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.

harm. At least at the pleading stage, however, plaintiffs have adequately identified the imminent potential of concrete and particularized harm that is not so conjectural or hypothetical as to preclude standing. *See Baur v. Veneman*, 352 F.3d 625, 633 (2d Cir. 2003) ([T]he courts of appeals have generally recognized that threatened harm in the form of an increased risk of future injury may serve as injury-in-fact for Article III standing purposes.")[2]

2. *Causation*

Defendants argue that the various harms plaintiffs contend their members will suffer are not actually caused by the FDA's approval of Experior. Indeed, the complaint's lengthy description of the alleged harms flowing from various feedlot and factory farming practices supports a reasonable inference that even assuming Experior were now to be banned, many of the injuries to which plaintiffs point would continue unabated. Nevertheless, plaintiffs' allegations that the situation is bad even without Experior do not preclude them from plausibly contending that Experior will make things worse.

That other factors, and other actors, may play a role in the constellation of circumstances that will result in cognizable harm does not mean no injury will be traceable to the FDA's approval of Experior. Indeed, part of plaintiffs' claim is that the FDA failed to give adequate attention to the *cumulative* effects of Experior and such other factors. Such effects are necessarily traceable to the challenged agency action.

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[2] Some of defendants' arguments seem to conflate the standing inquiry with merits questions. The FDA suggests, for example, that plaintiffs cannot show imminent harm because the permissible residual levels of Experior in beef is safe for human consumption. While standing inquiry does require plaintiffs to make credible allegations of harm, it would be premature to dismiss plaintiffs' contentions of harm here by assuming that the FDA correctly evaluated the risks.

This order does not necessarily preclude defendants from challenging standing at a later stage in the proceedings, on a more developed record, if warranted.

3. *Redressability*

Defendants' contention that plaintiffs cannot establish redressability is premised on their arguments that the alleged harms are not traceable to the approval of Experior. Because that premise fails, as discussed above, so does the attack on redressability. Accordingly, the motions to dismiss for lack of standing must be denied.

B. Exhaustion

The APA requires "that plaintiffs exhaust available administrative remedies before bringing their grievances in federal court." *Idaho Sporting Congress, Inc. v. Rittenhouse*, 305 F.3d 957, 965 (9th Cir.2002) (citing 5 U.S.C. § 704). FDA regulations set out the exhaustion requirement and procedure in 21 C.F.R. § 10.45, which provides, in relevant part:

> A request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under §10.25(a) . . . before any legal action is filed in a court complaining of the action or failure to act. If a court action is filed complaining of the action or failure to act before the submission of the decision on a petition under §10.25(a) . . . the Commissioner shall request dismissal of the court action or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust administrative remedies, the lack of final agency action as required by 5 U.S.C. 701 et seq., and the lack of an actual controversy as required by 28 U.S.C. 2201.

It is notable that the FDA has not requested dismissal or referral on grounds of a failure to exhaust. This suggests that in the FDA's view, the exhaustion requirement has been satisfied. Elanco nonetheless contends plaintiffs were required to exhaust their administrative remedies by filing a "citizens petition" pursuant to §10.30. Such a citizen's petition, however, is only one of the kinds of "petitions" specified in §10.25(a) as a means of obtaining a final administrative decision ripe for court review. That section provides, in relevant part:

> An interested person may petition the Commissioner to issue,

> amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. A petition must be *either*:
>
> (1) In the form specified in other applicable FDA regulations . . . *or*
>
> (2) in the form for a citizen petition in §10.30.

(emphasis added).

Here, as noted above, plaintiff ALDF filed a petition for stay under §10.35. Decisions on such petitions are final agency actions, ripe for court review. *See* §10.45(d).

To argue plaintiffs must have *additionally* filed a citizen petition under §10.30, Elanco relies on *Center for Food Safety v. Hamburg*, 696 F. App'x 302 (9th Cir. 2017), in which it also intervened, and where ALDF was also party, represented by the same counsel as here.[3] In *Hamburg*, however, no stay petition under §10.35 had been filed. The court's pronouncement that a citizen petition was required in those circumstances does not support a conclusion that one would be necessary where a §10.35 petition was filed.[4] Accordingly, Elanco's motion to dismiss or to stay this action pending exhaustion is denied.

C. First claim for relief

Finally, Elanco argues the first claim for relief is subject to dismissal under Rule 12(b)(6) for "failure to request any relief." The claim asserts the FDA's denial of the stay petition violated the APA because it "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that

[3] In *Hamburg*, the FDA had not initially challenged exhaustion, but did so after Elanco raised the issue. *See Ctr. for Food Safety v. Hamburg,* 142 F. Supp. 3d 898, 900 n.2 (N.D. Cal. 2015). In contrast, here the FDA has not joined in the exhaustion argument.

[4] Admittedly, the relief sought in the stay petition was not completely coextensive with the relief being sought here. Nevertheless, Elanco has not made a persuasive showing that pursuing a §10.35 petition is insufficient to satisfy the purposes of the exhaustion requirement. The FDA had the opportunity to consider the basic arguments plaintiffs are making here and to reconsider its decision, and elected not to do so.

runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."

It may be, as Elanco suggests, that the primary intended purpose of the first claim for relief is to establish there is exhaustion as to the entire complaint. It is not clear that plaintiffs necessarily would want an adjudication only that the FDA erred in denying the stay petition. In theory, though, plaintiffs could prevail on that claim whether or not they prevailed on the bigger issue of whether approval of Experior was properly granted. That the complaint does not explicitly and unambiguously include a prayer for relief limited to setting aside the denial of the stay petition is not a basis to dismiss the first claim for relief.

V. CONCLUSION

The motions to dismiss are denied.

IT IS SO ORDERED.

Dated: February 23, 2021

RICHARD SEEBORG
Chief United States District Judge