No. 24-3296

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

SANDRA YOUSEFZADEH, ET AL., NEWTON'S PHARMACY, INC.,

PLAINTIFFS-APPELLANTS,

(For Continuation of Caption See Inside Cover)

On Appeal from the United States District Court
for the Eastern District of New York
Case No. 1:23-md-03089-BMC
The Honorable District Judge Brian M. Cogan, Presiding

BRIEF OF AMICUS CURIAE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA SUPPORTING DEFENDANTS-APPELLEES

Christopher J. Walker
U.S. CHAMBER LITIGATION CENTER
1615 H Street, NW
Washington, DC 20062
(202) 463-5337

ROBERT E. DUNN
ISAAC J. WEITZHANDLER
EIMER STAHL LLP
1999 South Bascom Avenue
Suite 1025
Campbell, CA 95008
(408) 889-1690
rdunn@eimerstahl.com
iweitzhandler@eimerstahl.com

Counsel for Amicus Curiae Chamber of Commerce of the United States of America

GWEN THOMAS, RHONDA NITTO,

PLAINTIFFS,

V.

JOHNSON & JOHNSON CONSUMER INC., RB HEALTH (US) LLC, TARGET CORPORATION, BAYER HEALTHCARE, LLC, A DELAWARE LIMITED LIABILITY CORPORATION, WALMART INC., A DELAWARE CORPORATION, CVS PHARMACY, INC., A DELAWARE CORPORATION, WALGREEN CO., AN ILLINOIS CORPORATION, THE PROCTER & GAMBLE COMPANY, HALEON US HOLDINGS LLC, PUBLIX SUPER MARKETS, INC., AMAZON.COM, INC., AMAZON.COM SERVICES LLC, KENVUE, INC., GLAXOSMITHKLINE LLC, RITE AID CORPORATION, ALBERTSONS COMPANIES, INC., COSTCO WHOLESALE CORP.,

DEFENDANTS-APPELLEES,

DOES 1-200, GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS (US) LLC, RECKITT BENCKISER LLC, MERCK, MCNEIL CONSUMER HEALTHCARE, SANOFI-AVENTIS U.S. LLC, CHURCH & DWIGHT CO. INC., ASSOCIATED WHOLESALE GROCERS INC, VALU MERCHANDISERS CO., PFIZER INC., PERRIGO COMPANY PLC, HELEN OF TROY LIMITED, DIERBERGS MARKETS, INC., RECKITT BENCKISER PHARMACEUTICALS INC., THE KROGER CO., HARRIS TEETER, LLC, HARRIS TEETER SUPERMARKETS, INC., DOLGENCORP, INC., FAMILY DOLLAR, LLC.,

DEFENDANTS.

CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America states that it is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

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STATEMENT OF INTEREST OF AMICUS CURIAE[1]

The Chamber of Commerce of the United States of America (the Chamber) is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

In the context of over-the-counter (OTC) drugs regulated by the Food and Drug Administration (FDA) monographs, the Chamber's members have a strong interest in the certainty and stability provided by FDA's uniform, national regime for drug product labels. An important reason

[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amicus curiae*, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E). All parties have consented to the filing of this brief.

why Congress chose to prevent states from creating their own labeling requirements for these products is that Congress wanted to protect the stability and predictability of monograph labeling requirements for manufacturers and retailers—and for consumers, who benefit from the clarity and nationwide consistency produced by FDA's monograph regime. More broadly, the Chamber's members have a strong interest in ensuring that statutory preemption provisions, including provisions that utilize language similar to the operative preemption language at issue here, are correctly interpreted to cut off improper litigation and to ensure uniform regulation of matters that Congress chose to govern by federal law alone.[2]

INTRODUCTION AND SUMMARY OF ARGUMENT

When Congress establishes a detailed regulatory scheme, it often chooses to expressly preempt related state requirements. That approach makes sense. It ensures comprehensive regulation while maintaining national uniformity and avoiding conflicting state standards that drive

[2] This brief limits its focus to the question of whether the Plaintiffs' claims under state law are preempted by federal law, and does not analyze any other questions presented in this appeal.

up costs on businesses and, ultimately, consumers. But if plaintiffs could avoid even the broadest preemption clauses with artful pleading and rhetorical sleight of hand, Congress's will would be subverted. That is what Plaintiffs are trying to do in this case.

I.A. In the Food, Drug, and Cosmetic Act (FDCA), Congress established a detailed federal regulatory scheme for drugs. The FDCA sets out an intricate system for the approval of new drugs. And it creates a separate, similarly detailed system (or "monograph") under which certain drugs can be sold over the counter without a prescription. Alongside this detailed scheme, Congress included a broad express preemption clause that prohibits states from imposing any requirement "that is different from or in addition to, or that is otherwise not identical with," the federal requirements. 21 U.S.C. § 379r(a)(2).[3]

[3] Several other statutes contain preemption clauses with similar or materially identical language. *See, e.g.*, 21 U.S.C. § 379s(a) (prohibiting any state cosmetic labeling or packaging requirement "that is different from or in addition to, or that is otherwise not identical with," federal requirements); 21 U.S.C. § 360k(a) (provision related to medical devices that prohibits states from establishing requirements "different from, or in addition to" any requirements applicable under federal law); 7 U.S.C. § 136v(b) (Federal Insecticide, Fungicide, and Rodenticide Act preempts

This case is about oral phenylephrine, a nasal decongestant the FDA approved to be sold over the counter. To comply with federal requirements, oral phenylephrine must be labeled as a "nasal decongestant," and the label must say that it relieves nasal congestion. 21 C.F.R. § 341.80. If a manufacturer's label meets these and other regulatory requirements, it is "generally recognized as safe and effective and is not misbranded" under federal law. 21 U.S.C. § 355h(a)(1).

Plaintiffs allege that Defendants know that oral phenylephrine is ineffective in relieving nasal congestion and that they violated state consumer protection laws by marketing oral phenylephrine as a nasal decongestant. Plaintiffs contend that state law requires Defendants' drug labels to say that oral phenylephrine is *not* a nasal decongestant—the opposite of what federal law demands. The state-law requirements Plaintiffs seek to impose are plainly different from, in addition to, or

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state requirements "in addition to or different from" federal requirements); 21 U.S.C. § 678 (Federal Meat Inspection Act preempts state requirements "in addition to, or different than" federal requirements.).

otherwise not identical with, the federal requirements governing oral phenylephrine. Plaintiffs' state-law claims are therefore preempted.

I.B Plaintiffs try to avoid this straightforward conclusion by arguing that the relevant state-law requirements are parallel to the FDCA's general prohibitions on misbranding. But Plaintiffs cannot avoid preemption by pointing to these general federal prohibitions because FDA made a specific judgment, applying its scientific expertise and exercising its congressionally delegated authority, that the nasal decongestants at issue here are safe and effective and *not* misbranded when labeled consistent with the monograph. To be sure, Congress created a specific procedure for revising monographs, and the FDA is certainly free to revise the cough-and-cold monograph when and if it decides that such revision is appropriate. *See* 21 U.S.C. § 355h(b)(4); *see also* 21 C.F.R. § 10.30 (allowing any interested person to petition FDA to make a national requirement).[4] But unless and until the FDA revises the

[4] FDA is, in fact, considering such a potential revision now. FDA News Release, *FDA Proposes Ending Use of Oral Phenylephrine as OTC Monograph Nasal Decongestant Active Ingredient After Extensive Review*, U.S. Food & Drug Administration (Nov. 7, 2024), *available at*

monograph, Defendants' products are legal if sold consistent with the current monograph's requirements, and state law may not impose labeling requirements that are different from federal requirements.

Plaintiffs' state-law claims contradict both Congress's and FDA's judgment. Pretending that state-law claims are parallel merely because they recite the federal prohibitions on misbranding—when the claims contradict how FDA has applied those prohibitions to the specific products at issue—would nullify Congress's preemption provision. Moreover, it would create a circuit split in how the federal courts of appeals interpret this preemption language.

The Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), cannot save Plaintiffs' state-law claims, either. The district court did not improperly defer to the FDA's interpretation of any ambiguous statutory provision. On the contrary, the district court exercised its independent judgment to interpret the FDCA's

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https://www.fda.gov/news-events/press-announcements/fda-proposes-ending-use-oral-phenylephrine-otc-monograph-nasal-decongestant-active-ingredient-after. "For now, companies may continue to market OTC monograph drug products containing oral phenylephrine as a nasal decongestant." *Id.*

preemption provision using standard tools of statutory interpretation.

I.C Plaintiffs' state-law claims are also not saved by the FDCA's saving clause for claims that arise under "product liability law," because Plaintiffs have asserted consumer deception claims, not product liability claims. A claim sounds in product liability when the plaintiff alleges personal injury, death, or property damage caused by a defective product. Plaintiffs have asserted no such injury, but rather claim that they would not have purchased Defendants' products but for their allegedly misleading labels.

II. While the plain language of Congress's preemption provision resolves this case, it bears emphasis that Congress made a wise choice to promote uniformity in interstate commerce and to preempt different state labeling regimes. Under Plaintiffs' theory, states would be able to impose one-off labeling requirements that vary from FDA's specific requirements. That fragmented framework would mean that identical products governed by a single FDA monograph could bear different warnings in different states and would lead to manufacturers' overloading their product labels with unwarranted warnings. Such

inconsistency and over-warning would cause consumer confusion, contrary to Congress's decision to create a uniform, nationwide regime administered by FDA. Complying with multiple state-law labeling requirements would also raise the cost of distributing drugs, which would reduce the availability of affordable products for consumers.

ARGUMENT

I. FEDERAL LAW PREEMPTS PLAINTIFFS' STATE-LAW CLAIMS.

The district court properly dismissed Plaintiffs' state-law claims as preempted. Section 379r(a) provides that no state can establish or continue any requirement for the labeling of an OTC drug that is different from or in addition to, or that is not identical with, federal requirements, including FDA labeling requirements. Plaintiffs' state-law claims here attempt to impose requirements that the FDA did not adopt.

A. Congress Preempted All Requirements That Are Not Identical to Federal Requirements.

The FDCA establishes a detailed statutory framework for the regulation of OTC drugs. First, the FDCA forbids the sale of misbranded drugs, 21 U.S.C. § 331(a), and provides that drugs are misbranded if the label is "false or misleading," 21 U.S.C. § 352(a). An OTC drug is

"generally recognized as safe and effective and is not misbranded" if it meets two sets of requirements: a set of general requirements for all OTC drugs and a set of conditions specific to that drug, listed in a regulation called a "monograph." 21 C.F.R. § 330.1.

"Like a recipe," this monograph "provides the conditions under which" an OTC drug is generally recognized as safe and effective. *Nat. Res. Def. Council, Inc. v. FDA*, 710 F.3d 71, 75 (2d Cir. 2013), *as amended* (Mar. 21, 2013). An OTC drug's label has four parts: a statement of identity (saying what the drug is), the indications for use (how the drug can be used), warnings, and directions for use. *See, e.g.*, 21 C.F.R. § 341.80. Like other monographs, the monograph for nasal decongestant drug products specifies exactly what the indications must say, as well as additional language that may be included. *See id*. Relevant here, an OTC nasal decongestant must say either "[f]or the temporary relief of nasal congestion" or "[t]emporarily relieves nasal congestion." 21 C.F.R. § 341.80(b)(1). This statement "may be followed" by any of several possible phrases, such as "due to the common cold," "due to a cold," or "due to hay fever." *Id.* § 341.80(b)(1)(i), (ii). For the indications, the statute and

regulations also permit manufacturers to include "[o]ther truthful and nonmisleading statements, describing only the [approved] indications for use." *Id.* § 341.80(b).

Critically, the FDCA preempts "any requirement that relates to the regulation of a drug . . . that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter." 21 U.S.C. § 379r(a). Cases interpreting the FDCA's preemption clause and similar preemption provisions in other statutes confirm that state law may not impose labeling requirements that are different from those required under federal law.

Indeed, this Court in *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31 (2d Cir. 2020), interpreted the FDCA's similar provision for cosmetics, which preempts any state requirement "different from or in addition to, or that is otherwise not identical with," the FDCA's cosmetics requirements. 21 U.S.C. § 379s(a). The FDCA requires that a cosmetics container state "the net quantity of contents"—*i.e.* how much of the product is inside the container. *Critcher*, 959 F.3d at 35 The plaintiffs in *Critcher* alleged that the label's volume description was misleading because although it

accurately stated the net volume (and thus complied with the FDCA's requirements), it failed to mention that a small portion of that volume could not be accessed. *Id.* at 36. The plaintiffs argued that state law required "an additional disclosure" stating that some of the net volume was inaccessible. *Id.*

This Court held that plaintiffs' state-law claims were preempted because the plaintiffs could not "us[e] state law to impose labeling requirements on top of those already mandated in the FDCA and the regulations promulgated thereunder." *Id.* And the disclaimers plaintiffs sought to include were "'different from,' or 'in addition to'—or otherwise 'not identical with'" the labeling "requirements that federal law already imposes." *Id.* "This is exactly what the FDCA does not permit." *Id.* That analysis is binding, and it applies here.

Other circuits have interpreted similar preemption statutes and reached the same conclusion. For example, in *Weber v. Allergan, Inc.*, the Ninth Circuit interpreted the preemption provision in the FDCA's Medical Device Amendments (MDA), which preempts any state requirement "different from, or in addition to" the federal requirements.

940 F.3d 1106, 1110–11 (9th Cir. 2019) (quoting 21 U.S.C. § 360k(a)). The court held that the only state-law requirements that are *not* preempted are those that are identical to "a particular pre-market approval or other FDA requirement." *Id.* at 1112. The Seventh Circuit reached a similar conclusion in interpreting the FDCA's food labeling provisions. *See Turek v. Gen. Mills, Inc.*, 662 F.3d 423 (7th Cir. 2011). In that case, as here, the challenged labeling was "compliant with [FDA] regulation," and "[t]he disclaimers that the plaintiff want[ed] added to the labeling . . . [we]re not identical to the labeling requirements imposed on such products by federal law." *Id.* at 427. Accordingly, the court held that the proposed disclaimers were "barred" by the FDCA. *Id.*

Many district courts have also interpreted the FDCA's preemption provision in the context of OTC drugs and concluded that similar claims seeking to impose alternative labels were preempted. For example, in a series of cases challenging the labels on OTC acne medications, the plaintiffs claimed that manufacturers should have included warnings stating that one component of the acne medications degraded into benzene, which is toxic. *See, e.g.*, *Howard v. Alchemee, LLC*, No. 2:24-cv-

01834-SB-BFM, 2024 WL 4272931 (C.D. Cal. Sept. 19, 2024). The court rejected that claim, holding that because the monograph did not require a warning, the plaintiff's "allegation that [the manufacturer] should have warned about the presence of benzene on [the drug's] label is therefore preempted because it would be an 'addition' not required by federal law." *Id.* at *3. Similarly, in *Smoter v. Mentholatum Co.*, No. 24 CV 4155, 2025 WL 273437 (N.D. Ill. Jan. 17, 2025), the court reasoned that because "[t]he provided language for labelling topical OTC acne medication does not include warnings about benzene," "to the extent the plaintiffs argue the labels of the [acne medications] should have warned them of the possibility of benzene or included benzene as an ingredient, these claims are preempted by federal law and must fail." *Id.* at *2. In another case, the court reasoned that plaintiff's claims were preempted because "the FDA's monograph for [the OTC medication at issue] already regulates the labeling of the Products, and the monograph requires neither the disclosure nor the warning that [plaintiff] seeks." *Eisman v. Johnson & Johnson Consumer, Inc.*, 2:24-cv-01982-ODW (AJRx), 2025 WL 24102, at *4 (C.D. Cal. Jan. 17, 2025).

The same is true here. Plaintiffs contend that Defendants should not be allowed to call oral phenylephrine a nasal decongestant. *See* Opening Br. at 23. But under the FDCA and its regulations, oral phenylephrine's "statement of identity" must "identif[y] the product as a 'nasal decongestant.'" 21 C.F.R. §§ 201.61(b), 341.80(a). Plaintiffs' requested relief, which would require Defendants to omit the statement that oral phenylephrine is a decongestant, is plainly "different from," "in addition to," and "not identical with," the federal labeling requirement. 21 U.S.C. § 379r(a)(2).

Plaintiffs also claim that it is deceptive for Defendants not to disclose that oral phenylephrine allegedly is ineffective because it does not relieve nasal congestion. Opening Br. at 28–29, n.12. But again, FDA's monograph requires the label for OTC oral phenylephrine to state that the drug "temporarily relieves nasal congestion." 21 C.F.R. § 341.80(b)(1).[5] A state-law requirement to say the opposite—that oral

[5] Defendants may also say that oral phenylephrine is "[f]or the temporary relief of nasal congestion," or use "[o]ther truthful and nonmisleading statements" that say the same thing. 21 C.F.R. § 341.80(b)(1).

phenylephrine *does not* relieve nasal congestion—is unquestionably "different from," "in addition to," and "not identical with" the FDCA's requirement. 21 U.S.C. § 379r(a)(2). Indeed, it would flatly contradict the required statement.

Finally, Plaintiffs argue that it was misleading for Defendants to refer to some oral phenylephrine as "maximum strength," again because oral phenylephrine allegedly does not work. Opening Br. at 35–36. As with the other contentions described above, this argument contradicts the monograph provision requiring the statement that oral phenylephrine relieves nasal congestion. 21 C.F.R. § 341.80(b)(1). Moreover, the maximum strength statement is "based entirely upon FDA-approved labeling and advertising" and "simply restates" the maximum approved dosage. *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1283–84 (C.D. Cal. 2008).

In sum, because Plaintiffs' state-law claims rest on the notion that state law imposes requirements that are different from, in addition to, or otherwise not identical with, federal requirements, those state-law claims are preempted.

B. Plaintiffs Cannot Avoid Preemption By Reframing Their State-Law Claims As Parallel To the General Prohibitions on Misbranded Drugs.

Plaintiffs attempt to avoid preemption by arguing that the state-law requirements they seek to enforce simply parallel federal law. This argument is based on rhetorical sleight of hand, and courts have uniformly rejected it.

Although some courts have allowed plaintiffs to bring claims under state laws that parallel federal law, those courts have held that "the plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted)." *Elkind v. Revlon Consumer Prods. Corp.*, No. 14-CV-2484(JS)(AKT), 2015 WL 2344134, at *6 (E.D.N.Y. May 14, 2015) (citation omitted) (alteration adopted; emphasis in original); *see also Booker v. E.T. Browne Drug Co.*, 20-CV-03166 (PMH), 2021 WL 4340489, at *6 (S.D.N.Y. Sept. 23, 2021) ("the conduct underlying the claim *must violate* the FDCA"). Under this theory, if state law independently imposes a requirement that is identical to a requirement in the FDCA, such that a violation of the state law necessarily is also a

violation of the FDCA, a claim under the state law is not expressly preempted.[6]

Plaintiffs attempt a similar argument here, but even if those decisions are correct Plaintiffs cannot "thread [the] very narrow needle" required "to avoid preemption." *Booker*, 2021 WL 4340489, at *6. Plaintiffs' state-law claims are brought under statutes that forbid deceptive practices. Plaintiffs highlight the similarity between those statutes and the FDCA's

[6] For example, FDCA lays out specific processes for manufacturing drugs, *see Williams v. Galderma Lab'ys*, No. 24 CV 2222, 2024 WL 4213220, at *5 (N.D. Ill. Sept. 17, 2024) (citing 21 U.S.C. § 331(a)); 21 C.F.R. § 351(a)(2)(B)), and the MDA establishes analogous processes for medical devices, *see Weber*, 940 F.3d at 1113–14 (discussing 21 C.F.R. §§ 820.72–820.90). Some state laws impose the same exact obligations. *See, e.g.*, *Bausch v. Stryker Corp.*, 630 F.3d 546, 554 (7th Cir. 2010). Where such a parallel state law exists, some courts have held that a plaintiff may sue under that state law for conduct that would also violate the federal statute, so long as there is no other part of the federal statute or implementing regulations that conflicts with the alleged state-law obligation. *See, e.g., Weber*, 940 F.3d at 1111 (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008)); *see also Barnes v. Unilever U.S. Inc.*, No. 21 C 6191, 2023 WL 2456385, at *5 (N.D. Ill. Mar. 11, 2023) ("unfair practices claims are accordingly parallel to federal law . . . because the claims do not impose any requirements that differ from federal law"). However, some judges have argued that state-law claims "defined *entirely* by a federal regulation adopted under the FDCA" are "*impliedly* preempted." *Davidson v. Sprout Foods, Inc.*, 106 F.4th 842, 862–63 (9th Cir. 2024) (Collins, J., dissenting) (first emphasis in original; second emphasis added).

general prohibition against false and misleading labeling and contend that because the state and federal laws use similar language, their state-law claims are not preempted. Opening Br. at 28–29 (citing 21 U.S.C. § 352(a)(1)). But Plaintiffs ignore the monograph's specific provisions for nasal decongestants. Comparing the monograph's more specific provisions with Plaintiffs' interpretation of state law reveals that Plaintiffs' alleged requirements *do not* parallel federal law. Instead, under Plaintiffs' interpretation, state law would require Defendants to say the opposite of what federal law requires. *See supra*, Section I.A.

The public enforcement provision of the FDCA illustrates the absurdity of Plaintiffs' argument. Plaintiffs' state law claims must parallel the requirements of the FDCA, which is enforced by the FDA. *See supra*, Section I.A. If Plaintiffs' claims actually paralleled the FDCA's requirements, such that Defendants' alleged misconduct also violated the FDCA, the necessary implication is that the FDA could sue an OTC drug manufacturer for complying with the FDA's own monograph. That cannot be the law.

Plaintiffs' argument invites this Court to violate the Supreme Court's admonition that complex statutes like the FDCA must be interpreted "as a symmetrical and coherent regulatory scheme." *Gustafson v. Alloyd Co.*, 513 U.S. 561, 569 (1995); *see also Corley v. United States*, 556 U.S. 303, 314 (2009) ("A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) (alterations adopted)). Here, the FDCA provides that a "drug is deemed to be generally recognized as safe and effective" if it is "in conformity with the requirements for nonprescription use of a final monograph issued under [21 C.F.R. § 330, *et seq*.]" and the other requirements imposed by the FDCA. 21 U.S.C. § 355h(a)(1)(A). The FDA's monographs for OTC drugs are a core component of the overall regulatory scheme, and this Court should not render section 355h and the FDA's implementing regulations "inoperative or superfluous." *Corley*, 556 U.S. at 314 (citation omitted).

This Court has already considered and rejected Plaintiffs' theory. *See Critcher*, 959 F.3d at 37. In *Critcher*, the plaintiffs argued that their

state-law claims "enforce[d] the general FDCA requirement[] . . . that labels not be 'false and misleading in any particular[.]'" *Critcher*, 959 F.3d at 37 (citing 21 U.S.C. § 362(a)).[7] In response, the court noted that in addition to the FDCA's general prohibition against misbranding cosmetics, the FDA had "promulgated rules" of a "technical nature." *Id.* at 38. Considering "Congress's broad, categorical statement of preemption in the FDCA," the court reasoned that if it interpreted state law to impose "*additional* labeling requirements, [it] would be construing state law to impose many 'requirements' that are not contained in the federal statute, or in the regulations issued thereunder, and to disrupt what Congress intended to be a uniform—and federally-led—regulatory scheme." *Id.* (emphasis in original).

Other courts have similarly rejected the argument that state law can impose labeling requirements that are "fundamentally at odds with the FDA's monograph[s]." *Eisman*, 2025 WL 241024, at *5 (citation omitted). Indeed, if Plaintiffs "were permitted to proceed on the theory that [their]

[7] The plaintiffs in *Critcher* also argued that their state-law claims paralleled a general provision of the FDCA that is not relevant here. 959 F.3d at 37–38 (citing 21 U.S.C. § 362(d)).

claims are parallel to" federal regulations just because the FDCA prohibits misbranding, "any finding of liability . . . would conflict with preexisting regulations" deeming the drug at issue *not* misbranded. *Seale v. GSK Consumer Health, Inc.*, 718 F. Supp. 3d 1208, 1222 (C.D. Cal. 2024). As another court recently recognized, Plaintiffs' "theory" is "essentially an attack on the FDA's determination that" the drugs at issue are "generally recognized as safe and effective and not misbranded if they comply with the monograph." *Howard*, 2024 WL 4272931, at *7 (cleaned up). Indeed, if Plaintiffs' argument sufficed to avoid preemption, the preemption provision would be illusory, as a plaintiff could always point to parallel general language in the statute and ignore FDA regulations inconsistent with state law. That reading of the preemption provision "would do exactly what Congress, in passing § 379r of the FDCA, sought to forbid: us[e] state law causes of action to bootstrap labeling requirements that are not identical with federal regulation." *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 376 (S.D.N.Y. 2014) (internal quotation marks and citation omitted).

Contra Plaintiffs' contention (Opening Br. at 17–20), the Supreme Court's recent decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), does not authorize this Court to ignore the FDA's monograph in determining the scope of FDCA preemption. In *Loper Bright*, the Supreme Court held that the Administrative Procedure Act (APA) does not allow courts to defer to an agency's interpretation of an ambiguous statute. 603 U.S. at 391 (quoting 5 U.S.C. § 706). Here, however, the district court did not give *Chevron* deference to the FDA's interpretation of the FDCA's preemption provision, so *Loper Bright* does not undermine the district court's analysis.

Plaintiffs' real complaint is not that the district court improperly deferred to the FDA's interpretation of the statute, but rather that the district court considered the monograph a federal "requirement" for purposes of preemption. But Congress expressly authorized the FDA to promulgate monographs for OTC drugs, 21 U.S.C. § 355h(a)(1), and it expressly deemed drugs marketed in conformance with those monographs "safe and effective" when it passed the CARES Act in 2020, *id.* § 355h(a)(1). Exercising that expressly delegated authority, the FDA

promulgated its monograph for oral phenylephrine, 21 C.F.R. § 341.80, and the district court correctly concluded that each provision of that monograph is "a requirement under [the FDCA]" for preemption purposes. 21 U.S.C. § 379r(a)(2).[8]

C. Plaintiffs' State-Law Claims Are Not Product Liability Claims and Thus Are Not Saved From Preemption.

Plaintiffs also try to rescue their state-law claims from preemption by arguing that they are "product liability" claims and thus fall within the FDCA's saving clause. Opening Br. at 15. That argument fails because

[8] To the extent Plaintiffs are contending that the monograph is *factually* incorrect because oral phenylephrine is ineffective, that is not a question of statutory interpretation, but rather a veiled arbitrary-and-capricious challenge to the FDA's regulation. It would be especially inappropriate to second-guess the factual foundation for the agency's monograph in the context of a tort suit where the agency is not even a party, particularly when Congress has provided a separate avenue for challenging the contents of a monograph. *See* 21 U.S.C. § 355h(b)(1)(A) (interested party may request administrative order regarding safety and efficacy of OTC drugs); 21 U.S.C. § 355h(b)(2)(A)(iv)(III) (dispute resolution process for OTC drug orders); 5 U.S.C. § 553(e) ("Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule."); 5 U.S.C. § 704 (judicial review available for final agency action); *see also* 21 C.F.R. § 10.30 (authorizing citizen petitions to FDA).

these claims do not involve any alleged personal injury, death, or property damage.

The FDCA's saving clause provides that "[n]othing in" the preemption clause "shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." 21 U.S.C. § 379r(e). The FDCA does not define "product liability law," and "where a federal statute uses a term with a settled meaning in the common law, 'a court must infer, unless the statute otherwise dictates, that Congress meant to incorporate the established meaning' of the term." *In re Acetaminophen - ASD-ADHD Prods. Liab. Litig.*, 22md3043 (DLC), 2023 WL 3045802, at *4 (S.D.N.Y. Apr. 21, 2023) (quoting *Felder v. U.S. Tennis Ass'n*, 27 F.4th 834, 843 (2d Cir. 2022)). Applying this inference, courts have uniformly interpreted "product liability law" to exclude claims for false and deceptive advertising.

As the court explained in *In re Acetaminophen*, "product liability law refers to a body of law, originally developed through the common law, aimed at providing relief for personal and property damage caused by defective products." *Id.* Black's Law Dictionary defines a product liability

action as a claim "for personal injury, death, or property damage caused by the manufacture, construction, design, formulation, installation, preparation, or assembly of a product." *Products-Liability Action*, Black's Law Dictionary (12th ed. 2024). In other words, if a defective product injures the consumer or his or her property, the claim sounds in product liability. By contrast, the claim that a product does not work as advertised, or does not have the advertised properties, is a claim for deceptive practices or false advertising. *See, e.g.*, N.Y. Gen. Bus. Law § 349(a) (declaring unlawful all "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state"); *People by James v. PepsiCo, Inc.*, 222 N.Y.S.3d 907, 915 (N.Y. Sup. Ct. 2024) ("Because the legislature was concerned with the impact of deceptive conduct on consumer purchases, General Business Law § 349 prohibits deceptive acts and practices that misrepresent the nature or quality of products and services.") (citing *Himmelstein, McConnell, Gribben, Donoghue & Joseh, LLP v. Matthew Bender & Co.*, 37 N.Y.3d 169, 176 (2021)).

Here, Plaintiffs are not seeking recovery for alleged injuries caused by ingestion of oral phenylephrine. Instead, they are seeking to recover for the cost of purchases they allegedly made after being deceived by labels falsely claiming that oral phenylephrine relieves congestion. That claim sounds in consumer deception, not products liability, and courts have recognized that "product liability law does not include pure economic loss actions" like those Plaintiffs assert here. *Goldstein v. Walmart, Inc.*, 637 F. Supp. 3d 95, 113, n.7 (S.D.N.Y. 2022) (internal quotations and citations omitted); s*ee also, e.g.*, *Mills v. Warner-Lambert Co.*, 581 F. Supp. 2d 772, 790–93 (E.D. Tex. 2008) (citing Tex. Civ. Prac. & Rem. Code § 82.001(2)) ("Plaintiffs' claims [under Texas law] do not arise out of personal injury, death, or property damage . . . [a]s such, they are not products liability actions." (internal quotations omitted)); *Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 790 (2002) ("Under the product liability law of California, injury to the plaintiff from a defective product is an essential element of a cause of action.") (citations omitted).

In short, Plaintiffs' state-law claims do not arise under "product liability law," and thus the saving clause in section 379r(e) does not apply.

II. CONGRESS'S DECISION TO EMPOWER FDA TO IMPOSE UNIFORM LABELING REQUIREMENTS REPRESENTS SOUND POLICY

"It is Congress's job to craft policy and [the courts'] to interpret the words that codify it." *Bd. of Trs. of Bakery Drivers Loc. 550 & Indus. Pension Fund v. Pension Benefit Guar. Corp.*, 136 F.4th 26, 31 (2d Cir. 2025) (citing *Lackey v. Stinnie*, 145 S. Ct. 659, 669 (2025)).

In enacting the preemption provision here, Congress demonstrated its intent to provide consumers with labels that effectively and uniformly convey crucial health and safety information. Permitting states to impose "[d]ifferent or additional requirements," as Plaintiffs urge this Court to do, would not only "work against [the] national marketplace," but also "confuse consumers, raise prices, [and] undermine public confidence in our regulatory system." S. Rep. No. 105-43, at 64 (1997).

A. Non-uniform Safety and Labeling Requirements Would Generate Customer Confusion.

One inevitable consequence of permitting each state to impose its own labeling requirements—or of allowing juries to determine when labels

are misleading on a case-by-case basis—is consumer confusion. Consumers typically purchase OTC products without the assistance of a medical professional, so it is especially important for them to be able to understand what they are purchasing. If the same OTC drug bore different warnings in different states, consumers across the country would be confused about the actual risks associated with those products.

FDA has designed OTC drug labels to facilitate consumer understanding. In adopting a standardized "Drug Facts" label for all OTC products in 1999, FDA emphasized the importance of clear, readable labels with "the least amount of information possible to assure proper self-selection and use" of the medication. *Over-The-Counter Human Drugs; Labeling Requirements*, 64 Fed. Reg. 13,254, 13,269 (Mar. 17, 1999). Jumbled warnings and indications that change from state to state would undermine the goal of assuring proper self-selection and use of OTC medication.

Moreover, if labels were overloaded with disclaimers to avoid potential litigation or liability, this could cause consumers to discount all the warnings. For decades, FDA has expressed concern that, for OTC

products, "if labeling contains too many required statements, . . . the impact of all warning statements on the label will be reduced." General Labeling Conditions, 40 Fed. Reg. 11,717, 11,717 (Mar. 13, 1975). Indeed, FDA considers overwarning to be a concern even for prescription drug labels. When working with manufacturers to develop an appropriate label, FDA ensures that there is a "hierarchy of label information . . . designed to 'prevent overwarning' so that less important information does not 'overshadow' more important information." *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 304 (2019) (quoting 73 Fed. Reg. 49,603, 49,605–49,606 (Aug. 22, 2008)). FDA further seeks to ensure that labels "exclude 'exaggeration of risk, or inclusion of speculative or hypothetical risks,' that 'could discourage appropriate use of a beneficial drug.'" *Id.* (quoting 73 Fed. Reg. 2848, 2851 (Jan. 16, 2008)) (alteration adopted). Allowing states to tack on additional warnings would weaken the important warnings that FDA has chosen and would risk discouraging the appropriate use of safe and effective drugs.

The accompanying Senate Report to the bill that established § 379r highlighted exactly these concerns. "Different or additional requirements

a[t] the State or local level can work against our national marketplace, confuse consumers, raise prices, undermine public confidence in our regulatory system and in products important to the public health, and result in divergent public health protection throughout the country." S. Rep. No. 105-43, at 64. Congress considered these risks and determined that uniformity was necessary.

That choice makes sense. Because "[n]onprescription drugs are subject to careful and comprehensive regulation by the FDA," there would be little benefit to any extra layer of regulation. *Id.* Congress thus made the choice to bar states from "impos[ing] different or additional requirements that relate to the subject matter covered by … Federal laws as they apply to nonprescription drugs and cosmetics," including "requirements imposed on product manufacture or composition, labeling, advertising, or any other form of public notification or communication." *Id.*

B. A Patchwork of Labeling Regimes Would Increase Costs for Businesses Providing Needed Medications and, Ultimately, for Consumers.

Allowing idiosyncratic labeling requirements under state law would also increase regulatory compliance and litigation costs. The concern that a regulatory patchwork would "raise prices" for OTC products was top of

mind when Congress enacted the preemption provision here. S. Rep. No. 105-43, at 64. Minimizing costs to consumers by limiting litigation over requirements that FDA chose not to impose is a worthwhile goal that Congress properly pursued.

Navigating a labyrinth of varying state requirements would impose higher costs and burdens on pharmaceutical manufacturers and, ultimately, on consumers. If each state could have its own unique labeling requirements, companies would have to perform continuous monitoring across 50 states, engage in frequent legal consultations, and undertake label redesigns. As the Seventh Circuit put it, "[m]anufacturers might have to print 50 different labels, driving consumers who buy . . . products in more than one state crazy." *Turek*, 662 F.3d at 426. Such an approach would increase costs for all manufacturers, large and small, and could force small and mid-sized firms out of the market altogether. The result would be to reduce the availability of affordable FDA-approved products for ordinary consumers.

Opening the door to state-law litigation over requirements that FDA chose not to impose would also force drug manufacturers and retailers to engage in costly legal battles to defend against state-specific claims that may differ from jurisdiction to jurisdiction. This is no small risk. The U.S. tort system's commercial-liability costs totaled $347 billion in 2021, an increase of 19 percent over the year before. *See* Press Release, U.S. Chamber of Com. Inst. for Legal Reform, *New U.S. Chamber Study Shows Lawsuit System Costs Small Businesses $160 Billion* (Dec. 5, 2023), *available at* https://instituteforlegalreform.com/press-release/new-u-s-chamber-study-shows-lawsuit-system-costs-small-businesses-160-billion/. Those costs are often passed on to consumers, who face higher prices and fewer valuable products to choose from.

Congress wisely determined that the costs of a patchwork regulatory system were too great to foist on businesses and consumers. It accordingly adopted, "as a general rule, the requirement of national uniformity in the regulation of nonprescription drugs." *Goldstein*, 637 F. Supp. 3d at 104 (quoting S. Rep. No. 105-43, at 64); *see also* 21 U.S.C. § 379r. "Under the legislation, national uniformity is provided for all of

the types of requirements for nonprescription drugs . . . under State laws that are related to requirements included in the Federal laws, e.g., requirements to prevent adulteration or misbranding or other illegal marketing or to issue public notice about the safety of constituents." *Goldstein*, 637 F. Supp. 3d at 104 (quoting S. Rep. No. 105-43, at 64). Simply put, Congress chose to preempt "[s]tate suits seeking to require product labels inconsistent with the federal objective of national uniformity." *Silva v. Haleon US Inc.*, 758 F. Supp. 3d 1082, 1088 (N.D. Cal. 2024) (quoting *Eckler v. Neutrogena Corp.*, 238 Cal. App. 4th 433, 455 (2015)). That policy choice should be respected.

CONCLUSION

This Court should hold that the state-law claims at issue in this case are preempted by the FDCA.

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Respectfully submitted,

/s/ *Robert E. Dunn* _
ROBERT E. DUNN
ISAAC J. WEITZHANDLER
EIMER STAHL LLP
1999 South Bascom Avenue
Suite 1025

Campbell, CA 95008
(408) 889-1690
rdunn@eimerstahl.com
iweitzhandler@eimerstahl.com

Christopher J. Walker
U.S. CHAMBER LITIGATION CENTER
1615 H Street, NW
Washington, DC 20062
(202) 463-5337

Counsel for Amicus Curiae Chamber of Commerce of the United States of America

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), I certify the following:

This Brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) and Circuit Rule 29.1(c) and 32.1(a) because it contains 6,187 words, excluding the parts of the Brief exempted by Federal Rule of Appellate Procedure 32(f).

This Brief complies with all typeface requirements of Federal Rules of Appellate Procedure and 32(a)(5)–(6) and Circuit Rule 32.1(a), because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Century Schoolbook.

Dated June 6, 2025.

/s/ *Robert E. Dunn*
ROBERT E. DUNN

CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of June 2025, I filed the foregoing Brief with the Clerk of the Court using the CM/ECF System, which will send notice of such filing to all registered CM/ECF users.

/s/ *Robert E. Dunn*
ROBERT E. DUNN