authority of a health care practitioner to prescribe or administer" drugs approved for human use. *Id.* § 396.

150. If the FDA lacks authority to prohibit or interfere with the off-label use of ivermectin to treat COVID-19, the FDA cannot act with the false imprimatur of its authority to the same effect.

151. The FDA's actions to prohibit or otherwise interfere with the use of ivermectin to treat COVID-19 are thus in excess of its statutory jurisdiction, authority, or limitations.

COUNT FIVE

(Declaratory Judgment)

152. The allegations in each of the preceding paragraphs are expressly incorporated herein as if restated in full.

153. For the same reasons described in each of the previous counts, Plaintiffs are entitled to a declaratory judgment that the Defendants have been and are violating the law.

154. Plaintiffs are further entitled to a declaratory judgment that the FDA cannot interfere with the practice of medicine, that the FDA cannot issue statements about how or whether health professionals should use ivermectin off-label to treat patients, and that such FDA actions have no legal effect and do not bind health professionals or patients.

PRAYER FOR RELIEF

Plaintiffs respectfully request that the Court:

A. Hold unlawful and set aside any FDA actions directing or opining on whether ivermectin should be used for certain off-label purposes, including treatment of COVID-19;

B. Issue declaratory relief declaring such actions of Defendants unlawful;

C. Issue declaratory relief declaring that the FDA cannot interfere with the practice of medicine, that the FDA cannot issue statements or directives about how or whether health professionals should use ivermectin off-label to treat patients, and that such FDA actions have no legal effect and do not bind health professionals or patients.

D. Issue injunctive relief enjoining all Defendants from engaging in such actions;

E. Award reasonable attorney fees and allowable costs, including under the Equal Access to Justice Act; and

F. Grant Plaintiffs such other and further relief to which they are justly entitled at law and in equity.

Dated: June 2, 2022

Respectfully submitted,

/s/ R. Trent McCotter

C. BOYDEN GRAY (*pro hac vice forthcoming*)
R. TRENT MCCOTTER (So. Dist. No. 3712529)
JONATHAN BERRY (*pro hac vice forthcoming*)
MICHAEL BUSCHBACHER (*pro hac vice forthcoming*)
JARED M. KELSON (*pro hac vice forthcoming*)
BOYDEN GRAY & ASSOCIATES
801 17th St. NW, #350
Washington, DC 20006
(202) 706-5488
mccotter@boydengrayassociates.com