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

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,	)	No. 3:22-cv-184
Defendants.	)	

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT

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INTRODUCTION

The U.S. Food and Drug Administration ("FDA") is a gatekeeper with authority to "approve" when a drug can be introduced to the market in the United States and what labeling it can use. 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 interfere with the practice of medicine, the regulation of which is—and always has been—reserved to states. In fact, the Federal Food, Drug, and Cosmetic Act includes express language to prohibit the FDA from "interfer[ing]" with the practice of medicine. *See* 21 U.S.C. § 396.

The FDA breached this critical boundary between federal and state authority by repeatedly 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. This includes formal, unequivocal, and conclusory actions to prohibit or otherwise interfere with the use of ivermectin to treat COVID-19, including a publication titled, "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," Ex. 1,[1] which on its face seeks to influence a decision that is preserved by statute for the doctor-patient relationship. Other public directives are even more direct, stating: "Q: Should I take ivermectin to

[1] "Ex." citations reference exhibits attached to the Amended Complaint.

prevent or treat COVID-19? A: No," Exs. 2, 3; or "You are not a horse. You are not a cow. Seriously, y'all. Stop it," Ex. 4; or "You are not a horse. Stop it with the #ivermectin. It's not authorized for treating #COVID," Ex. 6.

Plaintiffs in this case—Robert L. Apter, M.D., FACEP; Mary Talley Bowden, M.D.; and Paul E. Marik, MBBCh, M.Med, FCCM, FCCP—have successfully treated thousands of patients for COVID-19. But they have also been and continue to be harmed in their efforts by the FDA's unlawful interference in the practice of medicine. Specifically, they have been pressured in their professional medical judgment, unable to prescribe ivermectin, and threatened with or subjected to professional discipline. This has further resulted in both reputational and monetary harm. Am.Comp. ¶ 121.

Common sense confirms that the only reason the FDA would issue its ivermectin statements in the first place is because of the predictable and intended effects they would have on health professionals, regulatory boards, hospitals, patients, and the broader public to stop the use of ivermectin to treat COVID-19—precipitating the very harms caused to Plaintiffs. The FDA clearly desired these effects, or the entire endeavor would have been pointless. But now the FDA argues that its actions lack even plausible traceability to their intended outcome. The FDA cannot accomplish exactly what it intended, but then seek to wash its hands of the consequences.

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. If the FDA is not limited to its statutory lane, its unlawful actions will no doubt persist and be repeated, damaging the carefully constructed

statutory wall between federal and state regulatory powers, and between the FDA and the professional judgment of health professionals.

BACKGROUND

FDA's Statutory Authority

The FDA has authority under the Federal Food, Drug, and Cosmetic Act ("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(a), (d); *see* 21 C.F.R. § 201.57. Once approved, doctors are free to prescribe these drugs for "off-label" purposes. Such practice is common—one study found that 21% of all prescriptions were for off-label use, and that number jumps to 36.2% in intensive care units. Am.Comp. ¶ 62.

The FDA lacks authority to prohibit, direct, or advise against off-label uses of approved human drugs. The FDCA is clear 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." 21 U.S.C. § 396. Courts, including the Fifth Circuit, have consistently interpreted this prohibition as applying to the prescription or administration of drugs as well. *See U.S. ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 328 (5th Cir.

2017).[2] The prohibition in 21 U.S.C. § 396 was added to the FDCA specifically to "emphasize that the FDA should not interfere in the practice of medicine." H.R. Rep. No. 105-399, at 97 (1997).

Consistent with this general prohibition, when Congress has authorized the FDA to limit particular uses of an approved drug, it has done so explicitly. *E.g.*, 21 U.S.C. § 333(e). No such limitation applies here.

The FDA thus cannot take actions, including pressure campaigns and jawboning, that interfere with "the practice of medicine, which is the exclusive realm of individual states." *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 505 (6th Cir. 2006); *see, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) ("[T]he FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals."); *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."); *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

[2] *See also Med. Mut. of Ohio v. AbbVie Inc.*, 784 F. App'x 457, 457 (7th Cir. 2019); *Markland v. Insys Therapeutics, Inc.*, 758 F. App'x 777, 780 (11th Cir. 2018); *U.S. ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 615 (2d Cir. 2016); *U.S. ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 454 n.2 (4th Cir. 2013); *United States v. Caronia*, 703 F.3d 149, 167 (2d Cir. 2012); *United States v. Muoghalu*, 662 F.3d 908, 911 (7th Cir. 2011); *In re Gilead Sci. Sec. Litig.*, 536 F.3d 1049, 1051 & n.2 (9th Cir. 2008); *Smith v. C.R. Bard, Inc.*, 730 F. Supp. 2d 783, 803 (M.D. Tenn. 2010).

condition is at the heart of the practice of medicine.").

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

FDA and Ivermectin

On March 5, 2021, the FDA published "Why You Should Not Take Ivermectin to Treat or Prevent COVID-19" on its website. Ex. 19. The title of the publication states an official government position that ivermectin should not be used for the treatment or prevention of COVID-19. *Id.* Nowhere did this publication acknowledge that doctors can lawfully prescribe ivermectin for that use, instead stating only that "[i]f you have a prescription for ivermectin for an FDA-approved use, get it from a legitimate source and take it exactly as prescribed." *Id.* at 2. This erroneously conveyed that ivermectin can only be prescribed and used for FDA-approved purposes. Ironically, the FDA took this action

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.*

The FDA later amended "Why You Should Not Take Ivermectin to Treat or Prevent COVID-19" to state that "[i]f your health care provider writes you an ivermectin prescription, fill it through a legitimate source such as a pharmacy, and take it *exactly* as prescribed"—removing "for an FDA-approved use"—but that pseudo-concession is buried in the middle of the document and does not influence the effect of the title, which unequivocally discourages the use of ivermectin to treat or prevent COVID-19. Ex. 1, at 2.

The FDA has also published an Ivermectin FAQ, entitled "COVID-19 and Ivermectin Intended for Animals." Ex. 2. The Ivermectin FAQ begins with, "Q: Should I take ivermectin to prevent or treat COVID-19?" and flatly answers that question, "A: No." *Id.* It continues that "[w]hile there are approved uses for ivermectin in people and animals, it is not approved for the prevention or treatment of COVID-19. You should not take any medicine to treat or prevent COVID-19 unless it has been prescribed to you by your health care provider and acquired from a legitimate source." *Id.* None of this changes the FDA's unequivocal direction that ivermectin should not be used to treat COVID-19 and clear message that doctors should not (and possibly cannot) prescribe it for that use.

The FDA also maintains a COVID-19 FAQ that similarly states, "Q: Should I take ivermectin to prevent or treat COVID-19?" and answers that question, "A: No." Ex. 3. The answer also links to "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." *Id.* The COVID-19 FAQ continues that "[w]hile there are approved uses for ivermectin in people and animals, it is not approved for the prevention or treatment of

COVID-19," followed by a link to "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." *Id.* None of this changes the FDA's unequivocal direction that ivermectin should not be used to treat COVID-19.

On August 21, 2021, the FDA tweeted, "You are not a horse. You are not a cow. Seriously, y'all. Stop it." Ex. 4. 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. The FDA posted the same image and message to LinkedIn and Facebook. Ex. 5. The August 21, 2021, tweet was viewed by over 24 million people in two days—not including the millions more who saw the tweet reproduced on other platforms or in mainstream media—quickly becoming the most viewed tweet in FDA history. Ex. 20.

The FDA celebrated its successful messaging. Erica Jefferson, Associate Commissioner for External Affairs, explained that the agency saw this as an "opportunity to remind the public" of the FDA's position on ivermectin, creating "a unique viral moment" where the FDA could "reach the 'everyday' American …. in a time of incredible misinformation." Ex. 21, at 6. 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.*

Also on August 21, 2021, the FDA posted to Instagram a picture of horse with the caption, "You are not a horse. Stop it with the #ivermectin. It's not authorized for treating #COVID." Ex. 6. The post misleadingly depicts ivermectin as a horse medication not approved for human use and unequivocally directs the public not to use it to treat COVID-

19. The FDA internally stated that the August 21, 2021, tweet and posts were part of a "new engagement strategy" to influence the public. Ex. 20.

The FDA then sent a letter to the Federation of State Medical Boards and National Association of Boards of Pharmacy 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. 22.

The FDA's "new engagement strategy" resulted in its foreseeable and intended effect of stopping doctors from using ivermectin to treat COVID-19. The FDA was delighted to see media outlets parrot its message, referring to ivermectin as "horse dewormer" and "horse paste." Am.Comp. ¶¶ 102–04. As intended, others pushed the narrative with headlines like "Say 'Neigh' to Ivermectin" and "You Are Not a Horse." *Id.*

Individual health professionals even joined the refrain, with some referencing the FDA and publicly labeling health professionals who prescribe ivermectin, including Plaintiffs, as quack doctors practicing veterinary medicine on humans. *See* Exs. 23–24.

Again, following the FDA's lead, the American Medical Association, American Pharmacists Association, and American Society of Health-System Pharmacists 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. 25. This joint statement was issued a mere 11 days after the FDA's "Stop it with the #ivermectin" post. State pharmacy boards likewise issued statements on

dispensing ivermectin, which directly linked to the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." *See, e.g.*, Ex. 26.

Hospitals also started relying on the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" and August 21, 2021, tweet—even reproducing the tweet in court filings—to justify prohibiting the use of ivermectin to treat patients regardless of whether the drug was prescribed by a doctor. Ex. 12, at 3; Ex. 27, at 8–9, 21.

On April 26, 2022, the FDA continued its relentless campaign against ivermectin, again pushing its narrative that the drug is only for animal use. The tweet reads: "Hold your horses, y'all. Ivermectin may be trending, but it still isn't authorized or approved to treat COVID-19." Ex. 7. 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.*

Defendants are wrong to frame these actions as only a concerned response to "multiple reports of patients who required medical attention, including for hospitalization, after self-medicating with ivermectin intended for livestock." MTD1. That assertion is undermined by at least three considerations:

First, the article "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" was initially published on March 5, 2021, predating the reports about use of animal ivermectin in August 2021. *Second*, the FDA was still using the "horse paste" trope as late as April 26, 2022, long after any concern would have abated from reports about animal-ivermectin use. *Third*, internal correspondence from the FDA confirms the agency's goal was to use the situation as an "opportunity to remind the public of [its] own warnings for ivermectin," Ex. 21, at 5, and to try a "new engagement strategy," Ex. 20, which explains

its dramatic response to a mere *four* people using animal ivermectin in a country of 330+ million, *see* Ex. 21, at 1–3. Moreover, the FDA's statements repeatedly referenced ivermectin—*not* "animal ivermectin."

Procedural History

Plaintiffs filed suit in the Southern District of Texas on June 2, 2022, and amended their complaint on August 8, 2022, alleging Defendants acted ultra vires and violated the Administrative Procedure Act. On August 26, 2022, Defendants filed a motion to dismiss under Federal Rule of Procedure 12(b)(1) and (6), arguing that Plaintiffs lack constitutional standing to pursue their claims, and invoking sovereign immunity and failure to exhaust administrative remedies.[3]

[3] At the September 14 scheduling conference, Judge Edison asked whether venue was proper in this case. Under 28 U.S.C. § 1391(e)(1)(C), a suit against a federal agency or officer in his official capacity may be brought "in any district in which … the plaintiff resides." Plaintiff Bowden resides in this District. Am.Compl. ¶ 49. Although she resides in Houston, there is no statute or local rule requiring a plaintiff in the Southern District to file in the division in which she resides. Under 28 U.S.C. § 1404(b), however, "upon motion, consent or stipulation of all parties," a court can transfer a civil matter "to any other division in the same district," but Defendants in this case declined to seek that relief in their Rule 12(b) motion, and thus they have forfeited any objection, *see* Fed. R. Civ. P. 12(h). Moreover, as Judge Kent noted in his famous opinion where a defendant challenged venue in Galveston, "Plaintiff picked Galveston as her forum of choice even though she resides in San Antonio," which of course is outside the Southern District altogether. *Smith v. Colonial Penn Ins. Co.*, 943 F. Supp. 782, 784 (S.D. Tex. 1996). Judge Kent "decline[d] to disturb the forum chosen by the Plaintiff," whose "choice of forum is 'most influential and should rarely be disturbed unless the balance [of inconvenience] is strongly in defendant's favor.'" *Id.* at 784–85. In this case, Defendants have identified no inconvenience in litigating in Galveston. On the other hand, Plaintiffs chose Galveston because of the generally faster pace of litigation—which was a notable factor in deciding not to seek a preliminary injunction in this matter—and because Galveston is the site of numerous pending challenges to federal government actions involving COVID-19 treatments, which lie at the heart of this case, as well. *See, e.g.*, *Texas v. Biden*, No. 3:21-cv-309 (S.D. Tex.); *Rodden v. Fauci*, No. 3:21-cv-317 (S.D. Tex.); *Feds for Med. Freedom v. Biden*, No. 3:21-cv-356 (S.D. Tex.).

ARGUMENT

I. Plaintiffs Have Standing

To establish standing to sue, as required by Article III of the U.S. Constitution, Plaintiffs must plausibly allege (1) "a concrete and particularized injury," (2) "that is fairly traceable to the challenged conduct," and (3) "is likely to be redressed by a favorable judicial decision." *Hollingsworth v. Perry*, 570 U.S. 693, 704 (2013). Standing "incorporates concepts concededly not susceptible of precise definition" and is not "a mechanical exercise." *Allen v. Wright*, 468 U.S. 737, 751 (1984).

Courts also "must accept as true all material allegations of the complaint and construe the complaint in favor of the complaining party." *Ass'n of Am. Physicians & Surgeons v. Tex. Med. Bd.*, 627 F.3d 547, 550 (5th Cir. 2010) (cleaned up).

Plaintiffs plausibly allege facts that satisfy all three elements of standing.

A. Injury

In its motion to dismiss, Defendants notably do *not* flatly assert that Plaintiffs have failed to demonstrate any cognizable Article III injury. Rather, Defendants carefully word their briefing to contend only that "*[m]any* of Plaintiffs' allegations fail to show the requisite injury in fact," MTD12, which tacitly acknowledges that *some* of Plaintiffs' allegations *do* show the requisite injury and thus are sufficient for Article III purposes, *see also id.* (arguing injuries are insufficient "*to the extent* they do not allege concrete injuries to Plaintiffs"). And all that is needed is *some* concrete injury—indeed, "it need not measure more than an identifiable trifle." *OCA-Greater Houston v. Texas*, 867 F.3d 604, 612 (5th Cir. 2017) (cleaned up).

In any event, Defendants are wrong about Plaintiffs' showing. The Amended Complaint is replete with specific examples of how Plaintiffs have been harmed. Pharmacists have refused to fill ivermectin prescriptions from Dr. Apter for his patients, citing the FDA's actions regarding using the drug to treat COVID-19, which delays his ability to treat patients when early treatment is vital. Am.Comp. ¶¶ 14–16. In his experience, patients believe that FDA's pronouncements are authoritative and want care that complies with such pronouncements. *Id.* ¶ 17. 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.* He has also been referred to the Washington Medical Commission and Arizona Medical Board for disciplinary proceedings for prescribing ivermectin to treat COVID-19, and the referrals expressly include copies of the FDA's publications directing against that use. *Id.* ¶ 18.

Pharmacists have similarly refused to fill Dr. Bowden's prescriptions for ivermectin, citing FDA directives not to use the drug to treat COVID-19. *Id.* ¶ 27. Her Patients have delayed seeking treatment because the FDA says not to use ivermectin for that purpose. *Id.* ¶ 29.

Dr. Bowden was derided by Houston Methodist Hospital and forced to resign her privileges there as a result. *Id.* ¶ 21. This has further resulted in both reputational and monetary harm, not to mention the abuse she now endures online. *Id.* ¶¶ 12, 105, 121. And Dr. Marik was forced to resign from his positions at Eastern Virginia Medical School ("EVMS") and Sentara Norfolk General Hospital—even after developing EVMS's COVID-19 treatment protocol—for continuing to promote ivermectin to treat COVID-19

after the FDA's attempts to stop use of those drugs for that purpose. *Id.* ¶¶ 38–39, 42. The undeniable timing of these injuries immediately following when the FDA began its pressure campaign against ivermectin in earnest highlights the predominant role that issue played in their forced resignations.

These are all certainly cognizable and concrete injuries. In response, Defendants suggest that because Plaintiffs have continued to prescribe ivermectin, they have not been harmed. MTD12. But Plaintiffs' ability to prescribe ivermectin in *some* cases does not negate the many times the FDA's actions have interfered—and will continue to interfere—in others. *See, e.g.*, Am.Comp. ¶¶ 14–17, 25, 27–29, 40–43. Indeed, Defendants do not dispute that Plaintiffs have plausibly alleged "interference" with the practice of medicine.

By providing in 21 U.S.C. § 396 that the FDA shall not "limit or interfere" with the doctor-patient relationship, Congress prohibited more than direct regulation. While "limit" denotes establishing "the final or furthest confines, bounds, or restriction of something," *Am. Heritage Dict. of the Eng. Language* 758 (William Morris ed., 1969) (def. 1), "interfere" extends beyond legal restraint and means "to be a hinderance or obstacle," or to "intervene or intrude in the affairs of others," *Am. Heritage Dict. of the Eng. Language* 683 (defs. 1, 3); *see also* 7 *Oxford Eng. Dict.* 1102 (2d ed. 1989) (def. 4(b)) ("To meddle with; to interpose and take part in something, esp. without having the right to do so[.]"). It therefore encompasses hindrance in the doctor-patient relationship, including actions that would "deter off-label use." *Buckman Co.*, 531 U.S. at 350.

Accordingly, Plaintiffs have a statutorily protected interest against FDA interference with their practice of medicine, and a "plaintiff suffers an 'injury in fact' when

his legally protected interest has been invaded"—as has occurred here—and the resulting injury is "concrete" and "actual"—as has also occurred here, as explained above. *Kiser v. Reitz*, 765 F.3d 601, 607 (6th Cir. 2014) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). The FDA is unlawfully "intruding upon decisions statutorily committed to the discretion of health care professionals." *Buckman Co.*, 531 U.S. at 350. Congress recognized the harms that would occur if the FDA engaged in such interference and expressly barred it. *See* 21 U.S.C. § 396. Defendants cannot now dispute the existence of the very same harms Congress anticipated and sought to avoid.

Defendants also argue that being subjected to state medical board disciplinary proceedings is not a cognizable harm. MTD13. But where "a plaintiff has engaged in a course of [protected] conduct and the state has instructed him to stop or face disciplinary action, … a plaintiff has adequately alleged a concrete and imminent harm sufficient to meet the 'injury in fact' requirement." *Kiser*, 765 F.3d at 608.

Defendants also argue that Plaintiffs cannot assert harm to third parties like their patients or outside pharmacists, MTD13–14, but that misunderstands the argument and is wrong in any event. Plaintiffs have suffered injury to their *own* practice of medicine due to their inhibited ability to prescribe and administer ivermectin, and that unfettered ability is protected by statute from federal interference. *See* 21 U.S.C. § 396. In any event, Defendants' argument ignores unique considerations inherent in the practice of medicine that the Supreme Court has held can allow "providers to invoke the rights of their actual or potential patients," *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2118 (2020), especially regarding treatments that have been heavily stigmatized, in this case by

Defendants as being animal-only medicines. Given the groundswell of harm visited on anyone who challenges Defendants on ivermectin, Defendants blink reality by claiming there is no reason those patients would be "unable or unwilling to seek legal or other relief themselves." MTD14.

Plaintiffs have demonstrated numerous different injuries, any one of which is sufficient for purposes of standing.

B. Fairly Traceable

"Proximate causation is not a requirement of Article III standing, which requires only that the plaintiff's injury be fairly traceable to the defendant's conduct." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 134 n.6 (2014). An injury is "fairly traceable" if it "relies … on the predictable effect of Government action on the decisions of third parties," even when those decisions are illogical or "unlawful." *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2565–66 (2019). Traceability "requires no more than *de facto* casualty." *Id.* (quoting *Block v. Meese*, 793 F.2d 1303, 1309 (D.C. Cir. 1986)).

The FDA is the common cause behind Plaintiffs' injuries, which began only after the FDA embarked on its campaign to stop the use of ivermectin to treat COVID-19. The agency has consistently asserted itself as the authoritative voice on drugs in the United States, and now leverages its influence in a novel way to pressure professional and patient judgment about the use of ivermectin, thereby interfering with Plaintiffs' practice of medicine. *See* Ex. 20 (FDA admitting to this "new engagement strategy").

Defendants acknowledge Plaintiffs' allegations are that the cited statements "influenced the thinking" of third parties about the "use of ivermectin to prevent or treat

COVID-19," and those third parties then "allegedly took actions that caused Plaintiffs' injuries." MTD15. But Defendants express disbelief that this simple chain of alleged events was fairly predictable. Common sense dictates that there was no reason for Defendants to issue the ivermectin statements *except* to cause such reactions. Defendants told the entire country to "Stop it with the #ivermectin," with the tweets being the most-viewed in FDA history, yet Defendants now insist that it is not even plausible that patients, pharmacists, and hospitals may have reacted by doing just that.

Defendants claim their ivermectin directions only "generally recommended to *consumers* … that they should not take ivermectin to prevent or treat COVID-19," MTD16, but Defendants are forced to acknowledge in the very same breath that the FDA did in fact send a letter about ivermectin to the Federation of State Medical Boards and the National Association of Boards of Pharmacy, *id.* n.13. Combined with the FDA's public pressure campaign telling people to "Stop it with the #ivermectin," it was predictable and intended that those regulatory boards—who obviously want to stay in the FDA's good graces—would react by focusing their attention on doctors seeking to use ivermectin.

Defendants even acknowledge their goal of "want[ing] consumers to be aware of the [FDA's] concerns about using ivermectin to prevent or treat COVID-19." MTD17. That is a crucial admission because *patients* are consumers and part of the doctor-patient relationship that Congress expressly sought to protect from FDA "interfere[nce]." Defendants likewise insist their "cited statements simply communicated FDA's recommendations regarding the use of ivermectin to prevent or treat COVID-19." MTD15. Defendants ignore that such recommendations are "at the heart of the practice of

medicine," *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 400, which necessarily interferes with the doctor-patient relationship in violation of 21 U.S.C. § 396, and Defendants also elide that their actions clearly went beyond recommendations or recitations of fact—e.g., "Stop it," "Stop it with the #ivermectin," etc.

Defendants also try to excuse the FDA's actions by citing to myriad language buried in some of the documents 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." MTD7, 17. But when such statements fall under a title of "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," or follow "Q: Should I take ivermectin to prevent or treat COVID-19? A: No," they convey the message that ivermectin should be taken as prescribed only when doctors prescribe the drug *for purposes other than COVID-19*. Indeed, that was explicit in the first draft of the publication, which told patients to follow ivermectin prescriptions only "for an FDA-approved use." Ex. 19, at 2. Moreover, Defendants cannot justify an unlawful foray into the practice of medicine with a few subsequent, ambiguous statements, especially when its actions are viewed as a whole.

Defendants insist that it is merely "speculation" that any of the harms visited on Plaintiffs were a "'predictable' response to the cited FDA statements," MTD17, but the Amended Complaint includes significant facts demonstrating not only that Plaintiffs' harms are closely tied to the FDA's actions, but also that such harms are entirely predictable. For example, the FDA's actions have been used as evidence in state regulatory board proceedings. Am.Comp. ¶¶ 18, 108. Plaintiff Apter is currently subject to such proceedings, which expressly rely on the FDA's statements at issue here. *Id.* ¶ 18.

Pharmacists have expressly cited FDA directives in refusing to fill Dr. Bowden's prescriptions for ivermectin. *Id.* ¶ 27. And her patients have delayed seeking treatment because the FDA says not to use ivermectin to treat COVID-19. *Id.* ¶ 29.

Courts have also recognized the legal effects and implications of the FDA's actions, citing the FDA's statements as evidence about the effectiveness of ivermectin to treat COVID-19 and the appropriate standard of care. Am.Comp. ¶¶ 109–10; *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. & Suburb. 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, 672–73 (N.Y. Sup. Ct. 2021).

Nor can Defendants claim, especially at this stage of the pleadings, that such reactions were not foreseeable. As the Amended Complaint demonstrates at length, health professionals, state regulatory boards, patients, and the public are heavily influenced or feel bound by the FDA's actions, regardless of their technical legal effects, which is reinforced by courts relying on those same statements and "guidance" to determine legal standards. Those involved in interfering with Plaintiffs' practice of medicine explicitly rely on FDA directives not to use ivermectin to treat COVID-19.

Given all this, it is more than "fair" to conclude that Defendants' statements on ivermectin are "traceable" to the harm suffered by Plaintiffs. Indeed, leading health professionals, scientists, and researchers recognize that the FDA is interfering with the practice of medicine vis-à-vis ivermectin. *See* Am.Comp. ¶¶ 111–14. For example, Peter A. McCullough, M.D., MPH—a renowned epidemiologist—explained the impetus for the effectual ban on the use of ivermectin:

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

Am.Comp. ¶ 112. 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.* Pierre Kory, M.D., MPA—a distinguished and highly published critical care specialist—has made similar observations. *See* Am.Comp. ¶ 114.

Members of Congress likewise recognize that the FDA is illegally interfering with the practice of medicine, noting that Defendants have "taken steps to curtail the use of potential early treatments," including through the FDA's "mocking of ivermectin, conflating a widely-available human drug that was the basis for Nobel prize winning research, with its veterinary version," and have "created a new industry standard that restricts doctors' abilities to prescribe certain off-label treatments for COVID-19." Ex. 28, at 2–3. The letter also cites "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." *Id.* at 3 n.11.

When the actions of third parties consistently cite to the same FDA directions, Plaintiffs' injuries do not turn on "guesswork as to how independent decisionmakers will exercise their judgment." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 413 (2013). Rather, the link is at least "fair" and likely, if not undeniable. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562 (1992) (plaintiffs may "adduce facts showing that … choices [of third parties] have been or will be made in such manner as to produce causation and permit redressability of injury").

C. Redressability

Plaintiffs' injuries are redressable by vacatur, declaratory, and injunctive relief against Defendants. Critically, at this stage, Plaintiffs "need only show that a favorable ruling could potentially lessen [their] injury," and they "need not definitively demonstrate that a victory would completely remedy the harm." *Sanchez v. R.G.L.*, 761 F.3d 495, 506 (5th Cir. 2014) (cleaned up); *see also Friends of the Earth, Inc. v. Laidlaw Env't. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000) (holding that a plaintiff meets the redressability test if it is "likely"—not certain—"that the injury will be redressed by a favorable decision.").

"Causal connection and redressability are two sides of the same coin." *Animal Legal Def. Fund v. Veneman*, 469 F.3d 826, 835 (9th Cir. 2006). Thus, if the Court agrees with Plaintiffs that at least some of their harms are fairly traceable to Defendants' actions, then redressability is presumed. As Plaintiffs argued above when discussing traceability, the FDA would not have issued the challenged statements if it did not believe its actions would affect the use of ivermectin to treat COVID-19. Having succeeded in its pressure campaign,

Defendants cannot now disclaim that clearly intended effect, nor contend that vacating the challenged statements would somehow have no effect.

Moreover, Defendants acknowledge the allegation that a favorable ruling would mean Plaintiffs' professional judgment would no longer be subject to pressure from the FDA, but Defendants once again argue that Plaintiffs "have continued to prescribe ivermectin," and thus a favorable ruling would supposedly not provide any actual relief. MTD18 n.16. This is just a rehash of Defendants' unpersuasive argument about injury. *See* Part I.A, *supra*. As explained above, Defendants' statements have inhibited Plaintiffs' ability to practice medicine, and thus a favorable ruling would result in at least partial relief by removing that inhibition. Defendants never argue to the contrary. Rather, they erroneously seem to believe that so long as Plaintiffs prescribe even one dose of ivermectin, there is no harm that could be redressed.

Moreover, the Fifth Circuit has held that redressability is satisfied where the "fear of future prosecution may be alleviated" by a favorable ruling, especially where it could "arguably" result in "third parties" "chang[ing] … the policy" that negatively affects Plaintiffs. *McClure v. Ashcroft*, 335 F.3d 404, 411 (5th Cir. 2003). Here, the judgment of other health professionals and entities in the causal chain of Plaintiffs' injuries would also be freed from this material interference. For decades, health professionals, hospitals, and state regulatory boards have supported the off-label prescription of approved drugs and would likely revert to that norm, at least in part (which is sufficient for redressability). Am.Comp. ¶¶ 61–66, 124. And Patients will no longer be caught between the FDA's pressure campaign and Plaintiffs' advice, restoring the primacy of the doctor-patient

relationship. Am.Comp. ¶¶ 17, 24, 27. Their patients have been unable to timely receive prescribed treatments because of the FDA's actions, which would likely be alleviated if health professionals and other entities are freed from the FDA's interference.

Defendants argue that intervention by this Court "would not likely change the independent third parties' scientific understanding of the risks and benefits of using ivermectin." MTD18. But that is a red herring because the third parties here repeatedly point *to the FDA* and its statements that ivermectin should not be used to treat or prevent COVID-19 or its directives to "Stop it."

Defendants also dismiss the consequences of the requested relief as "speculative." MTD19. But decades of consistent medical practice, and observation of the pervasive off-label prescription of drugs throughout medicine, establish a compelling baseline that would be at least partially restored once the FDA ceases its unlawful interference, and the potential of even partial relief is sufficient to withstand a motion to dismiss. *Sanchez*, 761 F.3d at 506. Given all this, the "speculative" assertion here is actually the one made by Defendants that third parties would continue to rely blindly on FDA actions that have been vacated and declared unlawful.

* * *

The FDA undertook a singularly effective campaign against ivermectin. It cannot now seek to disclaim those intended and predictable effects. And Plaintiffs have provided "substantial evidence," including "declarations and affidavits detailing specific instances," "of a causal relationship between the government policy and the third-party conduct, leaving little doubt as to causation and the likelihood of redress." *Renal Physicians Ass'n*

v. HHS, 489 F.3d 1267, 1275 (D.C. Cir. 2007) (quoting *Nat'l Wrestling Coaches Ass'n v. Dep't of Educ.*, 366 F.3d 930, 941 (D.C. Cir. 2004)); *see* Am.Comp. ¶ 128. That is more than sufficient to demonstrate standing.

II. Sovereign Immunity Does Not Apply

The government next claims that sovereign immunity bars this suit. MTD21–28. That is incorrect for several reasons.

First, Plaintiffs allege an ultra vires claim, Am.Comp. ¶¶ 129–31, and it is well established that sovereign immunity does not bar a suit alleging that "a Federal officer act[ed] in excess of his authority or under authority not validly conferred." *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 690–91 (1949); *see also id.* ("[I]n case of an injury threatened by his illegal action, the officer cannot claim immunity from injunction process.") (quoting *Phila. Co. v. Stimson*, 223 U.S. 605, 620 (1912)). Ultra vires actions "may be made the object of specific relief," especially when the remedy is "merely ordering the cessation of the conduct complained of," not "affirmative action by the sovereign or the disposition of unquestionably sovereign property." *Id.* at 689, 691 n.11; *see also, e.g.*, *Universal Life Church Monastery Storehouse v. Nabors*, 35 F.4th 1021, 1041 (6th Cir. 2022); *Strickland v. United States*, 32 F.4th 311, 363 (4th Cir. 2022); *Danos v. Jones*, 721 F. Supp. 2d 491, 496 (E.D. La. 2010) ("[O]ther courts, including a panel of the Fifth Circuit Court of Appeals, albeit in an unpublished opinion, have implicitly recognized the continuing vitality of the *ultra vires* exception by analyzing its application to claims against federal officials in recent opinions."), *aff'd,* 652 F.3d 577 (5th Cir. 2011).

Plaintiffs have expressly asserted that Defendants "lack[ed] ... delegated power" and acted in excess of their authority under 21 U.S.C. § 396. *Larson*, 337 U.S. at 690. This clear statutory limitation means Defendants acted "without any authority whatever." *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 101 n.11 (1984) (cleaned up). Accordingly, the ultra vires claim is not barred by sovereign immunity.

Second, as Defendants acknowledge, Congress expressly waived sovereign immunity in 5 U.S.C. § 702 for *both* ultra vires *and* APA claims. *See* MTD21. To invoke that waiver, a plaintiff need only (1) "identify some 'agency action' affecting him in a specific way," and (2) have "'suffered legal wrong because of the challenged agency action, or [be] adversely affected or aggrieved by that action within the meaning of a relevant statute.'" *Ala.-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484, 499 (5th Cir. 2014) (quoting *Lujan v. Nat'l Wildlife Found.*, 497 U.S. 871, 883 (1990)). For APA claims, the agency action must also be "final." *See id.*

Plaintiffs have adequately alleged "agency action" affecting them. The APA provides that "agency action" "includes the whole or part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act," and the use of "includes" makes clear the list is not exhaustive. 5 U.S.C. § 551(13); *cf. Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 162 (2012). Binding Fifth Circuit precedent holds that "[t]he APA defines the term 'rule' broadly enough to include virtually every statement an agency may make." *Avoyelles Sportsmen's League, Inc. v. Marsh*, 715 F.2d 897, 908 (5th Cir. 1983). As a result, statements of agency policy and even purely informational statements are "rules." *See id.*; *Data Mktg. P'ship, LP v. Dep't of Lab.*, 45

F.4th 846, 855 (5th Cir. 2022) (finding an informational letter was agency action); *see also South Dakota v. Ubbelohde*, 330 F.3d 1014, 1028 (8th Cir. 2003) ("Where a policy statement purports to create substantive requirements, it can be a legislative rule regardless of the agency's characterization."). Accordingly, the FDA statements here easily qualify as rules and thus agency action. Defendants' only response is a passing reference to an out-of-circuit decision. MTD24.

In any event, in this context, Congress expressly recognized that one specific action the FDA *cannot* take is to "interfere" with the practice of medicine, 21 U.S.C. § 396, and thus FDA acts that amount to such interference is, by statute, prohibited "agency action." It would be passing strange if an agency could issue directives or medical recommendations, violate its statutory authority, and cause concrete harm to Plaintiffs without doing anything that would arise to the minimal level of "agency action," especially when Congress expressly foresaw the possibility that the FDA would do so.

Plaintiffs have similarly "suffered legal wrong" and are "adversely affected or aggrieved … within the meaning of a relevant statute," *Ala.-Coushatta Tribe of Tex.*, 757 F.3d at 488–99 (quoting *Lujan*, 497 U.S. at 883), because of the FDA's actions, which interfere with Plaintiffs' practice of medicine protected by 21 U.S.C. § 396. Notably, Defendants do not dispute that Plaintiffs have stated a plausible claim of such interference.

Defendants' "agency actions" are also "final." *See Ala.-Coushatta Tribe*, 757 F.3d at 488–99. A final agency action (1) "must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature," and (2) "must be one by which rights or obligations have been determined, or from which legal

consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (cleaned up). Both requirements are satisfied here.

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)). As the D.C. Circuit explained while rejecting a "hypertechnical" approach, "a series of agency pronouncements" may constitute final agency action if their "cumulative effect" causes injury. *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 435 n.7 (D.C. Cir. 1986).

The first requirement of finality is satisfied because publication of unqualified directives against using ivermectin to treat COVID-19 constitutes the culmination of the decisionmaking process. The FDA has publicly and repeatedly maintained this position for over a year—hardly a "tentative" position, MTD24, unless Defendants are suggesting they plan to disclaim their numerous statements about ivermectin. Nor is there anything "tentative" about "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," Ex. 1; or "No," Exs. 2, 3; or "Seriously, y'all. Stop it," Ex. 4; or "Stop it with the #ivermectin," Ex. 6. The possibility that the FDA might change positions in the future does not alter the fact that the agency has taken an official position now. *Data Mktg. P'ship*, 45 F.4th at 854. As the Fifth Circuit recently explained, "[w]ere it otherwise, no agency action would be final because an agency could always revisit it. And that can't be right." *Id.*

The second requirement for finality is also satisfied. Defendants argue that because the FDA "imposed no obligations and denied no relief," did not compel anyone, and inflicted no "direct consequences" on Plaintiffs, any agency action was not final. MTD25–

26. That is an incorrect statement of the law. As the Fifth Circuit held in *Texas v. EEOC*, 933 F.3d 433 (5th Cir. 2019), an agency's guidance document "is 'binding as a practical matter'"—and thus "final" for APA purposes—where "'private parties can rely on it *as a norm* or safe harbor by which to shape their actions.'" *Id.* at 443–44 (emphasis added). **"**What matters is whether the document has practical binding effect such that affected private parties *are reasonably led to believe* that failure to conform will bring adverse consequences." *Id.* at 442 (emphasis added). The FDA's statements on ivermectin are regularly relied on to establish the appropriate standard of care and dictate the practice of medicine, including by courts in legal proceedings, and Dr. Apter currently faces the possibility of professional discipline that relies on the FDA's publications. *See, e.g.*, Am.Comp. ¶ 110. It is indisputable that, at the very least, the FDA's statements on ivermectin dictate a "norm." *EEOC*, 933 F.3d at 444.

Defendants also suggest that "policy statements" cannot be final action, MTD26 n.24, but Fifth Circuit "precedent establish[es] that a 'policy statement' can nonetheless be 'final agency action' under the APA." *State v. Biden*, 10 F.4th 538, 550 (5th Cir. 2021).

Defendants next discount the effects of the FDA's actions as "indirect" to Plaintiffs, MTD26, but that's irrelevant—the Supreme Court found final agency action in *Bennett* even though the direct effects of the agency action were on a third party, not the parties who brought suit. *See Bennett*, 520 U.S. at 177–78.

In any event, legally binding effects are not necessary to render agency action "final" for purposes of judicial review when the action in question is expressly prohibited by statute regardless of such effects. Congress recognized the unique ability of Defendants

to "interfere" with the doctor-patient relationship and prohibited it. Defendants' view here would in many cases make this prohibition a mere suggestion that's never judicially enforceable even when it concretely harms doctors, like Plaintiffs. That decision by Congress weighs heavily in the "pragmatic" interpretation of finality.

For these reasons, the FDA's actions are final for purposes of judicial review. *See La. State v. U.S. Army Corps of Eng'rs*, 834 F.3d 574, 583 (5th Cir. 2016) ("Judicially reviewable agency actions normally affect a regulated party's possible legal liability").

Accordingly, sovereign immunity does not bar any part of this suit.

III. Plaintiffs Were Not Required to File a Citizen Petition with the FDA

Defendants claim that Plaintiffs fail to state a claim for which relief can be granted because they were required to raise their claims through a "citizen petition" under 21 C.F.R. § 10.25(a) before filling suit, even though Defendants themselves took the disputed final actions without providing any process. MTD28–30. The Court should reject this claim.

At the outset, it is particularly clear that the administrative exhaustion provisions do not apply to Plaintiffs' ultra vires claim, because the FDA only "has primary jurisdiction to make the initial determination on *issues within its statutory mandate*." 21 C.F.R. § 10.25(b) (emphasis added). The premise of an ultra vires claim is that the FDA acted *outside* its statutory mandate, and thus § 10.25(a) does not apply to an ultra vires claim.

In any event, if Defendants were correct, the FDA could take final action without ever providing notice or administrative process, then escape—or at least significantly delay—any judicial review simply by citing its own internal regulations (not statutes) requiring myriad administrative procedures before any challenger could file suit. Such a

counterintuitive outcome should be avoided absent clear text encompassing the relevant claims. But Plaintiffs' claims here do not fall within § 10.25(a), which is aimed at scenarios where there was at least an opportunity to petition the FDA *before* it took final action, which aligns with the commonsense notion that exhaustion "prevent[s] premature interference with agency processes," a rationale that makes no sense where the agency took final action without any "processes" at all. *Weinberger v. Salfi*, 422 U.S. 749, 765 (1975).

Defendants also cite 21 C.F.R. § 10.45(b) for the proposition that Plaintiffs were required to file a citizen petition, but Plaintiffs do not request "that the Commissioner take or refrain from taking any form of administrative action." 21 C.F.R. § 10.45(b). Defendants have *already* taken final action. Plaintiffs instead ask this Court to vacate those ultra vires actions and declare them unlawful—the "action" Plaintiffs seek is that of the Court alone.

Thus, as one court noted in a case challenging an FDA regulation as illegal, "this court is not convinced that the plaintiffs' claims fall into either of the categories of claims for which a citizen petition is appropriate or required pursuant to 21 C.F.R. § 10.25(b). If this action were for review of a specific administrative enforcement action, then it clearly would fall within the scope of the FDA's administrative remedies, as an action requesting that the Commissioner 'refrain from taking [a] form of administrative action,' and exhaustion of administrative remedies would clearly be required. It is not. It is, instead, a challenge to the validity and constitutionality of certain FDA regulations." *Farm-to-Consumer Legal Def. Fund v. Sebelius*, 734 F. Supp. 2d 668, 701–02 (N.D. Iowa 2010). Similarly, Plaintiffs here challenge final agency action as illegal and ultra vires, where there was no opportunity for *anyone* to submit a citizen petition before the action was taken.

Defendants are in effect insisting that Plaintiffs cannot sue without formally seeking reconsideration of the action Defendants already took. But Congress foreclosed that situation in 5 U.S.C. § 704, which provides, "Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application … for any form of reconsideration."

In any event, "because the [FDA's] citizen petition procedure is a regulatory rather than a statutory creation, we have discretion to waive the exhaustion requirement." *Cody Lab'ys, Inc. v. Sebelius*, 446 F. App'x 964, 969 (10th Cir. 2011) (APA claims); *see McCarthy v. Madigan*, 503 U.S. 140, 144 (1992); *Darby v. Cisneros*, 509 U.S. 137, 153–54 (1993) (noting rule for non-APA claims). The Court would "balance the interest of the individual in retaining prompt access to a federal judicial forum against countervailing institutional interests favoring exhaustion." *McCarthy*, 503 U.S. at 146. Given the ongoing negative effects Plaintiffs are enduring because of Defendants, there is a strong interest in prompt judicial review. By contrast, Defendants should not be rewarded for insisting that any challenge follow more administrative process than Defendants themselves were willing to provide before taking final agency action injuring Plaintiffs.

In the event this Court determines a citizen petition is necessary, however, the Court should stay the case pending those administrative proceedings. *See* 21 C.F.R. §§ 10.25(b), (c),10.45(b); *Ctr. for Food Safety v. Hamburg*, 696 F. App'x 302, 304 (9th Cir. 2017).

CONCLUSION

The Court should deny Defendants' motion to dismiss.

September 23, 2022

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