No. 22-40802

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

Robert L. Apter, Medical Doctor, FACEP; Mary Talley Bowden, Medical Doctor; Paul E. Marik, MBBCh, M.MED, FCCM, FCCP,

Plaintiffs-Appellants,

v.

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.

On Appeal from the U.S. District Court
for the Southern District of Texas

REPLY BRIEF FOR APPELLANTS

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CERTIFICATE OF INTERESTED PERSONS

Apter et al. v. Dep't of Health & Human Services et al.
No. 22-40802

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Fifth Circuit Local Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

Appellants

1. Robert L. Apter
2. Mary Talley Bowden
3. Paul E. Marik

Appellees

4. Department of Health and Human Services
5. Xavier Becerra
6. Food and Drug Administration
7. Robert M. Califf

Amicus Curiae

8. Association of American Physicians and Surgeons ("AAPS")

9. Front Line COVID-19 Critical Care Alliance ("FLCCC")

10. America's Frontline Doctors ("AFLDS")

Counsel

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12. U.S. Department of Justice: Brian Boynton, Alamdar S. Hamdani, Daniel Tenny, Ashley C. Honold, Samuel R. Bagenstos, Mark Raza, Wendy S. Vicente, Leah A. Edelman, Isaac Belfer, and Oliver McDonald, Counsel for Appellees

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14. FLCCC: Alan Dumoff, Counsel for Amicus Curiae

15. AFLDS: David A. Dalia, Counsel for Amicus Curiae

Dated: March 30, 2023

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INTRODUCTION AND SUMMARY

"All the officers of the government, from the highest to the lowest, are creatures of the law and are bound to obey it." *United States v. Lee*, 106 U.S. 196, 220 (1882). In its opening brief, Appellants demonstrated that sovereign immunity does not shield the U.S. Food and Drug Administration ("FDA")[1] from suit over its unlawful actions regarding ivermectin. Appellants' ultra vires claim can proceed under either the ultra vires exception to sovereign immunity or the waiver of sovereign immunity in the Administrative Procedure Act ("APA") for non-statutory claims. Appellants' APA claims can similarly proceed under the waiver of sovereign immunity in that statute.

FDA responds that the ultra vires doctrine doesn't apply because the agency has authority under the Federal Food, Drug, and Cosmetic Act ("FDCA") to disseminate information consistent with its purpose or regarding danger to health. *See* 21 U.S.C. §§ 375(b), 393(b). FDA also argues for the first time that the Public Health Service Act allows it to inform the public of pertinent health information, which likewise justifies

[1] Appellants sued FDA, the Department of Health and Human Services, the Secretary of Health and Human Services, and the Commissioner of Food and Drugs (collectively, "FDA").

the agency's statements. *See* 42 U.S.C. § 242o(b). And FDA claims that the waivers of sovereign immunity in the APA don't apply because its publications weren't "agency action" or "final," largely because they were allegedly just informational.

These arguments lack merit. For one thing, they depend on the Court construing the facts in the light most favorable to FDA, which is the opposite of what Rule 12 requires. *See In re Supreme Beef Processors, Inc.*, 391 F.3d 629, 633 (5th Cir. 2004). Moreover, nothing in the FDCA or Public Health Service Act authorizes FDA to advise the public on whether to use specific drugs for specific purposes, let alone say "Stop" an off-label use, and 21 U.S.C. § 396 expressly prohibits the agency from doing so. The definition of "agency action" under this Court's longstanding precedent also covers what FDA has done here, and Appellants have pled more than enough facts to plausibly show that FDA's actions have determined rights and obligations, or otherwise resulted in the legal consequences necessary to constitute "final" agency action.

The heart of FDA's response is that its statements were purely "informational." Resp.Br.1, 2, 3, 15, 24, 25, 26, 28. That is wrong.

Statements identifying whether a drug is approved and for what purposes, or notifying the public about adverse event reports, are informational. Dispensing medical advice and directing the public on what FDA-approved drugs should or should not be used, and for what purposes, is not. In fact, in the rare instances when Congress has authorized FDA to limit particular uses of an approved drug, it has done so explicitly, *e.g.*, 21 U.S.C. § 333(e) (restricting off-label use of "human growth hormone"), and it is undisputed that Congress has not done so for ivermectin. At the least, FDA's arguments require drawing inferences about the agency's actions in *its* favor, which is inappropriate. Plaintiffs have plausibly pled (and supported with extensive evidence) that FDA has unlawfully inserted itself into the doctor-patient relationship.

This Court should reject FDA's overt attempt to recharacterize its actions to avoid judicial scrutiny, especially when the agency has witnessed their real-world effects for the two years and nonetheless maintained the relevant publications on official FDA platforms. Judges are "not required to exhibit a naiveté from which ordinary citizens are free," *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2575–76 (2019) (quotation omitted), and just as "[m]en must turn square corners when

they deal with the Government, … the Government should turn square corners in dealing with the people." *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020).

Appellants have also demonstrated standing, although this Court need not reach that issue because the District Court did not opine on it. In any event, FDA's arguments that Appellants' injuries are not traceable to the agency and would not be redressed—in any way—by a favorable ruling rests on the untenable assumption that the countless third parties who explicitly rely on FDA's actions were not actually influenced by that agency and would not plausibly change their behavior if a court held those agency actions unlawful and vacated them. *That* is not plausible and, yet again, depends on turning the pleading standard on its head to draw inferences in FDA's favor.

*

FDA undertook a singularly effective campaign against ivermectin but now seeks to disclaim its intended and predictable effects. FDA plainly desired those effects, or the entire endeavor would have been pointless. The agency cannot have it both ways.

This Court should reverse and remand for further proceedings.

ARGUMENT

I. SOVEREIGN IMMUNITY DOES NOT APPLY TO THE ULTRA VIRES CLAIM BECAUSE FDA OFFICIALS ACTED IN CLEAR EXCESS OF THEIR AUTHORITY

In their opening brief, Op.Br.25–31, Appellants showed that sovereign immunity does not bar their ultra vires claim because FDA doesn't have, and never had, authority to issue medical recommendations or directives, which "is at the heart of the practice of medicine." *Judge Rotenberg Educ. Ctr., Inc. v. FDA*, 3 F.4th 390, 400 (D.C. Cir. 2021). The FDCA, in fact, expressly forbids it. Op.Br.32–38. FDA's actions here were thus "without any 'colorable basis for the exercise of authority,'" and sovereign immunity does not apply. *Danos v. Jones*, 652 F.3d 577, 583 (5th Cir. 2011) (quoting *Pennhurst State Sch. & Hosp. v. Halderman,* 465 U.S. 89, 101 n. 11 (1984)).[2]

1. Citing its statutory mission in 21 U.S.C. § 393(b), FDA responds that Congress charged it with "protecting public health and ensuring that regulated medical products are safe and effective," and the

[2] FDA suggests that the ultra vires exception to sovereign immunity may not have survived the 1976 amendments to the APA. Resp.Br.18. Because FDA does not actually make or develop that argument, it is forfeited. *Feds for Med. Freedom v. Biden*, __ F.4th __, 2023 WL 2609247, at *11 (5th Cir. Mar. 23, 2023). And, in any event, the ultra vires exception survived. Op.Br.26 (collecting cases).

agency "has inherent authority to communicate information to the public" to further that purpose. Resp.Br.18–19 (quoting ROA.1652–53). This is wrong for at least four reasons.

First, statements of purpose do not provide a colorable basis for agency action, including communication with the public. *See* Op.Br.30–31 (collecting authorities). The Supreme Court has "long rejected the notion that '*whatever* furthers the statute's primary objective must be the law.' Even if Congress could have done more, still it 'wrote the statute it wrote—meaning, a statute going so far and no further.'" *Cyan, Inc. v. Beaver Cnty. Emps. Ret. Fund*, 138 S. Ct. 1061, 1073 (2018) (citation omitted). Moreover, the notion that FDA has "inherent authority" is contradicted by Supreme Court precedent that "an agency literally has no power to act … unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986).

Second, FDA was not ensuring that a regulated product was safe and effective. Ivermectin was approved by FDA in 1996 as safe and effective for human use, which involves an extensive statutory process under 21 U.S.C. § 355. FDA has not revisited that decision, which would require additional procedures under the FDCA. FDA was instead trying

to prohibit or discourage use of an approved human drug for a particular off-label use, which is an authority the agency doesn't have. Op.Br.25–30.

Third, FDA does not have a general duty under § 393(b) to protect public health. FDA is directed to "promote the public health by promptly and efficiently reviewing clinical research and *taking appropriate action on the marketing of regulated products*." *Id.* FDA was not "taking appropriate action on … marketing" here.[3]

Fourth, FDA's repeated attempts to recast its actions as merely "informational" is wrong. *See* Resp.Br.1, 2, 3, 15, 24, 25, 26, 28. Statements like "Stop it" and "Stop it with the #ivermectin" are unequivocal directives, not information sharing. FDA is otherwise dispensing medical advice about how doctors and patients should or should not use ivermectin. FDA even acknowledges that at the very least it was giving "advice" and making "recommendations." *E.g.*, Resp.Br.15,

[3] The District Court stated that Appellants don't dispute FDA "has authority, generally, to make public statements in-line with these purposes." ROA.1652–53. Appellants don't dispute that FDA can notify the public whether a drug is approved for a particular purpose or if the agency has received adverse event reports, but Appellants have never agreed that FDA can practice medicine and tell the public what drugs to use for what purposes.

16, 24, 31. Ironically, "recommend" is the same word FDA uses to describe what *medical doctors* do when treating patients. *E.g.*, Resp.Br.11. Appellants have thus plausibly pled that FDA was not merely sharing information but was interfering with the practice of medicine.

2. FDA next asserts its actions were permissible because the FDCA authorizes the agency to "cause to be disseminated information regarding ... drugs[] ... in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer," and "collecting, reporting, and illustrating the results of [its] investigations." 21 U.S.C. § 375(b). The District Court did not rely on this provision, and in any event, it does not support FDA's actions here.

FDA has used this authority to issue reports of adverse events associated with approved drugs and warnings about misbranded drugs, but the agency doesn't identify any instance where it sought to interfere with or effectively prohibit a particular off-label use of an approved drug.[4]

[4] *See, e.g.*, *FDA Warns Company for Putting Consumers at Risk Through Distribution of Non-Compliant and Misbranded Drug Ingredients* (Jan. 27, 2021), https://www.fda.gov/news-events/fda-brief/fda-brief-fda-warns-company-putting-consumers-risk-through-distribution-non-compliant-and-misbranded; *FDA Warns About Serious Problems with High Doses of the Allergy Medicine Diphenhydramine* (Sept. 24, 2020), https://go.usa.gov/xSMKw.

The former is information sharing that Appellants don't quarrel with, while the latter is an unlawful attempt to engage in the practice of medicine by telling doctors and patients what already-approved drugs can or should be used, and for what purposes. If FDA had alerted the public about adverse event reports from self-administered use of animal ivermectin, Appellants wouldn't be here. What Appellants object to—and what FDA doesn't even attempt to explain—is its decision to use adverse event reports about self-administered animal ivermectin as reason to engage in a concerted campaign "to remind the public" not to use the human drug for COVID-19. ROA.1248. Those actions transgressed a bright line FDA was not authorized to cross.

3. FDA now claims for the first time that it has authority under the Public Health Service Act to "issue information related to public health, in the form of publications or otherwise, for the use of the public." 42 U.S.C. § 242o(b). This argument is not properly before the Court. *See Gilbert v. Donahoe*, 751 F.3d 303, 311 (5th Cir. 2014) (explaining, in the context of Rule 12, the Court may "affirm on any ground supported by the record, including one not reached by the district court" *only* when "the

argument was raised below"). And, again, FDA wasn't issuing information, it was giving medical advice.

4. The FDCA is also explicit in 21 U.S.C. § 396 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 to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." At least six circuits—including this Court—multiple district courts, and FDA itself have interpreted this prohibition as applying to the prescription or administration of drugs. Op.Br.33–35; *U.S. ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 328 (5th Cir. 2017).

FDA has abandoned the District Court's argument that this Court's citation to § 396 in the drug context isn't persuasive because it's prefaced with an introductory "*see*" signal. *See* ROA.1651. Instead, FDA argues that § 396 applies only to devices, and the repeated citations "merely stand for the proposition that FDA generally does not interfere with doctors' prescribing approved drugs to their patients for off-label use." Resp.Br.20. That explanation cannot justify the citations. *See* Op.Br.35–37. Moreover, regardless of whether the citations mean § 396 "applies" to

drugs or that this provision merely underscores the structure and limitations of the act as a whole, the result is the same. It has long been understood that Congress did not give FDA—either expressly or through implication—authority to interfere in the off-label use of prescription drugs. Op.Br.28–29. This is dispositive because "agencies, as mere creatures of statute, must point to explicit Congressional authority justifying their decisions," *Clean Water Action v. EPA*, 936 F.3d 308, 313 n.10 (2019), which FDA has failed to do.

To escape the implications—if not outright mandate—of § 396, FDA dismisses the Supreme Court's conclusion in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), that the provision prohibits anything that would "deter off-label use." *Id.* at 350; *see* Resp.Br.21–22. FDA reasons that the Court "did not consider or address whether Section 396 prohibits FDA from doing anything that would deter off-label us of drugs, which would presumably encompass a wide range of conduct that could not plausibly be unlawful." Resp.Br.22.

Not so. *Buckman* held that allowing fraud-on-the-FDA claims under state law might "cause the [FDA's] reporting requirements to deter off-label use," which would in turn violate § 396. 531 U.S. at 350. The

state-law claims were therefore preempted. *Id.* The Court's determination that § 396 prohibits any FDA action that would "deter off-label use"—even indirectly through state law—was the basis for that holding. Appellants have provided considerable evidence that FDA's actions here have materially deterred off-label ivermectin use, while FDA fails to provide a single example of similar deterrence from conduct "that could not plausibly be unlawful." Resp.Br.22.

FDA tries to excuse its actions even if § 396 applies because Appellants have continued to prescribe ivermectin. Resp.Br.20. The agency's position is apparently that if Appellants can prescribe the drug at least sometimes, then FDA did not "limit or interfere" with its use. That interpretation would read "interfere" out of the statute, which applies even to indirect or limited attempts to influence medical practice, even when they don't change the ultimate outcome. Op.Br.32–33. FDA then cites myriad statements from some of its publications that supposedly acknowledge or imply doctors can prescribe ivermectin for COVID-19, Resp.Br.21, but *none* of those statements actually say doctors can prescribe ivermectin for COVID-19, and all in fact appear after statements that the public "should not use ivermectin to treat or prevent

COVID-19." Nor does FDA even attempt to justify its commands to "Stop it" or "Stop it with the #ivermectin," which in no way imply that doctors can still prescribe or patients can take ivermectin for COVID-19. Those statements explicitly attempt to the stop that practice, which is more than sufficient to survive a motion to dismiss.

The lack of authority is reinforced by federalism norms that require FDA to point to clear statutory authorization before intruding on an area of traditional state power. Op.Br.29–31. The practice of medicine is undoubtedly beyond FDA's authority, left to "the exclusive realm of individual states." *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 505 (6th Cir. 2006). FDA simply ignores this issue.

*

The FDCA doesn't grant FDA authority to issue directives or recommendations on the use of FDA-approved drugs or to interfere with the practice of medicine, and § 396 expressly bars the agency from doing so (or clearly indicates that limitation). The agency thus acted "without any authority whatever." *Pennhurst*, 465 U.S. at 101 n.11 (quotation omitted). In addition, "conduct by federal officers forbidden by statute is not shielded by sovereign immunity even though the officer is not acting

completely beyond his authority." *Id.* at 136 n.11 (Stevens, J., dissenting) (collecting cases). Accordingly, the ultra vires claim is not barred by sovereign immunity.[5]

II. THE APA SEPARATELY WAIVES SOVEREIGN IMMUNITY FOR THE ULTRA VIRES CLAIM

Appellants' opening brief also showed the APA waives sovereign immunity for all non-statutory claims seeking equitable relief, including the ultra vires claim here. Op.Br.39–44.[6] To invoke that waiver, Appellants need only be "adversely affected or aggrieved by [agency] action within the meaning of a relevant statute." *Ala.-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484, 489 (5th Cir. 2014) (quotation omitted). Indeed, "section 702 of the APA waives sovereign immunity for *all* suits seeking equitable relief." *Trudeau v. FTC*, 456 F.3d 178, 186 & n.11 (D.C. Cir. 2006) (cleaned up) (cited by *Alabama-Coushatta*); *see id.* at 187 ("Congress intended to waive immunity for 'any' and 'all' actions

[5] FDA adds in a footnote that it sometimes imposes risk mitigation measures under 21 U.S.C. § 355-1 for certain drugs. Resp.Br.5 n.2. FDA has never claimed this provision has any relevance to this case.

[6] "These suits are called 'nonstatutory' because they are not brought under the statutes that specially provide for review of agency action." *Jaffee v. United States*, 592 F.2d 712, 718 n.12 (3d Cir. 1979).

for equitable relief against an agency[.]" (citations omitted)); *Jaffee*, 592 F.2d at 719.

"There is no requirement of 'finality' for this type of waiver to apply." *Ala.-Coushatta*, 757 F.3d at 489. To the extent FDA suggests finality is required, Resp.Br.23, that argument is foreclosed by this Court's precedent.

FDA argues this waiver doesn't apply "because FDA here merely issued informational statements and did not alter any legal rights or responsibilities." *Id.* That misses the mark. Courts "must look beyond the label to the substance of an administrative action," *Avoyelles Sportsmen's League, Inc. v. Marsh*, 715 F.2d 897, 908 (5th Cir. 1983), and FDA's actions here weren't merely "informational," *see supra* Part I. They were undoubtedly intended to influence public behavior regarding human ivermectin, not merely convey information, for example, about self-administered use of the animal drug.

In any event, FDA's publications were agency action even if informational. FDA argues that numerous courts don't consider informational statements to be agency action, but fails to cite a single case in this jurisdiction with that holding. That's because this Court held

in *Avoyelles* that "[t]he APA defines the term 'rule' broadly enough to include virtually every statement an agency may make." 715 F.2d at 908. Moreover, many of the cases cited by FDA are about whether agency action is *final*,[7] which is *not* a requirement for this waiver of sovereign immunity. *Ala.-Coushatta*, 757 F.3d at 489.

FDA does not dispute that *Avoyelles*'s definition of a "rule" is binding. Instead, FDA says Appellants "strip" that language "from its context," because this Court was determining whether EPA statements were "legislative rules" that required notice-and-comment rulemaking. Resp.Br.25. But before deciding whether something is a "legislative rule," courts must first determine whether it's a "rule" at all, which led this Court to conclude that the term includes "virtually every statement an agency may make." *Avoyelles*, 715 F.2d at 908. This conclusion was necessary to the Court's analysis, and provided the foundation for determining whether the rule at issue was "legislative." *Avoyelles* is therefore binding on what constitutes a "rule" and qualifies as agency

[7] *See* Resp.Br.24 (citing *Parsons v. U.S. Dep't of Justice*, 878 F.3d 162, 169 (6th Cir. 2017) (final agency action); *Invention Submission Corp. v. Rogan*, 357 F.3d 452, 459 (4th Cir. 2004) (same)*; Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 313 F.3d 852, 861 (4th Cir. 2002) (same)).

action. FDA's claim that its statements "do not constitute 'rules' under the APA" or agency action is thus wrong. Resp.Br.23.[8]

The Supreme Court has also noted that "[t]he term 'agency action' … assure[s] the complete coverage of every form of agency power, proceeding, action, or inaction." *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 238 n.7 (1980) (quotation omitted). It "includes the supporting procedures, findings, conclusions, or statements or reasons or basis for the action or inaction." *Id.* (quotation omitted). The term is exceedingly broad.

FDA's insistence on some formal alteration of legal rights and responsibilities is irrelevant to this waiver of sovereign immunity and looks like an impermissible attempt to backdoor a finality requirement, which this Court has expressly rejected. *See Ala.-Coushatta*, 757 F.3d at 489. Appellants need only be "adversely affected or aggrieved by [agency] action within the meaning of a relevant statute," *id.* (quotation omitted), which requires that they be within the "zone of interests" protected by

[8] FDA also claims that following *Avoyelles* at face value would contradict "longstanding doctrine set out by … this Court," but FDA fails to cite any contradictory Fifth Circuit caselaw. Resp.Br.26.

the statute constituting "the gravamen of the complaint," *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 883 (1990). Appellants are plainly within the zone of interests of the FDCA, especially because Congress specifically designed that statute so FDA couldn't interfere in the practice of medicine.

FDA adds that it just "expressed its view on the safety and efficacy of using ivermectin to prevent or treat COVID-19, but had no occasion to have an 'official position' in any formal sense." Resp.Br.25. But FDA has no authority to express that view except through the drug approval process, *see* 21 U.S.C. § 355, which FDA did not follow. Instead, the agency claims authority to issue drive-by statements and publications adjacent to (but clearly outside) its regulatory authority, which it knows and intends will affect the public, then hides behind the hollow assertion that its actions don't count because they weren't formal. The ultra vires doctrine does not require finality precisely to ensure judicial review of these sorts of unlawful actions. *Jaffee*, 592 F.2d at 719.

Relatedly, FDA's claim that its "informational statements" "do not 'direct' consumers, or anyone else, to do or refrain from doing anything," Resp.Br.25, is not credible. Most notably, "Stop it" and "Stop it with the

#ivermectin" were not informational, *see supra* Part I, and obviously *do* direct the public to follow FDA's preferred course of action.

III. THE APA WAIVES SOVEREIGN IMMUNITY FOR THE APA CLAIMS

The APA also waives sovereign immunity for APA challenges to final agency action. Op.Br.44–50. Agency action is final when it "mark[s] the consummation of the agency's decisionmaking process," and determines "rights or obligations" or produce "legal consequences." *Texas v. EEOC*, 933 F.3d 433, 441 (5th Cir. 2019) (quoting *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997)). FDA's actions here were official agency positions, some maintained now for almost two years, with profound consequences for Appellants and others across the country. This renders them "final" action under the "flexible" and "pragmatic" approach to APA finality. *Qureshi v. Holder*, 663 F.3d 778, 781 (5th Cir. 2011) (quotation omitted).

FDA has abandoned any argument that its publications weren't the culmination of its decisionmaking process, but rather insists they weren't final because they didn't determine rights, obligations, or legal consequences, reflect a legal position, or have any binding effect. Resp.Br.23, 27–29. Again, not so. Appellants have cited numerous

examples where FDA's actions *did* have legal consequences, including by numerous courts to determine the appropriate standard of care. Op.Br.47–48. Amicus FLCCC adds even more. FLCCC.Br.5–13.

An explicit declaration of legal consequences is not required for finality—the agency action need only have "*practical* binding effect." *EEOC*, 933 F.3d at 442 (emphasis added); *see also Writers Guild of Am., West, Inc. v. Am. Broad. Co.,* 609 F.2d 355, 365 (9th Cir. 1979) ("Regulation through 'raised eyebrow' techniques or through forceful jawboning is commonplace in the administrative context, and in some instances may fairly be characterized ... as official action by the agency."). Appellants plausibly alleged FDA publications about ivermectin have had such an effect. Op.Br.48.

This Court has also looked to whether an agency's actions have created a "norm" for private parties to follow, including to avoid liability from third parties. *EEOC*, 933 F.3d at 444. FDA itself desired and created such a norm, issuing multiple publications and directing the Federation of State Medical Boards and the National Association of Boards of Pharmacy to one of its anti-ivermectin reports. ROA.1256. By doing so, FDA "intended" its reports and statements "to be a playbook for [doctors]

to use." *EEOC*, 933 F.3d at 444. The message to doctors like Appellants could not have been clearer—"don't prescribe ivermectin for COVID-19 or else." This Court sitting *en banc* recently held that such a government threat was sufficient to obtain judicial review even when the government had not identified precisely what the "or else" would actually be. *See Feds for Med. Freedom*, __ F.4th __, 2023 WL 2609247, at *15.

FDA also excuses the effects of its actions because other entities were allegedly speaking out against ivermectin. Resp.Br.27–28. But none of FDA's examples are persuasive. FDA first omits that several of these entities, including the American Medical Association and the American Society of Health-Systems Pharmacists, expressly cited FDA's anti-ivermectin statements. FDA also fails to acknowledge that the Centers for Disease Control took *no position* on ivermectin but likewise cited FDA's statements, noting that "FDA has cautioned about the potential risks of use for prevention or treatment of COVID-19" and pointing to FDA's anti-ivermectin material.[9]

[9] *See CDC Health Advisory: Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Use of Products Containing Ivermectin to Prevent or Treat COVID-19* (Aug. 26, 2021), https://emergency.cdc.gov/han/2021/pdf/CDC_HAN_449.pdf.

FDA also asserts the World Health Organization opposed the use of ivermectin for COVID-19, but then glaringly fails to explain why statements by a foreign entity with no regulatory authority in the United States would carry the same weight as the premier drug regulatory agency here. And while Merck made statements about ivermectin, it is passing strange that FDA would even suggest assertions about the efficacy of a generic drug from a pharmaceutical company, which was currently developing competing drugs, would carry any weight, let alone the same weight as the repeated and categorical statements made by FDA. Moreover, as a regulated entity, Merck has an incentive to echo its regulator's views. Thus none of FDA's examples support the agency's position, and many of them actually support Appellants' view on the effects of FDA's actions.

FDA otherwise contends that any harm or legal consequences were the result of independent third-party actions. Resp.Br.29. This position is based on the erroneous premise that agency actions are final only when they formally "'*create* civil or criminal liability for noncompliance.'" Resp.Br.29 (emphasis added) (quoting ROA.1659–60). This Court has held that action is final when it merely "*tend[s] to expose* parties to civil

or criminal liability for noncompliance." *La. State v. U.S. Army Corps of Engineers*, 834 F.3d 574, 583 (5th Cir. 2016) (emphasis added). FDA never explains why its actions do not, at the very least, "tend to expose" Appellants to liability, and indeed they have already suffered harm because of FDA's actions. *See also infra* Part IV. FDA argues that "the Supreme Court has made clear that agency action is not made reviewable under the APA even if it tends to influence third parties," Rep.Br.28, but *Dalton v. Specter*, 511 U.S. 462 (1994), and *Franklin v. Massachusetts*, 505 U.S. 788 (1992), are easily distinguishable. Both involved recommendations by a subordinate and the "crucial" fact that the final government action was taken by the President, who is not subject to the APA, *Specter*, 511 U.S. at 469–70; *Franklin*, 505 U.S. at 800–01.

Finally, "final" agency action does not require legally binding effects when it is clearly outside the agency's authority or prohibited by statute. Congress recognized the unique ability of FDA to "interfere" with the doctor-patient relationship and intentionally sought to avoid or foreclose that possibility. Failure to find "final" agency action here would in many cases make these congressional decisions a mere suggestion that's never judicially enforceable even when it concretely harms doctors, like

Appellants. That consideration should weigh heavily in the "flexible" and "pragmatic" approach to finality. *Qureshi*, 663 F.3d at 781 (quotation omitted).

IV. APPELLANTS HAVE STANDING

The District Court did not opine on whether Appellants have standing. This Court need not reach that issue, either, but can leave it to the District Court to consider in the first instance.

If this Court considers standing, Appellants have suffered interference with their practice of medicine and reputational harm for almost two years, which clearly traces to FDA's campaign against ivermectin and would be remedied by equitable relief. This is more than sufficient to demonstrate standing. *See* Op.Br.50–64.

FDA does not dispute that Appellants suffered injuries from third parties. *See* Resp.Br.31. Instead, FDA responds that Appellants "have not plausibly alleged that these alleged injuries are fairly traceable to FDA's statements" because "[t]hose statements were not the legal cause of third-party action toward plaintiffs." *Id.* That's not the law.

As Appellants explained, *see* Op.Br.56–61, the Supreme Court has been clear that "[p]roximate causation is not a requirement of Article III

standing," *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 134 n.6 (2014), and an injury is "fairly traceable" if it "relies … on the predictable effect of Government action on the decisions of third parties," even when those third parties' decisions are illogical or "unlawful." *Dep't of Com.*, 139 S. Ct. at 2565–66; *see also Tozzi v. HHS*, 271 F.3d 301, 308–09 (D.C. Cir. 2001). Traceability is also satisfied if government action played a "substantial factor motivating the third parties' actions," *Cmty. for Creative Non–Violence v. Pierce,* 814 F.2d 663, 669 (D.C. Cir. 1987), and can even be established in retrospect, *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992). In other words, traceability "requires no more than *de facto* causality," *Dep't of Com.*, 139 S. Ct. at 2565–66 (quotation omitted).

FDA doesn't address *any* of these cases, and Appellants have already explained at length why their injuries are fairly traceable to FDA under *every one* of these tests. Op.Br.56–61. When the actions of third parties consistently cite to the same FDA directives, Appellants' 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.

At the very least, Appellants have established that it's plausible their injuries can be traced to FDA.

FDA repeatedly insists its statements were "directed at consumers." Resp.Br.31–33. That is both wrong and beside the point. As FDA is forced to concede, it sent letters to the Federation of State Medical Boards and the National Association of Boards of Pharmacy and directed them to the agency's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," Resp.Br.32, and a "predictable effect" of doing so would be for those regulatory boards to parrot FDA's message to their own doctors and pharmacists, *Dep't of Com.*, 139 S. Ct. at 2565–66.[10] Moreover, the Supreme Court has already "repudiate[d] the suggestion that merely because the order is not in terms addressed to those whose rights are affected, they cannot seek its review." *Columbia Broad. Sys. v. United States*, 316 U.S. 407, 420 (1942). FDA's undeniable purpose was to convince consumers to refuse ivermectin even when their doctors recommended it, meaning the "predictable effect" would be interference

[10] FDA claims it's "unclear" whether Appellants are challenging these letters. Resp.Br.32. Appellants point to the letters because they demonstrate FDA's goal of causing the precise kinds of harms that ultimately befell Appellants, or at least establish a clear causal chain back to FDA.

with Appellants' ability to practice medicine and settle on a course of treatment with their patients without FDA influencing those decisions. *See* Op.Br.57. FDA was looking for ways to promote its position on ivermectin and celebrated its success. *See* Op.Br.12–20. Either way, there is traceability.

FDA continues its flawed argument by pointing to statements in a few of its publications that might indicate discretion to prescribe ivermectin for COVID-19. Resp.Br.31. Specifically, "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" states 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," and recommends that consumers "[t]alk to [their] health care provider[s] about available COVID-19 vaccines and treatment options." ROA.973–74; *see also* ROA.976 (Ivermectin FAQ). These are red herrings. *First*, FDA does not even attempt to justify the categorical statements like, "You are not a horse. You are not a cow. Seriously, ya'll. Stop it." or "Stop it with the #ivermectin." Those were among the most widely shared agency publications, celebrated by FDA for reaching a nationwide audience—and they contained not even the pretense of a

disclaimer by FDA. *See* Op.Br.15–16. *Second*, even those statements to which FDA points appear only *after* the same publications say not to use ivermectin for COVID-19, and *none* of the statements dispel those categorical remarks by, for example, adding a comment that doctors *can* prescribe ivermectin for that purpose. *Third*, as time has proven, it is indisputable as a factual matter that FDA's hidden "disclaimers" in certain statements did not prevent health professionals, regulatory boards, hospitals, patients, and the broader public from relying on FDA's statements and treating them as absolute, even to establish legal liability.

Tellingly, FDA offers no response whatsoever to Appellants' recitation of medical experts, researchers, and members of Congress who likewise explain how injuries of the type Appellants have suffered are directly traceable to FDA's statements. *See* Op.Br.59–61; ROA.957–99.

FDA also maintains that "there is no basis" for concluding that anyone relied on the agency's statements "when other organizations with scientific expertise were delivering the same message." Resp.Br.33. But as explained above, *see supra* Part III, those other entities often explicitly cited FDA, which just confirms Appellants' point that outside groups

were taking cues from FDA, which is unsurprising given FDA's unique regulatory authority in this area.

Regarding reputational harms, FDA makes the strange assertion that Appellants "cannot demonstrate that the statements of others are traceable to FDA's statements," Resp.Br.35, even though the Amended Complaint expressly cites an example where one pharmacist with roughly a million followers on TikTok displayed FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" and then berated Appellant Dr. Bowden for prescribing ivermectin because "FDA said nope." ROA.955. Others have publicly labeled health professionals who prescribe ivermectin, including Appellants specifically, as quack doctors practicing veterinary medicine on humans, *see, e.g.*, ROA.1261, which is directly tied to FDA's horse-themed anti-ivermectin campaign.

FDA further claims the involvement of third parties means Appellants' injuries are not redressable. *See* Resp.Br.33–35. That is wrong for the exact same reason—FDA completely ignores that third parties are *explicitly* relying on FDA's ivermectin statements. That is as clear as causality gets. And notably FDA never disputes that the Court can "presume[]" redressability once Appellants' injuries are found "fairly

traceable" to FDA's actions. Op.Br.62 (citing *Ctr. for Biological Diversity v. Exp.-Imp. Bank of the U.S.*, 894 F.3d 1005, 1012 n.2 (9th Cir. 2018)). Nor does FDA dispute that redressability requires only that a favorable ruling "could potentially lessen" the injury, Op.Br.61 (quoting *Sanchez v. R.G.L.*, 761 F.3d 495, 506 (5th Cir. 2014)), or that third parties "arguably" would "chang[e] … the policy" that has injured Appellants, Op.Br.63 (quoting *McClure v. Ashcroft*, 335 F.3d 404, 411 (5th Cir. 2003))—thresholds Appellants easily surpass here.

This Court in *Menard v. FAA*, 548 F.3d 353 (5th Cir. 2008), found standing from injuries caused by third parties under the "moral suasion" of an "advisory" determination by the Federal Aviation Administration. *Id.* at 357. This Court was satisfied that "moral suasion" is "sufficiently 'potent' to have significant practical effects." *Id.* (quotation omitted). The decision even noted that the "advisory" determination would "be significant in other arenas," including other litigation. *Id.* And this Court didn't hesitate to conclude that reversing that determination would redress the harm. *Id.* The "moral suasion" of FDA—the premier drug regulator in the United States—is no different, nor is the plausible redressability.

FDA also discounts Appellant's standing based on injuries to Appellants arising from pharmacists refusing to fill prescriptions, insurance companies refusing to pay for ivermectin for COVID-19, and patients even delaying treatment, all because of FDA. Resp.Br.35. The agency fails to recognize that each of these consequences harms Appellants directly by interfering in the doctor-patient relationship and their practice of medicine. The injury is thus directly to Appellants.

Further, the Supreme Court has explained that a "historical or common-law analogue for th[e] asserted injury" or "close relationship to a harm traditionally recognized as providing a basis for a lawsuit in American courts" is evidence of standing, even if the harm is not an "exact duplicate" or would be "difficult to prove or measure." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2200, 2204, 2211 (2021) (cleaned up). FDA never disputes Appellants' showing that interference with the doctor-patient relationship was recognized at common law. Op.Br.55. Instead, FDA claims that "the tort of interference with the physician-patient relationship" has "no apparent relevance here," Resp.Br.38, yet its own repeated statements show the agency's goal was to influence "consumers'" decisions—which includes Appellants' patients—about

receiving ivermectin to treat COVID-19. Resp.Br.31–33; *see id.* at 15, 16, 24, 31 (acknowledging FDA was giving "advice" and making "recommendations" regarding treatment). That decision is integral to the doctor-patient relationship.

But even if the injuries were framed only as those of Appellants' patients, FDA still applies *June Medical Services LLC v. Russo*, 140 S. Ct. 2103 (2020), too narrowly, which did not require challenging a regulation enforceable "*against the litigant*," Resp.Br.36–37 (emphasis in original). The Supreme Court specifically acknowledged that it has allowed "providers to invoke the rights of their actual or potential patients" to challenge government regulations, *June Med. Servs.*, 140 S. Ct. at 2118, and the very first case cited is *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016), where a group of doctors sued about surgical-center requirements that burdened their patients, *id.* at 2314–15. There is no reason this precedent shouldn't extend to the present case, where agency action has interfered with Appellants' ability to treat patients, and in a context where the treatment is controversial (a point FDA never disputes) and where early treatment is essential and does not allow time for litigation as the need arises.

Finally, FDA rehashes its same unpersuasive theory that just because Appellants have been able to prescribe *some* ivermectin, there has been no injury at all. Resp.Br.37. Plaintiffs' ability to prescribe ivermectin in *some* cases does not negate the many times FDA's actions have interfered—and will continue to interfere—in others.

CONCLUSION

The Court should reverse and remand for further proceedings.

Dated: March 30, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 30, 2023, I electronically filed the foregoing document with the Clerk of this Court by using the CM/ECF system, which will serve all parties automatically.

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitations of Fifth Circuit Rule 32 and Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 6471 words, excluding the portions exempted by Rule 32(f). This brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure Rule 32(a)(5)–(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Century Schoolbook and 14-point font.

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