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

REPLY 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

NANDAN M. JOSHI
ALLISON M. ZIEVE
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
(202) 588-1000
njoshi@citizen.org

ERIC S. ZELL (OH 0084318)
* Counsel of record
National Association of Consumer Advocates
1629 K St NW, Suite 604
Washington, DC 20006
202-984-7706 x112

Attorneys for Amici Curiae

JAMES C. FRASER* (PHV-27929-2026)
*Counsel of record
ERIC N. HEYER (PHV-27925-2026)
THOMPSON HINE LLP
1919 M Street NW, Suite 700
Washington, DC 20036
(202) 331-8800
james.fraser@thompsonhine.com
eric.heyer@thompsonhine.com

MATTHEW T. ANDERSON (0082730)
Luper Neidenthal & Logan
A Legal Professional Association
1160 Dublin Road, Suite 400
Columbus, Ohio 43215
(614) 221-7663
manderson@LNLattorneys.com

BENJAMIN G. SANDLIN (0098918)
Thompson Hine LLP
312 Walnut Street, Suite 2000
Cincinnati, Ohio 45202
Ben.Sandlin@ThompsonHine.com
(513) 352-6700

Counsel for Appellee Central Tobacco & Stuff Inc.

DAVE YOST (0056290)
Ohio Attorney General

MATHURA J. SRIDHARAN (0100811)*
Solicitor General
* Counsel of record

SAMUEL C. PETERSON (0081432)
ZACHERY P. KELLER (0086930)
Deputy Solicitors General
30 East Broad Street, 17th Floor
Columbus, Ohio 43215
(614) 466-8980
Mathura.Sridharan@OhioAGO.gov

Counsel for Appellant Attorney General Dave Yost

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ARGUMENT

When Congress enacted the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009), it carefully preserved the states' authority to regulate the "sale," "distribution," and "advertising and promotion of … tobacco products." 21 U.S.C. § 387p(a)(1), (2)(B). Recently, the Seventh Circuit became the fifth federal court of appeals to hold that section 387p allows states to ban the sale of tobacco products entirely. *See Wisconsinites for Alternatives to Smoking & Tobacco, Inc. v. Casey*, 172 F.4th 976 (7th Cir. 2026) (*WAST*); *see also R.J. Reynolds Tobacco Co. v. City of Edina*, 60 F.4th 1170 (8th Cir. 2023); *R.J. Reynolds Tobacco Co. v. Cty. of Los Angeles*, 29 F.4th 542 (9th Cir. 2022); *National Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013); *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428 (2d Cir. 2013). No federal court of appeals has held otherwise.

Nonetheless, appellee Central Tobacco and Stuff, Inc. (Central Tobacco) argues that the State of Ohio cannot enforce the state's Consumer Sales Practices Act against local retailers that sell flavored electronic cigarettes (e-cigarettes) because the state's claims apply only to e-cigarettes that the Food and Drug Administration (FDA) has not authorized to be "introduced … into interstate commerce." 21 U.S.C. § 387j(c)(1)(A). Relying on *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), Central Tobacco argues that a state-law claim that takes account of an e-cigarette's regulatory status under federal law impermissibly impinges on the FDA's exclusive authority under 21 U.S.C. § 337 to enforce the Food, Drug, and Cosmetic Act (FDCA).

As amici explained in their opening brief, *Buckman* had nothing to do with state-law claims that incorporate a product's regulatory status under the FDCA. Rather, *Buckman* addressed fraud-on-the-FDA claims that frustrate the FDA's regulatory processes—concerns not even arguably present in this case. And while only the FDA may bring an enforcement action to enforce the FDCA, Ohio does not seek to enforce the FDCA, but state law. Unlike in *Buckman*, Ohio's claims here do not interfere with the FDA's regulatory processes or its enforcement discretion any more than a state's decision to ban all e-cigarettes would. There is thus no basis for concluding that the FDCA preempts Ohio's claims.

I. *Buckman* does not support preemption of Ohio's claims.

A. *Buckman* addressed a specific type of state-law claim: a so-called fraud-on-the-FDA claim. In *Buckman*'s own words: "[W]e hold that the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." 531 U.S. at 348; *see id.* at 343–44 ("We hold that such claims [*i.e.*, 'fraudulent representations to the [FDA]'] are pre-empted by the [FDCA]."). The Court explained that allowing plaintiffs to use state law to assess whether the FDA's authorization of a medical device was procured by fraudulent representations would "impact … the administration of the [FDA's] duties," *id.* at 351 n.6, and "exert an extraneous pull on the scheme established by Congress," *id.* at 353. Specifically, the Court was concerned that fraud-on-the-FDA claims would "skew[]" the FDA's ability to "achieve a somewhat delicate balance of statutory objectives," *id.* at 348, because they would deter medical-device manufacturers from seeking FDA marketing authorization for medical devices with off-label uses and incentivize applicants to

provide the FDA with unwanted information to avoid liability under state law, *id.* at 350–51. These concerns do not arise here, where the state-law claims would have no effect on the FDA's regulation of tobacco products.

The Seventh Circuit's recent decision in *WAST* is illustrative. That case concerned a Wisconsin law that "requires FDA authorization before electronic nicotine delivery systems may be sold." *WAST*, 172 F.4th at 980. In affirming the district court's denial of a preliminary injunction, the Seventh Circuit explained that *Buckman* concerned "non-federal enforcement of fraud-on-the-FDA claims, which caused over-disclosure of information to the FDA in medical device applications." *Id.* at 987. The court further observed that "[t]he Court in *Buckman* was also concerned [that the fraud-on-the-FDA] claims could 'exert an extraneous pull on the scheme established by Congress,' creating tension between FDA determinations (favoring more minimal disclosures) and state court adjudications (incentivizing greater disclosures)." *Id.* (quoting *Buckman*, 531 U.S. at 353). The Wisconsin law did not raise those concerns, the court concluded, because "relying on the FDCA to provide a standard is different from enforcing [the FDCA]," *id.*, and "[a] state law that mirrors a federal standard does not create a conflict" with federal law because "they impose the same standards," *id.* at 988. Moreover, "ask[ing] whether a product has FDA approval … does not involve an adjudication of a violation." *Id.* Because "adjudication [was] not needed" to determine whether a particular e-cigarette product had been authorized by the FDA, the Seventh Circuit concluded that Wisconsin did not

"infring[e] upon the FDA's enforcement authority." *Id.* at 987 (citing *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004)).

Moreover, as amici's opening brief explained, Br. 11, the U.S. Supreme Court has consistently described *Buckman*'s preemptive scope in narrow terms. *See Wyeth v. Levine*, 555 U.S. 555, 565–66 n.3 (2009) (explaining that *Buckman* "involved state-law fraud-on-the-agency claims"); *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 604 (2011) (plurality op.) (explaining that *Buckman* involved a "uniquely federal area[] of regulation" that "directly interfered with the operation of the federal program"); *Arizona v. United States*, 567 U.S. 387, 402 (2012) (noting that *Buckman* concerned "fraud on the [FDA]"); *Kansas v. Garcia*, 589 U.S. 191, 212 (2020) (explaining that *Buckman* concerned a "state tort claim for fraud on the [FDA]" that "threatened serious disruption of the sensitive and highly technical process of approving medical devices"). These descriptions are inconsistent with a reading of *Buckman*, such as that proffered by Central Tobacco, that would invalidate any state law that aligns its regulation of tobacco products with the federal regulatory scheme.

B. Although Ohio's claims do not allege fraud on the FDA, Central Tobacco seizes on *Buckman*'s statement that "the existence of [the FDCA was] a critical element in [the plaintiffs'] case," 531 U.S. at 353, to argue that any state-law claim that draws on federal regulatory distinctions must also be preempted. Appellee's Br. 11, 21, 27. But as amici have explained, Br. 16, that reading of *Buckman* is implausible. Much of *Buckman*'s conflict analysis would have been surplusage if the

Supreme Court had intended to establish a bright-line rule that any state-law claim that recognizes the existence of the FDCA is automatically preempted.

Indeed, prior to *Buckman*, the Supreme Court had already decided that common-law claims could be based on "allegations" that a medical-device manufacturer "violated FDA regulations" without triggering 21 U.S.C. § 360k, which preempts state requirements on medical devices that are "different from, or in addition to" the FDA's requirements. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996); *see also id.* at 482–83 (describing claims). *Buckman* addressed *Lohr* and, in doing so, did not indicate that the outcome would have been different under an implied-preemption theory. *See Buckman*, 531 U.S. at 352. Instead, *Buckman* explained that *Lohr* concerned a state-law claim that did not arise "solely from a violation of FDCA requirements," whereas fraud-on-the-FDA claims "exist solely by virtue of the FDCA disclosure requirements" that govern the information that medical-device applicants submit to the FDA. *Id.* at 352–53; *see also id.* at 344–45, 348–49 (discussing disclosure requirements imposed on applicants seeking marketing authorization for medical devices from the FDA). State laws that seek to regulate such disclosure requirements necessarily regulate a manufacturer's "dealings with the FDA"—a "relationship" that is "inherently federal" because it "originates from, is governed by, and terminates according to federal law." *Id.* at 347.

Thus, when *Buckman* states that "the existence of [the FDCA] is a critical element in their case," it is referring to the "sort of litigation" that was before it: one that involved "fraud-on-the-agency claims." *Id.* at 353. Central Tobacco errs in

seeking to take that phrase out of context to suggest that any state regulation of tobacco products that aligns with a federal regulatory standard is impliedly preempted for interfering with the FDA's enforcement authority. *See Olivier v. City of Brandon*, 146 S. Ct. 916, 925 (2026) (stating "general language in judicial opinions should be read as referring in context to circumstances similar to the circumstances then before the Court" (internal quotation marks omitted)).

C. In a footnote, Central Tobacco asserts that allowing Ohio's claims to move forward would "interfere[] with Congress's stated purpose of giving the FDA 'flexible enforcement authority' as to 'less harmful tobacco products,' like [e-cigarettes], so as to reduce the morbidity and mortality associated with combustible cigarettes." Appellee's Br. 36 n.31 (quoting Tobacco Control Act, § 3(4), 123 Stat. at 1782). In fact, allowing Ohio's state-law claims to move forward would have no effect on the FDA's enforcement flexibility. The FDA retains the sole authority to decide which e-cigarettes to authorize under the Tobacco Control Act, and it retains sole authority to decide whether to enforce the FDCA's requirements against any unauthorized e-cigarettes. Ohio seeks only to enforce state laws against the sale of unauthorized cigarettes.

To the extent Central Tobacco contends that Ohio's claims conflict with the FDA's nonbinding guidance as to its own enforcement priorities, *see* Appellee's Br. 17, that argument is baseless. Even if the FDA formally authorizes a tobacco product to be marketed in the United States, the Tobacco Control Act preserves state authority to ban that product, as every federal court of appeals to have addressed the

issue has held. *See supra* p.1. Nothing in the Tobacco Control Act suggests that the states' authority can be removed by the FDA's guidance as to how it will allocate its own enforcement priorities, particularly where the FDA recognizes that its guidance is "nonbinding" and "does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization" from the FDA. *See* Enforcement Priorities for Electronic Nicotine Delivery Systems and Other Deemed Products on the Market Without Premarket Authorization (Revised) (Apr. 2020), at 3, https://www.fda.gov/media/133880/download; *see also* Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization (May 2026), at 3 ("[A]ll new tobacco products on the market without authorization are illegally marketed products."), https://www.fda.gov/media/192403/download.

D. Central Tobacco disagrees with the Seventh Circuit's conclusion in *WAST* that *Buckman*'s conflict analysis comes into play only if state law compels an adjudication about an FDCA question that conflicts with the FDA's determination on that question. *See* Appellee's Br. 31 (citing *WAST*, 172 F.4th at 988–89). According to Central Tobacco, the majority in *Buckman* rejected Justice Stevens' concurring opinion, which opined that, "[i]f the FDA determines both that fraud has occurred and that such fraud requires the removal of a product from the market, state damages remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme." *Buckman*, 531 U.S. at 354. Justice Stevens' hypothetical scenario, however, was not before the Court in *Buckman*, and the majority opinion does not purport to address it, much less to reject Justice Stevens'

concurrence. *Cf. Princeton Univ. v. Schmid*, 455 U.S. 100, 102 (1982) ("We do not sit to decide hypothetical issues or to give advisory opinions about issues as to which there are not adverse parties before us.").

Central Tobacco also argues that the United States and the FDA have argued in various court filings that states may not supplement federal remedies if the FDA concludes that a violation of the FDCA has occurred. *See* Appellee's Br. 32–34. That question is irrelevant here because "ask[ing] whether a product has FDA approval … does not involve an adjudication of a violation." *WAST*, 172 F.4th at 988. In any event, the federal government's court filings are not law, and the only relevant judicial decision that Central Tobacco cites, *Amarin Pharma, Inc. v. International Trade Commission*, 923 F.3d 959 (Fed. Cir. 2019), holds that a plaintiff does not state a cognizable Tariff Act claim where the claim "is based on proving violations of the FDCA and *where the FDA has not taken the position* that the articles at issue do, indeed, violate the FDCA." *Id*. at 968 (emphasis added). That holding has no bearing here, where the FDA has taken a position on whether a particular e-cigarette product has received federal marketing authorization.

II. The Tobacco Control Act preserves state authority to regulate tobacco products.

As amici have explained, Br. 6–7, 20–22, Congress took great care in the Tobacco Control Act to protect the states' historic role in regulating tobacco products. Not only did Congress expressly preserve the states' own authority over "the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age," 21 U.S.C. § 387p(a)(1); *see also id*.

§ 387p(a)(2)(B), Congress contemplated that states would play a role in enforcing federal regulation of tobacco products sold by retailers, *id.* § 372(a)(1)(B)(i). The statutory text reflects Congress's "explicit decision to preserve for the states a robust role in regulating, and even banning, sales of tobacco products." *WAST*, 172 F.4th at 984–85 (quoting *Cty. of Los Angeles*, 29 F.4th at 550 (quoting *U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 436)).

Central Tobacco downplays the significance of Congress's decision to respect state authority over the sale of tobacco products, and its arguments do not hold water. Central Tobacco argues that section 387p merely codifies the FDA's pre-Tobacco Control Act regulation of "cigarettes and smokeless tobacco as drug delivery devices," which required states to obtain an FDA exemption from preemption to "adopt minimum purchase ages, vending machine access restrictions, and advertising restrictions 'more stringent' than those in the FDA's regulations." Appellee's Br. 26–27; *see also id.* at 7–8, 14–15; 61 Fed. Reg. 44396 (Aug. 28, 1996). But the FDA's 1996 rule (which never went into effect) would have regulated tobacco products as medical devices, and thus incorporated 21 U.S.C. § 360k—the express preemption provision concerning medical devices. *See* 61 Fed. Reg. at 44548–50. Section 360 requires states to obtain an exemption from the FDA, if they seek to impose, with respect to a medical device, a requirement "different from, or in addition to, any [FDA] requirement." When Congress enacted the Tobacco Control Act, however, it did not treat tobacco products as medical devices or apply section 360k to tobacco products. Instead, it enacted section 387p, which expressly preserves state authority over the sale and

advertising of tobacco products and affirmatively protects that authority from the statute's preemptive reach. 21 U.S.C. § 387p(a)(1), (2)(B). "Where Congress uses certain language in one part of a statute and different language in another, it is generally presumed that Congress acts intentionally." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 544 (2012). Here, the differences between section 360k and 387p confirm that Congress intended to preserve state regulatory authority to a greater extent than the FDA's 1996 tobacco rule would have allowed.

To the extent that Central Tobacco argues that the reference in section 387p to states' authority to regulate use of "tobacco products by individuals of any age" suggests that Congress intended to confine states to age-based restrictions, *see* Appellee's Br. 15, 27, that "interpretation turns the plain meaning of this phrase on its head." *Cty. of Los Angeles*, 29 F.4th at 560 (internal quotation marks omitted). "'Of any age' suggests that state and local governments are not limited to enacting only age-based rules, but rather can enact regulations for people 'of any age'—in other words, for everyone." *Id.*

Central Tobacco also argues that Congress adopted the FDA's conclusion from the 1996 rule that "a complete ban on the sale of tobacco products would be counterproductive." Appellee's Br. 14. But Congress's decision not to ban tobacco products throughout the United States does not cabin states' authority to regulate tobacco products within their borders. "The text of the [Tobacco Control Act] reveals where Congress decided to preempt state law, and where Congress expressly preserved state authority and limited preemption," and "this mandate provid[es]

states the final authority on which tobacco products may be sold in their respective marketplaces." *WAST*, 172 F.4th at 989–90 (citations omitted); *see City of Edina*, 60 F.4th at 1178 (rejecting argument that Congress sought to "give tobacco companies an unqualified right to sell each and every tobacco product not banned on a federal level").

Finally, Central Tobacco argues that allowing states to regulate tobacco sales and advertising would enable states to use sales restrictions to circumvent the Tobacco Control Act's limits on state authority. Appellee's Br. 25–26; *see also* 21 U.S.C. § 387p(a)(2)(A) (preempting state requirements "different from, or in addition to, any requirement under the [Tobacco Control Act] relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products"). But the federal courts of appeal have rejected the argument that "every sales ban is a backdoor requirement relating to tobacco product standards." *WAST*, 172 F.4th at 989 (internal quotation marks and ellipses omitted; quoting *U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 434); *see City of Edina*, 60 F.4th at 1175–77; *Cty. of Los Angeles*, 29 F.4th at 556–60; *Nat'l Ass'n of Tobacco Outlets*, 731 F.3d at 82–83 & n.11. Given the breadth of statutory language "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, those courts have consistently "respect[ed] the areas Congress excepted from preemption," *WAST*, 172 F.4th at 985. This Court should do the same.

CONCLUSION

The Court should reverse the judgment of the Fifth District.

Respectfully submitted,

/s/ *Eric Zell*

NANDAN M. JOSHI
ALLISON M. ZIEVE
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
(202) 588-1000
njoshi@citizen.org

ERIC S. ZELL (OH 0084318)
* Counsel of record
Litigation Director
National Association of Consumer Advocates
1629 K St NW, Suite 604
Washington, DC 20006
202-984-7706 x112

Attorneys for Amici Curiae Public Citizen and National Association of Consumer Advocates

May 15, 2026

CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing was served this day, May 15, 2026, upon the following via electronic mail to the email addresses indicated below:

JAMES C. FRASER* (PHV-27929-2026)
*Counsel of record
ERIC N. HEYER (PHV-27925-2026)
THOMPSON HINE LLP
1919 M Street NW, Suite 700
Washington, DC 20036
(202) 331-8800
james.fraser@thompsonhine.com
eric.heyer@thompsonhine.com

MATTHEW T. ANDERSON (0082730)*
Luper Neidenthal & Logan
A Legal Professional Association
1160 Dublin Road, Suite 400
Columbus, Ohio 43215
(614) 221-7663
manderson@LNLattorneys.com

BENJAMIN G. SANDLIN (0098918)
Thompson Hine LLP
312 Walnut Street, Suite 2000
Cincinnati, Ohio 45202
Ben.Sandlin@ThompsonHine.com
(513) 352-6700

Counsel for Appellee Central Tobacco & Stuff Inc.

DAVE YOST (0056290)
Ohio Attorney General

MATHURA J. SRIDHARAN (0100811)*
Solicitor General
* Counsel of record

SAMUEL C. PETERSON (0081432)
ZACHERY P. KELLER (0086930)
Deputy Solicitors General
30 East Broad Street, 17th Floor
Columbus, Ohio 43215
(614) 466-8980
Mathura.Sridharan@OhioAGO.gov

Counsel for Appellant Attorney General Dave Yost

/s/ *Eric S. Zell*
One of the Attorneys for Amicus Curiae Public Citizen and National Association of Consumer Advocates