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

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

Defendants' Motion to Dismiss the Amended Complaint

OF COUNSEL:

SAMUEL R. BAGENSTOS
General Counsel
U.S. Department of Health and Human Services

MARK RAZA
Associate General Counsel
Food and Drug Division
U.S. Department of Health and Human Services
Chief Counsel
Food and Drug Administration

WENDY S. VICENTE
Acting Deputy Chief Counsel, Litigation
Food and Drug Administration

LEAH A. EDELMAN

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

ARUN G. RAO
Deputy Assistant Attorney General

GUSTAV W. EYLER
Director

HILARY K. PERKINS
Assistant Director

ISAAC C. BELFER
Attorney-In-Charge
D.C. Bar No. 1014909
OLIVER MCDONALD
Of Counsel
N.Y. Bar No. 5416789
Trial Attorneys

Associate Chief Counsel
Food and Drug Administration

Consumer Protection Branch
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
(202) 305-7134 (Belfer)
(202) 305-0168 (McDonald)
(202) 514-8742 (fax)
Isaac.C.Belfer@usdoj.gov
Oliver.J.McDonald@usdoj.gov

Counsel for Defendants

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INTRODUCTION

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

Plaintiffs are three doctors who prescribed ivermectin or promoted its use to prevent or treat COVID-19. They allege that their ability to practice medicine was harmed and that FDA's statements regarding the use of ivermectin to prevent or treat COVID-19 indirectly caused that harm by influencing third parties, such as their employers. Plaintiffs' claims, however, suffer from several fatal defects.

First, the Amended Complaint should be dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) because Plaintiffs fail to meet their burden to show standing. Plaintiffs' allegations of injury are insufficient to the extent they do not allege personal, concrete injuries to Plaintiffs. Their alleged injuries also are not traceable to the FDA statements cited in the Amended Complaint, which were purely informational, but instead were caused by the decisions of independent third parties, such as their employers. Finally, their alleged injuries

are not likely to be redressed by the requested relief because even if the Court vacated the cited statements, that would not likely cause those independent third parties to change their decisions.

Second, the Amended Complaint should be dismissed under Rule 12(b)(1) for the additional reason that Plaintiffs fail to identify an applicable waiver of sovereign immunity. The Administrative Procedure Act ("APA") does not provide a waiver because Plaintiffs have not shown that the cited FDA statements are "agency action" or "final agency action." The cited statements are not "agency action" because they do not meet the APA's definition of that term. They also are not "final." They did not determine rights or obligations or have any legal consequences, but instead were purely informational.

Finally, the Amended Complaint should be dismissed under Rule 12(b)(6) for failure to state a claim. Plaintiffs do not allege that the arguments they raise in this lawsuit were ever before FDA for administrative resolution. Thus, Plaintiffs are foreclosed from raising those arguments before this Court.

BACKGROUND

I. Factual Background

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

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

unlawful to distribute a "new animal drug," unless FDA approves it as safe and effective for a particular intended use. *Id.* § 360(b).[1]

Where FDA has approved a drug for a particular human use, the agency generally does not object if physicians choose to prescribe that drug for some other unapproved use (sometimes called an "off-label" use) for their patients.[2] This general position on the off-label prescription of human drugs does not, however, extend to prescribing animal drugs for human use. FDA does not evaluate the safety of animal drugs for use in humans, and the use of animal drugs in humans can cause serious harm.

Congress charged FDA with protecting the public health and ensuring the safety and effectiveness of medical products. *See* 21 U.S.C. § 393(b)(1), (b)(2)(B). In that capacity, the agency routinely communicates with the public, including health care providers and consumers, regarding medical products' safety and efficacy. *See, e.g., id.* § 375(b) (FDA may "disseminate[] information" about the products it regulates "in situations involving . . . imminent danger to health or gross deception of the consumer"); *cf. Shurtleff v. City of Bos.*, 142 S. Ct. 1583, 1589 (2022) ("When the government wishes to state an opinion, to speak for the community, to formulate policies, or to implement programs, it naturally chooses what to say and what not to say. That must be true for government to work." (internal citation omitted)). In addition to reviewing proposed labeling for

[1] A new animal drug may also be legally distributed for use in animals under limited other circumstances. *See* 21 U.S.C. §§ 360b(a)(1)(B)–(D), 360bbb-3, 360ccc, 360ccc-1.

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

medical products, FDA communicates directly to the public about the safety and effectiveness of medical products through, among other things, the Federal Register, its website, social media, direct mailings, and journals. These communications include Drug Safety Communications, press releases, articles in FDA Consumer Magazine, notices of recalls, articles in scientific journals, YouTube videos, Instagram posts, and tweets regarding safety information about human medical products on @FDAMedWatch.

To take a few examples: In October 2002, FDA warned the public about a bone cement used in vertebroplasty and kyphoplasty procedures even though the product had long been used in other procedures.[3] In September 2017, FDA issued a drug safety communication that warned about incorrect dosing of the liver disease medicine Ocaliva.[4] In September 2020, FDA issued a warning regarding a "Benadryl Challenge" encouraged in videos on the social media application TikTok after receiving reports of teenagers requiring emergency treatment or dying after participating in such challenges.[5] And in March 2021, FDA issued a warning that, although the over-the-counter nasal decongestant propylhexedrine is safe and effective when used as directed, the abuse and misuse of propylhexedrine could lead to serious harm, such as heart and mental health problems, hospitalization, disability, or death.[6]

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[3] *See* http://web.archive.org/web/20021201185006/http://www.fda.gov/cdrh/safety/bonecement.html.

[4] *See* https://go.usa.gov/xSMKp.

[5] *See* https://go.usa.gov/xSMKw.

[6] *See* https://go.usa.gov/xSMKG.

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

Drug products containing ivermectin as the active ingredient are approved to treat parasites and certain skin conditions in humans.[7] FDA has also approved drug products containing ivermectin to treat certain parasites in various animal species and to prevent heartworm disease in some small animal species, with dosages and formulations that vary based on the species and the condition to be treated. *See, e.g.*, Ex. 2 at 2.[8] For example, the labeling for the product marketed under the name Zimecterin Gold, Am. Compl. ¶ 75, which is approved for use in horses and available without a prescription (i.e., over-the-counter), warns that the product is "[n]ot for use in humans" and "should not be used in other animal species" because "severe adverse reactions," including death, could result.[9] The FDA-approved labeling for human-use Stromectol® (ivermectin) describes adverse events observed in cases of accidental intoxication with or significant exposure to animal-use versions of ivermectin, including rash, nausea, vomiting, diarrhea, seizure, difficulty breathing, abdominal pain, and contact dermatitis.[10]

During the COVID-19 pandemic, FDA received multiple reports of patients who required medical attention, including hospitalization, after self-medicating with ivermectin products intended for livestock. Ex. 1 at 3; Ex. 19 at 2. In response, FDA made public statements regarding the use of ivermectin to prevent or treat COVID-19. The Amended Complaint identifies seven such

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[7] *See* https://go.usa.gov/xSMkc (label for Stromectol, the drug product referenced in ECF No. 12 (Am. Compl.) ¶ 74).

[8] Citations to exhibits refer to the exhibits to the Amended Complaint. Cited page numbers refer to the page numbers assigned by PACER.

[9] *See* https://go.usa.gov/xSM8F.

[10] *See* https://go.usa.gov/xSMkc (Stromectol label), at 8–9.

statements: an article and two FAQs posted on FDA's website, Exs. 1–3, 19, two tweets linking to the article, Exs. 4, 7, an Instagram post, Ex. 6, and a letter to two organizations, Ex. 22 (hereafter, the "cited statements" or "cited FDA statements"). None of the cited statements asked or instructed doctors not to prescribe ivermectin products to prevent or treat COVID-19.

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

The article also described the conditions for which drug products containing ivermectin are approved for use in humans and the conditions for which drug products containing ivermectin are approved for use in animals, and it explained that the human versions are "very different" from the animal versions. *Id.* at 3. In particular, it explained that "[m]any inactive ingredients found in animal products aren't evaluated for use in people" or are "included in much greater quantity than those used in people." *Id.* It discussed the risks of humans taking

ivermectin products approved for use in animals and advised: "Never use medications intended for animals on yourself." *Id.*

The current version of the article, which has the same title and has been online since September 7, 2021, contained much of the same content. *See* Ex. 1. However, the current version removed the statement that FDA had not yet "reviewed data to support [the] use of ivermectin" to prevent or treat COVID-19 and instead emphasized that FDA has not approved ivermectin to prevent or treat COVID-19 or granted emergency use authorization for that use. *Id.* at 2. The article advised, "If your health care provider writes you an ivermectin prescription, fill it through a legitimate source such as a pharmacy, and take it *exactly* as prescribed." *Id.* at 3 (emphasis in original). And the article recommended: "Talk to your health care provider about available COVID-19 vaccines and treatment options. *Your provider can help determine the best option for you*, based on your health history." *Id.* at 4 (emphasis added).

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

On April 10, 2020, FDA posted on its website a frequently-asked-questions webpage titled "FAQ: COVID-19 and Ivermectin Intended for Animals." Ex. 2.

The FAQ was directed to consumers. *See, e.g.*, *id.* at 2 (answering the question, "Should I take ivermectin to prevent or treat COVID-19?"). The FAQ explained that "there are approved uses for ivermectin in people and animals, but it is not approved for the prevention or treatment of COVID-19." *Id.* It advised that "[a]ny use of ivermectin for the prevention or treatment of COVID-19 should be avoided as its benefits and safety for these purposes have not been established. Data from clinical trials are necessary for us to determine whether ivermectin is safe and effective in treating or preventing COVID-19." *Id.* The FAQ noted that although "[a] recently released research article described the effect of ivermectin on SARS-CoV-2 in a laboratory setting . . . [a]dditional testing [was] needed to determine whether ivermectin might be appropriate to prevent or treat [COVID-19]." *Id.* (citations omitted). Nonetheless, the FAQ recognized that doctors may choose to prescribe ivermectin products approved for human use to prevent or treat COVID-19, and it advised consumers "not [to] take any medicine to treat or prevent COVID-19 *unless it has been prescribed to you by your health care provider and acquired from a legitimate source*." *Id.* (emphasis added). Finally, the FAQ explained that "[p]eople should never take animal drugs" because that "could cause serious harm." *Id.* A similar FAQ webpage also advised against taking ivermectin "for the prevention or treatment of COVID-19," explaining that it was not "approved or authorized" for those uses, and included a link to the cited FDA article on that topic. Ex. 3 at 2. Like the cited article and the other cited FAQ, this FAQ was also directed to consumers. *See id.* (answering the question, "Should I take ivermectin to prevent or treat COVID-19?").

In December 2021, FDA sent a letter to the Federation of State Medical Boards and the National Association of Boards of Pharmacy. The letter was not directed to physicians' prescribing practices, but instead focused on FDA's receipt of "complaints about compounding pharmacies selling drug products containing ivermectin, *claiming that they can treat or prevent COVID-19*." Ex. 22 at 2 (emphasis added). The letter explained that although "ongoing" clinical trials were investigating ivermectin's potential use to prevent or treat COVID-19, the "currently available data [did] not show" that the drug is "safe or effective" for that use. *Id.* The letter concluded that using ivermectin to prevent or treat COVID-19 "may pose risks to patient health" and that products claiming to be safe and effective for that purpose when they have not been shown to be "can place consumers at risk of serious harm." *Id.*[11]

II. Procedural History

Plaintiffs—three physicians who prescribed ivermectin or promoted its use to prevent or treat COVID-19—filed suit on June 2, 2022. ECF No. 1; Am. Compl. ¶¶ 10–43. They filed an Amended Complaint on August 8, 2022. They allege that Bowden's and Marik's employers forced them to resign from their jobs; Bowden

[11] The cited FDA statements were consistent with an April 2020 letter from FDA to "Stakeholders," which Plaintiffs apparently do not challenge. In that letter, FDA explained that "[a]dditional testing is needed to determine whether ivermectin might be safe or effective to prevent or treat . . . COVID-19." Ex. 27 at 23–24. The letter expressed FDA's "concern[] about the health of consumers who may self-medicate by taking ivermectin products intended for animals, thinking they can be a substitute for ivermectin intended for humans." *Id.* It warned against the human use of animal drugs because they "can cause serious harm in people," as "FDA has only evaluated their safety and effectiveness in the particular animal species for which they are labeled." *Id.* The letter advised that "[p]eople should not take any form of ivermectin *unless it has been prescribed to them by a licensed health care provider and is obtained through a legitimate source*." *Id.* (emphasis added).

was "derided by" her employer and "publicly ridiculed"; patients have delayed seeking Bowden's care; and Apter faces professional disciplinary proceedings. *E.g.*, *id.* ¶¶ 18, 21, 29, 42; 121. They further allege that the cited FDA statements interfered with their ability to practice medicine and exercise professional medical judgment, and stopped them from using ivermectin to treat COVID-19. *E.g.*, *id.* ¶¶ 4, 10, 14, 24–25, 42, 106, 118, 121–22, 148. They also allege that Apter's and Bowden's patients were harmed because pharmacists refused to fill some patients' ivermectin prescriptions; insurance companies refused to pay for those prescriptions; and some patients declined or delayed treatment with ivermectin. *E.g.*, *id.* ¶¶ 15–17, 24, 27–29. They claim that these alleged injuries were indirectly caused by the cited FDA statements. *Id.* ¶¶ 10–43.

Count One seeks "non-statutory review" on the theory that the cited FDA statements exceeded FDA's statutory authority.[12] *Id.* ¶¶ 129–31. Count Two alleges that the cited statements were "arbitrary and capricious" under the APA because they were not the product of reasoned decision-making. *Id.* ¶¶ 132–44. Counts Three and Four are also asserted under the APA and, like Count One, claim that the cited statements exceeded FDA's statutory authority. *Id.* ¶¶ 145–56. Count Five seeks a declaratory judgment for the reasons stated in the other counts. *Id.* ¶¶ 157–59.

[12] Plaintiffs appear to concede FDA's authority to warn consumers not to use animal-use ivermectin. *See, e.g.*, Am. Compl. ¶ 1 ("The FDA generally cannot ban particular uses of *human* drugs once they are otherwise approved . . . ." (emphasis added)). Plaintiffs also concede FDA's authority "to communicate the risks of using approved drugs." *Id.* ¶ 151.

ARGUMENT

The Amended Complaint should be dismissed for two independent reasons. First, it should be dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) because Plaintiffs have failed to show that they have standing and have failed to identify an applicable waiver of sovereign immunity. Second, the Amended Complaint should be dismissed for failure to state a claim under Rule 12(b)(6) because Plaintiffs do not plausibly allege that the arguments they raise were ever before FDA for administrative resolution.

I. This Case Should Be Dismissed for Lack of Subject Matter Jurisdiction

Subject matter jurisdiction must "be established as a threshold matter." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94–95 (1998). The Court is "presume[d]" to "lack jurisdiction" unless Plaintiffs meet their "burden of establishing it." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (quotations omitted); *see Brownback v. King*, 141 S. Ct. 740, 749 (2021) (plaintiff "must plausibly allege all jurisdictional elements"). Challenges to subject matter jurisdiction must be resolved "prior to addressing the merits." *Alabama-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484, 487 (5th Cir. 2014); *see Daves v. Dallas Cnty.*, 22 F.4th 522, 532 (5th Cir. 2022) (en banc). For the reasons discussed below, Plaintiffs have failed to meet their burden to show subject matter jurisdiction. *See DaimlerChrysler*, 547 U.S. at 342 n.3.

A. Plaintiffs Have Not Met Their Burden to Show Standing

To show Article III standing, Plaintiffs "must clearly allege . . . facts demonstrating" (1) an injury in fact that is "concrete, particularized, and actual or imminent"; (2) "fairly traceable to the challenged conduct of the defendant"; and (3) likely "redressable by a favorable ruling." *Spokeo, Inc. v. Robins*, 578 U.S.

330, 338 (2016); *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). Plaintiffs "must demonstrate standing for each claim . . . and for each form of relief." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2208 (2021).

1. Plaintiffs' Allegations of Injury Are Insufficient to the Extent They Do Not Allege Concrete Injuries to Plaintiffs

Many of Plaintiffs' allegations fail to show the requisite injury in fact because they do not allege concrete injuries to Plaintiffs. For example, Plaintiffs allege that FDA "interfere[d] with the practice of medicine." Am. Compl. ¶ 10; *see also, e.g.*, *id.* ¶¶ 5, 7, 24, 42, 121, 148. But that vague and conclusory statement does not adequately allege a concrete injury to Plaintiffs. *See Spokeo*, 578 U.S. at 338; *Clapper*, 568 U.S. at 409. Plaintiffs also allege that the cited FDA statements "stopp[ed] doctors from using ivermectin to treat COVID-19," Am. Compl. ¶ 106; *see also id.* ¶¶ 4, 25, 118, 121, 148, "interfered with [their] ability to exercise professional medical judgment in practicing medicine, *id.* ¶ 14, or put "pressure on [their] professional judgment," *id.* ¶¶ 121–22. Yet Plaintiffs allege that they have continued to prescribe ivermectin to prevent or treat COVID-19 despite the cited FDA statements. *See id.* ¶¶ 22, 26 (Bowden "continues to treat COVID-19 patients" and "prescribes ivermectin to treat COVID-19"); *see also id.* ¶ 29 (Bowden's patient filled ivermectin prescription); *id.* ¶ 13 (Apter "has frequently prescribed ivermectin" to patients). Thus, Plaintiffs have not plausibly alleged that the cited FDA statements injured them. *See Mora v. Univ. of Tex. Sw. Med. Ctr.*, 469 F. App'x 295, 299 (5th Cir. 2012) (an "allegation [that] is contradicted by the other facts alleged in the complaint" is "implausible on its face").

In addition, Apter alleges that he "has been referred to the Washington Medical Commission and Arizona Medical Board for disciplinary proceedings

for prescribing ivermectin to treat COVID-19." Am. Compl. ¶ 18; *see also id.* ¶ 121. But he does not allege that these disciplinary proceedings have resulted in any adverse action against him, that they have deprived him of due process, or that they have caused him any other concrete injury. Merely "[h]aving to defend oneself in a legal proceeding ordinarily does not give rise to a redressable injury." *Simic v. City of Chi.*, 851 F.3d 734, 739–40 (7th Cir. 2017) (explaining that, although "being prosecuted and tried without probable cause [might] give[] rise to a federal constitutional claim," simply "undergoing trial in a criminal prosecution does not give rise to a due process violation").

Plaintiffs also make allegations about alleged harm to independent third parties. For example, Plaintiffs allege injury to their patients, such as pharmacists refusing to fill their patients' ivermectin prescriptions, insurance companies refusing to pay for those prescriptions, and patients declining or delaying treatment with ivermectin. *E.g.*, Am. Compl. ¶¶ 15–17, 24, 27–29. Plaintiffs also make allegations about injuries to unnamed doctors and patients. *E.g.*, *id.* ¶¶ 4–5, 7, 10, 16–17, 25, 43, 105–06, 109, 114, 118, 148. But these alleged injuries to independent third parties do not show any "personal injury" to Plaintiffs. *California v. Texas*, 141 S. Ct. 2104, 2113 (2021) (quotations omitted); *see Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004) ("We have adhered to the rule that a party generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." (quotations omitted)); *Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 544 (6th Cir. 2021) (observing in dicta that plaintiff "has not identified a harm to *physicians* merely because the drug may not be available to *patients*").

The Supreme Court has identified "certain, limited exceptions" to "[t]his fundamental restriction on [courts'] authority" when "three important criteria are satisfied": (1) "The litigant must have suffered an injury in fact"; (2) "the litigant must have a close relation to the third party"; and (3) "there must exist some hindrance to the third party's ability to protect his or her own interests." *Powers v. Ohio*, 499 U.S. 400, 410–11 (1991) (citations and quotations omitted); *see Kowalski*, 543 U.S. at 128–30. Here, Plaintiffs fail to satisfy at least the third criterion because they have not alleged any "hindrance" to these third parties' ability to protect their own interests. For example, Plaintiffs have not shown why patients whose pharmacists allegedly refused to fill their ivermectin prescriptions are unable or unwilling to seek legal or other relief themselves. *See AIDS Healthcare Found., Inc. v. City of Baton Rouge/Par. of E. Baton Rouge*, No. 17-cv-229, 2017 WL 2899689, at *4 (M.D. La. July 7, 2017) (medical clinic "failed to demonstrate that it has standing to rely on alleged injuries sustained by its patients" because "there is no indication that [those patients] are unable or unwilling to bring claims on their own behalves"). Plaintiffs therefore cannot rely on alleged injuries to their patients; contrary to their allegation, there is no general rule allowing physicians to "invoke the rights of their actual or potential patients." Am. Compl. ¶ 125. Similarly, Plaintiffs have not shown why unnamed doctors and patients who were allegedly harmed by the cited FDA statements are unable or unwilling to seek legal or other relief themselves.

Finally, the Supreme Court has recognized that plaintiffs may have standing to assert the rights of third parties if "enforcement of the challenged restriction *against the litigant* would result indirectly in the violation of third parties' rights."

Kowalski, 543 U.S. at 130 (emphasis in original) (quotations omitted). But here, no FDA "restriction" is being "enforce[d]" against Plaintiffs. Plaintiffs challenge only informational statements by FDA that carried no legal consequences for Plaintiffs or anyone else.

2. Plaintiffs' Injuries Are Not Fairly Traceable to the Cited FDA Statements

To the extent Plaintiffs have shown an adequate personal injury, they have not shown that such injury is "fairly traceable" to the cited FDA statements. *Spokeo*, 578 U.S. at 338. The cited statements simply communicated FDA's recommendations regarding the use of ivermectin to prevent or treat COVID-19. They "neither require[d] nor forb[ade] any action on the part of" Plaintiffs or anyone else, *Summers v. Earth Island Inst.*, 555 U.S. 488, 493–94 (2009), nor did they direct that Plaintiffs face any adverse consequences for prescribing or promoting ivermectin to prevent or treat COVID-19.

Unable to allege that the cited FDA statements directly caused their alleged injuries, Plaintiffs rely instead on an indirect theory of causation. Regarding Bowden, however, the Amended Complaint does not allege that her employer's decision to "deride[]" her and "force[] [her] to resign," Am. Compl. ¶ 21, was based on the cited FDA statements, so Plaintiffs fail to show traceability for those alleged injuries. For other alleged injuries, Plaintiffs allege an indirect causal chain: the cited statements allegedly influenced the thinking of independent third parties about the use of ivermectin to prevent or treat COVID-19, and those independent third parties then allegedly took actions that caused Plaintiffs' injuries. For example, Plaintiffs allege that the cited FDA statements influenced decisions by unnamed third parties to refer them to state medical boards for

disciplinary proceedings, by their employers to force them to resign, by their patients to delay seeking their care, and by members of the public to berate them. *E.g.*, Am. Compl. ¶¶ 18, 29, 41–42, 105. But standing "is ordinarily substantially more difficult to establish" when "a causal relation between injury and challenged action depends upon the decision of an independent third party." *Daves*, 22 F.4th at 542–44 (quotations omitted). And the third-party actions that allegedly injured Plaintiffs were independent—they did not result from any "determinative or coercive effect" of the cited FDA statements. *Bennett v. Spear*, 520 U.S. 154, 169 (1997); *see also Physicians for Integrity in Med. Rsch., Inc. v. Ostroff*, 670 F. App'x 450, 451 (9th Cir. 2016) ("Patients who choose to stop seeing Dr. Desai as a result of Dr. Desai's comments regarding roflumilast, or who end up finding him less reputable, are making an independent choice unrelated to the FDA's actions.").

Plaintiffs cannot establish standing based on this indirect causal chain because they have not shown that the third-party decisions that allegedly harmed them were a "predictable" response to the cited FDA statements. *Daves*, 22 F.4th at 543 (quotations omitted). The cited statements did not state that *doctors* may not (or even should not) prescribe human-use ivermectin to prevent or treat COVID-19. Instead, they generally recommended to *consumers* (who can purchase the ivermectin product for horses over-the-counter) that they should not take ivermectin to prevent or treat COVID-19.[13] Moreover, the September

[13] Similarly, FDA's December 2021 letter to the Federation of State Medical Boards and the National Association of Boards of Pharmacy—which was issued *after* Bowden's resignation—does not state that doctors should not prescribe human-use ivermectin to prevent or treat COVID-19. *See* Ex. 22. Instead, it addressed "compounding pharmacies selling drug products containing ivermectin, claiming that they can treat or prevent COVID-19." *Id.* at 2.

2021 article and the April 2020 FAQ advised consumers 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," indicating that doctors have discretion to prescribe ivermectin products. Ex. 1 at 3; *see also* Ex. 2 at 2.[14] The article likewise recommended that patients talk to their doctors to determine their best treatment options. Ex. 1 at 2.

Thus, assuming the third parties that allegedly injured Plaintiffs read the cited FDA statements, they would likely have concluded that FDA wanted consumers to be aware of the agency's concerns about using ivermectin to prevent or treat COVID-19, but that doctors have discretion to prescribe ivermectin for that use. Plaintiffs allege, however, that these third parties referred them to state medical boards for disciplinary proceedings, forced them to resign, delayed seeking their care, and "derided" and "ridiculed" them for prescribing ivermectin to prevent or treat COVID-19. *E.g.*, Am. Compl. ¶¶ 15, 18, 21, 27–29, 42, 105. These actions were not a "predictable" response to the cited FDA statements, *Daves*, 22 F.4th at 543 (quotations omitted), and only through impermissible "speculation" could they be attributed to those statements, *Clapper*, 568 U.S. at 414.[15]

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[14] The cited tweets included links to the article. *See* Ex. 4; Ex. 7; Am. Compl. ¶¶ 92, 100. Although the March 2021 version of this article stated that patients should use ivermectin if it was prescribed "for an FDA-approved use," Ex. 19 at 3, that text was removed when the article was updated in September 2021, and Plaintiffs do not allege that any of the third-party conduct that allegedly injured them was caused by the earlier version of the article. *See infra* n.23.

[15] Even if Plaintiffs could assert alleged injuries to independent third parties, they would fail to show traceability. For example, Plaintiffs have not shown that pharmacies' alleged refusal to fill patients' ivermectin prescriptions or insurance companies' alleged refusal to pay for those prescriptions were a "predictable" response to the cited FDA statements. *Daves*, 22 F.4th at 543 (quotations omitted).

3. Plaintiffs' Injuries Are Not Likely Redressable by the Requested Relief

Even if the Court granted Plaintiffs' requested relief, that would not likely redress their injuries. *Spokeo*, 578 U.S. at 338; *see El Paso Cnty. v. Trump*, 982 F.3d 332, 341 (5th Cir. 2020), *cert. denied sub nom. El Paso Cnty. v. Biden*, 141 S. Ct. 2885 (2021), *reh'g denied*, 142 S. Ct. 51 (2021). Plaintiffs seek, *inter alia*, a declaration that FDA did not have authority to make the cited statements and an injunction prohibiting FDA from making such statements. Am. Compl. 43–44. They argue that, if the cited FDA statements are vacated, "[h]ealth professionals and state regulatory boards" will "revert to [the] norm" of "support[ing] the off-label prescription of approved drugs" and that "patients will no longer be caught between" the cited statements and "Plaintiffs' advice." *Id.* ¶ 124.[16]

A ruling that the cited statements exceeded FDA's legal authority or violated the APA would not likely redress Plaintiffs' injuries because it would not likely change the independent third parties' scientific understanding of the risks and benefits of using ivermectin to prevent or treat COVID-19. Thus, the requested relief would not likely give the third parties any reason to reconsider their actions that allegedly harmed Plaintiffs.[17] *See Renal Physicians Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 489 F.3d 1267, 1278 (D.C. Cir. 2007) (even if governmental action is a "contributing factor in bringing about a specific harm,"

[16] Plaintiffs also argue that their "professional judgment would no longer be subject to pressure from the FDA." Am. Compl. ¶ 124. But Plaintiffs have continued to prescribe ivermectin to prevent or treat COVID-19 despite this alleged pressure. *See id.* ¶¶ 13, 22, 26, 29. Thus, removing the alleged pressure would not redress any alleged injuries.

[17] Plaintiffs also cannot show redressability regarding the earlier version of FDA's article, Ex. 19, because that version has not been online since September 2021, well before this action was filed. *See Grupo Dataflux v. Atlas Glob. Grp., L.P.*, 541 U.S. 567, 570–71 (2004).

there is no redressability where "the undoing of the governmental action will not undo the harm[] because the new status quo is held in place by other forces," such as the knowledge and incentives of independent third parties). It is, at best, "speculative" whether the requested relief would redress Plaintiffs' injuries, which is insufficient. *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 43 (1976); *see El Paso Cnty.*, 982 F.3d at 341–42.

That is especially so given that Merck, the sponsor of Stromectol® (ivermectin), issued a statement on February 4, 2021—more than a month before FDA's article was first published—that advised against using ivermectin to prevent or treat COVID-19,[18] and many organizations, such as the World Health Organization,[19] have issued similar advisories. *See, e.g.*, Ex. 12 at 6 (noting statements by "[the American Medical Association ("AMA")], [the American Society of Health-System Pharmacists ("ASHP")], [the Centers for Disease Control and Prevention ("CDC")], FDA and Merck"); Ex. 25 (joint statement of the AMA, American Pharmacists Association, and ASHP, citing statements by CDC, FDA, the National Institutes of Health, the World Health Organization, Merck, and the Infectious Diseases Society of America); Am. Compl. ¶¶ 102–08. There is no reason to think these organizations would retract their statements if the Court held that the cited FDA statements exceeded FDA's legal authority.

Plaintiffs ask the Court to declare that the cited FDA statements "have no legal effect and do not bind health professionals or patients." Am. Compl. at 44.

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[18] *See* https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/.

[19] *See* https://www.who.int/news-room/feature-stories/detail/who-advises-that-ivermectin-only-be-used-to-treat-covid-19-within-clinical-trials.

But the cited statements were purely informational and did not purport to have any "legal effect." *See supra* pp. 5–9. A declaration of what is already true would have "no effect" on Plaintiffs and could "not redress" their injuries. *Sykes v. FEC*, 335 F. Supp. 2d 84, 92 (D.D.C. 2004) (quotations omitted).

Finally, Plaintiffs have failed to show redressability for Marik's and Bowden's alleged injuries for two additional reasons. First, Marik's state medical licenses are all expired, Ex. 10 at 10, and he has not alleged that he intends to renew them. Thus, the requested relief could not remedy any of his alleged injuries. Second, Marik and Bowden were allegedly forced to resign for reasons other than prescribing or promoting ivermectin to prevent or treat COVID-19. Marik "was forced to resign from his positions at EVMS and Sentara Norfolk General Hospital for promoting the use of ivermectin—*as well as other safe, cheap, and effective off-label FDA-approved drugs*—to treat COVID-19." Am Compl. ¶ 42 (emphasis added). And Bowden was disciplined for "using her social media accounts to express her personal and political opinions about the COVID-19 vaccine and treatments."[20] The requested relief would not affect these other reasons for why Marik and Bowden were allegedly forced to resign and thus would not remedy their alleged injuries. *See* 15 Moore's Federal Practice - Civil § 101.42 (2022) ("[T]he redressability element [of Article III standing] is not satisfied if a favorable result would eliminate one of multiple causes of an injury without actually decreasing the injury at all.").[21]

[20] https://www.nbcnews.com/news/us-news/suspended-texas-doctor-promoted-ivermectin-covid-treatment-resigns-hos-rcna5833 (linked in Ex. 24).

[21] Even if Plaintiffs could rely on alleged injuries to independent third parties to support standing, they would fail to show redressability. For example, Plaintiffs have not shown that the requested relief would likely give the

B. Plaintiffs Have Not Shown a Waiver of Sovereign Immunity

In a suit against the federal government, the Court lacks subject matter jurisdiction unless Plaintiffs show a waiver of sovereign immunity. As the Fifth Circuit explained, "[i]t is well settled that the United States may not be sued except to the extent that it has consented to suit by statute" and that, absent such consent, "the court lacks jurisdiction." *Alabama-Coushatta*, 757 F.3d at 488–89 (quotations omitted). Waivers of sovereign immunity are "strictly construed" in favor of the government. *Lane v. Pena,* 518 U.S. 187, 192 (1996).

Plaintiffs assert both a nonstatutory cause of action (Count I) and APA causes of action (Counts II–IV).[22] Fifth Circuit precedent establishes that the APA, 5 U.S.C. § 702, waives sovereign immunity for nonstatutory and APA causes of action only where there is "agency action" and the plaintiff has "suffered legal wrong because of the challenged agency action, or is adversely affected or aggrieved by that action within the meaning of a relevant statute." *Alabama-Coushatta*, 757 F.3d at 488–89; *see Walmart Inc. v. U.S. Dep't of Just.*, 21 F.4th 300, 310–11 (5th Cir. 2021) (suit barred by sovereign immunity because plaintiff did not show "agency action"); *Louisiana v. United States*, 948 F.3d 317, 322 (5th Cir. 2020). For APA causes of action, the sovereign immunity waiver also requires "final agency action." *Alabama-Coushatta*, 757 F.3d at 488–89 (explaining that the finality requirement of 5 U.S.C. § 704 "has been read into §

pharmacies that allegedly refused to fill patients' ivermectin prescriptions or the insurance companies that allegedly refused to pay for those prescriptions any reason to reconsider those decisions. *See Renal Physicians*, 489 F.3d at 1278.

[22] Count V seeks a declaratory judgment based on Counts I–IV. Am. Compl. ¶¶ 157–59.

702" for APA claims); *see also Sierra Club v. Peterson*, 228 F.3d 559, 569 (5th Cir. 2000) (en banc); *Qureshi v. Holder*, 663 F.3d 778, 781 (5th Cir. 2011).

The cited FDA statements are not "agency action" because they are not "the whole or 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). Instead, they were "purely informational." *Sprint Nextel Corp. v. FCC*, 508 F.3d 1129, 1132 (D.C. Cir. 2007) ("purely informational" press release was not reviewable agency action). The cited statements simply communicated FDA's views about the risks of using ivermectin to prevent or treat COVID-19 and its nonbinding advice that consumers "*should* not use ivermectin" for that purpose (not "may not" or "must not"). Ex. 1 at 2 (emphasis added); *see* Ex. 2 at 2; Ex. 3 at 2; Ex. 4 at 2; Ex. 6 at 2; Ex. 7 at 2; Ex. 19 at 2; Ex. 22 at 2. As the Amended Complaint implicitly concedes, the cited statements "discourag[ed]," but did not prohibit, "the use of ivermectin to treat or prevent COVID-19." Am. Compl. ¶ 86. The September 2021 article and April 2020 FAQ also encouraged consumers to follow their doctors' advice: "[i]f your health care provider writes you an ivermectin prescription, fill it through a legitimate source such as a pharmacy, and take it *exactly* as prescribed." Ex. 1 at 3; *see also* Ex. 2 at 2. The article also recommended that consumers "[t]alk to your health care provider about available COVID-19 vaccines and treatment options" because "*[y]our provider can help determine the best option for you*, based on your health history." Ex. 1 at 4 (emphasis added).

The language of the cited tweets and Instagram post does not make them "agency action." The cited August 2021 tweet stated, "You are not a horse. You are not a cow. Seriously, y'all. Stop it," Ex. 4 at 2, and the cited Instagram post

from the same day stated, "You are not a horse. Stop it with the #ivermectin. It's not authorized for treating #COVID," Ex. 6 at 2. The cited April 2022 tweet stated, "Hold your horses, y'all. Ivermectin may be trending, but it still isn't authorized or approved to treat COVID-19," Ex. 7 at 2. Plaintiffs do not plausibly allege that anyone would have understood the informal language in the cited tweets and Instagram post to be "order[s]," 5 U.S.C. § 551(13), prohibiting the use of ivermectin to prevent or treat COVID-19. Moreover, FDA's "Stop it" and "Hold your horses" statements plainly referred to taking animal-use ivermectin, especially given that both tweets and the Instagram post included images of horses. *See* Exs. 4, 6–7. Plaintiffs do not allege that they prescribe or promote animal-use ivermectin for human use, nor that doing so would fall within the "practice of medicine." Am. Compl. ¶ 1 (alleging that FDA "generally cannot ban" off-label "uses of [approved] human drugs"). And both tweets linked to the cited article,[23] which included an image of a horse and explained that it was prompted by "multiple reports of patients who have required medical attention, including hospitalization, after self-medicating with ivermectin intended for livestock." Ex. 1 at 2–3; *see* Ex. 19 at 2. The cited article also advised consumers to fill an ivermectin prescription "through a legitimate source such as a pharmacy, and take it *exactly* as prescribed." Ex. 1 at 3; *see* Ex. 19 at 3.

The cited FDA statements do not meet the definition of any action included in the definition of "agency action." 5 U.S.C. § 551(13). For example, they are not an "order" because they are not "a final disposition," formulated through an FDA "adjudication" process, that "ha[s] some determinate consequences" for

[23] The August 21, 2021, tweet initially linked to the original version of the article and then linked to the new version once it went live in September 2021.

Plaintiffs. 5 U.S.C. § 551(6)–(7); *Int'l Tel. & Tel. Corp. v. Loc. 134, Int'l Bhd. of Elec. Workers*, 419 U.S. 428, 443 (1975). They did "not order anybody to do anything," and "standing alone, [they bound] no one." *Int'l Tel. & Tel.*, 419 U.S. at 443 (quotation omitted). Nor are the cited statements a "sanction" because there is no indication that FDA was "intent on penalizing [Plaintiffs] through adverse publicity." *Indus. Safety Equip. Ass'n v. EPA*, 837 F.2d 1115, 1119, 1121 (D.C. Cir. 1988); *see* 5 U.S.C. § 551(10). Nor are they a "rule" because they did not purport to bind FDA or anyone else. *See* 5 U.S.C. § 551(4); *Amoco Prod. Co. v. Watson*, 410 F.3d 722, 732 (D.C. Cir. 2005) (Roberts, J.), *aff'd sub nom. BP Am. Prod. Co. v. Burton*, 549 U.S. 84 (2006).

In addition to failing to show that the cited FDA statements are "agency action," Plaintiffs failed to show that they "suffered legal wrong because of" the cited statements. *Alabama-Coushatta*, 757 F.3d at 488–89; *see supra* pp. 12–17. For this reason as well, Plaintiffs have not shown a waiver of sovereign immunity under the APA. *See Alabama-Coushatta*, 757 F.3d at 488–89.

Furthermore, even if Plaintiffs had shown that the cited FDA statements are "agency action," there would be no waiver of sovereign immunity for Plaintiffs' APA claims because the statements are not "final." They did not mark the "consummation" of FDA's decisionmaking process regarding the use of ivermectin to prevent or treat COVID-19. *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (quotations omitted). Instead, they presented FDA's tentative recommendations based on "[c]urrently available data," while explaining that "[a]dditional testing is needed" and that "[c]linical trials" are "ongoing." Ex. 1 at

3; Ex. 2 at 2; *see also* Ex. 19 at 3 (noting that "initial research is underway"); *Bennett*, 520 U.S. at 177–78.

The cited FDA statements also were not actions "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett*, 520 U.S. at 178 (quotations omitted); *Qureshi*, 663 F.3d at 781; *see La. State v. U.S. Army Corps of Eng'rs*, 834 F.3d 574, 580–81 (5th Cir. 2016). Instead, they were "purely informational in nature; [they] imposed no obligations and denied no relief"; and "[c]ompelling no one to do anything, [they] had no binding effect whatsoever." *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 427 (D.C. Cir. 2004) (Roberts, J.); *see Barry v. SEC*, No. 10-cv-4071, 2012 WL 760456, at *6 (E.D.N.Y. Mar. 7, 2012) (press release was not final agency action because it did not determine any "rights or obligations" or have any "legal consequences"). Even if the cited FDA statements "put pressure" on Plaintiffs, that would not show final agency action because "any such consequences are practical, as opposed to legal, ones." *La. State*, 834 F.3d at 583.

It is well established that FDA warning letters, which are posted on FDA's website, are not "final agency action" because, like the cited FDA statements, they are "informal and advisory" communications about FDA's "position on a matter" and do not "compel[] action" by anyone. *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012); *see also Swisher Int'l, Inc. v. FDA*, No. 21-13088, 2022 WL 320889, at *5 (11th Cir. Feb. 3, 2022); *Cody Labs., Inc. v. Sebelius*, 446 F. App'x 964, 969 (10th Cir. 2011); *cf. Am. Paper Inst., Inc. v. EPA*, 882 F.2d 287, 289 (7th Cir. 1989); *Dow Chem. v. EPA*, 832 F.2d 319, 324 (5th Cir. 1987). It is even clearer that the cited FDA statements are not final agency action

because, unlike warning letters, they were not directed at particular entities and did not allege violations of law.

It is not enough for agency conduct to affect the plaintiffs indirectly by influencing independent third parties; instead, final agency action must "directly affect" the plaintiffs. *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992). In *Franklin*, the Court held that an agency report was not "final agency action" because it "carrie[d] no direct consequences" and "serve[d] more like a tentative recommendation than a final and binding determination." *Id.* at 797–98; *see Dalton v. Specter*, 511 U.S. 462, 469–70 (1994). Here, similarly, the cited FDA statements "carrie[d] no direct consequences" for Plaintiffs, but instead provided nonbinding "recommendations" to consumers about the use of ivermectin to prevent or treat COVID-19. *Franklin*, 505 U.S. at 798. The actions that directly affected Plaintiffs were the actions of independent third parties such as their employers and patients. Even if the cited FDA statements were "persuasive" to these independent third parties and "made business more difficult" for Plaintiffs, such an "indirect effect" on Plaintiffs from independent third parties is "not a regulatory effect reviewable in court." *Invention Submission Corp. v. Rogan*, 357 F.3d 452, 459–60 (4th Cir. 2004) (citing *Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 313 F.3d 852, 861 (4th Cir. 2002)).[24] Moreover, even assuming *arguendo* that Plaintiffs could assert their patients' injuries, the actions that directly

[24] The Fourth Circuit explained: "We do not think that Congress intended to create private rights of actions to challenge the inevitable objectionable impressions created whenever controversial research by a federal agency is published. Such policy statements are properly challenged through the political process and not the courts." *Invention Submission*, 357 F.3d at 459 (quoting *Flue-Cured Tobacco*, 313 F.3d at 861) (internal quotation marks omitted).

affected their patients were the actions of independent third parties such as pharmacies and insurance companies.

Plaintiffs assert that "legally binding effects are not necessary to render an agency action 'final' for purposes of judicial review when the action in question is prohibited by statute regardless of such effects." Am. Compl. ¶ 139. But even if that were true, Plaintiffs still have not shown that the cited FDA statements are "agency action" in the first place. Plaintiffs also assert that "[s]tatements with the false imprimatur of authority, intended to stop non-conforming practice and be interpreted by the public as authoritative, have the effect of determining rights and obligations, or otherwise resulting in legal consequences." *Id.* ¶ 138. But the cited statements purported to provide only recommendations about what people "should" do, *e.g.*, Ex. 1 at 2; Ex. 2 at 2; Ex. 3 at 2; they did not purport to create any rights or obligations or have any legal consequences, and there is no indication that FDA intended to convey that they did. *See Bennett*, 520 U.S. at 178; *Qureshi*, 663 F.3d at 781.

Although Plaintiffs allege that FDA's "statements are regularly relied on to establish the appropriate standard of care and dictate the practice of medicine," Am. Compl. ¶ 138, the cited FDA statements made clear that doctors retain discretion to prescribe ivermectin to prevent or treat COVID-19. *See, e.g.*, Ex. 1 at 3–4; Ex. 2 at 2. And in any event, any "indirect effects" from independent third parties that were persuaded by the cited FDA statements do not make those statements final agency action. *See Invention Submission*, 357 F.3d at 459–60.

In sum, Plaintiffs have failed to show a waiver of sovereign immunity for any of their causes of action because the cited FDA statements are not agency

action, let alone final agency action. *See Alabama-Coushatta*, 757 F.3d at 488–89. Thus, the court lacks jurisdiction and the action must be dismissed. *See id.*

II. The Amended Complaint Fails to State a Plausible Claim for Relief

If the Court were to find that one or more of the cited statements were final agency action—which Defendants do not concede—the Amended Complaint should be dismissed under Rule 12(b)(6) because it does not contain "sufficient factual material, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation omitted). All of Plaintiffs' claims, including their APA claims and ultra vires claim, are entirely premised on arguments raised for the first time before this Court. By failing to present their arguments to FDA, Plaintiffs forfeited them, thus depriving their claims of any plausible legal basis.

The long-standing rule of "issue exhaustion . . . require[s] parties to give the agency an opportunity to address an issue before seeking judicial review of that question." *Carr v. Saul*, 141 S. Ct. 1352, 1358 (2021); *see United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952); *Adamski v. McHugh*, 304 F. Supp. 3d 277, 236–39 (D.D.C. 2015). A court "will not ordinarily consider arguments that a litigant could have raised before an agency but chose not to." *Palm Valley Health Care, Inc. v. Azar*, 947 F.3d 321, 327 (5th Cir. 2020) (citation omitted).

Requiring litigants to raise their arguments before the agency in the first instance "ensures simple fairness to the agency" and provides for a "full airing of the issues before the agency" prior to litigation. *Id.* Presenting arguments to the agency gives it "the opportunity to correct its own errors" and "produce a useful record for subsequent judicial consideration." *McCarthy v. Madigan*, 503 U.S. 140,

145–46 (1992). Moreover, agency actions are frequently of a discretionary nature or require expertise, and "the agency should be given the first chance to exercise that discretion or to apply that expertise." *McKart v. United States,* 395 U.S. 185, 194 (1969). The issue exhaustion requirement is "analog[ous] to the rule that appellate courts will not consider arguments not raised before trial courts." *Sims v. Apfel*, 530 U.S. 103, 108–09 (2000). As in an appellate court, the "focal point" for review under the APA "should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). An agency's decision is not "arbitrary and capricious in failing to identify, raise, and resolve *sua sponte* an issue never presented" to the agency. *Fleming v. U.S. Dep't of Agric.*, 987 F.3d 1093, 1100 (D.C. Cir. 2021).

In *Palm Valley Health Care v. Azar*, for example, the plaintiff sought administrative review of a Medicare overpayment finding regarding home health care coverage. 947 F.3d at 324. Despite having "many opportunities" to raise its arguments with the agency, the plaintiff ultimately advanced an argument in court that it had never presented to the agency: that the agency had applied the wrong definition of the term "homebound." *Id.* at 325, 327. The Court of Appeals affirmed the district court's dismissal of that count because the plaintiff "failed to exhaust its challenge to the 'homebound' standard." *Id.* at 328.

As in *Palm Valley Health Care*, Plaintiffs failed to raise their arguments with FDA despite having the opportunity to do so. For example, Plaintiffs acknowledge that the cited FDA article states, "[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," but object that that this statement

"is buried in the middle of the document and does not influence the effect of the title," which they contend "discourage[s] the use of ivermectin to treat or prevent COVID-19." Am. Compl. ¶ 86. Plaintiffs similarly make a variety of arguments about ivermectin and contend that the cited FDA statements were arbitrary and capricious because the agency "fail[ed] to address or respond to *any* of the scientific evidence showing that ivermectin is an effective prophylactic or acute treatment for COVID-19." *Id.* ¶¶ 73, 76–77, 80–81, 132–44. Plaintiffs also argue that FDA lacked authority to make the challenged statements at all. *See id.* ¶¶ 129–31, 145–56. Plaintiffs could have presented their arguments to FDA through a Citizen Petition.[25] That process allows any "interested person [to] petition the Commissioner to . . . take or refrain from taking any . . . form of administrative action" by filing a Citizen Petition. 21 C.F.R. § 10.25(a); *see id.* § 10.30; *see also id.* § 10.45. Plaintiffs did not file a Citizen Petition and do not allege that their arguments were raised with FDA through any other method. Thus, even if the Court were to find that Plaintiffs challenge final agency action, they forfeited their ability to raise their arguments in this case by not first raising them with FDA. Because Plaintiffs' arguments "cannot [be] consider[ed]" by the Court, their claims should be dismissed. *Palm Valley Health Care*, 947 F.3d at 327.

CONCLUSION

For the foregoing reasons, the Amended Complaint should be dismissed for lack of subject matter jurisdiction or, in the alternative, for failure to state a claim.

[25] Plaintiffs remain free to present their arguments to FDA through a Citizen Petition (or some other method).

August 26, 2022

Respectfully submitted,

/s/ Isaac C. Belfer
ISAAC C. BELFER
Attorney-In-Charge
D.C. Bar No. 1014909
OLIVER MCDONALD
Of Counsel
N.Y. Bar No. 5416789
Trial Attorneys
Consumer Protection Branch
Civil Division
U.S. Department of Justice
PO Box 386
Washington, DC 20044-0386
(202) 305-7134 (Belfer)
(202) 305-0168
(202) 514-8742 (fax)
Isaac.C.Belfer@usdoj.gov
Oliver.J.McDonald@usdoj.gov

Counsel for Defendants

CERTIFICATE OF CONFERENCE

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

August 26, 2022

/s/ Isaac C. Belfer
Isaac C. Belfer

CERTIFICATE OF SERVICE

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

August 26, 2022

/s/ Isaac C. Belfer
Isaac C. Belfer