FILED

MAY 3 2021

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

CENTER FOR FOOD SAFETY, Petitioner, v. U.S. FOOD & DRUG ADMINISTRATION; JANET WOODCOCK, in her official capacity as Acting Commissioner,[**] Respondents, IMPOSSIBLE FOODS INC., Intervenor.	No. 20-70747 FDA No. FDA- 2018-C-4464 MEMORANDUM[*]

On Petition for Review of an Order of the
Food & Drug Administration

Argued and Submitted April 14, 2021
Seattle, Washington

[*] This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

[**] Pursuant to Federal Rule of Appellate Procedure 43(c)(2), Janet Woodcock is automatically substituted as the Acting Commissioner of the U.S. Food and Drug Administration.

Before: O'SCANNLAIN, GRABER, and CALLAHAN, Circuit Judges.
Dissent by Judge O'SCANNLAIN

Petitioner Center for Food Safety ("CFS") seeks review of Respondent United States Food and Drug Administration's ("FDA") denial of its objections to the agency's approval of soy leghemoglobin as a color additive for use in Intervenor Impossible Foods Inc.'s ("Impossible") products. We have jurisdiction under 21 U.S.C. § 371(f)(1).[1] Reviewing the FDA's decision for substantial evidence, Id. § 371(f)(3), we deny CFS's petition.

1. The FDA applied the correct standard for evaluating the safety of soy leghemoglobin as a color additive; it did not violate the Federal Food, Drug, and Cosmetic Act. The agency stated that federal color additive regulations "define 'safe' to mean that there is convincing evidence that establishes with reasonable certainty that no harm will result" from soy leghemoglobin's use. Listing of Color Additives Exempt from Certification; Soy Leghemoglobin, 84 Fed. Reg. 37573, 37574 (Aug. 1, 2019) (citing 21 C.F.R. § 70.3(i)). It is clear from reading the

[1] At a minimum, Janet Maker's declaration establishes a sufficient injury in fact to satisfy Article III. Maker consumed Impossible's product, stopped consuming it because of a health condition that the product could affect adversely, and would consume the product again were she adequately assured of its safety. By discounting Maker's reliance on evidence of adverse effect, the dissent conflates the standing inquiry with the merits. See Citizens for Better Forestry v. U.S. Dep't of Agric., 341 F.3d 961, 971–72 (9th Cir. 2003); Ecological Rights Found. v. Pac. Lumber Co., 230 F.3d 1141, 1151 (9th Cir. 2000).

FDA's decision as a whole that the FDA performed the appropriate analysis. Isolated instances in which the FDA phrased the safety standard differently do not establish that the agency used the wrong standard.

2. Substantial evidence supports the FDA's decision to approve soy leghemoglobin as a color additive. See Nat. Res. Def. Council v. U.S. EPA, 735 F.3d 873, 877 (9th Cir. 2013) (stating standard). CFS's contention that one study Impossible commissioned did not conform to the FDA's "Redbook" is unavailing; the agency's recommendations regarding the design of toxicology studies are non-binding. See Nat'l Family Farm Coal. v. U.S. EPA, 966 F.3d 893, 920 (9th Cir. 2020) (explaining that the agency's reliance on studies that did not precisely track non-binding guidelines did not undermine its decision). The FDA provided adequate justification for why it viewed that study as reliable despite its durational and size deviations from the Redbook guidelines.

Additionally, the FDA did not err by relying on the study, which Impossible had submitted with its prior notification that soy leghemoglobin is generally recognized as safe for use as a food additive. The agency performed internal scientific assessments and reviewed other evidence of safety, beyond its evaluation of the study at issue. The agency's expertise and experience in reviewing studies

are entitled to deference. N. Plains Res. Council, Inc. v. Surface Transp. Bd., 668 F.3d 1067, 1075 (9th Cir. 2011).

PETITION DENIED.

Center for Food Safety v. U.S. Food & Drug Administration, No. 20-70747

O'SCANNLAIN, J., dissenting:

I respectfully dissent because I believe that we lack jurisdiction to entertain this petition challenging the FDA's approval of soy leghemoglobin for use as a color additive in beef analogue products. I would dismiss the petition for review on the basis that the Center for Food Safety ("CFS") lacks constitutional standing.

I

Whether a party has standing to sue is a "'threshold issue' concerning an 'essential and unchanging part of the case-or-controversy requirement of Article III.'" *Gonzalez v. U.S. Immigr. & Customs Enf't*, 975 F.3d 788, 802 (9th Cir. 2020) (quoting *Horne v. Flores*, 557 U.S. 433, 445 (2009)). Simply put, a federal court lacks subject matter jurisdiction over a dispute in which the petitioner lacks Article III standing. *See Cetacean Cmty. v. Bush*, 386 F.3d 1169, 1174 (9th Cir. 2004) (citing *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 101 (1998)). "'Without jurisdiction, the court cannot proceed at all in any cause; it may not assume jurisdiction for the purpose of deciding the merits of the case.'" *Carijano v. Occidental Petroleum Corp.*, 686 F.3d 1027, 1029 (9th Cir. 2012) (Kozinski, J., dissenting from denial of reh'g en banc) (quoting *Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 431 (2007)).

DOCKET ALARM

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.