UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

MICHELLE PRZYBOCKI, *et al.*, Plaintiffs, v. UNITED STATES DEPARTMENT OF AGRICULTURE, *et al.*, Defendants.	Case No. 2:23-cv-00455-ART-DJA ORDER

Plaintiffs Michelle Przybocki, Ketan Vakil, and Gourmend Foods, LLC ("Gourmend") bring this action against the United States Department of Agriculture ("USDA"), the United States Department of Agriculture Food Safety and Inspection Service ("FSIS"), the United States Food and Drug Administration ("FDA"), and each of these agency's respective heads in their official capacities. Plaintiffs allege that the government Defendants have violated their First Amendment rights through an alleged ban on labeling food as "low-FODMAP" (FODMAP stands for fermentable oligosaccharides, disaccharides, monosaccharides and polyols). Now pending is the government Defendants' Motion to Dismiss. (ECF No. 37.) For the reasons stated, the Court will grant Defendants' motion and dismiss this action without prejudice.

I. FACTUAL AND PROCEDURAL HISTORY

The facts are taken from the allegations in Plaintiffs' complaint. (ECF No. 1.) Plaintiff Michelle Przybocki suffers from a severe case of irritable bowel syndrome ("IBS"). Her condition requires her to seek out low-FODMAP foods. Because of the alleged ban on labeling foods as low-FODMAP, Przybocki struggles to discern what packaged foods are low-FODMAP.

Plaintiffs Ketan Vakil and Gourmend want customers to know their foods are low-FODMAP. The labels on Gourmend's products are regulated by the USDA, FSIS, and the FDA. According to Plaintiffs, while federal regulations allow for

nutrient content claims in food labels, implied or undefined nutrient content claims are disallowed. For the purposes of determining whether a nutrient content claim is implied or undefined, defined means defined in the federal regulations. Because low-FODMAP statements are not defined in the federal regulations, Plaintiffs allege that such statements are banned.

Gourmend applied to FSIS for low-FODMAP label approval and was denied. Vakil alleges that he was expressly instructed by FSIS to remove references to digestible, gut loving, and FODMAP from the Gourmend label. Gourmend further alleges it was expressly instructed by the USDA to remove all references to being low-FODMAP or easy to digest from the Gourmend label. Gourmend says the USDA instructed him that no version of the references could be included on the label because they were banned. Gourmend further alleges that the FSIS Deputy Director of Labeling and Program Delivery, Jeffrey Canavan, told Gourmend that the USDA and FSIS discussed Gourmend's label with colleagues at the FDA and the FDA agreed that the statements on the Gourmend were categorically banned. Gourmend alleges that Canavan explained that the Agencies consider the term "low-FODMAP" and any related factual statements to be undefined nutrient content claims and therefore banned.

Plaintiffs say that the alleged ban is an unconstitutional restraint of speech in violation of the First Amendment and that they have been harmed by the alleged constitutional violation. Plaintiffs request an order declaring the alleged ban unconstitutional and an injunction prohibiting Defendants from enforcing the alleged ban.

Defendants moved to dismiss Plaintiff's complaint, arguing that 1) Plaintiffs' claims are not justiciable; 2) Plaintiffs failed to plausibly allege any final agency action; 3) Plaintiffs' claims are not ripe; 4) Plaintiffs' failed to exhaust administrative remedies with respect to their claims against the USDA; 5) Plaintiffs have alleged no injury in fact that is fairly traceable to the FDA, so their

claims against the FDA should be dismissed for lack of standing or for lack of ripeness; 6) Przybocki lacks standing to bring her claim; and 7) venue is improper in the District of Nevada. (ECF No. 37.) Plaintiffs responded (ECF No. 40), and Defendants replied (ECF No. 43).

II. DISCUSSION

Many of Defendants' arguments challenge this Court's jurisdiction to decide Plaintiffs' case. A defendant may seek dismissal of a claim for lack of subject matter jurisdiction. Fed. R. Civ. P. 12(b)(1). The party asserting claims in federal court bears the burden of demonstrating the court's jurisdiction over those claims. *See In re Dynamic Random Access Memory (DRAM) Antitrust Litig.*, 546 F.3d 981, 984 (9th Cir. 2008). 12(b)(1) attacks on subject matter jurisdiction "may be facial or factual." *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). "In a facial attack, the challenger asserts that the allegations contained in a complaint are insufficient on their face to invoke federal jurisdiction." *Id.* Facial attacks are treated "no different from any other motion to dismiss on the pleadings for lack of jurisdiction, and we apply the same standards in evaluating its merit." *Doe v. Holy See*, 557 F.3d 1066, 1073 (9th Cir. 2009). A court therefore determines "whether the complaint alleges sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Terenkian v. Republic of Iraq*, 694 F.3d 1122, 1131 (9th Cir. 2012) (internal quotation marks and citations omitted).

"By contrast, in a factual attack, the challenger disputes the truth of the allegations that, by themselves, would otherwise invoke federal jurisdiction." *Safe Air for Everyone*, 373 F.3d at 1039. "In resolving a factual attack on jurisdiction, the district court may review evidence beyond the complaint without converting the motion to dismiss into a motion for summary judgment." *Id.*

Some of Defendants' arguments instead rely on Fed. R. Civ. P. 12(b)(6). A court may dismiss a plaintiff's complaint for "failure to state a claim upon which

relief can be granted." Fed. R. Civ. P. 12(b)(6). A properly pleaded complaint must provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). While Rule 8 does not require detailed factual allegations, it demands more than "labels and conclusions" or a "formulaic recitation of the elements of a cause of action." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555). All factual allegations set forth in the complaint are taken as true and construed in the light most favorable to the plaintiff. *Lee v. City of Los Angeles*, 250 F.3d 668, 679 (9th Cir. 2001). Thus, to survive a motion to dismiss, a complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). But even a facially plausible claim may be dismissed under Fed. R. Civ. P. 12(b)(6) for "lack of a cognizable legal theory." *Solida v. McKelvey*, 820 F.3d 1090, 1096 (9th Cir. 2016). Thus, to survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6) a claim must be both factually plausible and legally cognizable.

Applying each of these standards, the Court will address Defendants' arguments for dismissal.

A. Plaintiffs' Alleged Ban Is Sufficient to Create a Justiciable Case or Controversy.

Defendants first argue that this Court lacks jurisdiction because this matter does not present a justiciable case or controversy. "[The Court's] role is neither to issue advisory opinions nor to declare rights in hypothetical cases, but to adjudicate live cases or controversies consistent with the powers granted the judiciary in Article III of the Constitution." *Thomas v. Anchorage Equal Rts. Comm'n*, 220 F.3d 1134, 1138 (9th Cir. 2000). According to Defendants, Plaintiffs have failed to plausibly allege the existence of a ban by the USDA and FDA on low-FODMAP statements in product labeling. Defendants argue that the Court cannot decide whether the alleged ban violates the First Amendment because the

question is predicated on a hypothetical or theoretical scenario and is therefore not justiciable.

Contrary to Defendants' arguments, Plaintiffs cite a variety of federal regulations and official agency guidance that can be plausibly read to ban low-FODMAP statements in product labeling, even if the regulations and guidance do not explicitly mention "FODMAP." For example, Plaintiffs cite to official FDA guidance stating that "[o]nly those [nutrient content] claims, or their synonyms, that are specifically defined in the [FDA's] regulations may be used. All other claims are prohibited." U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: A FOOD LABELING GUIDE 72 (2013), https://www.fda.gov/media/81606/download (citing 21 C.F.R. § 101.13(b)). Plaintiffs also cite to official USDA guidance that says "[a] food label may not bear an express or implied claim that characterizes the level of a nutrient in a food (nutrient content claim) unless the term has been defined by regulations." U.S. DEP'T OF AGRIC., A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS 73 (2007), https://www.fsis.usda.gov/sites/default/files/media_file/2021-07/Labeling_Requirements_Guide.pdf (citing 9 C.F.R. § 317.313(b); 9 C.F.R. § 381.413(b)). Further, Plaintiffs allege that they were expressly instructed by the USDA and FSIS, after these agencies consulted with colleagues in the FDA, that the statement "low-FODMAP" and other related statements are categorically banned under federal law because they are undefined nutrient content claims. (ECF No. 1 at ¶¶ 123-43.)

Given these regulations, the official guidance from the governing agencies, and the allegations in Plaintiffs' complaint concerning statements made by at least one representative of the Defendants, the Court finds that Plaintiffs have plausibly alleged that the statement "low-FODMAP" and related statements are banned under federal law because they are undefined nutrient content claims, despite no explicit language in federal statutes or regulations banning such

statements in food labeling. *See Cal. Pro-Life Council, Inc. v. Getman*, 328 F.3d 1088, 1095 (9th Cir. 2003) ("'But if [a statute] arguably covers [a plaintiff's conduct], and so may deter constitutionally protected expression . . . there is standing.'" (quoting *Majors v. Abell*, 317 F.3d 719, 721 (7th Cir. 2003))).

B. Gourmend and Vakil's Claim Against the USDA Is Justiciable, but Their Claim Against the FDA Is Not.

A plausible ban does not alone satisfy the Constitution's case or controversy requirement. Defendants argue that Plaintiffs Gourmend and Vakil[1] have not established that they have standing to bring their claims against the USDA and FDA or that their claims are ripe for review.[2] "Whether the question is viewed as one of standing or ripeness, the Constitution mandates that prior to our exercise of jurisdiction there exist a constitutional 'case or controversy,' that the issues presented are 'definite and concrete, not hypothetical or abstract.'" *Thomas*, 220 F.3d at 1139 (quoting *Railway Mail Ass'n v. Corsi*, 326 U.S. 88, 93 (1945)). In cases like this, where a plaintiff is mounting a pre-enforcement challenge to a proscriptive statute or regulation, courts "consider whether the plaintiffs face 'a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement,' or whether the alleged injury is too 'imaginary' or 'speculative' to support jurisdiction." *Id.* (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)). "[N]either the mere existence of a proscriptive statute nor a generalized threat of prosecution satisfies the 'case or controversy' requirement." *Id.* Instead, there must be a genuine threat of imminent prosecution. *Id.*

Determining if a threat is genuine involves the application of three factors: "(1) whether the plaintiffs have articulated a concrete plan to violate the law in

[1] The Court will address standing arguments as to Przybocki separately.

[2] Courts "need not delve into the nuances of the distinction between the injury in fact prong of standing and the constitutional component of ripeness" when "the analysis is the same." *Thomas*, 220 F.3d at 1139.

question, (2) whether the prosecuting authorities have communicated a specific warning or threat to initiate proceedings, and (3) the history of past prosecution or enforcement under the challenged statute." *Cal. Pro-Life Council, Inc.*, 328 F.3d at 1094 (internal quotation marks omitted). The Ninth Circuit has recognized when applying this test that "'[o]ne does not have to await the consummation of threatened injury to obtain preventive relief.'" *Id.* (quoting *Ariz. Right to Life Political Action Comm. v. Bayless*, 320 F.3d 1002, 1006 (9th Cir. 2003)). "In an effort to avoid the chilling effect of sweeping restrictions, the Supreme Court has endorsed what might be called a 'hold your tongue and challenge now' approach rather than requiring litigants to speak first and take their chances with the consequences." *Ariz. Right to Life Political Action Comm.*, 320 F.3d at 1006. Thus, self-censorship is a constitutionally recognized injury. *Cal. Pro-Life Council, Inc.*, 328 F.3d at 1095.

The three factors weigh in Gourmend and Vakil's favor in their claim against the USDA and FSIS. First, Gourmend and Vakil have articulated sufficient intention to violate the alleged ban. These Plaintiffs applied to the FSIS, a part of the USDA, for approval of a beef broth label that included "low-FODMAP" and related statements. After receiving instructions from an agency representative that such statements were banned, these Plaintiffs "held their tongues" and challenged the alleged ban with this lawsuit. These Plaintiffs specifically allege that but for the alleged ban, they would be providing "more low-FODMAP information on its food labels to consumers." (ECF No. 1 at ¶ 158.) Gourmend and Vakil have satisfied the first factor.

Second, Gourmend and Vakil allegedly received correspondence from a representative of the FSIS expressly instructing them to not place "low-FODMAP" or related statements on their beef broth label because such statements were banned. This directly communicated warning from a representative of the agency enforcing the alleged ban is sufficient to satisfy the second factor.

Third, Plaintiffs allege that because the USDA and FSIS require pre-approval of food labels under their jurisdiction, those agencies' history of enforcement is evident in the lack of labels bearing "low-FODMAP" statements in the market.

Taken together, the factors support a finding that Gourmend and Vakil have suffered the "constitutionally recognized injury of self-censorship" and therefore have alleged a justiciable claim against the USDA and FSIS. *Cal. Pro-Life Council, Inc.*, 328 F.3d at 1095.

As to the FDA, Gourmend and Vakil have failed to establish any "injury in fact." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). An injury in fact must be "concrete and particularized" and "actual or imminent," not "conjectural or hypothetical." *Id.* Gourmend and Vakil allege that the FDA does not have a pre-approval process for labels under its jurisdiction. Plaintiffs say that they are currently selling five products under the FDA's jurisdiction, and that all five products bear "low-FODMAP" and other allegedly banned statements on their labels. Plaintiffs do not allege that they have received any warning letters or threats from the FDA, although they do allege that the FDA has a history of sending such notices to sellers who violate labeling laws. Gourmend and Vakil make no allegation that they will cease selling the products under the FDA's jurisdiction because of fear of prosecution or enforcement of the ban.

As alleged, Plaintiffs have not suffered a "self-censorship" injury with regards to the products under the FDA's jurisdiction. Plaintiffs have also not "held their tongue" as they have with the beef broth label under the USDA's jurisdiction. Plaintiffs allege that they are currently still selling the products with the "low-FODMAP" label and that no enforcement actions from the FDA have resulted. As alleged, Plaintiffs have not suffered an injury in fact that can support standing for their claim against the FDA. Gourmend and Vakil's claim against the FDA is therefore dismissed for lack of standing.

C. Plaintiffs' Claim Against the USDA and FSIS Does Not Require Final Agency Action.

Defendants also argue that Plaintiffs fail to state a cognizable cause of action because they do not plausibly allege a final agency action. The final agency action requirement applies to claims brought under the Administrative Procedure Act ("APA") challenging agency action. *See* 5 U.S.C. § 704. Under the statute, only "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review." *Id.*

If Plaintiffs had brought their claim under the APA, Defendants would be correct. However, Plaintiffs' claim is not brough under the APA. Neither cause of action listed in Plaintiffs' complaint references the APA, (ECF No. 1 at ¶¶ 183-228), and Plaintiffs expressly stated in their response to Defendants' Motion to Dismiss that their claim does not challenge agency action. Therefore, the Court finds that final agency action is not a requirement for Plaintiffs' claim.

D. Gourmend and Vakil Failed to Exhaust Administrative Remedies with the USDA and FSIS, Which Warrants Dismissal.

Defendants next argue that Gourmend and Vakil's claim against the USDA and FSIS must be dismissed for failure to exhaust administrative remedies. The parties agree that an exhaustion statute applies: "a person shall exhaust all administrative appeal procedures established by the Secretary or required by law before the person may bring an action in a court of competent jurisdiction against (1) the Secretary; (2) the Department; or (3) an agency, office, officer, or employee of the Department." 7 U.S.C. § 6912(e). The parties also agree that Plaintiffs failed to exhaust the USDA's established administrative appeal procedures for label applicants to seek review of adverse determinations. But, as the parties note, the USDA's exhaustion requirement is not jurisdictional. *See McBride Cotton & Cattle Corp. v. Veneman*, 290 F.3d 973, 980 (9th Cir. 2002). The task for this Court, then, is to determine if the Plaintiffs failure to exhaust administrative remedies should be excused. *Id.*

Because "administrative review prior to judicial intervention" is important, "a court should require compliance with an exhaustion statute unless the suit alleges a constitutional claim which is (1) collateral to a substantive claim of entitlement, (2) colorable, and (3) one whose resolution would not serve the purposes of exhaustion." *Id.* (internal quotation marks removed). Here, Plaintiffs claim against the USDA and FSIS fails to satisfy the first and third requirement.

First, the Court finds that Gourmend and Vakil's constitutional claim against the USDA and FSIS is not collateral to their substantive claim of entitlement. "A claim is collateral if it is not 'bound up with the merits so closely that [the court's] decision would constitute interference with agency process.'" *Id.* (quoting *Johnson v. Shalala*, 2 F.3d 918, 922 (9th Cir.1993)). In *McBride*, the plaintiffs facially challenged an agency policy that allowed the Secretary of Agriculture, without notice, to take through administrative offset pro-rata shares of contractual payments owed to the plaintiffs to satisfy delinquent debts owed by non-plaintiffs. *Id.* at 976. The plaintiffs claimed that the no-notice policy violated their due process rights and statutory law. *Id.* Because there was no administrative process through which the plaintiffs could challenge the no-notice policy, the court found that review of the plaintiffs' claims would not constitute interference with agency process. *Id.* at 981.

Here, the alleged ban Plaintiffs are challenging rests on the premise that "low-FODMAP" and related statements are nutrient content claims, and that because the term "FODMAP" is not defined in the USDA's food labeling regulations, it is effectively banned in violation of Plaintiffs' First Amendment rights. This constitutional claim is not collateral to Plaintiffs' substantive claim of entitlement. Unlike in *McBride*, the Plaintiffs' claim here can be addressed by an administrative process that will determine if the statement "low-FODMAP" is a nutrient content claim. If this Court decides that question in the first instance and then determines if the regulation violates the First Amendment, it will

necessarily interfere with agency process. The Court therefore finds that Gourmend and Vakil's claim against the USDA and FSIS is not excused from the exhaustion requirement and must therefore be dismissed.

Similarly, administrative exhaustion in this case would not be futile. *Id.* at 982. "The purpose of exhaustion is to allow the agency, in the first instance, to develop a detailed factual record and utilize its expertise in applying its own regulations to those facts." *Id.* Here, allowing the USDA and FSIS to develop a factual record and apply its regulations to the question of whether "low-FODMAP" is a nutrient content claim will assist a court in resolving Plaintiffs' claim. The Court therefore finds that the Plaintiffs' failure to exhaust is not excused for this independent reason as well.

E. Przybocki Lacks Standing for Her Claim Against the Government Defendants.

The Court turns lastly to Przybocki's claim against the government defendants. Przybocki pleads a cause of action based on her First Amendment rights as a recipient of information. She alleges that but for the alleged ban, she would have better access to information in grocery stores about which products are low-FODMAP.

"To 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 Board of Pharmacy v. Vs. Citizens Consumer Council*, 425 U.S. 748, 756–57 (1976). Przybocki makes both general allegations of willing speakers and specific allegations about her co-Plaintiffs. For example, Przybocki alleges that but for the ban, "more businesses would provide" information about low-FODMAP on their food labels, that these businesses include Gourmend, and that based upon information and belief, "many additional businesses would provide more low-FODMAP information on their food labels" but for the alleged ban. (ECF No. 1 at

¶¶ 190-192.)

First, the Court finds that Przybocki's general allegations about "more businesses" are too "conjectural or hypothetical" to establish injury in fact. *Lujan*, 504 U.S. at 560. Przybocki's allegations rely on a chain of hypotheticals to create injury. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 (2013) (holding that a "speculative chain of possibilities" does not establish injury). Essentially, Przybocki argues that she suffers an injury every time she visits a grocery store because "many businesses" are self-censoring low-FODMAP statements because of the alleged ban. But Przybocki's complaint lacks concrete allegations to support this argument. Przybocki must provide specific allegations about willing speakers who are currently self-censoring because of the alleged ban that sell products in grocery stores that she visits. Because her complaint lacks concrete allegations, the Court finds that Przybocki has not established a sufficient injury in fact to support standing based on speech that would be made by "many businesses."

Second, the Court finds that Przybocki has not suffered a sufficient "injury in fact" as to her inability to access information that Gourmend would provide but for the alleged ban. First, there is no allegation that Gourmend sells any of its products in retail stores that Przybocki visits. Second, all Gourmend's products, except its beef broth, currently carry "low-FODMAP" labels which Przybocki can see in a grocery store. The only speech that Gourmend and Vakil are currently "self-censoring" because of the alleged ban is the beef broth label. Finally, information about Gourmend's beef broth being low-FODMAP is available on a website which Przybocki can view. Taken together, Przybocki has not sufficiently alleged an informational injury because of Gourmend's self-censorship in response to the alleged ban. Przybocki's allegations do not support a finding that she lacks access to information about low-FODMAP products in grocery stores she visits because of the alleged ban. Her claim is therefore

dismissed for lack of standing.

III. CONCLUSION

IT IS THEREFORE ORDERED that Defendants' Motion to Dismiss is GRANTED. (ECF No. 37.) Plaintiffs' complaint is therefore dismissed without prejudice and with leave to amend.

DATED THIS 17th day of July 2024.

ANNE R. TRAUM
UNITED STATES DISTRICT JUDGE