UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ANIMAL LEGAL DEFENSE FUND, et al.,

Plaintiffs,

v.

ALEX AZAR, et al.,

Defendants.

Case No. 20-cv-03703-RS

ORDER DENYING MOTIONS TO DISMISS

I. INTRODUCTION

Plaintiffs challenge the decision of the Food and Drug Administration (FDA) to approve the animal drug Experior for use in cattle feedlots. Experior is touted to reduce the amount of ammonia gas released from the waste of cattle raised for beef. Plaintiffs contend the FDA did not properly announce the approval in the Federal Register, that Experior has not been shown to be safe and effective, and that the FDA did not adequately consider the drug's environmental impacts. The FDA moves to dismiss, arguing plaintiffs lack Article III standing. Elanco Health, the manufacturer of Experior, has intervened as a defendant and also moves to dismiss. Elanco offers substantially the same arguments regarding standing, but also contends plaintiffs failed to exhaust administrative remedies. For the reasons explained below, the motions to dismiss will be denied.

II. BACKGROUND

Plaintiffs are advocacy groups Animal Legal Defense Fund ("ALDF"), Food & Water Watch ("FWW"), and Food Animal Concerns Trust ("FACT"). As noted, they challenge the FDA's approval of Experior, asserting claims under the Administrative Procedures Act ("APA"), 5 U.S.C. § 551, *et seq*. for alleged underlying failures to comply with the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4321 *et seq.* Experior purportedly has been shown to lower ammonia gas emissions from cattle waste, where the animals are raised in pastures and then "finished" on feed while in confinement in the last weeks or months prior to slaughter. Experior is classified as an adrenergic agonist/antagonist, which is a subtype of a broader category of drugs known as beta-adrenergic agonist/antagonists ("β-AA"). It is the first approved animal drug that activates from the beta-3 receptor ("beta-3") subtype and the first approved for the purpose of reducing gas emissions from an animal or its waste.

Plaintiffs allege that β-AA drugs like Experior are linked to "significantly higher mortality rates in cows due to a host of fatal respiratory, cardiac, and digestive issues, in addition to significant behavioral issues that make animals more likely to be abused and suffer in ways that directly impact food safety and worker health." Plaintiffs contend the drugs also contaminate the environment.

Plaintiffs allege the application for approval of Experior was insufficient to establish its safety, or that when actually used under approved conditions, it will have its intended effect of reducing the release of ammonia gas. Plaintiffs contend the FDA also failed to consider the food safety and public health risk of its decision. They allege β-AA drug residues end up in meat products and have been linked to human heart and respiratory issues in consumers, producers, and farm workers. Plaintiffs assert β-AA drugs also increase the likelihood that an animal will experience injury and stress at industrial animal feeding operations—so-called "factory farms"—and at the slaughterhouse, which in turn makes animals more susceptible to pathogens, and increases their susceptibility to and shedding of zoonotic bacteria such as salmonella.

Plaintiffs complain the Environmental Assessment ("EA") prepared in support of Experior's approval also failed adequately to analyze whether it will have a significant impact on the environment. They insist the EA made no meaningful attempt to address the cumulative impacts of the "current rampant use of β-AAs and other animal drugs in cows slaughtered for food in the United States." Plaintiffs contend the FDA's Finding of No Significant Impact did not consider any alternatives, involve the public in the review process, or explain why an Environmental Impact Statement ("EIS") was not required under NEPA.

Following the approval, plaintiff ALDF filed a timely Petition for Stay of Action under 21 C.F.R. § 10.35. The petition alleged that the FDA failed to analyze sufficiently Experior's environmental impact, did not consider alternatives to Experior's approval, and failed to prepare an EIS addressing the effects Experior may have on animals, humans, and the environment. The petition requested the FDA to stay Experior's approval until the agency addressed ALDF's concerns. The FDA denied the petition. This action followed shortly thereafter.

III. LEGAL STANDARD

The FDA challenges the sufficiency of the jurisdictional allegations in the amended complaint under Federal Rule of Civil Procedure 12(b)(1). *See Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). Although a court may "assume [a plaintiff's] allegations to be true and draw all reasonable inferences in [its] favor," *Wolfe v. Strankman*, 392 F.3d 358, 362 (9th Cir. 2004), "plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing the[] elements" of standing, *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). "Where, as here, a case is at the pleading stage, the plaintiff must 'clearly . . . allege facts demonstrating' each element" of standing to secure this Court's jurisdiction. *Id*. (quoting *Warth v. Seldin*, 422 U.S. 490, 518 (1975)). "[W]hen considering a motion to dismiss pursuant to Rule 12(b)(1) the district court is not restricted to the face of the pleadings, but may review any evidence, such as affidavits and testimony, to resolve factual disputes concerning the existence of jurisdiction." *Gordon v. United States*, 739 F. App'x 408, 411 (9th Cir. 2018) (quoting *McCarthy*

v. United States, 850 F.2d 558, 560 (9th Cir. 1988) (alteration in original)).

Elanco's motion also invokes Rule 12(b)(6) of the Federal Rules of Civil Procedure. A motion under that rule tests the legal sufficiency of the claims alleged in the complaint. *See Conservation Force v. Salazar*, 646 F.3d 1240, 1241-42 (9th Cir. 2011). Dismissal under Rule 12(b)(6) may be based on either the "lack of a cognizable legal theory" or on "the absence of sufficient facts alleged under a cognizable legal theory." *Id.* at 1242 (internal quotation marks and citation omitted). When evaluating such a motion, the court must accept all material allegations in the complaint as true and construe them in the light most favorable to the non-moving party. *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1140 (9th Cir. 2017).

IV. DISCUSSION

A. Standing

To satisfy Article III standing requirements, a plaintiff must show "(1) it has suffered an 'injury-in-fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc., v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992)).

The FDA first argues the plaintiff organizations cannot establish standing for themselves as entities (which the FDA refers to as "organizational standing"). Plaintiffs, however, expressly disclaim any intent to assert such standing, arguing instead that they have "associational standing." There is no dispute that an organization may have standing if it can show "that its members, or any one of them, are suffering immediate or threatened injury as a result of the challenged action of the sort that would make out a justiciable case had the members themselves brought suit. . . ." *See Hunt v. Wash. State Apple Growers Ass'n*, 432 U.S. 333, 342 (1977). Specifically, "an association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane

to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Id.* at 343. There is no challenge here to plaintiffs' assertion that the interests they seek to protect are germane to their purposes and that participation of their individual members is not required. The issue, therefore, is solely whether one or more of plaintiffs' members would otherwise have standing to sue in their own right.

1. *Injury-in-fact*

The FDA and Elanco both contend plaintiffs cannot show any of their members have suffered the requisite injury-in-fact to support standing. Defendants advance two basic arguments. First, defendants contend because Experior has not come to market yet and no firm date for its release has been set, plaintiffs cannot show imminent harm. Elanco, however, has announced that the drug will be available in the first quarter of this year. While that may not be certain, it is neither "conjectural or hypothetical," and satisfies the requirement that the harm be imminent.[1]

Second, defendants insist that because plaintiffs cannot identify specific feedlots that will purchase and use Experior, they cannot show that any of their members have the geographical proximity to suffer any of the alleged effects of Experior on the environment, or that any beef they purchase for consumption necessarily will come from cattle treated with the drug. The requirement defendants seek to impose, however, would effectively insulate the FDA's decision-making from review until the product had entered the market and its use at specific feedlots could somehow be discovered, or detected in the environment, or in beef products sold to consumers. Plaintiffs' claim is that the FDA was derelict in its duty to ensure the safety of Experior and to weigh its environmental impacts *before* it is released on the market.

Defendants may be correct that plaintiffs have not yet shown that any of its members *certainly* will be exposed to Experior or that any such exposure *certainly* will cause measurable

[1] Of course, cognizable harm may not arise the first day the product is available for sale, but the fact that some of the alleged injury will develop over time does not mean it is insufficiently imminent.

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