PUBLIC VERSION

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

ROBERT L. APTER, *et al.*, Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Case No. 3:22-cv-184 JUDGE JEFFREY V. BROWN

Defendants' Renewed Motion to Dismiss the Amended Complaint

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INTRODUCTION

During the COVID-19 pandemic, the U.S. Food and Drug Administration ("FDA") received multiple reports of patients who required medical attention, including hospitalization, after self-medicating with ivermectin products intended for animals. In response, FDA posted an article on its website explaining that drug products containing ivermectin have been approved for certain uses in humans and that other drug products containing ivermectin have been approved for certain uses in animals, but that they have not been approved or authorized to prevent or treat COVID-19. The article warned consumers that it could be dangerous for humans to use ivermectin to treat COVID-19. FDA tweeted links to the article and communicated similar information through an Instagram post, two FAQ pages on its website, and a letter to two organizations (collectively, the "Statements").

Doctors Robert L. Apter, Mary Talley Bowden, and Paul E. Marik, who prescribed or promoted ivermectin to prevent or treat COVID-19, brought suit to challenge FDA's Statements. They asserted both an *ultra vires* claim and claims under the general provisions of the Administrative Procedure Act ("APA"), but the Fifth Circuit has upheld this Court's dismissal of the latter claims. All that remains in this case is Plaintiffs' claim that the recommendations in the Statements that consumers not use ivermectin to prevent or treat COVID-19 are *ultra vires*.

Plaintiffs lack standing to assert that claim. On the face of the Amended Complaint, Plaintiffs do not plausibly allege personal, concrete injuries that are fairly traceable to any recommendations in the Statements. Plaintiffs' alleged injuries were caused by independent third parties, such as their employers

allegedly forcing them to resign, and do not support standing because the third parties' actions were not a predictable response to any allegedly *ultra vires* elements in the Statements. Furthermore, the Amended Complaint contradicts Plaintiffs' allegation that they were "unable to prescribe" ivermectin, and Plaintiffs cannot show standing based on the vague allegation that FDA interfered with the "practice of medicine" or based on alleged injuries to third parties. Finally, Plaintiffs have not plausibly alleged redressability. A declaration that FDA's recommendations to consumers exceeded the agency's authority would not likely cause sophisticated actors in the healthcare field, such as state medical boards and hospitals, to take any action that would remedy Plaintiffs' alleged injuries.

In addition to their facial challenge, Defendants assert a factual challenge and adduce evidence that confirms Plaintiffs' lack of standing. For example, the evidence shows that [redacted]. The evidence also shows that Bowden and Marik voluntarily resigned their positions and that their resignations were not fairly traceable to the Statements. Finally, the evidence confirms that none of Plaintiffs' alleged injuries, including [redacted] or their voluntary resignations, are likely to be redressed by the requested relief.

BACKGROUND

I. Factual Background

A. FDA's Critical Role in Protecting the Public Health

The Federal Food, Drug, and Cosmetic Act ("FDCA") regulates the manufacturing, labeling, and distribution of drugs in the United States. 21 U.S.C. § 301 *et seq.* Under the FDCA's comprehensive regulatory scheme, it is unlawful to distribute a "new drug" in interstate commerce without FDA approval, which requires the manufacturer to show that the drug is both safe and effective for its intended uses. *Id.* §§ 321(p), 331(d), 355(a), (b). Similarly, the FDCA generally makes it unlawful to distribute a "new animal drug" unless FDA approves it as safe and effective for a particular intended use. *Id.* § 360(b).

Congress charged FDA with protecting the public health and ensuring the safety and effectiveness of medical products. *See* 21 U.S.C. § 393(b)(1), (b)(2)(B). In furtherance of that mission, under its inherent authority and pursuant to various express authorities, the agency communicates with the public, including health care providers and consumers, regarding medical products' safety and efficacy. *See, e.g., id.* § 375(b); 42 U.S.C. § 242*o*; *cf. Shurtleff v. City of Boston*, 142 S. Ct. 1583, 1589 (2022). FDA communicates directly to the public about the safety and effectiveness of medical products through, among other things, the Federal Register, its website, social media, direct mailings, and journals. These communications include Drug Safety Communications, press releases, notices of recalls, articles in scientific journals, YouTube videos, Instagram posts, and tweets regarding safety information about human medical products on @FDAMedWatch. *See*, *e.g.*, https://perma.cc/2Z2F-SK6W (2016 recommendation against the use of lidocaine to treat teething pain); https://perma.cc/VH86-

UYZ6 (2017 safety communication warning of risks of a certain drug combination).

FDA's longstanding position is that, in general, the agency does not regulate the practice of medicine, meaning that with certain limited exceptions, health-care professionals may choose to prescribe or use a legally marketed human drug for an unapproved use (sometimes referred to as "off-label" use) when they judge that the unapproved use is medically appropriate for an individual patient.[1]

B. The Approved Uses of Ivermectin and FDA's Statements Regarding the Use of Ivermectin to Prevent or Treat COVID-19

Drug products containing ivermectin as the active ingredient are approved to treat parasites and certain skin conditions in humans. Am. Compl. ¶ 74. FDA has also approved different drug products containing ivermectin to treat certain parasites in various animal species and to prevent heartworm disease in some small animal species, with dosages and formulations that vary based on the species and the condition to be treated.[2] *See, e.g.*, Ex. 2 at 2.[3]

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[1] In certain circumstances, FDA imposes restrictions on prescribing approved drugs. *See, e.g.*, 21 U.S.C. § 355-1 (authorizing FDA to require formal plans for certain drugs to help ensure that those drugs' benefits outweigh their risks).

[2] *See, e.g.*, Am. Compl. ¶ 75 (citing Zimecterin Gold, which is approved for use in horses). The labeling for Zimecterin Gold warns that the product is "[n]ot for use in humans" and "should not be used in other animal species" because "severe adverse reactions," including death, could result. https://go.usa.gov/xSM8F.

[3] Citations to numbered exhibits refer to the exhibits to the Amended Complaint. Unless otherwise indicated, cited page numbers refer to the page numbers assigned by CM-ECF.

During the COVID-19 pandemic, FDA received multiple reports of patients who required medical attention, including hospitalization, after self-medicating with ivermectin products intended for animals. Exs. 1 at 3; 19 at 2. In response, FDA made public statements warning consumers about the risks of using ivermectin to prevent or treat COVID-19. The Amended Complaint identifies seven Statements: an article and two FAQs posted on FDA's website, Exs. 1–3, 19; two tweets linking to the article, Exs. 4, 7; an Instagram post, Ex. 6; and a letter to two organizations, Ex. 22. *See* Am. Compl. ¶ 4. None of the Statements recommended or instructed doctors not to prescribe ivermectin products to prevent or treat COVID-19 or pharmacies not to fill prescriptions for ivermectin.

The article, titled "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," was first posted on March 5, 2021. Ex. 19. It was directed to consumers. *See id.* at 3 ("Never use medications intended for animals on yourself."). It noted the "growing interest" in using ivermectin to treat COVID-19 but that FDA "ha[d] not reviewed data to support [this] use of ivermectin" and "ha[d] not approved ivermectin" for this use. *Id.* at 2. It warned that using a COVID-19 treatment that is "not approved or authorized by the FDA, unless part of a clinical trial, can cause serious harm." *Id.* It explained that ivermectin could be dangerous if, for example, it "interact[s] with other medications," and advised 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." *Id.* at 3.

That version of the article was replaced on September 7, 2021, with a version that removed the statement that FDA had not yet "reviewed data to support [the] use of ivermectin" to prevent or treat COVID-19 and instead emphasized that

FDA has not approved ivermectin to prevent or treat COVID-19 or granted emergency use authorization for that use. Ex. 1 at 2. The article advised, "If 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." *Id.* at 3 (emphasis in original). And the article recommended: "Talk to your health care provider about available COVID-19 vaccines and treatment options. *Your provider can help determine the best option for you*, based on your health history." *Id.* at 4 (emphasis added).

FDA publicized its article on Twitter with tweets linking to the article. For example, an August 21, 2021 tweet stated, "You are not a horse. You are not a cow. Seriously, y'all. Stop it," Ex. 4 at 2, and an April 26, 2022 tweet stated, "Hold your horses, y'all. Ivermectin may be trending, but it still isn't authorized or approved to treat COVID-19," Ex. 7 at 2. Similarly, on August 21, 2021, FDA posted on Instagram an image of a horse with the caption: "You are not a horse. Stop it with the #Ivermectin. It's not authorized for treating #COVID." Ex. 6 at 2.

On April 10, 2020, FDA posted an FAQ on its website titled "FAQ: COVID-19 and Ivermectin Intended for Animals." Ex. 2. The FAQ was directed to consumers. *See id.* at 2 (answering the question, "Should I take ivermectin to prevent or treat COVID-19?"). The FAQ explained that "there are approved uses for ivermectin in people and animals, but it is not approved for the prevention or treatment of COVID-19." *Id.* It added that "[a]ny use of ivermectin for the prevention or treatment of COVID-19 should be avoided as its benefits and safety for these purposes have not been established. Data from clinical trials are necessary for us to determine whether ivermectin is safe and effective in treating

or preventing COVID-19." *Id.* The FAQ noted that although "[a] recently released research article described the effect of ivermectin on SARS-CoV-2 in a laboratory setting . . . [a]dditional testing [was] needed to determine whether ivermectin might be appropriate to prevent or treat [COVID-19]." *Id.* (citations omitted). Nonetheless, the FAQ recognized that doctors may choose to prescribe ivermectin products approved for human use to prevent or treat COVID-19, and it advised consumers "not [to] 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.* (emphasis added). A similar consumer-directed FAQ webpage also advised against taking ivermectin "for the prevention or treatment of COVID-19," explaining that it was not "approved or authorized" for those uses, and included a link to the cited FDA article on that topic. Ex. 3 at 2.

In December 2021, FDA sent a letter to the Federation of State Medical Boards and the National Association of Boards of Pharmacy based on FDA's receipt of "complaints about compounding pharmacies selling drug products containing ivermectin, *claiming that they can treat or prevent COVID-19*." Ex. 22 at 2 (emphasis added). The letter explained that although clinical trials were "ongoing," the "currently available data [did] not show" that the drug is "safe or effective" for that use. *Id.* The letter concluded that using ivermectin to prevent or treat COVID-19 "may pose risks to patient health" and that products claiming to be safe and effective for that purpose when they have not been shown to be "can place consumers at risk of serious harm." *Id.*

C. The Plaintiffs

1. Apter

Dr. Apter, who is licensed to practice in Arizona and Washington and sees patients through myfreedoctor.com, "ha[s] frequently prescribed ivermectin" to his patients to prevent or treat COVID-19. Ex. 8 ¶¶ 2, 6; *see* Am. Compl. ¶ 13. Apter alleges that he has been "referred" to the Arizona Medical Board and the Washington Medical Commission "for disciplinary proceedings for prescribing ivermectin to treat COVID-19." Ex. 8 ¶ 18; *see* Am. Compl. ¶ 18.

[redacted]

In September 2021, a pharmacist filed a complaint with the Washington Medical Commission after a follow-up about one of Apter's ivermectin

prescriptions. When the pharmacist asked Apter about his patient's diagnosis, Apter allegedly "responded 'for scabies,' without asking for/verifying the patient information." Ex. B at 4. When the pharmacist "asked him to verify the diagnosis per his medical records, he claimed that he was unable to find this patient in his medical record system." *Id.* Apter "did not appear to have any recollection of the patient and was unable to locate any documentation supporting an appropriate diagnosis or valid doctor-patient relationship." *Id.*

The Washington Medical Commission subsequently issued a Statement of Charges that alleged that Apter "failed to meet the standard of care in his treatment of" his patients in several respects, none of which related to FDA's "recommendations" in the Statements. Ex. C at 5. For example, the Commission alleged that Apter prescribed medication based "solely on an online questionnaire and online chat" without "establish[ing] a physician-patient relationship," "failed to provide or obtain adequate informed consent to [patients] when prescribing an off-label medication or prior to conducting the visits via telemedicine," "failed to discuss with [patients] the use of vaccines or other methods to prevent a COVID-19 infection," "failed to adequately evaluate" patients when they reported symptoms, and "misrepresented to pharmacy staff" the purpose of his prescriptions. *Id.* at 6. The Statement of Charges also alleged, for example, that Apter failed to meet the standard of care when he prescribed a medication (not ivermectin) and issued mask and vaccine exemptions. *Id.* at 16, 19, 22–23. [redacted]

2. Bowden

Dr. Bowden is a Texas physician and the owner of BreatheMD, a medical practice where she treats patients with COVID-19, including by prescribing ivermectin. Ex. 9 ¶¶ 2, 8, 14. She had privileges at Houston Methodist Hospital but alleges that those privileges were suspended, after which she "voluntarily resigned on November 15, 2021. *Id.* ¶ 7.

The available evidence shows that, in April 2021, Houston Methodist required all medical staff to be vaccinated against COVID-19. Ex. E. Bowden attested to the hospital that she had received the COVID-19 vaccine or planned to receive it no later than June 7, 2021, Ex. F, but ultimately "decide[d] not to get" the COVID-19 vaccine. Ex. G at 42. In her words, Bowden "became an opponent of" both "vaccine mandates" and "the vaccines themselves," and she "began sharing [her] opinions on Twitter, including [her] view that vaccine mandates are 'wrong.'" *Id.* at 31.

On November 11, 2021, Houston Methodist asked Bowden to provide proof of vaccination status within seven days, noting that her recent statements on social media "raise[d] questions" about her "compliance with the vaccination requirement." Ex. H. The letter explained that failure to comply with the immunization requirement could "result in automatic relinquishment of clinical privileges." *Id.* The letter also addressed Bowden's social media activity and reminded Bowden that she had agreed to meet the institution's standards of professional conduct, and that "public use of vulgar, offensive and abusive language directed at others" contradicted those standards. *Id.*; *see* Ex. I (November 7, 2021 tweet: "C*nt? B*tch?").

According to a complaint filed by the Texas Medical Board, the next day the hospital sent Bowden another letter noting that she had behaved in an "unprofessional and inappropriate" manner to a hospital Department Chair and advising that the hospital's medical executive committee "was beginning an investigation and implementing a precautionary suspension of her privileges for no longer than 30 days." Ex. J at 7–8. The hospital's CEO told the press that she had been suspended for "inappropriate behavior," including "using vulgar and foul language while expressing her opinions." Ex. R at 4.

Bowden resigned on November 15, 2021, explaining that she did so voluntarily, Ex. 9 at 2, and saying in a resignation letter that she "decided to part ways with Houston Methodist because of the accusation that [she] ha[d] been spreading 'dangerous misinformation.'" Ex. K. Bowden subsequently filed a defamation suit against the hospital and its CEO alleging that they published intentionally false statements about her, that their conduct was motivated by "bias and prejudice," and that her reputation had been "severely compromised" as a "direct result" of the alleged defamation. Ex. L ¶¶ 11, 25(d), 26, 31.

On November 20, 2021, Bowden wrote a message to her patients about her relationship with other medical institutions. Ex. G at 47. Another hospital had denied her request for privileges, and a surgery center told her that she could not continue operating at the facility unless she provided proof that she had been vaccinated, which was "not going to work for" her. *Id.* She announced that she was "shifting [her] practice focus to treating the unvaccinated." *Id.*

3. Marik

Dr. Marik was a professor at Eastern Virginia Medical School (EVMS) and Director of the Intensive Care Unit at Sentara Norfolk General Hospital (Sentara). Ex. 10 at 3. His medical license expired in June 2021. *Id.* at 10. He does not allege that he ever prescribed a patient ivermectin to prevent or treat COVID-19 or that his employers prohibited him from promoting ivermectin for that use.

Marik alleges that he developed a "protocol" for treating COVID-19 that included ivermectin, *id.* at 3, and that EVMS directed him to remove the protocol from its servers and refrain from discussing it publicly after FDA's August 21, 2021 tweet. Am. Compl. ¶ 40. Notably, a paper Marik published about the protocol in the Journal of Intensive Care Medicine was retracted in November 2021 after Sentara notified the journal that "[t]he data from Sentara . . . reported in th[e] paper are inaccurate." Ex. M.

On September 27, 2021 Sentara decided to add ivermectin and five other drugs to the "do not endorse" section of its treatment guidelines for treatment of COVID-19, meaning that those medications would not be "verified or dispensed" for that use at the hospital. Ex. 12 at 3, 6. Marik alleges that Sentara's treatment guidelines harmed his ability to practice medicine. Am. Compl. ¶¶ 40–42. He states that he was "forced to resign from his positions at EVMS and Sentara . . . 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.* ¶ 42.

The available evidence shows that Sentara initially allowed ivermectin to be used to treat COVID-19 at the hospital, and eight patients received the drug for

that purpose. Ex. N[4] at 129–30. Sentara's decision to add ivermectin to the "do not endorse" section of the guidelines was based "primarily" on "clinical trials." *Id.* at 133. The hospital noted that many "professional societies across the United States, including the Infectious Disease Society of America," called for medical professionals to stop prescribing ivermectin to treat COVID-19. *Id.* at 135. For example, the hospital knew that the American Medical Association (AMA), the American Society of Health-System Pharmacists (ASHP), and the American Pharmacists Association (APhA) called for an "immediate end" to that use in a joint statement. *Id.* That statement expressed "alarm" over "reports that outpatient prescribing for and dispensing of ivermectin ha[d] increased . . . exponentially over the past few months." Ex. 25 at 2. It further observed that "[t]he National Institutes of Health, World Health Organization, and Merck (the manufacturer of the drug) all state there is insufficient evidence to support the use of ivermectin to treat COVID-19." *Id.* at 3. It added that "[c]alls to poison control centers due to ivermectin ingestion have increased five-fold from their pre-pandemic baseline," and that the drug had "potentially toxic effects, including nausea, vomiting, and diarrhea." *Id.* "For more information," the statement "encouraged" the reader to "consult" FDA's article, "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" and a CDC Health Alert. *Id.* Even under Sentara's guidelines, Marik was not prohibited from writing a prescription for ivermectin to treat COVID-19 outside the hospital or informing

[4] Citations to Exhibit N are to the page numbers of the transcript, not the sheet of the condensed transcript or to the page numbers assigned by ECF.

patients about the treatment and encouraging them to seek it elsewhere. Ex. N at 122, 138.

Ultimately, Marik "felt it was time to focus [his] attention and energy to other interests" and "resigned," which was "not an easy decision to make." Ex. O. He planned to "dedicate more time to multiple causes," including serving as "co-founder of the Front Line COVID-19 Critical Care Alliance (FLCCC)." *Id.* Marik and the FLCCC continued to promote Marik's "Hospital Treatment Protocol for COVID-19," which included ivermectin. Ex. P.

II. Procedural History

A. Plaintiffs' Amended Complaint

Plaintiffs filed their Amended Complaint on August 8, 2022. Count One alleges an *ultra vires* claim for "non-statutory review," which requires Plaintiffs to show that FDA "was acting without any authority whatever, or without any colorable basis for the exercise of authority" when it made the Statements. *Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 587–88 (5th Cir. 2023) (quotations omitted); *see* Am Compl. ¶¶ 129–31. Count Five seeks a declaratory judgment on the same ground. Am. Compl. at ¶¶ 157–59. The other counts have been dismissed, as described below.

B. Prior Proceedings

In December 2022, this Court granted Defendants' motion to dismiss the Amended Complaint on sovereign-immunity grounds. *Apter v. U.S. Dep't of Health & Hum. Servs.*, 644 F. Supp. 3d 361, 372 (S.D. Tex. 2022). Specifically, the Court ruled that the Administrative Procedure Act's ("APA") waiver of sovereign immunity did not apply because Plaintiffs did not challenge final

agency action. *Id.* at 370. It further held that Plaintiffs could not proceed under the *ultra vires* doctrine, as "distinct" from the APA, because FDA had not acted outside of a statutory limitation on its power and had "at least a colorable basis in authority" to make the Statements. *Id.* at 368–69.

On appeal, the Fifth Circuit agreed that the Statements are not final agency action because they did not "plausibly determine[] 'rights or obligations,'" nor did they "plausibly constitute[] action 'from which legal consequences will flow.'" *Apter*, 80 F.4th at 594 (quoting *Data Marketing P'ship, LP v. U.S. Dep't of Labor*, 45 F.4th 846, 853 (5th Cir. 2022)). Thus, Plaintiffs are "bar[red]" from proceeding solely under the APA. *Id.* at 587. However, the Fifth Circuit held that Plaintiffs could "use the APA to assert their *ultra vires* claim[]." *Id.* at 595. On the one hand, the court explained that "FDA cites plenty of statutory authority allowing it to issue *information*," and it noted Plaintiffs' agreement that "FDA has statutory authority to share data, facts, and knowledge." *Id.* at 588–89. On the other hand, the court concluded that "mak[ing] medical *recommendations*" might exceed the agency's statutory authority. *Id.* at 589.

The Court of Appeals remanded and expressed "no view" on whether Plaintiffs have standing, entrusting the "initial determination" of that issue to this Court's "sound judgment." *Apter*, 80 F.4th at 595. This Court then authorized Defendants to file a renewed motion to dismiss. ECF No. 55.

LEGAL STANDARDS

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) challenges a court's subject-matter jurisdiction. Subject-matter jurisdiction, including standing, must "be established as a threshold matter." *Steel Co. v.*

Citizens for a Better Env't, 523 U.S. 83, 94–95 (1998). The Court is "presume[d]" to "lack jurisdiction" unless Plaintiffs meet their "burden of establishing it." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (quotations omitted). Challenges to subject-matter jurisdiction must be resolved "prior to addressing the merits." *Alabama-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484, 487 (5th Cir. 2014).

"A motion to dismiss for lack of standing may be either 'facial' or 'factual.'" *Superior MRI Servs., Inc. v. All. Healthcare Servs., Inc.*, 778 F.3d 502, 504 (5th Cir. 2015) (quoting *Paterson v. Weinberger*, 644 F.2d 521, 523 (5th Cir. 1981)). In a "facial" motion, the allegations in a complaint "are presumed to be true." *Paterson*, 644 F.2d at 523. Under a "factual" challenge, the defendant "submits affidavits, testimony, or other evidentiary materials." *Id.* A plaintiff then "must prove the existence of subject-matter jurisdiction by a preponderance of the evidence" and is "obliged to submit facts through some evidentiary method to sustain his burden of proof." *Id.* (quotations omitted). In a factual challenge, "no presumptive truthfulness attaches to the [plaintiff's] jurisdictional allegations, and the court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." *Evans v. Tubbe*, 657 F.2d 661, 663 (5th Cir. 1981).

ARGUMENT

The Amended Complaint should be dismissed for lack of subject-matter jurisdiction because Plaintiffs have failed to establish standing. To show Article III standing, Plaintiffs "must clearly allege facts demonstrating each element" of standing, *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (cleaned up): (1) an injury in fact that is "concrete, particularized, and actual or imminent"; (2) "fairly

traceable to the challenged action"; and (3) likely "redressable by a favorable ruling," *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). Plaintiffs "must demonstrate standing for each claim . . . and for each form of relief." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2208 (2021). "To request prospective injunctive or declaratory relief," a litigant cannot rely on "allegations of past harm," but "must demonstrate continuing harm or a real and immediate threat of repeated injury in the future." *James v. Hegar*, 86 F.4th 1076, 1081 (5th Cir. 2023) (quotations omitted). "The threat of future injury must be *certainly* impending; mere allegations of possible future injury will not suffice." *Id.* (quotations omitted).

Because the Fifth Circuit affirmed the dismissal of Plaintiffs' APA claims and narrowed this case to Plaintiffs' *ultra vires* claim, Plaintiffs must now show a cognizable injury that is fairly traceable to any recommendations in the Statements and that would likely be redressed by the relief sought. *See Clapper*, 568 U.S. at 409; Am. Compl. ¶¶ 131, 158–59. Under either a facial or a factual challenge, they cannot.

First, Plaintiffs cannot show standing based on alleged injuries caused by independent third-party conduct, such as third parties' referring Apter for disciplinary proceedings or third-party hospitals' "forcing" Bowden and Marik to resign. ***Second***, the Amended Complaint itself, as well as external evidence, refutes Plaintiffs' allegation that they were unable to prescribe ivermectin to prevent or treat COVID-19. ***Third***, Plaintiffs' abstract allegation that FDA interfered with their practice of medicine does not show a concrete, particularized injury to Plaintiffs, and Plaintiffs have not shown that they can assert alleged injuries to third parties such as their patients. ***Finally***, none of

Plaintiffs' alleged injuries are likely to be redressed by the relief they seek.

I. Alleged Injuries Caused By Independent Third Parties Do Not Support Plaintiffs' Standing

A. Plaintiffs' Allegations Are Facially Deficient

Taken at face value, Plaintiffs' allegations of injury caused by independent third parties do not plausibly show standing. Specifically, Apter alleges that unnamed third parties referred him to state medical boards for disciplinary proceedings. Am. Compl. ¶ 18. Bowden alleges that she was derided by Houston Methodist Hospital, "publicly ridiculed," and forced to resign her privileges at the hospital, *id.* ¶ 21, and that patients have delayed seeking treatment from her, *id.* ¶ 29. Finally, Marik alleges that he was forced to resign his employment at EVMS and its associated hospital, Sentara, *id.* ¶ 42.

As an initial matter, Apter's allegations do not show a concrete injury: he does not allege that he has been disciplined and merely "[h]aving to defend oneself in a legal proceeding ordinarily does not give rise to a redressable injury." *Simic v. City of Chi.*, 851 F.3d 734, 739–40 (7th Cir. 2017). [redacted] and does not allege any deprivation of due process. Bowden's allegations are facially deficient because her decision to "voluntarily resign[]" from Houston Methodist Hospital, Ex. 9 ¶ 7, was "a self-inflicted injury," *Ctr. for Biological Diversity v. EPA*, 937 F.3d 533, 541 (5th Cir. 2019). Moreover, she does not allege that the hospital's actions were attributable to FDA's Statements. *See* Am. Compl. ¶ 21.

More generally, all three Plaintiffs' alleged injuries were caused by "the decision[s] of . . . independent third part[ies]." *Daves v. Dallas Cnty.*, 22 F.4th 522, 543 (5th Cir. 2022) (en banc) (quoting *California v. Texas*, 141 S. Ct. 2104, 2117

(2021)). The third parties' actions were undoubtedly "independent": Plaintiffs have not plausibly alleged that FDA's Statements had any "determinative or coercive effect" on the third parties, such as the hospitals where plaintiffs worked, *Bennett v. Spear*, 520 U.S. 154, 169 (1997), and the Fifth Circuit held that the Statements did not establish a "legal standard," "plausibly determine[] 'rights or obligations,'" or "plausibly constitute[] action 'from which legal consequences will flow.'" *Apter*, 80 F.4th at 594 (quoting *Data Marketing P'ship*, 45 F.4th at 853); *see also Physicians for Integrity in Med. Rsch., Inc. v. Ostroff*, 670 F. App'x 450, 451 (9th Cir. 2016) ("Patients who choose to stop seeing Dr. Desai as a result of Dr. Desai's comments regarding roflumilast, or who end up finding him less reputable, are making an independent choice unrelated to the FDA's actions.").

Standing is "substantially more difficult" for Plaintiffs to establish, since the Statements "neither require nor forbid any action" on their part. *Summers v. Earth Island Inst.*, 555 U.S. 488, 493–94 (2009). In this context, Plaintiffs must offer more than "speculation" about the third parties' decisions. *Daves*, 22 F.4th at 543 (quoting *Clapper*, 568 U.S. at 414). Instead, they must show that the third parties' actions were a "predictable" response to any recommendations in the Statements. *Id.* (quoting *California*, 141 S. Ct. at 2117).

Even on the face of the Amended Complaint, Plaintiffs have not met that burden. The Statements generally recommended to *consumers* (who can purchase the ivermectin product for horses over-the-counter) that they should not take ivermectin to prevent or treat COVID-19 and did not proclaim that *doctors* may not (or even should not) prescribe human-use ivermectin to prevent or treat

COVID-19. Moreover, the September 2021 article and the April 2020 FAQ expressly recognized that doctors have discretion to prescribe ivermectin. For example, the statements advised 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." Ex. 1 at 3; *see also* Ex. 2 at 2.[5] The article likewise recommended that patients talk to their doctors to determine their best treatment options. Ex. 1 at 2. Thus, assuming the third parties that allegedly injured Plaintiffs read the FDA's Statements, they would likely have concluded that FDA expressed concern about the risks, but that doctors have discretion to prescribe ivermectin for COVID-19. Moreover, it is implausible that the sophisticated actors in the health-care field that allegedly injured plaintiffs, such as hospitals and state medical boards, base their decisions on FDA's recommendations to consumers in the Statements. Thus, the independent, third-party decisions that allegedly injured Plaintiffs were not a "predictable" response to any recommendations in the Statements, *Daves*, 22 F.4th at 543 (quoting *California*, 141 S. Ct. at 2117), and only through impermissible "speculation" could their decisions be attributed to those Statements, *id.* (quoting *Clapper*, 568 U.S. at 414).

B. The Available Evidence Confirms that Plaintiffs Lack Standing

Defendants also assert a factual challenge to Plaintiffs' standing. In a factual challenge, Plaintiffs' jurisdictional allegations lose their presumption of

[5] The cited tweets included links to the article. *See* Ex. 4; Ex. 7; Am. Compl. ¶¶ 92, 100. Although the March 2021 version of this article stated that patients should use ivermectin if it was prescribed "for an FDA-approved use," Ex. 19 at 3, that text was removed when the article was updated in September 2021, and Plaintiffs do not allege that any of the third-party conduct that allegedly injured them was caused by the earlier version of the article.

truthfulness and can be tested against the evidence, and the available evidence confirms that Plaintiffs lack standing.

Even assuming that being referred to state medical boards is a cognizable injury in fact, [redacted] The complaint initiating the Washington Medical Commission proceeding alleged that, during a pharmacist's follow-up call with Apter about one of his ivermectin prescriptions, Apter did not ask for any identifying patient information before telling the pharmacist the medication was prescribed "for scabies." Ex. B at 4. Apter allegedly "claimed that he was unable to find this patient in his medical record system," and "did not appear to have any recollection of the patient and was unable to locate any documentation supporting an appropriate diagnosis or valid doctor-patient relationship." *Id.*

As discussed above, Bowden's decision to "voluntarily resign[]" from Houston Methodist Hospital, Ex. 9 ¶ 7, was "a self-inflicted injury" that does not support standing. *Ctr. for Biological Diversity*, 937 F.3d at 541; *supra* p. 18. The available evidence confirms that her resignation is not fairly traceable to the Statements. According to Bowden, she resigned because of the hospital's independent decision to accuse her of spreading "dangerous misinformation." Ex. K. But the Texas Medical Board alleged that the hospital suspended her privileges after she allegedly was "unprofessional and inappropriate" to a

hospital Department Chair, Ex. J at 6–7, and the hospital's CEO stated that the suspension was for, among other things, "using vulgar and foul language," Ex. R at 4. Bowden later explained that she resigned her privileges because she had decided to "shift[]" her "practice focus to treating the unvaccinated." Ex. G at 47. Neither Bowden's stated reason for resigning nor her suspension were based on the Statements.

Finally, Marik claims he was "forced to resign" his employment because he "promot[ed]" ivermectin and other FDA-approved drugs to treat COVID-19, Am. Compl. ¶ 42, but his organization, the FLCCC, announced that he resigned "to dedicate more time to multiple causes" because he "felt it was time to focus [his] attention and energy" on "other interests," such as his role in the FLCCC. Ex. O. As with Bowden, Marik's decision to resign was "a self-inflicted injury" that does not support standing. *Ctr. for Biological Diversity*, 937 F.3d at 541. To the extent Marik's claimed injuries are allegedly related to his promotion of ivermectin at all, they at most were based on the independent decision of Sentara to update its "COVID-19 Comprehensive Treatment Guidelines" (v.26) — to not endorse (i.e., "not verif[y] or dispense[]") ivermectin for treatment of COVID-19 in its hospitals. Ex. 12 at 6. Sentara's independence in that regard is obvious, as it cited how the "[c]oncentrations" of ivermectin that would "inhibit" the virus "would be difficult to achieve in humans" and would be "extremely toxic"—something not found in FDA's Statements—and noted the absence of information from a randomized controlled trial that might support its use. *Id.*; *see also* Ex. N at 133 (Sentara "primarily" looked at clinical trials when making its decision). But, in any event, Sentara did not prohibit doctors from prescribing

ivermectin to prevent or treat COVID-19 outside its hospitals or from encouraging their patients to use ivermectin for that purpose. *Id.* at 122, 138. Thus, the evidence does not support Marik's allegation that he was "forced to resign" his employment because he "promot[ed]" ivermectin, Am. Compl. ¶ 42, let alone his claim that his alleged injury was fairly traceable to FDA's Statements.

II. Plaintiffs Continue to Prescribe and Promote Ivermectin to Prevent or Treat COVID-19

Plaintiffs allege that they have been "unable to prescribe" ivermectin due to FDA's Statements, Am. Compl. ¶ 121, but this allegation "is contradicted by the other facts alleged in the complaint" and is therefore "implausible on its face." *Mora v. Univ. of Tex. Sw. Med. Ctr.*, 469 F. App'x 295, 299 (5th Cir. 2012). The Amended Complaint alleges that Apter "has frequently prescribed ivermectin" to his patients, Am. Compl. ¶ 13, and he does not claim that myfreedoctor.com, through which he has seen over 6,000 patients related to COVID-19, has prevented him from prescribing ivermectin, *see* Ex. 8 ¶ 6. The Amended Complaint likewise alleges that Bowden, who owns her own clinic, BreatheMD, "prescribes ivermectin to treat COVID-19." Am. Compl. ¶¶ 22, 26; *see also* https://perma.cc/AAU4-ZBC (BreatheMD blog entry); *see generally* Ex. Q.

As for Marik, he only alleges that his resignation was related to his promotion of ivermectin to treat COVID-19 and does not allege that he was ever unable to prescribe it to treat COVID-19. Am. Compl. ¶¶ 38–43. Like the other Plaintiffs, Marik has continued to promote the use of ivermectin to treat COVID-19 after resigning his employment. *See*, *e.g.*, Ex. P. The fact Marik has not prescribed ivermectin in recent years is readily explained: his Virginia medical

license expired in June 2021, and he does not have active licenses in other states. Ex. 10 at 10. His lack of a valid credential (not FDA's Statements) is what prevents him from prescribing ivermectin in the future.

III. Plaintiffs' Assertions Regarding "Interference" With Their Practice of Medicine Do Not Support Standing

Plaintiffs also allege that FDA's Statements "interfered with [their] ability to exercise professional judgment in practicing medicine." Am. Compl. ¶¶ 14, 24, 42, 121. This vague and conclusory assertion does not adequately allege a concrete injury. *See Spokeo*, 578 U.S. at 338; *Clapper*, 568 U.S. at 409.

Plaintiffs' more specific allegations fare no better. Plaintiffs allege that FDA's Statements have caused their patients to be unable to fill prescriptions for ivermectin, Am. Compl. ¶ 15; have caused patients to delay seeking treatment from Bowden, *id.* ¶ 29; and that those circumstances have caused hospitalizations and deaths, which causes the patients, patients' families, and healthcare providers to suffer distress, *id.* ¶ 43. But these alleged injuries to third parties do not satisfy the requirement of "personal injury" to Plaintiffs. *California*, 141 S. Ct. at 2113 (quotations omitted). Courts "have adhered to the rule that a party generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004) (quotations omitted); *see Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 544 (6th Cir. 2021) (observing in dicta that plaintiff "has not identified a harm to *physicians* merely because the drug may not be available to *patients*"). Contrary to Plaintiffs' allegation, no general rule of standing allows physicians to "invoke the rights of their actual or potential patients." Am. Compl. ¶ 125.

Courts recognize "certain, limited exceptions" to the rule against asserting third parties' interests. *Powers v. Ohio*, 499 U.S. 400, 410–11 (1991). But to avail themselves of an exception, Plaintiffs must first establish the Court's jurisdiction through their own standing. *Ward v. Santa Fe Indep. Sch. Dist.*, 393 F.3d 599, 606 (5th Cir. 2004). As discussed herein, Plaintiffs cannot meet those fundamental prerequisites, so they cannot invoke the interests of third parties.

Regardless, Plaintiffs also cannot meet the "important criteria" for invoking the interests of third parties: "some hindrance to the third party's ability to protect his or her own interests" and "a close relation to the third party." *Powers*, 499 U.S. at 410–11 (citations omitted). Most glaringly, Plaintiffs have not shown any "hindrance to the third part[ies'] ability to protect [their] own interests." *Id.*; *see Kowalski*, 543 U.S. at 128–30. For example, Plaintiffs have not shown why patients whose pharmacists allegedly refused to fill their ivermectin prescriptions cannot seek legal recourse themselves. *See AIDS Healthcare Found., Inc. v. City of Baton Rouge/Par. of E. Baton Rouge*, No. 17-cv-229, 2017 WL 2899689, at *4 (M.D. La. July 7, 2017) (medical clinic "failed to demonstrate that it has standing to rely on alleged injuries sustained by its patients" because "there is no indication that [those patients] are unable or unwilling to bring claims on their own behalves"). Moreover, as commenters on Bowden's website confirmed, patients are able to get their ivermectin prescriptions filled and do not have to seek legal recourse. *See* https://perma.cc/AAU4-ZBC. Furthermore, Plaintiffs have not shown the requisite "close relation to the third part[ies]." *Powers*, 499 U.S. at 410–11; *see Kowalski*, 543 U.S. at 128–30.

Finally, the Supreme Court has recognized that plaintiffs may have standing

to assert the rights of third parties if "enforcement of the challenged restriction against the litigant would result indirectly in the violation of third parties' rights." *Kowalski*, 543 U.S. at 130 (cleaned up). But here, FDA's Statements imposed no restrictions on anyone. As the Court of Appeals recognized, they did not establish a "legal standard" and were not actions "by which rights or obligations have been determined, or from which legal consequences will flow." *Apter*, 80 F.4th at 594–95 (quotation omitted).

IV. Plaintiffs' Injuries Are Not Likely to Be Redressed by the Requested Relief

Even if the Court granted Plaintiffs' requested relief, that would not likely redress their injuries. *Spokeo*, 578 U.S. at 338; *see El Paso Cnty. v. Trump*, 982 F.3d 332, 341 (5th Cir. 2020). Plaintiffs' sole surviving claim seeks, *inter alia*, a declaration that FDA did not have authority to make the recommendations in the Statements and an injunction prohibiting FDA from issuing such recommendations. Am. Compl. pp. 43–44. But these remedies would not "redress [Plaintiffs'] particular injur[ies]." *Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018) (quoting *DaimlerChrysler*, 547 U.S. at 353).

Plaintiffs argue that, if the Statements are vacated, "[h]ealth professionals and state regulatory boards" will "revert to [the] norm" of "support[ing] the off-label prescription of approved drugs." Am. Compl. ¶ 124. But the question is not whether the third parties will "support[] the off-label prescription of approved drugs" generally, but instead whether they will likely reverse their actions that allegedly harmed Plaintiffs. It is purely speculative to assert that a ruling that the "recommendations" in the Statements were *ultra vires* would likely cause the independent third parties who allegedly took actions that injured Plaintiffs to

reverse those actions. It is far more likely that the relevant third-party actions would be "held in place by other forces," namely those third parties' independent scientific knowledge about the therapeutic risks and benefits of using ivermectin to prevent or treat COVID-19, even if the Court granted the requested relief. *Renal Physicians Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 489 F.3d 1267, 1278 (D.C. Cir. 2007) (no redressability even if governmental action is a "contributing factor in bringing about a specific harm"). For example, Sentara has made clear that it will not change its position on using ivermectin to prevent or treat COVID-19 "until further studies" show that it is "safe and effective." Ex. 12 at 5.

This third-party knowledge is based on scientific assessments from yet more independent third parties. For example, Merck, the sponsor of Stromectol® (ivermectin), issued a statement on February 4, 2021—more than a month before FDA's article was first published—that advised against using ivermectin to prevent or treat COVID-19.[6] Many entities, such as the World Health Organization,[7] have issued similar advisories. *See, e.g.*, Ex. 12 at 6 (noting that recommendations had been issued by "[s]everal organizations, including" the AMA, the ASHP, the Centers for Disease Control and Prevention, FDA, and Merck); Ex. 25 (joint statement of the AMA, APhA, and ASHP, citing statements by CDC, FDA, the National Institutes of Health, the World Health Organization, Merck, and the Infectious Diseases Society of America); Am. Compl. ¶¶ 102–08. Plaintiffs provide no reason why these scientific organizations would retract

[6] *See* https://perma.cc/CEK9-FPAR.

[7] *See* https://perma.cc/4R9K-WCZN.

their statements if the Court were to hold that the portions of the cited FDA statements making recommendations to consumers exceeded FDA's legal authority (particularly while leaving intact the portions of FDA's Statements providing scientific and factual information).[8] Thus, it is, at best, "speculative" whether the requested relief would redress Plaintiffs' alleged injuries. *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 43 (1976); *see Dep't of Educ. v. Brown*, 143 S. Ct. 2343, 2353 (2023) (injury is not "redressable when the prospect of redress turns on" a party's "wholly discretionary decision"); *El Paso Cnty.*, 982 F.3d at 341–42.

For similar reasons, even if Plaintiffs could assert their patients' interests, Plaintiffs' allegation that "patients will no longer be caught between" the Statements and "Plaintiffs' advice," Am. Compl. ¶ 124, does not show redressability. Even if FDA's recommendations to consumers were vacated, the factual information FDA provided would remain, as would the recommendations and information provided by Merck and many medical and public health organizations. Moreover, to the extent pharmacies are declining to fill prescriptions for ivermectin to prevent or treat COVID-19, the requested relief would not likely redress the patients' alleged injuries because it would not change pharmacists' knowledge about the risks and benefits of that use.

Plaintiffs also argue that their "professional judgment would no longer be subject to pressure from the FDA." Am. Compl. ¶ 124. But Apter and Bowden have continued to prescribe ivermectin to prevent or treat COVID-19 and Marik has continued to promote ivermectin to treat COVID-19 despite this alleged

[8] For example, the NIH has continued to "recommend[] against the use of ivermectin for the treatment of COVID-19." https://perma.cc/3H93-KDNB (Dec. 20, 2023).

"pressure" from FDA's Statements. *See supra*, pp. 23–24. Thus, removing any "psychic" pressure they feel would not redress any actual injury. *Steel Co.*, 523 U.S. at 107.

Plaintiffs' redressability argument fails for an additional reason. They ask the Court to declare that the Statements "have no legal effect and do not bind health professionals or patients." Am. Compl. at 44. But the Court of Appeals has already expressly held that the Statements have no legal effect, as this Court held and as FDA has maintained all along. *Apter*, 80 F.4th at 595. A declaration of what is already true would have "no effect" on Plaintiffs and could "not redress" their injuries. *Sykes v. FEC*, 335 F. Supp. 2d 84, 92 (D.D.C. 2004) (quotations omitted); *cf. Steel Co.*, 523 U.S. at 109 (absent "a continuing violation or the likelihood of a future violation, injunctive relief will not redress [an] injury").

Nothing about the Plaintiffs' individual situations leads to a different outcome. [redacted] even assuming having to defend against a disciplinary proceeding is a cognizable injury, [redacted] *See supra* p. 21; *Ctr. for Biological Diversity, Inc. v. BP Am. Prod. Co.*, 704 F.3d 413, 425 (5th Cir. 2013).

As to Bowden, the requested relief would not undo her voluntary

resignation of her privileges at Houston Methodist, Ex. K, nullify her apparent past noncompliance with Houston Methodist's standards of professional conduct or vaccination requirements, Exs. G at 42; H; I; R at 4, or alter the statements by Houston Methodist that Bowden alleges derided her and caused her to be ridiculed, Am. Compl. ¶ 21.

Plaintiffs cannot show the requested relief could remedy any alleged harm to Marik's "ability to practice medicine" because his medical licenses are all expired, Ex. 10 at 10, and he has not alleged that he intends to renew them. Marik also alleges that he was forced to resign for "promoting the use of ivermectin—*as well as other safe, cheap, and effective off-label FDA-approved drugs*—to treat COVID-19." Am Compl. ¶ 42 (emphasis added). The requested relief would not affect these other reasons for his allegedly "forced" resignation and thus would not remedy his alleged injuries. The requested relief also would not affect Marik's stated reason for resigning: to "dedicate more time" to "causes" like the FLCCC. Ex. O. Finally, the requested relief could not restore Marik's ability to promote the use of ivermectin to prevent or treat COVID-19 because Marik never lost that ability, having continued to promote that use even after he resigned. Ex. P.

Finally, Plaintiffs cannot show redressability (let alone any other requirement for standing) regarding the first version of FDA's consumer update, Ex. 19, because that version has not been online since September 2021, well before this action was filed, *see Grupo Dataflux v. Atlas Glob. Grp., L.P.*, 541 U.S. 567, 570–71 (2004).

CONCLUSION

For the foregoing reasons, the Amended Complaint should be dismissed.

PUBLIC VERSION

December 22, 2023

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PUBLIC VERSION

CERTIFICATE OF CONFERENCE

On August 2, 2022, pursuant to Rule 6 of the Rules of Practice of the Galveston Division of the U.S. District Court for the Southern District of Texas, Defendants' counsel sent Plaintiffs' counsel a letter stating the bases for their intended motion to dismiss and informing Plaintiffs of their right to amend their Complaint within 14 days. On August 4, 2022, the parties met and conferred regarding Defendants' intended motion to dismiss. On August 8, 2022, Plaintiffs filed their Amended Complaint. ECF No. 12.

December 22, 2023

/s/ Isaac C. Belfer
Isaac C. Belfer

PUBLIC VERSION

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

January 19, 2024

/s/ Isaac C. Belfer
Isaac C. Belfer