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

Eli Lilly and Company has sued Revive Rx, LLC under the unfair-competition statutes of seven states. Eli Lilly alleges that Revive improperly manufactures and sells mass quantities of a weight-loss drug that competes with Eli Lilly's Mounjaro® and Zepbound® GLP-1 medications but that are not approved by federal or state regulatory agencies and evades state and federal "new drug" laws. (Docket Entry No. 97). The court previously granted in part and denied in part Revive's motion to dismiss for failure to state a claim. (Docket Entry No. 92). The court dismissed Eli Lilly's claims under Texas law with prejudice because amendment would be futile, dismissed the claims under Hawaii law without prejudice, and allowed the remaining claims to proceed. (*See id.*). Eli Lilly amended its complaint, (Docket Entry No. 97); Revive answered, (Docket Entry No. 99); and Eli Lilly replied, (Docket Entry Nos. 100, 101), as required by this court's Memorandum and Opinion on the motion to dismiss, (*see* Docket Entry No. 92 at 61).

Revive has moved for judgment on the pleadings. (Docket Entry No. 108). Revive argues that: (1) because compounded pharmaceuticals are not "new drugs" under the state laws at issue, Revive is not unfairly competing; (2) violations of "new drug" laws are not predicate acts of unfair competition under the state laws; and (3) the exclusivity provisions in the Connecticut and

Washington food-and-drug laws preclude Eli Lilly's claims under the unfair-competition statutes of those states. (*See generally id.*). Eli Lilly has responded, (Docket Entry No. 112), and Revive has replied, (Docket Entry No. 115).

Based on the motion, the response, the reply, extensive oral argument by both parties' able counsel, and the applicable law, the court denies Revive's motion for judgment on the pleadings. (Docket Entry No. 108). The reasons are explained in detail below.

I. The Legal Standards

A motion under Federal Rule of Civil Procedure 12(c) is designed to resolve cases in which the material facts are not in dispute and a judgment on the merits can be made based on the pleadings and judicially noticed facts. *Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 312 (5th Cir. 2002). The Rule 12(c) and 12(b)(6) standards are the same. *Gentilello v. Rege*, 627 F.3d 540, 543–44 (5th Cir. 2010). Both allow dismissal if a plaintiff fails "to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). That standard 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); *Eli Lilly & Co. v. Revive Rx, LLC*, 812 F. Supp. 3d 708, 723 (S.D. Tex. 2025).

II. Analysis

Revive argues that: (1) it should not be liable because compounded drugs are not "new drugs"; (2) even if compounded drugs are "new drugs," because states generally allow compounding, violations of "new drug" laws are not predicate acts of unfair competition under the state laws; and (3) the exclusive-enforcement provisions in the Connecticut and Washington Food, Drug, and Cometic Acts bar Eli Lilly's claims under those states' unfair-competition statutes. (Docket Entry No. 108; Docket Entry No. 115).

Each of Revive's three arguments for dismissal is analyzed below.

A. Unfair Competition and "New Drugs"

1. Are Compounded Medications "New Drugs"

Revive argues that compounded medications are not "new drugs" under the laws of each of the states at issue. (Docket Entry No. 108 at 3–12). Revive's argument has three parts. The first is that when Congress enacted the Food, Drug, and Cosmetic Act, compounded medications were not "new drugs" subject to federal premarket approval requirements, *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 389 (5th Cir. 2008), because they merely combined and mixed the ingredients in existing drugs, *Zyla Life Scis., LLC v. Wells Pharma of Houston, LLC*, 134 F.4th 326, 330 (5th Cir. 2025). The second is that when states enacted their "new drug" laws, they adopted the federal definition that exempted compounded medications from premarket approval

requirements. *See Taggart v. Lorenzen*, 587 U.S. 554, 560 (2019). Finally, Revive argues that even though federal law *now* considers a compounded medication to be a "new drug" because of the 1997 amendments to the federal Food, Drug, and Cosmetic Act, *see Mukasey*, 536 F.3d at 400, 406, the states' definition of a "new drug" did not change in lockstep with the federal definition.

Revive's argument is unpersuasive. A pharmacy-compounded medication can be a "new drug" under federal and state law. This conclusion follows from the text of the federal and state statutes. Congress broadly defined a "new drug":

> (1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or
>
> (2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

21 U.S.C. § 321(p).

Under the 1938 Act, "a 'new drug' was one not generally recognized by qualified experts *as safe* for its intended use." *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612–13 (1973) (emphasis added). In 1962, Congress amended the definition of a "new drug" to be "a drug not generally recognized among experts *as effective as well as safe* for its intended use." *Id.* at 613 (emphasis added). Since the 1960s, the federal definition of "new drug" has been tied

to whether the "article[] intended for use in" medical treatment or to affect bodily "function[s]," 21 U.S.C. § 321(g)(1), is safe and effective, *id.* § 321(p).[1]

Some states define "new drug" using language materially identical to the federal statute. For example, Connecticut defines a "new drug" to mean "any drug the composition of which is such that such drug is not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended or suggested in its labeling," or "which has not, otherwise than in [clinical] investigations, been used to a material extent or for a material time under such conditions." CONN. GEN. STAT. § 21a-92(18); ALASKA STAT. § 17.20.370(15) (similar); HAW. REV. STAT. § 328-4(b) (similar); N.C. GEN. STAT. § 106-121(12) (similar); TENN. CODE § 53-1-102(27) (similar); WASH. REV. CODE § 69.04.018 (similar). Other states incorporate the federal definition wholesale. For example, Colorado does not define "new drug" but instead bars the sale of "any new drug not authorized to move in interstate commerce under appropriate federal law." COLO. REV. STAT. § 12-280-131(1);[2] *see also* ALASKA STAT. § 17.20.110(a)(1) (exempting drugs for which "an application for it has become effective under the federal act"); CONN. GEN. STAT. §

[1] The 1962 Act recognizes that pharmacies may compound drugs but does not exempt compounded drugs from the "new drug" definition. The 1962 amendments exempt from registration and inspection requirements licensed "pharmacies . . . which do not . . . compound . . . drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail." 21 U.S.C. §§ 360(g)(1), 374(a)(2)(A). This provision "suggests Congress's awareness of compounding and its ability to create exceptions for compounding when it chooses to do so." *Mukasey*, 538 F.3d at 398 n.33. "That Congress chose not to do so with respect to the FDCA's 'new drug' definition is instructive." *Id.* "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." *Id.* (cleaned up) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)).

[2] While the motions were pending, Colorado amended its "new drug" statute to exclude from its scope "a compounded drug or device if the compounding of the drug or device is undertaken in accordance with applicable federal and state law." COLO. REV. STAT. § 12-280-131(2)(b). The fact that Colorado carved out legally compounded drugs from its "new drug" statute suggests that it treats compounded drugs as "new drugs." *See Mukasey*, 536 F.3d at 398 n.33, 400, 406.

21a-110(a) (similar); HAW. REV. STAT. § 328-17 (similar); N.C. GEN. STAT. § 106-135(a) (similar); TENN. CODE § 53-1-110 (similar); WASH. REV. CODE § 69.04.570 (similar).

These "new drug" definitions do not create an exception for compounded drugs. *See United States v. Carter*, 15 F.4th 26, 35 (1st Cir. 2021) (Barron, J.) (explaining that "compounded drugs" seem "to fit within that definition"). A "new drug" is "*any* drug" the composition of which is not safe and effective under the relevant criteria. "Read naturally, the word 'any' has an expansive meaning, that is, one or some indiscriminately of whatever kind." *FDA v. R. J. Reynolds Vapor Co.*, 606 U.S. 226, 237 (2025) (cleaned up). "If a compounder changes the composition of an approved drug—by mixing or combining an approved drug with something else to create a different substance or by creating special dosage or delivery forms of an approved drug inconsistent with a drug's labeling—the composition of the individualized concoction created by a compounding pharmacist will not have been previously approved for use." *Mukasey*, 536 F.3d at 395 (footnote omitted). "[I]t does not matter that the substance has been created through compounding rather than manufacturing—whether it be through rigorous research and development by a pharmaceutical company, through individualized compounding by a pharmacist or through cut-rate production by a rogue manufacturer." *Id.* Because "the definition of 'new drug' focuses on the drug's composition and use rather than on the process by which it was created," "[r]egardless of how and by whom it was created, 'any' such substance constitutes a 'new drug' within the meaning of" the relevant statutes. *Id.*

Both practice and precedent support this reading. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394 (2024); *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944). In 1963, the Food & Drug Administration promulgated regulations stating that the "newness of a drug may arise by reason" of "a combination of two or more substances, none of which is a new drug," or "the

proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug." 21 C.F.R. 130.1(f)(2)–(3) (1963), https://perma.cc/QG64-6CPH. Since the regulation issued, courts have consistently found persuasive arguments that a drug is a "new drug" because it is a novel and unsafe or ineffective combination of two existing drugs. *See, e.g.*, *United States v. 41 Cases, More or Less*, 420 F.2d 1126, 1128, 1131–32 (5th Cir. 1970); *United States v. Coli-Trol 80*, 518 F.2d 743, 746 (5th Cir. 1975).[3] The rationale is that "even though the component parts of a new drug may be generally recognized as safe and effective, the combination itself may not be" because "a single component of a drug may react with other components, thereby reducing the total effect of the drug or producing unexpected side effects." *United States v. Promise Toothpaste*, 624 F. Supp. 776, 778 (N.D. Ill. 1985) (first citing *Coli-Trol 80*, 518 F.2d at 746; and then citing *X–Otag Plus Tablets*, 441 F. Supp. at 111), *aff'd*, 826 F.2d 564 (7th Cir. 1987). Under the original federal Food, Drug, and Cosmetic Act, the core act of pharmaceutical compounding—combining two or more "old drugs" or ingredients, (*see* Docket Entry No. 108 at 4)—can create a "new drug." The present regulations maintain this approach. *See* 21 C.F.R. § 310.3(h)(2)–(3); *see id.* § 330.10(a)(4)(iv).

Revive argues that the case law addresses manufactured drugs, not drugs created through pharmaceutical compounding. (*See* Docket Entry No. 115 at 9–10). But, as discussed, the statutory text does not support this distinction. *See Mukasey*, 536 F.3d at 394–95. The cases do not create or recognize an exception from classification as a "new drug" for drugs created under a

[3] The Fifth Circuit is not alone. *See, e.g.*, *Pfizer, Inc. v. Richardson*, 434 F.2d 536, 537, 545–46, 547–58 (2d Cir. 1970) (Friendly, J.); *United States v. Mykocert*, 345 F. Supp. 571, 575 (N.D. Ill. 1972); *United States v. Entrol-C Medicated*, 513 F.2d 1127, 1129 (9th Cir. 1975); *United States v. X-Otag Plus Tablets*, 441 F. Supp. 105, 111 (D. Colo. 1977), *aff'd in part, remanded in part*, 602 F.2d 1387 (10th Cir. 1979); *United States v. Hormonin*, 498 F. Supp. 424, 432 (D.N.J. 1980), *aff'd*, 672 F.2d 904 (3d Cir. 1981); *United States v. Neo-Terramycin*, 540 F. Supp. 363, 376 (N.D. Tex. 1982), *aff'd*, 725 F.2d 976 (5th Cir. 1984); *United States v. Vital Health Prods., Ltd.*, 786 F. Supp. 761, 771 (E.D. Wis. 1992), *aff'd sub nom. United States v. LeBeau*, 985 F.2d 563 (7th Cir. 1993).

physician's prescription. (*Contra* Docket Entry No. 115 at 10 (attempting to distinguish "a licensed pharmacy dispensing drugs to patients pursuant to prescription orders")).

Revive instead argues that the longstanding federal practice of allowing states to regulate compounding applies here. (*See* Docket Entry No. 108 at 4–6; Docket Entry No. 115 at 6–9). According to Revive, after the federal Food, Drug, and Cosmetic Act was enacted, pharmacists "continued to provide patients with compounded drugs without applying for FDA approval of those drugs." *Thompson v. W States Med. Ctr.*, 535 U.S. 357, 362 (2002). Revive argues that this practice shows that compounding "fell outside the FDCA's premarket approval scheme for new drugs." *Zyla*, 134 F.4th at 330.[4] Compounding, in Revive's view, is just different.

One problem with Revive's argument is that "historical practice, detached from statutory text, is not controlling." *Watson v. Republican Nat'l Comm.*, No. 24-1260, ___ U.S. ___, 2026 WL 1855462, at *8 (U.S. June 29, 2026). Courts in the Fifth Circuit have characterized the Food & Drug Administration's decision not to regulate pharmacies under the federal Food, Drug, and Cosmetic Act "as a matter of policy." *Pros. & Patients for Customized Care v. Shalala*, 56 F.3d 592, 593 n.3 (5th Cir. 1995). Both the Southern District of Texas and Fifth Circuit rejected challenges to the 1992 policy guidance from the Food & Drug Administration that warned

[4] On its face, *Zyla*'s statement makes Revive's argument. But, respectfully, this sentence in *Zyla* is dicta. *See Olivier v. City of Brandon*, 607 U.S. 552, 565 (2026). The *Zyla* court made this comment in passing as part of its background section. *See Zyla*, 134 F.4th at 330. The "question actually before the" Fifth Circuit, *Cohens v. Virginia,* 19 U.S. (6 Wheat.) 264, 399 (1821) (Marshall, C.J.), was whether the federal Food, Drug, and Cosmetic Act preempted state unfair-competition laws, *see Zyla*, 134 F.4th at 328. The court's suggestion that compounded medications were not "new drugs" under federal law was not "a legal rule or principle" relevant to the ultimate decision in the case. *See Gilmore v. Georgia Dep't of Corr.*, 144 F.4th 1246, 1272 (11th Cir. 2025) (en banc) (Rosenbaum, J., concurring in part and concurring in the judgment) (quoting *Andrew v. White*, 604 U.S. 86, 92 (2025)); *United States v. Files*, 63 F.4th 920, 927–30 (11th Cir. 2023) (Newsom, J.). The statement is also out of step with other Fifth Circuit cases that strongly suggest the opposite conclusion. *See Mukasey*, 536 F.3d at 394–400; *Pros. & Patients for Customized Care v. Shalala*, 56 F.3d 592, 593 n.3 (5th Cir. 1995). Yet the *Zyla* court did not cite this case law, much less give these cases the attention it would have had the issue been core to resolving the appeal. *Zyla*'s comment is worth respectful consideration, but it is not binding.

compounding pharmacies of liability under the Act. *Pros. & Patients for Customized Care v. Shalala*, 847 F. Supp. 1359, 1361 (S.D. Tex. 1994), *aff'd*, 56 F.3d 592 (5th Cir. 1995). In *Professionals & Patients for Customized Care*, the district court stated, consistent with the statutory text, that "[t]here is no general exemption for pharmacies from the provisions of the Federal Food, Drug and Cosmetic Act"; that "extemporaneously compounded drugs are new drugs subject to the FDC Act"; and that "[d]rugs compounded in pharmacies are not exempt from the adulteration, misbranding, and new drug provisions of the FDC Act." *Id.* at 1363–64. The Fifth Circuit affirmed, explaining that the FDCA "does not expressly exempt 'pharmacies' or 'compounded drugs'" and that the FDA "historically" did not regulate "pharmacies engaged in traditional compounding" as a "matter of policy." *Shalala*, 56 F.3d at 593 n.3. The Fifth Circuit later reached a similar conclusion in *Mukasey*, reasoning that the "plain text" of the "new drug" statute was unambiguous "as applied to compounding." *See* 536 F.3d at 396. The *Mukasey* court explained that the statute could reasonably cover compounded drugs because Congress expected the FDA to exercise its statutory enforcement discretion to permit traditional compounding. *See id.* at 399–400 (citing 21 U.S.C. § 336). Compounding pharmacies were not regulated due to agency discretion, not an absence of statutory authority.[5]

In some cases, courts have held that the government proved that compounded drugs were "new drugs." Notably, in *United States v. Sene X Eleemosynary Corporation*, 479 F. Supp. 970 (S.D. Fla. 1979) (Aronovitz, J.), the government sued several defendants, including a registered pharmacist and a pharmacy, for compounding and distributing "'GH-3 (Equivalent),' an orally

[5] Other circuits have also concluded that "new drugs" include compounded drugs. *See United States v. Algon Chem. Inc.*, 879 F.2d 1154, 1158 (3d Cir. 1989) ("The statutory definition of a 'new drug' . . . does not exempt drugs that are compounded by veterinarians."); *Carter*, 15 F.4th at 35, 43–45 (explaining that the FDA "exercise[d] [a] discretionary abstention from the policing of prescription-based compounding pharmacies," but that the FDA never "disavowed its legal right to regulate compounders").

administered solution of buffered procaine hydrochloride 2%, as well as GH-3 Topical Cream Formulation, a skin cream." *Id.* at 972. The pharmacist "compound[ed] the GH-3 at his pharmacy, utilizing procaine that ha[d] been shipped in interstate commerce." *Id.* at 973. The court held that "GH-3 [was] not generally recognized by experts as safe and effective for the use(s) for which it [was] recommended or promoted by the defendants, and [was], therefore, a new drug." *Id.* at 977.[6] The court granted the government's motion for a preliminary injunction, ordering the defendants to stop producing and distributing the compounded medications. *See id.* at 982–83.

United States v. Baxter Healthcare Corporation, 712 F. Supp. 1352 (N.D. Ill. 1989), *aff'd*, 901 F.2d 1401 (7th Cir. 1990), is another example. Baxter operated two regional centers that compounded 35 different products containing 17 different active ingredients. *Id.* at 1354. The products were sold in powder or liquid form, and a "nurse, technician, or doctor [had to] reconstitute the powder or dilute the liquid with an appropriate solvent prior to giving the drug to a patient." *Id.* at 1355. Baxter decided that, "rather than have a physician or hospital solvate or dilute the compound," it would do so "itself via the" compounding center. *Id.* "Baxter would then sell its single-dose 'multipacks' and its pooling bags to physicians and hospitals." *Id.* Baxter argued that, because its compounding centers were doing "exactly what a doctor or hospital would do with FDA-approved ingredients," it complied with federal law. *Id.* The district court and the Seventh Circuit rejected those arguments, explaining that a "new drug" is defined by the "product

[6] Revive argues that *Sene X* does not favor Eli Lilly because the court did not resolve "whether the customary or usual practice of pharmacy is exempt from the Act's new drug provisions." 479 F. Supp. at 978. But the *Sene X* court held that a compounded pharmaceutical was a "new drug," *see id.* at 977, which is inconsistent with Revive's argument that a compounded drug is facially excluded from the statute. Even worse for Revive, the case considered the pharmaceutical-practice argument to be an affirmative defense on which the defendants bore the burden of proof. *See id.* at 978. The *Sene X* opinion characterized the "customary practice of pharmacy" argument as a purported "exemption from the Act's new drug provisions" and held that some of the defendants had "no colorable claim to that defense." *Id.* at 978 n.1. *Sene X* supports Eli Lilly's position that compounded drugs can be "new drugs" and that defendants bear the burden of proving that their production of new drugs is consistent with traditional pharmacy practices.

as a whole, 'complete with active and inactive ingredients.'" *Id.* at 1356 (quoting *United States v. Generix Drug Corp.*, 460 U.S. 453, 459 (1983)). The district court also rejected Baxter's argument that its compounded products fell within "exceptions to the [new drug] rule," in part because Congress and the FDA knew that medical practitioners would "manipulate[] these compounds in preparation for administration." *Id.* at 1356–58. Baxter claimed a compounding exception, and the court rejected that claim.

Revive argues that these cases are inapposite because they concerned bad actors that did not practice "real" pharmacy, *see Sene X*, 479 F. Supp. at 979, or that were clearly manufacturers, *see Baxter*, 712 F. Supp. at 1354–55. Revive's attempts to distinguish these cases are unpersuasive. They are premised on the argument that a bona fide pharmacy that compounds medications cannot be liable because everyone agrees that compounding is acceptable to some degree. *See Thompson*, 535 U.S. at 360–62. But that outcome follows from state and federal safe-harbors for approved pharmacy practice, *see Eli Lilly*, 812 F. Supp. 3d at 736–37, not from the statutory definition of a "new drug." The definition does not exempt a drug created under a physician's prescription from classification as a "new drug." (*Contra* Docket Entry No. 115 at 10 (attempting to distinguish "a licensed pharmacy dispensing drugs to patients pursuant to prescription orders")).

Baxter is consistent with this approach. Baxter argued, like Revive, that the government's position would make liable "every physician or hospital that solvates, dilutes or pools" medication. *Baxter*, 712 F. Supp. at 1358. The district court dismissed that argument as resting on the flawed "premise that enforcement of the law is an all-or-nothing matter." *Id.* The court reasoned that Congress focused its regulation on "the commercial distribution of drugs, rather than physician or pharmacist encounters with individual patients." *Id.* The court also explained that should the Food

& Drug Administration "choose to regulate legally the preparation of drug doses by physicians, pharmacists, or hospitals, th[e] court would not be the place to call for a halt to such activity." *Id.* The "new drug" statute was sufficiently broad that "[s]uch objections would be better directed at Congress or the agency itself." *Id.* at 1359.

Finding little support in federal law, Revive shifts to state law. Revive argues that reading state food-and-drug and pharmacy statutes together suggests that they do not consider compounded medications to be "new drugs." (Docket Entry No. 108 at 6–11). Revive relies on the specific-over-general cannon; the "*in pari materia*" or harmonization canon; and "elephant-in-mouseholes" or "major questions" doctrine. (*See id.*). These interpretive canons differ slightly, but Revive uses them to make the same underlying point: because the states regulate pharmacy practices directly, pharmacies can be held liable only under those state statutes, not under separate new-drug statutes. (*See id.*). Revive warns that failing to apply these canons will make certain statutory provisions a nullity, impose "presumptive[]" or "strict[]" liability on pharmacies, and "ban broad swaths of private conduct." (*Id.* at 6–8). The court finds these arguments unpersuasive, for the reasons the Fifth Circuit articulated in *Mukasey*.[7]

In *Mukasey*, ten pharmacies specializing in compounding prescription drugs for human and animal use sued various federal agencies, seeking declaratory and injunctive relief permitting them to continue compounding drugs without obtaining the FDA approval required for "new drugs" under the federal Act. *See* 536 F.3d at 387. The pharmacies invoked the major-questions doctrine

[7] Revive argues that because state statutes exclude from their definition of "manufacture" drugs compounded under a physician's prescription, the court should not consider compounded medications to be "new drugs." (Docket Entry No. 108 at 9–11). This argument cuts against Revive because it shows the states' "awareness of compounding and [their] ability to create exceptions for compounding when [they] choose[] to do so." *Mukasey*, 538 F.3d at 398 n.33. The states did not exempt from the definition of "new drugs" those created under a physician's prescription. *But see* COLO. REV. STAT. § 12-280-131(2)(b) (excepting legally compounded medications from the "new drug" statute).

to argue that Congress did not intend to make the ubiquitous practice of compounding illegal. *See id.* at 398–99. The Fifth Circuit rejected the invocation of the doctrine, for two reasons: first, many compounded medications may not be "new drugs"; and second, Congress expected the Food & Drug Administration to exercise its enforcement discretion wisely. *See id.* Based on these reasons, the Fifth Circuit concluded that "[c]onstruing the FDCA to give the FDA authority over compounding" would not dissuade pharmacies from the practice and "would thus not necessarily 'lead to a result so bizarre that Congress could not have intended it.'" *Id.* at 399 (quoting *Johnson v. Sawyer*, 120 F.3d 1307, 1319 (5th Cir. 1997)).

Both reasons apply to Revive's arguments under state law. The Fifth Circuit's first rationale—that compounding may not create a "new drug"—is particularly persuasive here because it provides a clear limit on pharmacies' potential liability and places a meaningful burden of proof on unfair-competition plaintiffs. (*See* Docket Entry No. 115 at 11–15 (arguing fiercely about which party bears the burden of proof)). Unfair-competition plaintiffs may struggle or fail to prove their claims against traditional compounding pharmacies in two ways.

First, compounding may not create a "new drug" by definition. Plaintiffs bear the burden of proving a lack of "substantial evidence of the safety and efficacy of the combination of the generally recognized components." *Hormonin*, 498 F. Supp. at 432. "[I]f one considers 'compounding' to include creating specialized dosage forms consistent with the instructions on a drug's label, that would be a kind of compounding that would not result in a 'new drug' under the FDCA's definition." *Mukasey*, 536 F.3d at 398–99. "The specialized dosage form would not be a new drug, because it would be a composition used 'under the conditions prescribed, recommended, or suggested in the [approved] labeling' of the drug." *Id.* at 399 n.34 (alteration in original) (quoting 21 U.S.C. § 321(p)). Manufacturers typically "recognize the need for

compounding," so they "include instructions for compounding specialized dosage forms, such as oral suspensions, in some of their package inserts, which are the instructions for use that accompany any drug product and must be approved prior to distribution by the FDA." *Id.* (citation omitted). "That sort of on-label compounding would be perfectly permissible even without exempting compounded drugs from the 'new drug' definition." *Id.* at 399.

Second, unfair-competition plaintiffs may struggle to prove damages in suits against pharmacies practicing traditional compounding. Compounding creates "medication tailored to the needs of an individual patient" when "commercially available" options will not do. *Thompson*, 535 U.S. at 360–61. The common cases for compounding include a patient who can ingest only a specific form of a drug that is not the FDA-approved version, *Outsourcing Facilities Ass'n v. FDA*, No. 4:25-CV-0174-P, 2025 WL 1239727, at *2 (N.D. Tex. Apr. 24, 2025) (discussing "a liquid version of a medication for a patient who has trouble swallowing solids"), is "allergic to the FDA-approved version of a new drug," or "need[s] other medications that do not interact well with the new drug," *Eli Lilly*, 812 F. Supp. 3d at 717; *accord Eli Lilly & Co. v. Strive Pharmacy LLC*, No. 1:25-cv-00401, 2025 WL 2851658, at *1 (D. Del. Oct. 8, 2025). These examples comply with the FDA's guidance that "[c]ompounded drugs should only be used in patients whose medical needs cannot be met by an FDA-approved drug." FDA, *Compounding and the FDA: Questions and Answers* (Sept. 16, 2025), https://perma.cc/8UUE-XHAD. Dispensing compounded medications for such patients likely will not inflict competitive harm on manufacturers of FDA-approved drugs because it does not deprive those manufacturers of sales they would otherwise have made. (*See* Docket Entry No. 97 ¶¶ 92, 114, 136 (alleging lost sales)). The commercially available FDA-approved options that do not meet the patient's medical needs likely will not be prescribed to the patient. (*Contra id.* ¶¶ 60–61 (alleging that there is no unique medical need for a tirzepatide and

vitamin B6 combination drug)). When pharmacies practice traditional compounding, plaintiffs are unlikely to prove the causation or damages elements of unfair-competition claims.

In short, the interpretive cannons that Revive relies on do not support excepting compounded medications from the definition of a "new drug." "[T]here is reason to think pharmacies would continue to compound even if compounded drugs were deemed 'new drugs.'" *Mukasey*, 536 F.3d at 399. Unfair-competition plaintiffs are unlikely to succeed against pharmacies that dispense compounded medications to patients with legitimate medical needs that commercially available medications cannot satisfy. Plaintiffs' unfair-competition claims are, as a practical matter, likely to be plausible only when there is some "evidence of large-scale compounding activity, third party resale or wholesale distribution efforts, or other significant indicators of questionable and non-traditional pharmaceutical behavior." *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 932 (Utah 2003) (holding that plaintiffs cannot bring strict product liability claims against compounding pharmacies without such evidence). Even if Revive's fear that unfair-competition plaintiffs have an easy prima-facie burden is correct, pharmacies can likely claim safe harbors under federal and state pharmacy law. *See Eli Lilly*, 812 F. Supp. at 736–37, 748–51. Adopting Eli Lilly's interpretation of state "new drug" laws does not impose "presumptive[]" or "strict[]" liability on pharmacies or "ban broad swaths of private conduct." (Docket Entry No. 108 at 6–8).

For these reasons, the court concludes that compounded drugs can be "new drugs" under federal and state law.

2. The Burden of Proof

Throughout its motion, Revive blends its argument on the burden of proof with its argument for dismissal. (*See* Docket Entry No. 108 at 3–11, 25). In its reply and during oral

argument, Revive clearly requested a ruling on which party bears the burden of proving compliance—or lack thereof—with state pharmacy laws. (*See* Docket Entry No. 115 at 11–15; Docket Entry No. 118 at 4:10–24 (explaining that the "shift[]" in the "burden of proof" is "really what generated" the Rule 12(c) motion)). Revive takes issue with this court's ruling on its motion to dismiss, which characterized Revive's statutory defenses as "affirmative defenses" on which it bore the burden of proof. *Eli Lilly*, 812 F. Supp. 3d at 736–37. Revive argues that the ruling requires it "to prove a negative." (Docket Entry No. 108 at 7). Revive's argument on the burden of proof has force, particularly in the context of unfair-competition laws that generally require a showing that the challenged conduct offends public policy, is immoral, or causes substantial harm. (*See* Docket Entry No. 112 at 12–13 (arguing that Alaska, Connecticut, Hawaii, North Carolina, and Washington use public policy as a standard for unfair competition)). If state pharmacy law allows compounding within certain limits, then compounding within those limits may not offend public policy. In those circumstances, it makes sense that Eli Lilly should bear the burden of proving that Revive's conduct is contrary to public policy because Revive exceeds those limits.

Eli Lilly responds that the Fifth Circuit decision in *Zyla* and this court's ruling on the motion to dismiss preclude Revive's argument. (*See* Docket Entry No. 112 at 4–6). The court is not persuaded. *Zyla* addressed a federal "preemption defense" under 21 U.S.C. § 353b. *See* 134 F.4th at 331 n.2. This court's Memorandum and Opinion on the motion to dismiss addressed Revive's assertion of specific exemptions under the unfair-competition statutes at issue. *See Eli Lilly*, 812 F. Supp. 3d at 736–37. Both *Zyla* and this court addressed paradigm affirmative defenses. *See Wyeth v. Levine*, 555 U.S. 555, 569 (2009) (discussing Wyeth's "burden in establishing a pre-emption defense" under "the federal drug regulatory scheme"); *Cunningham v. Cornell Univ.*, 604 U.S. 693, 701 (2025) (relying 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.'" (quoting *FTC v. Morton Salt Co.*, 334 U.S. 37, 44–45 (1948))). By contrast, Revive argues that Eli Lilly cannot establish a key element of its claim—that Revive's conduct is "unfair"—without proving that Revive violated state pharmacy laws. (*See* Docket Entry No. 115 at 11–15). Neither *Zyla* nor this court addressed that argument.[8]

A ruling on Revive's burden-of-proof argument is premature. Revive's first set of arguments seeks the conclusion that compounded drugs are not "new drugs" under the relevant states' laws. (*See* Docket Entry No. 108 at 3–12). For the reasons explained, the court does not find that argument persuasive. Revive's second set of arguments seeks the conclusion that selling "new drugs" without premarket approval is not unfair competition for reasons specific to the law of each state at issue. (*See id.* at 12–24). This set of arguments is analyzed below, reaching the conclusion that Revive's arguments are largely unpersuasive. Neither argument pressed the most persuasive point: if Revive's conduct is consistent with state pharmacy law, Revive's business may not "offend[] public policy as it has been established by statutes, the common law, or otherwise" or be "immoral, unethical, oppressive, or unscrupulous." *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244 n.5 (1972). Revive did not clearly make that argument in its opening brief, and Eli Lilly did not have a chance to respond to it directly. (*Compare* Docket Entry No. 112 at 14–15 (arguing that a "new drug" statute violation is unfair competition), *with* Docket Entry No.

[8] Eli Lilly relies on the comment in *Zyla* that "[i]f anyone sells drugs in violation of these state ["new drug"] laws, competitors may bring suit under traditional state unfair-competition law." 134 F.4th at 331. This comment, made in the background section of the opinion, is dicta. *See id.* *Zyla* addressed preemption, not the merits of state-law claims. *See Cohens*, 19 U.S. (6 Wheat.) at 399. This comment was not necessary to deciding the appeal. *See Andrew*, 604 U.S. at 92; *Files*, 63 F.4th at 927–30. The parties' briefs did not even address whether the plaintiff's claims were valid under the state unfair-competition statutes, as Revive now does. This court is not bound by *Zyla*'s comment.

115 at 17 (arguing against Eli Lilly's "strict liability" approach)).[9] The court declines to rule on an issue that is not fully briefed. *See In re Container Store Grp., Inc.*, 676 B.R. 356, 388 (S.D. Tex. 2026) (citing *ODonnell v. Harris County*, 808 F. Supp. 3d 738, 755 n.4 (S.D. Tex. 2025)).

The parties argued briefly whether Eli Lilly's Second Amended Complaint adequately alleges a breach of state pharmacy laws. Eli Lilly argued that, "in any event," "Revive is not lawfully compounding." (Docket Entry No. 112 at 6 (emphasis omitted)). Eli Lilly alleges that Revive "fails to obtain necessary prescriptions," "produces more than limited quantities of prescription drugs in advance of prescriptions," "and regularly produces large volumes of prescription drugs that are essentially copies of FDA-approved medicines." (Docket Entry No. 97 ¶ 65). Based on these allegations, Eli Lilly argues that Revive is not a legitimate compounding pharmacy but is instead "engaged in the illegal mass-production of unapproved prescription drugs." (*Id.*). Revive replies that that the state laws at issue do not bar the mass production of compounded drugs and that "merely dispensing compounded medicine without premarket approval isn't, without more, prohibited." (Docket Entry No. 115 at 13).

Eli Lilly's complaint sufficiently alleges breaches of the state pharmacy laws at issue. *See Schaerrer*, 79 P.3d at 932 (listing indicators that a pharmacy is breaching state law); *Sene X*, 479 F. Supp. at 978–79 (same). Eli Lilly squarely alleges that Revive compounds drugs without the necessary prescriptions, (Docket Entry No. 97 ¶ 65), which Revive argues is the critical safe harbor under the state laws, (Docket Entry No. 108 at 10–11 (arguing that the presence of a prescription distinguishes permissible compounding from manufacturing)).

[9] For example, the parties have not debated whether Eli Lilly could prove the "unfair" element even if Revive complied with state pharmacy laws, either in whole or in part.

The parties' arguments on the individual states' pharmacy laws were limited. The parties have not briefed in detail how the relevant states distinguish permissible compounding from impermissible compounding or manufacturing. Revive argues that there are no limits on producing and dispensing compounded medication if there is a prescription. (*See* Docket Entry No. 108 at 1 (arguing that there is no "cap on the volume of medicine that may be dispensed after receipt of a prescription")). Eli Lilly has not contested Revive's view of state pharmacy law, in part because it has not had to do so to survive dismissal. But the details of state pharmacy law are likely important to deciding this case. Eli Lilly's arguments are likely stronger in the states that allow pharmacies to compound only limited amounts of drugs and dispense them to patients who have a unique medical need. Revive's arguments are likely stronger in the states that allow compounding pharmacies to produce and dispense without limit what are essentially copies of commercially available drugs. A detailed assessment of these issues, on a state-by-state basis, will be necessary to rule on the parties' upcoming summary judgment motions and, depending on their disposition, to write jury instructions.

For these reasons, the court declines at this stage of the litigation to rule on the burden-of-proof issue and to enter judgment on Eli Lilly's claims for failure to allege a breach of state pharmacy laws.

B. State-Specific Arguments

Revive moves for judgment on the pleadings on Eli Lilly's claims under Alaska, Colorado, Connecticut, Hawaii, North Carolina, Tennessee, and Washington law. (Docket Entry No. 108 at 12–24).

1. Alaska

Alaska's Unfair Trade Practices Act ("AUTPA") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce." ALASKA STAT. § 45.50.471(a). Plaintiffs can prove violations under either the "per se" or the "general" approach. *Borgen v. A & M Motors, Inc.*, 273 P.3d 575, 583 (Alaska 2012). The Alaska Act defines "a long list of subparagraphs describing types of conduct that are by definition unfair or deceptive acts or practices." *Id.* Conduct that does not fall within these categories may still be unfair if it: (1) "offends public policy as it has been established by statutes, the common law, or otherwise"; (2) "is immoral, unethical, oppressive, or unscrupulous"; or (3) "causes substantial injury to consumers (or competitors or other businessmen)." *State v. O'Neill Investigations, Inc.*, 609 P.2d 520, 535 (Alaska 1980) (quoting *Sperry & Hutchinson*, 405 U.S. at 244 n.5). "All three *Sperry* factors are not necessary to a finding of unfairness." *Alaska Tr., LLC v. Ambridge*, 372 P.3d 207, 226 n.113 (Alaska 2016). "A practice may be unfair because of the degree to which it meets one of the criteria or because to a lesser degree it meets all three." *Id.* (quoting *Robinson* v. *Toyota Motor Credit Corp.*, 775 N.E.2d 951, 961 (Ill. 2002)).

Revive argues that Eli Lilly's allegations that it violated the "new drug" statute do not state a predicate act of unfair competition. (Docket Entry No. 108 at 13–15). Revive argues that selling new drugs is not unfair competition either per se or unfair under the general test. (*See id.*). Eli Lilly responds that, although selling a "new drug" is not necessarily per se unfair, Revive's conduct in selling its new weight-loss drug is unlawful and therefore per se unfair. (*See* Docket Entry No. 112 at 17–19). For example, Eli Lilly argues that Revive has misrepresented the fact that its weight-loss drugs lack government approval by "selling drugs that require premarket approval without getting those approvals." (*Id.* at 18 (citing ALASKA STAT. § 45.50.471(b)(3), (b)(4),

(b)(6))). Eli Lilly also argues that selling unapproved "new drugs" is itself unfair under the general test, because selling illegal and potentially unsafe products is offensive to public policy and dangerous for consumers. (*See id.* at 14–15).

Eli Lilly has adequately alleged that Revive is unfairly competing by breaching Alaskan public policy, to the detriment of consumers and competitors. *See Alaska Tr.*, 372 P.3d at 226 n.113. Eli Lilly has alleged that Revive is dispensing to Alaskans untested drugs that are not generally recognized as safe. (Docket Entry No. 97 ¶¶ 44–51, 67–70, 72–77, 90–92). Placing unlawful and unsafe products into the stream of commerce is injurious behavior that is against public policy. *See Gonzales v. Safeway Stores, Inc.*, 882 P.2d 389, 397 (Alaska 1994) ("This class is liable for selling dangerously defective or adulterated products."); *see also United States v. Roux Lab'ys, Inc.*, 456 F. Supp. 973, 976 (M.D. Fla. 1978) ("The purpose of the statute is to keep impure and adulterated foods, drugs, and cosmetics, out of the channels of interstate commerce, which affect the lives and health of the public in innumerable phases.").

Revive responds that even if it is violating the Alaskan "new drug" statute, it is not violating the State's public policy because Alaskan law expressly allows compounding. (*See* Docket Entry No. 108 at 12–15). Revive adds that Alaska's unfair-competition statute was modeled after the Federal Trade Commission Act, which focused on antitrust and anticompetitive behavior. (*Id.*). But Eli Lilly alleges that Revive is mass manufacturing its weight-loss drug without receiving the necessary prescriptions, in violation of the Alaskan pharmacy laws. (*See id.* ¶ 65). Eli Lilly alleges that by selling unapproved drugs without undergoing the rigorous approval process its law-abiding competitors must complete, Revive gains an unfair competitive advantage. (*See id.* ¶¶ 82, 125); *see also Eli Lilly*, 812 F. Supp. at 732. In short, Eli Lilly alleges that Revive's compounding practices violate Alaskan law in several ways, to the detriment of consumers and law-abiding

competitors. Eli Lilly alleges conduct within the "penumbra . . . of unfairness" that the AUTPA condemns. *O'Neill*, 609 P.2d at 535 (quoting *Sperry & Hutchinson*, 405 U.S. at 244 n.5).[10]

2. Colorado

Colorado's Consumer Protection Act prohibits "deceptive trade practice[s]." COLO. REV. STAT. § 6-1-105. "A person engages in a deceptive trade practice when, in the course of the person's business, vocation, or occupation, the person" "[r]efuses or fails to obtain all governmental licenses or permits required to perform the services or to sell the goods, food, services, or property as agreed to or contracted for with a consumer." *Id.* § 6-1-105(z); *see Telebrands Corp. v. VindEx Sols. LLC*, No. 21-CV-00898-BLF, 2022 WL 1062051, at *8 (N.D. Cal. Apr. 8, 2022) ("By alleging that Defendants sold TENS units within the course of their business without the requisite FDA clearance, Telebrands argues it has adequately pled the first and second elements of a CCPA claim."); *Walter v. Hall*, 940 P.2d 991, 999 (Colo. App. 1996) (affirming a jury verdict finding that the defendants' failure to obtain an easement violated § 6-1-105(z)).

Eli Lilly alleges that Colorado requires an approved drug application before anyone can sell that "new drug," (Docket Entry No. 97 ¶¶ 16–38), and that Revive has not registered with the FDA and has not obtained approval for its tirzepatide products, (*id.* ¶¶ 62–65). Revive argues that it is not violating § 6-1-105(z) because it has a valid Colorado pharmacy license that allows it to dispense compounded drugs. (Docket Entry No. 108 at 16 (citing Docket Entry No. 70-1 at 8)). Revive argues further that there is no liability under § 6-1-105(z) when "there is a dispute over

[10] The parties debate in passing and in footnotes whether the court can consider the alleged per se violations because Revive discusses them only in its reply, not its complaint. The parties also debate whether Eli Lilly's reply adequately alleges a per se violation of Alaska's unfair-competition statute. (Docket Entry No. 108 at 14–15; Docket Entry No. 112 at 17–19, 17 n.10, 18 n.11; Docket Entry No. 115 at 15 n.6). The parties do not argue the merits of the alleged per se violations or the exemption in sufficient detail for the court to address them.

whether the defendant was required to obtain the alleged license or permit." (*Id.* (citing *Mangone v. U-Haul Int., Inc.*, 7 P.3d 189 (Colo. App. 1999)).

The court declines to enter judgment on Eli Lilly's claim under Colorado law at this stage of the litigation. The parties have not adequately briefed the specific requirements of Colorado's pharmacy law and how it distinguishes between compounding and manufacturing. Colorado law excepts from its "new drug" statute "a compounded drug or device if the compounding of the drug or device is undertaken in accordance with applicable federal and state law." COLO. REV. STAT. § 12-280-131(2)(b). Licensed pharmacies, like Revive, may compound drugs without obtaining premarket approval. *See id.* §§ 12-280-103(10), 12-280-131(2)(b). But Colorado law requires manufacturers to obtain proper licenses and premarket approval for the drugs they sell and distribute. *See id.* §§ 12-280-114(2)(b), 12-280-131(2)(a). Whether Revive is violating § 6-1-105(z) turns on whether Revive is properly compounding under its Colorado license or inappropriately manufacturing without a license or premarket approval. To the extent that distinction turns on whether Revive has physician prescriptions for its compounded medications, *see id.* § 12-280-103(26), (53), Eli Lilly alleges that Revive did not obtain the necessary prescriptions, (Docket Entry No. 97 ¶ 65).

Eli Lilly has adequately alleged a violation of § 6-1-105(z).[11]

3. Connecticut

The Connecticut Unfair Trade Practices Act provides that "[n]o person shall engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade

[11] Eli Lilly appears to argue that Revive needs FDA approval to dispense compounded medications even though Colorado law would otherwise allow Revive to dispense such medications under its state pharmacy license. (*See* Docket Entry No. 112 at 19). The court does not address this argument because resolving it is not necessary to rule on Revive's motion. The parties did not brief what it means to compound "in accordance with applicable federal and state law," COLO. REV. STAT. § 12-280-131(2)(b), especially if applicable federal and Colorado law adopt inconsistent definitions of compounding and manufacturing.

or commerce." CONN. GEN. STAT. § 42-110b(a). Connecticut law includes a list of per se violations and allows plaintiffs to allege claims under the *Sperry & Hutchinson* factors previously discussed. *McLaughlin Ford, Inc. v. Ford Motor Co.*, 473 A.2d 1185, 1191 (Conn. 1984). Revive argues that Eli Lilly has not alleged a per se violation of the Connecticut Unfair Trade Practices Act, that its claims fail under the *Sperry & Hutchinson* factors, and that Eli Lilly cannot use the Unfair Trade Practices Act to avoid the bar on private enforcement of the Connecticut Food, Drug, and Cosmetic Act. (*See* Docket Entry No. 108 at 17–18, 24–25). The court is not persuaded.

"CUTPA's coverage is broad and its purpose remedial." *Cheshire Mortg. Serv., Inc. v. Montes*, 612 A.2d 1130, 1147 (Conn. 1992) (cleaned up). As with Alaska's unfair-competition law, "[a]ll three [*Sperry & Hutchinson*] criteria do not need to be satisfied to support a finding of unfairness under the Connecticut Unfair Trade Practices Act. A practice may be unfair because of the degree to which it meets one of the criteria or because to a lesser extent it meets all three." *Id.* at 1143–44 (quoting *McLaughlin*, 473 A.2d at 1192 n.15). Although the Federal Trade Commission Act and its origins are instructive, the Connecticut Supreme Court has been "mindful" that its "legislature deliberately chose not to define the scope of unfair or deceptive acts proscribed by CUTPA so that courts might develop a body of law responsive to the marketplace practices that actually generate such complaints." *Cenatiempo v. Bank of Am., N.A.*, 219 A.3d 767, 783 (Conn. 2019) (cleaned up). As a result, "CUTPA has come to embrace a much broader range of business conduct than does the common-law tort action." *Id.* (cleaned up). And "because CUTPA is a self-avowed remedial measure, it is construed liberally in an effort to effectuate its public policy goals." *Id.* (cleaned up). As a result, "there is no unfair method of competition, or unfair or deceptive act or practice that cannot be reached under CUTPA." *Id.* (cleaned up).

Eli Lilly adequately alleges an unfair practice under the Connecticut Unfair Trade Practices Act. Eli Lilly alleged that Revive is dispensing untested drugs that are not generally recognized as safe. (Docket Entry No. 97 ¶¶ 44–51, 67–70, 72–77, 90–92). Revive characterizes the alleged misconduct as "aggressive" or "hard-nosed" business tactics, not unfair competition. (Docket Entry No. 108 at 18 n.18 (quoting *Landmark Inv. Grp., LLC v. Calco Const. & Dev. Co.*, 60 A.3d 983, 992 (Conn. 2013)). But the complaint allegations do not fit this description. Instead, Eli Lilly alleges "a conscious, systematic departure from known, standard business norms," *Cenatiempo*, 219 A.3d at 783, that is not "legitimate," *Sporty's Farm LLC v. Sportsman's Mkt., Inc.*, 202 F.3d 489, 501 (2d Cir. 2000). Eli Lilly alleges that Revive is mass manufacturing untested and dangerous drugs without receiving the necessary prescriptions, in violation of state and federal compounding requirements. (*See* Docket Entry No. 97 ¶ 65). Eli Lilly's complaint alleges violations of drug and pharmacy laws that embody an important public policy of protecting "the lives and health of the public in innumerable phases." *Roux Lab'ys*, 456 F. Supp. at 976. Preventing the sale of dangerous products is obviously an important public policy goal.

Revive argues that Eli Lilly fails to allege a substantial injury. (Docket Entry No. 108 at 17–18). Under the substantial-injury prong, the alleged injury "must be substantial"; "must not be outweighed by any countervailing benefits to consumers or competition that the practice produces"; and "must be an injury that consumers themselves could not reasonably have avoided." *McLaughlin*, 473 A.2d at 1192. Revive argues that if Eli Lilly's theory prevails, "consumers and competition will be harmed" because "pharmacies will be prohibited from dispensing compounded alternatives" that "Connecticut law otherwise permits Revive to dispense." (Docket Entry No. 108 at 18).

Revive's argument fails at this stage of the case because "whether a defendant's acts constitute deceptive or unfair trade practices under CUTPA is a question of fact" not readily resolved on a motion on the pleadings. *Naples v. Keystone Bldg. & Dev. Corp.*, 990 A.2d 326, 337 (Conn. 2010) (cleaned up); *Recycling, Inc. v. Gallo*, 720 A.2d 242, 259 (Conn. App. 1998). It is particularly difficult to find Revive's argument on one factor dispositive because Eli Lilly can succeed by alleging a violation of one factor alone or two factors in combination. *See Montes*, 612 A.2d at 1143–44 (quoting *McLaughlin*, 473 A.2d at 1192 n.15). In addition, Eli Lilly's complaint allegations conflict with Revive's theory on the substantial-injury element. CUPTA is "equally applicable when a business person or competitor claims substantial injury." *McLaughlin*, 473 A.2d at 1192. Eli Lilly alleges that Revive gains an unfair advantage by selling copies of drugs in which Eli Lilly invested heavily to develop and could not sell without completing a costly premarket approval process. (*See id.* ¶¶ 82, 125); *see also Eli Lilly*, 812 F. Supp. at 732. Eli Lilly alleges that excessive compounding undermines the "new-drug approval process and intellectual-property protections" afforded to those who invest in developing innovative pharmaceuticals. *Eli Lilly*, 812 F. Supp. at 717; (Docket Entry No. 97 ¶¶ 16–19, 66). There are factual disputes on the extent of the harms to Eli Lilly and on the extent of the costs and benefits to consumers of a business practice that may increase the supply of some drugs but undercut the incentives for new-drug innovation.

Lastly, Revive argues that Connecticut's Food, Drug, and Cosmetic Act is not enforceable under the state's unfair-competition statute because "all [] proceedings for the enforcement, or to restrain violations, of" the Act "shall be by and in the name of the state of Connecticut." CONN. GEN. STAT. § 21a-99. The court does not find this provision dispositive, for the reasons set out in *Patane v. Nestlé Waters North America, Inc.*, 478 F. Supp. 3d 318, 328–29 (D. Conn. 2020). Connecticut law is clear that "a plaintiff may predicate a CUTPA claim on violations of statutes

or regulations that themselves do not allow for private enforcement." *Cenatiempo*, 219 A.3d at 784 n.16; *see also Artie's Auto Body, Inc. v. Hartford Fire Ins. Co.*, 119 A.3d 1139, 1150–51 (2015) (allowing a CUTPA claim based on a violation of the Connecticut Unfair Insurance Practices Act that "does not authorize a private right of action but, instead, empowers the commissioner to enforce its provisions through administrative action"). An express bar on private enforcement under a statute is potentially different from the mere absence of a private cause of action. But the Connecticut Supreme Court has allowed Connecticut Unfair Trade Practices Act claims based on statutes that vest exclusive enforcement authority in the State. *See, e.g.*, *Eder Bros. v. Wine Merchants of Conn., Inc.*, 880 A.2d 138, 146–47, 149–50 (2005) (allowing a CUTPA claim based on alleged violations of the Liquor Control Act even though the Liquor Control Act vests exclusive authority for its enforcement in the Department of Consumer Protection).

In *Eder Brothers*, wholesale wine distributors sued a competitor in the wholesale wine distribution business, alleging that the defendant's business practices violated the Liquor Control Act and the Connecticut Unfair Trade Practices Act. *Id.* at 141. The trial court held that the plaintiffs' claims failed because the legislature had vested exclusive authority to enforce the Liquor Control Act in the State. As a result, the plaintiffs could not seek redress for the alleged violations under either the Liquor Control Act or the Connecticut Unfair Trade Practices Act. *See id.* at 142. The Connecticut Supreme Court affirmed in part and reversed in part. The Court agreed that the legislature "intended to convey the duty of enforcing [the Liquor Control Act] exclusively to the department." *Id.* at 146. But it held that the plaintiffs could state a claim under the Connecticut Unfair Trade Practices Act, the State's exclusive jurisdiction notwithstanding, because a defendant "does not necessarily have to be found to have violated the Liquor Control Act in order to be found to have violated CUTPA for conduct controlled by the Liquor Control Act." *Id.* at 150. The

inability to sue under the Liquor Control Act was "irrelevant" so long as "a violation of the regulatory principles embodied in and underlying that act" qualifies as "unfair" under CUPTA. *Id.* The reasoning applies with equal force to Eli Lilly's claims under the Connecticut Food, Drug, and Cosmetic Act. *See Patane*, 478 F. Supp. 3d at 328–29.

The Connecticut legislature could have barred claims under its Unfair Trade Practices Act, including by providing alternative avenues for plaintiffs to obtain a "full measure of relief." *See, e.g.*, *Blass v. Rite Aid of Conn., Inc.*, 16 A.3d 855, 860–63 (2009), *aff'd*, 16 A.3d 737 (2011). "Here, however, the CFDCA provides no alternative means of recovery for" competitors. *Patane*, 478 F. Supp. 3d at 329. The Connecticut legislature could also have enacted a "statute that precludes the use of CUTPA to seek a remedy for a violation of the CFDCA." *Id.*; *see, e.g.*, *Water Pollution Control Auth. of the City of Norwalk v. Flowserve US, Inc.*, 782 F. App'x 9, 15 (2d Cir. 2019) (per curiam) (holding that the plaintiff could not state a CUTPA claim based on violations of the Connecticut Product Liability Act because that Act includes a provision making it the exclusive remedy for an injury from a defective product). The Connecticut legislature did not enact such a statute. Instead, it left untouched the Connecticut Unfair Trade Practices Act's remedial purpose, *Cheshire Mortg.*, 612 A.2d at 1147, and broad reach, *Cenatiempo*, 219 A.3d at 783.

Eli Lilly has adequately alleged a violation of the Connecticut Unfair Trade Practices Act.

4. Hawaii

Hawaii's unfair-competition statute provides that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful." HAW. REV. STAT. § 480-2(a). The "consumer protection statute is remedial in nature and must be liberally construed in order to accomplish the purpose for which it was enacted." *Hawaii Cmty.*

Fed. Credit Union v. Keka, 11 P.3d 1, 17 (Haw. 2000). The Hawaiian legislature has defined a set of per se violations and has also allowed plaintiffs to prove that alleged misconduct is generally unfair. *Kawakami v. Kahala Hotel Invs., LLC*, 421 P.3d 1277, 1290 (Haw. 2018). "A practice is unfair if it (1) offended public policy, (2) was immoral, unethical, oppressive, or unscrupulous, or (3) substantially injured Hawai'i consumers." *State ex rel. Shikada v. Bristol-Myers Squibb Co.*, 526 P.3d 395, 420 (Haw. 2023) (citing *Hungate v. Law Office of David B. Rosen*, 391 P.3d 1, 18 (Haw. 2017)).

Not every violation of Hawaiian law is actionable under § 480-2(a). *See Keka*, 11 P.3d at 17 n.15 (explaining that violations of the Truth in Lending Act are not necessarily offensive to public policy); *Heejoon Chung v. U.S. Bank, N.A.*, 250 F. Supp. 3d 658, 691 n.28 (D. Haw. 2017) ("[A] RESPA violation is not a per se UDAP violation."). A violation of another statute is not necessary to prove an unfair-competition claim. *See Shikada*, 526 P.3d at 424 ("Public policy covers a broad range, from state and federal law, to common law, to Hawai'i policy."). "A practice may be unfair because of the degree to which it meets one of the [*Sperry & Hutchinson*] criteria or because to a lesser extent it meets all three." *Hungate*, 391 P.3d at 18 (quoting *Kapunakea Partners v. Equilon Enters., LLC*, 679 F. Supp. 2d 1203, 1210 (D. Haw. 2009)).

Revive repeats its arguments that Eli Lilly has not alleged an unfair business practice. Revive argues that Hawaii's unfair-competition statute is closely tied to concerns about monopolies and restraints of trade. (Docket Entry No. 108 at 18–19). Revive argues that its conduct enhances competition by "providing consumers with more options for tirzepatide (once a physician has determined that is what the patient needs)." (*Id.* at 19). But for the reasons already explained, in both this opinion and in the Memorandum and Opinion denying the motion to dismiss, Eli Lilly has alleged that Revive's unfair business practices harm competition. Hawaii's

unfair-competition statute condemns unlawful conduct that allows "defendants 'to obtain the business of customers through' means that 'law-compliant' competitors c[an] not." *Eli Lilly*, 812 F. Supp. 3d at 732 (quoting *Gurrobat v. HTH Corp.*, 323 P.3d 792, 813 (Haw. 2014)). Eli Lilly has alleged that Revive violates important public policies embodied in state and federal "new drug" and pharmacy laws, and that Revive gains a business advantage by doing so. (Docket Entry No. 97 ¶¶ 82, 125). Eli Lilly has adequately alleged a violation of Hawaii's unfair-competition statute.

5. North Carolina

In North Carolina, "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are declared unlawful." N.C.G.S. § 75–1.1(a). "The Act was clearly intended to benefit consumers, but its protections extend to businesses in appropriate contexts." *HAJMM Co. v. House of Raeford Farms, Inc.*, 403 S.E.2d 483, 492 (N.C. 1991) (first citing *Pearce v. Am. Defender Life Ins. Co.*, 343 S.E.2d 174 (N.C. 1986); and then citing *United Lab'ys., Inc. v. Kuykendall*, 370 S.E.2d 375 (1988)). Although "a violation of a regulatory statute which governs business activities may also be a violation of" the unfair-competition statute, such a "violation does not automatically result in an unfair or deceptive trade practice." *Walker v. Fleetwood Homes of N.C., Inc.*, 653 S.E.2d 393, 398 (N.C. 2007) (cleaned up). "Whether a trade practice is unfair or deceptive usually depends upon the facts of each case and the impact the practice has in the marketplace." *Marshall v. Miller*, 276 S.E.2d 397, 403 (N.C. 1981). "A practice is unfair when it offends established public policy as well as when the practice is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers." *Id.*

Revive argues that North Carolina courts require egregious or aggravating circumstances, *Dalton v. Camp*, 548 S.E.2d 704, 711 (N.C. 2001), violations of detailed statutory schemes, *Cross v. Ciox Health, LLC*, 438 F. Supp. 3d 572, 586 (E.D.N.C. 2020), or inequitable assertions of power

or position, *Johnson v. Phoenix Mut. Life Ins. Co.*, 266 S.E.2d 610, 622 (N.C. 1980), before finding unfair competition. (Docket Entry No. 108 at 20–21). Revive also argues that "the historical absence of" regulation under the Federal Trade Commission Act "is a strong indication that" North Carolina's unfair-competition statute should not apply. (Docket Entry No. 108 at 21). Revive's arguments are unpersuasive.

First, North Carolina courts have required egregious or aggravating circumstances, such as abuses of power or position, only for "run-of-the-mill" employment or contract disputes. *See Dan King Plumbing Heating & Air Conditioning, LLC v. Harrison*, 869 S.E.2d 34, 43 (N.C. App. 2022) ("The ["aggravating circumstances"] doctrine comes into play when a plaintiff's UDTP claim is centered around the defendant's breach of a contract."). This standard follows from a traditional application of the *Sperry & Hutchinson* factors because employment disputes and contract breaches are not readily offensive to public policy, immoral, or substantially injurious to the consumer population. *See Dalton*, 548 S.E.2d at 712 (holding that the conduct alleged was not "aggravating or egregious enough to overcome the longstanding presumption against unfair and deceptive practices claims as between employers and employees"). After all, "contract law recognizes the theory of 'efficient breach' because it is sometimes rational and preferable for parties to breach rather than perform their contracts." *United States v. Bynon*, No. CR H-26-23, 2026 WL 1595296, at *4 (S.D. Tex. June 3, 2026) (quoting *United States v. Blankenship*, 382 F.3d 1110, 1133–34 (11th Cir. 2004)). This case law places no special burden on Eli Lilly, and its complaint adequately alleges an "unfair" business practice.

Second, North Carolina's unfair-competition statute does not require that the alleged acts violate a separate, detailed statutory scheme. In considering whether a statutory violation is "automatically" an unfair act, courts assess whether the predicate statute "defined in detail" the

practices declared unlawful. *Walker*, 653 S.E.2d at 399. But even if a statutory violation is not per se unfair, the "violation may be evidence of" an unfair practice. *Id.* "Thus, even though defendant's violations of" certain statutes or regulations may not be "unfair or deceptive trade practices *per se*, those violations are potentially relevant to any claim that defendant violated" the unfair-competition statute. *Id.*

For example, in *Cross*, on which Revive relies, the court rejected the argument that a HIPAA violation was an unfair trade practice because the violation was not itself an unfair practice "*and* because" the plaintiffs did "not *otherwise* allege[] an unfair and deceptive act." *Cross*, 438 F. Supp. 3d at 588 (emphasis added); *see also Walker*, 653 S.E.2d at 399–400 (concluding that the alleged regulatory violation was not unfair under the *Sperry & Hutchinson* factors). The case law Revive cites does not undermine the court's previous analysis of the *Sperry & Hutchinson* factors.

Third, regulatory practice under the Federal Trade Commission Act has not limited the otherwise straightforward application of the *Sperry & Hutchinson* factors. *See, e.g.*, *Greathouse v. Cap. Plus Fin. LLC*, 690 F. Supp. 3d 610, 641–42 (N.D. Tex. 2023) (applying the factors in a straightforward manner). In *HAJMM*, the Supreme Court of North Carolina relied on the absence of securities regulation under the Federal Trade Commission Act to conclude that the State's unfair-competition statute did not cover transactions involving fund certificates. 403 S.E.2d at 493 (citing *Skinner v. E.F. Hutton & Co., Inc.*, 333 S.E.2d 236, 241 (1985)). The court interpreted the meaning of "commerce" to exclude securities transactions. *See id.* ("Issuance and redemption of securities are not in this sense business activities."); *Dalton*, 548 S.E.2d at 711 ("Examples of business activity beyond the scope of the statutory definition include: professional services, most employer-employee disputes, and securities transactions." (internal citations omitted)). Other factors, such as pervasive securities regulation under other statutes, contributed to that conclusion.

See Skinner, 333 S.E.2d at 241.[12] The court did not see a "good reason to treat the certificates differently" from securities. *HAJMM*, 403 S.E.2d at 493. But *HAJMM* does not provide guidance on how to apply the *Sperry & Hutchinson* factors to "the purchase and sale of goods." *Id.* The absence of regulation under the Federal Trade Commission Act, without more, does not preclude unfair-competition liability. *See Cenatiempo*, 219 A.3d at 783 (explaining that the unfair-competition statute is purposely broad and undefined so that "courts might develop a body of law" under it over time).

Revive's motion for judgment on Eli Lilly's claims under North Carolina law is denied.

6. Tennessee

The Tennessee Consumer Protection Act provides that "[a]ny person who suffers an ascertainable loss of money or property, real, personal, or mixed, or any other article, commodity, or thing of value wherever situated, as a result of the use or employment by another person of an unfair or deceptive act or practice described in § 47-18-104(b) and declared to be unlawful by this part, may bring an action individually to recover actual damages." TENN. CODE § 47-18-109(a)(1). Plaintiffs may prove unfair-practices claims under a per se or general unfairness theory. *See Mills v. Partin*, No.M-08-136COAR3CV, 2008 WL 4809135, at *5 (Tenn. Ct. App. Nov. 4, 2008) ("[A] trial court may find a violation of a specific act or practice prohibited in subsection (b) or it may find a general violation of subsection (a).").

[12] Revive argues in half a sentence, (Docket Entry No. 108 at 21), that "pervasive and intricate regulation by other statutory schemes that contain separate enforcement, supervisory, and remedial provisions" may preclude liability under North Carolina's unfair-competition statute. *Champion Pro Consulting Grp., Inc. v. Impact Sports Football, LLC*, 845 F.3d 104, 110 (4th Cir. 2016) (internal quotation marks omitted) (quoting *Hagy v. Advance Auto Parts, Inc.*, No. 3:15–CV–509–RJC–DCK, 2016 WL 5661530, at *2 (W.D.N.C. Sept. 28, 2016)); *see Skinner*, 333 S.E.2d at 241. *But see Contant v. Bank of Am. Corp.*, No. 17 CIV. 3139 (LGS), 2018 WL 5292126, at *14 (S.D.N.Y. Oct. 25, 2018) ("Absent a showing that the overlapping regulatory regime provides plaintiffs an adequate remedy, courts have held NCUTPA to apply."). The argument was not sufficiently raised. *Container Store*, 676 B.R. at 388 (citing *ODonnell*, 808 F. Supp. 3d at 755 n.4).

Unlike other states, Tennessee limits the general unfairness test to the substantial-injury prong of the *Sperry & Hutchinson* factors. "An act or practice is unfair where 'the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition.'" *Morrison v. Allen*, 338 S.W.3d 417, 439 (Tenn. 2011) (quoting *Tucker v. Sierra Builders*, 180 S.W.3d 109, 116–17 (Tenn. Ct. App. 2005)). "Even if an act or practice causes or is likely to cause substantial injury, it will not be considered unfair unless the injury is not reasonably avoidable by consumers themselves." *Tucker*, 180 S.W.3d at 117. "Consumers cannot reasonably avoid injury when a merchant's sales practices unreasonably create or take advantage of an obstacle to the free exercise of consumer decision-making." *Id.* "Practices that unreasonably interfere with consumer decision-making include (1) withholding important information from consumers, (2) overt coercion, or (3) exercising undue influence over a highly susceptible class of consumers." *Id.*

Eli Lilly alleges both general and per se violations of the Tennessee Consumer Protection Act. Eli Lilly alleges that "Revive has engaged in unfair trade practices by selling its unapproved combination tirzepatide and vitamin B6 injections in Tennessee without obtaining the requisite approvals to sell new drug products, in violation of Tennessee law." (Docket Entry No. 97 ¶ 144). Eli Lilly alleges that Revive's sales of compounded drugs are generally unfair because they "are substantially injurious to consumers and" their "utility . . . is outweighed by the harm to consumers." (*Id.* ¶ 148). Eli Lilly alleges that Revive's sales of compounded drugs are per se unfair because the Tennessee Consumer Protection Act bars "[a]dvertising, promoting, selling or offering for sale any good or service that is illegal or unlawful to sell in the state." TENN. CODE § 47-18-104(b)(43)(C).

Revive moves for judgment on Eli Lilly's general claim because Eli Lilly failed to allege that "Revive has unreasonably interfered with consumer decision making within the meaning of Tennessee law." (Docket Entry No. 108 at 22). Revive moves for judgment on Eli Lilly's per se claim because Section 47-18-104(b)(43)(C) covers only goods or services that are categorically unlawful. (*See id.* at 22–23 (citing *Westgate Resorts, Ltd. v. Wesley Fin. Grp., LLC*, 2023 WL 5062065, at *19 & n.14 (M.D. Tenn. Aug. 8, 2023)). The court finds both arguments unpersuasive.

First, Eli Lilly adequately alleges that Revive interfered with consumer decisions. Eli Lilly alleges that Revive is selling "drugs that have not been demonstrated to be safe or effective, without any disclosure of the risks entailed, and without the guardrails that are part of any proper clinical trial." (Docket Entry No. 97 ¶ 8). Eli Lilly alleges that Revive "promise[s] results that consumers will not obtain from Revive's products." (*Id.* ¶ 81). Eli Lilly further alleges that Revive "trad[es] on the credibility—earned through decades of safe and effective pharmaceutical manufacturing and years of clinical research and testing on tirzepatide specifically—of Lilly and its FDA-approved Mounjaro® and Zepbound®." (*Id.*). By "trading" on Eli Lilly's reputation, Revive leads consumers to believe, falsely, that its weight-loss products are just as safe and effective as Eli Lilly's FDA-approved products. (*See id.*). Eli Lilly alleges that Revive misleads consumers into thinking that because tirzepatide and vitamin B6 are safe, the compounded medications will be just as safe and effective. But "new drugs" include new combinations of existing drugs precisely because, "though the component parts of a new drug may be generally recognized as safe and effective, the combination itself may not be." *Promise Toothpaste*, 624 F. Supp. at 778 (first citing *Coli-Trol 80*, 518 F.2d at 746; and then citing *X–Otag Plus Tablets*, 441 F. Supp. at 111). Eli Lilly's complaint squarely raises this issue. (*See id.* ¶ 61 (alleging Eli Lilly

is not aware of studies showing that combining tirzepatide with vitamin B6 is safe)). The complaint allegations satisfy the Tennessee Consumer Protection Act's general test.

Second, Eli Lilly adequately alleges that Revive violated Section 47-18-104(b)(43)(C). That provision creates liability for the sale of goods that are "illegal or unlawful to sell in the state." TENN. CODE § 47-18-104(b)(43)(C). Compounded medications are "new drugs." *Id.* § 53-1-102(27). The "sale" of "new drugs" in the State is "prohibited," *id.* §§ 53-1-103(a)(4), 53-1-110(a), and subject to criminal penalties, *see id.* § 53-1-103(b)(1) ("Any person who violates subsection (a) commits a Class C misdemeanor."). When an act is prohibited and subject to criminal penalties, it is "illegal or unlawful." *See State v. Tolliver*, No. W21-01386CCAR3CD, 2023 WL 2673152, at *15 (Tenn. Crim. App. Mar. 29, 2023) (unlawful means criminally punishable); *State* v. *Hollon*, 671 S.W.3d 561, 567 (Tenn. Crim. App. 2023) (unlawful means "without legal justification"). The plain text covers Revive's sale of compounded drugs.

Revive argues that because "tirzepatide and compounding services are lawful, including in Tennessee," Revive's compounded weight-loss drugs are not illegal or unlawful "in the legally relevant sense." (Docket Entry No. 108 at 22). According to Revive, only the sale of goods that are "banned categorically" violates Section 47-18-104(b)(43)(C). Revive relies on *Westgate Resorts*, in which the court held that Section 47-18-104(b)(43)(C) did not create liability for the unauthorized practice of law. 2023 WL 5062065, at *14–*15. The court dismissed the plaintiff's allegations as a "semantic contortion" of the Tennessee Consumer Protection Act. *Id.* The court reasoned that, because the other subparts "pertain to radar detectors and radar jamming devices," Subpart (c) was not meant to address "unauthorized legal services." *Id.* Radar detectors and jamming devices, Revive suggests, are the sort of categorically banned devices to which Subpart

(c) should be limited. *See Sallee v. Barrett*, 171 S.W.3d 822, 829 (Tenn. 2005) (explaining the *ejusdem generis* canon).

Revive's argument has some appeal, but the court is ultimately not persuaded. Revive's rule creates challenging line-drawing problems. Few goods or services are categorically banned. Radar jammers, for example, can be sold to "law enforcement officers acting in their official capacity." TENN. CODE § 39-16-610(f). It can be difficult to determine whether a good or service is categorically banned (subject to a few exceptions) or generally permitted (but only after meeting several conditions). *Compare id.* § 39-16-610(b), (f), *with id.* § 23-3-103(a). The *Westgate* court saw radar jammers as falling into the former camp and legal services as falling into the latter camp. But many regulated goods or services—such as new drugs or controlled substances—fall somewhere in between. *See, e.g.*, *id.* §§ 39-17-418(a), 53-10-105(a), 53-1-110(a). The rule that is easier to administer is one that follows directly from the plain text: if the legislature has affixed criminal penalties to the sale of the good or service, *see Tolliver*, 2023 WL 2673152, at *15, then a seller can be liable under Section 47-18-104(b)(43)(C).

This rule satisfies the *ejusdem generis* canon on which Revive relies. "New drugs" and radar-jamming devices are in the "same general class," *Sallee*, 171 S.W.3d at 829, of goods that the Tennessee legislature has made "illegal or unlawful to sell in the state," TENN. CODE § 47-18-104(b)(43)(C); *see, e.g.*, *id.* §§ 39-16-610(g)(1), 53-1-103(b)(1) (making both violations a Class C misdemeanor). Commercial transactions are legal unless the State criminalizes them. *See State v. Boyd*, 925 S.W.2d 237, 243 (Tenn. Crim. App. 1995) ("Before conduct can now constitute a violation of the criminal law, it must be 'defined as an offense by statute, municipal ordinance, or rule authorized by and lawfully adopted under a statute.'" (quoting TENN. CODE § 39-11-102(a))). The sale of goods generally does not carry the threat of criminal penalties, even if most goods are

regulated to some degree. When the legislature chooses to affix criminal penalties to the sale of certain goods or services, it actively limits the scope of commerce that is otherwise permissible. The material line to draw based on Section 47-18-104(b)(43)'s Subparts is not between categorical (or near-categorical) and partial prohibitions but the fact of the prohibition in the first place.

This line adheres to the TCPA's structure and advances its remedial purpose. The TCPA does not apply to transactions "specifically permitted by law." *Eli Lilly*, 812 F. Supp. 3d at 748 (quoting *Johnson v. John Hancock Funds*, 217 S.W.3d 414, 423 (Tenn. Ct. App. 2006)); TENN. CODE § 47-18-111(a)(1). "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 v. Steele*, 730 S.W.2d 335, 337 (Tenn. Ct. App. 1987). If a ban on the sale of a good or service is not categorical, then Section 47-18-111(a)(1)'s exemption will readily protect those who act under appropriate authorization. Although the Tennessee legislature has placed the burden of proof on defendants to prove the exemption, TENN. CODE § 47-18-111(b), that choice sensibly ensures that those who are selling otherwise illegal goods are doing so under the conditions the Tennessee legislature has determined are necessary for public safety. To prophylactically limit the scope of Section 47-18-104(b)(43)(C) based on a concern that the statutory exemption addresses would depart from the legislature's instruction to construe the statute "liberally" to "promote" the protection of "consumers and legitimate business enterprises." *Id.* § 47-18-102(2).

For these reasons, Eli Lilly has adequately alleged violations of the TCPA. *See, e.g.*, *Hope Med. Enters. Inc. v. Fagron Compounding Servs., LLC*, No. 2:19-cv-07748, 2021 WL 4963516, at *16 (C.D. Cal. Oct. 26, 2021) (concluding that the sale of compounded medications violated

Section 47-18-104(b)(43)(C)), *rev'd on other grounds*, No. 22-55173, 2023 WL 4758454 (9th Cir. July 26, 2023).

7. Washington

In Washington, "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." WASH. REV. CODE § 19.86.020. The statute must be "liberally construed" so "that its beneficial purposes may be served." *Id.* § 19.86.920; *see Short v. Demopolis*, 691 P.2d 163, 166 (Wash. 1984). "[A]n unfair or deceptive act or practice under the CPA may be predicated on a per se violation of a statute *or* an unfair act or practice not regulated by statute but constituting a violation of the public interest." *Preston v. SB&C, Ltd.*, 588 P.3d 371, 375 (Wash. 2026) (emphasis in original); *see Greenberg v. Amazon.com, Inc.*, 553 P.3d 626, 638 (Wash. 2024) ("The first CPA element may be predicated on a per se violation of a statute or an unfair act or practice not regulated by statute but in violation of public interest."). "A per se unfair trade practice exists when a statute which has been declared by the Legislature to constitute an unfair or deceptive act in trade or commerce has been violated." *Hangman Ridge Training Stables, Inc. v. Safeco Title Ins. Co.*, 719 P.2d 531, 535 (Wash. 1986). "If a defendant's act or practice is not per se unfair, then the plaintiff must show the conduct is unfair 'under a case-specific analysis of those terms.'" *Greenberg*, 553 P.3d at 638 (quoting *Rush v. Blackburn*, 361 P.3d 217, 224 (Wash. Ct. App. 2015)).

Revive argues that Eli Lilly's claim fails under Washington law because (1) the sale of "new drugs" is not a per se violation; (2) "unfair competition" is limited to the letter of the Sherman, Clayton, or FTC antitrust statutes; and (3) Washington bars private enforcement of its FDCA, *see* WASH. REV. CODE § 69.04.180. (*See* Docket Entry No. 108 at 23–24). The court is not persuaded.

First, Washington's Consumer Protection Act is not limited to per se violations or by other regulatory regimes. "Unfair or deceptive conduct that violates the public interest may be based on actions contrary to a comprehensive statutory scheme . . . ." *Preston*, 588 P.3d at 375. But when conduct is "beyond the scope of" one regulatory scheme, "that does not mean it is exempt from suit under the broader scope of the CPA." *Id.* at 376. "A violation of the underlying policy of the" statutory scheme "can constitute a non-per-se CPA violation." *Id.* Or "in cases where a plaintiff alleges that an act or practice is unfair, but that act or practice is not regulated by statute, the plaintiff needs to show only that the defendant's conduct is in violation of public interest." *Greenberg*, 553 P.3d at 640–41.

In *Preston*, the Washington Supreme Court rejected the argument that either a failure to enumerate a statutory violation as per se unfair or a failure to prove a violation of a related and "intensive" regulatory scheme precluded liability under the CPA. *See* 588 P.3d at 376. To adopt that argument, the court explained, would be to "narrow the CPA to apply only to those situations where" another statutory "requirement establishes a per se violation." *Id.* Revive's "argument ignores the breadth of the CPA," which "is intended to be broad enough to reach 'unfair or deceptive conduct that inventively evades regulation.'" *Id.* (quoting *Panag v. Farmers Ins. Co. of Wash.*, 204 P.3d 885, 895 (Wash. 2009)).

Second, Washington's CPA is not limited by the antitrust statutes. "Because the act does not define 'unfair' or 'deceptive,'" the Washington Supreme Court "has allowed the definitions to evolve through a 'gradual process of judicial inclusion and exclusion.'" *Saunders v. Lloyd's of London*, 779 P.2d 249, 256 (Wash. 1989) (quoting *State v. Reader's Digest Ass'n*, 501 P.2d 290, 301 (Wash. 1972), *modified in Hangman Ridge*, 719 P.2d at 535–36). The Washington Supreme Court has been clear that "[u]nlike the FTC Act," the "CPA simply has no limitations on the range

of effect the defendant's conduct must have for a plaintiff to state a cognizable claim to relief." *Greenberg*, 553 P.3d at 640. Washington courts use all three *Sperry & Hutchinson* criteria "to promote the liberal construction of the CPA." *Id.* Those courts also consider other factors, following the guidance that "there may even be additional ways that a plaintiff can show that act or practice that is unregulated by statute is unfair." *Id.* at 641. The Washington Supreme Court has rejected arguments that the State's Consumer Protection Act should not regulate conduct simply because the federal antitrust laws do not reach it. *See id.* at 638–39, 644–45. The Court has also credited myriad policy goals, such as improving "access to health care." *Preston*, 588 P.3d at 375; *see, e.g.*, *Hangman Ridge*, 719 P.2d at 536 (listing various statutes that are per se violations of the Consumer Protection Act and relying on defective-product cases under the Act to define the elements of a claim). The food-and-drug laws advance important policy goals, and they are relevant to stating a Consumer Protection Act claim. *See Preston*, 588 P.3d at 375 ("actions contrary to a comprehensive statutory scheme" can be "unfair").

Revive's reliance on *State v. Black*'s comment that courts should adopt "a narrower interpretation of the words 'unfair method of competition' than that given by federal courts" is misplaced. 676 P.2d 963, 969 (Wash. 1984). *Black* interpreted the Consumer Protection Act's "unfair method of competition" language based on the Attorney General's "civil antitrust action." *Id.* at 965. The Washington Supreme Court assessed how the statute would govern antitrust claims, like those brought under the Sherman Act or Clayton Act. *See id.* at 967–69. The *Black* opinion did not address the CPA's bar on "unfair or deceptive acts or practices," WASH. REV. CODE § 19.86.020, or otherwise comment on the separate line of cases, starting with *Reader's Digest*, that applied the *Sperry & Hutchinson* factors and public-interest test, *see Hangman Ridge*, 719 P.2d at 535–37; *Greenberg*, 553 P.3d at 640–41; *Preston*, 588 P.3d at 375. And since *Black*, courts have

clarified its focus on protecting "reasonable business practices." *See Greenberg*, 553 P.3d at 652–54 (Keenan, J., concurring). The Consumer Protection Act's instruction that business practices are not unfair if they are "reasonable in relation to the development and preservation of business," WASH. REV. CODE § 19.86.920, provides a "reasonableness defense to [a] CPA claim," *Travis v. Wash. Horse Breeders Ass'n*, 759 P.2d 418, 424 (Wash. 1988), that is either "codified in the substantial injury test's countervailing benefits prong," *Greenberg*, 553 P.3d at 653–54 (Keenan, J., concurring), or, potentially, a separate jury instruction, *see Travis*, 759 P.2d at 424; *Greenberg*, 553 P.3d at 654 (Keenan, J., concurring). Though *Black* is important, it does not limit the CPA's breadth.

Third, Washington's bar on private enforcement of its Food, Drug, and Cosmetic Act does not preclude a claim under its Consumer Protection Act. The principles already discussed weigh heavily in favor of this conclusion. A plaintiff can prove a Consumer Protection Act violation based on "actions contrary to a comprehensive statutory scheme," *Preston*, 588 P.3d at 376, or actions that are "not regulated by statute" but are nonetheless "unfair," *Greenberg*, 553 P.3d at 638, 640–41. The Washington legislature intended the Consumer Protection Act "to reach 'unfair or deceptive conduct that inventively evades regulation.'" *Preston*, 588 P.3d at 376 (quoting *Panag*, 204 P.3d at 895). Applying similar principles, the Connecticut Supreme Court held that its unfair-competition statute could apply to conduct over which the state had exclusive regulatory authority. *See Eder Bros.*, 880 A.2d at 146–47, 149–50; *see also Patane*, 478 F. Supp. 3d at 328–29. Washington case law does not suggest a different outcome.

The Washington legislature knows how to preclude claims under the Consumer Protection Act. *See McCarthy Fin., Inc. v. Premera*, 347 P.3d 872, 875 (Wash. 2015) ("The CPA itself addresses the limited times when agency action exempts application of the CPA."). The

Washington legislature exempted claims under the Consumer Protection Act in two ways. First, it bars claims based on actions or transactions "permitted, prohibited or regulated" by "[1] the insurance commissioner of this state, [2] the Washington utilities and transportation commission," and "[3] the federal power commission." WASH. REV. CODE § 19.86.170. The fact of regulation by those agencies precludes the claim. *See Hall v. Walgreens Boots All., Inc.*, 565 P.3d 564, 568 (Wash. 2025) ("This difference must mean something . . . ."). Second, by contrast, for "any other regulatory body," WASH. REV. CODE § 19.86.170, the exemption is "limited to actions or transactions expressly permitted by the agency," *Hall*, 565 P.3d at 568. As a result, the Washington and Federal Food, Drug, and Cosmetic Acts do not automatically preclude litigation under the Consumer Protection Act. *See id.* at 569 (holding that the "statutory safe harbor applies only to activities or transactions expressly permitted by the FDA"). The Washington legislature's list of regulators further suggests that Section 69.04.180 does not prevent suits for violations of the State's food-and-drug laws or their underlying policies. *See Bour v. Johnson*, 864 P.2d 380, 383 (Wash. 1993) ("Legislative inclusion of certain items in a category implies that other items in that category are intended to be excluded.").

Revive's motion for judgment on Eli Lilly's claims under Washington law is denied.

III. Conclusion

The court denies Revive's motion for judgment on the pleadings. (Docket Entry No. 108).

SIGNED on August 4, 2026, at Houston, Texas.

Lee H. Rosenthal
Senior United States District Judge