

FOR PUBLICATION

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

MICHELLE PRZYBOCKI; KETAN
VAKIL; GOURMEND FOODS,
LLC,

Plaintiffs - Appellants,

v.

UNITED STATES DEPARTMENT
OF AGRICULTURE; BROOKE L.
ROLLINS; UNITED STATES
DEPARTMENT OF
AGRICULTURE FOOD SAFETY
AND INSPECTION SERVICE;
TREY FORSYTH; UNITED
STATES FOOD AND DRUG
ADMINISTRATION; KYLE
DIAMANTAS, Acting
Commissioner, U.S. Food and Drug
Administration,

*Defendants - Appellees.**

No. 24-7174

D.C. No.
2:23-cv-00455-
ART-DJA

OPINION

* As required by Federal Rule of Appellate Procedure 43(c)(2), Brooke L. Rollins, Trey Forsyth, and Kyle Diamantas are automatically substituted for Thomas J. Vilsack, Sandra Eskin, and Robert Califf, respectively.

Appeal from the United States District Court
for the District of Nevada
Anne R. Traum, District Judge, Presiding

Argued and Submitted November 14, 2025
San Francisco, California

Filed August 3, 2026

Before: Michelle T. Friedland and Jennifer Sung, Circuit
Judges, and P. Casey Pitts, District Judge.**

Opinion by Judge P. Casey Pitts

SUMMARY***

Standing / First Amendment

In an action brought by Michelle Przybocki, Ketan Vakil and his food company, Gourmend LLC, challenging United States Department of Agriculture and Food and Drug Administration statutes and regulations governing the inclusion of information regarding sugars known as “FODMAPs” on product labels, the panel (1) reversed the district court’s dismissal for lack of standing of plaintiffs’

** The Honorable P. Casey Pitts, United States District Judge for the Northern District of California, sitting by designation.

*** This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

claims against the FDA and Przybocki's claims against the USDA; and (2) in a separate memorandum disposition, affirmed the district court's dismissal for failure to exhaust administrative remedies of Vakil and Gourmend's claims against the USDA.

Przybocki, who struggles to digest FODMAPs and wants FODMAP levels to be included on food labels, and Vakil, who wishes to sell foods that include FODMAP levels on their labels through his company Gourmend, alleged that federal law prohibiting food companies from including FODMAP information on product labels violates their First Amendment rights to speak and to receive information.

The panel held that Przybocki adequately pleaded standing to sue as a listener based on her needs as a consumer of low-FODMAP foods and her allegation that food producers, including but not limited to Gourmend, would be reasonably likely to include FODMAP-related information on food labels in the absence of the challenged FDA and USDA regulations.

The panel also held that Vakil and Gourmend sufficiently pleaded Article III standing as speakers to pursue a pre-enforcement challenge against the FDA based on the government's threatened enforcement of the applicable food-labeling laws.

In a separate memorandum disposition, the panel affirmed the district court's dismissal of Vakil and Gourmend's claims against the USDA for failure to exhaust available administrative remedies.

COUNSEL

Justin M. Pearson (argued), Institute for Justice, Miami, Florida; Paul M. Sherman and Elizabeth L. Sanz, Institute for Justice, Arlington, Virginia; Joel Z. Schwarz and Matthew T. Dushoff, Saltzman Mungan Dushoff, Las Vegas, Nevada; for Plaintiffs-Appellants.

Laura E. Myron (argued) and Gerard Sinzdak, Attorneys, Appellate Staff, Civil Division; Yaakov M. Roth, Acting Assistant Attorney General; United States Department of Justice, Washington, D.C.; Nicole Leibow, Assistant United States Attorney; Sigal Chattah, United States Attorney; Office of the United States Attorney, United States Department of Justice, Las Vegas, Nevada; for Defendants-Appellees.

OPINION

PITTS, District Judge:

Millions of people suffer from digestive issues, including the inability to digest sugars called “FODMAPs.”¹ Plaintiff Michelle Przybocki has this condition and wants FODMAP levels to be included on the labels of the food she buys so that she can avoid foods high in FODMAPs and instead choose low-FODMAP foods. Plaintiff Ketan Vakil also avoids FODMAPs on the advice of his doctor. Through

¹ “FODMAPs” is an acronym for fermentable oligosaccharides, disaccharides, monosaccharides, and polyols.

his company, plaintiff Gourmend Foods, LLC, he wishes to sell foods that include FODMAP levels on their labels.

According to the plaintiffs, federal law prohibits food companies like Gourmend from including FODMAP information on their products' labels. Indeed, the United States Department of Agriculture's Food Safety and Inspection Service (FSIS) rejected Gourmend's proposed beef broth label precisely because it included the broth's FODMAP levels. Soon thereafter, Przybocki, Vakil, and Gourmend sued the Food and Drug Administration and the USDA, alleging violations of their First Amendment rights to speak and to receive information. The district court dismissed the suit, concluding that the plaintiffs failed to plead Article III standing and failed to exhaust their administrative remedies.

We reverse in part. Przybocki adequately pleaded standing to sue as a listener based on her needs as a consumer of low-FODMAP foods and her allegation that food producers, including but not limited to Gourmend, would be reasonably likely to include FODMAP-related information on food labels in the absence of the challenged FDA and USDA regulations. Vakil and Gourmend also sufficiently pleaded Article III standing to pursue claims against the FDA based on the government's threatened enforcement of the applicable food-labeling laws. For the reasons set forth in a separate memorandum disposition filed simultaneously herewith, however, we affirm the district court's dismissal of Vakil and Gourmend's claims against the USDA for failure to exhaust available administrative remedies.

REGULATORY FRAMEWORK

Two different federal agencies, the FDA and the USDA (with the assistance of its subagency the FSIS), administer

and enforce federal food-labeling laws. Under the Food, Drug, and Cosmetic Act, the FDA regulates false or misleading statements on most nonmeat food labels. *See* 21 U.S.C. §§ 321, 343. The applicable statutes and regulations mandate disclosures regarding certain nutrients, such as the number of calories and the amount of protein and carbohydrates. *See* 21 U.S.C. § 343(q); 21 C.F.R. §§ 101.9(c), 101.13(b). For example, a food label must disclose the “[t]otal fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein” in that food. 21 U.S.C. § 343(q)(1)(D). Federal regulations also permit companies to make certain “nutrient content claims” on food labels. 21 C.F.R. § 101.13. A nutrient content claim describes the level of a specific nutrient in a food, such as “low sodium.” *Id.* But a food company may not make nutrient content claims other than those specifically defined and permitted by statute or FDA regulations. *See id.* § 101.13(b); 21 C.F.R. pt. 105 (establishing regulations for “special dietary use” foods without including FODMAPs); 21 C.F.R. pt. 107 (establishing regulations for infant formula labels); 21 C.F.R. §§ 101.54–69 (establishing additional regulations for “nutrient content claims”). The regulations define nutrient content claims for various nutrients, including “fat,” “sugar” and “cholesterol,” but they do not define nutrient content claims for FODMAPs. 21 C.F.R. §§ 101.54–67. If an entity wishes to make a nutrient content claim that is not already defined by the regulations, the entity may petition the FDA for approval of the new nutrient-content claim. *Id.* § 101.69.

The USDA, rather than the FDA, regulates the labeling of certain other meat, poultry, and egg products. *See* 21 U.S.C. § 602; *Formal Agreement Between USDA and FDA Relative to Cooperation and Coordination*, Food & Drug

Admin. (Jan. 30, 2018), <https://www.fda.gov/food/international-interagency-coordination/formal-agreement-between-usda-and-fda-relative-cooperation-and-coordination> [https://perma.cc/RTN6-TKDY]. As with the FDA's regulatory regime, the statutes and regulations enforced by the USDA require nutritional labeling. *See, e.g.*, 9 C.F.R. § 317.300(a) ("Nutrition labeling must be provided for all meat and meat food products intended for human consumption and offered for sale ..."); *see also id.* § 317.309(c). Also like the FDA, the USDA regulates additional nutrient-content claims, *see id.* § 317.313(a)–(b), (e), and provides an application process for those seeking to make new nutrient-content claims, *id.* § 317.369.

While product marketers do not need advance approval for products whose labels are regulated by the FDA, a meat or meat-product label subject to the USDA's jurisdiction cannot be used until the USDA, through the FSIS, has granted it approval. *See* 21 U.S.C. § 607(e); 9 C.F.R. §§ 412.1(a), 500.8. As a result, any proposed product label making "nutrient content claims" and subject to the USDA's regulatory jurisdiction must receive affirmative approval from USDA before it can be used. *See* 9 C.F.R. § 317.313(a)–(b). If the USDA rejects a labeling application, the applicant has an "opportunity for a hearing," and the USDA's decision is subject to judicial review. *See* 21 U.S.C. § 607(e); 9 C.F.R. § 500.8(c); 7 C.F.R. § 1.145(i).

FACTUAL AND PROCEDURAL BACKGROUND

Plaintiff Michelle Przybocki alleges that she is one of tens of millions of people who struggle to digest FODMAPs. Przybocki is a speech therapist in Las Vegas, Nevada, who suffers from irritable bowel syndrome so severe that she

reported “debilitating pain” every time she ate. Przybocki’s doctor told her to follow a low-FODMAP diet to manage her symptoms. To follow her doctor’s recommendation, Przybocki wants information about FODMAP levels to be displayed on the labels of the food she buys. Przybocki believes, however, that many food companies do not list information about FODMAP levels on their products out of fear that doing so would violate federal food-labeling regulations regarding nutrient content claims.

Plaintiff Ketan Vakil runs a food company, Gourmend LLC, that produces low-FODMAP foods. Like Przybocki, Vakil follows a low-FODMAP diet on the advice of his doctor. Vakil founded Gourmend in 2018 to serve the potentially millions of consumers who seek reliably low-FODMAP foods.

Gourmend sells four low-FODMAP spice blends and one low-FODMAP chicken broth. Vakil and Gourmend have worked with Monash University in Australia to obtain Monash’s low-FODMAP certification for the five offerings. The labels for the five products state that the products are low-FODMAP, are certified by Monash University as such, and are “deliciously digestible” and “gut loving.” The parties agree that all five products fall within the FDA’s regulatory jurisdiction.

Gourmend has also developed a low-FODMAP beef broth. Unlike Gourmend’s other products, that product’s labeling is regulated by the USDA. Accordingly, in July 2022, Gourmend submitted a proposed beef broth label to the USDA and the FSIS for approval. Though the FDA had not previously raised concerns about Gourmend’s spice or chicken broth labels, the FSIS told Gourmend that it had to “remove all references to digestible, gut loving, and fodmap”

from the label or its application would not be approved. FSIS Deputy Director of Labeling and Program Delivery Jeffrey Canavan told Gourmend that the USDA and the FSIS had discussed Gourmend's proposed label with the FDA, and that the FDA agreed that the label's FODMAP content claim constituted an impermissible nutrient-content claim. Gourmend then applied for approval of a label that did not include "digestible," "gut-loving," "low FODMAP," "safely delicious," "triggers," or a heart. The FSIS approved the revised label with two unrelated modifications.

After the FSIS instructed Gourmend to remove the references to FODMAP levels from its beef broth label in order to receive approval, Przybocki, Vakil, and Gourmend sued the USDA, the FSIS, the FDA, and agency officials in the U.S. District Court for the District of Nevada. They alleged that the government's actions violated Przybocki's First Amendment right to receive information and Vakil's and Gourmend's First Amendment right to speak. The plaintiffs sought a declaratory judgment that the USDA and FDA statutes and regulations governing the use of FODMAP claims on product labels violate the First Amendment as well as injunctive relief prohibiting continued enforcement of those statutes and regulations.

The district court dismissed the plaintiffs' suit on two grounds relevant here.

First, the court held that Vakil and Gourmend had failed to plead an injury in fact arising from the FDA's conduct because they were selling FODMAP-labeled products and

had not received “any warning letters or threats from the FDA.”²

Second, the court held that Przybocki had not alleged an injury in fact arising from the government’s restriction on her right to receive information. The court concluded that Przybocki failed to plead that there were other speakers willing to convey FODMAP information who would do so in the absence of the USDA and FDA regulations. And the court concluded that Przybocki had not alleged an injury arising from the chilling of Gourmend’s speech because the plaintiffs had not alleged that Gourmend sells food in any store Przybocki frequents, because Gourmend’s products except its beef broth still carry the “low-FODMAP” labels, and because Przybocki can find information about Gourmend’s beef broth on its website.

The district court granted the government’s motion to dismiss without prejudice and with leave to amend. After the plaintiffs notified the district court that they would not be filing an amended complaint, the court entered final judgment. We have jurisdiction pursuant to 28 U.S.C. § 1291.

DISCUSSION

We address two issues in this opinion. We first consider whether Przybocki adequately pleaded standing to challenge the FDA and USDA regulations as a listener allegedly denied access to speech regarding FODMAP levels. Second, we consider whether Vakil and Gourmend adequately

² The court dismissed Vakil and Gourmend’s claims against the USDA for failure to exhaust available administrative remedies. We address that issue in a separate memorandum disposition and do not address any legal questions relating thereto in this opinion.

pleaded standing as speakers sufficient to allow them to pursue a pre-enforcement challenge against the FDA.³ We address a third issue, related to lack of administrative exhaustion of Vakil and Gourmend’s claims against the USDA, in a memorandum disposition filed simultaneously herewith.

We review de novo the issues of Article III standing, ripeness, and administrative exhaustion. *See Stockton v. Brown*, 152 F.4th 1124, 1135 (9th Cir. 2025); *VHT, Inc. v. Zillow Grp., Inc.*, 69 F.4th 983, 987 (9th Cir. 2023).

I. Przybocki’s Standing as a Listener

To establish Article III standing, a plaintiff must show “(i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief.” *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380 (2024). Where, as here, a defendant raises a facial challenge to plaintiff’s standing, we “[a]ccept[] the plaintiff’s allegations as true and draw[] all reasonable inferences in the plaintiff’s favor,” then “determine[] whether the allegations are sufficient as a legal matter to invoke the court’s jurisdiction.” *Leite v. Crane Co.*, 749 F.3d 1117, 1121 (9th Cir. 2014).

Listeners generally have a First Amendment right to receive information. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 756 (1976). But

³ In light of the USDA’s rejection of Vakil and Gourmend’s low-FODMAP beef broth label, we conclude that Vakil and Gourmend have Article III standing to challenge that rejection and the underlying regulations. *See Cal. Pro-Life Council, Inc. v. Getman*, 328 F.3d 1088, 1095 (9th Cir. 2003).

“[t]o establish actual injury from a restriction of the right to receive information, there must be a speaker who is willing to convey the information.” *Johnson v. Stuart*, 702 F.2d 193, 195 (9th Cir. 1983) (citing *Va. State Bd. of Pharmacy*, 425 U.S. at 756–57). And even if there is a willing speaker, a plaintiff alleging standing as a prospective listener based on “*someone else’s* censorship” must have a “concrete, specific connection to the speaker.” *Murthy v. Missouri*, 603 U.S. 43, 75 (2024).

The Supreme Court most recently addressed the requirements for listener standing in *Murthy v. Missouri*. In that case, the plaintiffs were states and social media users suing federal agencies and officials for allegedly pressuring social media companies to censor other users’ speech. *Id.* at 49. The plaintiffs argued that they had a “right to listen” to other users who had allegedly been censored. *Id.* at 74–75. The Supreme Court rejected the plaintiffs’ theory of standing, explaining that the plaintiffs’ “startlingly broad” theory “would grant all social-media users the right to sue over *someone else’s* censorship—at least so long as they claim an interest in that person’s speech.” *Id.* at 75. Rather than accept that “boundless” theory, the Court held that listener standing exists only where the listener has “a concrete, specific connection to the speaker” and can “identif[y] any specific speakers or topics that they have been unable to hear or follow.” *Id.* The Court distinguished the *Murthy* plaintiffs, who failed to identify any censored speaker to whom they had a concrete and specific connection, from two other groups of listeners whom the Court had previously found to have listener standing: professors challenging the denial of their academic invitee’s visa, and prescription-drug consumers challenging rules prohibiting pharmacists from advertising prescription drug

prices. *Id.* (discussing *Kleindienst v. Mandel*, 408 U.S. 753, 762 (1972), and *Va. State Bd. of Pharmacy*, 425 U.S. at 756–57).

We applied this rule in *Stockton v. Brown*, which considered whether certain doctors and individual citizens had standing to challenge state medical commission investigations and charges targeting physicians who were allegedly spreading COVID-19 misinformation. 152 F.4th at 1132. We held that plaintiff John Stockton, a podcast host interested in COVID-19 (as well as the NBA’s all-time assists leader), did not suffer an injury-in-fact as a listener where he pleaded only that he had “an avid interest in, and affection for,” one of the doctors’ speech, and did not plead that he “was prevented from” having the doctor on his podcast because of the state proceedings. *Id.* at 1134, 1146. We explained that Stockton and other plaintiffs who described themselves as “consumers of information” were unlike the prescription drug consumers in *Virginia State Board of Pharmacy* because that decision “h[eld] only that consumers of a product can challenge restrictions on the dissemination of information about that product.” *Id.* at 1148 (emphasis added). Nor were the plaintiffs similar to the professors in *Mandel*, who challenged the government’s refusal to allow their invited speaker to enter the United States. The professors had “specifically invited the third-party speaker to conferences for the purpose of making speeches and debating,” so they plainly had a “concrete connection” to the speaker. *Id.* at 1147. We further explained that Stockton’s theory of standing “would seemingly give any listener who has an interest in a speaker’s work standing to challenge laws that purportedly restrict the speaker’s speech,” and concluded that this was the kind of “startlingly

broad” theory of standing that had been rejected in *Murthy*. *Id.* at 1146.

Applying the principles set forth in *Murthy* and *Stockton*, we conclude that Przybocki pleaded a sufficiently “concrete [and] specific connection” to identified speakers who would like to include FODMAP-related claims on their products’ labels but refrain from doing so as a result of the challenged USDA and FDA regulations. *Murthy*, 603 U.S. at 75. Unlike the plaintiffs in *Stockton* who expressed a general interest in “hear[ing] information about COVID-19,” Przybocki does not have merely an “avid interest in, and affection for” FODMAP labeling. 152 F.4th at 1145–46. Instead, she is a prospective consumer who must identify foods’ FODMAP levels in order to plan a diet consistent with her doctor’s recommendation. Like the drug consumers in *Virginia State Board of Pharmacy*, she is a “consumer[] of a product ... challeng[ing] restrictions on the dissemination of information about that product.” *Id.* at 1148. Przybocki also identifies Vakil and Gourmend as willing speakers. According to the complaint, Vakil and Gourmend would like to sell products labeled as low-FODMAP, but they currently refrain from labeling Gourmend’s beef broth as low-FODMAP and are not developing new products with low-FODMAP labels due to the USDA and FDA regulations. In addition to those speakers, Przybocki alleges that other food companies would include FODMAP-related claims on their labels but for the challenged USDA and FDA regulations.

As to Gourmend, it is undisputed that Vakil has wanted to expand the company’s product offerings to include a low-FODMAP-labeled beef broth since 2022. Vakil and Gourmend submitted the proposed label to the FSIS, which required Vakil and Gourmend to “remove all references to digestible, gut loving, and fodmap.” As a result, Gourmend

used a beef-broth label that did not disclose the low-FODMAP information Vakil wanted, and Przybocki is unable to purchase a Gourmend beef broth that includes information about its FODMAP levels on the label. The plaintiffs also allege that Vakil and Gourmend “intend to sell additional low-FODMAP products with this labeling information, but the [USDA and FDA] [b]an has delayed them from doing so.” Because of these limitations on Gourmend’s labeling, Przybocki has been denied access to specific labeling information of significant and concrete interest to her.

The government argues that any restrictions on Gourmend’s labels do not harm Przybocki’s interests as a listener because “Gourmend is already speaking to” Przybocki through its website, which labels Gourmend’s beef broth as “low FODMAP.” But that argument ignores that the plaintiffs’ challenge involves more than just the beef broth label. According to the complaint, Gourmend would like to expand and sell new products with low-FODMAP labels but development is delayed or prevented because of the regulations. Thus, whether or not Gourmend is already speaking to Przybocki about the beef broth via its website, Przybocki is injured by the regulations because they are causing Gourmend to refrain from developing and speaking about new products.

Moreover, Przybocki’s injury as a listener is not alleviated by the fact that Gourmend could provide FODMAP information on its website about those products. Other than in the context of content-neutral regulations of the time, place, or manner of speech, we generally will not consider restrictions on speech to be permissible simply because other means of communicating that information are available. Indeed, in *Virginia State Board of Pharmacy*, the

state had stipulated that the challenged statute “d[id] not prohibit anyone from receiving [prescription drug pricing] information either in person or by phone” and that it “forb[ade] ‘only publish(ing), advertis(ing), or promot(ing)’ prescription drugs.” 425 U.S. at 782 (Rehnquist, J., dissenting); *see also id.* at 750 & n.2. Nonetheless, the Supreme Court concluded that the consumers challenging the state law had standing based on their right to receive information. *See id.* at 781–82 (Rehnquist, J., dissenting). Just as the plaintiffs in *Virginia State Board of Pharmacy* had standing despite their access to the pricing information through other channels, the fact that Przybocki can learn about the FODMAP levels of Gourmend’s products through Gourmend’s website does not remedy the First Amendment injury resulting from the government’s restriction of the products’ labeling. Indeed, Przybocki’s injury may well be more substantial than that of the consumers in *Virginia State Board of Pharmacy*. Although a prescription drug consumer’s interest in pricing information likely recedes once a purchase has been made, consumers of food products often have a continuing interest in the nutritional information that is provided on the products’ labels, given that their use of the products may occur long after the time of purchase.

In addition to alleging that Vakil and Gourmend are willing speakers, Przybocki also plausibly alleges that there are other food companies that would like to label their products with FODMAP levels but refrain from doing so due to the challenged regulations. The government nonetheless argues that Przybocki’s allegation regarding other food companies is “too ‘conjectural or hypothetical’ to establish injury in fact” because it is contingent on food producers choosing to provide more FODMAP information on their labels in the absence of the challenged regulations. *See Lujan*

v. Defs. of Wildlife, 504 U.S. 555, 560 (1992). In the government’s view, there is no guarantee that other food sellers would begin labeling their products as low-FODMAP absent the challenged regulations, so Przybocki has not shown that setting aside those regulations would redress her injury.

The government is certainly correct that “when the plaintiff is not [her]self the object of the government action or inaction [s]he challenges” and the government is instead regulating third parties, “standing is not precluded, but it is ordinarily substantially more difficult to establish.” *Id.* at 562 (citation modified). Plaintiffs generally must show that “third parties will likely react to the government regulation (or judicial relief) in predictable ways that will likely cause (or redress) the plaintiff’s injury.” *Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 112 (2025) (citation modified). But making such a showing does not require declarations from expert economists or “directly regulated third parties.” *Id.* at 120. Instead, the plaintiff “must simply ‘show a predictable chain of events’ that would likely result from judicial relief and redress [their] injury.” *Id.* at 121 (quoting *All. for Hippocratic Med.*, 602 U.S. at 385). In evaluating whether such circumstances exist, courts may consider “commonsense economic realities,” especially “[w]hen third party behavior is predictable.” *Id.* at 116, 121. For example, “[w]hen redress for a plaintiff’s injury depends on a third party’s independent action and the third party stands to profit by doing as the plaintiff hopes,” we may conclude that “the third party’s ‘pecuniary interests’ and the basic dynamic of ‘naked capitalism’ are enough to satisfy the redressability requirement.” *Teton Historic Aviation Found. v. U.S. Dep’t of Def.*, 785 F.3d 719, 728 (D.C. Cir. 2015) (quoting *Abigail*

All. for Better Access to Developmental Drugs v. Eschenbach, 469 F.3d 129, 135 (D.C. Cir. 2006)).

Given the prevalence of FODMAP-related digestive disorders today, one can plausibly infer that consumers, perhaps numbering in the tens of millions, want food labels to contain information about FODMAP levels. And given this consumer demand, the plaintiffs plausibly allege that food sellers “want to convey [] low-FODMAP information to Michelle [Przybocki] and other customers” because those food sellers would “stand[] to profit” by doing so. *Id.* at 728. We can also reasonably infer that food producers are not currently labeling their products with FODMAP information because they understand the regulations to prohibit such labels. On the basis of these allegations, the plaintiffs plausibly alleged that there are speakers other than Gourmend who are willing to convey FODMAP information to Przybocki and would do so in the absence of the regulations, and that she has a sufficiently close connection to those speakers to establish her Article III listener standing. *Stuart*, 702 F.2d at 195.

In sum, Przybocki has alleged facts from which we can infer the existence of speakers, including Gourmend and other food companies, who would include FODMAP-related information on their labels in the absence of the challenged regulations, and that Przybocki has a concrete and specific connection to those speakers. Przybocki therefore adequately pleaded Article III standing to challenge the FDA and USDA regulations at issue here.

II. Vakil and Gourmend’s Standing to Pursue Claims Against the FDA

We next consider whether Vakil and Gourmend adequately pleaded standing to sue the FDA based on the

alleged chilling of their own speech. We conclude that they did.

To establish their standing to pursue a pre-enforcement First Amendment challenge targeting the FDA's regulations, Vakil and Gourmend must plead "[1] an intention to engage in a course of conduct arguably affected with a constitutional interest, but [2] proscribed by a statute, and [3 that] there exists a credible threat of prosecution thereunder." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)). First Amendment pre-enforcement lawsuits "present unique standing considerations such that the inquiry tilts dramatically toward a finding of standing." *Libertarian Party of L.A. Cnty. v. Bowen*, 709 F.3d 867, 870 (9th Cir. 2013) (citation modified). As noted already, Vakil and Gourmend currently sell products regulated by the FDA that include FODMAP-related information on their labels and have not yet been the subject of any FDA enforcement action. We must therefore determine whether they nonetheless allege a "credible threat of prosecution" arising from the inclusion of FODMAP-related information in Gourmend's labels sufficient to plead Article III standing. *Susan B. Anthony List*, 573 U.S. at 159.

A mere possibility of prosecution does not establish injury in fact, *Thomas v. Anchorage Equal Rts. Comm'n*, 220 F.3d 1134, 1139 (9th Cir. 2000) (en banc), nor does a threat that is dependent upon a "highly attenuated chain of possibilities," *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410 (2013). In determining whether Vakil and Gourmend face a "credible threat of prosecution," we consider, first, "whether the plaintiffs have articulated a concrete plan to violate the law in question"; second, "whether the prosecuting authorities have communicated a specific

warning or threat to initiate proceedings”; and third, “the history of past prosecution or enforcement under the challenged statute.” *Clark v. City of Seattle*, 899 F.3d 802, 813 (9th Cir. 2018) (citation modified); *see also Cal. Pro-Life Council, Inc. v. Getman*, 328 F.3d 1088, 1094 (9th Cir. 2003) (applying these factors from *Thomas* to determine standing and explaining that *Thomas* did not overrule long-standing precedent “recognizing the validity of pre-enforcement challenges to statutes infringing upon constitutional rights”); *Imperial Sovereign Court of Montana v. Knudsen*, 170 F.4th 820, 835 (9th Cir. 2026) (explaining circumstances in which a plaintiff can show a credible threat of enforcement “even in the absence of any investigation or warning of prosecution”); *Matsumoto v. Labrador*, 122 F.4th 787, 797–98 (9th Cir. 2024) (same).

Here, the first two factors clearly favor finding a credible threat of prosecution, while the third factor weakly favors such a finding.

First, Vakil and Gourmend have a “concrete plan to violate the law in question.” *Clark*, 899 F.3d at 813. Gourmend continues to market its four spice blends and its chicken broth with labels that communicate low FODMAP levels, as it has since 2022. In other words, Gourmend has been labeling products in potential violation of the FDA’s regulations for years. The complaint also alleges that the challenged regulations “ha[ve] further chilled [Vakil] and Gourmend’s speech by causing them to delay plans for additional speech and additional low-FODMAP food products.” Thus, Gourmend either already offers or has a “concrete plan” to offer products that violate the applicable food-labeling laws through the inclusion of FODMAP-related information on their labels. *Id.*

Second, the government has provided Vakil and Gourmend with a “specific warning or threat to initiate proceedings.” *Id.* After Gourmend submitted its proposed beef broth label for approval, the FSIS rejected it and an FSIS official told Gourmend that “[a]ll of the references to gut loving, digestibility and fodmap must be removed.” Crucially, FSIS Deputy Director Jeffrey Canavan also told Gourmend that FSIS had discussed the application with FDA and that “both agencies view” the beef broth label’s claims as “undefined nutrient content claims.” We have previously explained that a First Amendment plaintiff faces a credible threat of enforcement “if the plaintiff’s intended speech arguably falls within the statute’s reach,” and quoted approvingly the Seventh Circuit’s explanation that “the threat [of prosecution] is latent in the existence of the [allegedly unconstitutional] statute.” *Cal. Pro-Life Council, Inc.*, 328 F.3d at 1095 (quoting *Majors v. Abell*, 317 F.3d 719, 721 (7th Cir. 2003)). Here, the government agencies’ own correspondence demonstrates that Vakil and Gourmend’s proposed speech “arguably falls within the statute’s reach,” such that the threat of prosecution is “latent in the existence of” the regulations. *Id.* And although the FDA has not issued warning letters to Vakil or Gourmend, “the government’s failure to *disavow* enforcement of [a] law ... weigh[s] in favor of standing.” *Tingley v. Ferguson*, 47 F.4th 1055, 1068 (9th Cir. 2022), *abrogated on other grounds by Chiles v. Salazar*, 146 S. Ct. 1010 (2026). At oral argument, the government confirmed that it could not provide any assurance that the FDA will not pursue an enforcement action against Vakil and Gourmend based on Gourmend’s existing labels.

Third, the government’s “history of past prosecution or enforcement” weakly favors Vakil and Gourmend. *Clark*,

899 F.3d at 813. Although the government has not yet challenged Gourmend’s FDA-governed labels, the FDA enforces bans on other unapproved nutrient-content claims, such as “low lactose content.” *See* FDA, *Warning Letter, Maine Natural Health, Inc.*, MARCS-CMS 525870 (Dec. 19, 2017) <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/maine-natural-health-inc-525870-12192017> [<https://perma.cc/RE43-PTJE>]. And FSIS Deputy Director Canavan’s letter, which noted the FDA’s agreement with FSIS that FODMAP content claims are impermissible nutrient-content claims, constitutes at least a “future warning of prosecution,” *see Unified Data Servs., LLC v. Fed. Trade Comm’n*, 39 F.4th 1200, 1211 (9th Cir. 2022), in the broader sense in which we have applied that rule in pre-enforcement challenges under the First Amendment, *see Libertarian Party of L.A. Cnty.*, 709 F.3d at 871 (holding that the government had “communicated a specific warning or threat of enforcement” by posting instructions for complying with the statute on its website). In any event, when the first two factors have been met, an imminent threat of prosecution may be found even where the third factor is neutral. *See, e.g., Project Veritas v. Schmidt*, 125 F.4th 929, 941–42 (9th Cir. 2025) (en banc).

Under these circumstances, Vakil and Gourmend alleged a “genuine threat of *imminent* prosecution” sufficient to establish their Article III standing to sue the FDA. *Clark*, 899 F.3d at 813.

CONCLUSION

For the foregoing reasons, we reverse the district court’s judgment as to Przybocki, Vakil, and Gourmend’s claims against the FDA and as to Przybocki’s claims against the

USDA. In a separate memorandum disposition, we affirm the district court's dismissal of Vakil and Gourmend's claims against the USDA for failure to exhaust available administrative remedies.

AFFIRMED IN PART, REVERSED IN PART. The parties shall bear their own costs on appeal.