

No. 22-1123

**In the United States Court of Appeals
for the District of Columbia Circuit**

JUUL LABS, INC.,

Petitioner,

v.

U.S. FOOD AND DRUG ADMINISTRATION,

Respondent.

On Petition for Review of an Order of the
U.S. Food and Drug Administration

**BRIEF FOR AMICUS CURIAE
NATIONAL ASSOCIATION OF CONVENIENCE STORES IN
SUPPORT OF EMERGENCY MOTION FOR STAY PENDING REVIEW**

Kyle Hawkins
LEHOTSKY KELLER LLP
919 Congress Ave.
Austin, TX 78701

Steven P. Lehotsky
Scott A. Keller
Gabriela Gonzalez-Araiza
LEHOTSKY KELLER LLP
200 Massachusetts Ave. NW
Washington, DC 20001
(512) 693-8350
steve@lehotskykeller.com

Counsel for Amicus Curiae

**CERTIFICATE OF PARTIES, RULINGS, AND RELATED CASES
PURSUANT TO CIRCUIT RULE 28(A)(1)**

A. Parties and Amici.

All parties appear in the Petitioner's Emergency Motion for Stay Pending Review. Proposed amici curiae, 38 National and State Electronic Nicotine Delivery System Product Advocacy Associations, have filed a motion for leave to file an amicus curiae brief in support of Petitioner. Amicus is not aware of any other parties or amici.

B. Ruling Under Review.

An accurate reference to the ruling at issue appears in the Petitioner's Emergency Motion for Stay Pending Review.

C. Related Cases.

An accurate statement regarding related cases appears in the Petitioner's Emergency Motion for Stay Pending Review. Amicus is not aware of additional related cases.

CORPORATE DISCLOSURE STATEMENT

Under Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, the National Association of Convenience Stores (NACS) certifies that it is a nonprofit, tax-exempt trade association headquartered in Virginia. NACS has no parent corporation, and no publicly held company has 10% or greater ownership in NACS. NACS further states that its general nature and purpose is to represent the interests of more than 1,500 retail and 1,600 supplier company members nationwide. NACS is the preeminent representative of the interests of convenience store operators.

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GLOSSARY OF ABBREVIATIONS**Abbreviation****Definition**

ENDS

Electronic nicotine delivery systems

FDA

U.S. Food and Drug Administration

NACS

National Association of Convenience Stores

INTEREST OF AMICUS CURIAE

Amicus National Association of Convenience Stores (“NACS”) is a trade association representing the interests of the retailers who bring Petitioner Juul Labs, Inc.’s e-cigarette products to adult consumers.¹ These retailers have collectively devoted millions of dollars in staffing, facilities, logistics, inventory, and contracts to the JUUL products banned in the FDA’s June 23 Order (“Order”). The FDA has expressly directed NACS members to comply with its Order or face enforcement actions. According to the FDA’s own press release about the Order: “In addition to ensuring that JUUL complies with this order . . . the FDA intends to ensure compliance by distributors and retailers. Specifically, the FDA notes that all new tobacco products on the market without the statutorily required premarket authorization are marketed unlawfully and are subject to enforcement action.”² NACS members, including its retail members and supplier company members that distribute these products, are thus among the targets of the Order.

¹ No counsel for any party authored this brief in whole or in part, and no entity or person, aside from amicus curiae, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E). Counsel for Petitioner and Respondent consent to the filing of this amicus brief. *See* Fed. R. App. P. 29(a)(2).

² News Release, U.S. Food & Drug Admin., FDA Denies Authorization to Market JUUL Products; Currently Marketed JUUL Products Must Be Removed from the US Market (June 23, 2022), <https://bit.ly/3Nx6ceO>.

SUMMARY OF ARGUMENT

If allowed to take effect, the Order threatens NACS members with harm independent of the harm JUUL describes in its stay application. The Order saddles retailers and distributors with inventory they cannot sell and contracts they cannot fulfill, waylaying a substantial portion of their business practically overnight. NACS's perspective will assist the Court's consideration of whether to grant a stay, particularly as to the interests of non-parties. *See Nken v. Holder*, 556 U.S. 418, 434 (2009) (courts should consider impact of stay on "other parties interested in the proceeding"); *In re NTE Conn., LLC*, 26 F.4th 980, 991 (D.C. Cir. 2022) (considering "third-party harms").

ARGUMENT

I. The FDA's Order Expressly Harms Numerous Entities That Sell JUUL's Products.

Electronic nicotine delivery systems, also known as ENDS or e-cigarettes, have become an important part of the national economy and are available to adult consumers through the work of a vast array of manufacturers, distributors, and retailers. JUUL is an ENDS manufacturer central to that ecosystem, but retailers and distributors will also face irreparable harm from the Order. Removing JUUL and its products from commerce wreaks havoc on an entire industry, upends an important segment of the economy, endangers countless jobs, and impedes small businesses' ability to operate. Due to the expedited nature of this stay request, this amicus brief references data and sources that are already publicly available. A stay of the Order will allow

this Court to receive record evidence in the normal course of judicial review that allows full consideration of the petition for review.

A. In recent years, a vast industry has sprung up around the market for popular e-cigarettes. *See Wages & White Lion Invs., L.L.C. v. U.S. Food & Drug Admin.*, 16 F.4th 1130, 1134 (5th Cir. 2021) (“[B]y the time the FDA got around to issuing the Deeming Rule [in 2016], manufacturers were widely marketing e-cigarettes throughout the United States.”). E-cigarettes work “by vaporizing a liquid . . . that can be inhaled,” leading to claims that they are “safer than existing tobacco products.” *Nicopure Labs, LLC v. Food & Drug Admin.*, 944 F.3d 267, 270-71 (D.C. Cir. 2019). Research already has emerged indicating that “daily e-cigarette use was associated with greater odds of cigarette discontinuation among smokers who initially had no plans to ever quit smoking.”³ Some e-cigarettes have been on the market over a decade. *See Nicopure Labs*, 944 F.3d at 275. In 2016, when the FDA began regulating e-cigarettes via its Deeming Rule, “as many as 25,000 products [were] already on the market.” *Vapor Tech. Ass’n v. U.S. Food & Drug Admin.*, 977 F.3d 496, 498 (6th Cir. 2020).

A vast chain of distributors help transport ENDS products from manufacturers like JUUL to a broad array of retailers—convenience stores,

³ Karin A. Kasza et al., *Association of E-Cigarette Use with Discontinuation of Cigarette Smoking Among Adult Smokers Who Were Initially Never Planning to Quit*, JAMA Network Open (Dec. 28, 2021), <https://bit.ly/3y9Myj6>.

specialty vape stores, smoke shops, and other small businesses—who in turn sell the products to adult consumers. A recent study highlighted the impact of that web of commerce on the economy of the State of Florida. As of 2018, Florida experienced over \$543 million in vapor product sales, which led to over 10,000 jobs, over \$480 million in wages and compensation, and almost \$1.5 billion in economic activity.⁴ Of those jobs, nearly 3,000 “are held by Floridians working for the 803 independent retail vape shops.”⁵ Almost 1,500 “are held by Floridians working in wholesale and other retail establishments (like convenience stores).”⁶ All told, over 5,500 “full-time-equivalent jobs in Florida depend on the manufacture, distribution and sale of vapor products in the state.”⁷

And that is just one state. Another recent study of the ENDS market in the United States found that nationwide “[a]bout \$8.1 billion in vapor sales lead[s] to 133,600 jobs and \$22.1 billion in economic activity.”⁸ As a result, a proposed federal nicotine tax on ENDS “[w]ould lead to a reduction of

⁴ See Memorandum from John Dunham to the Vapor Technology Association, *Senate Bill 810’s Flavor Ban Will Decimate Florida’s Small Businesses*, Vapor Technology Association 1-2 (Mar. 19, 2020), <https://bit.ly/3I3h6Ym>.

⁵ *Id.* at 1.

⁶ *Id.*

⁷ *Id.*

⁸ Vapor Technology Association, *The Negative Economic Impacts of the New Nicotine Tax Imposed Only on Vapor Products in the Reconciliation Bill (HR 5376)* (Dec. 7, 2021), <https://bit.ly/3bFkNHL>.

nearly 42,800 full-time equivalent jobs and the loss of \$2.2 billion in wages and benefits” and “[w]ould negatively impact the size of the overall economy which would fall by about \$7.0 billion.”⁹ Put another way, of the \$22 billion ENDS industry value, almost \$7 billion is generated by the wholesalers and retailers participating in the vapor industry.¹⁰

B. Those figures contextualize the extraordinary impact the FDA’s Order will impose on countless distributors and retailers. The FDA acknowledges that JUUL is among “the companies that account for most of the U.S. market,” and that JUUL’s offerings “make up a significant part of the available products.”¹¹ JUUL led the U.S. e-cigarette market in 2018 and experienced \$1.3 billion in sales in 2021.¹² The most recent available data indicate that JUUL makes up about a third of the market share of e-cigarettes.¹³

⁹ *Id.*

¹⁰ John Dunham & Associates, *Economic Impact of the Vapor Industry 2021 United States*, Vapor Technology Association, <https://bit.ly/3AdcTPV>; see also John Dunham & Associates, *The Vapor Industry Economic Impact Study*, Vapor Technology Association 5 (Sept. 20, 2021), <https://bit.ly/3I8bjAP> (defining wholesalers as including firms involved in the distribution and storage of vapor products).

¹¹ U.S. Food & Drug Admin., *supra* note 2.

¹² Jennifer Maloney, *FDA to Order Juul E-Cigarettes Off U.S. Market*, Wall Street Journal (June 22, 2023), <https://on.wsj.com/3bH9f6D>.

¹³ *Reynold’s Vuse Continues to Build Market Lead Over Juul*, vaporvoice.net (May 12, 2022), <https://bit.ly/3NyfGq5>.

Such a central market figure necessarily relies on vast supply chains to move massive amounts of inventory. According to one study, some 22.4 million e-cigarette units were sold nationwide in June 2021.¹⁴ Applying JUUL's one-third market share to that figure suggests a monthly sale of over 7 million units nationwide.¹⁵ There is no doubt that the Order freezes retail sales of *millions* of JUUL units in inventory. Those units will take up retail backroom space and gather dust absent a stay. This is not costless: JUUL acknowledges that its products "are meant to be used soon after purchase" before "the flavor or quality decrease[s]."¹⁶ And the retailers saddled with this unsellable product foot the cost of storage and may have to absorb the entire cost of purchasing those products.

The Order also calls into question contractual obligations rendered economically infeasible. The contracts binding manufacturers, distributors, and retailers to one another can last years and cost millions of dollars. By effectively banning JUUL products overnight, the Order has injected chaos into

¹⁴ CDC Foundation, *Monitoring U.S. E-Cigarette Sales: National Trends* (June 2021), <https://bit.ly/3nuwcwx>.

¹⁵ *See id.*; *see also* Hannah Hammond, *Tobacco: Setting the Tone*, CSP (Apr. 11, 2022), <https://bit.ly/3ORWR2e> (indicating total smokeless tobacco sales of 1.4 billion units in 2021).

¹⁶ Juul, *How Long Should I Store My JUULPods? Do They Expire?*, <https://bit.ly/3ywd1c0> (last visited June 30, 2022).

those relationships and left the parties uncertain as to their rights, obligations, and duties.

The Order thus poses a severe threat to retailers and distributors. In light of the FDA's recent decision to authorize JUUL's competitor, NJOY, under the premarket tobacco product application pathway, retailers found the FDA's decision to shut down JUUL "very shocking."¹⁷ And with that shock comes uncertainty: some retailers initially pulled JUUL products from their shelves but kept them "in the backrooms at stores for now" in case "Juul receives a stay or its MDO is overturned."¹⁸ It makes little sense to subject businesses retailers and distributors to this on-again, off-again regime of legality, especially since e-cigarettes have been marketed for over a decade, and the exact JUUL products the FDA now seeks to ban have been sold widely for years. It is especially troubling that the FDA has not given anyone any explanation for its sudden decision some 13 years after ENDS systems first entered the market, to target JUUL for removal while adult consumers continue to purchase the same or similar products from JUUL's competitors. *See* Emergency Mot. for Stay Pending Review at 13-16.

¹⁷ Hannah Hammond, *Convenience-Store Retailers Shocked, Upset With Juul Decision*, CSP (June 24, 2022), <https://bit.ly/3a6tY3A>; *see also* U.S. Food & Drug Administration, *FDA Issues Marketing Decisions on NJOY Ace E-Cigarette Products* (Apr. 26, 2022), <https://bit.ly/3bFNgNE>.

¹⁸ Hammond, *supra* note 17.

There is simply no good reason to summarily shut down the manufacturer responsible for 10-digit sales figures and sow chaos in a complex supply chain, injuring its participants and sending ripple effects throughout the economy.

C. In addition to the costs of the JUUL products themselves, retailers and distributors will suffer losses due to the black market that will quickly develop in counterfeit products. Experience shows that when legitimate retailers stop selling tobacco products, a black market quickly fills the void.¹⁹ Such counterfeit products take sales away from legitimate convenience stores, vape shops, and distributors that sell these products. That means fewer customers coming through the doors of legitimate stores to purchase not only e-cigarettes, but other products as well. The number of customer “trips” made to a convenience store and the ancillary purchases they make in addition to their primary purchase during those trips are essential elements to the profitability of these stores.²⁰

By taking customers out of legitimate channels of commerce and moving them to the black market, the Order will inflict economic harms that

¹⁹ Angelica LaVito, *Fake Juul Pods Line Store Shelves, Worrying Users and Posing Another Threat to the Embattled Company*, CNBC (Aug. 26, 2019), <https://cnb.cx/2ZsNlwp>.

²⁰ See Jerry Soverinsky, *Purchase, Return, Repeat*, NACS Magazine (Sept. 2018) <https://bit.ly/3btTika>.

reverberate across the convenience industry far beyond the dollar figures associated with stranded, unsold JUUL products.

II. The Court Should Stay the FDA's Order.

In addition to the reasons JUUL identifies in its stay motion, a stay is warranted to stave off these harms to retailers and distributors of JUUL's products. As the Supreme Court explained in *Nken*, courts should consider four factors in deciding whether to stay an action pending review in the appellate court. 556 U.S. at 434. The third is "whether issuance of the stay will substantially injure the other parties interested in the proceeding." *Id.* (internal quotation marks and citation omitted). This Court has previously considered "third-party harms" in deciding whether to grant a stay. *E.g., In re NTE Conn.*, 26 F.4th at 991. And while "[o]rdinarily, economic loss does not, in and of itself, constitute irreparable harm," this Court has "[n]onetheless . . . recognized that financial injury can be irreparable where no adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation." *Id.* at 990 (cleaned up); *see also Beacon Assocs., Inc. v. Apprio, Inc.*, 308 F. Supp. 3d 277, 288 (D.D.C. 2018) (cognizable "irreparable injury" includes "loss of longstanding clients, loss of ability to compete for and attract new clients and partners, incalculable lost profits, and consequential damages"); 11A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2948.1 (3d ed.) ("Injury to reputation or goodwill is not easily measurable in monetary terms, and so often is viewed as

irreparable.”); *cf. In re Revel AC, Inc.*, 802 F.3d 558, 569-70 (3d Cir. 2015) (“[W]here factors of irreparable harm, *interests of third parties* and public considerations strongly favor the moving party, an injunction might be appropriate even though plaintiffs did not demonstrate as strong a likelihood of ultimate success as would generally be required.” (citation omitted) (emphasis added)).

Accordingly, it is appropriate to consider NACS members’ interests here. For the reasons set out above, retailers and distributors will suffer serious financial and operational harm if the Order is not stayed. That harm further tips the balance in favor of a stay. There is no sufficient justification to impose on NACS members uncertainty with regard to contractual obligations and unusable inventory and force upon them storage costs and lost revenue from a range of products in addition to e-cigarettes. These consequences are obvious, immediate, and ongoing. In contrast, the FDA waited years to regulate e-cigarettes and still more years to act on JUUL’s application—and now has identified no emergency requiring its out-of-the-blue order to take immediate effect. *See* Emergency Mot. for Stay Pending Review at 22-23. In these circumstances, the proper course is to put the Order on hold and allow meaningful judicial review.

CONCLUSION

The Court should grant Petitioner's emergency motion to stay the Order.

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Respectfully submitted.

Kyle Hawkins
LEHOTSKY KELLER LLP
919 Congress Ave.
Austin, TX 78701

/s/ Steven P. Lehotsky
Steven P. Lehotsky
Scott A. Keller
Gabriela Gonzalez-Araiza
LEHOTSKY KELLER LLP
200 Massachusetts Ave. NW
Washington, DC 20001
(512) 693-8350
steve@lehotskykeller.com

Counsel for Amicus Curiae

CERTIFICATE OF SERVICE

On June 30, 2022, this brief was served via CM/ECF on all registered counsel and transmitted to the Clerk of the Court.

/s/ Steven P. Lehotsky

Steven P. Lehotsky

CERTIFICATE OF COMPLIANCE

This brief complies with: (1) the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 2,343 words, excluding the parts of the brief exempted by Rule 32(f); and (2) the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface (14-point Palatino Linotype) using Microsoft Word (the same program used to calculate the word count).

/s/ Steven P. Lehotsky

Steven P. Lehotsky