

No. 22-1123

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**UNITED STATES COURT OF APPEALS  
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

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JUUL LABS, INC.,  
*Petitioner,*

v.

U.S. FOOD AND DRUG ADMINISTRATION,  
*Respondents.*

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

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**PETITIONER JUUL LABS, INC.'S REDACTED EMERGENCY MOTION  
FOR STAY PENDING REVIEW**

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JOHN C. O'QUINN, P.C.  
*Counsel of Record*  
JASON M. WILCOX, P.C.  
DEVIN S. ANDERSON  
KIRKLAND & ELLIS LLP  
1301 Pennsylvania Avenue, NW  
Washington, DC 20004  
(202) 389-5000  
john.oquinn@kirkland.com

*Counsel for Petitioner Juul Labs, Inc.*

June 27, 2022

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**CORPORATE DISCLOSURE STATEMENT**

Pursuant to Federal Rule of Appellate Procedure 26.1(a) and Circuit Rules 18(a)(4) and 26.1, Juul Labs, Inc. (a private, nongovernmental party) certifies that it does not have a parent corporation. Altria Group, Inc. owns a minority share of Juul Labs, Inc., and no other publicly held corporation owns 10 percent or more of the stock of Juul Labs, Inc.

## **CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES**

### **A. Parties and Amici**

Petitioner is Juul Labs, Inc. (JLI), and respondent is the U.S. Food and Drug Administration (FDA). No amici curiae have appeared in this Court.

### **B. Ruling Under Review**

JLI has petitioned for review of FDA's June 23, 2022 order denying its premarket tobacco product applications (PMTAs). A copy of the order is included in the Appendices accompanying this motion. SA1-16. FDA has not consented to the requested relief, which is a stay pending appeal of FDA's order.

### **C. Related Cases**

The June 23, 2022 order denying Juul Labs' applications has been previously before this Court on JLI's Emergency Motion for Administrative Stay, but it has not otherwise been before this Court, or any other court. Counsel is also not aware of any other related cases currently pending in any other court involving substantially the same parties and the same or similar issues.

June 27, 2022

s/John C. O'Quinn

JOHN C. O'QUINN

*Counsel of Record*

KIRKLAND & ELLIS LLP

1301 Pennsylvania Avenue, NW

Washington, DC 20004

(202) 389-5000

john.oquinn@kirkland.com

*Counsel for Petitioner Juul Labs, Inc.*

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## GLOSSARY OF ABBREVIATIONS

<b>Abbreviation</b>	<b>Definition</b>
ENDS	Electronic nicotine delivery system(s)
FDA	U.S. Department of Food and Drug Administration
JLI	Juul Labs, Inc.
PMTA	Premarket tobacco product application(s)
TCA	Family Smoking Prevention and Tobacco Control Act of 2009
SA	Sealed Appendix
PA	Public Appendix

## INTRODUCTION

Congress enacted the Family Smoking Prevention and Tobacco Control Act (TCA) to regulate tobacco products and encourage the development and introduction of alternatives to traditional cigarettes that reduce tobacco-related death and disease. The TCA permits FDA to withhold marketing authorization for tobacco products introduced after 2007, but only after considering the public-health impacts of such products on the population as a whole through the premarket-tobacco-product-application (PMTA) process. Juul Labs (JLI)'s PMTAs included over 110 scientific studies and over 125,000 pages of data and analysis demonstrating the substantial public-health benefits its electronic-nicotine-delivery-system (ENDS) products provide. Those studies show JUUL products are effective in switching smokers from combustible cigarettes, significantly reduce exposure to those harmful and often deadly toxicants, and have little appeal to non-smokers. Over two million adults have switched from cigarettes because of JLI's products and over a million deaths could be avoided over the coming years—the exact outcome Congress intended.

Instead of praising a significant public-health victory, FDA denied JLI's applications for arbitrary reasons and demanded that retailers remove all JUUL products from their shelves or face immediate action. That decision cannot be squared with the TCA, the Administrative Procedure Act, or the science, nor is there cause for forcing JLI off the market immediately. The TCA became law in 2009, yet

FDA waited seven years to deem ENDS products subject to regulation *at all*, allowed those products to remain on the market without even submitting a PMTA until September 2020, and then spent almost two years reviewing JLI's applications. Whatever one thinks of FDA's process, it shows there is no great public-health emergency if FDA's order is put on hold.

That drawn-out regulatory process produced a manifestly erroneous decision. Congress required FDA to evaluate *all* "valid scientific evidence" and weigh *all* potential public-health benefits against *all* potential public-health harms before rendering its decisions. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As it has with other PMTAs, FDA should have evaluated the totality of JLI's evidence, which conclusively established that the public-health benefits of JUUL products significantly outweigh any potential risks.

FDA instead rejected JLI's applications for deeply flawed reasons. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Had FDA done a more thorough review (like it did for other applicants), it would have seen [REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]. No other applicant has had their application denied for similar reasons, and FDA offered no explanation for why it held JLI to a different standard.

FDA reached these decisions against a backdrop of immense political pressure. Members of Congress through letters and at hearings pressed FDA officials to commit that JUUL products would not be authorized. One commentator even remarked that FDA had to deny JLI's applications or risk significant budget cuts. That level of congressional interference is unprecedented, inappropriate, and tainted the entire agency process. The TCA mandates that FDA's decision be based on science and evidence, not politics.

Absent a stay pending appeal, FDA's unlawful actions will cause JLI significant irreparable harm. FDA's order affects every product JLI sells and every adult who has switched from combustible cigarettes to a JUUL product. Taking those products off store shelves—even temporarily—would permanently [REDACTED]

[REDACTED]

[REDACTED] Consumers will switch to other products or return to cigarettes as stores fill the shelf space JUUL products used to occupy.

The public interest strongly favors a stay as well. As FDA officials have warned, removal of ENDS products creates a serious risk that individuals will revert

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to combustible cigarettes or look for products on the illicit market. That significant public-health risk will become a reality if JLI's products are removed from the market while this appeal is pending.

If this Court intervenes, [REDACTED] and an important alternative will remain on the market for adult smokers who have transitioned or who deserve the opportunity to transition away from cigarettes. If the Court does not intervene, JLI's products will disappear from store shelves and politics will have won over sound science and evidence. Courts around the country have issued stays in similar situations. *Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1134 (5th Cir. 2021); *Gripum LLC v. FDA*, 2021 WL 8874972 at \*1 (7th Cir. Nov. 4, 2021); *Bidi Vapor LLC v. FDA*, 2022 WL 2237403 at \*3–4 (11th Cir. Feb. 1, 2022). JLI will brief its petition as expeditiously as the Court deems appropriate, but in the meantime, the Court should likewise stay enforcement of FDA's arbitrary decision.

## **BACKGROUND**

### **A. The JUUL System**

Congress has recognized that combustible cigarettes “cause[] over 400,000 deaths in the United States each year” and that “approximately 8,600,000 Americans have chronic illnesses related to smoking.” Pub. L. No. 111-31, §2(13), 123 Stat. 1776, 1777 (2009). JLI designed its JUUL products to address that problem by

providing a less-harmful, noncombustible alternative for adult smokers. SA.63. Rather than burning tobacco, the JUUL System uses proprietary heating technology to heat a nicotine-containing liquid within a controlled temperature range to produce an aerosol that the user inhales. SA.87. JUUL products thus significantly reduce exposure to harmful or potentially harmful constituents associated with smoking cigarettes.

Although JUUL was not the first ENDS product, it was one of the first devices that adult smokers found sufficiently satisfying to switch from combustible cigarettes. For these smokers, the product needs to be easy-to-use and satisfy the nicotine cravings they previously sated through cigarettes. The JUUL products overcame this challenge through a combination of features that ensure consistent nicotine delivery that more closely resembles the experience of cigarette smoking. SA.63-64; SA.94. Since JUUL products were introduced in 2015, millions of adult smokers have used JUUL products as a substitute for cigarettes. SA.64; SA.94. More than half switched from cigarettes completely. SA.94.

JUUL products are sold in retail stores across the country. SA.64. Retailers who sell JUUL products must comply with JLI's rigorous access restrictions to prevent underage sales, and JLI conducts "secret shopper" audits to confirm retailers are complying with those requirements. SA.64. Consumers can also purchase JUUL products from JLI's website, where JLI uses industry-leading age-verification

techniques to ensure purchasers are at least 21 years old. SA.64–65. The U.S. is responsible for [REDACTED] of its revenue. SA.68.

### **B. The Tobacco Control Act And FDA Regulation**

Congress enacted the TCA to both regulate the tobacco industry and to “encourage the development of innovative products and treatments,” including treatments that are “nicotine-based,” to reduce the “consumption of tobacco” and the “harm associated with continued tobacco use.” 21 U.S.C. §387r(b)(1). The Act originally applied only to “cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco” products. *Id.* §387a(b). But Congress delegated to FDA discretion to “deem[]” other tobacco products subject to the TCA. *Id.*

In 2016—almost seven years after Congress passed the TCA—FDA issued a rule “deeming” ENDS products subject to the Act. *See* 81 Fed. Reg. 28,973. FDA recognized that the inhalation of nicotine poses “less risk to the user than inhalation of nicotine delivered by smoke from combusted tobacco products.” *Id.* at 28,981. FDA nevertheless subjected ENDS products to the TCA’s “premarket review” requirements, even though many ENDS products (including JUUL products) were already on the market. Those requirements include obtaining FDA authorization. 21 U.S.C. §§387j(a)(1)–(2).

The pathway to authorization for virtually all ENDS products requires the manufacturer to submit a PMTA that demonstrates the product “is appropriate for



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the protection of the public health.” *Id.* §387j(c)(4). The public-health showing involves a comprehensive, holistic analysis based on studies and other “valid scientific evidence” that balances the “risks and benefits to the population as a whole, ... taking into account (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will starting using such products.” *Id.* §§387j(c)(4)–(5).

FDA deferred its enforcement authority against ENDS products that were on the market while it completed the premarket-review process. *See, e.g.*, 81 Fed. Reg. at 28,977–78, 29,011, 29,014; *Cigar Ass’n of Am. v. FDA*, 5 F.4th 68, 73–74 (D.C. Cir. 2021). It extended its compliance period for years, stating that ENDS manufacturers could submit applications all the way through August 2022. PA.409-11. Following a legal challenge to its deferred-enforcement policy, FDA was required to impose a 2020 application deadline and committed to act on the applications by September 9, 2021—a deadline FDA promptly missed for virtually every major ENDS product. *See Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 481 (D. Md. 2019); *see also* PA.412-63.

### C. JLI’s PMTAs

In July 2020, JLI submitted PMTAs with 125,000 pages of information, data, and analysis, seeking authorization to market [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

JLI also put its products under the microscope, subjecting them to numerous comprehensive examinations to identify [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

JLI's applications showed: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] promptly responded with additional scientific data and analysis. JLI did not hear from FDA again on any substantive issues until its marketing-denial order.

#### **D. FDA's Order**

On June 22, 2022, almost two years after JLI's initial submission, JLI received word that FDA was planning to deny its application and order all JUUL products off the U.S. market. That notice came from the press, not FDA. PA.473–74. Apparently, officials with knowledge of FDA's order leaked the matter to the press, which left JLI and the market in disarray and which violated FDA confidentiality rules. 21 C.F.R. § 1114.47(b)(2)–(3).

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In the wake of that chaos, FDA issued its formal order the next day. SA.1-16;  
SA.17-61. FDA acknowledged that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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At the same time, FDA's press release stated that it "has not received clinical information to suggest an immediate hazard associated with the use of the JUUL device or JUULpods." PA.475. FDA nevertheless demanded that JLI stop selling its products and that wholesalers and retailers remove JUUL products "or risk enforcement action." PA.475. Commentators observed that JLI had been "singled out": there had been "so much opposition to Juul" from "legislators in state legislatures and Congress," that "FDA simply could not have authorized the sale of JUUL" without provoking a "fierce" backlash and jeopardizing its funding. PA.478.

#### **E. Impact Of FDA's Order**

FDA's order caused chaos. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

JLI asked FDA for a stay within hours of its decision. FDA denied JLI's request. PA.482. JLI immediately petitioned for review under 5 U.S.C. § 706 and 21 U.S.C. § 389l(a). The next day, this Court issued an administrative stay and set a briefing schedule for this motion.

## ARGUMENT

FDA's denial of JLI's applications is **contrary to the TCA** and is arbitrary and capricious. An immediate stay pending is **critical to protect JLI, its commercial partners, and its customers**, as JLI readily satisfies the four-factor balancing test. D.C. Cir. R. 18(a)(1); *Nken v. Holder*, 556 U.S. 418, 426 (2009); *see also Cuomo v. United States N.R.C. Regulatory*, 772 F.2d 972, 974 (D.C. Cir. 1985) ("high probability of success on the merits" not required for stay if strong showing of "irreparable injury"); 5 U.S.C. §705.<sup>1</sup>

### I. JLI Is Likely To Prevail On The Merits.

The Administrative Procedure Act directs courts to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. §706(2). Review under the Act is "highly deferential," *Ramaprakash v. FAA*, 346 F.3d 1121, 1124 (D.C. Cir. 2003), but "not toothless," *Multicultural Media, Telecom & Internet Council v. FCC*, 873 F.3d 932, 937 (D.C. Cir. 2017). Agency action is arbitrary and capricious if the agency's "explanation for its decision ... runs counter to the evidence before the agency, *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), if the agency "departs from agency precedent without

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<sup>1</sup> As multiple courts have found, once FDA denied JLI's oral stay request, JLI did not need to wait before seeking judicial review and a stay. *See Wages & White Lion*, 16 F.4th at 1135 n.1; *Breeze Smoke, LLC v. FDA*, 18 F.4th 499, 503 (6th Cir. 2021).

explanation,” *Ramaprakash*, 346 F.3d at 1124, or the agency fails to “reasonably consider[] the relevant issues,” *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). FDA got the science wrong—an issue JLI will address with the agency. But FDA’s order also violates these administrative-law principles in at least three ways, any one of which is sufficient to set aside the agency’s action.

First, FDA’s approach to JLI’s application—[REDACTED]  
[REDACTED]—stands in stark contrast to how it has handled applications by other manufacturers and defies the holistic public-health assessment the TCA demands. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] But FDA took into account a [REDACTED]  
[REDACTED] and granted [REDACTED] application. SA.490,503. [REDACTED] also received authorization for its [REDACTED]

[REDACTED]

[REDACTED]

This holistic approach FDA took with other applicants is consistent with fundamental administrative-procedure principles and the TCA. An agency must “reasonably consider[]” all “the relevant issues” before it, *Prometheus*, 141 S. Ct. at 1158, and the TCA directs FDA to examine *all* “valid scientific evidence,” and balance all of the data, 21 U.S.C. §§387j(c)(4)–(5). FDA’s order itself says, “FDA must weigh *all potential public health benefits against all potential public health harms.*” SA.1 (emphasis added).

Here, however, FDA concluded that [REDACTED]  
[REDACTED]  
[REDACTED] without offering any reason for treating JLI different than similarly situated applicants, *see United States v. Diapulse Corp. of Am.*, 748 F.2d 56, 62 (2d Cir. 1984); *Burlington N. & Sante Fe Ry. v. Surface Transp. Bd.*, 403 F.3d 771, 776–77 (D.C. Cir. 2005) (similar). This discriminatory treatment [REDACTED] in the MDO.

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]



FDA's approach is part of a larger pattern of FDA singling out JLI. Officials with knowledge of FDA's order first leaked to The Wall Street Journal that the agency would deny JLI's applications a full day before its actual decision. PA.473–74. FDA then issued a press release that was more strident and threatening **than the agency's typical statements when issuing denial orders and that alluded to the youth-vaping crisis, which was not cited in the order as a reason for denying JLI's PMTAs.** PA.475. No prior press release threatened retailers that they would “risk enforcement action” unless they *immediately* removed the products from their stores, and no prior press release suggested that consumers “switch to other ENDS products.” PA.475; PA.737–46.

Indeed, members of Congress have lobbied FDA for years to deny JLI's PMTAs. PA.747–58. After FDA's decision, Representative Krishnamoorthi boasted about the congressional pressure placed “on the FDA to deny JUUL's PMTA applications.” PA.759–61. Senator Durbin for years pushed FDA to “finally do the right thing” and take “JUUL off the market.” PA.750–52; PA.762. Under congressional questioning, former FDA Commissioner Woodcock claimed that **“JUUL is responsible for the youth vaping epidemic,”** while JLI's application was pending before the agency. PA.763–66. In light of these and other comments, pundits have noted that “FDA simply could not have authorized the sale of JUUL” without provoking a “fierce” backlash from “legislators in state legislators and

Congress,” and jeopardizing its funding. PA.478–81. That political pressure cannot justify holding JLI to a different standard than other ENDS manufacturers. *See, e.g., D.C. Fed’n of Civic Ass’ns v. Volpe*, 459 F.2d 1231, 1246 (D.C. Cir. 1972); *Pillsbury Co. v. FTC*, 354 F.2d 952, 954–55, 963 (5th Cir. 1966).

*Second*, FDA simply overlooked [REDACTED] it claimed it needed. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The data is right there in JLI’s original submission. [REDACTED]

[REDACTED]

[REDACTED]

---

<sup>2</sup> [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

FDA’s “explanation for its decision” [REDACTED]  
thus “runs counter to the evidence before” it. *State Farm*, 463 U.S. at 43. This court has not hesitated to set aside agency action on this basis. *See Genuine Parts Co. v. EPA*, 890 F.3d 304, 341, 346 (D.C. Cir. 2018) (failure “to address evidence that runs counter to the agency’s decision”); *Nat’l Lifeline Ass’n v. FCC*, 921 F.3d 1102, 1110–11 (D.C. Cir. 2019); *Shafer & Freeman Lakes Env’t Conservation Corp. v. FERC*, 992 F.3d 1071, 1089 (D.C. Cir. 2021). FDA’s failure to do a holistic review is not a [REDACTED] reason to shut down a business.

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This is not the first time FDA overlooked critical information in a PMTA. Last year, FDA rescinded a marketing-denial order after finding entire “randomized controlled trials” and “cross-sectional surveys” it originally failed to consider. PA.804-5. Since then, FDA has stayed other orders after concerns were raised about evidence it overlooked. PA.997–98,999–1000,1001–02. FDA’s rush to review its backlog of PMTA applications is clearly creating a haphazard regulatory process.

FDA’s failure to [REDACTED] fatally undermines [REDACTED]

[REDACTED]

[REDACTED] But if the Court concludes the agency violated the APA for [REDACTED], it should remand for the agency to reconsider its decision because FDA acknowledged that

[REDACTED]

[REDACTED] “[W]hen an agency relies on multiple grounds for its decisions, some of which are invalid,” the decision must be set aside unless “the agency would clearly have acted on [a valid] ground if the other [invalid grounds] are unavailable.” *Casino Airlines, Inc. v. NTSB*, 439 F.3d 715, 717–18 (D.C. Cir. 2006); *see also Bally’s Park Place, Inc. v. NLRB*, 646 F.3d 929, 939 (D.C. Cir. 2011).

*Third*, FDA arbitrarily departed from its iterative review process. As of the September 2020 PMTA submission deadline, FDA had issued marketing orders to

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applicants that were permitted to submit up to 14 amendments.<sup>4</sup> [REDACTED]

[REDACTED] FDA's departure from past practice and treatment of similarly situated applicants profoundly harmed JLI because JLI easily could have addressed FDA's concerns and pointed the agency to the relevant data in the PMTAs if FDA had only asked. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156–57 (2012) (agencies cannot “unfair[ly] surprise” regulated parties); *Westar Energy, Inc. v. FERC*, 473 F.3d 1239, 1241 (D.C. Cir. 2007); *Airmark*, 758 F.2d at 692. FDA's denial of JLI's PMTAs is unlawful and should be set aside.

## II. JLI's Harms Are Irreparable and Imminent Without A Stay.

JLI faces imminent, irreparable harm due to FDA's decision to ban its entire product portfolio. A business can establish irreparable harm by demonstrating “unrecoverable monetary losses,” *Nat'l Lifeline Ass'n v. FCC*, 2018 WL 4154794, \*1 (D.C. Cir. Aug. 10, 2018), the “inability to recruit and retain employees,” *Luokung Tech. Corp. v. Dep't of Defense*, 538 F. Supp. 3d 174, 194 (D.D.C. May. 5, 2021), or the “loss of customer goodwill and trust,” *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Wertz*, 298 F. Supp. 2d 27, 34 (D.D.C. 2002). Absent a stay, FDA's decision will cause each of these irreparable injuries, and ultimately shutter JLI's business.

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<sup>4</sup> See PA.489,818–819, 898

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The brief period between when FDA issued its order and this Court entered its temporary stay previewed the chaos that will ensue. Within 24 hours of the order's release, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. Exploiting the situation, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] None of that spending is recoverable from FDA. *See Consol. Edison Co. of New York v. Bodman*, 445 F.3d 438, 446 (D.C. Cir. 2006); *Ala. Ass'n of Realtors v. Dep't of Health & Human Servs.*, 141 S. Ct. 2485, 2489 (2021).

When FDA's order is eventually set aside, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] That lost business is unrecoverable.

*See Morgan Stanley DW Inc. v. Rothe*, 150 F. Supp. 2d 67, 77 (D.D.C. 2001).

Finally, removing JLI's products from the market will further damage relationships JLI built with its [REDACTED] and business partners. [REDACTED]

[REDACTED]

[REDACTED] [REDACTED] JLI likewise developed strong relationships with its retailers, distributors, and contract manufacturers by being a reliable business partner. SA. 67,70–71,73,75–76. [REDACTED]

[REDACTED] This damage to JLI's "business reputation" is again "irreparable." *Patriot, Inc. v. U.S. Dep't of Hous. & Urban Dev.*, 963 F. Supp. 1, 5 (D.D.C. 1997).

### **III. The Balance Of Harms And The Public Interest Strongly Favor A Stay.**

By contrast, FDA would suffer little or no harm from a stay pending review, and the public interest favors a stay. "Where, as here, the Government is the

opposing party, the last two factors merge: the government’s interest *is* the public interest.” *Shawnee Tribe v. Mnuchin*, 984 F.3d 94, 103 (D.C. Cir. 2021). Here, both factors weigh decisively in favor of relief.

FDA cannot show that there is an urgent public interest in removing JLI’s products from the market *right now*, rather than after this Court reviews FDA’s action. *See Cigar Ass’n*, 317 F. Supp. 3d at 563. The agency waited **seven years before deeming ENDS products subject to the TCA and FDA regulation**. *See* 81 Fed. Reg. 28,973. Then FDA announced that ENDS manufacturers could continue marketing their products without premarket authorization and without any enforcement consequences all the way through August of 2022. PA.988. When FDA moved that deadline up to September 2020, it did so because of a court order—not because it was concerned about the safety of ENDS products. *See Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479 (D. Md. 2019).

JLI submitted its PMTAs in July 2020, six weeks ahead of that court-imposed deadline. FDA then took almost two years—almost four times the 180-day review period Congress specified, *see* 21 U.S.C. §387j(c)(1)(A)—to review those applications and issue its order. Throughout that time, FDA exercised its enforcement discretion to allow JLI’s products (and others) to remain on the market. PA.439; PA.993–95. After its review, FDA acknowledged that it has not identified



“an immediate hazard associated with the use of the JUUL device or JUULpods.” PA.475.

Abruptly removing JUUL products from the market while this appeal is pending would harm the public. Millions of adult smokers use JUUL products as a substitute for combustible cigarettes, more than two million adult smokers have switched completely from cigarette smoking because of JUUL products. SA.86. Many of those former adult smokers may revert to cigarettes. FDA previously cautioned this “public health outcome[]” was to be “avoided if at all possible.” SA.818–33.

Hundreds of customers have contacted JLI, worried about losing the product that helped them switch from combustible-cigarette smoking. PA.996. JLI was flooded with comments like this: “I’m sorry if I sound like I’m panicking but your product is the only one that works and I smoked cigs for 25 years.” PA.1003–4. Unfortunately, some may turn to the illicit market—another problem FDA previously recognized. *See* 81 Fed. Reg. at 29,007. That is not in the public interest, and JLI’s likelihood of success further tips the public interest in favor of a stay. *See, e.g., Shawnee Tribe*, 984 F.3d at 103.

## CONCLUSION

This Court should stay FDA’s order pending review.

Respectfully submitted,

s/John C. O'Quinn

JOHN C. O'QUINN

*Counsel of Record*

JASON M. WILCOX

DEVIN S. ANDERSON

KIRKLAND & ELLIS LLP

1301 Pennsylvania Avenue, NW

Washington, DC 20004

(202) 389-5000

john.oquinn@kirkland.com

*Counsel for Petitioner Juul Labs, Inc.*

June 27, 2022

## CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This motion complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d) because it contains 5,190 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Circuit Rule 32(e)(1).

2. This motion complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the typestyle requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point font.

June 27, 2022

s/John C. O'Quinn  
John C. O'Quinn

**CERTIFICATE OF SERVICE**

I hereby certify that on June 27, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the CM/ECF system. I also caused the foregoing to be served by hand-delivery upon:

Lindsay Powell  
Alisa Klein  
U.S. Department of Justice, Civil Division, Appellate Staff  
950 Pennsylvania Ave., N.W.  
Washington, DC 20530  
lindsey.e.powell@usdoj.gov  
alisa.klein@usdoj.gov

s/John C. O'Quinn  
John C. O'Quinn