UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

ELI LILLY AND COMPANY, Plaintiff, v. ALDERWOOD SURGICAL CENTER LLC D/B/A ALLURE ESTHETIC, D/B/A GALLERY OF COSMETIC SURGERY, D/B/A SEATTLE PLASTIC SURGERY, et al., Defendants.	CASE NO. 2:24-cv-00878-LK ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS

This matter comes before the Court on Defendants' Motion to Dismiss. Dkt. No. 24. For the reasons explained below, the motion is granted in part and denied in part.[1]

I. BACKGROUND

A. The Parties

Plaintiff Eli Lilly and Company is a multinational pharmaceutical company headquartered

[1] Because this matter can be decided based on the written submissions, the Court denies Eli Lilly's request for oral argument. Dkt. No. 28 at 1.

in Indiana. Dkt. No. 1 at 5. Defendants are medical clinics in the greater Seattle region and two physicians who operate them. *Id.* The medical clinics, Alderwood Surgical Center LLC and Northwest Nasal Sinus Center P.S., operate under various trade names, each with its own website. *Id.* Alderwood does business as Allure Esthetic, Gallery of Cosmetic Surgery, and Seattle Plastic Surgery. *Id*. Northwest does business on its own website and under the trade name Northwest Face & Body. *Id.*[2]

The two physician defendants are Javad A. Sajan, M.D. and Craig R. Jonov, M.D. *Id*. at 5–6. Sajan owns Alderwood and Northwest. *Id*. Jonov holds himself out as an owner of Seattle Plastic Surgery, which is one of Alderwood's trade names. *Id.* at 6.

B. Eli Lilly's Medicines: Mounjaro® and Zepbound®

Eli Lilly sells Mounjaro® and Zepbound®, the only FDA-approved drugs containing the active ingredient tirzepatide. Dkt. No. 1 at 2. Mounjaro® and Zepbound® are prescribed for adults with type two diabetes, obesity, or excess weight and weight-related medical problems. *Id.*

The FDA approved Mounjaro® on May 13, 2022 and Zepbound® on November 8, 2023.[3] Before being approved, Eli Lilly's new medicines underwent years-long clinical trials, where they were tested for safety, quality, and effectiveness on thousands of patients. Dkt. No. 1 at 2. As a manufacturer of FDA-approved medicines, Eli Lilly follows the FDA's "good manufacturing practices," which are regulations that "provide for systems that assure proper design, monitoring,

[2] Unless stated otherwise, references in this opinion to Alderwood and Northwest are intended to encompass their respective trade names.

[3] *See* https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots-mounjaro (last accessed March 2, 2025) and https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management?os=bingquiz.comdFbing-weekly-quiz-answersdF&ref=app (last accessed March 2, 2025). The Court may take judicial notice of "matters of public record" without converting a motion to dismiss into one for summary judgment. *Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001). FDA releases and other matters published on its website are properly subject to judicial notice. *See, e.g.*, *Immanuel Lake v. Zogenix, Inc*., No. 19-CV-01975-RS, 2020 WL 3820424, at *5 (N.D. Cal. Jan. 27, 2020) ("Courts routinely take judicial notice of FDA guidance documents, many of which also appear on the FDA's public website." (cleaned up)); *Sneed v. AcelRx Pharms., Inc*., No. 21-CV-04353-BLF, 2024 WL 2059121, at *4 (N.D. Cal. May 7, 2024) (taking judicial notice of pages from FDA's website).

and control of manufacturing processes and facilities." *Id.* at 7–8 (cleaned up, quoting FDA explainer on good manufacturing practices). Eli Lilly is also subject to various controls on sterility and safe storage of FDA-approved medicines and must report adverse events. *Id.* at 3.

C. Compounded Tirzepatide

Some medical clinics, including Alderwood and Northwest, offer patients compounded versions of tirzepatide, the active ingredient in Mounjaro® and Zepbound®. Dkt. No. 1 at 3–5. Compounded drugs are created by combining, mixing, or altering the ingredients of a different medication to create a drug that is tailored to the needs of an individual patient. *Id.* at 10.

Compounded drugs differ from FDA-approved medicines in various ways. They do not go through the FDA's approval process and so are not tested for safety, quality, or efficacy in clinical trials. *Id.* at 11. Nor are compounders subject to the FDA's "good manufacturing practices" or the same controls on sterility and safe storages that manufacturers of FDA-approved medicines need to follow. *Id.* at 10. For these reasons, the FDA has warned that "compounded drugs pose a higher risk to patients than FDA-approved drugs." *Id.* at 3 (quoting FDA explainer on drug compounding).

D. Defendants' Advertising Practices

Eli Lilly alleges that Defendants improperly use its Mounjaro® and Zepbound® trademarks to promote the sale of compounded tirzepatide to patients, despite not selling either of Eli Lilly's medicines or being authorized to use Eli Lilly's trademarks. Dkt. No. 1 at 15–19. For example, Eli Lilly alleges that "on several of their websites, Defendants include a supposed 'Seattle Zepbound Weight Loss Program,' sometimes called simply 'ZEPBOUND SEATTLE[.]'" *Id.* at 3. According to Eli Lilly, these "Zepbound Consultations" lead to patients being injected with compounded tirzepatide; they are not administered Zepbound and "there is no such thing as generic or compounded ZEPBOUND®." *Id.* at 4–5. Other examples include promoting compounded

tirzepatide with the prominent header "Zepbound Bellevue & Kirkland." *Id.* at 16–17.

Eli Lilly alleges that this behavior is pervasive:

> On Defendant Northwest's version of this "Zepbound" webpage, Defendant Northwest uses the word "Zepbound" 28 times as part of selling its Unapproved Compounded Drugs. Defendant Alderwood similarly uses the word "Zepbound" 24 times, 33 times, and an astonishing 36 times on the "Zepbound" webpages on the websites of Seattle Plastic Surgery, Gallery of Cosmetic Surgery, and Allure Esthetic respectively—all while not selling ZEPBOUND®.

Id. at 17 (emphasis removed). Although Eli Lilly's complaint primarily gives examples of alleged misuse of the Zepbound® trademark, it also alleges that Defendants have misused the Mounjaro® trademark too. *See, e.g.*, *id.* at 3.

Eli Lilly alleges that these advertising practices are "designed to mislead patients into thinking they were receiving Eli Lilly's MOUNJARO® and ZEPBOUND® medicines—or that the compounded drugs they were receiving were FDA-approved and clinically tested like Eli Lilly's medicines—when they were instead receiving unapproved, unsafe, and unstudied compounded drugs." Dkt. No. 28 at 9; *see also, e.g.*, Dkt. No. 1 at 19.

E. Procedural History

On June 20, 2024, Eli Lilly filed a complaint alleging that Defendants' conduct violates the Lanham Act and Washington's Consumer Protection Act. Dkt. No. 1. The complaint contains four causes of action; the first three are brought under the Lanham Act, 15 U.S.C. § 1051, *et seq.*, and the fourth is brought under Washington's Consumer Protection Act ("CPA"), Wash. Rev. Code. § 19.86.010, *et seq.*:

- Count 1: Trademark Infringement in Violation of 15 U.S.C. § 1114;
- Count 2: Trademark Infringement, False Designation of Origin and Unfair Competition in Violation of 15 U.S.C. § 1125(a)(1)(A);
- Count 3: False and Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B); and

- Count 4: Unfair and Deceptive Trade Practices in Violation of Wash. Rev. Code. § 19.86.010, *et seq.*

Id. at 20–25. Eli Lilly seeks a declaratory judgment, injunctive relief halting the alleged wrongdoing, an order requiring Defendants to take various corrective actions, and an award of damages and fees. *Id.* at 25–27.

On September 18, 2024, Defendants filed a motion to dismiss. Dkt. No. 24. They argue that the federal trademark claims fail to state a claim for relief and that the federal Food, Drug, and Cosmetic Act ("FDCA") preempts Eli Lilly's state law claim and otherwise bars its federal false advertising claim. *Id.* at 5–9. They also argue that Eli Lilly's claims are barred by the patient-physician privilege and related public policy considerations. *Id.* at 9–11.

II. DISCUSSION

A. Jurisdiction

The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because Eli Lilly asserts claims under the Lanham Act, 15 U.S.C. § 1051 *et seq.* Dkt. No. 1 at 6. The Court has supplemental jurisdiction over Eli Lilly's state law CPA claim because it arises from the same underlying facts as the federal claims. *See* 28 U.S.C. § 1367(a); *Bahrampour v. Lampert*, 356 F.3d 969, 978 (9th Cir. 2004) ("A state law claim is part of the same case or controversy when it shares a common nucleus of operative fact with the federal claims and the state and federal claims would normally be tried together." (quotation marks omitted)).

Venue is proper in this Court because a substantial part of the events giving rise to the claim occurred in this judicial district. 28 U.S.C. § 1391(b)(2).

B. Legal Standards

When deciding a motion under Federal Rule of Civil Procedure 12(b)(6), a court must assume the truth of the complaint's factual allegations and credit all reasonable inferences arising

from those allegations. *Sanders v. Brown*, 504 F.3d 903, 910 (9th Cir. 2007). The court "need not accept as true conclusory allegations that are contradicted by documents referred to in the complaint." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). Instead, the plaintiff must point to factual allegations that "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Although "detailed factual allegations" are not required, a complaint must include "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.* A complaint "that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Id.* (quoting *Twombly*, 550 U.S. at 555).

C. Eli Lilly's State Law CPA Claim

Defendants argue that Eli Lilly's state law CPA claim is preempted by the FDCA. Dkt. No. 24 at 5–7. Eli Lilly contends that Defendants "ignore[] [its] actual allegations," and that the allegations they cite "do not support [their] characterization" of its claim. Dkt. No. 28 at 13. Before addressing the viability of the CPA claim, the Court briefly discusses the applicable legal and regulatory background.

1. Preemption Generally

"Preemption derives from the Supremacy Clause, which 'invalidates state laws that interfere with, or are contrary to, federal law.'" *Am. Apparel & Footwear Ass'n, Inc. v. Baden*, 107 F.4th 934, 938 (9th Cir. 2024) (quoting *Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 712 (1985)). Preemption is fundamentally a question of Congressional intent. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). Courts analyzing preemption are to presume that unless a "clear and manifest purpose of Congress" exists, federal acts should not supersede the states'

historic police powers. *Id.*; *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484–85 (1996).

Federal preemption can be either express or implied. *Kroessler v. CVS Health Corp*., 977 F.3d 803, 808 (9th Cir. 2020). Express preemption exists when a statute explicitly addresses preemption. *Id.* Implied preemption includes conflict and field preemption, *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013), which occur when a state law actually conflicts with federal law (conflict preemption) or a federal law occupies a legislative field to such an extent that it is reasonable to conclude that Congress left no room for state regulation in that field (field preemption), *see Chae v. SLM Corp*., 593 F.3d 936, 941 (9th Cir. 2010).

2. Preemption Under the FDCA

Congress enacted the FDCA to "promote the public health" by, among other things, ensuring that "human . . . drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). Congress gave the FDA the sole authority to police violations of the FDCA, 21 U.S.C. § 393, and foreclosed any private right of action by requiring that "proceedings for the enforcement, or to restrain violations" of the FDCA "shall be by and in the name of the United States," 21 U.S.C. § 337(a). The FDCA provides the FDA with a range of enforcement mechanisms, such as injunction proceedings, civil and criminal penalties, and seizure. 21 U.S.C. §§ 332–34, 372. Although citizens may petition the FDA to take administrative action, 21 C.F.R. §§ 10.25(a), 10.30, as noted, they cannot privately enforce the statute, *Perez v. Nidek Co., Ltd*., 711 F.3d 1109, 1119 (9th Cir. 2013).

The leading case on implied preemption[4] under the FDCA is *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341 (2001). There, the Supreme Court held that the FDCA impliedly preempts state law claims premised on FDCA violations. *Davidson v. Sprout Foods, Inc*., 106

[4] Express preemption does not apply here. Although the FDCA contains express preemption provisions covering food, 21 U.S.C. § 343-1, medical devices, *id.* § 360k, non-prescription drugs, *id.* § 379r, and cosmetics, *id*. § 379s, there is no express preemption provision covering prescription drugs, *see Wyeth*, 555 U.S. at 574.

F.4th 842, 848 (9th Cir. 2024) (citing *Buckman*). The *Buckman* preemption analysis depends on whether plaintiffs are "attempting to use causes of action available under state law to claim damages for violations of duties owed under the federal FDCA." *Id.* at 848. If so, the claim is impliedly preempted because it "inevitably conflict[s]" with the federal government's exclusive enforcement authority over the FDCA's regulatory scheme. *Id*. But if the claim relies on an independent state law duty, even if parallel to an FDCA duty, then it is not preempted under *Buckman*. *Id.* at 850.[5]

A pair of recent Ninth Circuit decisions illustrate this principle.

In *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc*., plaintiffs claimed that drug compounding facilities violated state statutes prohibiting the sale of drugs not approved by the FDA. 48 F.4th 1040, 1044 (9th Cir. 2022). The Ninth Circuit found that deciding the claim required litigating whether the facilities qualified for an exception to FDA approval, i.e., whether an FDCA violation had occurred. *Id*. at 1049. Because this was a task reserved for the FDA, the panel held that the claim was impliedly preempted as an attempt to privately enforce the FDCA's requirements for compounding facilities. *Id.* at 1050–51.

The second of these cases is *Hope Medical Enterprises, Inc. v. Fagron Compounding Services, LLC*, No. 22-55173, 2023 WL 4758454 (9th Cir. July 26, 2023). In that case, a drug manufacturer alleged that the defendants' sale of compounded drugs without premarket approval violated several states' unfair competition laws. *Id.* at *1. The district court denied the defendants'

[5] Ninth Circuit precedent discusses a "narrow gap" that plaintiffs must fit their claim through to escape FDCA preemption in certain circumstances: "the plaintiff must be suing for conduct that *violates* the FDCA" (or else the claim is expressly preempted) but "the plaintiff must not be suing *because* the conduct violates the FDCA" (or else it is impliedly preempted under *Buckman*). *Perez*, 711 F.3d at 1120 (cleaned up). But circumstances matter: *Perez* and other cases applying this "narrow gap" rule involve sections of the FDCA with an express preemption clause. *See id.* (medical device case subject to express preemption provision in § 360k(a)). Because there is no express preemption provision in the FDCA's section covering prescription drugs, Eli Lilly's claim need not run this gauntlet. So long as Eli Lilly's state law claim is not an attempt to privately enforce the FDCA's requirements, which would violate *Buckman*, it is not preempted.

motion to dismiss, but the Ninth Circuit reversed and held that "[f]ederal law preempts state law when the state requirement 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* (quoting *Stengel*, 704 F.3d at 1231). Because Hope Medical sought to "'enforce its interpretation' of the FDCA's rules for manufacturing compounded drugs against a competitor, the FDCA's prohibition on private enforcement and the doctrine of implied preemption bar[red] the suit." *Id.* (quoting *Nexus*, 48 F.4th at 1050–51).

3. Eli Lilly's CPA Claim is Dismissed

Defendants argue that Eli Lilly's claim is premised on an FDCA violation and so is preempted under the *Hope Medical* line of cases. Dkt. No. 24 at 6–7. Specifically, they contend that the CPA claim "seek[s] to impose [Eli] Lilly's interpretations of FDCA rules," under which Defendants' advertising of compounded tirzepatide violate the FDCA. *Id.* at 6–7. Therefore, Eli Lilly's "allegations go to the core of the FDA's enforcement authority[.]" *Id.* Eli Lilly contests Defendants' characterization of its allegations. Dkt. No. 28 at 13–14.

The parties' dispute over what exactly Eli Lilly is alleging highlights the key problem with its CPA claim: rather than explaining specifically how Defendants' acts constitute unfair and deceptive trade practices, Eli Lilly leaves Defendants (and this Court) to guess by stating in conclusory fashion that "Defendants' acts" meet the various requirements of the CPA. Dkt. No. 1 at 23–24. For ease of reference, these conclusory allegations are reproduced here:

> 99. Lilly repeats and realleges each and every allegation above as if fully set forth herein.
>
> 100. Defendants' acts constitute unfair and deceptive trade practices, in violation of the laws of the State of Washington, including RCW 19.86.010 et seq.
>
> 101. RCW 19.86.010 states that "Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."
>
> 102. Plaintiff is a "person" within the meaning of RCW 19.86.090 and has standing

to bring an action based on unfair and deceptive trade practices.

103. Defendants' acts unethically exploit the Lilly Marks in a material manner likely to deceive and mislead, and therefore be substantially injurious to, the public, including a substantial portion of consumers. These acts therefore offend the established public policy of the State of Washington.

104. Defendants' acts include making false or misleading representations in their advertising and promotional materials in a material manner likely to deceive and mislead, and therefore be substantially injurious to, the public, including a substantial portion of consumers. These acts therefore offend the established public policy of the State of Washington.

105. The public interest is harmed by Defendants' conduct because such conduct has the capacity to injure any of Defendants' patients or prospective patients. Members of the public are likely to suffer injury from Defendants' acts by purchasing Defendants' Unapproved Compounded Drugs that they believe to be Lilly's MOUNJARO® or ZEPBOUND®.

106. Defendants' Unapproved Compounded Drugs do not have the same safety, quality, and effectiveness as MOUNJARO® or ZEPBOUND®. Defendants' deceptive conduct and regulatory non-compliance therefore enabled it to obtain an unfair and illegal business advantage over Lilly.

107. Upon information and belief, Defendants' deceptive, unfair, and fraudulent business practices were willfully undertaken, as described in the allegations above.

108. As a direct and proximate result of Defendants' unfair and deceptive trade practices, Lilly has suffered and will continue to suffer significant monetary damages and discernible injury to its business, including by a loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® medicines and the Lilly Marks. Defendants therefore have unfairly profited from the actions alleged.

109. By reason of Defendants' acts, Lilly's remedy at law is not adequate to compensate for the injuries inflicted by Defendants. Accordingly, Lilly is entitled to entry of preliminary and permanent injunctive relief, in addition to treble damages, attorneys' fees, and costs.

Dkt. No. 1 at 23–25. This is a classic "shotgun pleading" wherein "each count adopts the allegations of all preceding counts, causing each successive count to carry all that came before and the last count to be a combination of the entire complaint." *Weiland v. Palm Beach Cnty. Sheriff's Off.*, 792 F.3d 1313, 1321 (11th Cir. 2015). This kind of complaint "mak[es] it nearly impossible for Defendants and the Court to determine with any certainty which factual allegations give rise to

which claims for relief." *Jackson v. Bank of Am., N.A.*, 898 F.3d 1348, 1356 (11th Cir. 2018); *see also E.K. v. Nooksack Valley Sch. Dist.*, No. C20-1594-JCC, 2021 WL 1531004, at *2 (W.D. Wash. Apr. 19, 2021) (same). Such a complaint therefore fails to satisfy Rules 8 and 10 of the Federal Rules of Civil Procedure, which require that a complaint include "a short and plain statement of the claim showing that the pleader is entitled to relief," and that "each claim founded on a separate transaction or occurrence . . . must be stated in a separate count" if "doing so would promote clarity." Fed. R. Civ. P. 8(a)(2), 10(b); *see also Twombly*, 550 U.S. at 555 (a complaint must "give the defendant fair notice of what the claim is and the grounds upon which it rests" (cleaned up)).

Eli Lilly does not explain in Count IV how "Defendants' acts" (1) "constitute unfair and deceptive trade practices," (2) "exploit the Lilly Marks in a material manner likely to deceive and mislead," (3) "include making false or misleading representations in their advertising and promotional materials in a material manner likely to deceive and mislead," (4) "ha[ve] the capacity to injure any of Defendants' patients or prospective patients," or (5) resulted in "significant monetary damages and discernible injury to [Eli Lilly's] business." Dkt. No. 1 at 23–24. Nor does it identify which of Defendants' acts it is referring to. Instead, Eli Lilly apparently relies on its "incorporation by reference" paragraph, requiring Defendants and this Court to inspect the numerous preceding paragraphs to identify potential facts supporting these allegations. "[W]hile incorporation by reference is a useful tool to streamline pleadings, it is not intended to create guesswork as to which facts support which claims." *E.K.*, 2021 WL 1531004, at *3 (cleaned up). The Court cannot do Eli Lilly's job for it by picking out needles of factual support for its CPA claim from its 98-paragraph haystack. *In re Borsotti*, No. CC-19-1193-FSG, 2021 WL 1103624, at *5 (B.A.P. 9th Cir. Mar. 23, 2021) (the district court "is always a neutral arbiter that should not help any party prosecute" his or her case); *see also Todd R. v. Premera Blue Cross Blue Shield of*

Alaska, 825 F. App'x 440, 442 (9th Cir. 2020) ("Under the principle of party presentation, courts must presume that parties represented by competent counsel know what is best for them, and are responsible for advancing the facts and argument entitling them to relief." (quotation marks and citation omitted)). Furthermore, Eli Lilly cannot salvage its deficient complaint by supplying specifics and/or new theories in its response brief. *See, e.g.*, Dkt. No. 28 at 14 ("As accurately characterized, Eli Lilly's CPA claim alleges that Alderwood's advertising conveys the false impression that its compounded drugs have received FDA approval and have . . . passed clinical tests just like [Eli] Lilly's medicines."). "It is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." *Frenzel v. AliphCom*, 76 F. Supp. 3d 999, 1009 (N.D. Cal. 2014); *see also Fairhaven Health, LLC v. BioOrigyn, LLC*, No. C19-1860-RAJ, 2020 WL 5630473, at *10 (W.D. Wash. Sept. 21, 2020).

In the one paragraph that includes some semblance of a theory for its CPA claim, Eli Lilly veers into FDCA territory. It complains that Defendants' unspecified "deceptive conduct and *regulatory non-compliance*" enabled them to "obtain an unfair and illegal business advantage over [Eli] Lilly." Dkt. No. 1 at 24 (emphasis added). The FDCA's prohibition of private rights of action prevents Eli Lilly from litigating non-compliance with its regulations. *Nexus Pharms., Inc.*, 48 F.4th at 1048–49; *see also* 21 U.S.C. § 353a.

For these reasons, Eli Lilly's CPA claim is dismissed. Defendants argue that Eli Lilly should not be afforded leave to amend its complaint, Dkt. No. 24 at 11, but such leave should be denied "only if there is strong evidence of undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, or futility of amendment[.]" *Sonoma Cnty. Ass'n of Retired Emps. v. Sonoma Cnty.*, 708 F.3d 1109, 1117 (9th Cir. 2013) (cleaned up). The deadline for amending pleadings has not yet passed, Dkt. No. 33 at

1, Eli Lilly has not previously amended its complaint, and Defendants make no showing that it has unduly delayed or acted in bad faith or with a dilatory motive. The Court therefore grants it leave to amend.

D. Eli Lilly's Federal False Advertising Claim is Not Barred by the FDCA

Defendants' argument that Eli Lilly's false advertising claim brought under the Lanham Act is barred by the FDCA lacks merit. As an initial matter, Defendants rely on outdated case law for the proposition that the FDCA limits claims under the Lanham Act. Dkt. No. 24 at 7–8. In 2014, the Supreme Court in *POM Wonderful* held that "the FDCA and the Lanham Act complement each other" and that "Congress did not intend the FDCA to preclude Lanham Act suits[.]" *POM Wonderful LLC v. Coca-Cola Co*., 573 U.S. 102, 106, 121 (2014). The two statutes have different goals: "the FDCA protects public health and safety" whereas "the Lanham Act protects commercial interests against unfair competition[.]" *Id.* at 115. After *Pom Wonderful*, there is a general presumption that Lanham Act claims based on FDCA-regulated products (including prescription drugs) are permissible. *Id.* at 115–16 ("Allowing Lanham Act suits takes advantage of synergies among multiple methods of regulation.").

Defendants offer no reason why this case should be an exception to that general rule. Although they argue that "the most critical issue to [Eli] Lilly's case is the issue of FDA approval for compounded Tirzepatide," Dkt. No. 24 at 8, that is not what Eli Lilly's complaint focuses on, nor a critical issue to its case. As Eli Lilly notes, "the parties agree that [Defendants'] compounded drugs have not received FDA approval." Dkt. No. 28 at 12. Instead, "[t]he most critical issue to [Eli] Lilly's false advertising claim is instead whether [Defendants'] advertising creates the false impression that the compounded drugs it offers are FDA-approved and clinically tested." *Id.*; *see also* Dkt. No. 1 at 18 (Defendants' "Seattle Zepbound Weight Loss Program" webpage "includes an entire section devoted explaining that 'Zepbound Seattle' (a non-existent product) 'is an FDA-

approved medication.'"); *id.* at 18–19 ("Defendants' prominent and misleading use of the Lilly Marks is likely to cause consumers to falsely believe that they are purchasing MOUNJARO® and/or ZEPBOUND®, that Defendants are a source for Lilly's FDA-approved treatment options MOUNJARO® and/or ZEPBOUND®, that Defendants' Unapproved Compound Drugs are as safe and effective as Lilly's FDA-approved treatment options MOUNJARO® and ZEPBOUND®, and/or that Defendants' services are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.") That is not, as Defendants argue, "an FDCA labeling and disclosure question[.]" Dkt. No. 29 at 5.

Based on the above, the Court finds the federal false advertising claim is not barred by the FDCA.

E. Eli Lilly States Federal Trademark Claims

Defendants argue that Eli Lilly fails to state plausible claims for federal trademark infringement and false designation of origin (counts 1 and 2). Dkt. No. 24 at 8–9.

Claims for federal trademark infringement under 15 U.S.C. § 1114 and false designation of origin under 15 U.S.C. § 1125 are typically analyzed together because the "analysis under the two provisions is oftentimes identical." *Brookfield Commc'ns, Inc. v. W. Coast Ent. Corp.*, 174 F.3d 1036, 1047 nn.6 & 8 (9th Cir. 1999). The main difference is that a Section 1114 claim requires ownership of a registered trademark while a Section 1125 claim does not, *see id.*, but Eli Lilly's ownership of the Mounjaro® and Zepbound® registered trademarks is not in dispute.

Thus, the analysis for both claims is the same here; that is, whether Eli Lilly's complaint plausibly alleges that "the defendant's use of the same or similar mark would create a likelihood of consumer confusion." *Murray v. Cable Nat. Broad. Co*., 86 F.3d 858, 860 (9th Cir. 1996); *see also United States Futsal Fed'n v. USA Futsal LLC*, No. 17-CV-04206-LB, 2018 WL 2298868, at *10–12 (N.D. Cal. May 21, 2018) (listing elements of both claims). "The confusion must be

probable, not simply a possibility." *Murray*, 86 F.3d at 861 (quotation marks omitted).

"Courts analyzing the likelihood of confusion look at eight factors: (1) the strength of the mark; (2) the similarity of the marks; (3) proximity of the goods/services; (4) similarity in the marketing channels used; (5) the type of goods/services and the degree of care likely to be exercised by purchasers; (6) evidence of actual confusion; (7) defendant's intent in selecting its mark; and (8) likelihood of expansion into other markets." *Lahoti v. Vericheck, Inc*., 636 F.3d 501, 507 (9th Cir. 2011) (citing *AMF Inc. v. Sleekcraft Boats*, 599 F.2d 341–49, 348 (9th Cir. 1979)). This is flexible test; the *Sleekcraft* factors are "not a rote checklist." *Rearden LLC v. Rearden Com., Inc*., 683 F.3d 1190, 1209 (9th Cir. 2012).

"Likelihood of confusion is typically a question of fact." *Motul S.A. v. USA Wholesale Lubricant, Inc*., 686 F. Supp. 3d 900, 914 (N.D. Cal. 2023); *see also Clicks Billiards, Inc. v. Sixshooters, Inc*., 251 F.3d 1252, 1264 (9th Cir. 2001). "Given the open-ended nature of this multi-prong inquiry . . . summary judgment on 'likelihood of confusion' grounds is generally disfavored," *Rearden*, 683 F.3d at 1210, and dismissals at the motion to dismiss stage on this basis even more so. For that reason, lower courts will rarely dismiss a complaint at the pleadings stage on likelihood of confusion grounds, because in most cases doing so would require it to make factual determinations. *See Gearhead Prods., Inc. v. Gearhead Outfitters, Inc*., No. 2:23-CV-02331-KJM-JDP, 2024 WL 3821881, at *5 (E.D. Cal. Aug. 14, 2024) (citing cases).

The Court finds that Eli Lilly's complaint sufficiently alleges likelihood of confusion. It alleges that (1) the marks Mounjaro® and Zepbound® are "inherently distinctive"; (2) the marks have been used to extensively market Eli Lilly's products throughout the United States "in many different channels, directed both to healthcare professionals and to patients"; (3) Defendants' use of the marks "conveys the unmistakable impression that Defendants are offering for sale Lilly's MOUNJARO® and ZEPBOUND®, and/or an FDA-approved generic version thereof," when they

are not; and (4) Defendants market their compounded tirzepatide side-by-side with Eli Lilly's marks in a manner that would "cause consumers to falsely believe that they are purchasing MOUNJARO® and/or ZEPBOUND®, . . . that Defendants' Unapproved Compound Drugs are as safe and effective as Lilly's FDA-approved treatment options MOUNJARO® and ZEPBOUND®, and/or that Defendants' services are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly." Dkt. No. 1 at 8–9, 15–19. Defendants argue that Eli Lilly's complaint does not plausibly show a likelihood of confusion, because "Defendants prescribe both Zepbound and compounded Tirzepatide to patients, as medical consultations warrant, in the exercise of the physician's discretion." Dkt. No. 24 at 9 (emphasis omitted). That argument is premised on a fact not in the complaint (that Defendants can prescribe Eli Lilly's medicines), and even if the Court were to consider it, it could not conclude that Defendants' advertising is incapable, as a matter of law, of creating a false impression among consumers.

F. Defendants' Other Arguments Also Fail

Defendants also argue that Eli Lilly's claims are barred by Washington's patient-physician privilege. Dkt. No. 24 at 9–11. That argument fails at the threshold. Where, as here, "a case involves both state and federal claims, the federal law of privilege applies to both," *Carter-Mixon v. City of Tacoma*, No. C21-05692-LK, 2022 WL 4366184, at *2 (W.D. Wash. Sept. 20, 2022) (quotation marks omitted), and there is not a federally recognized physician-patient privilege. Wright & Miller, 25 Fed. Prac. & Proc. Evid. § 5524 (1st ed.) ("In federal cases with pendent state claims, federal law applies and there is no [patient-physician] privilege"); *In re Grand Jury Proc.*, 867 F.2d 562, 564 (9th Cir. 1989) ("This circuit has not . . . adopted a physician-patient privilege"), *abrogated on other grounds by Jaffee v. Redmond*, 518 U.S. 1 (1996).

Nor will the Court grant Defendants' motion based on "serious public policy implications flowing from Eli Lilly's lawsuit against practicing physicians." Dkt. No. 24 at 11. Eli Lilly's suit

does not "interpose [it] between doctor and patient," nor does it "arguably constitute unlicensed practice of medicine" or "chill[] physician-patient communication by threatening doctors with expensive lawsuits if they do not prescribe Eli Lilly's medications[.]" *Id.* These concerns fundamentally mischaracterize what Eli Lilly's lawsuit is about. As Eli Lilly notes, its complaint does not target Defendants' prescribing practices, but rather their advertising practices. Dkt. No. 28 at 19. Defendants' attempt to make this case about both is not persuasive. For example, they argue that a consequence of Eli Lilly's suit is that "if a medical provider is going to describe certain drugs on its website, it thereafter must prescribe them to patients and to the exclusion of other products or else be subject to a barrage of trademark claims." Dkt. No. 29 at 3. Defendants' "if, then" framing of the public policy concerns does not accurately capture the gravamen of Eli Lilly's complaint or the nature of the offending advertisements, which do not simply "describe" Eli Lilly's medicines. *See, e.g.*, Dkt. No. 1 at 4 (advertisement using a "Zepbound, Seattle" headline and offering "free . . . Zepbound consultations" with a price listed directly below for "compounded tirzepatide" and no price listed for Zepbound).

III. CONCLUSION

For the reasons stated above, the Court GRANTS IN PART and DENIES IN PART Defendants' Motion to Dismiss. Dkt. No. 24. Should Eli Lilly choose to amend its complaint, it must file both a redlined and clean version of the amended complaint by no later than March 21, 2025.

Dated this 7th day of March, 2025.

Lauren King
United States District Judge