IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

ELI LILLY AND COMPANY,	§	
	§	
Plaintiff,	§	
v.	§	CIVIL ACTION NO. H-23-3521
	§	
REVIVE RX, LLC,	§	
	§	
Defendant.	§	

MEMORANDUM AND OPINION

Federal food-and-drug law has several goals. One is to provide widespread access to life-saving or life-improving drugs. Another is to provide and protect the intellectual-property rights that create the incentives to develop such drugs. Yet a third is to ensure that new drugs enter the market only if they are proven both efficacious and safe. Before new drugs are allowed to enter the market, the Food and Drug Administration subjects them to rigorous scientific review, including randomized and controlled clinical trials. Pharmaceutical companies spend billions of dollars and years on research and development as part of the review and approval process. To provide the incentives necessary for such years of expensive work, federal law rewards drug developers with intellectual-property rights and periods of market exclusivity during which they may sell the first, and often only, FDA-approved drug in a certain class.

Compounding pharmacies have a place in this heavily regulated environment. Not every patient who would benefit from a new drug is able to tolerate it. A patient may be allergic to the FDA-approved version of a new drug, or may need other medications that do not interact well with the new drug. Rather than ignore these complications, federal law allows pharmacies to compound—to take the active ingredient from a new drug and create a slightly different product

that fits a particular patient's specific needs. Because compounding works around both the new-drug approval process and intellectual-property protections, federal law limits the circumstances under which a pharmacy may compound drugs for patients. These limits include requiring a doctor to prescribe the compounded medication and forbidding compounding pharmacies from compounding regularly or in inordinately large amounts drug products that are essentially copies of approved and commercially available drugs. States across the country have incorporated federal standards in their own food-and-drug laws.

Among the most heavily demanded drugs in this country are drugs that reduce the appetite and enable weight loss. Eli Lilly and Company has sued Revive Rx, LLC for abusing this compounding exception to produce mass quantities of drugs that compete with Eli Lilly's Mounjaro® and Zepbound® GLP-1 medications. These medications are based on the active ingredient tirzepatide, which Eli Lilly discovered, that combat obesity and diabetes by targeting our bodies' hunger receptors. They are the only FDA-approved tirzepatide medications on the market. Revive, a nationwide pharmacy, dispenses tirzepatide products to many of its patients. The problem, in Eli Lilly's view, is that Revive is dispensing in mass quantities its own compounded tirzepatide products, not Eli Lilly's FDA-approved versions. Eli Lilly alleges that Revive is dispensing not bespoke tirzepatide products to fit patient-specific needs but mass-manufactured, fixed-dose combinations of tirzepatide and vitamin B6 in regular and inordinate amounts. In short, Eli Lilly alleges that Revive is manufacturing unapproved tirzepatide products in violation of state and federal law, to the detriment of patients, the public, and its business.

Eli Lilly sued Revive for unfair competition under the laws of Alaska, Colorado, Connecticut, Hawai'i, North Carolina, Tennessee, Texas, and Washington. (Docket Entry No. 59). Revive moved to dismiss, arguing that that those states' unfair-competition laws do not allow

claims based on mere compounding, a pharmaceutical practice that is permitted, authorized, and regulated by the states. (Docket Entry No. 70). Based on a careful review of the complaint; the motion to dismiss, the response, and the reply; supplemental briefs; the applicable law; and with the benefit of extensive oral argument by both parties' able counsel, the motion to dismiss is granted in part and denied in part. Eli Lilly's unfair-competition claim under Texas law is dismissed, with prejudice; its claim under Hawai'i law is dismissed, without prejudice; and the remaining claims survive Revive's motion to dismiss. Alaska's and North Carolina's laws include exemptions that may bar at least part of Eli Lilly's claims under them, so Eli Lilly must file a reply alleging facts that state a claim not subject to their statutory exemptions.

I. Background

A. Regulatory Background

The Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits companies from introducing a "new drug" into interstate commerce without FDA approval. 21 U.S.C. § 355(a). A manufacturer generally must submit a new drug application to obtain FDA approval. *Id.* § 355(b)(1). The FDA approves those applications only if it finds that the drug is safe and effective for its intended use under the conditions of use described in the drug's labeling. *Id.* § 355(c)(1)(A), (d). Once a new drug application is approved, facilities producing the new drug generally must comply with "current good manufacturing practice[s]," which "assure that such drug meets [federal] requirements . . . as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports . . . to possess." *Id.* § 351(a)(2)(B).

The FDA's approval process is strict. Each new drug must pass three increasingly demanding phases of medical scrutiny, including double-blind, multi-center, placebo-control clinical trials. *See id.* § 355(b)(1)(A)(i)–(viii), (d). "The FDA conducts inspections to ensure

compliance with" its "manufacturing regulations, reviews the drug's labeling to ensure appropriate disclosure of side effects, warnings, and contraindications, and monitors advertising and promotion to ensure it is not misleading." *Outsourcing Facilities Ass'n v. FDA*, No. 4:25-cv-0174-P, 2025 WL 1239727, at *1 (N.D. Tex. Apr. 24, 2025) (internal citations omitted). "The FDA also requires manufacturers to track and trace each finished product, to promptly report all adverse events, and to conduct further post-approval studies." *Id.* (internal citations omitted). Eli Lilly alleges that, on average, "it takes 10–15 years" to complete this process "and costs $2.6 billion to develop one new FDA-approved medicine." (Docket Entry No. 59 ¶ 19).

Congress rewards drug developers' efforts by awarding them "'new chemical entity exclusivity' whenever the FDA approves a new medicine for the first time." *Outsourcing Facilities*, 2025 WL 1239727, at *1 (citing 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii)). The FDA may not approve another manufacture's application for any drug with the same active ingredient for the next five years. *Id.*

Congress created exceptions to this period of market exclusivity. Drug compounding is one of them. "Drug compounding" refers to the "process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). It "is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product." *Id.* at 361. Compounding "is a traditional component of the practice of pharmacy." *Id.*

The FDCA allows licensed pharmacists and physicians to compound FDA-approved products to address patient-specific needs. *See* 21 U.S.C. § 353a. Pharmacists may, for example, create "a liquid version of a medication for a patient who has trouble swallowing solids,"

Outsourcing Facilities, 2025 WL 1239727, at *2, or "produce a version of that medication that does not contain [an] allergen" to which the patient is allergic, (Docket Entry No. 59 ¶ 40). "For patients with allergies or unique needs that make FDA-approved medications unsuitable, compounded drugs are a godsend." *Eli Lilly & Co. v. Strive Pharmacy LLC*, No. 1:25-cv-00401, 2025 WL 2851658, at *1 (D. Del. Oct. 8, 2025).

Drug compounding is an exception to both federal market-exclusivity awards and safety requirements. Pharmacies and physicians who compound drugs under 21 U.S.C. § 353a (commonly called Section 503A, as drawn from the FDA Modernization Act of 1997, Pub. L. No. 105-115 (1997)) do not need to follow the FDA's current good manufacturing practices. Outsourcing facilities that compound under § 353b (commonly called Section 503B), on the other hand, must follow the current good manufacturing practices and comply with federal registration and reporting requirements. *See id.* § 353b(b), (c); Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act, 83 Fed. Reg. 63651, 63652 (Dec. 11, 2018) [hereinafter cGMP Guidance Under Section 503B]. But under either Section, "compounded drugs are not subject to the safety requirements that apply to FDA-approved drugs because they do not undergo the FDA's premarket review for safety, effectiveness, and quality." *Outsourcing Facilities*, 2025 WL 1239727, at *2.

For this reason, the compounding exception, though important, is limited. Congress imposed six main conditions on drug compounding that limit the practice and ensure the exception does not undermine the regulatory scheme's goals of spurring innovation and ensuring public safety:

> First, [compounded drugs] must be compounded by a licensed pharmacist or physician in response to a valid prescription for an identified individual patient, or, if prepared before the receipt of such a prescription, they must be made only in "limited quantities" and in response to a history of the licensed pharmacist's or

> physician's receipt of valid prescription orders for that drug product within an established relationship between the pharmacist, the patient, and the prescriber. 21 U.S.C. § 353a(a).
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> Second, the compounded drug must be made from approved ingredients that meet certain manufacturing and safety standards, *id.* §§ 353a(b)(1)(A)–(B), and the compounded drug may not appear on an FDA list of drug products that have been withdrawn or removed from the market because they were found to be unsafe or ineffective, *id.* § 353a(b)(1)(C).
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> Third, the pharmacist or physician compounding the drug may not "compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product." *Id.* § 353a(b)(1)(D).
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> Fourth, the drug product must not be identified by the FDA as a drug product that presents demonstrable difficulties for compounding in terms of safety or effectiveness. *Id.* § 353a(b)(3)(A).
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> Fifth, in States that have not entered into a "memorandum of understanding" with the FDA addressing the distribution of "inordinate amounts" of compounded drugs in interstate commerce, the pharmacy, pharmacist, or physician compounding the drug may not distribute compounded drugs out of state in quantities exceeding five percent of that entity's total prescription orders. *Id.* § 353a(b)(3)(B).
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> Finally, . . . the prescription must be "unsolicited," *id.* § 353a(a), and the pharmacy, licensed pharmacist, or licensed physician compounding the drug may "not advertise or promote the compounding of any particular drug, class of drug, or type of drug," *id.* § 353a(c). The pharmacy, licensed pharmacist, or licensed physician may, however, "advertise and promote the compounding service." *Id.*

Thompson, 535 U.S. at 364–65.

The third restriction—which limits drug compounders from producing copies of commercially available drugs—is lifted temporarily when there is a drug "shortage." 21 U.S.C. § 353b(a)(2)(A)(ii). A "shortage" occurs during "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." *Id.* § 356c(h)(2). When a shortage occurs, the FDA places a drug on its "up-to-date list" of drugs "that are determined . . . to be in shortage in the United States." *Id.* § 356e(a). The Secretary must identify "[t]he name of the drug in shortage," "[t]he name of each manufacturer of such drug," "[t]he reason

for the shortage," and "[t]he estimated duration of the shortage as determined by the [FDA]." *Id.* § 356e(b)(1)–(4). After the Secretary places a drug on the list, "Congress permits . . . 503B compounders to compound from that drug's active ingredient—which is otherwise prohibited—including by compounding drugs that are 'essentially a copy' of an approved drug." *Outsourcing Facilities*, 2025 WL 1239727, at *2 (citing 21 U.S.C. §§ 353b(a)(2)(A)(ii), (a)(5), (d)(2)(A)).[1] When a shortage ends, the FDCA's usual restrictions apply again.

"In the face of this ever-expanding federal regulation of drugs . . . , the States have not forfeited their traditional prerogative to police drug safety." *Zyla Life Scis., L.L.C. v. Wells Pharma of Houston, L.L.C.*, 134 F.4th 326, 330 (5th Cir. 2025). States across the country have adopted their own food-and-drug laws that often mirror the federal FDCA. *See id.* As relevant in this lawsuit, Alaska, Colorado, Connecticut, Hawai'i, North Carolina, Tennessee, Texas, and Washington have incorporated federal new-drug approval requirements into their own regulatory regimes. *See, e.g.*, ALASKA STAT. ANN. § 17.20.110(a)(1)–(2); COLO. REV. STAT. § 12-280-131(1); CONN. GEN. STAT. ANN. § 21a-110(a); HAW. REV. STAT. §§ 328-17(a)(1)-(2); N.C. GEN. STAT. § 106-135; TENN. CODE ANN. § 53-1-110; TEX. HEALTH & SAFETY CODE § 431.114(a); WASH. REV. CODE. § 69.04.570. State regulators may enforce these statutes. The question presented on this motion to dismiss is whether private parties may do so too.

B. Factual Background and Procedural History

Eli Lilly and Company is an international medicine corporation that developed Mounjaro® and Zepbound®. (Docket Entry No. 59 ¶¶ 53, 57–58). Mounjaro® is FDA approved to treat type

[1] The parties dispute whether the restriction on producing drugs that are essentially copies of a commercially available drug lifts for both 503A and 503B compounders during a shortage. (*See, e.g.*, Docket Entry Nos. 87, 88). As explained in Part III.C, the FDCA's text and structure lifts the requirement only for 503B compounders.

2 diabetes in adults, and Zepbound® is FDA approved to treat chronic weight management and obstructive sleep apnea in certain adults. (*Id.* ¶ 58). Mounjaro® and Zepbound® are the only two FDA-approved medicines containing the macromolecule called tirzepatide, which Lilly discovered. (*Id.* ¶¶ 57, 59). Because Eli Lilly was the first to gain FDA approval for tirzepatide-based drugs, it enjoys a period of market exclusivity through at least May 2027. (*Id.* ¶ 59).

Revive Rx, LLC is a licensed pharmacy that is authorized to dispense drugs in about forty-four states across the country, including Alaska, Colorado, Connecticut, Hawai'i, North Carolina, Tennessee, Texas, and Washington. (*Id.* ¶ 62). Revive compounds and dispenses drugs that contain the active ingredient tirzepatide. (*Id.*).

Eli Lilly alleges that, unlike its medications, Revive's compounded drugs are not reviewed by FDA, not clinically studied, and often not manufactured under the current good manufacturing practices. (*Id.* ¶¶ 40–42). Eli Lilly alleges that, based on FDA guidance, compounded drugs "do not have the same safety, quality, and effectiveness assurances as approved drugs" and that "[u]nnecessary use of compounded drugs . . . exposes patients to potentially serious health risks." (*Id.* ¶ 43). Eli Lilly further alleges incidents of serious injuries and death caused by compounded drugs. (*Id.* ¶¶ 50, 51, 66–71). Eli Lilly alleges that Revive causes such harms because it does not comply with federal limits on compounding; Eli Lilly's complaint alleges that Revive unlawfully mass produces unapproved prescription drugs and ships them to patients across the country. (*Id.* ¶¶ 62, 65, 72–77).

The gravamen of Eli Lilly's complaint is that Revive is evading federally imposed intellectual-property protections and obligations, placing both its customers and goodwill at risk. (*Id.* ¶¶ 1–9). Eli Lilly alleges that Revive has a history of regulatory violations, including failures to comply with sanitation and instrument sterility requirements and uses of non-pharmaceutical-

grade components. (*Id.* ¶¶ 72–75). Revive, according to the complaint, has recalled compounded tirzepatide drugs because they were sub-potent and has recalled 751 vials of testosterone cypionate that were mislabeled as tirzepatide. (*Id.* ¶¶ 76). Eli Lilly alleges reports of customer complaints about Revive's compounded tirzepatide products, citing customer reviews that complained of watered-down and ineffective medication. (*Id.* ¶ 77). To Eli Lilly, Revive's compounding poses a serious threat not only to the safety of its customers but also the brand-image of the drug that it spent billions of dollars to invent. (*Id.* ¶¶ 78–81). Eli Lilly sued Revive under the unfair-competition laws of Alaska, Colorado, Connecticut, Hawai'i, North Carolina, Tennessee, Texas, and Washington, seeking damages for and a permanent injunction against Revive's allegedly unlawful manufacture, distribution, and dispensing of knockoff tirzepatide products. (Docket Entry No. 59 ¶¶ 82–175, Prayer).

Revive interprets Eli Lilly's complaint differently. It argues that compounding pharmacies provide a vital service. "Without compounders, patients would suffer from limited access." (Docket Entry No. 70 at 2 (citation omitted)). Nor could patients with allergies or unique needs could not access life-altering medications. (*Id.*). That's why, Revive argues, each state has its own set of laws and regulatory schemes that licenses pharmacies and establishes standards for dispensing medications, including compounded medications. (*See* Docket Entry No. 70 at 2–3). Revive highlights that federal law too exempts compounded drugs from the new-drug-approval requirement when certain conditions are met under Sections 503A or 503B of the FDCA. *See* 21 U.S.C. §§ 353a, 353b. In Revive's view, Eli Lilly is prosecuting conduct expressly sanctioned by both federal and state law, and sanctioned for the very reason that it provides a longstanding and necessary medical service. (*See* Docket Entry No. 76 at 1–3). Its bottom-line: Compounding

pharmacies "are as old as pharmacy itself," "are licensed by the states in which they operate," and simply "dispense drugs to patients, always pursuant to doctors' prescriptions." (*Id.* at 3).

Because federal law allows drug compounding under certain circumstances, Revive moved to dismiss Eli Lilly's complaint, arguing that federal law preempted Eli Lilly's state-law tort claims. (Docket Entry No. 14). Revive relied heavily on an opinion in *Zyla Life Sciences, LLC v. Wells Pharma of Houston, LLC*, No. 22-cv-4400, 2023 WL 6301651 (S.D. Tex., 2023), which granted a motion to dismiss unfair-competition claims analogous to Eli Lilly's claims under California, Colorado, Florida, Tennessee, South Carolina, and Connecticut law based on federal preemption. After Revive filed its motion, the plaintiff in *Zyla* appealed to the Fifth Circuit. This court stayed Revive's motion to dismiss pending the resolution of the appeal in *Zyla* because "[t]he Fifth Circuit's decision on the preemption question" was "likely to determine if and how this case may proceed." (Docket Entry No. 36 at 2).

In April 2025, the Fifth Circuit ruled in *Zyla* that federal law did not preempt the plaintiff's unfair-competition claims. *Zyla*, 134 F.4th at 339. This court reinstated this case in July 2025. (Docket Entry No. 57). Eli Lilly filed its first amended complaint shortly afterwards, reasserting its Texas common-law unfair competition claims and adding statutory claims under the laws of the host of states previously discussed. (Docket Entry No. 59). Revive moved to dismiss, arguing that these states' unfair-competition laws do not cover the legally permissible and heavily regulated conduct alleged. (Docket Entry No. 70).

II. The Legal Standard

Rule 12(b)(6) allows dismissal if a plaintiff fails "to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). Rule 12(b)(6) must be read in conjunction with Rule 8(a), which requires "a short and plain statement of the claim showing that the pleader is entitled to

relief." FED. R. CIV. P. 8(a)(2). "[A] complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678, (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

Rule 8 "does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.* (quoting *Twombly*, 550 U.S. at 555). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "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.* (quoting *Twombly*, 550 U.S. at 556). "Conversely, when the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court." *Cuvillier v. Taylor*, 503 F.3d 397, 401 (5th Cir. 2007) (cleaned up).

III. Analysis

Revive moves to dismiss each of the counts in Eli Lilly's complaint. Revive's arguments are tailored to the laws of each state on which Eli Lilly bases its counts, but common threads underlie the arguments that Revive makes. First, Revive argues that the alleged misconduct does not amount to an actionable unfair-competition tort; this theme applies to the claims under Texas, Hawai'i, and Colorado law. (Docket Entry No. 70 at 8–12, 16–22). Second, Revive argues that states' unfair-competition laws exempt regulated conduct, such as the alleged drug compounding; this theme applies to the remaining claims under Alaska, Connecticut, North Carolina, Tennessee, and Washington law. (*Id.* at 5–7, 7–8, 12–16). Lastly, Revive argues that, at a minimum, Eli Lilly

cannot recover damages for the period in which tirzepatide was in shortage—until December 19, 2024—because federal law authorizes compounding during shortages. (*Id.* at 23).

A. Unfair-Competition Claims under Texas, Hawai'i, and Colorado law

Revive argues that the alleged conduct does not amount to an actionable unfair-competition tort under Texas, Hawai'i, and Colorado law. (Docket Entry No. 70 at 8–12, 16–22). Revive's motion to dismiss Eli Lilly's claim under Texas law is granted, with prejudice; its motion to dismiss Eli Lilly's claim under Hawai'i is granted, without prejudice; and its motion to dismiss Eli Lilly's claim under Colorado law is denied.

1. Texas (Count 7)

Eli Lilly alleges that Revive competed unfairly in violation of Texas tort law. (Docket Entry No. 59 ¶¶ 152–65). Unfair competition under Texas law "is the umbrella for all statutory and nonstatutory causes of action arising out of business conduct which is contrary to honest practice in industrial or commercial matters." *Taylor Pub. Co. v. Jostens, Inc.*, 216 F.3d 465, 486 (5th Cir. 2000) (quoting *Am. Heritage Life Ins. Co. v. Heritage Life Ins. Co.*, 494 F.2d 3, 14 (5th Cir. 1974)); *accord United States Sporting Prods., Inc. v. Johnny Stewart Game Calls, Inc.*, 865 S.W.2d 214, 217 (Tex.App.—Waco 1993, writ denied); *Boltex Mfg. Co., L.P. v. Galperti, Inc.*, 827 F. App'x 401, 410 (5th Cir. 2020) (per curiam); *Decorative Ctr. of Houston, L.P. v. Direct Response Publications, Inc.*, 208 F. Supp. 2d 719, 735 (S.D. Tex. 2002). To state an unfair-competition claim, plaintiffs must allege (1) an illegal act by the defendant that (2) interfered with the plaintiff's ability to conduct its business. *W. Rsrv. Medtex Servs., LLC v. Stryker Corp*., No. 18-CV-2604, 2019 WL 13191641, at *8 (S.D. Tex. May 13, 2019) (citing *Taylor Pub. Co.*, 216 F.3d at 486). "Although the illegal act need not necessarily violate criminal law, it must at least be an independent tort." *Taylor Pub. Co.*, 216 F.3d at 486. In other words, "[u]nfair competition

is not," in and of itself, a "tort." *Engenium Sols., Inc. v. Symphonic Techs., Inc.*, 924 F. Supp. 2d 757, 791 (S.D. Tex. 2013). The cause of action must be grounded by the defendant's breach of some independently-recognized duty.

To establish the first element of its claim, Eli Lilly alleges that Revive sold unapproved, new drugs in violation of the Texas Food, Drug, and Cosmetic Act. (Docket Entry No. 36 ¶ 155). That statute prohibits the sale of new drugs, unless they are otherwise approved by federal or state law:

> (a) A person shall not sell, deliver, offer for sale, hold for sale or give away any new drug unless: (1) an application with respect thereto has been approved and the approval has not been withdrawn under Section 505 of the federal Act; and (2) a copy of the letter of approval or approvability issued by the United States Food and Drug Administration is on file with the department if the product is manufactured in this state.
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> (c) This section shall not apply: (1) to any drug that is not a new drug as defined in the federal Act; (2) to any drug that is licensed under the Public Health Service Act (42 U.S.C. 201 et seq.); or (3) to any drug approved by the department by the authority of any prior law.

TEX. HEALTH & SAFETY CODE § 431.114(a), (c).

The parties dispute whether Texas courts consider the alleged violations of the Texas Food, Drug, and Cosmetic Act to be unfair competition, actionable under its common law. (Docket Entry No. 70 at 19–21; Docket Entry No. 75 at 18–21).

Texas case law is sparse on whether violations of state statutes can form the basis of an unfair-competition claim. *See Decorative Ctr.*, 208 F. Supp. 2d at 735 n.32 ("It is not clear that a statutory violation satisfies this requirement."). Some courts have assumed that a plaintiff can state an unfair-competition claim by pointing to a violation of state law. *See, e.g.*, *Schoellkopf v. Pledger*, 778 S.W.2d 897, 904 & n.10 (Tex. App.—Dallas 1989, writ denied) (requiring "some finding of an independent substantive tort or other illegal conduct," such as "statutory violations").

But most complaints that proceed on a common-law unfair-competition claim allege torts or statutory violations that already "fall under the general umbrella of 'business conduct that is contrary to honest practice in industrial or commercial matters.'" *Engenium Sols.*, 924 F. Supp. 2d at 792 (quoting *Am. Heritage*, 494 F.2d at 14). These include "independent causes of action such as trade-secret law, 'palming off' or passing off, and misappropriation, to name only a few." *U.S. Sporting*, 865 S.W.2d at 217; *accord McCarley v. Welch*, 170 S.W.2d 330, 332 (Tex. App.—Dallas 1943, no writ); *see, e.g.*, *AKM Enters., Inc. v. Hayes*, 767 F. Supp. 3d 447, 453 (S.D. Tex. 2025) (unfair competition based on trade-secret statutes); *Boltex Mfg.*, 827 Fed. App'x. at 410 (unfair competition based on Lanham Act); *Engenium Sols.*, 924 F. Supp. 2d at 792 (unfair competition based on breach of fiduciary duty); *W. Rsrv. Medtec*, 2019 WL 13191641, at *8 (unfair competition based on tortious interference with prospective business relations); *Well Cell Glob. LLC v. Calvit*, No. H-22-cv-3062, 2023 WL 175193, at *8 (S.D. Tex. Jan. 12, 2023) (Rosenthal, J.) (unfair competition based on misappropriation of trade secrets and patent infringement). Eli Lilly's reliance on the Texas FDCA is novel.

The broadest use of the unfair-competition label as a basis for relief occurred in *Featherstone v. Independent Service Station Association of Texas*, 10 S.W.2d 124 (Tex. Civ. App.—Dallas 1928, no writ). It is the only case that either party cites in which a violation of a penal statute formed the basis of relief under the unfair-competition label. In *Featherstone*, a service-station operator sued some of his competitors claiming that their use of a lottery scheme in violation of the Texas Penal Code was injuring his business. 10 S.W.2d at 125. The operator sought injunctive relief, raising the question whether a Texas court would enjoin acts "merely on the ground that they constitute violations of penal statutes." *Id.* at 127. The court decided that it would. The court reasoned that the undisputed facts established that the defendants conducted an

illegal lottery scheme and that forcing the operator to rely on the unlikely prospect of a criminal prosecution under the statute would leave him without an adequate remedy at law. *Id.* at 126, 128–29. The court then concluded that the plaintiffs' "business and his right to conduct the same constitute property that a court of equity will protect," *id.* at 128, satisfying the exception to the traditional rule that "courts of equity have no criminal jurisdiction," *id.* at 127.

Featherstone does not stand for the proposition that a violation of state law will automatically establish the first element of a Texas unfair-competition claim. The operator filed a traditional suit in equity. "[E]quity has a different structure, one that emphasizes grievances (rather than wrongs) and narratives (rather than elements)." Samuel L. Bray & Paul B. Miller, *Getting into Equity*, 97 NOTRE DAME L. REV. 1763, 1772 (2022). "[T]o get into the equitable jurisdiction, you needed to have a good story, a real grievance, and a persuasive account of how you wanted equity to do something that was the sort of thing that equity does." *Id.* at 1775. As a result, the *Featherstone* court "did not create a 'generic tort of wrongful competition' or recognize a legal duty owed by businesses to their competitors or to their former customers or suppliers." *Reliable Ambulance Serv., Inc. v. Mercy Hosp. of Laredo*, No. 04-02-00188-CV, 2003 WL 21972724, at *2 (Tex. App.—San Antonio Aug. 20, 2003, pet. denied). It "did not discuss the concepts of duty or breach; nor did it contemplate the award of monetary damages." *Id.*; *accord City of Combine v. Robinson*, No. 05-10-01384-CV, 2011 WL 3570510, at *3 (Tex. App. Aug. 16, 2011—Dallas, no pet.). "Indeed, it was precisely because the[] hardships, inequities, and injustices" caused by the illegal lottery "were *not* actionable" as legal claims "that the grievances that lie in corrective equity had to be brought in equity." Bray & Miller, *supra*, at 1777. The *Featherstone* court's holding is limited to the "idea that equity will not do certain things unless property is involved" and its definition of property—the right to operate a business—that fits the exception. Aditya

Bamzai & Samuel L. Bray, Debs *and the Federal Equity Jurisdiction*, 98 NOTRE DAME L. REV. 699, 710 (2022).

Eli Lilly's claims cannot find support in *Featherstone*'s approach to equitable relief. Texas courts recognize that "*Featherstone* does not stand for the proposition that an injunction will issue because the complained-of conduct is a crime." *John Paul Mitchell Sys. v. Randalls Food Markets, Inc.*, 17 S.W.3d 721, 733 (Tex. App.—Austin 2000, rev. denied). Texas courts today are more stringent in superintending relief to statutory schemes or common-law remedies merely because doing so is allegedly "necessary to protect civil or property rights." *Featherstone*, 10 S.W.2d at 127. The Texas Supreme Court has "outright rejected a 'rule of necessary implication,'" under which courts will "imply a private cause of action to effectuate" a statute's aims when its "enforcement scheme fails to adequately protect intended beneficiaries." *Texas Med. Res., LLP v. Molina Healthcare of Texas, Inc.*, 659 S.W.3d 424, 432 (Tex. 2023) (quoting *Brown v. De La Cruz*, 156 S.W.3d 560, 567 (Tex. 2004)). Instead, "causes of action may be implied only when a legislative intent to do so appears in the statute as written." *Brown*, 156 S.W.3d at 567.

Based on this analysis, at least one Texas court declined to apply *Featherstone* to hold that any statutory violation can support a common-law unfair-competition claim. *Reliable*, 2003 WL 21972724, at *2–3. It instead applied Texas principles governing negligence per se, drawing on the Texas Supreme Court's recognition that the enactment of a criminal statute "does not necessarily mean that [the courts] may recognize a civil cause of action predicated upon that statute." *Id.* at *3 (alterations in original) (quoting *Reeder v. Daniel*, 61 S.W.3d 359, 362 (Tex. 2001)). Courts "must consider whether recognizing such an accompanying civil action would be inconsistent with legislative intent" in "determining whether a penal statute provides the basis for a civil cause of action." *Id.* (quoting *Reeder*, 61 S.W.3d at 362). *Reeder* directed Texas courts to

assess how the legislature has regulated the area, whether it enacted separate criminal and civil schemes relating to the conduct, whether the legislature considered and rejected a private right of action, and whether courts in other jurisdictions have recognized a similar cause of action. *See Reeder*, 61 S.W.3d at 363–64. In *Reliable*, the court applied *Reeder* and concluded that violations of the federal anti-kickback statute could not support "a common law cause of action by a competitor for damages and injunctive relief." 2003 WL 21972724, at *6.

Taken together, the case law suggests that a plaintiff can state a common-law unfair-competition claim based on violations of federal or state statutes if the complaint's allegations could satisfy the principles of negligence per se. This presents two threshold questions, *Morrison v. Quarrington*, No. 12-22-00302-CV, 2024 WL 2858838, at *9 (Tex. App.—Tyler May 15, 2024, pet denied) (citing *Perry v. S.N.*, 973 S.W.2d 301, 305 (Tex. 1998)): (1) whether the Texas legislature intended the statute to supply a cause of action or standard of care for a civil-tort claim, *see Reliable*, 2003 WL 21972724, at *6; *see also Brown*, 156 S.W.3d at 567; *Reeder*, 61 S.W.3d at 363–64; and (2) whether the plaintiff belongs to the class of persons the statute was designed to protect and suffered the type of injury the statute was designed to prevent, *see Perry*, 973 S.W.2d at 305; *Nichols v. McKinney*, 553 S.W.3d 523, 531 (Tex. App.—Waco 2018, pet. denied); *see also Reliable*, 2003 WL 21972724, at *6 (concluding that there is no "common law cause of action *by a competitor*" based on the federal anti-kickback statute (emphasis added)); *Engenium Sols.*, 924 F. Supp. 2d at 792 (asking whether the tort fell under the general umbrella of dishonest business conduct).

Under this formulation, there is no "common law cause of action by a competitor for damages and injunctive relief for violation," *Reliable*, 2003 WL 21972724, at *6, of the Texas Food, Drug, and Cosmetic Act.

Texas courts are unlikely to permit negligence per se actions for competitors based on violations of the Texas FDCA. The Texas FDCA is a comprehensive regulatory scheme, enforced by various officials from the local to the state level. TEX. HEALTH & SAFETY CODE § 431.054, .058, .0585, .060(a)–(b). It supplies an exhaustive list of thirty-seven prohibited categories of activity. *Id.* § 431.021(a)–(kk). Many of these prohibited activities are defined in greater detail throughout the subchapter, and those sections often provide specified exceptions to the prohibition, *see, e.g.*, *id.* § 431.113, ranging from the predictable, *id.* § 431.114(c) (excepting from liability drugs approved by state or federal authorities), to the surprisingly obscure, *id.* § 431.141(a) (excepting properly-labeled "coal-tar hair dye"). The Act further provides a sliding scale of remedies for violations of the activity, including criminal prosecutions, *id.* § 431.059, administrative and civil monetary penalties and assessments, *id.* § 431.054, .0585, injunctions to restrain prohibited actions, *id.* § 431.047, emergency orders to embargo, detain, condemn, or destroy prohibited items, *id.* § 431.045, .049, .0495, .050, .051, .053, and license revocation to prevent violators from conducting further business, *id.* § 431.207. The Texas legislature has actively regulated the area and created detailed criminal and civil enforcement schemes. *See Reliable*, 2003 WL 21972724, at *3 (citing *Reeder*, 61 S.W.3d at 363–64).

Courts have concluded that plaintiffs cannot state negligence per se claims under the federal FDCA for similar reasons. *See, e.g.*, *Baker v. Smith & Nephew Richards, Inc.*, 1999 WL 811334, at *8 (Tex. Dist. June 7, 1999), *aff'd on other grounds sub. nom., McMahon v. Smith & Nephew Richards, Inc.*, 2000 WL 991697 (Tex. App.—Houston [14th Dist.] July 20, 2000) (mem. op.); *accord Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002); *Jackson v. Tae Jin Kim*, No. 2:02-CV-200, 2004 WL 6040969, at *4 (E.D. Tex. Sept. 27, 2004); *Holland v. Hoffman-La Roche, Inc.*, No. 3-06-cv-1298-BD, 2007 WL 4042757, at *3 (N.D. Tex. Nov. 15,

2007); *Monk v. Wyeth Pharms., Inc.*, No. SA-16-cv-1273-XR, 2017 WL 2063008, at *8 (W.D. Tex. May 11, 2017); *Sweezey v. C.R. Bard Inc.*, No. 3:19-cv-2172-S, 2020 WL 1237394, at *1 (N.D. Tex. Mar. 12, 2020).

Eli Lilly responds that the text of the Texas FDCA is materially different from the federal FDCA. (Docket Entry No. 75 at 19–20). It highlights that federal law limits enforcement to government officials and provides that enforcement proceedings brought under the law "shall be by and in the name of the United States." 21 U.S.C. § 337(a). It argues that, in contrast, the Texas FDCA provides only that some Texas authorities "shall" enforce the act and that other officials "may" do so. TEX. HEALTH & SAFETY CODE § 431.054, .058, .0585, .060(a)–(b). Because Texas could have adopted the exclusivity language from federal law, but chose not to, Eli Lilly reasons that it can privately enforce violations of the Texas FDCA. Eli Lilly's close attention to the statute's text is helpful, but, in this case, it misses the forest for the trees. Although the Texas FDCA does not include the federal FDCA's express restriction on private enforcement, the structure of the Texas FDCA's enforcement scheme forecloses private enforcement through common-law unfair-competition torts.

Under the Texas FDCA, enforcement actions start with the Texas Department of State Health Services. The statute vests in the department the authority to inspect and subpoena entities suspected of violating it. *Id.* § 431.042–44. The statute then makes the department the first mover on enforcement actions against those entities. The department may move for injunctions or other emergency remedies under the statute. *Id.* § 431.045, .047, .0495. It may also assess administrative penalties. *Id.* § 431.054–56. Other state officials then act the request of the department. *See, e.g.*, *id.* § 431.058 (providing that the Attorney General of Texas "at the request of the department may bring a civil action to recover an administrative penalty"); *id.* § 431.0585(a)

("At the request of the department, the attorney general or a district, county, or city attorney shall institute an action in district court to collect a civil penalty from a person who has violated Section 431.021."); *id.* § 431.060(a) ("The attorney general, or a district, county, or municipal attorney to whom the department or a health authority reports a violation of this chapter, shall initiate and prosecute appropriate proceedings without delay."). The statute also vests the department with the discretion not "to report for prosecution or the institution of proceedings . . . a minor violation . . . if the department or health authority believes that the public interest is adequately served by a suitable written notice or warning." *Id.* § 431.061. Although the Texas FDCA does not include an express restriction on private enforcement, the statute's enforcement structure makes Eli Lilly's distinction one without a difference. Texas placed the discretion to enforce, or not to enforce, its FDCA almost exclusively in the Texas Department of State Health Services.

The Texas legislature—by vesting the bulk of the investigatory and prosecution authority in the department; by making other state officials agents of the department in enforcing the statute; and by vesting in the department the discretion not to report violations for enforcement by other state officials and entities—intended for the State to be the FDCA's enforcer. Allowing "a private citizen to assert a common law claim based solely on an alleged violation of this criminal statute, in a case in which the" State "has not sought to prosecute, enjoin, or civilly sanction the alleged violation, would thwart the carefully-crafted remedies provided by" Texas "in enacting this legislation and contravene" its "decision not to create a private right of action for a violation of the statute." *Reliable*, 2003 WL 21972724, at *6 (alterations adopted).

The purpose behind the Texas FDCA bolsters this reading of the text. The Texas FDCA, and its provision regulating the use of prescription drugs, were not enacted to protect competitors. *See id.* at *6 (declining to recognize an unfair-competition claim in part because Congress enacted

the anti-kickback statute to protect "the beneficiaries of federal health care programs, the taxpayers, and governmental budgets," not competitors). The Texas legislature enacted the FDCA to protect patients from unsafe and ineffective drugs. In determining penalties, administrative agencies and courts consider the "hazard posed to the public health and safety by the violation." TEX. HEALTH & SAFETY CODE § 431.0585(c)(3), 431.054(b)(3). The department's implementing regulations further emphasize that they "ensure the safety and efficacy of prescription drugs." 25 TEX. ADMIN. CODE § 229.419. Eli Lilly does not belong to the class of persons the statute was designed to protect and did not suffer the type of injury the statute was designed to prevent. *Perry*, 973 S.W.2d at 305. Personal injury or product-liability claims may be within the statute's wheelhouse, but unfair-competition claims are not.

Enforcing an unfair-competition tort through violations of the Texas FDCA also does not fit Texas's tort scheme in full view. "[O]ther protections" address the harms that Eli Lilly attempts to redress through the Texas FDCA. *Kinsel v. Lindsey*, 526 S.W.3d 411, 424 (Tex. 2017). Eli Lilly alleges that it is harmed because "sales made by Revive of its compounded tirzepatide products would have been made by Lilly but for Revive's unlawful and unfair competition." (Docket Entry No. 59 ¶ 80). But Texas law already includes the tort of misappropriation, which prevents competitors from using a product that the plaintiff developed through extensive time, labor, skill, and money. *U.S. Sporting*, 865 S.W.2d at 218; *Alcatel USA, Inc. v. DGI Techs., Inc.*, 166 F.3d 772, 788 (5th Cir. 1999). Eli Lilly also alleges that the poor quality of Revive's tirzepatide products harms its goodwill because "consumers are likely to conclude that tirzepatide is ineffective in general." (Docket Entry No. 59 ¶ 81). Yet Texas law guards against this harm by imposing liability on defendants who use "a trade name similar to that of the plaintiff on products that are markedly inferior or of a different quality and nature than those of the plaintiff." *Express*

One Int'l, Inc. v. Steinbeck, 53 S.W.3d 895, 899–900 (Tex. App.—Dallas 2001, no pet.); *see John Paul Mitchell Sys.*, 17 S.W.3d at 736. Eli Lilly may or may not be able to state claims under these torts. Federal intellectual-property law often preempts Texas misappropriation claims, *see Digital Drilling Data Sys., L.L.C. v. Petrolink Servs., Inc.*, 965 F.3d 365, 379 (5th Cir. 2020) (citing *Motion Med. Techs., L.L.C. v. Thermotek, Inc.*, 875 F.3d 765, 775 (5th Cir. 2017)), and Eli Lilly must establish a protectable intellectual-property or trademark interest in tirzepatide to state an infringement or dilution-like claim, *see Steinbeck*, 53 S.W.3d at 899. But the fact that the claims generally fit the allegations in Eli Lilly's complaint suggests that there is little reason to expand tort liability through the Texas FDCA.

A comparison of unfair-competition law in Texas, as opposed to those in other states, confirms this conclusion. Only "consumers," not competitors or even large companies like Eli Lilly, may enforce Texas's Deceptive Trade Practices Act. TEX. BUS. COM. CODE § 17.50(a); *see id.* § 17.45(4) (defining "consumer" to exclude "a business consumer that has assets of $25 million or more"). By contrast, other states' unfair-competition laws include far broader protections, allowing "a person" or "any person" to file suit. *See, e.g.*, ALASKA. STAT. 45.50.531(a); COLO. REV. STAT § 6-1-113(1)(c); CONN. GEN. STAT. § 42-110g(a); HAW. REV. STAT. § 480-2(e); N.C. GEN. STAT. ANN. § 75-16; TENN. CODE ANN. § 47-18-109(a)(1); WASH. REV. CODE 19.86.090. Their unfair-competition laws, as Eli Lilly argues throughout its brief, also include capacious language that make actionable violations of the state food-and-drug laws. (*See* Docket Entry No. 75). Texas does not have such a statute, which is why Eli Lilly relies on a novel common-law claim. These differences result from the Texas legislature's deliberate choices, which its courts cannot contravene. *See Texas Med. Res.*, 659 S.W.3d at 432.

For these reasons, Texas courts likely would not allow Eli Lilly to pursue an unfair-competition claim based on violations of the Texas FDCA. Eli Lilly's unfair-competition claim is not legally cognizable. It is dismissed with prejudice.

2. Hawai'i (Count 4)

Eli Lilly alleges that Revive competed unfairly in violation of Hawai'i's unfair-competition statute. (Docket Entry No. 59 ¶¶ 118–29). Revive moves to dismiss this count, arguing that Eli Lilly lacks standing to assert the claim as pleaded; that it failed to adequately define in its complaint the market that Revive allegedly harmed; and that it failed to adequately allege the nature of the unfair competition, as required by Hawai'i's law. (Docket Entry No. 70 at 10–12; Docket Entry No. 76 at 13–14). Revive's first two arguments fail but its third succeeds.

First, Eli Lilly has standing to sue under Hawai'i's unfair-competition law. Revive argues that the statute allows only consumers, not corporations such as Eli Lilly, to file civil suits under it. This argument is based on a misreading of the statute. Hawai'i's unfair-competition law provides in part:

> (a) Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful.
>
> (d) No person other than a consumer, the attorney general or the director of the office of consumer protection may bring an action based upon unfair or deceptive acts or practices declared unlawful by this section.
>
> (e) Any person may bring an action based on unfair methods of competition declared unlawful by this section

HAW. REV. STAT. ANN. § 480-2; *see id.* § 480-1 (defining "person" to include "corporations"); *id.* (defining "consumer" as natural persons who purchase goods or services or investments). Revive's argument that Eli Lilly is not a consumer, and is therefore barred by Section 480-2(d), misses that Eli Lilly is suing under Section 480-2(e). (*See* Docket Entry No. 59 ¶ 126). Section

480-2(d) concerns "unfair or deceptive acts or practices," and Section 480-2(e) concerns "unfair methods of competition." These are distinct claims, as Section 480-2(a)'s disjunctive language makes clear. It outlaws both unfair methods of competition and unfair or deceptive acts or practices. Eli Lilly's suit may proceed under Section 480-2(e).

Second, Eli Lilly adequately alleged the relevant market to state a claim for unfair competition in Hawai'i. Revive argues in its reply brief that Eli Lilly must allege a market definition, just as antitrust plaintiffs must. (Docket Entry No. 76 at 13–14). It argues that, "[o]rdinarily, the factual support needed to show injury to competition must include proof of the relevant geographic markets and demonstration of the restraint's anticompetitive effects within those markets." *Weisse v. LG Elecs., Inc.*, 650 F. Supp. 3d 1078, 1095 (D. Haw. 2023) (quoting *Sunday's Child, LLC v. Irongate Azrep BW LLC*, No. 13-cv-00502, 2017 WL 10651861, at *4 (D. Haw. Oct. 27, 2017)). In *Weisse*, the court found insufficient the plaintiffs' allegations that the defendants unfairly competed by selling defective air conditioners because the plaintiffs did not allege the market for similar products, including the products' price, value, warranties, potential for defect, and availability within Hawai'i. *Id.* Similarly, in *Sunday's Child*, the court dismissed the plaintiffs' unfair-competition claim because their "allegations fail[led] to identify the relevant market, the specific effect that Defendant's actions have had on that market, or proof of actual detrimental competitive effects." 2017 WL 10651861, at *4. These rulings trace back to the *Sunday's Child*'s court's analogy to the "Sherman Act" and the Ninth Circuit's requirements for antitrust claims under that federal statute. *See id.* (quoting *Les Shockley Racing, Inc. v. Nat'l Hot Rod Ass'n*, 884 F.2d 504, 508 (9th Cir. 1989)).

This Hawai'i Supreme Court, however, has repudiated such a requirement to state a claim for unfair competition. In *Field v. National Collegiate Athletic Association*, a suit over the

NCAA's allegedly improper decision to decertify the 2003 Seattle Bowl, the court clarified (1) that a plaintiff may "offer proof of the general market"; (2) need not prove that "the defendant's conduct in fact negatively affected the market beyond" its own injury; and (3) "need not be competitors or in competition with defendants to establish or recover from an unfair method of competition." 431 P.3d 735, 749 (Haw. 2018). The court relied on its previous ruling in *Gurrobat v. HTH Corporation*, where it held that a class of service employees stated an unfair-competition claim based on the defendants' allegedly unlawful withholding of a portion of a service charge that customers paid. 323 P.3d 792, 813–14 (Haw. 2014). The *Field* court explained that, "[i]n *Gurrobat*, the plaintiffs contended that the defendants' asserted unfair method of competition would reduce fair competition 'in the market for hotels, restaurants, and banquet service providers'—those generally in the field of competition with the defendant." *Field*, 431 P.3d at 749 (quoting *Gurrobat*, 323 P.3d at 813). *Gurrobat* "did not require the plaintiffs to define the market with great specificity in order to raise a genuine issue of material fact." *Id.* The court then concluded that the plaintiff "presented sufficient evidence to discern the affected market by describing" the defendants' business practices (the NCAA's certification process for bowl games), the relevant players in the market ("the member institutions that participate in the bowls"), and "the consumers that attend the bowls." *Id.*

The Hawai'i Supreme Court did not take the more demanding approach to market definition that federal courts borrowed from Ninth Circuit antitrust precedent. To the extent the Hawai'i Supreme Court analogized to federal antitrust law in interpreting the State's unfair-competition bar, it referred to standards governing per se violations of the Sherman Act for the proposition that "harm to a single business may suffice to establish an antitrust violation." *See id.* at 749 n.28 (citing *Klor's, Inc. v. Broadway-Hale Stores, Inc.*, 359 U.S. 207, 213 (1959)). Unlike

traditional rule-of-reason antitrust claims, claims for per se violations do not require proof of market definition. *See Big Bear Lodging Ass'n v. Snow Summit, Inc.*, 182 F.3d 1096, 1101–02 (9th Cir. 1999) ("Elaborate market analysis and case-by-case evaluation are unnecessary in cases involving *per se* antitrust violations because the anticompetitive effects of the practice are presumed."). A plaintiff does not need to plead market definition with particularity under Hawai'i's unfair-competition laws.

Eli Lilly's complaint adequately identifies "the general market at issue." *Field*, 431 P.3d at 749. It alleges in detail how prescription drugs are developed and reach the market, (Docket Entry No. 59 ¶¶ 16–38); why compounding drugs exist, the relevant regulations governing them, and how compounding pharmacies operate in the medicine supply-chain, (*id.* ¶¶ 39–52); and information about the specific drugs at issue in this case, as well as how both Eli Lilly and Revive sell products based on the same active ingredient, (*id.* ¶¶ 53–65). In short, the complaint adequately alleges the defendant's business practices (compounding and selling mass quantities of tirzepatide products), some of the relevant players in the market (Eli Lilly and Revive), and the consumers (the patients who take the drug). That is all the Hawai'i Supreme Court requires to state an unfair-competition claim. *See, e.g.*, *Field*, 431 P.3d at 749; *Gurrobat*, 323 P.3d at 813.

Third, Eli Lilly did not adequately allege a harm to competition. To "state a cause of action and recover money damages under HRS § 480-2(e), a plaintiff must" prove "(1) a violation of HRS chapter 480; (2) which causes an injury to the plaintiff's business or property; and (3) . . . the amount of damages." *Gurrobat.*, 323 P.3d at 812 (citing *Davis v. Four Seasons Hotel Ltd.*, 228 P.3d 303, 315 (Haw. 2010)). The second element is at issue here. To plead it, a plaintiff must allege that "he or she was harmed as a result of actions of the defendant that negatively affect

competition" and "how Defendants conduct would negatively affect competition." *Id.* (alterations adopted) (quoting *Davis*, 228 P.3d at 318).

Revive argues that Eli Lilly did not adequately allege how its compounding is anti-competitive. Revive argues that "it is not enough to allege harm to a competitor (e.g., that Defendants have gained a competitive advantage over other businesses by having lower prices), Plaintiffs must allege a harm to competition, (e.g., that Defendants' lower prices are predatory)." *Park v. Hawaii Med. Serv. Ass'n*, 582 F. Supp. 3d 760, 770 (D. Haw. 2022) (cleaned up). Eli Lilly responds that it need only show that the defendant's unlawful conduct "create[d] incentives . . . to purchase . . . from the defendant instead of competitors who did not engage in the unlawful conduct." *Gurrobat*, 323 P.3d at 813. Eli Lilly relies on its allegations that Revive gained an unfair advantage by ignoring the costs of obtaining pre-market approval for new drugs and the costs of ongoing FDA oversight, including the clinical trial process and compliance with current good manufacturing practices. (Docket Entry No. 59 ¶¶ 16–28, 62–65, 72–77, 112).

Eli Lilly's complaint almost states a claim. Revive is correct that Eli Lilly did not sufficiently link its allegations to a competitive harm. For example, in *Gurrobat*, the plaintiffs alleged that the defendants' "practice of withholding a portion of the service charge without disclosure to customers allowed them to charge lower base prices than law-compliant competitors, thereby reducing 'fair competition' in the market for hotels, restaurants, and banquet service providers." *Gurrobat*, 323 P.3d at 812. There are two parts to the Hawai'i Supreme Court's logic. First, the defendants' unlawful conduct allowed them "to lower their overall costs through retaining the tip income." *Id.* at 813. Second, *because* the defendants' retained costs were lower, they could "attract customers by being able to offer seemingly lower base prices." *Id.*; *see also id.* (noting, in addition, that the practice could "mislead customers into believing that the service

charge will be paid as tip income"). The unlawful conduct allowed the defendants "to obtain the business of customers through" means that "law-compliant" competitors could not. *Id.*

Eli Lilly's complaint includes the first, but not the second, aspect the nature-of-competition element. Eli Lilly alleges that Revive can manufacture tirzepatide products without having to incur "the cost of developing" the products and "the regulatory and financial burden of applying for" the products. (Docket Entry No. 59 ¶ 66). This allegation identifies a clear business advantage that Revive might gain by compounding tirzepatide. But Eli Lilly does not link this advantage to a competitive harm. It does not allege, for instance, that Revive can "offer seemingly lower base prices," *Gurrobat*, 323 P.3d at 813, because it does not have to amortize through each purchase the costs of developing the drug, of pushing its tirzepatide products through the regulatory process and to the market, or of enacting quality-control procedures to protect the products' brand image, (*cf.* Docket Entry No. 59 ¶¶ 39, 54–55). Instead, Eli Lilly alleges public-health harms that result from compounding and the risks that patients and the public may face by using compounded tirzepatide. (*Id.* ¶ 66–71). Eli Lilly's allegations are no doubt serious, but they are not harms to competition, actionable under Hawai'i's unfair-competition law.

Eli Lilly did not adequately allege a violation of Hawai'i's unfair-competition statute. But based on its complaint and its representations at oral argument, it likely can do so. Eli Lilly's claim under Hawai'i is dismissed, without prejudice. It has one more opportunity to state a claim.

3. Colorado (Count 2)

Eli Lilly alleges that Revive competed unfairly in violation of Colorado's Consumer Protection Act. (Docket Entry No. 59 ¶¶ 118–29). Colorado's consumer-protection statute "was enacted to regulate commercial activities and practices which, 'because of their nature, may prove injurious, offensive, or dangerous to the public.'" *Rhino Linings USA, Inc. v. Rocky Mountain*

Rhino Lining, Inc., 62 P.3d 142, 146 (Colo. 2003) (quoting *People ex rel. Dunbar v. Gym of America, Inc.*, 493 P.2d 660, 667 (Colo. 1972)). To state a claim, a plaintiff must allege "(1) that the defendant engaged in an unfair or deceptive trade practice; (2) that the challenged practice occurred in the course of defendant's business, vocation, or occupation; (3) that it significantly impacts the public as actual or potential consumers of the defendant's goods, services, or property; (4) that the plaintiff suffered injury in fact to a legally protected interest; and (5) that the challenged practice caused the plaintiff's injury." *Sewell v. Great N. Ins. Co.*, 535 F.3d 1166, 1173 (10th Cir. 2008) (quoting *Curragh Queensland Mining Ltd. v. Dresser Indus., Inc.*, 55 P.3d 235, 240 (Colo. App. 2002)).

Revive argues that Eli Lilly failed to state a claim because Eli Lilly alleged only a private issue with no real public impact. (Docket Entry No. 70 at 8–10). Whether an activity "significantly impacts the public" depends on "(1) the number of consumers directly affected by the challenged practice, (2) the relative sophistication and bargaining power of the consumers affected by the challenged practice, and (3) evidence that the challenged practice has previously impacted other consumers or has the significant potential to do so in the future." *Sewell*, 535 F.3d at 1173–74 (quoting *Rhino Linings USA, Inc.*, 62 P.3d at 149). Revive contends Eli Lilly brought a claim that is private in nature, first, because Eli Lilly's requested relief is premised on lost sales and loss of goodwill and, second, because Eli Lilly failed to allege that injured patients lack sophistication or bargaining power. (Docket Entry No. 70 at 9–10). Revive's arguments, at this stage of the proceedings, fail.

Revive's arguments are not independent reasons to dismiss Eli Lilly's claim. The Colorado Supreme Court has held that its consumer-protection statute protects "more than just actual or potential consumers." *Hall v. Walter*, 969 P.2d 224, 231 (Colo. 1998). It is not material that Eli

Lilly, a competitor, seeks redress for competitive harm. Nor does a plaintiff need to plead each public-interest factor. "No single factor is determinative, nor is it necessary that all be present." *Shekarchian v. Maxx Auto Recovery, Inc.*, 487 P.3d 1026, 1034 (Colo. App. 2019) (internal citations omitted). Courts have denied motions to dismiss, for instance, even though the plaintiffs failed to allege "the specific number of potential purchasers affected." *Ivar v. Elk River Partners, LLC*, 705 F. Supp. 2d 1220, 1242 (D. Colo. 2010). A court must weigh all the alleged facts to determine whether the plaintiff can plausibly state a claim for relief. *See Twombly*, 550 U.S. at 570. That is especially so here, where a jury will ultimately consider each public-interest factors in determining whether the alleged practices significantly impacted the public as actual or potential consumers. *See* COLO. PATTERN (CIV.) JURY INSTRUCTIONS § 29:4 (2025) [hereinafter COLO. PATTERN INSTRUCTIONS]; *see One Creative Place, LLC v. Jet Ctr. Partners, LLC*, 259 P.3d 1287, 1289 (Colo. App. 2011) (holding that, unless the facts are undisputed, a determination of whether there is a significant public impact is a factual one).

To state a claim for relief, Eli Lilly must allege that the defendants have engaged in a "broad scheme," buttressed by allegations of certain identifiable incidents of harm to consumers. *Ivar*, 705 F. Supp. 2d at 1242–43. In *Ivar*, the court denied a motion to dismiss a complaint that alleged that the defendants recorded development "lots' pre-incentive prices rather than the lower, actual sales prices" to mislead customers "into thinking the lots were worth substantially more than they in fact were." *Id.* at 1225. The court held that the plaintiffs stated a consumer-protection claim because they alleged "a broad scheme," did not allege that the plaintiffs were "sophisticated business people," and included "ten or so" examples of "unwitting consumers" who were fooled by the defendants. *See id.* at 1242.

Other courts have allowed claims to proceed, either passed a motion to dismiss or a motion for summary judgment, based on similar allegations or evidence of public impact. In *Shekarchian*, the court held that "the evidence supported a reasonable inference that Maxx Auto" engaged in an unfair or deceptive practice because it consistently had "between 300 and 500 vehicles parked in its lot" that were subject to "coercive release agreement[s]." 487 P.3d at 1034–34. Or in *Vista Resorts*, a court of appeals affirmed a judgment under the consumer-protection statute "based on evidence that 950 other consumers lodged complaints of product defect similar to those made by plaintiff." COLO. PATTERN INSTRUCTIONS, *supra*, § 29:4, source and authority n.3 (citing *Vista Resorts, Inc. v. Goodyear Tire & Rubber Co.*, 117 P.3d 60 (Colo. App. 2004)). Plaintiffs may state a public impact if they allege facts showing misconduct that "potentially affects a large swath of the public." *Crowe v. Tull*, 126 P.3d 196, 209 (Colo. 2006).

By contrast, Colorado courts will not allow claims to proceed if they are in essence individual contract or tort claims. In *Rhino Linings*, the Colorado Supreme Court held that a deceptive practice that affected only three dealers "out of approximately 550 worldwide" did "not significantly affect the public," in part because "the proper remedy" was "a private breach of contract action." 62 P.3d at 150; *see Martinez v. Lewis*, 969 P.2d 213, 222 (Colo. 1998) (finding no public interest because the "deceptive practices occurred only in the context of [a] private agreement to provide services for State Farm"). Similarly, a Colorado appeals court found no public impact where the "plaintiffs were the only purchasers whom the evidence showed had been directly affected by" the defendant's misconduct. *Hildebrand v. New Vista Homes II, LLC*, 252 P.3d 1159, 1169 (Colo. App. 2010) (citing *Anson v. Trujillo*, 56 P.3d 114, 118 (Colo. App. 2002)). The complaint must identify a class of the public affected by the defendant's alleged deceptive or unlawful conduct.

For similar reasons, plaintiffs cannot rely on misconduct that may be widespread but is unlikely to cause widespread harm. In *Curragh Queensland Mining*, a Colorado court held that, although a deceptive advertisement had been sent to a group of over 3,000 companies, it did not substantially impact the public because only a handful of potential recipients could have afforded the advertised product's high price. 55 P.3d at 240–41; *see Colorado Coffee Bean, LLC v. Peaberry Coffee Inc.*, 251 P.3d 9, 24–26 (Colo. App. 2009) (finding no direct public impact because, although the internet posting seeking possible franchise purchasers was widely available, only 68 packets of information were actually sent out to persons responding to the posting, nothing in the posting was untrue, and the posting was not an offer to contract). Even if several hundred individuals have been harmed, such evidence may be insufficient to prove a violation of Colorado's consumer-protection law if that figure is a minute percentage of the market for a given product or service. *See, e.g.*, *Coors v. Sec. Life of Denver Ins. Co.*, 91 P.3d 393, 399 (Colo. App. 2003) (holding that "an impact on at most one percent of the policyholders"—"approximately 200 out of 20,000 policyholders"—"could not constitute public impact"), *aff'd in part, rev'd in part*, 112 P.3d 59 (Colo. 2005). The throughline is that plaintiffs must allege both misconduct "directed to the market generally" and harms to "actual and prospective purchasers," *Hall*, 969 P.2d at 231, such that the defendant's misconduct "potentially affects a large swath of the public," *Crowe*, 126 P.3d at 209.

Eli Lilly's complaint meets this standard. As to compounding generally, Eli Lilly alleges that "[c]ompounded versions of tirzepatide can and have caused real harm"; that the FDA has sent letters warning about such incidents and has released statements about adverse events, which sometimes required hospitalization, related to dosing errors in compounded tirzepatide injections; that the "FDA had received at least one thousand reports of adverse events related to compounded

GLP-1 medications, including 480 reports related to the use of compounded tirzepatide"; and that public officials, including a majority of the states' Attorneys General, have recently warned about compounding pharmacies dispensing GLP-1 drugs such as tirzepatide. (Docket Entry No. 59 ¶¶ 66, 67, 69, 71 & n.33).[2] As to Revive's compounding specifically, Eli Lilly alleges that, at least in the past five years, the FDA, Texas Board of Pharmacy, and other regulators have cited Revive for violations of safety, sanitation, and licensing requirements; that Revive has twice had to recall compounded tirzepatide product, including one recall of 45 vials distributed nationwide and another Class I recall of 751 vials of testosterone cypionate that were mislabeled as compounded tirzepatide; and that some consumers have submitted reviews "identifying serious issues such as ineffective and improperly packaged products." (*Id.* ¶¶ 72–77).

Just as in *Ivar*, Eli Lilly has alleged "a broad scheme" that can harm consumers, buttressed by some specific examples of that harm. 705 F. Supp. 2d at 1242–43. Perhaps on a full record the extent of consumer harm will go no further than Eli Lilly's allegations, such that its proof of harm to the public will be too small to establish a violation of Colorado's statute. *See, e.g.*, *Coors*, 91 P.3d at 399. But at this stage, Eli Lilly's allegations, taken as true, show that Revive's compounded tirzepatide products "potentially affect[] a large swath of the public." *Crowe*, 126 P.3d at 209.

Revive's remaining response is that, because compounded drugs are dispensed under a doctor's prescription, the public impact is mediated by highly sophisticated doctors. (Docket Entry No. 76 at 10–11). It points to the learned-intermediary doctrine's "dispositive force" in certain areas of tort law as reason to dismiss Eli Lilly's claims. (*Id.* at 10). Revive's argument fails because the learned intermediary doctrine does not apply to Eli Lilly's theory of the case. Eli Lilly

[2] In 2019, Colorado amended its consumer-protection statute to eliminate the public-interest requirement in actions "brought by the attorney general or a district attorney." COLO. REV. STAT. § 6-1-103; *see State ex rel. Weiser v. Ctr. for Excellence in Higher Educ., Inc.*, 529 P.3d 599, 604 (Colo. 2023).

is alleging that compounding is a potentially unsafe pharmaceutical practice that has legal limits to ensure public safety. (Docket Entry No. 59 ¶ 44). It further alleges that Revive is ignoring the limitations that Congress and states have placed on compounding and is instead mass-producing tirzepatide, either in unsafe form or under unsafe pharmaceutical practices. (*Id.* ¶¶ 65, 72–77). The learned-intermediary doctrine does not apply to these allegations.

The Colorado Supreme Court has held that the risk-benefit test applies to product-liability claims based on allegedly unreasonably dangerous prescription drugs. *Ortho Pharm. Corp. v. Heath*, 722 P.2d 410, 414–15 (Colo. 1986), *overruled on other grounds by Armentrout v. FMC Corp.*, 842 P.2d 175 (Colo. 1992); *Barton v. Adams Rental, Inc.*, 938 P.2d 532, 537 & n.7 (Colo. 1997); *Walker v. Ford Motor Co.*, 406 P.3d 845, 850 (Colo. 2017); *accord* COLO. PATTERN INSTRUCTIONS, *supra*, § 14:3, notes on use n.4. The doctrine also does not bar liability in "manufacturing defect cases," where the question "is whether the product as produced conformed with the manufacturer's specifications." *Camacho v. Honda Motor Co.*, 741 P.2d 1240, 1247 (Colo. 1987). A doctor's role in writing a prescription for a tirzepatide product does not excuse Revive of liability if it mass-produces tirzepatide products that are unreasonably dangerous or if it compounds drugs that do not conform to a doctor's prescription. *See* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 cmt. b (1998) (explaining that "unqualified deference to these regulatory mechanisms," including prescribing doctors, "is considered by a growing number of courts to be unjustified"). Eli Lilly is in effect alleging product-liability claims through Colorado's consumer-protection statute. The learned intermediary doctrine does not prevent Eli Lilly from doing so.

Eli Lilly's theory of liability is no doubt novel, but Colorado's statute does not prevent it from surviving the arguments that Revive raises in its motion to dismiss. "Discovery may show a more limited reach" of compounding's alleged harms, and it may reveal the benefits that Revive

claims. *Ivar*, 705 F. Supp. 2d at 1243. Or discovery may demonstrate "a higher level of sophistication of the prospective purchasers" of Revive's products. *Id.* But, "at this stage of the proceedings," and on Eli Lilly's allegations, it is not "implausible that a public impact has occurred." *Id.*

Revive's motion to dismiss Eli Lilly's claim under Colorado law is denied.

B. Unfair-Competition Exemptions under Alaska, Connecticut, North Carolina, Tennessee, and Washington law

Revive argues that the unfair-competition laws of Alaska, Connecticut, North Carolina, Tennessee, and Washington exempt regulated conduct, such as the alleged pharmaceutical compounding, from liability. (Docket Entry No. 70 at 5–7, 7–8, 12–16). The court will address each state's exemption individually. But at the outset, the procedural posture limits the force of Revive's arguments. Revive's arguments generally do not warrant relief on a Rule 12(b)(6) motion to dismiss because each state's exemption, as the parties concede, provides an affirmative defense. (Docket Entry No. 89 at 41:11–42:10). Under Federal Rule of Civil Procedure 8(c), the burden to establish these defenses falls on Revive. *See* FED. RULE CIV. P. 8(c)(1) (requiring defendants, "[i]n responding to a pleading," to "affirmatively state any . . . affirmative defense"). Eli Lilly does not need to address statutory exemptions in its complaint; it does not need to allege both that Revive violated state law and that Revive does not fall within a statutory exemption.

The Supreme Court addressed a similar issue last term in *Cunningham v. Cornell University*, 604 U.S. 693 (2025). The question presented was whether plaintiffs attempting to state a claim under one part of the ERISA statute also had to plead that an exemption in a different part of the statute did not apply to the complaint's allegations. *Id.* at 695–96. The Court held that the plaintiffs did not have to plead that their claims fell outside of the statutory exemption. *Id.* at 696. The Court relied on the "well-settled 'general rule of statutory construction that the burden of

proving justification or exemption under a special exception to the prohibitions of a statute generally rests on one who claims its benefits.'" *Id.* at 701 (quoting *FTC v. Morton Salt Co.*, 334 U.S. 37, 44–45 (1948)). Because ERISA's statutory exemptions are affirmative defenses, they "must be pleaded and proved by the defendant who seeks to benefit from them." *Id.* at 702. "A plaintiff need only allege the three elements" of the relevant ERISA claim "because an 'affirmative defense' is 'not something the plaintiff must anticipate and negate in her pleading.'" *Id.* (quoting *Perry v. Merit Sys. Prot. Bd.*, 582 U.S. 420, 435 n.9 (2017)).

Cunninham's conclusion, applied to Revive's asserted statutory exemptions, effectively resolves Revive's motion to dismiss Eli Lilly's remaining claims. As the Fifth Circuit recognized in *Zyla*, on a motion to dismiss, a defendant "cannot have proven that it satisfies" the statutory requirements for authorized compounding because courts must "draw factual inferences in" the plaintiff's favor on the question of the defendant's "compliance with" federal and state law. 134 F.4th at 331 n.2 (discussing compliance with "§ 353b's many requirements").

This opinion continues, however, to address each state's unfair-competition exception, for two reasons. First, the parties dispute heavily the scope of each state's exemptions. Ruling on the scope of those exemptions now will provide the parties guidance in discovery and sharpen their inevitable summary-judgment motions. Second, the Supreme Court in *Cunningham* endorsed the use of Federal Rule of Civil Procedure 7, which empowers district courts to insist that plaintiffs file a reply addressing viable statutory exemptions, to identify claims that likely will not survive a future summary-judgment motion and should not entitle plaintiffs to impose on defendants the burden of costly discovery. 604 U.S. at 708; *see id.* at 711 (Alito, J., concurring) ("District courts should strongly consider utilizing this option—and employing the other safeguards that the Court describes—to achieve 'the prompt disposition of insubstantial claims.'" (quoting *Crawford-El v.*

Britton, 523 U.S. 574, 597 (1998))). Best practice is to review Revive's asserted statutory exemptions to see if Eli Lilly should file a reply to abate concerns that its claims, though well pleaded, are ultimately futile.

Based on that review, Eli Lilly plausibly can prove both that Revive violated Connecticut's, Tennessee's, and Washington's unfair-competition laws and that Revive's conduct does not enjoy the protection of those states' statutory exemptions. Alaska's and North Carolina's statutory exemptions, however, may bar at least part of Eli Lilly's claims under those states' consumer-protection laws, so Eli Lilly must file a reply alleging facts that state a claim not subject to their statutory exemptions.

1. Alaska (Count 1)

Eli Lilly alleges that Revive competed unfairly in violation of Alaska's Unfair Trade Practices and Consumer Protection Act. (Docket Entry No. 59 ¶¶ 82–94). It alleges that Revive "engages in unfair methods of competition and unfair practices . . . by unlawfully selling unapproved drugs in Alaska, including its combination tirzepatide and vitamin B6 injections, in violation of ALASKA STAT. ANN. §§ 17.20.110(a)(1)–(2), which proscribes the sale of unapproved new drugs." (Docket Entry No. ¶ 89). It further alleges that Revive's tirzepatide injections are "new drugs" under Alaska law because "they are not generally recognized among experts as safe for use under the conditions prescribed, recommended, or suggested in their labeling." (*Id.* ¶ 90). Revive argues that Eli Lilly "fails to state a claim under the Alaska UTPA because it exempts acts or transactions that are the subject of ongoing, careful regulation that prohibits the act complained of." (Docket Entry No. 70 at 5).

Alaska's unfair-competition statute does not apply to "an act or transaction regulated by a statute or regulation administered by the state, including a state regulatory board or commission,

unless the statute or regulation does not prohibit the practices declared unlawful in AS 45.50.471." ALASKA STAT. ANN. § 45.50.481(a)(1). "Put another way, if acts declared unlawful under the UTPA are prohibited by some other state law or regulation, then they are exempt from the UTPA." *Adkins v. Collens*, 444 P.3d 187, 195 (Alaska 2019). This exemption applies only to "those acts or transactions which are the subject of 'ongoing, careful regulation.'" *Matanuska Maid, Inc. v. State*, 620 P.2d 182, 186 (Alaska 1980). In *Matansuka Maid*, the defendant could not meet the exemption's first requirement because the "Restraint of Trade Act" was a "prohibitory statute" that was "unaccompanied by a regulatory framework." *Id.* "Regulation is . . . clearly distinct from and involves something more than mere prohibition," such as requiring "permission or registration" to engaging in the challenged conduct. *Id.* (quoting *State v. Reader's Dig. Ass'n, Inc.*, 501 P.2d 290, 303 (1972)). To qualify for the statutory exemption, a defendant must show (1) that its conduct is subject to ongoing, careful regulation, not a mere statutory prohibition, and (2) that such regulation prohibits the conduct that allegedly violates the Alaska UTPA. *Adkins*, 444 P.3d at 195. The regulation "must prohibit the specific act in question." *Id.*

Alaska's exemption facially applies to Revive's alleged misconduct. Under the Alaska FDCA, a person is prohibited from "sell[ing], deliver[ing], offer[ing] for sale, hold[ing] for sale, or giv[ing] away a new drug" without meeting the approval requirements in the statute. ALASKA STAT. ANN. § 17.20.110(a). The Alaska FDCA incorporates federal new-drug approval requirements and creates a new-drug approval process for drugs that are not subject to federal law. *Id.* § 17.20.111(a)(1)–(2). To sell a new drug in Alaska—"the specific [prohibited] act in question," *Adkins*, 444 P.3d at 195—Revive must obtain "permission" from a state or federal regulator, *Matanuska Maid*, 620 P.2d at 186 (quoting *Reader's Digest*, 501 P.2d at 303). Eli Lilly's

claim that Revive is "unlawfully selling unapproved drugs in Alaska," (Docket Entry No. ¶ 89), appears to fall within Section 45.50.481(a)(1)'s scope.

This conclusion holds even if the court frames the alleged prohibited conduct as compounding drugs in excessive amounts. Pharmacies and pharmacists that compound drugs "shall adhere to the guidelines established by the board in the pamphlet titled, '*Compounding Practices*,' dated February 2008." ALASKA ADMIN. CODE tit. 12, § 52.440. Alaska's *Compounding Practices* explain that pharmacists and pharmacies who violate traditional compounding practices are in fact manufacturing drugs. For example, "[c]ompounding drugs in an amount above that for which there is a historical basis [of valid prescription drug orders generated within an established doctor, pharmacist, and patient relationship] is considered manufacturing." DIV. CORP., BUS. & PRO. LICENSING, ALASKA DEP'T COM., CMTY. & ECON. DEV., STATUTES AND REGULATIONS: PHARMACY 61 (Apr. 2025). "The distribution of inordinate amounts of compounded products without a relationship between the pharmacist and the prescribing practitioner and patient is [also] considered manufacturing." *Id.* Under Alaska law, individuals and entities may not manufacture drugs without a license. *See* ALASKA STAT. ANN. § 08.80.157. Violations of that requirement are "class B misdemeanor[s]" and may warrant civil fines. *Id.* § 08.80.460(a)–(b). To sell inordinate amounts of compounded tirzepatide—"the specific [prohibited] act in question," *Adkins*, 444 P.3d at 195—Revive must obtain "permission" from a state regulator, *Matanuska Maid*, 620 P.2d at 186 (quoting *Reader's Digest*, 501 P.2d at 303). The statutory exemption facially applies to the alleged misconduct in Eli Lilly's complaint.

Eli Lilly offers two arguments in response. First, Eli Lilly argues that Alaska excepts from Section 45.50.481(a)(1)'s exemption conduct that qualifies as per se unfair or deceptive. (Docket Entry No. 75 at 11 (citing ALASKA STAT. ANN. §§ 45.50.471(b), 45.50.481(c))). It argues that

Revive's conduct is per se unfair or deceptive (1) because Revive is mispresenting that its tirzepatide products are approved and (2) because Revive violates labeling and advertising provisions of Alaska's FDCA. (*Id.* at 11–12). Revive disputes Eli Lilly's attempt to fit its claims within these exceptions to Alaska's statutory exemption and argues that Eli Lilly's complaint does not allege sufficient facts to establish the alleged per se violations. (Docket Entry No. 76 at 5–7). Whether Eli Lilly has alleged that Revive committed a per se violation of Alaska's UPTA is not properly presented on Revive's motion to dismiss under Rule 12(b)(6); the argument is a counter to an affirmative defense that Revive has not yet pleaded. *See Cunningham*, 604 U.S. at 708. If Eli Lilly seeks to avoid Revive's affirmative defense on this basis, it must file a reply to Revive's eventual answer.

Second, Eli Lilly argues that facial overlap between a regulatory regime and the alleged misconduct is insufficient to invoke Section 45.50.481(a)(1)'s exemption. (Docket Entry No. 75 at 12–23). It is an open question "whether regulations in place, which are arguably ineffective as a practical matter, satisfy the Safe Harbor provision of the UTPA." *Alaska v. Janssen Ortho LLC*, No. 3:11-cv-0002, 2012 WL 13034376, at *2 (D. Alaska Mar. 30, 2012). In *Janssen*, Alaska argued that the UTPA should apply to allegations of "unlawful off-label marketing" of certain prescription medicines approved by the FDA. *Id.* at *1. The State argued that the UTPA's exemption did not apply because the federal regulatory scheme "lack[ed] any real teeth" to curb the alleged misconduct, precluding a conclusion that the defendant's conduct was subject to "ongoing, careful regulation." *Id.* at *1–2. The district court certified the question for appeal, but the case settled before the Alaska Supreme Court could resolve the issue.

Some district courts have concluded "that mere citation to a broad regulatory scheme is insufficient to support dismissal of a UTPA claim," *White v. NYLIFE Sec.*, LLC, 551 F. Supp. 3d

974, 985 (D. Alaska 2021), and have doubted that the exemption should apply if the regulatory scheme is "seldom used by the state or individual plaintiffs to seek redress" for the alleged misconduct, *id.* at 983. This position aligns with the Alaska Supreme Court's holding that the exemption applies only to "ongoing, careful regulation" and its reasoning that courts should not construe the UTPA's exemptions in a manner that would "severely limit[]" its application and "frustrate the intent of the legislature." *Matanuska Maid*, 620 P.2d at 186. But to adopt Eli Lilly's argument would likely "necessitate a mini-trial to determine whether the regulator at issue was careful enough or its regulatory enforcement efforts were effective enough." *Janssen*, 2012 WL 13034376, at *2 (cleaned up). Eli Lilly has not explained why the Alaska legislature intended to so complicate its unfair-competition claims. Nor has Eli Lilly identified analogous state unfair-competition laws that require parties asserting similar exemptions to establish a track record of active state or federal regulation.

Eli Lilly's second argument presents a close legal question that is not adequately presented for resolution at this stage of the case. Revive bears the burden of proving its affirmative defense. If Eli Lilly's legal position is correct, then Revive must establish that Alaska is in fact actively regulating the sale of new drugs or excessive compounding. Revive may be able to develop such a record and prove its affirmative defense even under Eli Lilly's reading of Alaska law. The court will resolve Eli Lilly's argument on a fuller record and with sharper briefing on this specific legal question.

For these reasons, Eli Lilly's claims under Alaska law survive dismissal. If Revive asserts Section 45.50.481(a)(1) as an affirmative defense in its answer, and if Eli Lilly seeks to avoid the statutory exemption by asserting per se violations of Alaska's UTPA, then it must file a reply alleging facts that establishing such claims.

2. Connecticut (Count 3)

Eli Lilly alleges that Revive competed unfairly in violation of Connecticut's Unfair Trade Practices Act because it sold "unapproved drugs in Connecticut, including its combination tirzepatide and vitamin B6 injections, in violation of Connecticut law governing the sales of new drugs." (Docket Entry No. 59 ¶ 109). Revive responds that Eli Lilly pleaded into the law's safe harbor. (Docket Entry No. 70 at 7–8).

"CUTPA does not cover '[t]ransactions or actions otherwise permitted under law as administered by any regulatory board or officer acting under statutory authority of the state or of the United States.'" *Sterling v. Securus Techs., Inc.*, No. 3:18-cv-1310, 2019 WL 3387043, at *7 (D. Conn. July 26, 2019) (quoting CONN GEN. STAT. ANN. § 42-110c(a)). Revive argues that "[w]hen determining if a statutory exception exists, courts 'focus on the broader pattern of activity by the defendant, not the specific allegations of misconduct.'" *Id.* (quoting *Garcia v. Fry*, 186 F. Supp. 3d 228, 234–35 (D. Conn. 2016)). It contends that the broad pattern of activity that Lilly alleges that Revive engaged in—"compounding prescription drugs"—is permitted and highly regulated under state and federal law. *See, e.g.*, CONN. GEN. STAT. ANN. § 20-633b(c) (authorizing compounding that complies with federal and state regulations); 21 U.S.C. § 353a (authorizing and regulating compounding pharmacies under federal law). Eli Lilly responds that in assessing the safe harbor, courts should consider "the specific actions alleged in the complaint," not whether the broad "type or category of activity involved" is regulated. *State v. Tomasso*, No. 02-cv-44002651, 2005 WL 1091763, at *3–5 (Conn. Super. Ct. Apr. 1, 2005) (defining the specific actions as "bribery and steering of state contracts" rather than defendant's "contracting for public works projects"). It argues that Revive is violating the conditions under which state law authorizes compounding, so CUTPA's safe harbor does not apply.

Eli Lilly's narrow approach to the CUTPA's safe harbor controls. The best interpretation of Section 42-110c(a), under principles recognized by Connecticut courts, is that regulators must authorize the specific misconduct alleged in the complaint to exempt the defendant from CUTPA liability. *Tomasso*'s analysis of first principles of statutory interpretation to resolve this legal question is highly persuasive, and the cases on which Revive relies are materially distinguishable, both on their facts and in their reasoning.

Connecticut courts "look to the words of the statute itself, to the legislative history and circumstances surrounding its enactment, to the legislative policy it was designed to implement, and to its relationship to existing legislation and common law principles governing the same general subject matter." *Bender v. Bender*, 785 A.2d 197, 205 (Conn. 2001) (quoting *Frillici v. Town of Westport*, 650 A.2d 557, 563–64 (Conn. 1994)); *accord Reyes v. State*, 306 A.3d 515, 524 (Conn. App. 2023). Because the "governing statutes in Massachusetts are virtually identical to" Connecticut's unfair-competition laws, the State's courts "repeatedly look[] to the reasoning and decisions of the Supreme Judicial Court of Massachusetts with regard to the scope of CUTPA." *Normand Josef Enters., Inc. v. Conn. Nat. Bank*, 646 A.2d 1289, 1306 (Conn. 1994) (internal citations omitted). Each consideration weighs in Eli Lilly's favor.

The statute's text supports a narrow application of CUTPA's safe harbor. Section 42-110c(a) exempts "transactions or actions otherwise permitted under law as administered by any regulatory board or officer . . . ." Two features of this provision back Eli Lilly's argument. First, "the exception applies to actions permitted under law as administered by 'any regulatory board or officer' acting under statutory authority." *Tomasso*, 2005 WL 1091763, at *4 (quoting CONN GEN. STAT. ANN. § 42-110c(a)). The text does not refer to "extensive governmental control" in regulating the asserted misconduct. *Id.* The statute's use of the term "any" calls attention to

individual decisions by state regulators that authorize the specific transactions or actions at issue. The term "any" is commonly interchangeable with the singular article "a," *Marciano v. Jimenez*, 151 A.3d 1280, 1284 (Conn. 2016), and it modifies individual decisionmakers, such as boards or officers, instead of regulations or statutes that cover a field of activity. Second, the Section references transactions or actions "otherwise permitted under law," which "suggests that the transactions in question must be lawful in some respects and arguably unlawful in others, rather than generically valid transactions." *Tomasso*, 2005 WL 1091763, at *4 n.7. "The language of the exception suggests approval of specific actions by a specific decision-maker rather than supervision of the general activity by a state department." *Id.* at *4.

The statute's drafting history supports this reading of the text. "In 1973, § 42–110c(a) expressly excluded '[t]ransactions or actions otherwise permitted *or administered* by any regulatory board.'" *Mead v. Burns*, 509 A.2d 11, 17 (Conn. 1986) (alternations in original). But the legislature in 1976 "amended the CUTPA exemption section to substitute 'under law as administered' for 'or administered.'" *Id.* The statute's original use of "or administered" supports Revive's reading because the safe harbor distinguished permissible acts or transactions from impermissible but regulated acts or transactions yet exempted both from liability. The legislature then amended the statute "to prevent businesses from avoiding liability for pernicious actions by claiming that another agency administers its activities." *Tomasso*, 2005 WL 1091763, at *4 (cleaned up). The legislature removed from the exemption impermissible but regulated conduct. Now only those actions that are "permitted under law as administered by" state regulators—that is, actions that state regulators specifically permit through their administration of the law—are exempt. Connecticut's legislature amended CUTPA's exemption to eliminate the argument that Revive now makes.

Other courts, including Massachusetts courts, interpret their state's statutory exemption similarly. To prove that the Massachusetts statutory exemption applies, "a defendant must show more than the mere existence of a related or even overlapping regulatory scheme that covers the transaction. Rather, a defendant must show that such scheme affirmatively permits the practice which is alleged to be unfair or deceptive." *Tomasso*, 2005 WL 1091763, at *4 (quoting *Bierig v. Everett Square Plaza Assocs.*, 611 N.E.2d 720, 728 n.14 (Mass. App. 1993)); *accord Fleming v. Nat'l Union Fire Ins. Co.*, 837 N.E.2d 1113, 1121 (Mass. 2005) (adopting *Bierig*'s rule). The rule ensures that a business is not subject to liability "if it relies on activity permitted by law," *Rini v. United Van Lines, Inc.*, 903 F. Supp. 224, 231 (D. Mass. 1995) (citing *Ward v. Dick Dyer & Assoc., Inc.*, 403 S.E.2d 310 (S.C. 1987)), *rev'd on other grounds*, 104 F.3d 502 (1st Cir. 1997), or "does something required by law," *Tomasso*, 2005 WL 1091763, at *5 (quoting *Skinner v. Steele*, 730 S.W.2d 335, 337 (Tenn. Ct. App. 1987)). States treat these exemptions as provisions that "avoid conflict between laws," not as implied repeals of a cause of action for claims in certain regulated fields. *Id.* (quoting *Skinner*, 730 S.W.2d at 337). "Virtually every activity is regulated to some degree," so a broad "interpretation of the exemption would deprive consumers of a meaningful remedy in many situations." *Id.* (quoting *Skinner*, 730 S.W.2d at 337). States adopted Section 42-110c(a)'s language to ensure that liability still "attach[es] to the most serious of unfair trade practices." *Id.*

Each of the considerations relevant to interpreting Connecticut statutes weighs in favor of its narrow application. The text focuses on individual decisionmakers, not broad fields or regulations; the legislature amended the statute to limit its application to specifically approved actions; and persuasive authority interprets identical exemptions narrowly for the same reasons that the Connecticut legislature enacted and amended CUTPA.

Revive's argument relies primarily on Connecticut Supreme Court precedent. *See, e.g.*, *Connelly v. Hous. Auth. of City of New Haven*, 567 A.2d 1212, 1216 (Conn. 1990); *City of Danbury v. Dana Inv. Corp./Lot No. GO8065*, 730 A.2d 1128, 1140 (Conn. 1999). It argues that these cases compel an interpretation of Section 42-110c(a) that exempts "the broader pattern of activity by the defendant." *Garcia*, 186 F. Supp. 3d at 234. But *Garcia*'s reading of *Connelly* and *Danbury* is, respectfully, unpersuasive, for two reasons.

First, *Connelly*, *Danbury*, and their progeny, including *Garcia*, are materially distinguishable because the defendants were "creature[s] of statute" operated by state officials who took actions "expressly authorized and pervasively regulated" by the State or the federal government. *Connelly*, 567 A.2d at 1216. *Connelly* concerned a municipal housing authority that rented apartments under an express grant of authority, *see id.* at 1215–16; *Danbury* concerned "a municipality that [wa]s acting pursuant to statute in order to collect unpaid taxes by foreclosing on previously unchallenged tax liens," 730 A.2d at 1140; and *Garcia* concerned state marshals who, under their near-exclusive authority serve process, sought to serve wage executions, 186 F. Supp. 3d at 234–35. The exemption covered the defendant's actions almost by definition; they acted under their authorizing statutes and regulations. *See Lanciani v. Metro. Dist. Comm'n*, No. 04-cv-404000696, 2005 WL 1545201, at *3 (Conn. Super. Ct. June 1, 2005) (explaining that the relevant question under *Connelly* is whether the state agency was "acting under statutory authority").

Connecticut case law most commonly applies the exemption to suits against state-crated agencies and instrumentalities or their agents because they act directly under authorizing statutes or regulations. *See, e.g.*, *FDIC v. Weinstein*, No. 054078, 1995 WL 500642, at *3 (Conn. Super. Ct. Aug. 8, 1995); *Cap. Prop. Assocs. v. Cap. City Econ. Dev. Auth.*, No. 07-cv-044001293, 2006 WL 302073, at *3 (Conn. Super. Ct. Jan. 18, 2006); *Burton v. Dominion Nuclear Conn., Inc.*, No.

084040558, 2009 WL 242352, at *4 (Conn. Super. Ct. Jan. 7, 2009); *Pierce v. Lantz*, No. 084031139, 2010 WL 4884676, at *6 (Conn. Super. Ct. Aug. 10, 2010); *Wagner v. State*, No. 095026341S, 2010 WL 5064445, at *11 (Conn. Super. Ct. Nov. 17, 2010); *Peruta v. City of Hartford*, No. 09-cv-1946, 2012 WL 3656366, at *16 (D. Conn. Aug. 24, 2012); *Neighborhood Builders, Inc. v. Town of Madison*, 64 A.3d 800, 802–03 (Conn. App. 2013); *Hoydick Parnoff v. Town of Stratford*, 285 A.3d 802, 808 (Conn. App. 2022); *Tremont Pub. Advisors, LLC v. Materials Innovation & Recycling Auth.*, 286 A.3d 485, 488 (Conn. App. 2022); *Cheshire Hous. Auth. v. Garstang*, No. 23-cv-6028816, 2023 WL 7147993, at *2 (Conn. Super. Ct. Oct. 25, 2023); *cf. Higbie v. Hous. Auth. of Town of Greenwich*, No. 13-cv-6020272S, 2015 WL 5236728, at *5 (Conn. Super. Ct. July 31, 2015).

Second, *Connelly* and *Danbury* relied on more than just the CUTPA's exemption. Both cases concluded that the alleged misconduct were not necessarily covered acts or transactions under the CUTPA because "the type of transactions involved were not among the type to which the Federal Trade Commission Act has been applied." *Tomasso*, 2005 WL 1091763, at *3; *see Higbie*, 2015 WL 5236728, at *5 (explaining that *Connelly* blended the statute's trade-or-commerce requirement "with the issue of regulatory exemption"). Revive does not advance such an argument in its motion or reply. Because the defendants acted under an express delegation of authority and because the relevant acts or transactions were not within the scope of CUTPA, the Connecticut Supreme Court did not need "decide the precise question" of the level of generality at which should courts "define the 'transactions or actions'" at issue. *Tomasso*, 2005 WL 1091763, at *3. Nor did those cases apply the exemption despite recognizing that the defendants violated their authorizing statutes or regulations. They instead held that the defendants' actions were "expressly authorized." *See Connelly*, 567 A.2d at 1216 & n.7 (rejecting the plaintiff's contention

that the defendants violated federal regulations by failing to supply heat and hot water); *Danbury*, 730 A.2d at 1140 (explaining that the defense's allegations did "not invalidate the city's underlying foreclosure causes of action"). Connecticut Supreme Court precedent does not stand "for the proposition that the court must construe the 'transactions or actions' at issue in the broad, abstract way recommended by" Revive. *Tomasso*, 2005 WL 1091763, at *3.

The remaining cases on which Revive relies do not compel a different conclusion.[3] For example, Revive cites *Sterling* for the proposition that Connecticut courts focus on a broader pattern of activity, even for defendants who are not state entities. (Docket Entry No. 70 at 7). But the facts of the case support Eli Lilly's reading of the exemption. Securus provided "inmate calling services under the terms of a contract with the State of Connecticut" and charged fees "governed by a tariff agreement approved by the State." 2019 WL 3387043, at *8. "The allegedly exploitative fees charged thus were overseen and approved by the Connecticut Public Utilities Regulatory Authority," and the alleged kickbacks "were contractually required by the State of Connecticut and approved by the Connecticut Public Utilities Regulatory Authority." *Id.* (internal citations omitted). The State directed the defendant to conduct the alleged misconduct. *See Plainville Elec. Prods. Co. v. Bechtel Bettis, Inc.*, No. 3:06-cv-920, 2009 WL 801639, at *17 (D. Conn. Mar. 26, 2009) ("Allegedly unfair or deceptive trade practices do not give rise to a CUTPA claim where the defendant acts in good faith pursuant to a government contract that is based on lawful authority." (citing *Lawson v. Whitey's Frame Shop*, A.2d 1137, 1141–42 (Conn. 1997))). *Sterling* does not support Revive.

[3] Revive cites *Wind Corporation v. Wesko Locks, Ltd.*, No. 3:18-CV-292, 2018 WL 8729585, at *5 (D. Conn. Aug. 24, 2018), in support of its argument that courts take a broad approach to CUTPA's exemption. (Docket Entry No. 76 at 12). *Wind Corporation* supports Revive's position and adopts Revive's reading of *Connelly* and *Danbury*. But for the reasons explained, the court respectfully disagrees with *Wind Corporation*'s ruling.

CUTPA's exemption applies when the law authorizes the "specific actions alleged in the complaint." *Tomasso*, 2005 WL 1091763, at *5; *accord RW Grp., Inc. v. Pharmacare Mgmt. Servs., Inc.*, No. 07-cv-054003840, 2006 WL 1320225, at *8 (Conn. Super. Ct. Apr. 27, 2006); *RW Grp., Inc. v. Pharmacare Mgmt. Servs., Inc.*, No. 07-cv-054025109, 2009 WL 765673, at *6 (Conn. Super. Ct. Feb. 27, 2009); *JP Morgan Chase Bank Nat. Ass'n. v. O'Neil*, No. 09-cv-6002552S, 2011 WL 1408904, at *8 (Conn. Super. Ct. Mar. 24, 2011); *Mary Elizabeth Nursing Ctr., Inc. v. Lyon*, No. 116010713, 2012 WL 6924420, at *4 (Conn. Super. Ct. Dec. 24, 2012); *Mortg. Line of CT, LLC v. TaxServ Cap. Servs.*, LLC, No. CV146048065S, 2016 WL 720483, at *2 (Conn. Super. Ct. Jan. 29, 2016); *Patane v. Nestle Waters N. Am., Inc.*, 478 F. Supp. 3d 318, 330–31 (D. Conn. 2020). Eli Lilly alleges that Revive violates state and federal limits on otherwise authorized compounding. Section 42-110c(a) does not apply to the facts alleged.

3. North Carolina (Count 5)

Eli Lilly alleges that Revive competed unfairly in violation of North Carolina's Unfair and Deceptive Trade Practices Act. (Docket Entry No. 59 ¶¶ 130–139). Revive responds that an exception to the unfair-competition law applies. The law exempts "professional services rendered by a member of a learned profession." N.C. GEN. STAT. ANN. § 75-1.1(b).

This "learned profession" exemption applies if: (1) "the person or entity performing the alleged act" is "a member of a learned profession" and (2) "the conduct in question" is "a rendering of professional services." *Sykes v. Health Network Sols., Inc.*, 828 S.E.2d 467, 472 (N.C. 2019) (quoting *Wheeless v. Maria Parham Med. Ctr., Inc.*, 768 S.E.2d 119, 123 (N.C. App. 2014)). The second element is capacious: "a matter affecting the professional services rendered by members of a learned profession . . . falls within the exception." *Id.* (alteration in original) (quoting *Burgess v. Busby*, 544 S.E.2d 4, 11-12 (N.C. App. 2001)). Although the North Carolina Legislature has

not defined "learned profession," North Carolina courts have "long held that members of health care professions fall within the learned profession exemption to N.C.G.S. § 75-1.1." *Id.* (citing *Shelton v. Duke Univ. Health Sys., Inc.*, 633 S.E.2d 113, 117 (N.C. App. 2006)).

The parties do not dispute that, generally, pharmacists fall within the exemption. Based on this concession, Revive argues that "[p]harmacists are learned professionals whose services are exempted from the UDTPA." *Church Ekklasia Sozo Inc. v. CVS Health Corp.*, No. 3:20-cv-00382, 2022 WL 1572732, at *14 (W.D.N.C. Feb. 25, 2022). In *Church Ekklasia Sozo.*, the plaintiff, a non-profit that operates a drug rehabilitation program and a group of physicians, sued CVS Pharmacy under several theories when it declined to fill suboxone prescriptions for members of the program. *Id.* at *1. The court found that CVS met both prongs of the learned professional exemption because (1) the CVS pharmacists were licensed healthcare professionals and (2) the conduct alleged—refusing to fill a prescription and discussing the prescription with the patient—was "connected to the pharmacist's provision of medical services." *Id.* at *14. Revive argues that the same logic applies here, because "Revive is a compounding pharmacy," (Docket Entry No. 59 ¶ 11), and because Eli Lilly's complaint is based on the fact that Revive "sells compounded tirzepatide," which is "ship[ped] to patients" or "supplie[d] to patients." (*Id.* ¶ 62). In Revive's view, Eli "Lilly's complaint is based on Revive's distribution and sale of compounded drugs, which are created in the course of Revive's provision of medical services." (Docket Entry No. 70 at 13–14).

Eli Lilly responds that North Carolina law takes a more precise approach to the learned-profession exception, highlighting that the exception "does not shield [a] defendant from any claim under N.C.G.S. § 75-1.1 regardless of how far removed the claim is from that defendant's professional practice." *Sykes*, 828 S.E.2d at 474. For example, North Carolina courts do not

exempt from liability hospitals' misrepresentations that induce doctors to enter into employment agreements with the hospitals; such acts do not arise from the "rendition of professional services and ha[ve] no effect on the quality of the medical care provided." *Hamlet H.M.A., LLC v. Hernandez*, 821 S.E.2d 600, 608 (N.C. App. 2018), *aff'd, ordered not precedential*, 835 S.E.2d 436 (2019). Eli Lilly argues that drug manufacturing is not part of the practice of pharmacy, *see* N.C. GEN. STAT. ANN. § 90-85.3A(a), so North Carolina law does not exempt Revive on this complaint's allegations—that Revive "is mass-manufacturing its untested tirzepatide products at commercial scale without seeking, or obtaining, approval from FDA or any state agency," (Docket Entry No. 59 ¶ 7).

Revive has the better of the argument, but North Carolina law may not preclude completely Eli Lilly's claim. The critical question is whether "the heart of this action is directly related to providing patient care." *Sykes*, 828 S.E.2d at 473. In *Sykes*, the plaintiffs alleged that the defendants impermissibly terminated healthcare providers' "in-network access to patients when those providers exceed a certain average cost per patient." *Id.* The North Carolina Supreme Court held that the exemption applied because the harm caused by the alleged misconduct depended on chiropractic providers limiting the treatments provided to those patients. *Id.* The exemption shielded claims based on allegations that medical providers will "reduc[e] the level of services [that] patients receive." *Id.* By contrast, in *Hernandez*, the court held that employment agreements and medical-office leases do not fall within the exemption when those arrangements do not arise from the "rendition of professional services and ha[ve] no effect on the quality of the medical care provided." 821 S.E.2d at 608. Section 75-1.1 will foreclose Eli Lilly's claims if the alleged misconduct "affect[s] . . . the professional services rendered by members of a learned profession." *Skyes*, 828 S.E.2d at 472 (quoting *Burgess*, 544 S.E.2d at 11–12); *see, e.g.*, *Cameron v. New*

Hanover Mem'l Hosp., Inc., 293 S.E.2d 901, 920–21 (N.C. App. 1982) (exempting a hospital's denial of staff privileges to a physician); *Gaunt v. Pittaway*, 534 S.E.2d 660, 664 (N.C. App. 2000) (exempting defendant-doctors' allegedly defamatory statements about the plaintiff-doctor's training, expertise, and practice); *Shelton*, 633 S.E.2d at 117 (exempting a hospital's alleged misconduct in its billing practices for uninsured patients); *Wheeless v. Maria Parham Med. Ctr., Inc.*, 768 S.E.2d 119, 124 (N.C. App. 2014) (exempting an allegedly improper complaint to the medical board).

Large parts of Eli Lilly's claims depend on allegations about Revive's rendition of medical services and misuse of medical judgment. The line between compounding, which the parties concede is a traditional practice by pharmacists, and manufacturing, which is not a professional service, can depend on whether there is a legitimate medical prescription. (*See* Docket Entry No. 59 ¶ 47). Pharmacists may prepare compounded drugs only (1) "upon the pharmacy's receipt of a valid prescription order for an individual patient; or" (2) "in anticipation of a prescription order based on an established history of receiving prescription orders for the compounded drug preparation." 21 N.C. ADMIN. CODE 46.2801. Whether a prescription is valid and whether a prescriber has an established history of valid prescriptions depends on an "exercise of professional judgment." *Id.* § 46.1801. The learned-profession exemption covers some of Eli Lilly's allegations against Revive.[4]

Certain, limited theories in Eli Lilly's complaint may survive the exemption. Eli Lilly alleges that Revive "fails to obtain necessary prescriptions" for the tirzepatide products that it

[4] Eli Lilly relies on *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380, 418–420 (E.D. Pa. 2010), for the proposition that drug manufacturing is not exempt from the NCUDTPA. (Docket Entry No. 75 at 22). But the learned-profession exemption was not at issue in *Sheet Metal*. *See* 737 F. Supp. 2d at 418–20.

produces. (Docket Entry No. 59 ¶ 65). Discovery may show that Revive's business practice is to mass manufacture its compounded product, (*id.* ¶ 7), as a generic alternative without any assessment of patients' medical need and to dispense its product to third parties who are not related to Revive. Revive's conduct would transform from compounding pharmaceuticals, a practice of a learned profession, to manufacturing and distributing pharmaceuticals, which are not practices of a learned profession. *See* N.C. GEN. STAT. ANN. § 90-85.3A(a); *see also Thompson*, 535 U.S. at 370 (explaining that the government "needs to be able to draw a line between small-scale compounding and large-scale drug manufacturing"). This is a thin but important line. If Revive is producing its compounded tirzepatide for Revive pharmacists and Revive pharmacists are dispensing that compounded tirzepatide based what Eli Lilly argues is an erroneous medical judgment, then, as in *Church Ekklasia Sozo*, the learned-profession exemption will protect Revive. 2022 WL 1572732, at *14. Revive's production of compounded tirzepatide will directly "affect[] . . . the professional services rendered by" its pharmacists. *Skyes*, 828 S.E.2d at 472 (quoting *Burgess*, 544 S.E.2d at 11–12).

Because North Carolina's learned-profession exemption covers at least part of Eli Lilly's claims, if Revive pleads the exemption as an affirmative defense, Eli Lilly must file a reply clarifying the bases of its claims under North Carolina law and explaining how it does not fall within the exemption.

4. Tennessee (Count 6)

Eli Lilly alleges that Revive competed unfairly in violation of Tennessee's Consumer Protection Act. (Docket Entry No. 59 ¶¶ 140–51). Revive responds that an exception to the unfair-competition law applies. The TCPA does not apply to "[a]cts or transactions required or specifically authorized under the laws administered by, or rules and regulations promulgated by,

any regulatory bodies or officers acting under the authority of this state or of the United States . . . ." TENN. CODE ANN. § 47-18-111(a)(1).

Revive argues that Eli Lilly's "chief complaint is that Revive is compounding a drug that contains the active ingredient tirzepatide," which Tennessee law allows. (Docket Entry No. 70 at 14). It points to the Tennessee Pharmacy Practice Act of 1996, which "define[s] and regulate[s] the practice of pharmacy" and authorizes and licenses compounding pharmacies to operate in the state. TENN. CODE ANN. § 63-10-203; *see also id.* § 63-10-204(6) (defining compounding); *id.* § 63-10-210 (authorizing out-of-state pharmacies dispensing within the state to operate, provided the license fees are paid). It further highlights that licensed compounding pharmacies are subject to oversight by the Board of Pharmacy, which establishes rules for operation and minimum standards. *Id.* § 63-10-308(a). It concludes, based on these laws, that compounding is specifically and actively permitted by both state and federal regulatory authorities, such that the exemption under Section 47-18-111(a)(1) applies and that Eli Lilly fails to state a claim for unfair competition under the TCPA. (Docket Entry No. 70 at 14–15).

Tennessee courts have rejected Revive's broad approach to the TCPA's safe harbor, which uses language materially identical to Connecticut's. "The purpose of the exemption is to [e]nsure that a business is not subjected to a lawsuit under the Act when it does something required by law, or does something that would otherwise be a violation of the Act, but which is allowed under other statutes or regulations." *Skinner*, 730 S.W.2d at 337. In *Skinner*, the defendants argued that because they were engaged in "the sale of insurance policies and annuities," which was regulated, the safe harbor applied. *Id.* The Tennessee court rejected that argument, explaining that "authorization to engage in the business of selling annuities is not specific authorization to employ unfair or deceptive practices in that activity." *Id.* The question under Tennessee law is whether

the alleged "acts or practices are required or specifically permitted by law." *Johnson v. John Hancock Funds*, 217 S.W.3d 414, 423 (Tenn. Ct. App. 2006); *see, e.g.*, *Orr v. Ethicon, Inc.*, No. 2:20-cv-110, 2020 WL 9073528, at *4 (E.D. Tenn. Sept. 11, 2020) (holding that the plaintiff's claim that the defendant fraudulently sold a medical device did not fall within the TCPA's exemption).

Although compounding is allowed under certain conditions, Eli Lilly alleges that Revive is compounding tirzepatide products in violation of those conditions, including by selling unapproved tirzepatide products in excess of amounts otherwise permitted by state and federal law. (Docket Entry No. 59 ¶¶ 7, 9, 44, 140–50). Because Revive is alleged to transgress the limits under which it is "specifically permitted by law" to compound, *Johnson*, 217 S.W.3d at 423, the TCPA's safe harbor does not apply.

5. Washington (Count 7).

Eli Lilly alleges that Revive competed unfairly in violation of Washington's Consumer Protection Act. (Docket Entry No. 59 ¶¶ 166–75). Revive responds that the State's exception to the consumer-protection law applies. The WCPA does not "apply to . . . actions or transactions permitted by any other regulatory body or officer acting under statutory authority of this state or the United States"; provided that "actions or transactions specifically permitted within the statutory authority granted to any regulatory board or commission established within Title 18 RCW shall not be construed to be a violation of chapter 19.86 RCW." WASH. REV. CODE ANN. § 19.86.170.

Washington, like Connecticut and Tennessee, enacted a narrow exemption. The alleged misconduct "must be specifically and actively permitted by an agency to fall within the relevant statutory safe harbor." *Hall v. Walgreens Boots All., Inc.*, 565 P.3d 564, 568 (Wash. 2025). In *Hall*, the plaintiff alleged that the defendants "deceptively marketed a cough medicine as

nondrowsy even though drowsiness is a known side effect of the active ingredient," in violation of the WCPA. *Id.* at 565. The defendant responded that the Act's safe harbor applied because labelling decisions are heavily regulated. *See id.* at 566, 568. The Washington Supreme Court rejected the argument, explaining the FDA did not "specifically permit[] labeling these over-the-counter drugs nondrowsy." *Id.* at 568. Because the defendant did not have specific and affirmative authorization, the alleged misconduct fell "outside the statutory safe harbor." *Id.*

Eli Lilly alleges that Revive is compounding outside the limits of the specific conditions under which Revive may compound pharmaceuticals in Washington. (Docket Entry No. 59 ¶¶ 7, 9, 44, 166–75). Revive has not shown that Washington law "specifically permit[s]," *Hall*, 565 P.3d at 568, the mass-manufacturing of "untested tirzepatide products at commercial scale without seeking, or obtaining, approval from FDA or any state agency," (Docket Entry No. ¶ 7). The WCPA's safe harbor does not apply to the facts alleged.

C. Limited Damages During Tirzepatide's Shortage Period

Revive argues that, should any of Eli Lilly's claims survive dismissal, its damages "must be limited to periods when tirzepatide drugs were not in shortage." (Docket Entry No. 70 at 23; *see also* Docket Entry Nos. 87, 88). There are two aspects to Revive's argument: liability and damages. Neither warrant dismissal.

First, Revive's liability argument does not warrant dismissal. Revive's liability argument is based on compliance with federal law. Revive argues that when the FDA places a new drug on its shortage list, compounders may produce copies of that commercially available drug. (Docket Entry No. 76 at 22–23). Eli Lilly responds that only 503B outsourcing facilities, not 503A compounders such as Revive, may produce essentially copies of commercially-available drugs

during shortages and that Revive still violated several other federal and state requirements during tirzepatide's shortage period. (Docket Entry No. 87 at 2–5). Eli Lilly is correct on both fronts.

A drug shortage does not lift the regular-or-inordinate amount restriction for 503A compounders. The language lifting compounding restrictions during a shortage is in Section 503B. That Section provides that "an outsourcing facility" may compound pharmaceuticals "if each of" its "conditions [are] met." 21 U.S.C. § 353b(a). Those conditions include a limitation on "compound[ing] using bulk drug substances," *id.* § 353b(a)(2), and a requirement that the compounded "drug is not essentially a copy of one or more approved drugs," *id.* § 353b(a)(5). A designation that a drug is in shortage lifts both requirements. *See id.* § 353b(a)(2)(A)(ii) (excepting from the bar on "compounding using bulk drug substances" those drugs that appear "on the drug shortage list in effect . . . at the time of compounding, distribution, and dispensing"); *id.* § 353b(d)(2)(A) (excepting from the definition of "essentially a copy of an approved drug" those drugs that appear "on the drug shortage list in effect . . . at the time of compounding, distribution, and dispensing"). Section 503A includes no similar language that alters the obligations of those who compound under that Section during a drug shortage. Congress's "distinct statutory scheme" for 503B compounders is "significan[t]." *Babb v. Wilkie*, 589 U.S. 399, 412 (2020) (quoting *Lehman v. Nakshian*, 453 U.S. 156, 166 (1981)); *see Russello v. United States*, 464 U.S. 16, 23 (1983) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (cleaned up)).

Congress's scheme reflects careful policy choices. Outsourcing facilities that compound under Section 503B must register with the Secretary of Health and Human Services, 21 U.S.C. § 353b(b)(1)(A), are subject to inspection, *id.* § 353b(b)(1)(B), (b)(4), and must report frequently to

the Secretary, *id.* § (b)(2), (b)(5). They also must follow federal current good manufacturing practices. cGMP Guidance Under Section 503B, 83 Fed. Reg. at 63652; *accord Outsourcing Facilities*, 2025 WL 1239727, at *2. By contrast, Section 503A compounders are not subject to that suite of regulatory requirements. *See* 21 U.S.C. § 353a; *Outsourcing Facilities*, 2025 WL 1239727, at *2. Congress's decision to allow outsourcing facilities under 503B, but not other pharmacists under 503A, to compound during a shortage balances consumer safety and medical need. Congress allowed more heavily-regulated facilities, which are more likely to produce safe pharmaceuticals, to increase production during a shortage. The FDCA's text, structure, and purpose suggest that a drug shortage lifts certain compounding restrictions only for those who compound under Section 503B.

Revive's arguments to the contrary are not persuasive. (Docket Entry No. 70 at 23; Docket Entry No. 76 at 22–23; Docket Entry No. 88 at 1–3). Revive argues that the FDA does not consider drugs placed on the shortage list to be "commercially available" under Section 503A. *See* U.S. FOOD & DRUG ADMIN., COMPOUNDED DRUG PRODUCTS THAT ARE ESSENTIALLY COPIES OF A COMMERCIALLY AVAILABLE DRUG PRODUCT UNDER SECTION 503A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT GUIDANCE FOR INDUSTRY 5 (Jan. 2018); *see also Eli Lilly & Co. v. Alderwood Surgical Ctr. LLC*, 792 F. Supp. 3d 1213, 1215 & n.3 (W.D. Wash. 2025). But the FDA's guidance does not change the statute's text or structure. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412–13 (2024). A product is "commercially available" if it is "able to be bought and sold by people." *Commercially Available*, CAMBRIDGE DICTIONARY, https://perma.cc/3683-Z6ZE; *see, e.g.*, *N.B. Indus., Inc. v. Wells Fargo & Co.*, 465 F. App'x 640, 642 (9th Cir. 2012). Although a shortage exists "when the demand or projected demand for the drug within the United States exceeds the supply of the drug," 21 U.S.C. §§ 356c(h)(2),

manufacturers may still sell, and at least some consumers may still purchase, the drug in shortage. The FDA's guidance is best taken not as a persuasive interpretation of the statute, *cf. Loper Bright*, 603 U.S. at 388 (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 139–40 (1944)), but as an exercise of its prosecutorial discretion based on a finding that the public interest is best served by having both 503A and 503B compounders produce drugs placed on the shortage list, *see United States v. Bos. Farm Ctr., Inc.*, 590 F.2d 149, 151 (5th Cir. 1979) ("To guide its prosecutorial discretion in the bringing of non-rule enforcements of the Act the FDA may establish certain in-house guidelines . . . ."). [5] Whether the relevant states' laws consider material to liability the FDA's choice not to target Section 503A compounders for enforcement during a drug shortage is a separate question that the parties have not briefed.

The compounding restrictions that lift during a shortage period are also just a few of the many requirements that the FDCA places on drug compounders. *See* 21 U.S.C. § 353a(a)–(b). Whether Revive complied with these remaining requirements is not properly presented in this motion to dismiss because the court must "draw factual inferences in [Eli Lilly's] favor concerning [Revive's] compliance with" federal law. *See Zyla*, 134 F.4th at 331 n.2. Nor does Eli Lilly need to file a reply to address this issue because its complaint already contains allegations that Revive is not complying with the suite of federal statutes and regulations that limit compounding. (*See* Docket Entry No. 59 ¶¶ 7, 47, 63, 65, 73–77).

[5] Revive relies on *Outsourcing Facilities*'s statement that "[w]hen a drug is placed on the FDA's shortage list, Congress permits 503A compounders to compound copies of the drug and 503B compounders to compound from that drug's active ingredient." 2025 WL 1239727, at *2. But this statement is dicta. The case did not present the question whether 503A compounders may produce copies of commercially available drugs during a shortage; the question was whether the FDA properly ended a declared shortage. *See id.* at *3–8. This court respectfully disagrees with *Outsourcing Facilities*'s reading of the statutory scheme.

Second, the standard of review precludes crediting Revive's damages argument. Revive's argues that if tirzepatide is in shortage, then Eli Lilly cannot "lose any sales because it was operating at its full capacity." (Docket Entry No. 76 at 23). But this court must draw reasonable factual inferences in Eli Lilly's favor. *Iqbal*, 556 U.S. at 678. Eli Lilly alleges that it would have made more sales "but for Revive's unlawful and unfair competition." (Docket Entry No. 59 ¶ 8). The FDA may have declared a shortage even though Eli Lilly was not at full capacity, or, if Eli Lilly was originally at capacity, the FDA may have declared the shortage despite Eli Lilly having later increased its capacity. Whether Eli Lilly could have sold more tirzepatide during the shortage period is a factual question on which, in this posture, the court cannot rule for Revive.

Revive also does not explain how Eli Lilly's inability to prove damages from lost sales precludes its claims. Eli Lilly alleges that Revive's products harmed its reputation and goodwill. (Docket Entry No. 59 ¶ 81). Revive's sales during the shortage period could have caused such a harm. Revive only briefly suggests that Eli Lilly would be unable to receive damages for an injury to goodwill or business reputation. (*See* Docket Entry No. 88 at 3–4). But most of the relevant states appear willing in certain circumstances to award damages for loss of goodwill or business reputation. *See, e.g.*, *State v. Alaska Laser Wash, Inc.*, 382 P.3d 1143, 1150 (Alaska 2016); *L. Offs. of Frank N. Peluso, P.C. v. Rendahl*, No. 11-cv-5013762S, 2012 WL 3875113, at *4 (Conn. Super. Ct. Aug. 15, 2012); *Sprague v. California Pac. Bankers & Ins. Ltd.*, 74 P.3d 12, 23 & n.12 (2003); *Precision Mach. Design, LLC v. JBD Holdings, Inc.*, 886 S.E.2d 193, at *6 (N.C. App. 2023); *Andrews v. Sprinkle*, No. 2012-02242, 2013 WL 5498093, at *18 (Tenn. Ct. App. Sept. 30, 2013); *Lewis River Golf, Inc. v. O.M. Scott & Sons*, 845 P.2d 987, 989–90 (Wash. 1993); *cf. Wojtowicz v. Greeley Anesthesia Servs., P.C.*, 961 P.2d 520, 523 (Colo. App. 1997) (declining to award liquidated damages based on harm to goodwill because the plaintiff proved no injury).

Revive may show later that Eli Lilly is not entitled to an award of damages based on damage to its goodwill or reputation. But Revive's motion to dismiss has not sufficiently established such legal principles to warrant granting it.

Revive's motion for partial dismissal of Eli Lilly's prayer for damages is denied, without prejudice. It may make similar arguments throughout this case as the record and legal issues develop.

IV. Conclusion

Eli Lilly's unfair-competition claim under Texas law is dismissed, with prejudice; its claim under Hawai'i law is dismissed, without prejudice; and its remaining claims survive Revive's motion to dismiss. Statutory exemptions to Alaska's and North Carolina's unfair-competition laws may bar at least part of Eli Lilly's claims under them; Eli Lilly must file a reply alleging facts that state a claim not subject to their statutory exemptions.

Eli Lilly must amend its complaint by 21 days from the issuance of this Memorandum and Opinion; Revive must answer, or move to dismiss, Eli Lilly's second amended complaint by 14 days after Eli Lilly files it; and Eli Lilly must file its reply by 7 days after Revive files its answer.

SIGNED on December 16, 2025, at Houston, Texas.



Lee H. Rosenthal
Senior United States District Judge