In the
Supreme Court of Ohio

STATE OF OHIO EX REL. ATTORNEY GENERAL DAVE YOST, Plaintiff-Appellant, v. CENTRAL TOBACCO AND STUFF INC. D/B/A CENTRAL TOBACCO, Defendant-Appellee.	:	Case No. 2025-1510 On appeal from the Delaware County Court of Appeals, Fifth Appellate District Court of Appeals Case No. 24 CAE 11 0103

BRIEF OF AMICI CURIAE PUBLIC CITIZEN AND NATIONAL ASSOCIATION OF CONSUMER ADVOCATES IN SUPPORT OF PLAINTIFF-APPELLANT STATE OF OHIO EX REL. ATTORNEY GENERAL DAVE YOST

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

INTEREST OF AMICI CURIAE

Public Citizen is a nonprofit consumer-advocacy organization with members in all 50 states. Appearing before Congress, administrative agencies, and courts, Public Citizen works for the enactment and enforcement of laws protecting consumers, workers, and the general public. Public Citizen has a longstanding interest in fighting broad claims that federal regulation preempts state laws that protect consumers, and it has appeared as amicus curiae in many cases raising preemption issues, including preemption under the Food, Drug, and Cosmetic Act (FDCA). *See, e.g.*, *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299 (2019); *Jones v. Medtronic, Inc.*, 745 Fed. App'x 714 (9th Cir. 2018). Public Citizen has also filed amicus briefs supporting the regulation of tobacco products under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), Pub. L. No. 111-31, 123 Stat. 1776 (2009). *See, e.g.*, *RJ Reynolds Tobacco Co. v. FDA*, 96 F.4th 863 (5th Cir. 2024); *Cigar Ass'n of Am. v. FDA*, 964 F.3d 56 (D.C. Cir. 2020).

The National Association of Consumer Advocates (NACA) is a nonprofit association of more than 1,600 attorneys and consumer advocates committed to representing consumers' interests. NACA's members are private and public sector attorneys, legal services attorneys, law professors, and law students whose primary focus is the protection and representation of consumers. NACA members have represented hundreds of thousands of consumers in small-damages actions and consumer class actions. NACA is a national organization committed to promoting justice for consumers, with an emphasis on those of modest means or those who are otherwise especially vulnerable, and its members have long advocated to ensure that

consumers have a remedy and means of redress for injuries caused by unfair practices.

STATEMENT OF THE CASE AND FACTS

Amici Public Citizen and NACA defer to the statement of the case and facts set forth in appellant's merits brief.

ARGUMENT

Proposition of Law: *Neither the federal Food, Drug, and Cosmetic Act, nor the federal Tobacco Control Act, preempts state-law claims alleging that the sale of illegal tobacco products violates Ohio's Consumer Sales Practices Act.*

The State of Ohio seeks to protect consumers from being misled by in-state retailers into purchasing flavored electronic cigarettes (e-cigarettes) that have not been approved by the Food and Drug Administration (FDA) under the Tobacco Control Act. To that end, the Attorney General brought this action against Central Tobacco and Stuff, Inc. (Central Tobacco), alleging that Central Tobacco offered unauthorized e-cigarettes for sale in violation of Ohio's Consumer Sales Practices Act, which prohibits the use of "an unfair or deceptive act or practice in connection with a consumer transaction." R.C. 1045.02(A). In the decision below, the Fifth District held that Ohio's regulation of unauthorized e-cigarettes was preempted by the FDCA, of which the Tobacco Control Act is a part. According to the lower court, *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), bars state-law claims "that would not exist in the absence of the FDCA." *State ex rel. Att'y Gen. Dave Yost v. Cent. Tobacco & Stuff Inc.*, 2025-Ohio-4613, ¶ 41 (5th Dist.) (App. Op.).

This Court should reverse. The Tobacco Control Act expressly preserves state regulation of the sale of tobacco products. In concluding otherwise, the Fifth District

did not consider the Tobacco Control Act's express preservation of state laws that regulate the sale of tobacco products and, instead, misapplied *Buckman*'s conflict analysis to require preemption of state laws whenever those laws incorporate FDCA standards. *Buckman*, however, only requires preemption of "fraud-on-the FDA" claims that frustrate the FDA's regulatory processes, not garden-variety consumer-protection claims that rest on FDCA standards. Moreover, under the Tobacco Control Act, Ohio may bar retailers from selling e-cigarettes altogether, including those e-cigarettes that the FDA has approved. That Ohio seeks to bar retailers from selling e-cigarettes that the FDA has *not* approved makes Ohio law *more* in line with the FDA's action than a hypothetical complete ban on the sale of e-cigarettes. A reading of *Buckman* that would invalidate only the more targeted state action is insensible, and this Court should reject it.

I. Ohio's claims against Central Tobacco do not conflict with the FDCA.

"Preemption is based on the Supremacy Clause" of the U.S. Constitution and "specifies that federal law is supreme in case of a conflict with state law." *Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 477 (2018). Under express preemption, state law must yield to federal law where Congress has used "explicit statutory language" to preempt state law. *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Under implied preemption, federal law preempts state law that "regulates conduct in a field that Congress intended the Federal Government to occupy exclusively" or state law that "actually conflicts with federal law." *Id.* An actual conflict arises if "it is impossible for a private party to comply with both state and federal requirements" or "state law 'stands as an obstacle to the accomplishment and execution of the full

purposes and objectives of Congress.'" *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

Regardless of the category of preemption at issue, "the purpose of Congress is the ultimate touchstone." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (quoting *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485 (1996)); *see New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995) ("[P]re-emption claims turn on Congress's intent."). "When a federal law contains an express pre-emption clause," courts should "focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 594 (2011) (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)). When considering field or conflict preemption, "the text and structure of the [federal] statute at issue" inform the question whether state law is "preempted by implication." *Kansas v. Garcia*, 589 U.S. 191, 208 (2020) (quoting *CSX Transp., Inc.*, 507 U.S. at 664). And when "Congress has legislated in a field which the States have traditionally occupied, [courts] start with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Lohr*, 518 U.S. at 485 (cleaned up).

Under a straightforward application of these principles, federal law does not preempt Ohio's claim that retailers violate the Consumer Sales Practices Act when they sell e-cigarettes that have not been authorized by the FDA. At the outset, the state law at issue here unquestionably falls within Ohio's historic police power to

regulate the sale of goods such as tobacco products within its borders. *See R.J. Reynolds Tobacco Co. v. Cty. of Los Angeles*, 29 F.4th 542, 548 (9th Cir. 2022) (recognizing, in the context of preemption analysis under the Tobacco Control Act, the "states and localities' longstanding role as the primary regulators of tobacco products."); *Austin v. Tennessee*, 179 U.S. 343, 348–49 (1900) (holding that states may "prohibit the[] sale" of cigarettes "for the protection of the public health," particularly the health of "young people."); *cf. Tennessee Wine & Spirits Retailers Ass'n v. Thomas*, 588 U.S. 504, 523 (2019) (recognizing the "States' use of the police power to regulate the alcohol trade"). Moreover, preemption analysis has "consistently respected" state laws that protect consumers "against fraud and deception" because they "embod[y] a traditional state interest." *Head v. New Mexico Bd. of Examiners in Optometry*, 374 U.S. 424, 445 (1963); *see In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 177 (1st Cir. 2009) (stating that "policing deceptive conduct is … a traditional area of state concern").

Against that backdrop, the Tobacco Control Act expressly confirms that Congress did not intend to restrict states' authority to regulate retailers' sale of tobacco products. Under 21 U.S.C. § 387p, entitled "Preservation of State and local authority," Congress provided that the Tobacco Control Act shall not "be construed to limit" states' authority "to enact, adopt, promulgate, or enforce any law … that is in addition to, or more stringent than, requirements established" under the Act. *Id.* § 387p(a)(1). This preservation of state authority expressly extends to state laws "relating to or prohibiting the *sale, distribution*, possession, exposure to, access to,

advertising and promotion of, or use of tobacco products by individuals of any age." *Id.* (emphases added). And while the Act expressly preempts state laws that are "different from, or in addition to," the Act's requirements in areas such as "adulteration" and "misbranding," *id.* § 387p(a)(2)(A), it excludes state laws "relating to the *sale, distribution*, possession, information reporting to the State, exposure to, access to, the *advertising and promotion of*, or use of, tobacco products by individuals of any age" from the provision's preemptive reach, *id.* § 387p(a)(2)(B) (emphases added).

The plain language of section 387p thus makes doubly sure that states retain their historic authority to police the sale of tobacco products and the manner in which retailers promote them. Through this "unique tripartite preemption structure," the Tobacco Control Act "carefully balances federal and local power by carving out the federal government's sole authority to *establish* the standards for tobacco products, while preserving state, local, and tribal authority *to regulate or ban altogether sales of some or all tobacco products*." *Cty. of Los Angeles*, 29 F.4th at 548 (second emphasis added).

In addition, the Tobacco Control Act does not impliedly preempt state regulation. As section 387p confirms, Congress has not preempted the field of tobacco regulation or the sale of tobacco products. *See Arizona v. United States*, 567 U.S. 387, 401 (2012) ("Field preemption reflects a congressional decision to foreclose any state regulation in the area, even if it is parallel to federal standards."). And Ohio state law prohibiting the sale of e-cigarettes that have not been authorized by the FDA does

not conflict with any provision of the Tobacco Control Act. If the FDA has not authorized an e-cigarette product, an Ohio retailer can "comply with both" the FDCA and "its state-law duty" not to sell the unauthorized product. *Mutual Pharm'l Co. v. Bartlett*, 570 U.S. 472, 480 (2013). And because the FDCA bars commerce in tobacco products that have not obtained required FDA approval, *see* 21 U.S.C. §§ 331(a), (c); 387b(6)(A); 387j(a), (c), a state law barring in-state sales of the same tobacco products poses no "obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines*, 312 U.S. at 67. To the contrary, such a state law advances and executes Congress's purposes and objectives.

Consistent with the foregoing principles, federal courts of appeals have consistently held that the FDCA does not preempt state laws that bar the sale of a class of tobacco products. *See R.J. Reynolds Tobacco Co. v. City of Edina*, 60 F.4th 1170, 1179 (8th Cir. 2023) ("The Tobacco Control Act does not expressly or impliedly preempt Edina's prohibitions on selling flavored tobacco."); *Cty. of Los Angeles*, 29 F.4th at 561 ("Los Angeles's ban on the sale of flavored tobacco products is neither expressly nor impliedly preempted by the Tobacco Control Act."); *National Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 82 (1st Cir. 2013) (rejecting argument that local restriction on selling or offering for sale any flavored tobacco product was preempted by the Tobacco Control Act); *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428, 430 (2d Cir. 2013) (same).

II. *Buckman* does not preclude state laws that regulate the sale of tobacco from looking to federal law to draw regulatory distinctions.

The Fifth District did not dispute Ohio's authority to regulate—even ban—the sale of tobacco products within the state. Instead, relying on *Buckman*, the Fifth District concluded that Ohio could not regulate the sale of tobacco products based on whether the product had been approved by the FDA. *See* App. Op. ¶¶ 41, 45. In the Fifth District's view, a state law that incorporates federal law in this manner impermissibly conflicts with the FDA's exclusive authority to enforce the requirements of the FDCA. *Buckman*, however, concerns a specific type of claim—fraud on the FDA—and its impact on the federal regulatory scheme. *Buckman* neither requires state laws to turn a blind eye to federal law, nor suggests that state laws expressly *permitted* by the Tobacco Control Act cannot take account of the federal regulatory status of tobacco products.

A. *Buckman*'s preemption analysis focuses on federal interests that are not present here.

In *Buckman*, the plaintiffs brought a claim for damages under state law for injuries suffered from orthopedic bone screws. The plaintiffs alleged that "fraudulent representations" made by the defendants to the FDA led the FDA to grant marketing permission, which, in turn, caused the plaintiffs' injuries. *Buckman*, 531 U.S. at 343.

At the outset, the Supreme Court recognized that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347. Further, "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied, such as to warrant a presumption

against finding federal pre-emption of a state-law cause of action." *Id.* (internal quotation marks and citation removed).

With that in mind, the Court concluded, "the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." *Id.* at 348. The Court explained that these unusual fraud-on-the-FDA claims conflicted with the "federal statutory scheme" because the FDA uses its authority "to punish and deter fraud against the [FDA] … to achieve a somewhat delicate balance of statutory objectives." *Id.* The Court was concerned that this balance "can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* Specifically, the FDCA established two processes for FDA to allow medical devices to enter the market: pre-market approval and a streamlined "§ 510(k) process" for devices that are "substantially equivalent" to devices already on the market. *Id.* at 344–45. In addition, the FDCA did not bar practitioners from using FDA-approved devices for unapproved "off-label" purposes. *Id.* at 350. The Court was concerned that allowing a state-law, fraud-on-the-FDA claim that examined the information that applicants submitted to the FDA for approval of medical devices would disrupt the agency's regulatory processes. "Would-be applicants may be discouraged from seeking § 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates (such as petitioner) to unpredictable civil liability." *Id.* The Court also worried that applicants seeking to avoid state-law liability would "have an incentive to submit a deluge of information that the [FDA] neither wants nor needs," resulting in harm to the "comparatively speedy § 510(k)

process." *Id.* at 351. In short, the conflict in *Buckman* arose because of "the likely impact that the fraud-on-the-FDA claims would have on the administration of the [FDA's] duties." *Id.* at 351 n.6 (internal quotation marks omitted).

The Supreme Court has consistently interpreted *Buckman* in this way. In *Wyeth v. Levine*, 555 U.S. 555 (2009), for example, the Court explained that *Buckman* "involved state-law fraud-on-the-agency claims," as opposed to state-law claims where the presumption against preemption applies. *Id.* at 565–56 n.3. In *Whiting*, a four-justice plurality explained that *Buckman* involved a "uniquely federal area[] of regulation" that "directly interfered with the operation of the federal program." 563 U.S. at 604 (op. of Roberts, C.J.). And in *Arizona*, the Court recognized that *Buckman* concerned "fraud on the [FDA]." 567 U.S. at 402. Most recently, in *Garcia*, the Court confirmed that, in *Buckman*, the "state tort claim for fraud on the [FDA]" was preempted because it "threatened serious disruption of the sensitive and highly technical process of approving medical devices." 589 U.S. at 212. Where these features are not present—that is, where the claim does not concern fraud-on-the-FDA and does not disrupt the FDA's regulatory processes—the conflict between state and federal law that *Buckman* identified does not exist.

In this case, the conflict identified in *Buckman* does not exist. Ohio does not contend that Central Tobacco made a "fraudulent representation" to the FDA. *Buckman*, 531 U.S. at 343. Rather, Ohio argues that Central Tobacco offered for sale e-cigarettes that the FDA has not approved and that Central Tobacco misled consumers about whether the e-cigarettes were approved for sale. Unlike the

plaintiffs in *Buckman*, Ohio does not seek "to wield state law to vindicate a wrong committed *against the Federal Government*." *Zyla Life Sciences, L.L.C. v. Wells Pharma of Houston, L.L.C.*, 134 F.4th 326, 337 (5th Cir. 2025), *cert. pet. filed*, No. 25-257 (S. Ct. Sept. 2, 2025). Rather, Ohio's claims "focus on harm that is allegedly perpetrated against consumers rather than the FDA." *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 944 (8th Cir. 2011) (internal quotation marks and brackets removed).

Moreover, because Ohio "is not policing the uniquely federal relationship" between the FDA and e-cigarette sellers and retailers, "there is no reason to think that allowing [Ohio's] claims to proceed will '*directly interfere*[]' with the operation of the federal program." *Zyla Life Sciences*, at 337–38 (quoting *Whiting*, 563 U.S. at 604 (plurality op.)). In particular, if state law bars Ohio retailers from selling unauthorized e-cigarettes, no action "deemed appropriate by the [FDA] will later be judged insufficient in state court," the FDA will not be "deluge[d]" with "unwanted 'information,'" applicants will not be "deter[red]" from seeking FDA approval for their e-cigarettes, and the FDA will not be faced with "harmful delays" in processing applications. *Id.* at 338 (quoting *Buckman*, 531 U.S. at 351).

In sum, because "this case involves neither misrepresentations made directly to [the FDA] nor any concerns similar to the administrative efficiency concerns noted by the *Buckman* court," the "narrow scenario" at issue in *Buckman* is not presented. *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 176.

B. This Court should reject a reading of *Buckman* that would prevent states from enforcing state laws that reference federal law.

Despite *Buckman*'s focus on fraud-on-the-FDA claims, some courts, like the Fifth District here, have interpreted *Buckman* to preempt any state-law claim that incorporates a federal standard as an element, irrespective of whether the state law would impede the FDA's regulatory processes. This interpretation is grounded in "certain language in *Buckman*" about the FDA's role in implementing and enforcing the FDCA. *Zyla Life Sciences*, 134 F.4th at 338. But when viewed in context, and in light of other Supreme Court preemption cases, *Buckman*'s statements about the FDA's role in enforcing the FDCA do not invalidate every state-law claim that, as the Fifth District put it, "would not exist in the absence of the FDCA." App. Op. ¶ 41. This Court should reject an interpretation of *Buckman* that would hamstring states' ability to tailor their regulation of tobacco products to federal standards.

1. Decisions reading *Buckman* more broadly take out of context a passage responding to a particular argument made in that case. Read in context, that passage presents no basis for holding Ohio's claims preempted in this case.

Specifically, in *Buckman*, the plaintiffs argued that the Court's rejection of preemption in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), and *Lohr*, 518 U.S. 470, should lead to the same result as to the fraud-on-the-FDA claims at issue. *See Buckman*, 531 U.S. at 352–53. In *Silkwood*, the Court had held that a "state-authorized award of punitive damages" for plutonium exposure was not preempted by the "federal remedial scheme" applicable to federally licensed nuclear facilities. 464 U.S. at 241, 257–58. In reaching that conclusion, the Court interpreted the

Atomic Energy Act to "disclaim[] any interest in promoting the development and utilization of atomic energy by means that fail to provide adequate remedies for those who are injured by exposure to hazardous nuclear materials." *Id.* at 257. In *Buckman*, the Court contrasted the Atomic Energy Act with the FDCA, which Congress had intended to "be enforced exclusively by the Federal Government." 531 U.S. at 352. Specifically, the Court cited 21 U.S.C. § 337(a), which states that "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." *Id.* at 349 n.4.

In *Lohr*, the Court addressed a provision of the FDCA that expressly preempts state requirements "different from, or in addition to, any requirement" applicable to a medical device. 518 U.S. at 481 (quoting 21 U.S.C. § 360k). The Court concluded that a state-law claim alleging that a device maker "violated FDA regulations" was not preempted because section 360k did not prevent states from "provid[ing] a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* at 495; *see also id.* at 513 (O'Connor, J., concurring in part and dissenting in part) ("I also agree that the Lohrs' claims are not pre-empted by § 360k to the extent that they seek damages for Medtronic's alleged violation of federal requirements."). In *Buckman*, the Court explained that "the fraud claims [in *Buckman*] exist solely by virtue of the FDCA disclosure requirements," rather than, as in *Lohr*, state-law claims "that parallel federal safety requirements." 531 U.S. at 353. Accordingly, the Court noted, "fraud-on-the-agency claims" do not "rely[] on traditional state tort law which had predated the federal enactments in questions,"

but regard "the existence of these federal enactments is a critical element in their case." *Id.*

2. Although *Lohr* holds that the FDCA does not *expressly* preempt state-law claims that are based on violations of FDA regulations, some courts have interpreted *Buckman* to require *implied* preemption any state law that incorporates an FDCA regulatory standard. As commonly formulated, the preemption test that these courts apply in the context of medical devices is that, to survive preemption, "[t]he plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by the FDCA's medical device preemption provision, 21 U.S.C. § 360k), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35, 41 (1st Cir. 2023) (cleaned up; emphasis altered); *see Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (same); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (same). The Fifth District here, for instance, followed an unpublished Sixth Circuit decision that had interpreted *Buckman* to mean that "[i]f [a state-law claim] would not exist in the absence of the FDCA, it is impliedly preempted" because it would be "in substance one seeking to enforce the FDCA." *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013); *see* App. Op. ¶¶ 40, 45.

As the Fifth Circuit Court of Appeals has explained, however, "[t]he problem in *Buckman* had nothing to do with state law mirroring federal requirements," but with the distinct question whether state law can be used to vindicate wrongs

committed against a federal agency. *Zyla Life Sciences*, 134 F.3d at 337. *Buckman*'s discussion of "the FDCA's allocation of enforcement discretion to the Federal Government," the court noted, "must be understood in [that] context." *Id.* at 338; *see also Olivier v. City of Brandon*, ___ U.S. ___, 2026 WL 783725 (Mar. 20, 2026) ("This Court has often cautioned that general language in judicial opinions should be read as referring in context to circumstances similar to the circumstances then before the Court and not referring to quite different circumstances that the Court was not then considering." (internal quotation marks omitted)). *Buckman* would have had no reason to consider the "inherently federal" nature of the "relationship between a federal agency and the entity it regulates," 531 U.S. at 347, if the FDA's enforcement authority under section 337 preempted any state-law claim that was grounded on the FDCA's standards. Likewise, *Buckman*'s extensive analysis of how fraud-on-the-FDA claims "exert an extraneous pull on the scheme established by Congress" would have been unnecessary if any state-law claim that looked to the FDCA for a "critical element" were automatically preempted. *Id.* at 353; *see id.* at 348–51. *Buckman* addressed these issues only in the context of evaluating whether the specific "fraud-on-the-agency claims [t]here" were preempted. *Id.* at 353. *Buckman*'s reasoning does not support preempting state law more broadly.

Further, *Buckman* itself understood that *Lohr* contemplated "state-law causes of action that parallel federal safety requirements." 531 U.S. at 353. *Buckman* thus recognized that implied preemption of fraud-on-the-FDA claims does not wholly impair the states' authority to regulate medical devices under the FDCA. That

recognition is consistent with the principle that "[i]mplied preemption analysis does not justify a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives." *Whiting*, 563 U.S. at 607 (plurality op.) (internal quotation marks omitted). Rather, "a high threshold must be met if a state law is to be pre-empted for conflicting with the purposes of a federal Act." *Id.* (internal quotation marks omitted).

In *Wyeth*, for instance, the U.S. Supreme Court held that a state-law claim for inadequate warnings on a drug label did not conflict with the FDCA. In particular, the Court rejected the argument that allowing state-law damages actions would "obstruct the purposes and objectives of federal drug labeling regulation" by "interfer[ing] with "Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives." 555 U.S. at 573. *Wyeth* distinguished *Buckman* because "that case involved state-law fraud-on-the-agency claims, and [*Buckman*] distinguished state regulation of health and safety as matters to which the presumption [against preemption] does apply." *Id*. at 565–66 n.3. Thus, *Wyeth*'s analysis of conflict preemption—which permitted states to impose requirements on drug labels that were *different from* FDA-approved labels—is inconsistent with a "broad[] reading of *Buckman*" that would preempt "parallel state regulation" that *mirrored* FDCA standards. *Zyla Life Sciences*, 134 F.4th at 338; *see also id*. at 336–37 ("If regulating the same primary conduct in different ways does not upset federal enforcement prerogatives, it follows *a fortiori* that regulating it in parallel ways does not either.").

The U.S. Supreme Court's later decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), confirms this point. There, the Court addressed 21 U.S.C. § 360k, which preempts state requirements on medical devices that are "different from, or in addition to," federal requirements under the FDCA. While *Riegel* holds that section 360k expressly preempts common-law claims that impose *different or additional* requirements on medical devices, it makes clear that section 360k "does not prevent a State from providing a damages remedy for claims *premised on a violation of FDA regulations*." *Id.* at 330 (emphasis added).

The U.S. Supreme Court has applied that same principle to other statutes. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 448 (2005) (holding that, under the Federal Insecticide, Fungicide, and Rodenticide Act, "a state cause of action that seeks to enforce a federal requirement 'does not impose a requirement that is "different from, or in addition to," requirements under federal law.'" (quoting *Lohr*, 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part))); *see also Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 467 n.10 (2012) (explaining that, because the "express preemption provision" in the Federal Meat Inspection Act (FMIA) "prevents States from imposing only 'addition[al]' or 'different' requirements, … States may exact civil or criminal penalties for animal cruelty or other conduct that also violates the FMIA.").

The outcomes in these cases are not outliers—they reflect the background principle that, "[o]rdinarily, state causes of action are not pre-empted solely because they impose liability over and above that authorized by federal law." *California v.*

ARC Am. Corp., 490 U.S. 93, 105 (1989). Although Congress could displace state regulation entirely by occupying the field, *see*, *e.g.*, *Arizona*, 567 U.S. at 401,"in the vast majority of cases where federal and state laws overlap, allowing the States to prosecute is entirely consistent with federal interests," *Garcia*, 589 U.S. at 212. In the absence of an actual conflict between state and federal law, the FDA's authority to enforce the provisions of the FDCA under section 337 does not, by itself, "preclude parallel or non-parallel state regulation of the same conduct." *Zyla Life Sciences*, 134 F.4th at 338 & n.8.

3. For the foregoing reasons, the unpublished Sixth Circuit decision in *Loreto*, on which the Fifth District relied, App. Op. ¶¶ 40, 45, misinterpreted *Buckman* to impose a flat bar on state-law claims that "would not exist in the absence of the FDCA." 515 F. App'x at 579. Such a rule would categorically preempt any state law that incorporated federal regulatory distinctions for drugs, medical devices, or tobacco products covered by the FDCA, without regard to the presumption against preemption or any individualized showing that the state law frustrated the achievement of federal policy objectives. As explained above, neither *Buckman* nor any other U.S. Supreme Court decision respecting the FDCA supports such an expansive preemption regime.

Accordingly, in *Fenner v. General Motors, Inc.*, 113 F.4th 585 (6th Cir. 2024), the Sixth Circuit cautioned against reading *Loreto* so broadly. There, the court emphasized that "proof of fraud" against an agency is a critical consideration in deciding whether a state law is preempted under *Buckman*. *Id.* at 600–01 (citing

Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 966 (6th Cir. 2004), for the point that "*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims."). While *Fenner* followed *Loreto* in holding that a state-law claim alleging that a defendant is liable for violating federal law may be preempted under *Buckman*, *id.* at 601, the court held that claims that "do not implicate or challenge [the agency's] determinations" but involve advertisements and communications "*to the public*" were not preempted, *id.* at 596; *see id.* at 602. Likewise, here, Ohio alleges that Central Tobacco has violated state law by selling an unauthorized tobacco product and by falsely representing "to the public" that it was authorized. Although the facts that Ohio must prove to prevail on its claim would *also* prove a violation of the Tobacco Control Act, Ohio's claim does not depend on the existence of an FDCA violation or draw into question any prior determination by the FDA. *See id.* at 599 (holding that claim relating to use of device to defraud consumers was not preempted even if "devices also enabled Defendants to commit fraud on the [agency]."). Because Ohio's claims "do not depend on proving fraud on the [agency] or a violation of federal law," *id.* at 602, the claims are not preempted under *Buckman*.

III. Any application of *Buckman* should respect the states' regulatory role under the Tobacco Control Act.

Even in cases involving implied preemption, courts "give great weight to Congress' inclusion of a provision preserving states' enforcement authority." *Cty. of Los Angeles*, 29 F.4th at 561 (cleaned up). When Congress has "specifically preserved such authority for the States, it stands to reason that Congress did not intend to

prevent the States from using appropriate tools to exercise that authority." *Whiting*, 563 U.S. at 600–01 (plurality op.). Although a saving clause does not "foreclose or limit the operation of ordinary conflict pre-emption principles," a saving clause can inform the question whether state law "conflicts with the federal regulation." *Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323, 329 (2011); *see id*. at 335 (rejecting preemption theory that would be inconsistent with "a statutory saving clause that foresees the likelihood of a continued meaningful role for state tort law"). "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there is between them." *Wyeth*, 555 U.S. at 575 (brackets removed) (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–67 (1989)).

As discussed above, the Tobacco Control Act includes a provision that sets the metes and bounds of preemption of state law, and expressly preserves the states' authority to regulate the sale and distribution of tobacco products. *See supra* Section I. Moreover, although *Buckman* stated that "Congress intended that the [medical device laws] be enforced exclusively by the Federal Government," 531 U.S. at 352 (citing 21 U.S.C. § 337(a)), the Tobacco Control Act evinces the opposite intention: The Act specifies that, "to the extent feasible," the federal government is required to enter into contracts with states to "carry out inspections of retailers within that State in connection with the enforcement" of the FDCA's provisions governing tobacco products. 21 U.S.C. § 372(a)(1)(B)(i). Congress's decision to maintain an active role

for the states in the regulation of tobacco products reflects the states' historic and "almost exclusive[]" role in regulating tobacco products "with little federal involvement" before the Tobacco Control Act was enacted in 2009. *Cty. of Los Angeles*, 29 F.4th at 547. Interpreting *Buckman* to prevent states from incorporating federal standards into state law would undermine Congress's express judgment that states should retain a substantial regulatory and enforcement role with respect to tobacco products.

To be sure, federal courts have been divided on how to apply *Buckman* in the context of the Tobacco Control Act. *See Rocky Patel Premium Cigars, Inc. v. Bonta*, 2025 WL 3903972 (C.D. Cal. Dec. 23, 2025) (rejecting preemption under *Buckman*), *appeal filed*, No. 25-8060 (9th Cir.); *NOVA Distro, Inc. v. Miyares*, 2025 WL 3680321 (E.D. Va. Dec. 18, 2025) (finding preemption under *Buckman*); *Vapor Tech. Ass'n v. Graham*, 2025 WL 3281428 (S.D. Miss. Nov. 25, 2025) (rejecting preemption under *Buckman*), *appeal filed*, No. 26-60013 (5th Cir.); *Wisconsinites for Alternatives to Smoking & Tobacco, Inc. v. Casey*, 2025 WL 2582099 (W.D. Wisc. Sept. 5, 2025) (rejecting preemption under *Buckman*); *Vapor Tech. Ass'n v. Wooten*, 2025 WL 1787420 (E.D.N.C. June 27, 2025) (rejecting preemption under *Buckman*); *Iowans for Alternatives to Smoking & Tobacco, Inc. v. Iowa Dep't of Revenue*, 781 F. Supp. 3d 724 (S.D. Iowa 2025) (finding preemption under *Buckman*); *see also Grand River Enters. Six Nations, Ltd. v. Knudsen*, 2024 WL 2992503 (9th Cir. 2024) (applying *Buckman* without evaluating effect of saving clause in Tobacco Control Act on implied preemption); *Yimam v. Myle Vape Inc-20*, 2020 WL 13614925 (D.C. Super. 2020)

(same). In light of the saving clause, however, the conclusion that *Buckman* preempts state incorporation of FDCA standards would lead to the peculiar outcome that the "proper exercise of state police powers" permits states to "lawfully enact[] legislation banning flavored tobacco products" so long as they do so without regard to "whether the FDA had authorized or reviewed those products," *NOVA Distro, Inc.*, 2025 WL 3680321, at *23 n.15 (internal quotation marks removed), while state regulations that are "*identical to*, or that solely incorporate, federal requirements" would be preempted, *id.* at *15; *see Iowans for Alternatives to Smoking & Tobacco, Inc.*, 781 F. Supp. 3d at 741 (interpreting *Buckman* to prohibit states from "conditioning sales based on FDA authorization status" even though Tobacco Control Act preserves states' authority to "ban all [e-cigarettes] or ban all flavored products … through proper exercise of their police powers."). For the reasons given above, a reading of *Buckman* that produced such a disjointed regulatory regime, far from avoiding a conflict between state and federal law, would undermine the balance that Congress struck in the Tobacco Control Act that largely preserves the states' historic role in regulating tobacco products.

CONCLUSION

The Court should reverse the judgment of the Fifth District.

Respectfully submitted,

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