United States District Court
Southern District of Texas
ENTERED
December 06, 2022
Nathan Ochsner, Clerk

In the United States District Court for the Southern District of Texas

GALVESTON DIVISION

No. 3:22-cv-184

ROBERT APTER, *ET AL.*, *PLAINTIFFS*,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *ET AL.*, *DEFENDANTS*.

MEMORANDUM OPINION AND ORDER

JEFFREY VINCENT BROWN, *UNITED STATES DISTRICT JUDGE*:

The defendants have moved to dismiss under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). Dkt. 25. The motion is granted.

I. Background

The plaintiffs, Robert L. Apter, Talley Bowden, and Paul E. Marik, have sued the Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of Health and Human Services; the Food and Drug Administration; and Robert M. Califf, in his official capacity as Commissioner of Food and Drugs. Dkt. 12. They allege that the Food and Drug Administration ("FDA") has illegally interfered with the practice of

medicine. *Id.* ¶¶ 1–9.

The three plaintiffs are physicians who claim they have been harmed by the FDA's statements on the use of ivermectin to treat COVID-19. Dkt. 12 ¶¶ 4, 10, 106. The plaintiffs specifically point to six publications by the FDA:

(1) An article entitled *Why You Should Not Use Ivermectin to Treat or Prevent COVID-19*. Dkt. 12-1;

(2) An ivermectin FAQ that asks, "Should I take ivermectin to prevent or treat COVID-19?" and answers, "No. While 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. A recently released research article . . . described the effect of ivermectin on SARS-CoV-2 in a laboratory setting. These types of laboratory studies are commonly used at an early stage of drug development. Additional testing is needed to determine whether ivermectin might be appropriate to prevent or treat coronavirus or COVID-19." Dkt. 12-2;

(3) A COVID-19 FAQ that asks, "Should I take ivermectin to prevent or treat COVID-19?" and answers, "No. While there are approved uses for ivermectin in people and animals, it is not approved or authorized for the prevention or treatment of COVID-19. Read more about why you should not use ivermectin to treat or prevent COVID-19," and links to the article in (1). Dkt. 12-3;

(4) A tweet/LinkedIn post/Facebook post that reads, "You are not a horse. You are not a cow. Seriously, y'all. Stop it," and links to the article in (1). Dkt. 12-4;

(5) An Instagram post of a horse with the caption, "You are not a horse. Stop it with the #ivermectin. It's not authorized for

treating #COVID." Dkt. 12-6; and

(6) A tweet that reads, "Hold your horses, y'all. Ivermectin may be trending, but it still isn't authorized or approved to treat COVID-19," and links to the article in (1). Dkt. 12-7.

While the plaintiffs acknowledge the FDA's authority to regulate drugs, they claim that the FDA has no authority to "prohibit, direct, or advise against off-label[1] uses of drugs approved for human use." Dkt. 12 ¶¶ 51–53. The plaintiffs rely on 21 U.S.C. § 396, which states that nothing in the Federal Food, Drug, and Cosmetic Act[2] "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." *Id.* ¶ 56. They claim that § 396 also applies to the prescription and administration of drugs. *Id.* ¶ 57.

The plaintiffs assert five claims for relief: (1) *ultra vires* acts; (2) APA[3] violation: arbitrary or capricious; (3) APA violation: not in accordance with law; (4) APA violation: in excess of statutory authority; and (5) declaratory judgment in accordance with claims 1–4. Dkt. 12 ¶¶ 129–159.

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[1] When a doctor prescribes an FDA-approved drug for a purpose different than that which it was approved for, it is considered "off-label."

[2] 21 U.S.C. § 301 et seq.

[3] The Administrative Procedure Act, 5 U.S.C. § 501 et seq.

The defendants have moved to dismiss under Rules 12(b)(1) and 12(b)(6).[4] Dkt. 25.

II. Legal Standard

Rule 12(b)(1) requires dismissal if the court "lacks the statutory or constitutional power to adjudicate the case." *Home Builders Ass'n of Miss., Inc. v. City of Madison*, 143 F.3d 1006, 1010 (5th Cir. 1998). The party asserting jurisdiction bears the burden of proof. *Howery v. Allstate Ins. Co.*, 243 F.3d 912, 916 (5th Cir. 2001). To test whether the party asserting jurisdiction has met its burden, a court may rely upon: "(1) the complaint alone; (2) the complaint supplemented by undisputed facts evidenced in the record; or (3) the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Barrera–Montenegro v. United States*, 74 F.3d 657, 659 (5th Cir. 1996). In considering a motion to dismiss for lack of subject-matter jurisdiction, the court accepts all factual allegations in the plaintiffs' complaint as true. *Den Norske Stats Oljeselskap As v. HeereMac Vof*, 241 F.3d 420, 424 (5th Cir. 2001).

[4] Because the jurisdictional grounds are dispositive, the court does not reach the merits under 12(b)(6).

III. Analysis

"It is axiomatic that the United States may not be sued without its consent and that the existence of consent is a prerequisite for jurisdiction." *United States v. Mitchell*, 463 U.S. 206, 212 (1983). "A waiver of sovereign immunity cannot be implied but must be unequivocally expressed." *United States v. Mitchell*, 445 U.S. 535, 538 (1980) (quoting *United States v. King*, 395 U.S. 1, 4 (1969)). "[T]he United States may not be sued except to the extent that it has consented to suit by statute," and "[w]here the United States has not consented to suit or the plaintiff has not met the terms of the statute, the court lacks jurisdiction and the action must be dismissed." *Alabama-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484, 488 (5th Cir. 2014) (quoting *Koehler v. United States*, 153 F.3d 263, 266 (5th Cir. 1998)). "[A] waiver of the Government's sovereign immunity will be strictly construed, in terms of its scope, in favor of the sovereign." *Lane v. Pena*, 518 U.S. 187, 192 (1996).

One way for plaintiffs to overcome sovereign immunity is claiming an *ultra vires* act. Where an "officer's powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions"; they are instead "ultra vires his authority and therefore may be made the object of specific relief." *Danos v. Jones*, 652 F.3d 577, 583 (5th

Cir. 2011) (quoting *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949)). To successfully claim an *ultra vires* act, "the complaint must allege facts sufficient to establish that the officer was acting 'without any authority whatever,' or without any 'colorable basis for the exercise of authority.'" *Danos*, 652 F.3d at 583 (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 101 n.11 (1984)). The *ultra vires* doctrine is a *narrow* exception to sovereign immunity. *Pennhurst State Sch. & Hosp.*, 465 U.S. at 116.

The APA provides another opportunity for plaintiffs to overcome sovereign immunity. "Section 702 of the APA 'waives sovereign immunity for actions against federal government agencies, seeking nonmonetary relief, if the agency conduct is otherwise subject to judicial review.'" *Louisiana v. United States*, 948 F.3d 317, 321 (5th Cir. 2020) (quoting *Alabama-Coushatta Tribe*, 757 F.3d at 488). To seek judicial review, § 702 requires the plaintiffs to meet two requirements.

First, the plaintiffs must identify an agency action. *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 882 (1990); 5 U.S.C. § 702. Agency action is defined by 5 U.S.C. § 551(13) to "include[] the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C. § 551(13); *see* 5 U.S.C. § 701(b)(2) ("For the purpose

of this chapter . . . 'agency action' ha[s] the meaning[] given . . . by section 551 of this title.").

Second, the plaintiffs "must show that [they have] 'suffered legal wrong' because of the challenged agency action, or are 'adversely affected or aggrieved' by that action 'within the meaning of a relevant statute.'" *Lujan*, 497 U.S. at 883.

While these two requirements apply to all waivers of sovereign immunity under § 702, the APA distinguishes between two different types of claims: (1) causes of action under the general provisions of the APA, "where a 'person suffer[s] legal wrong because of the agency action,'" and (2) statutory and non-statutory causes of action, "where a person is 'adversely affected or aggrieved by agency action within the meaning of a relevant statute.'" *Alabama-Coushatta Tribe*, 757 F.3d at 489 (quoting 5 U.S.C. § 702). "[T]o be 'adversely affected or aggrieved . . . within the meaning' of a statute, the plaintiff[s] must establish that the injury . . . falls within the 'zone of interests' sought to be protected by the statutory provision whose violations forms the legal basis for his complaint." *Lujan*, 497 U.S. at 883.

"When . . . review is sought . . . under the *general review provisions* of the APA, the 'agency action' . . . must be 'final agency action.'" *Id.* at 882

(emphasis added) (quoting 5 U.S.C. § 704). To be a final agency action, the action must "(1) 'mark the consummation of the agency's decisionmaking process,' and (2)" be an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Sierra Club v. Peterson*, 228 F.3d 559, 565 (5th Cir. 2000) (quoting *Bennett v. Spear*, 520 U.S. 154, 178 (1997)). "A final action must be an 'identifiable action or event.'" *Id.* (quoting *Lujan*, 497 U.S. at 899).

In contrast, when review is sought pursuant to a statutory or non-statutory cause of action—completely apart from the general provisions of the APA—there is no finality requirement; the plaintiff need only show "agency action" within the meaning of 5 U.S.C. § 551(10). *Alabama-Coushatta Tribe*, 757 F.3d at 489.

The court believes, and the parties seem to agree, that the plaintiffs' claim in Count 1 could be analyzed under either the non-statutory claim standard of the APA or the *ultra vires* doctrine. *See* Dkts. 25 at 29 (labeling Count 1 as a non-statutory cause of action and explaining § 702's application on such a claim); 27 at 30 (arguing the *ultra vires* claim and simultaneously noting that § 702 waives sovereign immunity for both *ultra vires* and APA claims). The APA and *ultra vires* jurisprudence, however, are two distinct

waivers of sovereign immunity, and thus it would be incorrect to use the two interchangeably.

The court analyzes Count 1 under the *ultra vires*-act jurisprudence because the plaintiffs label it that way in their complaint, Dkt. 12 at 37, and because the plaintiffs emphasized that their claim under the *ultra vires* jurisprudence was separate from their claims under the APA during the motion hearing, Dkt. 43 at 26 ("[T]his court should be careful to . . . view the *ultra vires* claim and the APA claim separately."). Counts 2–4 are claims made under the general provision of the APA.

A. *Ultra Vires* Acts

The defendants argue that the plaintiffs fail to establish subject-matter jurisdiction as sovereign immunity bars their claims. Dkt. 25 at 10. The plaintiffs respond that the statements were *ultra vires* and thus sovereign immunity does not bar their suit. Dkt. 27 at 29.

The plaintiffs argue that the FDA's statements were *ultra vires* acts because they exceeded the FDA's authority as limited by 21 U.S.C. § 396. Dkt. 12 ¶¶ 129–131. Section 396 provides:

> Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any

> condition or disease within a legitimate health care practitioner-patient relationship.

21 U.S.C. § 396 (emphasis added).

The plaintiffs contend that courts have "consistently interpreted this prohibition as applying to the prescription or administration of drugs as well." Dkt. 27 at 9. Yet as far as cases from this circuit go, they rely on just one that acknowledges the fact[5] that "the FDA does not restrict physicians from prescribing an otherwise FDA-approved drug for an off-label use," and then, notably, cites to § 396 using a *see* citation. *United States ex rel King v. Solvay Pharm., Inc.*, 871 F.3d 318, 328 (2017). The Fifth Circuit's use of "*see*" regarding § 396 does not stand for the proposition that § 396 applies equally to drugs as it does to devices. Indeed, the use of a *see* signal explicitly acknowledges that there is an "inferential step" required between the statute's plain language and the court's assertion. THE BLUEBOOK: A UNIFORM SYSTEM OF CITATION R.1.2, at 62 (Columbia Law Review Ass'n et al. eds., 21st ed. 2020) (explaining that a *see* signal is used when "there is an inferential step between the authority cited and the proposition it supports"). In some circumstances, this may be a comfortable inference for the court to make. In the context of an *ultra vires* claim, however, it is too much—the *ultra vires*-

[5] The defendants do not dispute that this is generally the case. Dkts. 25 at 11; 42 at 11.

act exception to sovereign immunity is intended to be narrow. *Pennhurst State Sch. & Hosp.*, 465 U.S. at 116. This court will not be persuaded to rely on a *see* signal to expand the plain-text meaning of the Food, Drug, and Cosmetic Act and inappropriately enlarge the scope of the *ultra vires*-act exception to sovereign immunity.

To be *ultra vires*, there must be (1) an officer, (2) whose powers are limited by statute, who (3) acted outside of those limitations. *Larson*, 337 U.S. at 689. Further, the act must be without any authority whatsoever or be made without any colorable basis for authority. *Danos*, 652 F.3d at 583. That is not the case here. First, while § 396 limits the FDA's powers as applied to medical devices, it does not do so in the context of drugs. As there is no statute limiting the FDA's actions here, it cannot have acted outside of any statutory limitations.[6]

Further, it cannot be said that the FDA had no colorable basis of authority. The FDA is charged by Congress with protecting public health and ensuring that regulated medical products are safe and effective, among other

[6] Perhaps if the plaintiffs were alleging that the statements interfered with the authority to administer or prescribe a legally marketed medical device, which § 396 specifically prohibits, they would sufficiently be alleging an *ultra vires* act and the complaint could survive a motion to dismiss on those grounds. The fact of the matter, however, is that the statute says devices, not drugs—and this case is about drugs.

things. 21 U.S.C. §§ 393 (b)(1)–(b)(2). The plaintiffs do not dispute that the FDA has the authority, generally, to make public statements in-line with these purposes. Although the FDA could have, and perhaps should have, been more prudent in their communications, they had at least a colorable basis in authority—and there is no statute saying otherwise.

So the complaint fails to allege an *ultra vires* act that would vest this court with subject-matter jurisdiction in the face of the defendants' sovereign immunity.

B. General APA Claims

When a plaintiff makes a claim under the general provisions of the APA, the APA "provides judicial review of 'final agency action for which there is no other adequate remedy in a court.'" *Data Mktg. P'ship v. U. S. Dep't of Labor*, 45 F.4th 846, 853 (5th Cir. 2022) (quoting 5 U.S.C. § 704). To warrant judicial review here, the plaintiffs must allege a final agency action and "must show that [they have] 'suffer[ed] legal wrong' because of the challenged agency action, or [are] 'adversely affected or aggrieved' by that action 'within the meaning of a relevant statute.'" *Lujan*, 497 U.S. at 882–83 (quoting 5 U.S.C. § 702). The FDA's statements are not final agency action.

To be a final agency action, the action must "(1) 'mark the consummation of the agency's decisionmaking process,' and (2) 'by which

rights or obligations have been determined, or from which legal consequences will flow.'" *Sierra Club*, 228 F.3d at 565 (quoting *Bennett*, 520 U.S. at 178).

Assuming arguendo that the statements were in fact agency action, the plaintiffs have not alleged a waiver of sovereign immunity under the general provisions of the APA as the statements do not rise to the level of *final* agency action. While the finality requirement is "flexible" and "pragmatic," the statements here are not final agency action. *See Abbott Lab. v. Gardner*, 387 U.S. 136, 149–50 (1967)

As to the first prong of the final-agency-action test, at least some of the statements do not mark the consummation of the agency's decisionmaking process. "Agency action may mark the consummation of the agency's decisionmaking process if the agency action 'is not subject to further agency review,' which occurs when the agency has 'asserted its final position on the factual circumstances underpinning' the agency action." *Louisiana State v. U.S. Army Corps of Eng'rs*, 834 F.3d 574, 581 (5th Cir. 2016) (internal citation omitted) (quoting *Sackett v. EPA*, 566 U.S. 120, 127 (2012), and *Alaska Dep't of Envtl. Conservation v. EPA*, 540 U.S. 461, 483 (2004)). However, an agency's ability to simply "change its position or its reasons for the decision" does not alone bar finality. *Data Mktg. P'ship*, 45 F.4th at 854.

Some of the statements at issue here imply a lack of finality, as they include language indicating that they were made based on "[c]urrently available data," "[a]dditional testing [was] needed," "[c]linical trials [were] ongoing," and "initial research [was] underway." Dkts. 25-1 at 3; 25-2 at 2; 25-29 at 3. Other statements, like the Instagram post, do not have this qualifying language and could potentially represent the consummation of the agency's decisionmaking process—except that no case law establishes the proposition that fleeting content on social media can mark the consummation of an agency's decisionmaking process. Though of course the FDA could revisit the statements and change its opinion, either by taking them down or making new statements, that alone is insufficient to prevent an agency action from being final. *Data Mktg. P'ship*, 45 F.4th at 854. The court will not reach that question, however, because the statements fail the second prong of the final-agency-action test.

None of the statements determine rights, obligations, or legal consequences. "[L]egal consequences are created whenever the challenged agency action has the effect of committing the agency itself to a view of the law that, in turn, forces the plaintiff either to alter its conduct, or expose itself to potential liability." *Texas v. EEOC*, 827 F.3d 372, 282 (5th Cir. 2016) ("*EEOC I*"). When considering whether agency action meets this prong of the

final-agency-action test, courts consider a variety of factors, including "whether an agency intends to bind itself to a particular legal position," whether the action appears on its face to be binding or is applied in a way that is binding, whether there is mandatory language, whether the action retracts an agency's discretion to adopt a different view of the law, whether the action creates safe harbors protecting parties from adverse actions, and when "affected private parties are reasonably led to believe that failure to conform will bring adverse consequences." *Texas v. EEOC*, 933 F.3d 433, 441–43 (5th Cir. 2019) ("*EEOC II*").

There is a plethora of case law that outlines when agency action is final. *See, e.g., Louisiana State*, 834 F.3d at 583 (collecting cases where agency action was final[7]); *see also Data Mktg. P'ship*, 45 F.4th at 854 (holding that an advisory opinion that bound the agency and withdrew previously held

[7] Among others, *Louisiana State* cites *Bennett*, 520 U.S. at 170, 178 "(noting that the Fish and Wildlife Service's 'Biological Opinion,' which stated that the Bureau of Reclamation's operation of a federal reclamation scheme threatened two endangered species of fish, had 'direct and appreciable legal consequences' because disregarding the Biological Opinion's conclusions threatened the future prospect of substantial civil and criminal penalties)" and "*Frozen Food Express v. United States*, 351 U.S. 40, 44 (1956) (order of Interstate Commerce Commission was final agency action because it 'warns every carrier, who does not have authority from the Commission to transport [specified] commodities, that it does so at the risk of incurring criminal penalties')." *Louisiana State*, 834 F.3d at 583.

discretion was final agency action, while information letters did not bind the agency and were not final).

The plaintiffs rely on *EEOC II* for the proposition that an agency's guidance document is final for APA purposes where "private parties can rely on it as a norm or safe harbor by which to shape their actions." Dkt. 27 at 33 (quoting *EEOC II*, 933 F.3d at 443–44). The plaintiffs argue that this is the case here, as the FDA's statements created a norm as to ivermectin use in a COVID-19 context, and thus the statements here are as final as the guidance document in *EEOC II* was final. *Id.*

The statements here, however, are unlike the guidance documents in *EEOC II*. In *EEOC II*, the guidance documents announced the EEOC's interpretation of law, described how the EEOC would handle fact patterns under that interpretation, and how affected employers, individuals, and EEOC staff should respond. *EEOC II*, 933 F.3d at 437–39. The court held that the guidance documents were final agency action that established rights, obligations or legal consequences, as the guidance told EEOC staff what was illegal, established a framework for employers to follow to comply with law, and created safe harbors for employers to avoid liability. *Id.* at 443–47. Thus, the guidance was binding as a practical matter because private parties could rely on it as a norm or safe harbor to shape their actions around to avoid

liability. *Id.* at 443–44. Although the EEOC did not have power to bring an enforcement action under the guidelines against the plaintiff State of Texas, the EEOC did have the power to bring such an action against a private employer. *Id.* at 444. The court determined that the finality of the action did not depend on the plaintiff's identity, but on the action itself, and how the action binds the agency. *Id.* at 444–45.

The FDA statements here do not come close to determining the rights, obligations, and legal consequences determined by the guidance in *EEOC II*. Here, there is no indication the FDA has adopted a legal position, no indication of any future liability on non-complying parties, and no establishment of safe harbors. The statements do not, in contrast to the *EEOC II* guidance, have the "effect of committing the agency itself to a view of the law that, in turn, forces the plaintiff to alter its conduct, or expose itself to potential liability." *Id.* at 446 (citing *EEOC* I, 827 F.3d at 383). While the FDA statements communicate the FDA's stance on ivermectin, they do not attempt to delve into the legality of any issue in the way that the *EEOC II* guidance did. Further, the FDA does not have the power to "enforce" the statements against the plaintiffs or anyone else, unlike in *EEOC II*. Thus, shaping behavior around the statements here would not protect the plaintiffs, or anyone else, from liability at the hands of the FDA. Finally,

unlike in *EEOC II*, the statements here do not bind the federal agency. The statements here do not outline the agency's legal position on a doctor's authority to prescribe ivermectin to patients and the possible consequences of doing so, or how a doctor can avoid facing liability for prescribing ivermectin, or use any similar language indicating that the statements determine rights, obligations, or legal consequences. The statements here are unlike the guidance documents in *EEOC II* and are not final agency action.

The plaintiffs also rely on *Louisiana State v. U.S. Army Corp of Eng'rs*, 834 F.3d 574, 583 (5th Cir. 2016), to support their contention that the FDA statements are final agency action. Dkt. 27 at 34. In *Louisiana State*, the Fifth Circuit held that a federal agency's "Final Deauthorization Report," which certified part of a plan but did not bind or regulate the plaintiff, did not create any legal consequences as required for final agency action. *Louisiana State*, 834 F.3d at 583. In support of this conclusion, the court explained that final agency actions "normally affect a regulated party's possible legal liability; these consequences tend to expose parties to civil or criminal liability for non-compliance with the agency's view of the law or offer a shelter from liability if the regulated party complies." *Id.*

While the plaintiffs allege that the FDA's statements have incited third parties to investigate and fire the plaintiffs, the FDA's statements do not state

the FDA's view of the law or create civil or criminal liability for non-compliance, just as the report in *Louisiana State* did not create legal consequences. A state-medical-board investigation and losing one's job—at the hands of non-agency third parties—are not the types of consequences that meet the finality requirement.

Louisiana State also provides a contrasting point—the court in that case ruled that a memorandum of agreement that was binding, final, and contractual in nature determined "rights and obligations and ha[d] legal consequences," and thus was final agency action. *Id.* Under the memorandum of agreement, the agency could have sued the plaintiff to enforce the terms. *Id.* at 584. When compared to the two different documents in *Louisiana State*, the statements here are more like the report than the memorandum of agreement; the FDA cannot "enforce" the statements here against the plaintiffs or anyone else. Like the report in *Louisiana State*, the statements here are not final agency action.

The complaint has failed to allege a final agency action that would allow an exception to sovereign immunity under the APA.[8]

* * *

[8] As the complaint does not allege final agency action, the court does not reach whether the plaintiffs suffered legal harm as a result of final agency action. *Alabama-Coushatta Tribe*, 757 F.3d at 489.

As the complaint does not allege facts that overcome the defendants' assertion of sovereign immunity, the defendants' motion to dismiss is granted. Dkt. 25.

Signed on Galveston Island this 6th day of December, 2022.

JEFFREY VINCENT BROWN
UNITED STATES DISTRICT JUDGE