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.*

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