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NOT FOR PUBLICATION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

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[*] 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.

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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)).

For this reason, I believe that we are constitutionally obligated to examine CFS's Article III standing before considering the merits of its petition for review. *See L.A. Cnty. Bar Ass'n v. Eu*, 979 F.2d 697, 700 (9th Cir. 1992) ("[S]tanding is a threshold question which we must resolve before proceeding to the merits."). We must not cut to the chase, so to speak, even when it may promote judicial convenience or efficiency to gloss over jurisdictional prerequisites. To do so would carry the court "beyond the bounds of authorized judicial action and thus offend[] fundamental principles of separation of powers." *Carijano*, 686 F.3d at 1030 (Kozinski, J., dissenting from denial of reh'g en banc) (quoting *Steel*, 523 U.S. at 94.). I would therefore begin by addressing CFS's standing to sue.

II

Here, CFS maintains that it has associational standing. To establish such standing, CFS must demonstrate that: (1) its members would otherwise have standing to sue in their own right; (2) the interests that it seeks to protect are germane to the organization's purpose; and (3) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977).

In turn, to satisfy the first prong of *Hunt*'s standard for associational standing, CFS must demonstrate that at least one of its members: (1) has suffered an injury in fact that is (a) concrete and particularized and (b) actual or imminent,

rather than conjectural or hypothetical; (2) the injury is fairly traceable to the FDA's challenged action; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. *See Nat. Res. Def. Council v. U.S. E.P.A.*, 735 F.3d 873, 878 (9th Cir. 2013) ("*NRDC*").

To establish the requisite injury in fact, CFS has attached declarations from four of its members. Three of them—Natasha Kaluza, M'Lisa Kelley, and Micah Thomas—state that they previously purchased and consumed Impossible Foods' beef analogue products containing soy leghemoglobin, but that they ceased to do so after learning of alleged deficiencies in the FDA's review of the potential health effects of soy leghemoglobin. The fourth CFS member, Janet Maker, also states that she purchased and consumed Impossible Foods' beef analogue products, and that she is similarly concerned as to whether they are safe to eat, particularly considering that she is in remission from breast cancer. Nevertheless, Maker states that she will likely consume Impossible Foods' beef analogue products again in the future.

CFS maintains that its members have suffered two kinds of injury. First, a health injury, in the form of an increased risk of adverse health effects, such as inflammatory disease and cancer, resulting from exposure to beef analogue products containing soy leghemoglobin. Second, an economic injury, in the form

of costs incurred in avoiding beef analogue products out of concern for such adverse health effects. I consider the sufficiency of each asserted injury in turn.

A

To sustain CFS's claim for prospective relief as it relates to the asserted health injury, such injury must be one that is likely to develop because of either: (1) past—and therefore irreversible—exposure to beef analogue products containing soy leghemoglobin; or (2) inevitable future exposure to such products. CFS has failed to make an adequate showing with respect to either mode of health injury.

1

An increased risk of health injury from past exposure to an allegedly dangerous food product is a "probabilistic harm," and therefore constitutes an injury in fact only where there exists a "credible threat that the probabilistic harm will materialize." *NRDC*, 735 F.3d at 878. Previously, we have relied upon government confirmation of petitioner allegations in determining whether a credible threat of harm exists. *See, e.g.*, *Cent. Delta Water Agency v. United States*, 306 F.3d 938, 950 (9th Cir. 2002) (finding credible threat of harm from water management plan where agency's own modeling showed environmental violation); *accord Baur v. Veneman*, 352 F.3d 625, 637 (2d Cir. 2003) (finding credible threat of harm from downed cattle where government studies and

statements confirmed such cattle were especially susceptible to disease). Government confirmation provides a firm factual basis for a petitioner's health concerns, which suggests that the claimed injury is not merely speculative.

But here, there is no such confirmation of CFS's members' "concern" regarding potential adverse health effects of soy leghemoglobin. The only evidence—of any kind—substantiating a health concern is a blog post on a third-party website, referenced in Maker's declaration, which criticizes the FDA's reliance upon a rat-feeding study insofar as that study allegedly revealed adverse effects in rats exposed to soy leghemoglobin.

The FDA determined, however, that any observed effects from the study were not toxicologically relevant, because they were "within historical ranges of control values, did not show a dose-response relationship, and did not occur in both sexes." Moreover, there is nothing elsewhere in the record to suggest that the FDA—or anyone else, for that matter—has credited any of the health concerns articulated by Maker or CFS's other members. Indeed, Maker's stated intent to continue eating beef analogue products, regardless of whether the FDA orders additional studies, would seem further to undermine the claim that adverse effects are likely to materialize as a result of exposure to such products. Accordingly, CFS has not demonstrated a "credible threat" that its members' past exposure to soy leghemoglobin will result in a health injury. *Cf*. *NRDC*, 735 F.3d at 878.

With respect to *future* exposure to the alleged risk of health injury, if a petitioner can avoid such exposure altogether, there can be no credible threat of harm. *See Coal. for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1280 (D.C. Cir. 2012) (Kavanaugh, J.) (holding that association lacked standing to challenge FDA's approval of thimerosal for use in vaccines because association's members could access all vaccines in thimerosal-free versions).

To be sure, where exposure to a verified risk of health injury cannot reasonably be avoided, we have at times recognized an adequate injury in fact. In *NRDC*, for example, we concluded that an association had standing to challenge the EPA's decision to register a pesticide for use with manufactured textiles. *See* 735 F.3d at 878. The association's members demonstrated that textiles were ubiquitous, and that there was little or no public information as to which chemicals had been used to treat them, making it impossible for the members to reduce their, or their children's, exposure to the allegedly dangerous pesticide. *Id.* Together with evidence substantiating the petitioner's concern regarding the pesticide's effects, we determined that a credible threat of harm existed. *Id.*

Here, by contrast, beef analogue products containing soy leghemoglobin are clearly identifiable and far from ubiquitous, such that CFS's members can readily avoid exposure to them. They need only consult the product label and then decline

to purchase items that contain the additive. Accordingly, there is no credible threat that CFS's members will suffer a health injury from further exposure to beef analogues. Any such exposure would be self-inflicted, and thus inadequate to support Article III standing. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 416 (2013).

B

Finally, CFS also maintains that, even if the health injuries allegedly resulting from soy leghemoglobin are avoidable, the cost of avoiding such exposure constitutes an independent economic injury. However, there is no evidence in the declarations, or anywhere else in the record, suggesting that avoiding beef analogues requires CFS's members to incur any quantifiable avoidance costs. Any avoidance costs here are properly characterized as trivial or *de minimis*, and are therefore not cognizable as an injury in fact. *Cf. Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 155 (2010) (recognizing adequate injury in fact where farmers specified substantial increased administrative costs incurred in avoiding contamination from genetically engineered seeds).

III

Based on the reasoning articulated above, I would conclude that CFS has failed to demonstrate an injury in fact sufficient to establish Article III standing.

Accordingly, I would dismiss the petition for review for lack of jurisdiction, and without consideration of any of CFS's arguments on the merits.