

1 JEFFREY BOSSERT CLARK
 Acting Assistant Attorney General
 2 DANIEL J. FEITH
 Deputy Assistant Attorney General
 3 GUSTAV W. EYLER
 Director
 4 HILARY K. PERKINS
 Assistant Director
 5 JONATHAN E. AMGOTT (DCBN 1031947)
 Trial Attorney
 6 Consumer Protection Branch
 U.S. Department of Justice
 7 P.O. Box 386
 Washington, DC 20044-0386
 8 Telephone: 202-532-5025
 Facsimile: 202-514-8742
 9 E-mail: Jonathan.E.Amgott@usdoj.gov
 Attorneys for Federal Defendants
 10 ALEX AZAR, STEPHEN HAHN, and
 11 U.S. FOOD AND DRUG ADMIN.
 12

13 THE UNITED STATES DISTRICT COURT
 14 FOR THE NORTHERN DISTRICT OF CALIFORNIA
 15 SAN FRANCISCO DIVISION

16 ANIMAL LEGAL DEFENSE FUND,
 17 FOOD & WATER WATCH, and FOOD
 18 ANIMAL CONCERNS TRUST,

19 Plaintiffs,
 20 v.

21 ALEX AZAR, Secretary of the United States
 Department of Health and Human Services;
 22 STEPHEN HAHN, Commissioner of the
 United States Food and Drug Administration;
 23 and UNITED STATES FOOD AND DRUG
 ADMINISTRATION,

24 Defendants,

25 and

26 ELANCO ANIMAL HEALTH,

27 Intervenor-Defendant.
 28

No. 3:20-CV-03703-RS

**FEDERAL DEFENDANTS' NOTICE OF
 MOTION AND MOTION TO DISMISS FIRST
 AMENDED COMPLAINT**

Hearing Date: Thursday, January 14, 2021
 Hearing Time: 1:30 p.m.
 Courtroom: 3

Hon. Richard Seeborg

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1 **NOTICE OF MOTION AND MOTION TO DISMISS**

2 **TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:**

3 **PLEASE TAKE NOTICE** that on Thursday, January 14, 2021, at 1:30 p.m., or as soon thereafter
4 as they may be heard in San Francisco Courthouse, Courtroom 3 (17th Floor), Defendants Alex Azar,
5 Stephen Hahn, and the United States Food and Drug Administration (“FDA,” and collectively, “Federal
6 Defendants”), by and through counsel, will and hereby do move to dismiss this action, filed on June 4,
7 2020, by Plaintiffs Animal Legal Defense Fund (“ALDF”), Food & Water Watch (“FWW”), and Food
8 Animal Concerns Trust (“FACT”) (collectively, “Plaintiffs”), for lack of Article III standing, pursuant to
9 Rule 12(b)(1) of the Federal Rules of Civil Procedure. Defendants’ Motion is based on this Notice, the
10 Points and Authorities incorporated herein, any matters for which the Court may take judicial notice, and
11 any written and oral argument and authorities that are presented at or before the hearing on this Motion.

12 **RELIEF SOUGHT**

13 Defendants seek an order dismissing the First Amended Complaint (hereinafter, “Amended
14 Complaint”) under Rule 12(b)(1) because Plaintiffs have not established organizational standing, nor do
15 they show associational standing through their members, who lack an injury in fact that is fairly traceable
16 to Defendants’ action nor is it likely redressable by a ruling in their favor.

17 **MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF FEDERAL**
18 **DEFENDANTS’ MOTION TO DISMISS THE FIRST AMENDED COMPLAINT**

19 **INTRODUCTION**

20 Plaintiff organizations ALDF, FWV, and FACT ask this Court to vacate FDA’s approval of the
21 new animal drug Experior, which is approved to reduce ammonia gas emissions from cattle. Experior
22 belongs to a subtype of a broader category of drugs called “beta-agonists” that facilitate increased
23 industrial meat production. Plaintiffs allege that beta-agonists inflict harmful collateral effects on cows,
24 humans, and the environment. Invoking these concerns, Plaintiffs claim that FDA’s approval of Experior
25 violated the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, the National
26 Environmental Policy Act (“NEPA”), 42 U.S.C. § 4321 *et seq.*, and the Administrative Procedure Act
27 (“APA”), 5 U.S.C. § 551, *et seq.* But Plaintiffs lack Article III standing to bring this suit, and their claims
28

1 should therefore be dismissed.

2 The first deficiency fatal to Plaintiffs’ action is the dearth of a constitutional injury in fact, either
3 to Plaintiffs or to their members. Because Plaintiffs have not alleged that they diverted their resources to
4 address their asserted harms, they have not established organizational standing. *See, e.g., Smith v. Pac.*
5 *Props. & Dev. Corp.*, 358 F.3d 1097, 1101, 1105 (9th Cir. 2004). Nor have Plaintiffs established
6 associational standing through their members, because those members have not suffered harms that are
7 both concrete and particularized, and actual or imminent. *See, e.g., Hunt v. Wash. State Apple Advert.*
8 *Comm’n*, 432 U.S. 333, 342–43 (1977). All of Plaintiffs’ alleged harms fall short of the “certainly
9 impending” or “substantial risk” threshold. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014)
10 (quoting *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409, 414 n.5 (2013)).

11 Even if the Amended Complaint made out a legally cognizable injury (it does not), Plaintiffs are
12 unable to establish causation because they have not shown that any of the purported harms are fairly
13 traceable to FDA’s approval of Experior. *See Tyler v. Cuomo*, 236 F.3d 1124, 1131–32 (9th Cir. 2000).
14 Instead, the alleged harms to Plaintiffs’ members are caused by the practices of industrial farms, by other
15 drugs used on food-producing cattle, or by the decisions of independent third parties, including feedlot
16 operators, or of Plaintiffs’ members themselves. (*See, e.g., Am. Compl.* ¶¶ 22, 63–75, 91–120.)

17 Yet even if the Court were to reach the third element, Plaintiffs still do not satisfy the
18 constitutional minimum to bring this case. They have not shown—beyond mere speculation—that any
19 harm fairly traceable to FDA’s approval of Experior is likely redressable by this Court. *See Tyler*, 236
20 F.3d at 1131–32. Plaintiffs do not allege that withdrawal of Experior’s approval will lead to fewer
21 industrial farms or reduce the use of similar drugs. Indeed, they do not allege that it would have any
22 impact on the decisions of third parties concerning the feedlot industry and other beta-agonists. Nor
23 could that withdrawal remedy precautions that Plaintiffs’ members themselves may have already taken.
24 Plaintiffs have therefore not shown that the relief they seek will remedy their alleged injuries.

25 For these reasons, and as further explained below, the Court should grant Federal Defendants’
26 Motion and dismiss Plaintiffs’ claims.

STATEMENT OF ISSUES TO BE DECIDED

Whether Plaintiffs failed to establish organizational standing or associational standing through their members, thereby requiring dismissal of the Amended Complaint for lack of Article III standing under Fed. R. Civ. P. 12(b)(1).

BACKGROUND

On November 6, 2018, FDA approved the new animal drug Experior (lubabegron Type A medicated article), manufactured by Elanco, US, Inc. (“Elanco”) (First Amended Complaint (“Am. Compl.”), ECF No. 30, ¶¶ 1–2.) Experior has been shown to lower ammonia gas emissions in cattle fed in confinement for slaughter for the last 14–91 days on feed. (*See id.* ¶ 1.) Experior is classified as an adrenergic agonist/antagonist, which is a subtype of a broader category of drugs known as beta-adrenergic agonist/antagonists. (*See id.* ¶¶ 3, 63.) Experior marks the first new animal drug that FDA’s Center for Veterinary Medicine has approved that activates from the beta-3 receptor (“beta-3”) subtype and the first new animal drug approved to reduce gas emissions from an animal or its waste. (*See id.* ¶ 123.)

On December 6, 2018, Plaintiff ALDF sought a stay of Experior’s approval by submitting a Petition for Stay of Action under 21 C.F.R. § 10.35 (“Petition”). (*See Am. Compl.* ¶¶ 10, 125.) The Petition alleged that FDA failed to sufficiently analyze Experior’s environmental impact, did not consider alternatives to Experior’s approval, and failed to prepare an Environmental Impact Statement (“EIS”) addressing the effects Experior may have on animals, humans, and the environment. (*Id.* ¶ 9.) The Petition requested that FDA stay Experior’s approval until the agency addressed ALDF’s concerns. (*See id.* ¶¶ 9, 10, 125–26.)

FDA responded to ALDF’s Petition on May 20, 2019 (“Response”) by denying ALDF’s request to stay the approval. (*See Am. Compl.* ¶¶ 11, 128–30.) FDA’s Response addressed each point raised in the Petition and concluded that none of ALDF’s arguments established any basis recognized by statute or regulation for a stay. (*See id.*)

On June 4, 2020, Plaintiffs filed suit, asking this Court to, *inter alia*, “[v]acate FDA’s decision to approve Experior.” (Compl., ECF No. 1, at 34, ¶ 3.) Plaintiffs’ Amended Complaint filed on September 29, 2020, asserts claims under the FDCA, NEPA, and the APA. (*See Am. Compl.* at 35–38.) In addition Federal Defendants’ Motion to Dismiss – Case No. 3:20-CV-03703-RS

1 to requesting vacatur of the approval, Plaintiffs pursue declaratory and injunctive relief that includes
2 “enjoining the use of Experior” until, in their view, FDA’s approval process “complies” with those three
3 statutes. (*Id.* at 38, Request for Relief ¶ 4.) Elanco has been permitted to join this case as an Intervenor-
4 Defendant. (ECF No. 25.) Federal Defendants now move to dismiss this action in its entirety because
5 Plaintiffs lack Article III standing.

6 **LEGAL STANDARD**

7 Federal Defendants challenge the sufficiency of the jurisdictional allegations in the Amended
8 Complaint under Federal Rule of Civil Procedure 12(b)(1). *See Safe Air for Everyone v. Meyer*, 373 F.3d
9 1035, 1039 (9th Cir. 2004). Although a court may “assume [a plaintiff’s] allegations to be true and draw
10 all reasonable inferences in [its] favor,” *Wolfe v. Strankman*, 392 F.3d 358, 362 (9th Cir. 2004), “plaintiff,
11 as the party invoking federal jurisdiction, bears the burden of establishing the[] elements” of standing,
12 *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). “Where, as here, a case is at the pleading stage,
13 the plaintiff must ‘clearly . . . allege facts demonstrating’ each element” of standing to secure this Court’s
14 jurisdiction. *Id.* (quoting *Warth v. Seldin*, 422 U.S. 490, 518 (1975)). “[W]hen considering a motion to
15 dismiss pursuant to Rule 12(b)(1) the district court is not restricted to the face of the pleadings, but may
16 review any evidence, such as affidavits and testimony, to resolve factual disputes concerning the
17 existence of jurisdiction.” *Gordon v. United States*, 739 F. App’x 408, 411 (9th Cir. 2018) (quoting
18 *McCarthy v. United States*, 850 F.2d 558, 560 (9th Cir. 1988) (alteration in original)).

19 **ARGUMENT**

20 This matter fails to satisfy minimum constitutional requirements for a federal case. Rooted in
21 Article III’s limitation of judicial power to cases and controversies, the standing “doctrine limits the
22 category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong.”
23 *Spokeo*, 136 S. Ct. at 1547. A plaintiff must show that it has: “(1) suffered an injury in fact, (2) that is
24 fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a
25 favorable judicial decision.” *Id.* That showing must be made for “each claim” asserted, *DaimlerChrysler*
26 *Corp. v. Cuno*, 547 U.S. 332, 352 (2006), and “separately for each form of relief sought,” *Friends of*
27 *Earth, Inc. v. Laidlaw Env’tl. Servs. (TOC), Inc.*, 528 U.S. 167, 185 (2000).

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1 Organizational plaintiffs may establish standing in one of two ways: (1) directly, by demonstrating
2 that the organizations themselves satisfy each element of the standing inquiry; or (2) by association,
3 through one or more of their members who can meet the standing elements. *See Havens Realty Corp. v.*
4 *Coleman*, 455 U.S. 363, 378–79 (1982); *see also Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*,
5 429 U.S. 252, 260–64 (1977).

6 Where, as here, plaintiffs are not themselves “the object” of a challenged government action,
7 standing is “substantially more difficult to establish.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562
8 (1992). In these instances, independent third parties attenuate the causal chain and undermine the court’s
9 ability to furnish redress. *Id.*

10 This is a paradigmatic case of failure to establish standing. The organizations not only fail to
11 demonstrate cognizable injury, but also fail to show that the government action caused their alleged harms
12 or that such harms would be redressed by this Court. Because Plaintiffs have not discharged their burden,
13 the Court should dismiss this case for lack of jurisdiction.

14 **I. Neither Plaintiffs Nor Their Members Have Suffered An Injury In Fact.**

15 **A. Plaintiffs Do Not Have Organizational Standing Because The Organizations Have**
16 **Not Established Their Own Injury In Fact.**

17 An organization may assert injury in fact on its own behalf if it alleges: “(1) frustration of its
18 organizational mission; and (2) diversion of its resources” to combat the defendant’s actions. *Pac. Props.*,
19 358 F.3d at 1101, 1105. This standard requires a showing “that the defendant’s actions run counter to
20 the organization’s purpose, that the organization seeks broad relief against the defendant’s actions, and
21 that granting relief would allow the organization to redirect resources currently spent combating the
22 specific challenged conduct to other activities that would advance its mission.” *Rodriguez v. City of San*
23 *Jose*, 930 F.3d 1123, 1134 (9th Cir. 2019), *cert. denied*, No. 19-1057 (Oct. 13, 2020). An organization
24 cannot “manufacture the [diversion of resources] injury by incurring litigation costs or simply choosing
25 to spend money fixing a problem that otherwise would not affect the organization at all.” *Id.* (quoting *La*
26 *Asociacion de Trabajadores de Lake Forest v. City of Lake Forest*, 624 F.3d 1083, 1088 (9th Cir. 2010)).

27 Even assuming that the Amended Complaint sufficiently pleads that FDA’s approval of Experior
28 Federal Defendants’ Motion to Dismiss – Case No. 3:20-CV-03703-RS

1 frustrates Plaintiffs’ missions, Plaintiffs have not established organizational standing because their
2 Amended Complaint lacks any allegations regarding resource diversion. Plaintiffs make no effort to
3 articulate how, if at all, they have expended financial or other resources in response to Experior’s
4 approval. Nor do they argue that they have redirected such resources from other initiatives.

5 Plaintiffs’ failure to allege diversion of resources is fatal to any claim of organizational standing.
6 *See Greenlining Inst. v. Fed. Commc’ns Comm’n*, 802 F. App’x 232, 233–34 (9th Cir. 2020) (no standing
7 for organizations that failed to prove either prior and ongoing diversion of resources, or an “estimate of
8 the resources that will be diverted as a result of the [challenged government] order”); *Citizens for Quality
9 Educ. San Diego v. Barrera*, 333 F. Supp. 3d 1003, 1021 (S.D. Cal. 2018) (no standing where “neither
10 organization allege[d] a diversion of resources” (emphasis omitted)); *Haynie v. Harris*, No. C 10-01255
11 SI, 2014 WL 899189, at *7 (N.D. Cal. Mar. 4, 2014) (Illston, J.) (no standing where sole allegation of
12 diversion of resources was one organization’s “allegations that it paid for the defense of several
13 members,” and organizations did “not allege that they have incurred any expenses aside from the
14 litigation costs”), *aff’d*, 658 F. App’x 834 (9th Cir. 2016).

15 Plaintiffs are likewise unable to secure Article III standing by relying on FDA’s denial of Plaintiff
16 ALDF’s Petition, or on the alleged deprivation of opportunities to participate in the administrative
17 process. (*See* Am. Compl. ¶¶ 35–36, 3d Claim ¶ 24.) FDA regulations provide broad opportunities for
18 citizens to petition FDA for different types of relief—including through submitting “citizen petitions”
19 and “petitions for stay of action”—and to comment on petitions that are submitted. *See* 21 C.F.R.
20 §§ 10.30, 10.35. But in order to seek review of FDA’s handling of the administrative process in federal
21 court, a plaintiff must be able to satisfy the traditional Article III standing elements. *See Klamath Water
22 Users Ass’n v. Fed. Energy Regulatory Comm’n*, 534 F.3d 735, 738 (D.C. Cir. 2008); *Physicians for
23 Integrity in Med. Rsch., Inc. v. Comm’r*, No. CV1108334GAFFMOX, 2012 WL 12882760, at *2 (C.D.
24 Cal. May 23, 2012), *aff’d sub nom. Physicians for Integrity in Med. Rsch., Inc. v. Hamburg*, 556 F. App’x
25 621 (9th Cir. 2014).

1 **B. Plaintiffs Do Not Have Associational Standing Because Their Members Have Not**
 2 **Suffered Injury In Fact.**

3 To establish associational standing on behalf of their members, an organization “must allege that
 4 its members, or any one of them, are suffering immediate or threatened injury as a result of the challenged
 5 action of the sort that would make out a justiciable case had the members themselves brought suit.” *Hunt*,
 6 432 U.S. at 342–43.

7 The requirements for injury in fact are familiar: Plaintiffs must allege that their members¹
 8 “suffered ‘an invasion of a legally protected interest’ that is ‘concrete and particularized’ and ‘actual or
 9 imminent, not conjectural or hypothetical.’” *Spokeo*, 136 S. Ct. at 1548 (quoting *Lujan*, 504 U.S. at 560).
 10 “The Supreme Court has repeatedly refused to recognize a generalized grievance against allegedly illegal
 11 government conduct as sufficient to confer standing.” *Carroll v. Nakatani*, 342 F.3d 934, 940 (9th Cir.
 12 2003).

13 When the injury has not yet been inflicted, a “threatened injury must be *certainly impending* to
 14 constitute injury in fact,” for “[a]llegations of *possible* future injury” remain purely conjectural. *Clapper*,
 15 568 U.S. at 409 (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)) (alteration in original); *see*
 16 *also Susan B. Anthony List*, 573 U.S. at 158 (suggesting “substantial risk” remains a valid formulation of
 17 the threshold as well (quoting *Clapper*, 568 U.S. at 414 n.5)). In *Clapper*, for example, the Supreme
 18 Court determined that the respondents’ fears of surveillance did not reflect a “certainly impending” threat
 19 sufficient to establish injury in fact. *Id.* at 410, 417.

20 Although the immediacy requirement is loosened in the context of procedural injury, *Lujan*, 504
 21 U.S. at 572 n.7, “deprivation of a procedural right without some concrete interest that is affected by the
 22 deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing,” *Summers v.*

23 ¹ Although the Amended Complaint discusses “members and supporters” of Plaintiff FACT (Am. Compl.
 24 ¶ 30; *see also id.* ¶¶ 31–32.), it is not clear that FACT is a membership organization. *See* FACT, IRS
 25 2019 Form 990, at 6 (representing that FACT does not have any members, in response to Part VI, Section
 26 A, Question 6), *available at* <https://foodanimalconcernstrust.org/financials> (last visited Oct. 29, 2020);
 27 *see Gordon*, 739 F. App’x at 411 (permitting reliance on material outside of pleadings to resolve factual
 28 dispute on jurisdictional challenge). If FACT does not have members, Plaintiffs cannot rely on
 allegations regarding “supporters” of FACT to establish associational standing, *see Hunt*, 432 U.S. at 342
 (describing membership basis for associational standing), and such allegations should be disregarded.

1 *Earth Island Inst.*, 555 U.S. 488, 496 (2009). Thus, for alleged environmental harms arising from a
2 deprivation of a procedural right, plaintiffs claiming a procedural injury must still allege “a ‘geographic
3 nexus’ between the individual asserting the claim and the location suffering an environmental impact,”
4 *Nuclear Info. & Res. Serv. v. Nuclear Regulatory Comm’n*, 457 F.3d 941, 949–50 (9th Cir. 2006) (quoting
5 *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934, 938 (9th Cir. 2005)), *i.e.*, “that they will suffer
6 harm as a result of their proximity to the area where the alleged environmental impact will occur,” *id.* at
7 952.

8 Here, Plaintiffs have not established that the harms they allege are concrete and particularized and
9 actual or imminent because they do not even allege that Experior is on the market (*see* Am. Compl. ¶ 33.),
10 let alone allege which feedlots will use Experior once it is (*see, e.g., id.* ¶ 26 (alleging their members live
11 “downstream from cattle feedlots that *may* give their cows Experior” (emphasis added)); *id.* ¶ 28 (raising
12 concerns about “the *future* use of Experior by feedlots” (emphasis added))). Further, they do not
13 adequately establish that they live or recreate in areas likely to be affected by harms they allege. Even
14 for purported environmental harms arising out of Plaintiffs’ procedural claim under NEPA, because
15 Plaintiffs “have not alleged with any specificity what geographic areas are most likely to be affected,
16 other than to assert that the [approval] impact[s] [feedlots] nationwide,” they have failed to establish a
17 concrete interest in the challenged agency action. *Nuclear Info.*, 457 F.3d at 953.

18 Grouping by category harms allegedly suffered by Plaintiffs’ members, Plaintiffs allege that their
19 members are harmed by FDA’s approval of Experior because: (1) Experior *may* contaminate “air and
20 water” in the vicinity of feedlots where Experior *may be* used and allegedly “near” where Plaintiffs’
21 members live or recreate (*see* Am. Compl. ¶¶ 3, 9, 20, 23, 24, 26–28, 30, 74, 79-81, 90, 101–04.);
22 (2) Experior *may* allow industrial farming operations to “greenwash” environmental impacts and
23 accelerate the industry’s growth (*see id.* ¶¶ 34, 91–120.); (3) Experior *may* have an impact on Plaintiffs’
24 recreational activities, including wildlife that Plaintiffs’ members enjoy watching and/or eating (*see, e.g.,*
25 *id.* ¶¶ 20, 21, 23, 26, 28, 31, 74, 102, 111.); and (4) Experior *may* affect food safety (*see, e.g., id.* ¶¶ 3, 8,
26
27

1 22, 26– 27, 30, 32, 71, 72, 74–75, 101–04, 119.).²

2 Despite Plaintiffs’ attempt to make member-specific allegations in their Amended Complaint,
3 their efforts fall short of establishing standing because such harms are speculative. And the allegations
4 that Plaintiffs’ members are likely to suffer such harms fail to demonstrate a personalized stake in the
5 outcome of this matter. Indeed, for each of the four categories of alleged harm described above, Plaintiffs
6 fail to show that their members face imminent harm and/or that a geographic nexus exists between their
7 members and any alleged environmental impact. Accordingly, Plaintiffs have not demonstrated that their
8 members sustained an injury in fact, and therefore Plaintiffs lack standing.

9 **1. Air And Water Contamination**

10 Plaintiffs allege that their members may be harmed by Experior emanating from feedlots
11 contaminating air and water, including drinking water, near where members live or recreate. (Am.
12 Compl. ¶¶ 19, 20, 23, 24, 26–28, 31.) Plaintiffs do not allege that Experior has caused any such
13 contamination yet. Indeed, they do not even allege that any feedlot has used Experior or allege any basis
14 for identifying which feedlots will use Experior and cause such contamination in the future. Without
15 such information, it is impossible to determine which geographic area(s) may be affected by Experior
16 contamination, and Plaintiffs have thus failed to establish a requisite “geographic nexus” for their claimed
17 injuries. *See Nuclear Info.*, 457 F.3d at 952–53 (holding petitioners did not sustain injury in fact, because
18 they had not pled “with any specificity what geographic areas are most likely to be affected, other than
19 to assert that the regulations impact highways nationwide”).

20 Assuming, *arguendo*, that Plaintiffs had adequately alleged which feedlots were likely to use
21 Experior, their injury allegations would still fall short because they fail to adequately allege their
22 members’ proximity to those feedlots. For instance, ALDF claims that “many” of its members “live near,
23

24 ² In addition to these categories of alleged harm, Plaintiffs mention additional generalized harms
25 throughout their complaint: feedlot worker safety concerns (*see* Am. Compl. ¶¶ 3, 8, 70–71, 119); injuries
26 to animals that consume beta-agonists (*see id.* ¶¶ 3, 27, 67–69, 75, 93, 136–39.); exposure to antibiotic-
27 resistant bacteria (*see id.* ¶¶ 85–88, 114–18.); effects of climate change (*see id.* ¶ 108.); and harm to
28 “tourism-dependent communities” (*id.* ¶ 111.). Those adverse impacts, however, are not connected to an
alleged injury to any of their members, so they cannot establish standing. *See Lujan*, 504 U.S. at 575
(grievance not specific to plaintiffs is insufficient).

1 recreate near, and closely monitor [concentrated animal feeding operations (“CAFO”)] in their
2 communities” (Am. Compl. ¶ 19.), and the Amended Complaint discusses unnamed individual members
3 purportedly affected by environmental contamination. (See Am. Compl. ¶ 23 (recreating near
4 “waterways downstream from cow feedlots in Texas”); ¶ 24 (“lives on the banks of the Mississippi River”
5 in Iowa); ¶ 27 (“lives [in Iowa] adjacent to fields where manure from feedlots is spread); ¶ 28 (recreating
6 in “water downstream from cattle feedlots” and in “conservation areas adjacent to and downstream from
7 cow feedlots”); ¶ 31 (“lives directly on Lake Michigan, a waterway with documented impacts from cattle
8 feedlot pollution” and refers to “feedlots near Lake Michigan”).) Yet the Amended Complaint does not
9 define the loose concept of nearness, nor does it suggest the distance that any Experior-induced
10 contamination could be expected to travel.

11 Even when discussing individual members, Plaintiffs actually say little about the proximity of
12 their members’ activities to feedlots. For example, “downstream” can mean an immediately adjacent
13 property or a property miles away, especially on a river as long as the Mississippi. See Nat’l Park Serv.,
14 *Mississippi River Facts*, <https://www.nps.gov/miss/riverfacts.htm> (last visited Oct. 29, 2020)
15 (documenting length upwards of 2,300 miles); see also *Ashley Creek Phosphate Co.*, 420 F.3d at 938–39
16 (no injury in fact for lack of “judicially recognizable geographic nexus” between plaintiff’s interest and
17 the affected site 250 miles away). The individual³ who lives “directly on” Lake Michigan (Am. Compl.
18 ¶ 31.) may live a hundred miles away or even on the other side of the lake from any feedlot using
19 Experior—assuming any feedlots that drain to Lake Michigan actually use Experior at all. Even for
20 members who claim connection to properties “adjacent” to feedlots (Am. Compl. ¶¶ 27–28.), Plaintiffs
21 fail to provide information about the size of the properties affected, the proximity to the property line of
22 any disposal that may lead to contamination, or the distance that any contamination would be reasonably
23 expected to travel. Because Plaintiffs do not clearly plead how “near” their members are to feedlots, how
24 close they would need to be to experience any impacts by contamination from the feedlots, or that any

26 ³ Plaintiffs allege that this individual is a member of FACT, but as discussed above, if Plaintiffs cannot
27 substantiate that FACT has members, this individual’s alleged injuries should not be considered for
28 purposes of standing. See *supra* note 1.

1 such contamination spill-over would happen near their members, they have not alleged a concrete harm
2 sufficient to establish injury in fact. *See Nuclear Info.*, 457 F.3d at 949–50 (discussing concreteness).

3 Further, Plaintiffs allege that one member in Idaho “*enjoys visiting* conservation areas *adjacent*
4 *to*” feedlots (Am. Compl. ¶ 28 (emphasis added).), but absent any indication of when such a visit last
5 took place, or the frequency of such visits, aside from the conclusory and vague allegation of “concrete
6 plans to visit . . . in the future” (*id.*), allegations of harm to this member from the approval of Experior
7 are no more concrete. *See Wilderness Soc., Inc. v. Rey*, 622 F.3d 1251, 1256 (9th Cir. 2010) (rejecting
8 “‘some day’ general intention to return to the national forests of two geographically large states” as “too
9 vague” because member did “not show that he is likely to encounter an *affected* area of [a specific forest]
10 in his future visits”).

11 It is also highly speculative to claim that Experior will, in fact, contaminate the air and water near
12 feedlots and in turn harm Plaintiffs’ members. The Amended Complaint recites a litany of air and water
13 problems allegedly attributable to feedlots in general (*see* Am. Compl. ¶¶ 93–111.), but any such
14 problems predate the use of Experior. Plaintiffs presuppose that cattle farms will mismanage Experior-
15 laden waste, including animal manure and uneaten medicated feed, in a way that would contaminate the
16 environment. (*See id.* ¶¶ 149–50; *see also id.* ¶ 27 (raising concerns of one of Plaintiffs’ members who
17 “lives adjacent to fields where manure from feedlots is spread”).) Yet Plaintiffs fail to justify their
18 confidence that Experior, even if in use, would result in such effects. (*See, e.g., id.* ¶ 149 (asserting
19 “Experior itself *will* enter the environment through manure” (emphasis added).) Even if Experior were
20 to contaminate the environment, Plaintiffs have not shown that their members would be affected, due to
21 the proximity issues described above.

22 **2. Industrial Farming Operations**

23 Plaintiffs claim that their “members and supporters”⁴ share the organizations’ concern “that
24

25 ⁴ For standing purposes, the Court should disregard allegations here and elsewhere in the Amended
26 Complaint as to Plaintiffs’ “supporters,” for only their members’ concerns could support associational
27 standing. *See Hunt*, 432 U.S. at 342 (describing membership basis for associational standing); *Warth*,
28 422 U.S. at 511 (“[A]n association may have standing solely as the representative of its members.”). For
the remainder of this brief, Defendants shall refer solely to the alleged concerns of Plaintiffs’ members.
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1 FDA’s approval of Experior will further entrench the harmful CAFO industry by making it possible for
2 large feedlots to ‘greenwash’ their operations by claiming lower emissions of ammonia, which is known
3 to harm human health, rural quality of life, and the environment.” (Am. Compl. ¶ 34.) They profess that
4 their members “are also aware that Experior is likely to increase cow herd size and density at feedlots,”
5 a trend that allegedly “will encourage construction of new feedlots.” (*Id.*) These allegations are
6 insufficient to establish standing because an ideological opposition to expanded feedlots is not cognizable
7 under Article III; instead, they must show an injury that is concrete and particularized and actual or
8 imminent.

9 Plaintiffs do not begin to establish that such harm is “actual or imminent.” They cite no examples
10 of a feedlot that has been expanded or built as a result of Experior’s approval; nor do they cite any
11 information that suggests that such activity has even been proposed. Instead, they allege that FDA’s
12 approval of Experior *may* lead to the construction of new feedlots. Presumably, this, in turn, *may* lead to
13 harms including contaminated groundwater, surface water, and air pollutants, which *may* harm
14 individuals in the vicinity of these feedlots, some of whom *may* be ALDF or FWW members. Such
15 attenuated allegations do not amount to an “actual” injury or an “imminent” threat, but instead fall within
16 the category of “conjectural” or “hypothetical” harms that do not amount to cognizable injury in
17 fact. *Lujan*, 504 U.S. at 560 (quoting *Whitmore*, 495 U.S. at 155). Plaintiffs have not demonstrated that
18 any member “is *immediately* in danger of sustaining some *direct* injury as the result of the challenged
19 official conduct and the injury or threat of injury is both real and immediate, not conjectural or
20 hypothetical.” *Scott v. Pasadena Unified Sch. Dist.*, 306 F.3d 646, 656 (9th Cir. 2002) (quoting *City of*
21 *Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983)).

22 Further, even under the theory of a deprivation of procedural rights, Plaintiffs must establish a
23 geographic nexus between their members and expanded feedlots. See *Nuclear Info.*, 457 F.3d at 949–
24 50. Their failure to do so deprives them of Article III standing. See *Lujan*, 504 U.S. at 575 (“generalized
25 grievance[s]’ [are] inconsistent with ‘the framework of Article III’ because ‘the impact on [Plaintiffs] is
26 plainly undifferentiated and “common to all members of the public”” (quoting *United States v.*
27 *Richardson*, 418 U.S. 166, 171, 176–77 (1974))). Although Plaintiffs make general allegations, using
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1 relative terms, that certain of their members live or recreate “near” or “downstream” from CAFOs (*see*,
2 *e.g.*, Am. Compl. ¶¶ 19, 20, 23, 26, 27, 28, 31) or eat fish caught downstream of CAFOs (*see, e.g.*, Am.
3 Compl. ¶¶ 20, 23), these vague allegations regarding unnamed members do not establish the necessary
4 geographic proximity, nor do they provide enough information for the Court or Defendants to
5 meaningfully investigate them. *See supra* Part I.B.1.

6 Such attenuated and hypothetical allegations do not establish a certainly impending harm or
7 substantial risk to Plaintiffs’ members. *See Susan B. Anthony List*, 573 U.S. at 158; *see also Ass’n of*
8 *Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 19 (D.D.C. 2008) (rejecting pharmacists’
9 standing to challenge FDA approval because their “claim that their risk of legal liability ha[d] increased
10 [was] speculative” absent factual support), *aff’d*, 358 F. App’x 179 (D.C. Cir. 2009) (*per curiam*).

11 **3. Outdoor Recreation And Wildlife Observation**

12 Plaintiffs also allege that Experior will detrimentally impact their members’ recreational
13 opportunities, including participating in water activities, observing wildlife, and eating wild fish, based
14 on Experior’s anticipated contributions to water pollution and its purported effects on “wildlife in areas
15 downstream from cow feedlots.” (Am. Compl. ¶¶ 20, 21, 23–24, 26, 28, 30, 31, 74, 102, 111.) Here
16 again, harm to such interests will constitute an injury in fact only if Plaintiffs establish a “geographical
17 nexus” between their members and the alleged harm. *Nuclear Info.*, 457 F.3d at 952 (explaining that to
18 properly assert that their “aesthetic or recreational interest[s]” have been harmed, “environmental
19 plaintiffs must allege that they will suffer harm by virtue of their geographic proximity to and use of areas
20 that will be affected by the [agency’s] policy.”) (second alteration in original) (emphasis, citations, and
21 quotation marks omitted)); *see also Lujan*, 504 U.S. at 566 (“[P]laintiff must use the area affected by the
22 challenged activity and not an area roughly ‘in the vicinity’ of it.”); *Tulacz v. Tri-Cty. Metro. Transp.*
23 *Dist. of Oregon*, No. CIV. 91-1010-JO, 1992 WL 205942, at *4 (D. Or. July 14, 1992) (allegation that
24 plaintiff operated vehicle in affected area not sufficient to establish geographic nexus for purposes of
25 standing).

26 As with their allegations of environmental impacts discussed above, Plaintiffs do not establish the
27 geographic locations of feedlots that have used or will use Experior. *See supra* Part I.B.1. Nor do they
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1 clearly plead how “near” their recreational interests are to any such feedlots, how close they would need
2 to be to experience any impacts by contamination from the feedlots, or that any such contamination spill-
3 over would happen near their members. (*See* Am. Compl. ¶¶ 20, 21, 23–24, 26, 28, 30–31.) Thus, they
4 have not alleged a concrete harm sufficient to establish injury in fact. For reasons discussed above, such
5 generalized descriptions fail to establish the nexus required for injury in fact. *See supra* Part I.B.1.

6 **4. Food Safety**

7 Plaintiffs also fail to establish a cognizable harm based on members’ consumption of food,
8 including beef; nor could they. Plaintiffs claim that their members “consume beef purchased from
9 grocery stores and restaurants, which *can be* sourced from feedlots that *will likely* use Experior.” (Am.
10 Compl. ¶ 22 (emphasis added); *see also* ¶¶ 3, 8, 26, 30, 32, 71–72, 75.) But these allegations are wholly
11 speculative and lack a connection between the members and the sources of beef.

12 Plaintiffs do not claim that beef currently on the market comes from feedlots that use Experior.
13 Nor is there any suggestion *when* cows raised with Experior could reach the market, *where* that beef
14 would be available to grocery stores or restaurants, or *how likely* those grocery stores and restaurants are
15 to select that beef. Plaintiffs merely speculate about “*possible* future injury” to their members, which
16 does not qualify as a “certainly impending” harm. *Clapper*, 568 U.S. at 409. Nor do Plaintiffs’ members
17 face a “substantial risk of harm” “in light of the attenuated chain of inferences necessary to find harm
18 here.” *Id.* at 414 n.5.

19 Moreover, nowhere do Plaintiffs provide specific allegations about how Experior has or
20 imminently will harm human health through beef consumption. Instead, Plaintiffs allege that their
21 members have “concerns,” “fear[s],” or “skepticism of the safety of beef.” (Am. Compl. ¶¶ 22–24.) But
22 unsubstantiated fears do not give rise to Article III standing. *Clapper*, 568 U.S. at 420 (denying standing
23 where plaintiffs “present no concrete evidence to substantiate their fears, but instead rest on mere
24 conjecture”). In toxic exposure cases, “Plaintiffs must plead a credible or substantial threat to their health
25 or that of their children to establish their standing to bring suit.” *Herrington v. Johnson & Johnson*
26 *Consumer Cos.*, No. C 09-1597 CW, 2010 WL 3448531, at *3–4 (N.D. Cal. Sept. 1, 2010) (Wilken, J.)
27 (dismissing for lack of standing claim based on alleged injury from exposure to “probable human
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1 carcinogens” as “too speculative and uncertain to confer Article III standing”); *see also, e.g., Boysen v.*
 2 *Walgreen Co.*, No. C 11-06262 SI, 2012 WL 2953069, at *7 (N.D. Cal. July 19, 2012) (Illston, J.) (same
 3 for lead and arsenic); *In re Fruit Juice Prods. Mktg. & Sales Practices Litig.*, 831 F. Supp. 2d 507, 512
 4 (D. Mass. 2011) (same for lead); *Koronthaly v. L’Oreal USA, Inc.*, 374 F. App’x 257 (3d Cir.
 5 2010), *aff’g* No. 07–CV–5588, 2008 WL 2938045 (D.N.J. July 29, 2008) (same); *Frye v. L’Oreal USA,*
 6 *Inc.*, 583 F. Supp. 2d 954 (N.D. Ill. 2008) (same); *cf. Backus v. Gen. Mills, Inc.*, 122 F. Supp. 3d 909,
 7 921–23 (N.D. Cal. 2015) (Henderson, J.) (rejecting argument that alleged impact of trans fats on disease
 8 risk supported standing, where plaintiff “fail[ed] to allege a *substantially* increased risk” under *Clapper*
 9 (emphasis added)).

10 Judge Wilken’s decision in *Herrington* is instructive. There, plaintiffs alleged an injury based on
 11 exposure to “probable human carcinogens,” while failing to allege (1) that the substances were “in fact
 12 carcinogenic for humans” or (2) “that the amounts of the substances” to which they had been exposed
 13 “have caused harm or create a credible or substantial risk of harm.” *Herrington*, 2010 WL 3448531, at
 14 *3. Judge Wilken dismissed for lack of standing, reasoning that allegations that the substances “*may* be
 15 carcinogenic for humans,” and “that there *could* be no safe levels for exposure to carcinogens” were “too
 16 attenuated and not sufficiently imminent to confer Article III standing.” *Id.*

17 So too here. Plaintiffs do not allege that Experior is actually harmful to humans, let alone that the
 18 amounts to which they might be exposed will cause “harm or create a credible or substantial risk of harm.”
 19 *Id.* Faced with strict FDA regulations restricting Experior residues in cattle liver tissue to just 10 parts
 20 per billion—the same standard applicable to arsenic in drinking water⁵—Plaintiffs provide no specific
 21 allegations about how treating cattle with Experior will lead to significant human health risks. They
 22 neither allege that such residues will harm human health, nor provide any basis—let alone a credible
 23 basis—for believing that food from cows treated with Experior would exceed those residue levels. *Cf.*
 24 *In re Fruit Juice Prods. Mktg.*, 831 F. Supp. 2d at 511–12 (dismissing “risk of future harm” claim as “too

25 _____
 26 ⁵ Compare 21 C.F.R. § 556.370 (b)(1) (setting tolerance for lubabegron [Experior] residues in cattle liver
 27 at 10 parts per billion (ppb)), with 40 C.F.R. § 141.62(b)(16) (setting the acceptable level of arsenic in
 28 drinking water at 10 ppb or 0.01 mg/L), and 21 C.F.R. § 165.110(b)(4)(iii)(A) (same for bottled water).
 (See also Am. Compl. ¶ 29 (professing FACT’s ancillary concern with arsenic).)

1 speculative,” absent any allegation “that the levels of lead in Defendants’ products violated any FDA
2 standards” or inflicted any injuries on consumers). Without more specific allegations, Plaintiffs have
3 established nothing more than a “highly speculative fear” that “relies on a highly attenuated chain of
4 possibilities,” *Clapper*, 568 U.S. at 410, viz. that Experior *may* be used to treat cows from which food is
5 derived that *may* be purchased by their members who *may* be harmed by eating such food through some
6 *unexplained* cause in which miniscule residues *could* cause adverse human health consequences.

7 Plaintiffs attempt to equate the anticipated effects of Experior on human health with allegedly
8 harmful effects of other beta-agonist drugs.⁶ (*See* Am. Compl. ¶¶ 63–75 (arguing that beta-agonists
9 increase the likelihood of injury to feedlot workers and food consumers).) That linkage is conclusory.
10 (*See, e.g., id.* ¶ 70 (taking generic preceding description of beta-agonist harms as support for this premise:
11 “Because Experior negatively influences animal behavior, it corresponds to an increased risk to humans
12 who work with them.”).) But even assuming that Experior has the same effect on food safety as other
13 beta-agonists, Plaintiffs do not point to a single member who has been harmed, or faces imminent harm,
14 as a result of eating food derived from cattle treated with beta-agonists. One member is concerned based
15 on “witness[ing]” pigs’ response to other beta-agonists⁷ (*id.* ¶ 27.), but that does not establish imminent
16 likelihood of injury from consuming food derived from cows treated with Experior. Although some
17 members allegedly propose altering their purchasing or consuming habits as a result of FDA’s approval
18 (*id.* ¶¶ 22–24, 26, 27, 30, 32.), it is unclear why they have not already done so, in response to other beta-

20 ⁶ Similarly, the Amended Complaint draws unfounded conclusions about Experior’s likely environmental
21 impact based on the alleged impact of other beta-agonists. (*See* Am. Compl. ¶ 74.) Plaintiffs go so far
22 as to claim that Experior “persists in the environment” for a long time based on its half-life (*id.*), but
23 Plaintiffs offer no support for the intimation that Experior already can be found in the environment.

24 ⁷ Any concerns about feedlot worker injury from animals fed beta-agonists (*see* Am. Compl. ¶¶ 3, 8, 70,
25 71, 119) do not establish associational standing for Plaintiffs, who have not alleged that any of their
26 members currently work on feedlots. Rather, “one FWW member . . . has experience working on a
27 feedlot,” while others “work . . . near and downstream from cattle feedlots.” *Id.* ¶¶ 26, 27. They have
28 not alleged that working near or downstream from cattle feedlots—nor working on a feedlot in the past—
expose workers to injury from animals fed Experior or any other beta-agonists.

1 agonists on the market.⁸ For these reasons, the allegation that FDA’s approval of Experior renders
2 Plaintiffs’ members food derived from treated cattle unsafe—or raises concerns sufficient to generate
3 changes in consumer behavior—is purely hypothetical.

4 Further, many of the allegations about the harmful effects of beta-agonists are highly speculative.
5 For example, Plaintiffs claim that beta-agonists may render cows non-ambulatory, which may in turn
6 cause these cows to pick up pathogens from the dirt and “carry [them] into the slaughterhouse.” (Am.
7 Compl. ¶¶ 70, 75.) But any such pathogens could have an impact on food purchased by Plaintiffs’
8 members only if cows that cannot walk nevertheless pass through the meat inspection process without
9 detection. A robust statutory and regulatory regime minimizes risk of that happening. *See* 21 U.S.C.
10 § 603(a) (establishing pre-slaughter inspection of animals, with those that “show symptoms of disease”
11 to “be set apart”); 9 C.F.R. § 309.2 (requiring disposal of “seriously crippled animals and non-ambulatory
12 disabled livestock”). Plaintiffs plead no facts demonstrating that such a scenario is likely, much less that
13 it poses a certainly impending harm to Plaintiffs’ members.

14 * * *

15 In short, neither Plaintiffs nor their members are cognizably harmed by FDA’s approval of
16 Experior. This action should therefore be dismissed for lack of standing.

17 **II. Plaintiffs Fail To Adequately Allege That Any Purported Harms Were Caused By FDA’s**
18 **Approval Of Experior.**

19 Even if the Plaintiffs plead a plausible injury in fact (they do not), the Court should dismiss their
20 claims for failure to establish the second prong of the standing inquiry. Plaintiffs have not fairly traced
21 their asserted harms to FDA’s approval of Experior.

22 “The line of causation between the defendant’s action and the plaintiff’s harm must be more than
23 attenuated.” *Wash. Env’tl. Council v. Bellon*, 732 F.3d 1131, 1141 (9th Cir. 2013) (quoting *Native Vill.*

24 _____
25 ⁸ Another member allegedly “fears that FDA’s approval of Experior may financially hurt his business of
26 selling natural drug-free beef, as he believes that increased drug use on cattle feedlots perpetuates a
27 growing public perception that all beef is unsafe to eat and that the labeling of all beef cannot be fully
28 trusted.” (Am. Compl. ¶ 31.) This is wholly speculative: there are no allegations that approval of other
beta-agonists has had such an effect on the member’s business, nor is there any suggestion of whether or
when such feared changes would affect his business.

1 of *Kivalina v. ExxonMobil Corp.*, 696 F.3d 849, 867 (9th Cir. 2012) (Pro, J., concurring)). Although a
2 causal inference may justifiably require multiple steps, those steps do not satisfy the pleading threshold
3 if they are “hypothetical or tenuous.” *Id.* at 1141–42 (quoting *Native Vill. of Kivalina*, 696 F.3d at 867
4 (Pro, J., concurring)). “[W]here the causal chain involves numerous third parties whose independent
5 decisions collectively have a significant effect on plaintiffs’ injuries, . . . the causal chain is too weak to
6 support standing.” *Id.* at 1142 (quoting *Native Vill. of Kivalina*, 696 F.3d at 867 (Pro, J., concurring)).

7 In this case, Plaintiffs attempt to draw a causal inference between FDA approval of Experior and
8 their asserted harms—but that approval has no fairly traceable relationship to the purported harms. Those
9 harms are instead attributable to third-party feedlot practices or other drugs. Nor does Plaintiffs’
10 members’ attempt to manufacture causation by inflicting harms on themselves provide sufficient basis
11 for standing.

12 **A. Many Of The Alleged Harms Are Attributable To Existing Third-Party Feedlot**
13 **Practices.**

14 The Amended Complaint includes a lengthy section on the purported harms of feedlots generally,
15 including air and water pollution, greenhouse gas emissions, and foodborne illnesses. (*See* Am. Compl.
16 ¶¶ 91–120.) This section is presumably intended to substantiate the harms allegedly suffered by
17 Plaintiffs. *See supra* Part I.B. (*See also* Am. Compl. ¶¶ 19–34.) Plaintiffs, however, do not link these
18 allegations to Experior. Instead, they claim that feedlots—which they do not allege are using Experior—
19 are the source of each of these harms. (*See, e.g., id.* ¶ 96 (“CAFOs are one of the largest sources of water
20 pollution in the country.”); ¶ 101 (“CAFOs must store [animal] waste for long periods of time
21 Unlined or inadequately lined manure storage lagoons can contaminate communities’ well water if the
22 manure leaks through the soil into aquifers below.”); ¶ 103 (“Nitrate contamination from cow manure
23 can also cause downstream communities to bear significant costs to treat municipal drinking water.”);
24 ¶ 105 (“The concentration of animals at CAFOs also produces air pollutants”); ¶ 108 (“CAFOs and
25 CAFO waste disposal also release the powerful greenhouse gases methane and nitrous oxide.”); ¶¶ 113–
26 14, 117 (“[U]se of antibiotics at CAFOs leads to the development and spread of antibiotic-resistant
27 bacteria [which] are capable of transferring to humans Upon human exposure, the resistant

1 bacteria can colonize the human gut and cause illnesses resistant to clinically important antibiotics.”).
2 Plaintiffs do not even allege that these third-party feedlots use Experior, let alone that such use is
3 somehow related to the list of harms they associate with feedlots.

4 **B. Many of the Alleged Harms Are Not Attributable to Experior Specifically.**

5 Causation is also lacking because Plaintiffs fail to tether their alleged harms to Experior as
6 opposed to other beta-agonists.⁹ In particular, the allegations about air and water contamination,
7 recreational harms, and food safety concerns relate to harms caused by beta-agonists in general but have
8 no specific or unique association with Experior.

9 Plaintiffs’ claims of contamination to their members’ air and water are based on information
10 related to ractopamine, which is a different drug than Experior and indeed a different subtype of beta-
11 agonist. (*See* Am. Compl. ¶ 74 (explaining how ractopamine allegedly “contaminates ground and surface
12 waters”); *id.* ¶ 139 (identifying ractopamine as a beta-2 drug).) Although Plaintiffs make brief reference
13 to Experior’s half-life, suggesting that it will generate similar harms because of its persistence, they
14 simply have not shown that FDA’s approval of Experior has caused the kinds of effects they describe.

15 It is also not clear how any recreational interests are negatively influenced by Experior’s approval.
16 Plaintiffs acknowledge that beta-agonists are a staple of the industrial meat processing industry (Am.
17 Compl. ¶ 64.), and any number of those drugs could have the alleged effects on recreation that concern
18 Plaintiffs’ members (*see id.* ¶ 111 (asserting that CAFOs create haze causing “significant losses of public
19 enjoyment of wildlife and wilderness areas”).).

20 Similarly, regarding food safety, the Amended Complaint asserts that beta-agonist drugs as a
21

22 ⁹ Plaintiffs include allegations about harms ostensibly caused by other new animal drugs approved by
23 FDA, including new animal drugs that include Experior along with other active ingredients, such as
24 monensin and tylosin. (*See* Am. Compl. ¶¶ 12, 76–90, 131.) Defendants note that Plaintiffs have not
25 submitted any petition to FDA with respect to its approvals of these other drugs. Thus, Plaintiffs plainly
26 have not exhausted administrative remedies for any challenge to these approvals. Nor, for reasons set
27 out in this brief, have Plaintiffs established injury in fact, causation, or redressability as to any alleged
28 harms caused by these drugs, so any such harms do not confer Article III standing in this litigation.

1 general category can cause health issues in cattle (Am. Compl. ¶¶ 66–70), and are detrimental to
2 consumers with “compromised cardiovascular systems” (*id.* ¶ 72). Plaintiffs further claim that human
3 “expos[ure] to or consum[ption]” of food derived from animals treated with beta-agonists has led to
4 “nausea, dizziness, respiratory issues, and other serious medical conditions.” (*Id.* ¶ 71). But Plaintiffs
5 do not allege that any of these harms have been attributed to Experior specifically, or even to the subtype
6 of beta-agonists to which Experior belongs.¹⁰ Nor can they explain how any alleged harms that may
7 occur would be traced to Experior, as opposed to other causes, including other beta-agonists that Plaintiffs
8 admit are administered to food-producing animals. (*See id.* ¶ 64.); *cf. Bellon*, 732 F.3d at 1142–43
9 (rejecting at summary judgment stage the sufficiency of “vague, conclusory statements” that agency non-
10 action causes greenhouse gas emissions).

11 At bottom, Plaintiffs do not allege that Experior is used on feedlots, so all of the harms allegedly
12 attributable to beta-agonists stem from drugs other than Experior. FDA’s Experior approval could not
13 conceivably have caused those harms.

14 **C. The Alleged Harms Would Be Caused, If At All, By Third Parties, Not Experior.**

15 Plaintiffs’ alleged injuries also cannot be “fairly traced” to FDA’s Experior approval because any
16 of the injuries alleged would occur only if third parties, such as feedlot operators, take (or fail to take)
17 independent action. *See Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41–42 (1976) (reciting Article
18 III restriction to “redress[ing] injury that fairly can be traced to the challenged action of the defendant,
19 and not injury that results from the independent action of some third party not before the court”).

20 For example, increasingly dense feedlots would generate increased environmental contamination
21

22 ¹⁰ Although Plaintiffs state that Experior is a beta 3-phenethanolamine adrenergic agonist/antagonist
23 (Am. Compl. ¶ 63. *But see id.* ¶ 139 (claiming it also has “some” beta 2 “activity”).), their Amended
24 Complaint discusses the effects of beta-agonists generally (including drugs that activate in the beta-1 and
25 beta-2 subtype receptors), without distinguishing among the three classes of beta-adrenergic receptors.
26 It is inappropriate to generalize effects of beta-agonists generally to Experior specifically. Experior is
27 the first new animal drug that FDA’s Center for Veterinary Medicine has approved that specifically
28 activates the beta-3 receptor. It is not reasonable to lump Experior in with other beta-agonists that activate
the beta-1 and beta-2 receptors and assume they will behave the same way. Plaintiffs’ overly-inclusive
approach to invoking scientific research regarding other beta-agonists (*id.* ¶ 66) has the improper effect
of conflating the findings of studies done on distinct types of beta-agonist drugs.

1 only if feedlot operators, or other decision-makers within the industrial farming industry, decide to
2 administer Experior to their cattle, and then based on decreased ammonia emissions, choose to expand
3 operations without taking steps to reduce adverse environmental effects from such expansion. This
4 strained chain of logic relies heavily on the actions of third parties, but the Amended Complaint lacks
5 any concrete allegations that such actions have been or will be taken in the immediate future. (*See* Am.
6 Compl. ¶ 34 (alleging only that Experior’s approval “will encourage construction of new feedlots”
7 because Experior “is likely to increase cow herd size and density at feedlots”); *see also id.* ¶ 106
8 (“Experior also enables CAFO operators to confine more cows per feedlot while touting lower ammonia
9 emissions”))

10 Such a causal chain of events, which relies on speculative assertions about the behavior of
11 independent third parties, is inadequate to establish the second prong of the standing inquiry. *Bellon*, 732
12 F.3d at 1144 (where “a multitude of independent third parties are responsible for the changes contributing
13 to Plaintiffs’ injuries, the causal chain is too tenuous to support standing”); *Ctr. for Biological Diversity*
14 *v. U.S. Dep’t of Interior*, 563 F.3d 466, 479 (D.C. Cir. 2009) (no standing where petitioner’s argument
15 that government action caused climate change “rel[ie]d on the speculation that various different groups
16 of actors not present in this case . . . might act in a certain way in the future”).

17 Similarly, concerns about foodborne illness due to animals that Experior may render non-
18 ambulatory or otherwise harm (Am. Compl. ¶¶ 70, 75, 119), would result, if at all, only from a series of
19 hypothetical actions far removed from FDA’s Experior approval. First, a feedlot operator would need to
20 hold cattle under stress conditions that make them “more susceptible to pathogens,” (*id.* ¶ 75), and to fail
21 to take precautions against infection by pathogens. The operator would then have to overlook the disease
22 or disability of such animals and take them to slaughter, while the animals would then need to escape
23 detection during the federally regulated inspection process. *See supra* Part I.B.4. (describing speculative
24 nature of that harm). Such hypothetical steps, all dependent on the actions of multiple third parties, cannot
25 reasonably be attributed to FDA’s Experior approval.

26 Nor can FDA’s approval be cited as the cause of any above-tolerance residues identified in the
27 edible tissues of treated animals at some future date. Independent feedlot operators would need to choose
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1 to administer Experior, and to do so in a manner that ignores established administration and disposal
2 requirements. *See supra* Part I.B.4. Such a causal chain is too attenuated to support Article III standing.

3 **D. Self-Inflicted Harms Are Not Fairly Traceable To FDA’s Approval.**

4 Plaintiffs also rely on their members’ alleged plans to alter food consumption habits or forego
5 recreation specifically in response to Experior. *E.g.*, Am. Compl. ¶¶ 22–24, 26–28, 31. But those
6 anticipated harms are merely “self-inflicted injuries [that] are not fairly traceable to the Government’s
7 [challenged] activities.” *Clapper*, 568 U.S. at 418 (deciding costs incurred to address surveillance fears
8 that were not injury in fact were not fairly traceable). Plaintiffs’ members may change their routines, but
9 they “cannot manufacture standing merely by inflicting harm on themselves based on their fears of
10 hypothetical future harm that is not certainly impending.” *Id.* at 416; *see also Or. Prescription Drug*
11 *Monitoring Program v. U.S. Drug Enf’t Admin.*, 860 F.3d 1228, 1235 (9th Cir. 2017) (relying on *Clapper*
12 to reject standing for intervenors who were *not* subject to an imminent threat but claimed that government
13 action “causes them psychological distress and *could change their future behavior* in seeking medical
14 treatment” (emphasis added)); *Radich v. Guerrero*, 729 F. App’x 623, 624 (9th Cir. 2018) (organization
15 did not sustain injury in fact based on claim that order would require it to “install metal detectors in
16 schools or hire security guards” as a precaution, when it was under no legal obligation to do so).

17 Here, the members’ anticipatory changes in food consumption or in recreation are not fairly
18 traceable to a certainly impending threat posed by Experior. They are instead attributable primarily to
19 the members’ own choices and, to a lesser extent, to beta-agonists in general, or the actions of third-party
20 feedlot operators. Accordingly, they do not establish standing.

21 **III. The Amended Complaint Fails To Allege That A Favorable Decision Would Redress**
22 **Plaintiffs’ Asserted Harms.**

23 Based on alleged violations of the FDCA, NEPA, and the APA, Plaintiffs seek declaratory relief,
24 vacatur of Experior’s approval, and an injunction barring Experior’s use. (Am. Compl. at 38.) But
25 because all of the complained-of harms are fairly traceable to sources other than Experior’s approval,
26 Plaintiffs have not shown that it is “‘likely,’ as opposed to merely ‘speculative,’ that the injury will be
27

1 ‘redressed’” by the proposed relief. *Lujan*, 504 U.S. at 561 (quoting *Simon*, 426 U.S. at 38).

2 To survive a motion to dismiss on the issue of redressability, a plaintiff “must allege facts from
3 which it reasonably could be inferred that, absent the [challenged action], there is a substantial probability
4 . . . that, if the court affords the relief requested, the asserted [injury] of [the plaintiff] will be removed.”
5 *Warth*, 422 U.S. at 504; *see also Juliana v. United States*, 947 F.3d 1159, 1170 (9th Cir. 2020) (“Redress
6 need not be guaranteed, but it must be more than ‘merely speculative.’” (quoting *M.S. v. Brown*, 902 F.3d
7 1076, 1083 (9th Cir. 2018))). This is a particularly high hurdle where the challenged action consists of
8 government regulation of third-party activities. *See Lujan*, 504 U.S. at 561–62. Even if a plaintiff can
9 show that government action caused harm, it still must establish that reversing the government action
10 would move third parties in a way that resolves the harm. *See id.*; *Levine v. Vilsack*, 587 F.3d 986, 992–
11 93, 997 (9th Cir. 2009) (remanding for dismissal an action asserting that certain poultry should be covered
12 by the Humane Methods of Slaughter Act, where plaintiffs’ redressability allegations relied upon the
13 Secretary of Agriculture’s addition of animals to the list of protected species under a separate statute, and
14 plaintiffs’ allegations that the Secretary would do so and that resulting regulations would make poultry
15 slaughter more humane were “conclusory and speculative”).

16 At the threshold, Plaintiffs have not alleged how their request for declaratory relief—standing
17 alone—would redress their grievances. Plaintiffs instead seem to rely on the other relief they requested
18 for standing purposes. *See Juliana*, 947 F.3d at 1170 (“A declaration, although undoubtedly likely to
19 benefit the plaintiffs psychologically, is unlikely by itself to remediate their alleged injuries absent further
20 court action.”).

21 But Plaintiffs fare no better in their request for vacatur of FDA’s approval of Experior and an
22 injunction against its use. They have not pled how third-party feedlots and other beta-agonists would be
23 affected by vacatur and an injunction limited to Experior. The injuries they attribute to feedlots pre-date
24 the approval of Experior (*see, e.g.*, Am. Compl. ¶¶ 103–04 (citing 2014 and 2017 examples)), or at least
25 its use on feedlots, given that Plaintiffs have not alleged that Experior is used on feedlots. And Plaintiffs
26 recognize that other beta-agonists are already on the market (including ractopamine, *see id.* ¶¶ 73–74,
27 139), but fail to allege that withdrawal of Experior will have any impact on the availability or use of these
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1 other drugs. The Amended Complaint contains no allegations that if Experior’s approval is withdrawn,
2 injuries induced by feedlots or other beta-agonists would disappear.

3 Similarly, Plaintiffs offer nothing to suggest that, upon withdrawal of Experior’s approval,
4 independent third parties, such as feedlot operators, would change their current practices to remedy
5 alleged harms that pre-date Experior’s introduction to the market. And any precautions previously taken
6 by Plaintiffs’ members to address harms induced by feedlots and other beta-agonists would still apply.
7 *Cf. Clapper*, 568 U.S. at 417 (“[E]ven before [the challenged statute] was enacted, [respondents] had a
8 similar incentive to engage in many of the countermeasures that they are now taking.”). Nor would any
9 members’ self-inflicted “harms” in anticipation of Experior specifically be redressed by vacatur of its
10 approval.

11 For these reasons, Plaintiffs cannot plausibly claim that withdrawal of Experior’s approval will
12 provide redress for the harms they identify.¹¹ Any allegations to the contrary need not be accepted at
13 face value, because this Court’s obligation “to take a plaintiff at its word at [the motion to dismiss] stage
14 in connection with Article III standing issues is primarily directed at the injury in fact and causation
15 issues, *not redressability*.” *Levine*, 587 F.3d at 996–97 (emphasis added). All of Plaintiffs’ claims should
16 therefore be dismissed for failure to establish the third prong of Article III standing. *See Allen v. Wright*,
17 468 U.S. 737, 758 (1984) (holding parents lacked standing to challenge IRS regulations granting tax
18 exemption to racially discriminatory schools because “it is entirely speculative” whether withdrawing the
19 exemption “would have a significant impact on the racial composition of the public schools”), *abrogated*
20 *on other grounds by Lexmark Int’l Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014); *Juliana*,
21 947 F.3d at 1164, 1170–71 (dismissing on redressability grounds based in part on recognition that
22 enjoining the government’s challenged environmental actions would not “suffice to stop catastrophic
23

24 ¹¹ Plaintiffs also briefly claim that a proper FDA review of Experior, or a Court-ordered vacatur of its
25 prior action, would facilitate redress by “providing them with accurate data on the risks that Experior
26 poses.” Am. Compl. ¶ 36. But this redress argument masks a fundamental flaw in the presumed injury:
27 Plaintiffs are not allowed to simply “reframe[] every procedural deprivation in terms of informational
28 loss.” *Wilderness Soc., Inc.*, 622 F.3d at 1260 (recognizing that some “concrete and particular” interest
must be harmed apart from the informational loss). Because Plaintiffs have not identified a concrete
interest harmed by any lack of information, that basis for redress fails.

1 climate change or even ameliorate [plaintiffs’] injuries”); *HomeAway Inc. v. City & Cty. of San Francisco*,
2 No. 14-CV-04859-JCS, 2015 WL 367121, at *13 (N.D. Cal. Jan. 27, 2015) (Spero, M.J.) (dismissing
3 relevant portion of complaint for failure to establish redressability, for “[n]either a declaration nor an
4 injunction *as to [the challenged government action]* would alter the effect of *preexisting* municipal code
5 provisions”).

6 **CONCLUSION**

7 Plaintiffs have identified a variety of alleged harms from feedlots, other beta-agonists, and the
8 actions of the industrial farming industry. Whatever the merits of those allegations, they do not help
9 Plaintiffs to establish standing in this case.

10 Neither Plaintiffs nor their members have been harmed by FDA’s approval of Experior, nor do
11 they sufficiently allege that its approval will harm them in the immediate future. Even if the Court were
12 to discern an injury in fact (it should not), that injury would stem from causes other than Experior. As
13 such, granting Plaintiffs’ requested relief—issuing declaratory judgments, vacating Experior’s approval,
14 and enjoining its use—would not redress the alleged environmental injuries to human health and welfare
15 identified in the Amended Complaint. All of the claims in the Amended Complaint should be dismissed
16 for lack of Article III standing.

17
18 DATED: October 29, 2020

Respectfully Submitted,

19 JEFFREY BOSSERT CLARK
20 Acting Assistant Attorney General

21 DANIEL J. FEITH
22 Deputy Assistant Attorney General

23 GUSTAV W. EYLER
24 Director

25 HILARY K. PERKINS
26 Assistant Director

27 /s/ Jonathan E. Amgott
28 JONATHAN E. AMGOTT
Trial Attorney
Consumer Protection Branch

1 U.S. Department of Justice
2 P.O. Box 386
3 Washington, DC 20044-0386
4 Telephone: 202-532-5025
5 Facsimile: 202-514-8742
6 E-mail: Jonathan.E.Amgott@usdoj.gov
7 D.C. Bar No. 1031947

8 PAUL E. SALAMANCA
9 Deputy Assistant Attorney General
10 United States Department of Justice
11 Environment and Natural Resources Div.

12 /s/ Michael S. Sawyer
13 MICHAEL S. SAWYER
14 Trial Attorney
15 Natural Resources Section
16 P.O. Box 7611 Washington, D.C. 20044
17 202-514-5273 || 202-305-0506 (fax)
18 Michael.Sawyer@usdoj.gov

19 *Attorneys for Federal Defendants*

20 Of Counsel:

21 ROBERT P. CHARROW
22 General Counsel

23 STACY CLINE AMIN
24 Chief Counsel
25 Food and Drug Administration
26 Deputy General Counsel
27 Department of Health and Human Services

28 ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

MICHAEL HELBING
Associate Chief Counsel for Enforcement
United States Food and Drug Administration
Office of the Chief Counsel
White Oak 31, Room 4421A
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Telephone: (240) 402-6165

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ATTESTATION

Pursuant to Local Rule 5-1(i)(3), as the ECF user whose user ID and password are being used in the electronic filing of this document, I attest that I file with the concurrence of the other signatory of this document.

/s/ Jonathan E. Amgott
Jonathan E. Amgott

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ANIMAL LEGAL DEFENSE FUND,
FOOD & WATER WATCH, and FOOD
ANIMAL CONCERNS TRUST,

Plaintiffs,

v.

No. 3:20-CV-03703-RS

ALEX AZAR, Secretary of the United States
Department of Health and Human Services;
STEPHEN HAHN, Commissioner of the
United States Food and Drug Administration;
and UNITED STATES FOOD AND DRUG
ADMINISTRATION,

Defendants,

and

ELANCO ANIMAL HEALTH,

Intervenor-Defendant.

[PROPOSED] ORDER

Having considered Defendants' Motion to Dismiss, and any opposition, reply, and oral argument presented, IT IS HEREBY ORDERED that this action is DISMISSED.

IT IS SO ORDERED.

Dated: _____

RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE