United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
September 1, 2023
Lyle W. Cayce
Clerk

No. 22-40802

ROBERT L. APTER; MARY TALLEY BOWDEN; and PAUL E. MARIK,

Plaintiffs—Appellants,

versus

DEPARTMENT OF HEALTH & HUMAN SERVICES; XAVIER BECERRA, *in his official capacity as Secretary of Health and Human Services*; FOOD & DRUG ADMINISTRATION; ROBERT M. CALIFF, *in his official capacity as Commissioner of Food and Drugs*,

Defendants—Appellees.

Appeal from the United States District Court
for the Southern District of Texas
USDC No. 3:22-CV-184

Before CLEMENT, ELROD, and WILLETT, *Circuit Judges*.

DON R. WILLETT, *Circuit Judge*:

"You are not a horse."

Or so the Food and Drug Administration ("FDA") alerted millions of Americans via social media, midway through the COVID-19 pandemic. The agency had discerned that some people were treating their symptoms using the animal version of a drug called ivermectin. FDA decided to target that practice via the "horse" message—and others like it. The messaging

traveled widely across legacy and online media. Left unmentioned in most of that messaging: ivermectin also comes in a human version. And while the human version of ivermectin is not FDA-approved to treat the coronavirus, some people were using it off-label for that purpose.

The Appellants are three medical Doctors who prescribed the human version of ivermectin to thousands of their patients. Each Doctor says that FDA's messaging interfered with their own individual medical practice. The Doctors sued FDA and the Department of Health and Human Services (together, the "Agencies"). They also sued two governmental employees in their official capacities (the "Officials"). The Doctors argue that FDA's "horse" message and similar public statements (together, the "Posts") violate FDA's enabling act ("Act") and the Administrative Procedure Act ("APA"). The district court held that sovereign immunity protects the Agencies and the Officials, and it dismissed the suit. We disagree.

First, the Doctors can use the APA to bypass sovereign immunity and assert their *ultra vires* claims against the Agencies and the Officials. FDA is not a physician. Thus, assuming FDA is correct that we must consider the merits to some degree even at the pleading stage, the Posts that issue medical advice to consumers are plausibly *ultra vires*. The Posts are plausibly agency action, too, because they publicly announce the general principle that consumers should not use ivermectin to treat the coronavirus, and because the Doctors fall within the Act's zone of interests. Second, because the Doctors can use the APA for their *ultra vires* claims, we need not consider the common-law version of that doctrine. Third, however, the Doctors' pure APA claim cannot go forward. That is because the Posts do not determine legal rights and thus lack the finality. Even though this last theory fails, the Doctors' first theory is enough to allow this suit to proceed.

We REVERSE and REMAND.

I

A

Ivermectin is a drug. About eighteen months into the COVID–19 pandemic, the Food and Drug Administration released an informal "Consumer Update" titled "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" ("Update"). The current version of the Update reads, in part (internal headings omitted):

> COVID-19. We've been living with it for what sometimes seems like forever. Given the number of deaths that have occurred from the disease, it's perhaps not surprising that some consumers are turning to drugs not approved or authorized by the Food and Drug Administration . . . .
> . . .
>
> There seems to be a growing interest in a drug called ivermectin for the prevention or treatment of COVID-19 in humans. Certain animal formulations of ivermectin such as pour-on, injectable, paste, and "drench," are approved in the U.S. to treat or prevent parasites in animals. For humans, ivermectin tablets are approved at very specific doses to treat some parasitic worms, and there are topical (on the skin) formulations for head lice and skin conditions like rosacea.
>
> However, the FDA has received multiple reports of patients who have required medical attention, including hospitalization, after self-medicating with ivermectin intended for livestock.
>
> - The FDA has not authorized or approved ivermectin for use in preventing or treating COVID-19 in humans or animals. Ivermectin is approved for human use to treat infections caused by some parasitic worms and head lice and skin conditions like rosacea.
>
> - Currently available data do not show ivermectin is effective against COVID-19. Clinical trials assessing

> ivermectin tablets for the prevention or treatment of COVID-19 in people are ongoing.
>
> - Taking large doses of ivermectin is dangerous.
> - 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.
> - Never use medications intended for animals on yourself or other people. Animal ivermectin products are very different from those approved for humans. Use of animal ivermectin for the prevention or treatment of COVID-19 in humans is dangerous.
>
> . . . .
>
> The FDA has not authorized or approved ivermectin for the treatment or prevention of COVID-19 in people or animals. Ivermectin has not been shown to be safe or effective for these indications.
>
> There's a lot of misinformation around, and you may have heard that it's okay to take large doses of ivermectin. It is <u>not</u> okay.
>
> . . . .
>
> 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.[1]

FDA also released a document titled "FAQ: COVID-19 and Ivermectin Intended for Animals" ("FAQ"). Together, the Update and the FAQ total about four pages. In addition to those releases, FDA also posted

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[1] Food and Drug Admin., *Why You Should Not Use Ivermectin to Treat or Prevent COVID-19* (Dec. 10, 2021), https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19 (emphases in original).

four items online between August 2021 and April 2022—one on its website, and three across social media. The website post reads, in part: "Q: Should I take ivermectin to prevent or treat COVID-19. A: No." The three social media posts are similar. They say, in full:

- "You are not a horse. You are not a cow. Seriously, y'all. Stop it."
- "You are not a horse. Stop it with the #ivermectin. It's not authorized for treating #COVID."
- "Hold your horses, y'all. Ivermectin may be trending, but it still isn't authorized or approved to treat COVID-19."

FDA included an image of a horse in each of the three social media posts. We refer to these six items as the "Posts" (that is: the Update, the FAQ, the website post, and the three social-media posts).

In an internal email, a member of FDA's communications team referred to the Posts as part of a new engagement strategy. The strategy played well, and media outlets nationwide ran headlines and stories emphasizing FDA's "horse" messages. Medical organizations also took note of the Posts, as did pharmacy boards and hospitals. Federal and state courts, too, began citing the Posts in cases involving ivermectin. All told, the Posts—and particularly the Update—saw citations in newspapers, magazines, digital media outlets, medical and professional advisories, legal complaints, and judicial opinions across the Nation.

The Plaintiffs–Appellants in this case are three Doctors who have prescribed the human version of ivermectin to thousands of patients suffering from the coronavirus. The Doctors allege that the Posts interfered with their individual "ability to exercise professional medical judgment in practicing medicine." The Doctors also allege that the Posts harmed their reputations. Further, Dr. Apter alleges that he was "referred to [two state medical boards]

. . . for prescribing ivermectin to treat COVID-19," and that "[t]he referrals include copies of FDA's [Posts]." Dr. Apter and Dr. Bowden each say that pharmacies have refused to fill ivermectin prescriptions for their patients because of FDA's Posts. Dr. Bowden also lost her admitting privileges at a hospital after "tweeting about using ivermectin to treat patients with COVID-19." And Dr. Marik lost his positions at a medical school and at a hospital "for promoting the use of ivermectin."

B

The Doctors sued FDA, arguing that the Posts are *ultra vires* under FDA's enabling Act and unlawful under the APA.[2] The Doctors asked the district court to:

- set the Posts aside, and declare them unlawful;
- declare that FDA cannot interfere with the practice of medicine;
- declare that "FDA cannot issue statements or directives about how or whether health professionals should use ivermectin off-label to treat patients, and that such FDA actions have no legal effect and do not bind health professionals or patients"; and to
- enjoin FDA "from engaging in such actions."

FDA moved to dismiss the Doctors' complaint under Rule (12)(b)(1), invoking sovereign immunity and arguing that the Doctors lack standing to sue under Article III. While noting that "FDA could have, and perhaps

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[2] FDA's enabling act is the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399i (the "Act"). By "APA," we mean the Administrative Procedure Act, 5 U.S.C. §§ 551–59, 701–06. Separately, while this case's caption includes additional defendants (beyond FDA), the distinctions between them are not relevant for most aspects of this appeal, and the parties refer primarily to FDA. Except where noted, we do the same.

should have, been more prudent in their communications," the district court nonetheless held that sovereign immunity protects FDA and the other defendants, and it therefore dismissed the suit.[3]

The district court first held that the Doctors cannot rely on the narrow *ultra vires* exception to sovereign immunity.[4] The district court began with the premise that an act is *ultra vires* only if it is "without any authority whatsoever" or is "made without any colorable basis for authority."[5] The court noted that Congress charged FDA "with protecting public health and ensuring that regulated medical products are safe and effective."[6] And it observed that "FDA has the authority, generally, to make public *statements* in-line with these purposes."[7] Therefore, the district court held, "it cannot be said that the FDA had no colorable basis of authority" to issue the Posts.[8]

The district court then turned to § 396 of the Act, which says that "[n]othing 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."[9] The Doctors argued that this section prohibits FDA from recommending for or against the off-label use of any

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[3] *Apter v. U.S. Dep't of Health & Hum. Servs.*, ___ F. Supp. 3d ___, No. 3:22-CV-184, 2022 WL 17578869, at *5, *7 (S.D. Tex. Dec. 6, 2022).

[4] *Id.* at *5.

[5] *Id.* at *4 (citing *Danos v. Jones*, 652 F.3d 577, 583 (5th Cir. 2011)).

[6] *Id.* at *5 (citing 21 U.S.C. § 393(b)(1)–(b)(2)).

[7] *Id.* (emphasis added).

[8] *Id.*

[9] *Id.* at *4 (quoting 21 U.S.C. § 396).

drug.[10] The district court deemed § 396 inapplicable, holding that the section's plain text refers only to "devices"—not "drugs."[11]

Next, the district court concluded that the Posts are not final agency action, and thus that the APA's waiver of sovereign immunity is also unavailable. The court reasoned that the Posts lack finality because "[n]one of the statements determine rights, obligations, or legal consequences."[12] Moreover, "at least some of the statements do not mark the consummation of the agency's decisionmaking process."[13] Instead, the Posts "include language indicating that they were made based on 'currently available data,' [and that] 'additional testing was needed,' 'clinical trials were ongoing,' and 'initial research was underway.'"[14] As the district court explained, "there is no indication the FDA has adopted a legal position, [and] no indication of any future liability on non-complying parties."[15] The court expressly declined to analyze the Doctors' hybrid theory, under which the general waiver of sovereign immunity in the APA also waives sovereign immunity for non-statutory causes of action such as *ultra vires* suits.[16]

Because the district court relied on sovereign immunity, it did not address Article III standing. The Doctors timely appealed.

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[10] "Off-label" use occurs when a drug is used "for some other purpose than that for which it has been approved by the FDA." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

[11] *Apter*, 2022 WL 17578869, at *4 & n.6.

[12] *Id.* at *6.

[13] *Id.* at *5.

[14] *Id.* (alterations adopted).

[15] *Id.* at *7.

[16] *See id.* at *3 ("The APA and *ultra vires* . . . are two distinct waivers of sovereign immunity, and thus it would be incorrect to use the two interchangeably.").

II

The district court had federal-question jurisdiction under 5 U.S.C. § 702 and under 28 U.S.C. §§ 1331, 1346, 1361, and 2201. We have appellate jurisdiction under 28 U.S.C. §§ 1291 and 1292. We review dismissals for sovereign immunity and lack of subject-matter jurisdiction de novo,[17] "accept[ing] all factual allegations in the plaintiff's complaint as true."[18] "[T]he party asserting federal subject-matter jurisdiction[] has the burden of proving" that jurisdiction is present.[19]

III

We begin with sovereign immunity.

"The United States may not be sued except to the extent that it has consented to suit . . . ."[20] As such, "where the United States has not consented to suit or the plaintiff has not met the terms of the statute [authorizing suit,] the court lacks jurisdiction and the action must be dismissed."[21] The Doctors rely on three theories to overcome sovereign immunity: (1) the *ultra vires* doctrine via the APA, (2) the *ultra vires* doctrine itself, and (3) the APA itself. The district court rejected all three paths.[22]

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[17] *Louisiana v. United States*, 948 F.3d 317, 320 (5th Cir. 2020).

[18] *Den Norske Stats Oljeselskap As v. HeereMac Vof*, 241 F.3d 420, 424 (5th Cir. 2001).

[19] *Alabama-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484, 487 (5th Cir. 2014).

[20] *Gonzalez v. Blue Cross Blue Shield Ass'n*, 62 F.4th 891, 898 (5th Cir. 2023) (alterations adopted) (internal quotation marks and citation omitted).

[21] *Id.*

[22] *Apter*, 2022 WL 17578869, at *4–7.

We conclude that the first path is open: the Doctors can use the APA to assert their *ultra vires* claims against the defendants. FDA can *inform*, but it has identified no authority allowing it to *recommend* consumers "stop" taking medicine. The Doctors can therefore use the APA to assert their *ultra vires* challenge to the Officials' actions, and to overcome the sovereign immunity that would otherwise protect the Agencies. Accordingly, we need not consider the second path, under which the Doctors attempt to assert their *ultra vires* claims using only the common law. However, we do reject the third path. The Posts are not "final" agency action, and immunity thus bars the Doctors' claims from proceeding solely under the APA's general provisions.

A

The Doctors can use the APA assert their *ultra vires* claims as a non-statutory cause of action against the Officials and against the Agencies.

1

At common law, "[t]he *ultra vires* exception to sovereign immunity . . . provides that 'where the officer's powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions.'"[23] "Such actions are '*ultra vires* [*i.e.* beyond] his authority and therefore may be made the object of specific relief.'"[24] "To invoke this exception, a plaintiff must 'do more than simply allege that the actions of the officer are illegal or unauthorized.'"[25] Rather, "[t]he complaint must allege facts sufficient to establish that the officer was acting 'without any authority

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[23] *Danos*, 652 F.3d at 583 (quoting *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949)).

[24] *Id.*

[25] *Id.* (quoting *Ala. Rural Fire Ins. Co. v. Naylor*, 530 F.2d 1221, 1226 (5th Cir. 1976)).

whatever,' or without any 'colorable basis for the exercise of authority.'"[26] Under the common-law *ultra vires* doctrine, then, a strong merits argument is needed to overcome sovereign immunity—even at the pleading stage.

As a threshold matter, FDA argues that we must apply the common law's merits-adjacent inquiry to the Doctors' "*ultra vires* claim" as a whole—even to the aspects of that claim that the Doctors assert under the APA. Assuming without deciding that FDA is correct about that, we conclude that the Doctors' *ultra vires* claim has merit enough to overcome immunity under the common law, and therefore under the APA as well.

For instance, one of the Doctors' foremost arguments under the *ultra vires* doctrine is that FDA has statutory authority to share data, facts, and knowledge, but not to recommend treatments or give other medical advice. The argument proceeds along these lines: (1) FDA cannot act without express statutory authority, (2) FDA does not have express authority to recommend against off-label uses of drugs approved for human use, (3) the Posts recommend against ivermectin, therefore (4) the Posts are beyond FDA's authority. We agree that, at this stage, FDA has not offered even a "colorable basis" for rejecting this argument.[27]

The district court rejected the third premise, reasoning that FDA, has authority "to make public statements," and that "there is no statute saying otherwise."[28] FDA echoes the district court's reasoning on appeal, claiming that it "has inherent authority to communicate information to the public." But this approach assumes that the Posts contain only factual statements and

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[26] *Id.* (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 101 n. 11 (1984)).

[27] *Id.*

[28] *Apter*, 2022 WL 17578869, at *5.

information, and that they do not contain any medical recommendations or advice. But FDA does not defend that assumption. Nor do we see much supporting the position. On the contrary, all six of the Posts contain syntax that is imperative rather than declaratory (for example: "Stop it," "Stop it with the #ivermectin," and "Q: Should I take ivermectin to prevent or treat COVID-19? A: No."). For that reason, we are unable to draw any analytical distinction between FDA making the Posts versus FDA telling Americans to "Stop it" with acetaminophen or antibiotics.

FDA does not argue that it actually *does* have authority to issue advice (as opposed to information). That is, FDA never disputes what we have labeled as the Doctors' second premise, above. Instead, FDA argues only that the Posts *do not contain* advice. For instance, FDA's brief argues that "FDA's informational statements do not 'direct' consumers, or anyone else, to do or refrain from doing anything." Likewise, FDA's brief says that the Posts are "purely informational." At the same time, however, FDA's brief also concedes that the Posts "provided recommendations" and "advise[d] consumers." Despite these concessions, FDA never points to any authority that allows it to issue recommendations or give medical advice.

Rather, FDA argues that some Posts included a hyperlink that leads to the Update. The Update, in turn, directs consumers to "[t]alk to your health care provider." But not all of the social-media posts included such a link. And even for those Posts that did include a link, the Posts themselves offer advice, not mere information. The same is true of the Update itself. It says: "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." But the Update's title is "Why You *Should Not* Use Ivermectin to Treat or Prevent COVID-19" (emphasis added). As with "Click It or Ticket," the trailing qualifier does not lessen the opening instruction's imperative character.

Finally, citing the purpose statement that appears in the Act, FDA also argues that its mission is to protect the public health. But "no legislation pursues its purposes at all costs."[29] That is why "statements of purpose . . . cannot override a statute's operative language."[30] Nothing in the Act's plain text authorizes FDA to issue medical advice or recommendations. FDA's argument from the Act's purpose statement thus leads nowhere. In sum, while FDA cites plenty of statutory authority allowing it to issue *information*, it never identifies even colorable authority allowing it to make medical *recommendations* (at least not without notice and comment). The Doctors can therefore use the *ultra vires* exception to sue the Agencies and the Officials—even if FDA is correct that the heightened, merits-adjacent test for common-law *ultra vires* claims also applies to *ultra vires* claims under the APA.[31]

2

Section 702 of "[t]he APA generally waives the Federal Government's immunity from a suit 'seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority.'"[32] When a plaintiff uses the APA to assert a "non-statutory cause of action"—such as an *ultra vires* claim—section 702 "contains two

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[29] *Rodriguez v. United States*, 480 U.S. 522, 525–26 (1987) (per curiam).

[30] *Sturgeon v. Frost*, 139 S. Ct. 1066, 1086 (2019) (alteration adopted) (internal quotation marks and citation omitted).

[31] The Doctors have identified at least one *argument* that is strong enough to bypass immunity under the common-law *ultra vires* doctrine (and therefore under the APA, too, even if FDA is correct that *ultra vires* claims under the APA face the same hurdle as common-law claims). Therefore, we need not and do not consider the merits of any of the Doctors' remaining *ultra vires* arguments—such as their argument under 21 U.S.C. § 396.

[32] *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 215 (2012) (quoting 5 U.S.C. § 702) (emphasis added).

separate requirements for establishing a waiver of sovereign immunity."[33] "First, the plaintiff must identify some 'agency action' affecting him in a specific way . . . ."[34] The action need not be final.[35] "Second, the plaintiff must show that he has '[been] . . . adversely affected or aggrieved by that action . . . ."[36] To satisfy this second requirement, "the plaintiff must establish that the injury he complains of falls within the 'zone of interests' sought to be protected by the statutory provision whose violation forms the legal basis for his complaint."[37] The Doctors' suit satisfies both requirements.

i

The Posts are "agency action." Under the APA, that term "includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act."[38] "Rule," in turn—

> means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services

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[33] *Alabama-Coushatta*, 757 F.3d at 489 (citing *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 882 (1990)).

[34] *Id.*

[35] *See id.* (citing *Trudeau v. Fed. Trade Comm'n*, 456 F.3d 178, 187 (D.C. Cir. 2006)).

[36] *Id.*

[37] *Louisiana*, 948 F.3d at 321 (alteration adopted) (internal quotation marks omitted) (quoting *Lujan*, 497 U.S. at 883).

[38] 5 U.S.C. § 551(13).

> or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing[.][39]

In other words, "[t]he APA defines the term 'rule' broadly enough to include virtually every statement an agency may make."[40] Agency rules fall into one of two categories: either substantive or non-substantive.[41] As distinct from substantive rules, "[n]on-substantive rules are those exempted from the notice-and-comment requirement because they lack the force of law."[42] Non-substantive rules "include rules governing internal agency organization or procedures; non-binding agency policy statements; and guidance documents interpreting existing rules."[43] The Posts did not go through notice-and-comment, so if they are APA "rules" at all, it is only because they are non-substantive rules. The Doctors argue that the Posts are rules—and thus "agency action"—under these definitions. We agree.

FDA does not dispute that the Posts are statements, and it does not deny authoring them. "Though there is room for disagreement about precisely what satisfies the definition of 'rule,'" we conclude that the Posts easily qualify.[44] Foremost, the Posts "announce [a] principle[] of general applicability and future effect."[45] FDA's Posts contain information, but they also contain the generally-applicable principle that consumers "Should Not

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[39] 5 U.S.C.§ 551(4).

[40] *Avoyelles Sportsmen's League, Inc. v. Marsh*, 715 F.2d 897, 908 (5th Cir. 1983); *see F.T.C. v. Standard Oil Co. of Ca.*, 449 U.S. 232, 238 n.7 (1980) (similar).

[41] *Walmart Inc. v. U.S. Dep't of Justice*, 21 F.4th 300, 308 (5th Cir. 2021).

[42] *Id.* On the other hand, "[s]ubstantive rules have the force of law, meaning that they bind the regulated public." *Id.*

[43] *Id.*

[44] *See Walmart*, 21 F.4th at 308.

[45] *Id.* (citing 5 U.S.C. § 551(4)).

Use Ivermectin to Treat or Prevent COVID-19." That principle aims to curb future action—not just label past action. The day after FDA issued the first "horse" message, FDA staffers noted that it was "the most popular post we've ever had on Twitter" and that they were "pleased with the response and the results." Staffers also described the Posts as part of a "new recommended approach" that comprised an "ambitio[us] effort to counter much of the vaccine [mis]information out there." The Posts directed consumers to take specific actions in keeping with the generally applicable principle that FDA had settled on and announced. That is "action" enough.

We find further support for this conclusion in *Walmart Inc. v. U.S. Department of Justice*.[46] There, a panel of this court held that an agency's "negotiating position" was not a non-substantive rule, and thus was not agency action, because (among other things) it did not "announce agency views to the public."[47] Furthermore, the plaintiff in that case "point[ed] to no rule, guidance, or other public document setting forth the positions it s[ought] to contest."[48] Here, by contrast, FDA has announced that the public should, among other things, "Stop it with the #ivermectin." That recommendation is a position that the Doctors wish to contest. The Posts reflecting the position are exactly the kind of "non-binding agency policy statement[]" that *Walmart* treated as a non-substantive rule.[49]

FDA argues that the Posts are "informational statements" that cannot qualify as rules because they "do not 'direct' consumers, or anyone

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[46] 21 F.4th 300, 308 (5th Cir. 2021).

[47] *Id.* at 309 (citing *Brown Express, Inc. v. United States*, 607 F.2d 695, 700–01 (5th Cir. 1979)); *see Phillips Petroleum Co. v. Johnson*, 22 F.3d 616, 619–20 (5th Cir. 1994)).

[48] *Id.* at 305.

[49] *Id.* at 308.

else, to do or refrain from doing anything." We are not convinced. As discussed above, each of the Posts contains imperative elements that go beyond mere factual communication. FDA also argues that the Posts cannot be rules because they do not "prescribe . . . policy." Again, we disagree. FDA concedes that the Posts "generally recommended that consumers not take ivermectin to prevent or treat COVID-19." For purposes of determining non-final agency action, we do not see any daylight between an agency that uses imperative language in recommending a general course of action and an agency that uses imperative language in prescribing a policy.

FDA also argues that the Posts are not rules because they are nonbinding, and because they did not mark the end of the agency's decisional process. But these arguments conflate the test for determining *action* with the test for determining *finality*. Our caselaw recognizes that "nonfinal action" is still action.[50] Otherwise "final" would have no meaning (since all "agency action" would be final by definition). Instead, we have held that, "when judicial review is sought pursuant to a . . . non-statutory cause of action that arises completely apart from the general provisions of the APA[,] . . . . [t]here is no requirement of 'finality'" for the § 702 "waiver to apply."[51] So it is here. The Doctors' *ultra vires* claim is a non-statutory cause of action. We reject FDA's attempt to impose a finality requirement for a waiver of sovereign immunity in this context. And we therefore conclude that the Posts qualify as "agency action."

ii

The Doctors are also within the zone of interests that the Act protects. The phrase "zone of interests" appears most often in cases discussing

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[50] *Qureshi v. Holder*, 663 F.3d 778, 781 (5th Cir. 2011).

[51] *Alabama-Coushatta*, 757 F.3d at 489.

prudential standing,[52] and it has also popped up in cases discussing whether the plaintiff has a cause of action.[53] But we know of only a single case from this circuit applying the zone-of-interests test in the sovereign-immunity context: *Louisiana v. United States*.[54] That case relied on *Lujan*—a leading case on standing.[55] From that reliance, we surmise that "zone of interests" means the same thing regardless of whether the context is prudential standing, causes of action, or sovereign immunity. At the same time, we also acknowledge that the "zone of interests" question is distinct from constitutional standing under Article III, and from a case's merits.

The zone-of-interests test "is not especially demanding."[56] "[I]n keeping with Congress's evident intent when enacting the APA to make agency action presumptively reviewable," the Supreme Court has "not require[d] any indication of congressional purpose to benefit the would-be plaintiff."[57] Instead, "[t]he test is satisfied if the claims are 'arguably within the zone of interests to be protected . . . by the statute.'"[58] "The Supreme Court has 'always conspicuously included the word *arguably* in the test to indicate that the benefit of *any doubt goes to the plaintiff*.'"[59] "Review is

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[52] *E.g.*, *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 127 (2014).

[53] *E.g.*, *Tenth St. Residential Ass'n v. City of Dallas,* 968 F.3d 492, 499 (5th Cir. 2020).

[54] 948 F.3d 317 (5th Cir. 2020).

[55] *See id.* at 321 (citing 497 U.S. 871).

[56] *Texas v. United States*, 50 F.4th 498, 520 (5th Cir. 2022) (internal quotation marks and citation omitted).

[57] *Patchak*, 567 U.S. at 225.

[58] *Texas*, 50 F.4th at 520 (quoting *Patchak*, 567 U.S. at 224).

[59] *Id.* (emphases added) (quoting *Patchak*, 567 U.S. at 225).

foreclosed 'only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit.'"[60]

Section 396 is titled "Practice of medicine," and its plain text protects some aspects of the "practitioner–patient relationship" from FDA's "limit[ation] or interfere[nce]."[61] As practitioners themselves, the Doctors' "interests" in the Act's "purposes" are much more than "marginal[]."[62] Indeed, the Act expressly shields the Doctors from certain kinds of FDA meddling. Whether that shield protects them from *this* alleged meddling is a merits question—not a zone-of-interests question. Likewise, even if the Doctors lack a cognizable injury under Article III of the Constitution, their claims are still at least "arguably"[63] within the Act's zone of interests.

FDA does little to contest this conclusion. It does not even address this kind of *ultra vires* claim in a separate section of its brief. Instead, FDA obfuscates. It treats a non-statutory cause of action under the APA (that is, an *ultra vires* claim that uses the APA as a vehicle to sue an agency) identically to a cause of action under the APA's general provisions. But *Alabama-Coushatta* instructs that these are actually "two distinct types of claims."[64] Here, because the Posts are agency action, and because the Doctors are within the Act's zone of interests, they can use the APA as a vehicle to assert their *ultra vires* claims against the Agencies.

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[60] *Id.* (internal quotation marks omitted) (quoting *Patchak*, 567 U.S. at 225).

[61] 21 U.S.C. § 396.

[62] *Texas*, 50 F.4th at 520 (internal quotation marks and citation omitted).

[63] *Texas*, 50 F.4th at 520 (quoting *Patchak*, 567 U.S. at 224).

[64] *Alabama-Coushatta*, 757 F.3d at 489.

B

As for the Doctors' common-law *ultra vires* claim, we begin by noting that, under our precedent, Congress apparently "d[id] away with the *ultra vires* doctrine and other fictions surrounding sovereign immunity" when it amended the APA in 1976.[65] We also note the D.C. Circuit's recent decision holding that common-law *ultra vires* claims are available only when there is no alternative procedure for review.[66] Similarly, the Ninth Circuit has held that common law *ultra vires* claims are available only when APA *ultra vires* claims are not.[67] Moreover, several other circuit courts have applied the common-law doctrine only when APA review was unavailable.[68] Here, because the Doctors can use the APA to assert their *ultra vires* claims, we decline to consider whether the Doctors might also be able to assert their *ultra vires* claims using only the common law version of that doctrine.

C

While the APA allows the Doctors to assert their *ultra vires* claims against both the Agencies and the Officials, we conclude that the Doctors cannot rely solely on "the general provisions of the APA."[69]

"[W]hen judicial review is sought pursuant *only* to the general provisions of the APA," a plaintiff who wishes to establish "that there was a waiver of sovereign immunity" must show that it has "suffer[ed] legal

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[65] *Geyen v. Marsh*, 775 F.2d 1303, 1307 (5th Cir. 1985).

[66] *See Fed. Express Corp. v. U.S. Dep't Commerce*, 39 F.4th 756, 763 (D.C. Cir. 2022).

[67] *E.V. v. Robinson*, 906 F.3d 1082, 1092–93 (9th Cir. 2018).

[68] *See, e.g.*, *Dotson v. Griesa*, 398 F.3d 156, 177 & n.15 (2d Cir. 2005); *Made in the USA Found. v. United States*, 242 F.3d 1300, 1308–09 n.20 (11th Cir. 2001); *Strickland v. United States*, 32 F. 4th 311, 366 (4th Cir. 2022).

[69] *Alabama-Coushatta*, 757 F.3d at 489 (emphasis added).

wrong" because of "*final* agency action."[70] "There are two requirements" for finality.[71] First, "the action must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature."[72] Second, "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow."[73]

The Doctors have not plausibly established the finality test's second prong, which requires them to show that FDA's actions "determined rights, produced obligations, or caused legal consequences."[74] "The Supreme Court has long taken a pragmatic approach to finality, viewing the APA's finality requirement as flexible."[75] The Doctors offer three reasons that the Posts are final. Yet even under the Supreme Court's "pragmatic" approach, we cannot conclude that the Posts plausibly determined "rights or obligations," or that they plausibly constituted action "from which legal consequences will flow."[76] As a result, the Posts are not *final* agency action.

First, quoting the panel decision in *Texas v. EEOC*, the Doctors say that "[w]hat matters is whether the [action] has *practical binding effect* such that affected private parties are reasonably led to believe that failure to

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[70] *Id.* (emphases added) (internal quotation marks omitted) (first citing 5 U.S.C. § 702, then citing *Lujan*, 497 U.S. at 882).

[71] *Data Mktg. P'ship, LP v. United States Dep't of Lab.*, 45 F.4th 846, 853 (5th Cir. 2022).

[72] *Id.* (internal quotation marks and citation omitted).

[73] *Id.* (internal quotation marks and citation omitted).

[74] *Data Mktg.*, 45 F.4th at 854.

[75] *Texas v. Equal Emp. Opportunity Comm'n*, 933 F.3d 433, 441 (5th Cir. 2019) (alteration adopted) (internal quotation marks and citations omitted) ("*EEOC*"); *see Qureshi*, 663 F.3d at 781 (similar).

[76] *Data Mktg.*, 45 F.4th at 853 (internal quotation marks and citation omitted).

conform will bring adverse consequences."[77] But *EEOC* is not as broad as the Doctors contend. The sentence they quote was elaborating on the sentence that preceded it: "That the agency's action *binds its staff* or creates safe harbors demonstrates that legal consequences flow from it . . . ."[78] The "practical binding effect," then, is an effect on the agency—not the public. The sentence that follows the Doctors' quote makes this abundantly clear: "Defendants do not dispute that the Guidance *binds EEOC*, and for good reason."[79] So too for the Doctors' argument based on the word "norm." While that word also appears in the *EEOC* case, it refers to an "agency's action [that] binds *it*"—that is, the agency—not an action that binds others.[80] The Posts do not "bind[] [FDA] and its staff to a legal position," so they are not norms, and their practical effect cannot carry the day.[81]

Second, the Doctors argue that "FDA has created a legal standard that governing entities are regularly relying on to establish the appropriate medical care and dictate the practice of medicine, including by courts in legal proceedings." Whatever else the Posts may be, dubbing them a "legal standard" goes too far. None of the cases that the Doctors cite treated FDA's views as a *legal* standard. Instead, some courts have relied on the Posts as *factual* evidence of FDA's views. For example, a Pennsylvania appellate court wrote that "multiple national health organizations, including the FDA, AMA, and WHO, have advocated against the use of ivermectin to treat COVID-19 based on the absence of conclusive studies to show

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[77] *EEOC*, 933 F.3d at 442 (emphasis added) (internal quotation marks and citation omitted).

[78] *Id.* (emphasis added).

[79] *Id.* at 443 (emphasis added).

[80] *Id.* (emphasis added).

[81] *Id.* at 441.

ivermectin is effective at treating COVID-19."[82] That is a statement of fact, not law. The Doctors have not identified any court decision that treated any of the Posts as a legal standard rather than factual evidence. And even if they had, *we* conclude that FDA's Posts do not set forth a legal standard.

Third, quoting the panel decision in *Louisiana State v. U.S. Army Corps of Engineers*, the Doctors emphasize that the Posts "*tend to expose* parties to civil or criminal liability for noncompliance with the agency's view of the law."[83] But the Doctors emphasize the wrong words—it is the last four that matter most. No post contains FDA's "view of the law."[84] Whether or not the Posts play a role in exposing the Doctors to legal consequences, that exposure does not trace to any of FDA's *legal* views. This argument, like the first two, does not show that the Posts "determined rights, produced obligations, or caused legal consequences."[85]

The Doctors respond that "legally binding effects are not necessary to render agency action 'final' . . . when the action in question is clearly outside the agency's statutory authority and further prohibited by statute." The Doctors do not elaborate on this theory, nor do they support it with any citation, so we need not address it further. Even were we inclined to consider the theory, we would likely reject it as conflating an *ultra vires* claim with a claim solely under the APA's general provisions. After all, "clearly outside the agency's statutory authority" is a pretty good definition of *ultra vires*.

Even though the Posts are "action," they are not action "by which rights or obligations have been determined, or from which legal consequences

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[82] *Shoemaker v. UPMC Pinnacle Hosps.*, 283 A.3d 885, 895 (Pa. Super. Ct. 2022).

[83] 834 F.3d at 583 (emphasis added by the Doctors).

[84] *Id.*

[85] *Data Marketing*, 45 F.4th at 854.

will flow."[86] While courts and other institutions may have treated FDA's views as relevant factual evidence—and may have treated the Posts as containing those views—the Posts themselves do not contain FDA's "view of the *law*." [87] They therefore lack finality, and that means that the Doctors' pure APA claim cannot overcome the defendants' sovereign immunity.

IV

Last, FDA urges us to affirm on the alternative basis that the Doctors lack standing under Article III. The district court's dismissal was final, so we have discretion to affirm on any basis that the record supports—including lack of standing.[88] Here, however, we see greater wisdom in remanding for the district court to address standing and any other jurisdictional issues in the first instance. We express no view on those issues, and instead we trust their initial determination to the district court's sound judgment.

V

FDA is not a physician. It has authority to inform, announce, and apprise—but not to endorse, denounce, or advise. The Doctors have plausibly alleged that FDA's Posts fell on the wrong side of the line between telling *about* and telling *to*. As such, the Doctors can use the APA to assert their *ultra vires* claims against the Agencies and the Officials.

Even tweet-sized doses of personalized medical advice are beyond FDA's statutory authority. We REVERSE the district court's judgment of dismissal, and we REMAND for further proceedings.

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[86] *Id.* at 853.

[87] *Louisiana State*, 834 F.3d at 583 (emphasis added).

[88] *See Walmart*, 21 F.4th at 307 ("Though the district court relied exclusively on sovereign immunity, [we] may affirm dismissal for any reason supported by the record.").