Case No. 26-12062

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants-Appellants,

v.

THE C STORE DEPOT, INC., and ZEST BRANDS, LLC,
Plaintiffs-Appellees.

On Appeal from an Order of the United States District Court for the Middle District of Florida, Case No. 8:26-cv-483-MSS-CPT

UNOPPOSED MOTION OF PUBLIC HEALTH AND MEDICAL ORGANIZATIONS TO FILE BRIEF AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1(a) and 11th Cir. R. 26.1-1 through 26.1-3, *amici curiae* are all non-profit organizations committed to advancing public health. No *amicus* has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the *amici* of this filing.

In addition to the persons listed in Defendants-Appellants' Certificate of Interested Persons, undersigned counsel of record certifies pursuant to Eleventh Circuit Rule 26.1-1 that the following additional persons have an interest in the outcome of this appeal:

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Schultz, William B.

Truth Initiative

Dated: August 27, 2026

/s/ William B. Schultz
Attorney for *Amici Curiae*

Pursuant to Federal Rule of Appellate Procedure 29(b)(3) and Eleventh Circuit Rule 29-1, movants American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Truth Initiative respectfully move the Court for leave to file a brief as *amici curiae* in support of Appellants. Both parties do not oppose the filing of this brief.

I. INTEREST OF MOVANTS

Movants are medical and public health organizations working on a daily basis to reduce tobacco-related disease and mortality. They include organizations with programs to assist individuals to quit the use of tobacco products and those representing physicians who counsel young patients and their families about the hazards of tobacco use. They share a strong interest in ensuring that youth are sufficiently protected from the adverse short- and long-term health effects of tobacco products, including unauthorized nicotine pouches.

II. MOVANTS' BRIEF WILL BE USEFUL TO THE COURT'S CONSIDERATION OF THE MERITS ON APPEAL.

Movants' brief complies with Federal Rule 29 and Eleventh Circuit Rule 29-2 and contains valuable insight to inform the Court's consideration of the merits of this appeal. As medical and public health organizations, movants are uniquely positioned to explain that (i) that the District Court erred in issuing a preliminary injunction allowing Appellees to market their products, and (ii) how the District

Court's cursory examination of the public interest prong failed to consider the widespread harms that tobacco products like those marketed by Appellees pose to public health, particularly to the health of young people.

II. CONCLUSION

Based on the foregoing, movants respectfully request that the Court grant this motion for leave to file a brief as *amici curiae* in support of Appellants and accept for filing the *amicus curiae* brief submitted contemporaneously with this motion.

Date: August 27, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 27, 2026, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

/s/ William B. Schultz
Attorney for *Amici Curiae*

CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2) because it contains 296 words, as counted by Microsoft Word, excluding the parts of the motion excluded by Federal Rule of Appellate Procedure 32(f). This motion complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared using Microsoft Word in 14-point Times New Roman font.

/s/ William B. Schultz
Attorney for *Amici Curiae*

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Dated: August 27, 2026

/s/ William B. Schultz
Attorney for *Amici Curiae*

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici curiae American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Truth Initiative are medical and public health organizations working on a daily basis to reduce tobacco-related disease and mortality. They include organizations with programs to assist individuals to quit the use of tobacco products and those representing physicians who counsel young patients and their families about the hazards of tobacco use. They share a strong interest in ensuring that youth are sufficiently protected from the adverse short- and long-term health effects of tobacco products, including unauthorized nicotine pouches.

STATEMENT OF THE ISSUES

The Statement of Issues, as reprinted from Defendants-Appellants' Brief, are as follows:

The Tobacco Control Act generally requires FDA premarket authorization

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[1] *Amici curiae* affirm that no party's counsel authored this brief in whole or in part, and that no party, party's counsel, or other person (other than *amici curiae*, their members, or their counsel) contributed money that was intended to fund preparing or submitting this brief. *See* Fed. R. App. P. 29(a)(4)(E). Both parties do not oppose the filing of this brief.

for new tobacco products. Pursuant to the Act, FDA has promulged regulations concerning premarket authorization, including the 2021 PMTA rule, which seeks to streamline the premarket authorization process by, among other things, describing the information that must be included in a PMTA so FDA can determine whether a product meets the Tobacco Control Act's requirements. Plaintiffs manufacture and sell oral synthetic nicotine pouches, which became subject to the Tobacco Control Act's premarket authorization requirements and relevant regulations as a result of Congress's 2022 amendment. The questions presented are:

1. Whether FDA violated the Regulatory Flexibility Act by failing to preemptively consider the economic impact of its PMTA rule on plaintiffs' oral synthetic nicotine products, which were not subject to the rule at the time it was issued and only became subject to the rule as a result of Congress's later statutory amendment.

2. Whether FDA satisfied the Regulatory Flexibility Act by certifying that the PMTA rule will not have a significant impact on a substantial number of small entities and explaining its reasons for concluding that the rule "will generate net benefits or negligible net costs for most affected small entities." 86 Fed. Reg. at 55405.

SUMMARY OF THE ARGUMENT

Amici curiae public health and medical organizations submit this brief to urge the Court to reverse the District Court's order granting the motion of Plaintiffs-Appellees The C Store Depot, Inc. and Zest Brand LLC (Appellees) for preliminary injunction. This brief demonstrates that the District Court erred in issuing a preliminary injunction allowing Appellees to market their products because appellees may not legally market synthetic nicotine pouches without FDA authorization. In addition, it demonstrates that the District Court's cursory examination of the public interest prong is flawed because it failed to consider the widespread harms that tobacco products like those marketed by Appellees pose to public health, particularly to the health of young people.

RELEVANT BACKGROUND

A. The Tobacco Control Act

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), giving the Food and Drug Administration (FDA) broad authority to regulate tobacco products and to curb the predatory conduct of the tobacco industry. The Tobacco Control Act gave FDA immediate regulatory authority over "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." 21 U.S.C. § 387a(b). Congress also permitted the FDA to extend the provisions of the Tobacco Control Act to "any other tobacco products

that the Secretary by regulation deems to be subject to" it. *Id.* Congress was particularly concerned that the "lack of government regulation has allowed the tobacco industry to design new products or modify existing ones in ways that increase their appeal to children and that contribute to the risk and incidence of disease." H.R. REP. NO. 111-58, pt. 1, at 4 (2009).

To address this problem, the Tobacco Control Act requires manufacturers of new tobacco products to submit applications for FDA to review and authorize *before* the product can be marketed, analogous to the approval process for new drugs, yet using a standard that recognizes that tobacco products—unlike drugs—are neither "safe" nor "effective." *See generally FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133-37 (2000) (interpreting 21 U.S.C. § 393(b)(2)). Under this framework, in general, a manufacturer may only market a "new" tobacco product (*i.e.*, a product introduced into commerce after February 15, 2007) if it first submits a premarket tobacco application (PMTA) demonstrating that the product is "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). When assessing if a proposed product meets this standard, FDA must consider "the risks and benefits to the population as a whole," including "the likelihood that those who do not use tobacco products will start using such products." *Id.* § 387j(c)(4)(B). Critically, tobacco products that are marketed without authorization are "adulterated" and cannot be lawfully sold. 21 U.S.C. §§ 331(a), 387b(6)(A).

B. The Deeming Rule

In 2016, recognizing that unregulated tobacco products were "widely available" and came "in many forms," FDA used its authority under the Tobacco Control Act, *see* 21 U.S.C. § 387a(b), to issue a rule that expanded the scope of products subject to regulation under the Act. *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act*, 81 Fed. Reg. 28,973, 28,982 (May 10, 2016) (the Deeming Rule). In the Deeming Rule, FDA deemed all products that meet the Tobacco Control Act's definition of "tobacco product" (except accessories of a newly deemed tobacco product) to be subject to the Act and to FDA's implementing regulations. 81 Fed. Reg. at 28,975; 21 C.F.R. § 1100.1. This greatly expanded FDA's regulatory oversight because, at the time of this rulemaking and subject to certain exceptions, "tobacco product" meant "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product . . . ." 81 Fed. Reg. at 28,983 (quoting 21 U.S.C. § 321(rr) (2009)). As a result of the Deeming Rule, many more types of tobacco products were required to submit PMTAs and obtain premarket authorization. *Id.* at 28,977. This included nicotine pouches, which entered the U.S. market the same year.[2]

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[2] Kristy L. Marynak, *et al.*, *Nicotine Pouch Unit Sales in the US, 2016-2020*, 326 JAMA 566, 566–568 (2021), https://doi.org/10.1001/jama.2021.10366.

The agency also anticipated that new types of tobacco products would be developed in the future, and that, if FDA waited for these new products to emerge before deeming them, the resulting delay of "months or even years" could "endanger the public health." *Id.* at 28,976. To avoid the potential grave harms to public health that could result from the entry of new tobacco products into the market without regulation, FDA required that new products undergo "an evaluation to ensure they meet the appropriate public health standard for the pathway before they can be marketed." *Id.* at 29,075. Consequently, FDA recognized that the Deeming Rule would "impose costs in the form of registration, submission, and labeling requirements" for such products. *Id.*

As required under the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 601-612, FDA considered the compliance costs for small businesses under the Deeming Rule and found that the Rule would have a "significant economic impact" on those entities. *Id.* at 29,074. Although not all costs could be quantified, FDA estimated a then-present value of total quantified costs over 20 years of nearly one billion dollars. *Id.*

C. The PMTA Rule

By 2021, FDA had received thousands of PMTAs, which "range[d] widely in the level of detail they contain[ed]." Premarket Tobacco Product Applications and Recordkeeping Requirements, 86 Fed. Reg. 55,300 (Oct. 5, 2021) (the PMTA Rule).

On October 5, 2021, to "improve the efficiency of the submission and review of PMTAs" and "provide applicants with a better understanding of the information a PMTA must contain," FDA promulgated the final PMTA Rule. The PMTA Rule clarified and standardized, in substance and format, the information required by the Tobacco Control Act to enable FDA to evaluate whether a tobacco product meets the statutory standards for marketing.

The PMTA Rule was issued after years of guidance provided to tobacco product manufacturers to assist the preparation of PMTAs that complied with the statute, *see* 86 Fed. Reg. at 55,303 (noting that FDA "issued guidance, conducted webinars, met with manufacturers, hosted public meetings regarding premarket submissions, and posted the technical project lead reviews (which describe the reviews completed on specific PMTAs) and marketing granted orders issued to date"), and after extensive notice-and-comment rulemaking. In short, the manufacturers of regulated tobacco products had plenty of advance notice and information about the requirements of a PMTA. Since the PMTA Rule was issued, FDA has received and accepted for filing hundreds of thousands of PMTAs whose sponsors were able to comply with the PMTA Rule's requirements.[3]

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[3] *See* U.S. FOOD & DRUG ADMIN., *PMTA Metrics for Acceptance, Filing and Review/Action Phases*, https://www.fda.gov/media/192290/download.

The PMTA Rule explained that it clarified the "content and format" of PMTAs that manufacturers had already been required to submit for years. *See* 86 Fed. Reg. at 55,303. Accordingly, because FDA "already included the costs to submit and review PMTAs for deemed tobacco products in the final RIA [Regulatory Impact Analysis]" for the Deeming Rule, it did not count those costs again when considering the costs of the "content and format" rule. *Id.* at 55,405. An agency's analysis under the RFA is only "part of [a court's] overall judgment whether a rule is reasonable." *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 539 (D.C. Cir. 1983).

As the Fifth Circuit has recently explained, a court's role in evaluating an agency's compliance with RFA requirements is limited "to determin[ing] whether an agency has made a 'reasonable, good-faith effort' to carry out the mandate of the RFA." *Kealani Distrib., LLC v. FDA*, 168 F.4th 741, 746 (5th Cir. 2026) (quoting *Alenco Commc'ns, Inc. v. FCC*, 201 F.3d 608, 625 (5th Cir. 2000)); *accord Assoc. Fisheries v. Daley*, 127 F.3d 104, 114 (1st Cir. 1997). Accordingly, "FDA's attribution of PMTA-related costs to the Deeming Rule . . . is a substantive factual conclusion underlying the FDA's certification" that "is outside of the scope of judicial review of alleged RFA violation." *Kealani*, 168 F.4th at 749; *see also Council for Urological Interests v. Burwell*, 790 F.3d 212, 227 (D.C. Cir. 2015)

(high level of deference to agency analysis underlying RFA certifications); *U.S. Cellular Corp. v. FCC*, 254 F.3d 78, 88 (D.C. Cir. 2001).

D. 2022 Amendment of the Tobacco Control Act

Shortly after FDA issued the PMTA Rule, a growing loophole in the regulatory scheme became apparent. The Tobacco Control Act only applied to products "made or derived from tobacco." 21 U.S.C. § 321(rr) (2009). While "nicotine is typically extracted from tobacco plants, it can also be extracted from other sources or synthesized in a laboratory."[4] In 2022, Congress revised the definition of "tobacco product" to include products "containing nicotine from any source . . . ." Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, § 111, 136 Stat. 49, 789-90 (2022) (amending 21 U.S.C. § 321(rr)). By the amendment expanding the statutory definition, Congress subjected additional products, including products already on store shelves (like nicotine pouches made with synthetic nicotine), to the Tobacco Control Act's PMTA requirement.

In general, the law allowed synthetic nicotine products that were on the market to remain on the market until May 14, 2022 (30 days after the effective date), without being considered in violation of the Tobacco Control Act. *Id.* § 111(d)(1). If a PMTA

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[4] Hassan Z. Sheikh, R47043, *Synthetic Nicotine: Frequently Asked Questions,* CONG. RSCH. SERV., 3 (March 9, 2022), https://www.congress.gov/crs_external_products/R/PDF/R47043/R47043.1.pdf (internal citation omitted).

was submitted for a product during that time, the product could remain on the market until July 13, 2022 (*i.e.*, 90 days after the effective date). *Id.* at note (2). After that period, however, all synthetic nicotine products remaining on the market without a marketing granted order, including products that were "the subject of a pending application," would be in violation of the Tobacco Control Act. *Id.* at note (3).

ARGUMENT

I. Appellees May Not Legally Market Synthetic Nicotine Pouches Without FDA Authorization.

The District Court erred in granting Appellees' preliminary injunction because, even if Appellees were to succeed on the merits of their claim—that FDA's RFA analysis of the PMTA Rule in 2021 was insufficient—Appellees would not be legally entitled to market their products. Thus, Appellees' contention that they would have been able to remain lawfully on the market indefinitely simply by having a pending PMTA reflects a misunderstanding of the law. Appellees do not challenge the Tobacco Control Act, Deeming Rule, or 2022 statutory amendment, which together prohibit the sale of synthetic nicotine pouches and other new tobacco products absent FDA authorization. 21 U.S.C. §§ 387b(6)(A), 387j(c)(2)(A). In other words, the PMTA Rule—which is the only FDA action challenged by Appellees—has no bearing on whether Appellees are required to receive premarket authorization from FDA to market their products.

The Tobacco Control Act is very specific as to what a manufacturer must demonstrate to obtain an order authorizing marketing of a new tobacco product. The basic required showing is that use of the product is "appropriate for the protection of the public health." 21 U.S.C. § 387a(c)(5). To support its marketing application, the manufacturer must submit "full reports of all information . . . concerning investigations which have been made to show the health risks of [the] tobacco product" and "whether such tobacco product presents less risk than other tobacco products," and detailed information about manufacturing. 21 U.S.C. § 387a(b)(1). Marketing a tobacco product without a marketing authorization will subject the manufacturer to severe sanctions, including criminal and civil monetary penalties. 21 U.S.C. §§ 331(a), 333(f)(9). Before FDA issued the PMTA Rule, manufacturers were prohibited from marketing tobacco products until they satisfied the requirements of section 387a(b)(1). Only after they satisfied those requirements, could they legally market their products.

Whether FDA complied with the "purely procedural requirement" of the RFA in issuing the PMTA Rule, *see Kealani*, 168 F.4th at 749 (holding FDA's RFA certification to the PMTA Rule was reasonable), does not and cannot alter or eliminate a core, *substantive* requirement of the Tobacco Control Act: the manufacturer of a new tobacco product must receive an authorization order from the agency before it can market its product. FDA's issuance of a refuse-to-file letter does

not alter this clear requirement of the Tobacco Control Act (as amended by Congress in 2022) and the Deeming Rule. In other words, Appellees' sales continue to be illegal as a result of *Congress* expanding the reach of the Tobacco Control Act to Appellees' products. Accordingly, Appellees have not satisfied the basic statutory requirements for premarket authorization, which have applied to their products since 2022, and which applied to other tobacco products before the PMTA Rule was issued.[5]

II. The Public Interest Weighs Strongly Against an Injunction That Permits the Sale of Unlawful Tobacco Products That Pose Significant Public Health Risks to Youth.

Critically, the District Court entirely failed to meaningfully consider the overwhelming harms to public health that tobacco products—including Appellees' nicotine pouches—pose, particularly to youth. The only public interest considerations the District Court purported to take into account were a history of "little enforcement action" by the agency and a stipulation by FDA in a different case raising different legal issues. Dkt. 61, at 24. Ignoring that the "public has a strong interest in the enforcement of the FDCA to protect public health," *MediNatura, Inc. v. FDA*, 998 F.3d 931, 945 (D.C. Cir. 2021), the District Court

[5] Any legitimate discretion that the agency has in enforcing the Tobacco Control Act does not change this, as the exercise of enforcement discretion does not make a product legal. *See* Br. of Appellants at 42.

determined that "claimed" public harm is not an "overriding factor." Dkt. 61, at 24. But tobacco products like nicotine pouches undeniably pose significant public health risks to youth.

From almost nonexistent sales in 2020, nicotine pouch sales have skyrocketed, particularly in the past few years. From May 2020 to May 2026, the last date for which data is available, monthly nicotine pouch sales in the United States increased more than 1,000 percent, from $47.8 million to $612.9 million.[6] This rapid increase has significant implications for public health, as indicated by survey data that already reveal concerning trends.

Since 2024, nicotine pouches have been the second most commonly used tobacco product among youth, behind e-cigarettes.[7] Use of nicotine pouches among high school students increased significantly between 2022 and 2025, even while use of combustible tobacco products and e-cigarettes declined.[8]

Surveys also show increases in use of nicotine pouches among young adults. The International Tobacco Control Youth Tobacco and Vaping Survey found a

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[6] CDC FOUND., *Monitoring Sales: Nicotine Pouch Trends* (Aug. 2026), https://tobaccomonitoring.org/wp-content/uploads/2026/08/Nicotine-Pouch-Sales-Data-Brief_5.17.2026.pdf.

[7] Eunice Park-Lee, *et al.*, *Tobacco Product Use Among Middle and High School Students in the United States: National Youth Tobacco Survey, 2025*, NICOTINE & TOBACCO RESEARCH (June 23, 2026), https://doi.org/10.1093/ntr/ntag116.

[8] *Id.*

statistically significant increase in nicotine pouch use among U.S. young adults (age 20-29) between 2022 and 2024, from 2.4 percent to 7.9 percent.[9] The Monitoring the Future survey found that past-year nicotine pouch use rates among young adults (19-30 years old) more than doubled between 2023 and 2025, from 4.8 percent to 12.7 percent.[10]

Nicotine pouches have features that may be particularly appealing to youth. Because they are small and do not require spitting, nicotine pouch use is very discreet and can easily be concealed from parents and teachers.[11] Moreover, the design of the Appellees' nicotine pouches increase the potential risk beyond that of the category overall. ZEO Universe nicotine pouches use "a mini-slim format" which Appellees claim is "thinner and more compact than standard pouches" and "sits flat against

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[9] Jessica L. Reid, *et al.*, *Awareness and Use of Oral Nicotine Pouches Among Youth and Young Adults, 2022–2024: Repeat Cross-Sectional Surveys in Canada, England, the USA and New Zealand*, 3 BMJ PUBLIC HEALTH e003457, supp. tbl. S4 (2025), https://doi.org/10.1136/bmjph-2025-003457.

[10] UNIV. OF MICH., *Elevated Use of Cannabis, Nicotine Among U.S. Adults Continues Into 2025* (Aug. 12, 2025), https://www.nih.gov/news-events/news-releases/elevated-use-cannabis-nicotine-among-us-adults-continues-into-2025.

[11] Dae-Hee Han, *et al.*, *Nicotine Pouch and E-Cigarette Use and Co-Use Among US Youths in 2023 and 2024*, 8 JAMA NETWORK OPEN e256739 (2025). https://doi.org/10.1001/jamanetworkopen.2025.6739; Alyssa F. Harlow, *et al.*, *Oral Nicotine Product Use and Vaping Progression Among Adolescents*, 155 PEDIATRICS e2024070312 (2025), https://doi.org/10.1542/peds.2024-070312.

your gum."[12] As ZEO states: "[Y]ou can still talk, drink, work, and go about your routine without anyone knowing it's there."[13] For youth who want to conceal their nicotine pouch use from adults, this slimmer design is especially appealing.

Decades of research has shown that added flavors improve the taste and reduce the harshness of tobacco products, making them more appealing and easier for beginners—especially youth—to initiate tobacco use and ultimately become addicted.[14] Previously confidential internal documents show that tobacco companies have deliberately added flavors to their products to lure youth.[15] In 2025, over 90 percent of youth nicotine pouch users reported using flavored nicotine pouches.[16] ZEO Universe nicotine pouches come in a variety of flavors, including "mint

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[12] ZEO UNIVERSE, *Nicotine Pouches*, https://perma.cc/6EDE-EVK7.

[13] *Id.*

[14] U.S. DEP'T OF HEALTH & HUMAN SERVS., *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General* (2012).

[15] *See, e.g.*, MKTG. INNOVATIONS, INC., *Youth Cigarette - New Concepts* (Sept. 1972), Truth Tobacco Industry Documents Library, UCSF Industry Documents Library, Marketing to Youth MSA Collection, https://www.industrydocuments.ucsf.edu/docs/hjfj0045/; J. Donati, Tatham-Laird & Kudner, Conference Report #23 (June 11, 1974), RJ Reynolds Records, Master Settlement Agreement, UCSF Industry Documents Library, Truth Tobacco Industry Documents Library, https://www.industrydocuments.ucsf.edu/docs/gtcx0091/; Gary N. Connolly, *The Marketing of Nicotine Addiction by One Oral Snuff Manufacturer*, TOBACCO CONTROL 4(1):73-79, 1995.

[16] Park-Lee, *supra* n. 7.

breeze," "pineapple tropic," "berry moonlight," "watermelon wave," "wintergreen ice," and "menthol evergreen." In addition, ZEO Universe nicotine pouches come in sleek, brightly colored containers reminiscent of candy or breath mints. FDA has already warned online retailers for selling products in containers that resemble Icebreakers candy.[17]

These features make it critically important that *before* these products can harm public health, FDA evaluate the science on these products, their potential appeal to youth, and other potential health risks. There is no safe tobacco product, including nicotine pouches.[18] Like all tobacco products, nicotine pouches contain nicotine, one of "the most addictive substances used by humans." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 270 (D.C. Cir. 2019).[19] When placed between the lip and gum, the pouch's nicotine is absorbed into the bloodstream.[20] Nicotine pouches can use either nicotine derived from tobacco or nicotine created in a lab (synthetic nicotine).

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[17] U.S. FOOD & DRUG ADMIN., Warning Letter (May 19, 2026), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/pouchlinecom-730123-05192026.

[18] CTRS. FOR DISEASE CONTROL & PREVENTION, *Nicotine Pouches* (Jan. 31, 2025), https://www.cdc.gov/tobacco/nicotine-pouches/index.html; *see also* CTRS. FOR DISEASE CONTROL & PREVENTION, *Health Effects of Vaping* (Jan. 31, 2025), https://www.cdc.gov/tobacco/e-cigarettes/health-effects.html.

[19] *Id.*

[20] *Id.*

Studies have found that nicotine level labeling on packages can be vague (*i.e.*, words or symbols of relative nicotine strength) or inaccurate and inconsistent with actual tested nicotine content in the pouches.[21] Studies have also found a range of nicotine in the freebase form in nicotine pouches, which can increase nicotine absorption and make the products more addictive.[22] Overall, studies show that some nicotine pouches can deliver similar levels of nicotine as cigarettes or traditional smokeless tobacco products.[23]

Appellees' products contain nicotine concentrations that raise especially strong public health concerns. ZEO Universe nicotine pouches come in strengths ranging from 4mg of nicotine up to 12mg of nicotine, enabling new users to start with low strength pouches and proceed to higher strength pouches as their addiction

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[21] Nadja Mallock, *et al.*, *Levels of Nicotine and Tobacco-Specific Nitrosamines in Oral Nicotine Pouches*, 33 TOBACCO CONTROL 193-199 (2024), doi: 10.1136/tc-2022- 057280; Hang Tran, *et al.*, *Total and Unprotonated (Freebase) Nicotine Content in New Types of Oral "Tobacco-Free" Nicotine Products*, 35 TOBACCO CONTROL 161 (2026), doi:10.1136/tc-2024-058914; Michelle K. Page, *et al.*, *Comparison of Nicotine and Selected Flavorings Content Between Tobacco-Free and Tobacco-Containing Oral Pouches*, 28 NICOTINE & TOBACCO RESEARCH 268 (2026), doi: 10.1093/ntr/ntaf105.

[22] Stephen Stanfill, *et al.*, *Characterization of Total and Unprotonated (Free) Nicotine Content of Nicotine Pouch Products*, 23 NICOTINE & TOBACCO RESEARCH 1590- 1596 (2021), doi: 10.1093/ntr/ntab030; Page, *supra* n. 21 .

[23] Nargiz Travis, *et al.*, *The Potential Impact of Oral Nicotine Pouches on Public Health: A Scoping Review*, 27 NICOTINE & TOBACCO RESEARCH 598 (2025), https://doi.org/10.1093/ntr/ntae131.

takes hold. The highest level, 12mg, is higher than any product that FDA has authorized for sale to date.[24] With repeated use, an individual's brain "gets used to having nicotine" to the point that the brain needs nicotine "just to feel okay,"[25] and a nicotine addiction can develop. Tobacco product use almost always begins during adolescence.[26] Adolescents "generally 'underestimate the tenacity of nicotine addiction and overestimate their' ability to stop using it." *Nicopure Labs*, 944 F.3d at 274 (quoting 81 Fed. Reg. at 28,981)). They are particularly vulnerable to the addictive effects of nicotine because the brain continues to develop until about age 25.[27] Almost 30 percent of youth who use nicotine pouches reported using on 20 or more days per month, and 22.4 percent reported daily use, an indicator of addiction.[28] Exposure to nicotine during this time may have lasting, adverse consequences on

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[24] U.S. FOOD & DRUG ADMIN., *Nicotine Pouch Products Authorized by the FDA*, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/nicotine-pouch-products-authorized-fda (last updated Aug. 19, 2026)

[25] CTRS. FOR DISEASE CONTROL & PREVENTION, *E-Cigarettes: Health Effects*, https://www.cdc.gov/tobacco/e-cigarettes/health-effects.html#cdc_generic_section_10-nicotine-addiction-and-withdrawal.

[26] U.S. DEP'T OF HEALTH & HUMAN SERVS., *Preventing Tobacco Use Among Youth and Young Adults*, *supra* n. 14.

[27] *Id.*

[28] Eunice Park-Lee, *et al.*, *E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States*, 2024, 73 MORBIDITY & MORTALITY WKLY. REP. 774 (2024), https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7335a3-H.pdf.

brain development.[29] Nicotine use can harm the parts of the adolescent brain responsible for attention, learning, mood, and impulse control.[30] In addition, adolescents who use nicotine products may be at an increased risk for future addiction to other drugs.[31] Hence, the United States Surgeon General has warned: "The use of products containing nicotine in any form among youth . . . is unsafe."[32]

Nicotine addiction can cause stress and harm mental health.[33] Overcoming an addiction to nicotine is difficult, and people often need to make multiple attempts to quit before succeeding.[34] Nicotine withdrawal can be accompanied by irritability,

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[29] U.S. DEP'T OF HEALTH & HUMAN SERVS., *The Health Consequences of Smoking: 50 Years of Progress: A Report of the Surgeon General* (2014), http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html; INST. OF MED., *Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products* (2015), https://www.hhs.gov/sites/default/files/consequences-smoking-exec-summary.pdf.

[30] U.S. DEP'T OF HEALTH & HUMAN SERVS., *The Health Consequences of Smoking*, *supra* n. 29.

[31] U.S. DEP'T OF HEALTH & HUMAN SERVS., *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General* (2016).

[32] *Id.*

[33] CTRS. FOR DISEASE CONTROL & PREVENTION, *E-Cigarettes: Health Effects,* https://www.cdc.gov/tobacco/e-cigarettes/health-effects.html#cdc_generic_section_11-nicotine-addiction-and-mental-health.

[34] Brenna VanFrank, *et al.*, *Adult Smoking Cessation — United States*, 2022, 73 MORBIDITY & MORALITY WKLY. REP. 633 (2024); Geoffrey T. Fong, *et al.*, *The Near-Universal Experience of Regret Among Smokers in Four Countries: Findings from the International Tobacco Control Policy Evaluation Survey*, 6 NICOTINE & TOBACCO RESEARCH, S341 (Sept. 3, 2004).

negative moods, sleep disruptions, concentration issues, hunger, and nicotine cravings.[35]

Nicotine use also poses other health risks. Nicotine is toxic to fetuses and presents a danger to those pregnant.[36] It can also cause an increase in blood pressure and heart rate, impact the flow of blood to the heart, induce narrowing of the arteries around the heart, and contribute to the hardening of the arterial walls.[37] Nicotine is known to suppress immune function throughout the body and can interfere with normal insulin function and blood sugar control.[38] Nicotine affects blood flow to the gums and could lead to inflammation of the gums and gum disease after continued use.[39]

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[35] CTRS. FOR DISEASE CONTROL & PREVENTION, *7 Common Withdrawal Symptoms and What You Can Do About Them* (Sept. 27, 2024), https://www.cdc.gov/tobacco/campaign/tips/quit-smoking/7-common-withdrawal-symptoms/index.html.

[36] U.S. DEP'T OF HEALTH & HUMAN SERVS., *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-attributable Disease: A Report of the Surgeon General* (2010), https://www.ncbi.nlm.nih.gov/books/NBK53017/.

[37] Thomas Münzel, *et al.*, *Nicotine and the Cardiovascular System: Unmasking a Global Public Health Threat*, EUR. HEART J. 1764 (2026).

[38] U.S. DEP'T OF HEALTH & HUMAN SERVS., *The Health Consequences of Smoking*, *supra* n. 29.

[39] Purima Kumar, *et al.*, *Living Under a Cloud: Electronic Cigarettes and the Dental Patient,* 151 J. AM. DENTAL ASS'N 155 (2020). https://jada.ada.org/action/showPdf?pii=S0002-8177%2820%2930004-0; Ranjan Malhotra, *et al.*, *Nicotine and Periodontal Tissues*, J. INDIAN SOC'Y PERIODONTOLOGY 72 (2010);14(1):72-79, doi:10.4103/0972-124X.65442.

These many complex scientific considerations are precisely the reason Congress required premarket review of tobacco products in the Tobacco Control Act. Under those premarket review requirements, the tobacco industry is prohibited from experimenting with the health of consumers, particularly young people. The District Court's decision to sidestep Congress's judgment and grant a preliminary injunction was wrong as a matter of law.

CONCLUSION

For these reasons and those set forth in Defendants-Appellants' brief, the Court should reverse the District Court's order granting Appellees' motion for a preliminary injunction.

Dated: August 27, 2026

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CERTIFICATE OF COMPLIANCE

1. The foregoing brief complies with the word limits set forth in Fed. R. App. P. 29(a)(5) and Fed. R. App. P. 32(g)(1) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), the word count feature in Microsoft Word reports that this document contains 4,535 words.

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Dated: August 27, 2026

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CERTIFICATE OF CONFERENCE

I hereby certify that, pursuant to Fed. R. App. P. 29(a)(2), on August 24, 2026, I contacted counsel for Appellants and Appellees by electronic mail and that Appellants and Appellees each represented that they do not object to the filing of the brief of *amici curiae*.

Dated: August 27, 2026

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CERTIFICATE OF SERVICE

I hereby certify that on August 27, 2026, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

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