UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.: 2:25–cv–03570–AB–MAR	Date: February 3, 2026

Title: *Eli Lilly and Company v. Willow Health Services, Inc.*

Present: The Honorable	**ANDRÉ BIROTTE JR., United States District Judge**
Evelyn Chun Deputy Clerk	N/A Court Reporter
Attorney(s) Present for Plaintiff(s): None Appearing	Attorney(s) Present for Defendant(s): None Appearing

Proceedings: **[In Chambers] ORDER GRANTING DEFENDANT'S MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT [Dkt. No. 57] AND DENYING AS MOOT DEFENDANT'S MOTION TO STAY DISCOVERY [Dkt. No. 62]**

Pending before the Court is Defendant Willow Health Services, Inc.'s ("Willow" or "Defendant") Motion to Dismiss (Dkt. No. 57, "Motion" or "Mot.") Plaintiff's First Amended Complaint (Dkt. No. 50, "FAC"), as well as Willow's Motion to Stay Discovery Pending Disposition of the Motion to Dismiss (Dkt. No. 62, "Motion to Stay"). In support of its Motion to Dismiss, Willow also filed a Request for Judicial Notice (Dkt. No. 58, "RJN"). Plaintiff Eli Lilly and Company ("Lilly" or "Plaintiff") filed Oppositions to the Motion to Dismiss (Dkt. No. 61, "Opp'n") and Motion to Stay (Dkt. No. 64). Willow filed Replies to each (Dkt. Nos. 63, 65). The Court took both of Willow's motions under submission and vacated the hearings set for January 16, 2026. *See* Fed. R. Civ. P. 78, C.D. Cal. L.R. 7-15. For the following reasons, Willow's Motion to Dismiss is **GRANTED** and Willow's Motion to Stay is **DENIED** as moot.

I. BACKGROUND

Plaintiff Eli Lilly and Company ("Lilly") is a global pharmaceutical manufacturer with nearly 150 years of experience developing and commercializing innovative medicines. FAC ¶¶ 2, 20–21. Lilly's products are manufactured under strict regulatory controls and distributed worldwide. *Id.* ¶¶ 21–22. Transforming an active pharmaceutical ingredient ("API") into a finished medication is a complex scientific process that requires adherence to Current Good Manufacturing Practices ("cGMP") and rigorous quality oversight. *Id.* ¶ 21. Lilly's manufacturing facilities are subject to routine FDA inspection and post-market surveillance requirements. *Id.* ¶ 22.

Relevant here, Lilly developed tirzepatide, a novel macromolecule that targets both glucagon-like peptide-1 ("GLP-1") and glucose-dependent insulinotropic polypeptide ("GIP") receptors. *Id.* ¶¶ 2, 32. These dual-receptor agonists improve blood sugar control and reduce appetite and food intake. *Id.* ¶ 2. Lilly spent nearly a decade conducting preclinical research and multi-phase randomized controlled clinical trials to evaluate the safety and effectiveness of tirzepatide. *Id.* ¶¶ 3, 23–28, 32. These studies included thousands of participants across dozens of completed clinical trials. *Id.* ¶ 32.

Following this extensive testing, the FDA approved two injectable tirzepatide-based medicines: MOUNJARO® for adults with type 2 diabetes and ZEPBOUND® for chronic weight management and obstructive sleep apnea in certain adults. *Id.* ¶¶ 2, 31–33. MOUNJARO® and ZEPBOUND® are the only FDA-approved medications containing tirzepatide. *Id.* ¶¶ 3, 35. Both products are administered exclusively by subcutaneous injection. *Id.* Lilly does not sell, and the FDA has not approved, any oral tirzepatide formulation. *Id.* ¶ 35.

FDA approval required Lilly to submit detailed information regarding the composition of its drugs, manufacturing processes, and clinical trial data demonstrating safety and efficacy. *Id.* ¶¶ 25, 28–30. Lilly's manufacturing practices remain subject to ongoing regulatory oversight, including adverse event reporting obligations and post-market studies. *Id.* ¶ 30. Lilly currently holds regulatory exclusivity for tirzepatide, which prevents FDA from accepting applications for competing tirzepatide products until at least May 2027. *Id.* ¶ 34.

Defendant Willow Health Services, Inc. ("Willow") operates a telehealth platform that markets and sells weight-loss treatments directly to consumers. *Id.* ¶ 1. Willow offers compounded tirzepatide products, including an injectable

formulation ("Willow's Tirzepatide Treatment") and an oral formulation ("Willow's Tirzepatide Drops"). *Id.* ¶ 4. These products are not FDA-approved and have not undergone clinical trials. *Id.* ¶ 4. Willow's products are compounded from bulk API sourced from third parties, rather than from Lilly. *Id.* ¶¶ 10, 41.

Compounded drugs exist outside the FDA's premarket approval framework. *Id.* ¶¶ 36–40. The FDA does not review compounded drugs for safety, effectiveness, or manufacturing quality before they are dispensed to patients. *Id.* ¶¶ 38–39. Compounding pharmacies are not subject to cGMP standards, routine inspections, or adverse event reporting requirements. *Id.* ¶¶ 39–40. FDA has warned that compounded drugs do not carry the same safety, quality, or effectiveness assurances as FDA-approved medicines and should generally be used only when no approved alternative exists. *Id.* ¶¶ 40–41.

FDA has expressed particular concern about compounded GLP-1 drugs. *Id.* ¶¶ 43–44. According to the FAC, much of the tirzepatide used for compounding is manufactured overseas, primarily in China, by facilities that are not subject to the same regulatory oversight as domestic manufacturers. *Id.* ¶¶ 41–42. FDA has publicly warned about dosing errors, adverse events, and the use of unapproved salt forms in compounded tirzepatide products. *Id.* ¶ 43.

Despite these regulatory differences, Willow's marketing presents its products as clinically validated and comparable to, or superior to, Lilly's FDA-approved medicines. *Id.* ¶¶ 5–7. Willow advertises that its tirzepatide treatment has undergone "extensive testing," is supported by "science," and produces significant weight loss outcomes. *Id.* ¶ 5. Willow's website includes imagery of physicians and references to board-certified doctors, reinforcing the impression of medical endorsement. *Id.*

Willow also claims that its product is a "premium" blend that delivers "better results" than tirzepatide generally. *Id.* ¶ 7. Immediately following these superiority claims, Willow reiterates that its medication undergoes extensive testing. *Id.* According to the FAC, Willow has no clinical studies supporting these claims. *Id.* ¶¶ 7, 81. No testing has been conducted on Willow's compounded products to demonstrate safety or effectiveness. *Id.* ¶ 81.

Willow further promotes its oral Tirzepatide Drops as an alternative to injectable medications. *Id.* ¶¶ 93–96. Although no oral tirzepatide formulation has been approved by the FDA, Willow markets its drops as effective and, at times, superior to injections. *Id.* ¶¶ 35, 93–96. The FAC alleges that no clinical data

supports the effectiveness of any oral tirzepatide product. *Id.* ¶ 93.

Willow also represents that its medications are custom, "personalized," and tailored to each patient's unique needs. *Id.* ¶¶ 9, 101. Willow claims to use "precision medicine" to personalize "trusted, clinically proven medications." *Id.* ¶ 9. According to the FAC, these statements reference Lilly's FDA-approved products. *Id.* ¶ 10. In practice, however, Willow compounds standardized formulations and distributes the same medication to all patients. *Id.* ¶¶ 117–118. Consumers seeking treatment through Willow complete an online intake questionnaire. *Id.* ¶ 122. The questionnaire purports to assess whether Willow's treatment is appropriate. *Id.* ¶ 11. Regardless of the information provided, Willow recommends its medication to all users. *Id.* ¶¶ 11, 122–124. Lilly alleges that this practice demonstrates that Willow's personalization claims are false. *Id.*

After Lilly filed this lawsuit, Willow added a disclaimer to its website stating that its products are not FDA-approved and have not undergone clinical trials. *Id.* ¶ 8. The disclaimer appears at the bottom of Willow's webpage and is not prominently displayed. *Id.* Lilly alleges that this disclosure does not alter Willow's overall marketing message. *Id.*

Lilly further alleges that consumer confusion regarding compounded GLP-1 drugs is widespread. *Id.* ¶¶ 45–49. A survey conducted by the National Consumers League found that many consumers incorrectly believe compounded GLP-1 drugs are FDA-approved and clinically tested. *Id.* ¶ 45. Another study published in *JAMA Health Forum* concluded that most websites advertising compounded GLP-1 drugs provide limited safety information and unauthorized efficacy claims. *Id.* ¶ 49.

According to the FAC, Willow's advertising mirrors the types of statements the FDA has identified as false and misleading in warning letters sent to compounders and telehealth companies. *Id.* ¶¶ 50–53. These include claims that products are "clinically proven," "backed by extensive clinical research," and "personalized." *Id.* ¶¶ 51–53. Lilly alleges that Willow's marketing contains the same categories of prohibited claims. *Id.* ¶ 53.

Lilly and Willow compete for consumers seeking tirzepatide-based weight-loss treatments. *Id.* ¶ 83. Lilly alleges that Willow's marketing falsely equates its untested compounded products with FDA-approved medicines, diverting sales and harming Lilly's reputation. *Id.* ¶¶ 83, 90, 132–134. Lilly further alleges that adverse events associated with compounded tirzepatide products are often mistakenly attributed to Lilly's medicines, further damaging its goodwill. *Id.* ¶¶

138–140. Based on these allegations, Lilly brings this action under the Lanham Act, seeking injunctive relief and damages for Willow's allegedly false and misleading advertising. *Id.* ¶ 13.

On August 29, 2025, the Court granted Willow's Motion to Dismiss the original Complaint but permitted Lilly leave to amend. Dkt. No. 47 (the "Order"). On September 30, 2025, Lilly filed its FAC and Willow now moves the Court to dismiss Lilly's FAC on two bases: (1) Lilly has not sufficiently alleged standing to bring this claim; and (2) the purportedly deceptive advertisements alleged in Lilly's FAC are nonactionable.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 8 requires a plaintiff's pleading to present a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2).

Under Federal Rule of Civil Procedure 12(b)(6), a defendant may move to dismiss a pleading for "failure to state a claim upon which relief can be granted." A complaint may be dismissed under Rule 12(b)(6) for the lack of a cognizable legal theory, or the absence of sufficient facts alleged under a cognizable legal theory. *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988). When ruling on a Rule 12(b)(6) motion, "a judge must accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). The court must further make all reasonable inferences in the plaintiff's favor. *Nordstrom v. Ryan*, 762 F.3d 903, 906 (9th Cir. 2014). But a court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted).

To defeat a Rule 12(b)(6) motion to dismiss, the complaint must provide enough factual detail to "give the defendant fair notice of what the…claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, (2007). The complaint must also be "plausible on its face," that is, it "must contain sufficient factual matter, accepted as true, 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). A plaintiff's "factual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id*. Labels, conclusions, and "a formulaic recitation of the elements of a cause of action will not do." *Id.*

III. DISCUSSION

A. Request for Judicial Notice

Willow requests the Court take judicial notice of two exhibits. *See* Dkt. No. 58, "RJN." Specifically, Willow requests the Court take notice of the following:

(i) Lilly's October 30, 2025 Form 8-K and Exhibit 99. Wesley Decl., Ex. B.; and
(ii) A certified transcript for Lilly's Q3 2024 earnings call. *Id*., Ex. C.

Although the scope of review on a motion to dismiss is generally confined to the contents of the complaint, a court may consider "certain materials—documents attached to the complaint, documents incorporated by reference in the complaint or matters of judicial notice—without converting the motion to dismiss into a motion for summary judgment." *Lacayo v. Seterus, Inc.*, No. CV 17-02783-AB (JEMx), 2017 WL 8115535, at *3 (C.D. Cal. Aug. 2, 2017) (quoting *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003)). Here, Willow alleges that the Court may take judicial notice of these exhibits because the information contained in both can "be accurately and readily determined from sources whose accuracy cannot reasonably be questioned," namely the official websites of the SEC and Lilly. RJN at 2–3. Further, Willow argues that the exhibits are relevant on the issue of standing because it arguably demonstrates that Lilly cannot demonstrate lost sales. *Id.* at 3.

It is well establish that courts may take judicial notice of SEC filings, including Forms 8-K and their exhibits, because these are publicly available documents filed with a governmental agency. *See, e.g., Wynn v. Chanos*, 75 F. Supp. 3d 1228, 1235 (N.D. Cal. 2014) ("SEC forms such as a Form 8–K or Form 10–K are matters of public record and may be subject to judicial notice."); *Oklahoma Firefighters Pension & Ret. Sys. v. IXIA*, No. CV–13–08440 MMM SHX, 50 F.Supp.3d 1328, 1348–49, 2014 WL 4978568, at *13 (C.D.Cal. Oct. 6, 2014). Accordingly, the Court **GRANTS** Willow's Request for Judicial Notice as to the first requested exhibit and takes notice of Lilly's October 30, 2025 Form 8-K and Exhibit 99.1. The exhibit will not be considered for the truth of the statements they contain, but for the fact that they were filed and provided certain information to the public. *See Genasys Inc. v. Vector Acoustics, LLC*, 638 F. Supp. 3d 1135, 1147 (S.D. Cal. 2022) ("A court [ ] only takes judicial notice of the 'content of the SEC Forms [ ] and the fact that they were filed with the agency. The truth of the

content, and the inferences properly drawn from them, however, is not a proper subject of judicial notice under Rule 201.' ") (citing *Gerritsen v. Warner Bros. Ent. Inc.*, 112 F. Supp. 3d 1011, 1031 (C.D. Cal. 2015)).

The treatment of transcripts from a company's public website is significantly more restrictive. " ' Private corporate websites, particularly when describing their own business,' are a source whose accuracy is reasonably questioned." *Genasys Inc.*, 638 F. Supp. 3d at 1146 (citing *Spy Optic, Inc. v. Alibaba.Com, Inc.*, 163 F. Supp. 3d 755, 763 (C.D. Cal. 2015)). Thus, if a court is to take judicial notice of a website, the court is merely taking "as true that the website exists and makes certain representations about the company to the public." *Woodside Invs., Inc. v. Complete Bus. Sols. Grp., Inc.*, No. 220CV00042JAMCKD, 2020 WL 869206, at *2 (E.D. Cal. Feb. 21, 2020). The court does not "assume the veracity of any of the representations the website contains." *Id.* "Federal courts considering the issue have expressed skepticism as to whether it is appropriate to take judicial notice of information or documents appearing on websites that are created and maintained by a party to the litigation." *Gerritsen v. Warner Bros. Ent. Inc.*, 112 F. Supp. 3d 1011, 1030 (C.D. Cal. 2015). The Court therefore **DENIES** Willow's Request for Judicial Notice as to the second exhibit. Even if the Court were to grant the Request for Judicial Notice as to this exhibit, the Court still would not consider them for the truth of the matter. Given the source of the exhibit, however, the Court declines to judicially notice the document all together.

B. Statutory Standing

At the outset, Willow once again argues that Lilly's False Advertising Lanham Act claim fails for lack of statutory standing. Mot. at 13. Because standing is a threshold issue, the Court will address Willow's jurisdictional challenges first. *See, e.g., Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574, 578 (1999) ("Customarily, a federal court first resolves doubts about its jurisdiction over the subject matter[.]").

To establish statutory standing under the Lanham Act, Plaintiff must satisfy a more demanding standard than constitutional standing. *See Vampire Fam. Brands, LLC v. MPL Brands, Inc.*, No. CV 20-9482-DMG (ASX), 2021 WL 4134841 (C.D. Cal. Aug. 6, 2021). The heightened standing test under the Lanham Act has both a "zone of interests" and a "proximate cause" requirement. *See Lexmark Int'l, Inc. v. Static Control Components, Inc.* ("*Lexmark*"), 572 U.S. 118, 131-32 (2014). The first prong obligates a plaintiff to adequately allege "an injury to a commercial interest in reputation or sales." *Id.* The second prong requires that

a plaintiff plead, with the requisite particularity, "economic or reputational injury flowing directly from the deception wrought by the defendant's advertising, which occurs when deception of consumers causes them to withhold trade from the plaintiff." *Id.* Put simply, Plaintiff must allege (1) a commercial injury, such as reputation or sales, and (2) that the injury is competitive, or harmful to the plaintiff's ability to compete with the defendant. *See Jack Russell Terrier Network of N. Cal. v. Am. Kennel Club, Inc.*, 407 F.3d 1027, 1037 (9th Cir. 2005).

i. Zone of Interest

Regarding the first part of this analysis, the "zone of interest" test is not a particularly demanding one, and the benefit of the doubt goes to the one alleging the cause of action. *Lexmark,* 572 U.S. at 130. "[T]he test forecloses suit only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress authorized the plaintiff to sue." *Id*. (citation and quotations omitted). In the false advertising context, Congress' goal was to protect persons engaged in commerce against unfair competition. *Id*. Thus, "to come within the zone of interests in a suit for false advertising under [the Lanham Act], a plaintiff must allege an injury to a commercial interest in reputation or sales" as opposed to an allegation a consumer or business was misled into purchasing disappointing or inferior products. *Id*. at 131–32.

1. Commercial Injury

If the plaintiff can demonstrate that the defendant is a direct competitor, there is a presumption of a commercial injury to plaintiff sufficient to establish standing. *TrafficSchool.com, Inc. v. Edriver Inc.* ("*TrafficSchool.com*"), 653 F.3d 820, 827 (9th Cir. 2011). In *TrafficSchool.com*, the Ninth Circuit explained that the presumption of a competitor suffering a commercial injury is because competitors "'vie for the same dollars from the same consumer group,' and a misleading ad can upset their relative competition." *Id.* (citing *Kournikova v. Gen. Media Commc'ns, Inc*., 278 F.Supp.2d 1111, 1117 (C.D. Cal. 2003).

Here, Willow argues that it is not a direct competitor of Lilly evidenced by the fact that "Lilly's allegations continue to lack any details showing a decrease in its sales, or details concerning Willow's sales figures." Mot. at 16. In fact, Willow highlights that Lilly actually had an *increase* in sales of Mounjaro and Zepbound. *Id.*. Lilly, in response, contends that because commercial injury is "generally presumed . . . when defendant and plaintiff are direct competitors" and because this

Court has already made a finding that Lilly's original complaint "sufficiently alleged that Defendant and Plaintiff are direct competitors," commercial injury has been sufficiently established. Opp'n at 10–11; *see TrafficSchool.com*, 653 F.3d at 827; Ord. 7.

In the Court's prior Order, the Court concluded that Lilly is entitled to a presumption of commercial injury because Lilly and Willow "vie for the same dollars from the same consumer group—consumers with diabetes or obesity who want to lose weight." Ord. at 8 (citing *TrafficSchool.com, Inc.*, 653 F.3d at 827) (internal quotations omitted). Notwithstanding this conclusion, the Court found that this presumption of commercial injury was successfully rebutted, after determining that a finding of direct competition "does not conclusively establish that Plaintiff has suffered a commercial injury." *Id.* Lilly, however, contends that the Court's interpretation of *TrafficSchool.com* is flawed and that the presumption of commercial injury cannot be rebutted. Opp'n at 10–11.

The Court recognizes a split of authority in the Ninth Circuit on whether a presumption of commercial injury arising from direct competition is sufficient on its own to establish standing, or whether a plaintiff must also allege concrete facts demonstrating lost or diverted sales. *Contrast Allbirds, Inc. v. Giesswein Walkwaren AG*, No. 19-CV-05638-BLF, 2020 WL 6826487, at *4 (N.D. Cal. June 4, 2020) ("[Plaintiff] must provide at least a second link in the chain of inferences because allegations of direct competition, standing alone, are not sufficient.") *with Tortilla Factory, LLC v. Better Booch, LLC*, 2018 WL 4378700, at *4 (C.D. Cal. Sept. 13, 2018) (allegations that defendant is a direct competitor "give[] 'rise to a presumed commercial injury that is sufficient to establish standing.'"). While the Court's prior determination was consistent with one line of authority, other Ninth Circuit decisions suggest that a plaintiff does need to allege specific facts of lost or diverted sales to sustain standing. *See, e.g., Obesity Rsch. Inst., LLC v. Fiber Rsch. Int'l, LLC*, 310 F. Supp. 3d 1089, 1116 (S.D. Cal. 2018) ("The law is clear that a party does not need to show a loss of sales.") (citing *Harper House, Inc. v. Thomas Nelson, Inc.*, 889 F.2d 197, 210 (9th Cir. 1989) ("Of course, because of the possibility that a competitor may suffer future injury ... a competitor need not *1117 prove [past] injury when suing to enjoin conduct that violates section 43(a).")).

The Ninth Circuit is yet to definitively resolve whether the presumption of commercial injury from direct competition is sufficient on its own at the pleading stage, or whether the plaintiff must also allege some concrete facts of lost or diverted sales. In *TrafficSchool.com*, the Ninth Circuit found that the plaintiffs

alleged facts to establish a sufficient injury by (1) "introduce[ing] ample evidence that [plaintiffs] compete[d] with defendants for referral revenue – sometimes partnering with the same third-party traffic school or driver's [education] course providers" such that "sales gained by one are thus likely to come at the other's expense"; and (2) presenting survey and testimonial evidence that being referred by DMV affected consumers' choice in traffic school and drivers education courses, such that the defendant's false advertisement (i.e., misleading customers into thinking they were referred by DMV) could lead to a bigger share of the referral market. 653 F.3d at 825–26. To be sure, the court never specified a particular number of links in the chain of inferences required to establish a finding of commercial injury, leaving the question of sufficiency to be evaluated based on the specific facts alleged in each case. *See id.* at 827 ("We need not decide today whether our presumption of commercial injury is conclusive or rebuttable because defendants didn't point to any evidence—such as an increase in plaintiffs' sales—that might tend to rebut the presumption.").

Here, Lilly has alleged that Willow's conduct "results in potential patients being lured away" and that "*Willow*['s] … materially false statements … influence consumers' … decision to purchase *Willow's* [drugs] instead of Lilly's FDA-approved medicines." FAC ¶¶ 13, 145. Lilly supplements those allegations by further alleging that the products compete at "similar prices" causing consumers make purchasing decisions "based on factors other than pricing, including comparative safety and effectiveness." *Id.* ¶ 142. This is a marked improvement from the allegations in Lilly's original Complaint, which the Court previously found merely asserted in a conclusory fashion that consumers "may" draw unwarranted conclusions about Plaintiff's medicines, without identifying a single lost sale, survey, or testimonial evidence demonstrating actual or potential harm. Ord. at 8. In light of the Ninth Circuit's lack of a definitive ruling on this issue, the Court concludes that these allegations, together with the presumption arising from direct competition, are sufficient to establish commercial injury at the pleading stage to place Lilly in the zone of interest in a suit for false advertising under the Lanham Act.

2. Reputational Injury

Because Lilly has successfully pleaded injury to a commercial interest putting it in the in the zone of interest in a suit for false advertising under the Lanham Act, it need not allege reputational injury. Under the Lanham Act, a plaintiff must allege an injury to a commercial interest in either reputation or sales—these are alternative, not cumulative requirements. *Lexmark*, 572 U.S. at

137. In *Lexmark*, the Supreme Court stated "to come within the zone of interests in a suit for false advertising under [the Lanham Act], a plaintiff must allege an injury to a commercial interest in reputation or sales." *Id*. at 131–32. The disjunctive "or" makes clear that either type of injury suffices. Courts within the Ninth Circuit have consistently allowed plaintiffs to proceed on the basis of alleged lost sales alone, without mandating separate allegations of reputational harm. *See, e.g., Obesity Rsch. Inst.*, 310 F. Supp. 3d at 1116–17 (finding that the plaintiff was within the zone of interests and had standing even though it did not plead reputational harm). Accordingly, the Court need not conduct an extensive analysis and concludes that Lilly has sufficiently alleged a commercial injury to establish standing.

ii. Proximate Cause

Determining that Lilly has alleged it falls within the zone of interest for purposes of Lanham Act standing, the Court now turns to whether Lilly has alleged proximate cause required under *Lexmark*. To establish proximate cause under the Lanham Act, a plaintiff "ordinarily must show economic or reputational injury flowing directly from the deception wrought by the defendant's advertising; and that that occurs when deception of consumers causes them to withhold trade from the plaintiff." *Lexmark*, 572 U.S. at 133. Proximate causation may be adequately alleged when "there is likely to be something very close to a 1:1 relationship between" a plaintiff's lost sales and the sales diverted to a defendant. *Id.* at 139.

In *Lexmark*, the plaintiff sufficiently alleged a "1:1 relationship between the number of refurbished Prebate cartridges sold (or not sold) by the remanufacturers and the number of Prebate microchips sold (or not sold) by [plaintiff]." 572 U.S. at 139. There, the plaintiff "adequately alleged proximate causation by alleging that it designed, manufactured, and sold microchips that both (1) were necessary for, and (2) had no other use than, refurbishing Lexmark toner cartridges." *Id.* Thus, "if the remanufacturers sold 10,000 fewer refurbished cartridges because of [the defendant's] false advertising, then it would follow more or less automatically that [the plaintiff] sold 10,000 fewer microchips for the same reason." *Id.* at 140.

Here, the Court's prior analysis regarding proximate cause remains unchanged. Lilly's FAC still fails to plead facts establishing a direct causal link between any advertisement by Willow and a patient choosing a compounded medication over Lilly's product. The FAC contains no allegations showing a 1:1 relationship, or anything approaching it, between lost sales and sales diverted to Willow, and it provides no chain of inferences connecting a patient's exposure to advertising with the ultimate purchase of a compounded drug. Critically, regardless

of advertising or patient intent, obtaining a prescription medication requires a physician to prescribe it. The physician's prescribing decision, not Willow's advertisements, is the proximate cause of the patient using the compounded medication instead of Lilly's product. Accordingly, the Court's prior conclusion—that Defendant's advertisements are not the proximate cause of lost sales—remains fully applicable.

Lilly's arguments in opposition, including its contention that this ruling would categorically eliminate Lanham Act claims for prescription drugs, are unavailing. Lilly points to cases such as *Adonis Health* and *Allergan* that allowed false advertising claims concerning prescription drugs to proceed, but these decisions do not disturb the Court's nuanced holding here: that proximate causation fails absent allegations showing a direct link between advertising and lost sales, compounded by the fact that prescriptions, a foreseeable and legally required step, determine whether a patient can actually obtain the product. *See Eli Lilly & Co. v. Adonis Health, Inc.*, No. 25-cv-03536-JST, 2025 WL 2721684, at *4 (N.D. Cal. Sept. 24, 2025); *Allergan USA Inc. v. Imprimis Pharms., Inc.*, 2017 WL 10526121, at *1 (C.D. Cal. Nov. 14, 2017). Lilly cites no new allegations addressing this point. For these reasons, the Court's prior proximate cause analysis stands, and the FAC cannot overcome this deficiency.

As such, the Court concludes Plaintiff has failed to adequately allege proximate causation. Because Plaintiff has failed to sufficiently allege both a commercial injury and proximate cause, Plaintiff has failed to establish standing under the Lanham Act. For this reason, the Court **GRANTS** Defendant's Motion to Dismiss Plaintiff's Lanham Act claims. Because the Court has determined that Lilly cannot establish Article III standing, it need not proceed with any further analysis of whether the challenged advertisements are actionable. All other arguments and issues are therefore moot.

C. Leave to Amend

If a motion to dismiss is granted, the court should "freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). A "district court must give plaintiffs at least one chance to amend a deficient complaint, absent a clear showing that amendment would be futile." *Natl. Council of La Raza v. Cegavske*, 800 F.3d 1032, 1041 (9th Cir. 2015). The purpose of granting leave to amend is to allow "plaintiff[s] with a meritorious claim to cure any technical defects." *Lopez v. Smith*, 203 F.3d 1122, 1129 (9th Cir. 2000). But leave to amend may be denied when "the court determines that the allegation of other facts consistent with the

challenged pleading could not possibly cure the deficiency." *Schreiber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986). And "the district court's discretion to deny leave to amend is particularly broad where plaintiff has previously amended the complaint." *In re Read–Rite Corp.*, 335 F.3d 843, 845 (9th Cir. 2003) (internal quotations and citation omitted).

Lilly has already amended their complaint once. Furthermore, their claims are deficient as a matter of law based on the fact that Lilly cannot establish Article III standing. Thus, Lilly's FAC cannot be cured by additional facts. For these reasons, the Court finds that amendment would be futile and **DENIES** leave to amend. *See Cafasso v. Gen. Dynamics C4 Sys.*, 637 F.3d 1047, 1058 (9th Cir. 2011) (a "'district court's discretion to deny leave to amend is particularly broad where plaintiff has previously amended the complaint.'").

D. Motion to Stay

In light of the Court's ruling on Willow's Motion to Dismiss, the Court finds that Willow's Motion to Stay is now moot. The Court therefore **DENIES** the Motion to Stay.

IV. CONSLUSION

Accordingly, Willow's Motion to Dismiss is **GRANTED** and Lilly's FAC is **DISMISSED** ***with*** **prejudice and** ***without*** **leave to amend.** Furthermore, Willow's Motion to Stay Discovery is **DENIED** as moot. Willow must file a proposed Judgment within 5 days of the issuance of this Order. Lilly will have 3 days thereafter to file any objections.

IT IS SO ORDERED.