

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
9 Facsimile: 202-514-8742
10 E-mail: Jonathan.E.Amgott@usdoj.gov
11 Attorneys for Federal Defendants
ALEX AZAR, STEPHEN HAHN, and
12 U.S. FOOD AND DRUG ADMIN.

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' REPLY BRIEF IN
SUPPORT OF THEIR MOTION TO DISMISS
THE FIRST AMENDED COMPLAINT**

Hearing Date: Thursday, January 14, 2021

Hearing Time: 1:30 p.m.

Courtroom: 3

Hon. Richard Seeborg

TABLE OF CONTENTS

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

STATEMENT OF ISSUES TO BE DECIDED 1

BACKGROUND 1

ARGUMENT 1

I. Plaintiffs Remain Unable To Demonstrate Injury In Fact And Therefore Lack Standing 2

 A. Plaintiffs’ Members Do Not Face Actual Or Imminent Harm 2

 B. Plaintiffs Also Fail To Establish That Exposure To An Enhanced Risk Alone Is Sufficient To Qualify As Injury In Fact..... 5

 C. Plaintiffs’ Members Lack A Concrete Interest Necessary For Procedural Injury 9

II. Plaintiffs Also Fail To Demonstrate Standing Because Their Members’ Harms, If Any, Are Fairly Traceable To Causes Other Than FDA’s Approval Of Experior 11

III. Plaintiffs Likewise Fail To Show That A Favorable Decision Would Redress Any Harms Sustained By Their Members 14

CONCLUSION..... 15

TABLE OF AUTHORITIES

CASES

1

2

3 *Ashley Creek Phosphate Co. v. Norton,*

4 420 F.3d 934 (9th Cir. 2005) 9

5 *Ashley Creek Props., L.L.C. v. Timchak,*

6 649 F. Supp. 2d 1171 (D. Idaho 2009),

7 *aff’d sub nom. Ashley Creek Props., L.L.C. v. Larson,*

8 403 F. App’x 273 (9th Cir. 2010) 9

9 *Baur v. Veneman,*

10 352 F.3d 625 (2d Cir. 2003) 5, 6, 7, 8

11 *Cantrell v. City of Long Beach,*

12 241 F.3d 674 (9th Cir. 2001) 9, 11

13 *Cent. Delta Water Agency v. United States,*

14 306 F.3d 938 (9th Cir. 2002) 5

15 *Citizens for Better Forestry v. USDA,*

16 341 F.3d 961 (9th Cir. 2003) 10

17 *Clapper v. Amnesty Int’l USA,*

18 568 U.S. 398 (2013) 3, *passim*

19 *Cottonwood Env’t Law Ctr. v. U.S. Forest Serv.,*

20 789 F.3d 1075 (9th Cir. 2015) 11

21 *Ctr. for Biological Diversity v. EPA,*

22 861 F.3d 174 (D.C. Cir. 2017) 11, 12

23 *Ctr. for Env’t Health v. Perdue,*

24 No. 18-cv-01763-RS, 2018 WL 9662437 (N.D. Cal. Aug. 21, 2018) 7, 13

25 *Ctr. for Food Safety v. Price,*

26 No. 17-CV-3833 (VSB), 2018 WL 4356730 (S.D.N.Y. Sept. 12, 2018) 13, 14

27 *Env’t Def. Fund v. EPA,*

28 922 F.3d 446 (D.C. Cir. 2019) 11

Fla. Audubon Soc’y v. Bentsen,

94 F.3d 658 (D.C. Cir. 1996) 5

Herrington v. Johnson & Johnson Consumer Cos.

No. C 09-1597 CW, 2010 WL 3448531 (N.D. Cal. Sept. 1, 2010) 8

Hunt v. Wash. State Apple Advert. Comm’n,

432 U.S. 333 (1977) 2

1 *In re Apple iPhone Antitrust Litig.*,
 No. 11-CV-06714-YGR, 2013 WL 4425720 (N.D. Cal. Aug. 15, 2013) 1

2

3 *Lujan v. Defs. of Wildlife*,
 504 U.S. 555 (1992) 9, 14

4 *Massachusetts v. EPA*,
 549 U.S. 497 (2007) 14

5

6 *McGee v. S-L Snacks Nat’l*,
 --- F.3d ---, 2020 WL 7087008 (9th Cir. Dec. 4, 2020) 8

7

8 *Mendia v. Garcia*,
 768 F.3d 1009 (9th Cir. 2014) 12

9

10 *Mendoza v. Perez*,
 754 F.3d 1002 (D.C. Cir. 2014) 13, 15

11

12 *Nat. Res. Def. Council v. U.S. Consumer Prod. Safety Comm’n*,
 No. 16-cv-9401 (PKC), 2017 WL 3738464 (S.D.N.Y. Aug. 18, 2017) 13

13

14 *Nat. Res. Def. Council, Inc. v. U.S. FDA*,
 710 F.3d 71 (2d Cir. 2013), *as amended* (Mar. 21, 2013) 6, 7, 13

15

16 *Nuclear Info. & Res. Serv. v. Nuclear Regul. Comm’n*,
 457 F.3d 941 (9th Cir. 2006) 9, 10

17

18 *San Diego Cnty. Gun Rights Comm. v. Reno*,
 98 F.3d 1121 (9th Cir. 1996) 12

19

20 *San Luis & Delta-Mendota Water Auth. v. Haugrud*,
 848 F.3d 1216 (9th Cir. 2017) 9

21

22 *Schmier v. U.S. Court of Appeals for the Ninth Circuit*,
 279 F.3d 817 (9th Cir. 2002) 2

23

24 *Sierra Club v. Trump*,
 977 F.3d 853 (9th Cir. 2020) 12, 14

25

26 *Spokeo, Inc. v. Robins*,
 136 S. Ct. 1540 (2016) 7

27

28 *Stauber v. Shalala*,
 895 F. Supp. 1178 (W.D. Wis. 1995) 7

Sugar Cane Growers Coop. of Fla. v. Veneman,
 289 F.3d 89 (D.C. Cir. 2002) 11

Summers v. Earth Island Inst.,
 555 U.S. 488 (2009) 7, 9, 10, 15

1 *Susan B. Anthony List v. Driehaus*,
2 573 U.S. 149 (2014) 5, 7

3 *Tozzi v. U.S. Dep’t of Health & Human Servs.*,
4 271 F.3d 301 (D.C. Cir. 2001) 12

5 *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State*,
6 454 U.S. 464 (1982) 3

7 *Warth v. Seldin*,
8 422 U.S. 490 (1975) 1

9 *Wilderness Soc’y, Inc. v. Rey*,
10 622 F.3d 1251 (9th Cir. 2010) 10

11 *Zeneca, Inc. v. Shalala*,
12 213 F.3d 161 (4th Cir. 2000) 4

13 **Other**

14 Fed. R. Civ. P. 12(b)(1) 1

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.