**No. 22-1123**

**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,
*Respondent*.

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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 TEMPORARY ADMINISTRATIVE STAY

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June 24, 2022

## 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. Atria 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. A copy of the order is attached as Exhibit 2. FDA has not consented to the requested relief, which is an administrative stay pending this Court's consideration of JLI's forthcoming emergency motion to stay.

### C. Related Cases.

The June 23, 2022 order denying JLI's applications has not been previously before this Court or any other court. Moreover, counsel is 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 24, 2022

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## EMERGENCY MOTION FOR ADMINISTRATIVE STAY

This is an emergency request for an administrative stay until this Court can receive full briefing on petitioner Juul Labs, Inc.'s forthcoming emergency motion for a stay pending review. JLI plans to file that motion by noon eastern on June 27, 2022. Specifically, pursuant to Federal Rule of Appellate Procedure 18(a)(2), JLI submits this *Emergency Motion for Administrative Relief* asking this Court to temporarily stay enforcement of the U.S. Food and Drug Administration's Marketing Denial Order of JLI's Premarket Tobacco Product Applications, which FDA issued yesterday, until this Court resolves JLI's forthcoming emergency motion for a stay pending review of FDA's Order.

FDA's extraordinary and unlawful action, which demands that JLI immediately halt essentially all of its business operations, warrants the emergency interim relief requested. The purpose of an "administrative stay is to give the court sufficient opportunity to consider the merits of the motion for a stay pending appeal." *Cobell v. Norton*, 2004 WL 603456, at *1 (D.C. Cir. Mar. 24, 2004); *see also Twelve John Does v. Dist. of Columbia*, 841 F.2d 1133, 1137 (D.C. Cir. 1988) (describing entry of a temporary administrative stay to permit time for full consideration of motions). Without an administrative stay, [redacted] —all before this Court has any

opportunity to consider the merits of JLI's arguments. Ex. 1, Decl. of David Dickey ¶ 9.

JLI manufactures, markets, and sells the JUUL System, which is an electronic nicotine-delivery system designed as an alternative to combustible cigarettes for adult current smokers. In July 2020 and pursuant to the process established by FDA, JLI submitted a 125,000-page premarket tobacco application, seeking authorization to market Virginia tobacco and menthol flavors in 3.0% and 5.0% nicotine concentrations. In support of its application, JLI conducted numerous nonclinical and clinical studies to evaluate individual health risks among users of JUUL products; developed an extensive behavioral-research program to assess tobacco-use patterns among purchasers of JUUL products—in particular complete switching from combustible cigarettes among adult smokers; and performed population modeling and analysis demonstrating the net-population benefit of marketing JUUL products over time. Among other things, these studies showed that JLI's products significantly reduce exposure to harmful and often deadly toxins compared to combustible cigarettes, transition and completely switch adult smokers from combustible cigarettes at rates well above the published literature for other alternative products, and had limited appeal among non-tobacco users. In addition, JLI proposed significant data-driven measures to mitigate the potential for underage

use focused on limiting appeal, restricting access, and enforcing against third parties that otherwise could undermine underage-use prevention.

Nevertheless, on June 23, 2022, FDA issued its order denying JLI's application. *See* Ex. 2, Marketing Denial Order at 1, 12. It did so despite authorizing applications by competing manufacturers of similar ENDS devices.[1] And it did so after immense political pressure from Congress once it became politically convenient to blame JLI for youth vaping, even though several of its competitors now have a larger market share and much higher underage-use rates.[2] Indeed, FDA's press release seems to allude to that political pressure. *See* Ex. 3, June 23, 2022 FDA News Release (comments by FDA Commissioner Robert M. Califf,

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[1] *See, e.g.*, Press Release, U.S. Food & Drug Administration, *FDA Issues Marketing Decisions on Vuse Cibe and Vuse Ciro E-Cigarette Products* (May, 12, 2022), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-decisions-vuse-vibe-and-vuse-ciro-e-cigarette-products (noting issuance of marketing granted orders to R.J. Reynolds Vapor Company for its Vuse Vibe e-cigarette device, as well as for its Vuse Ciro e-cigarette device); Press Release, U.S. Food & Drug Administration, *FDA Issues Marketing Decisions on NJOY Daily E-Cigarette Products* (June 10, 2022), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-decisions-njoy-daily-e-cigarette-products (noting issuance of marketing granted orders to NJOY LLC for its tobacco-flavored Daily disposable e-cigarettes).

[2] *See generally, Examining Juul's Role In The Youth Nicotine Epidemic: Part I, Hearing Before the Subcomm. on Econ. and Consumer Pol'y., H. Comm. on Oversight and Reform*, 116th Cong. (2019); *Examining Juul's Role In The Youth Nicotine Epidemic: Part II, Hearing Before the H. Subcomm. on Econ. and Consumer Pol'y., H. Comm. on Oversight and Reform*, 116th Cong. (2019).

M.D). To make matters worse, FDA ordered JLI not to "introduce or deliver for introduction [its] products into interstate commerce," Ex. 2, at 1, and its press release threatened retailers across the country that they would "risk enforcement action" if they failed to immediately remove *all* JLI products from their shelves, Ex. 3, at 1.

This regulation by press release had its intended effect. [redacted] JLI's only prospect for meaningful relief that permits it to continue selling its products is an immediate stay.

At every turn, FDA has singled JLI out and denied JLI an orderly process to resolve FDA's largely technical concerns. 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. Ex. 4 ("FDA to Order Juul E-Cigarettes Off U.S. Market"). FDA then issued a press release with quotes from the FDA Commissioner and other FDA officials that is more strident and threatening than the

agency's typical statements when issuing denial orders.[3] And when JLI requested an administrative stay to avoid a massive and irreparable disruption to its business, FDA refused. Ex. 5, Decl. of Sean Griffin ¶¶ 5–8.

Regulation through leaks and press releases is no way to handle agency action, much less to order a company to cease essentially all business operations. FDA's decision is arbitrary and capricious and lacks substantial evidence, and an immediate administrative stay is critical to protect JLI, its commercial partners, and its customers. For that reason, JLI readily satisfies the four factors necessary for obtaining an administrative stay. It is likely to "prevail on the merits," of its petition, the "prospect of irreparable injury" to JLI is substantial, there is "no possibility of harm" to the government, and the "public interest" favors maintaining the status quo. D.C. Cir. R. 18(a)(1); *Nken v. Holder*, 556 U.S. 418, 426 (2009); *see also* 5 U.S.C. §705.

JLI is likely to succeed on the merits of its petition. FDA's order is arbitrary and capricious because it fails to "reasonably consider[] the relevant issues and reasonably explain[]" itself. *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). It also "departs from agency precedent without explanation" in the

[3] *Compare* Ex. 3 *with* Press Release, U.S. Food & Drug Administration, *FDA Issues Marketing Denial Orders to Fontem US for myblu Products* (Apr. 8, 2022), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-denial-orders-fontem-us-myblu-products.

form of a "reasoned analysis." *Ramaprakash v. FAA*, 346 F.3d 1121, 1124 (D.C. Cir. 2003). FDA's decision cannot be squared with the applicable statutes or science. The order did not analyze the entirety of JLI's application before rendering its decision, despite acknowledging that its decision must be a holistic one. Ex. 2, at 1, 12. The order does not hide from this fact: FDA concedes that it "has not" entirely evaluated all "aspects of [JLI's] application, including for example, the potential benefit to adults as compared to the risk to youth posed by [JLI] . . . products." *Id.* at 12. This statement directly contradicts FDA's own press release, which purports to tie JLI to the "rise in youth vaping." Ex. 3, at 1. In fact, the order raises narrow toxicology concerns based on single-assay test results without weighing those isolated data points against the studies after studies JLI submitted demonstrating that its products are not toxic and contain many fewer potentially harmful constituents than combustible cigarettes. FDA's failure to evaluate all relevant factors amounts to arbitrary action. *See Michigan v. EPA*, 576 U.S. 743,752. The Fifth Circuit has faulted FDA for precisely this sort of practice when reviewing another PMTA application. *See Wages & White Lion Invs., LLC v. United States Food & Drug Admin.*, 16 F.4th 1130, 1135–40 (5th Cir. 2021).

Also problematic is FDA's departure from its common practices related to the withdrawal of marketed products. FDA has often refrained from abrupt, all-out product bans; instead, it typically grants transition periods for similarly disruptive

agency action even where—unlike here—a product poses a significant safety risk. *See, e.g.*, 73 Fed. Reg. 7565 (Feb. 2, 2008); 50 Fed. Reg. 27492 (July 3, 1985); 44 Fed. Reg. 45764, 45765 (Aug. 3, 1979) (granting a transition period of 125 days notwithstanding a "health risk posed by the continued use" of a new animal drug in light of the "economic disruption" that would be caused by "an immediate ban"). Indeed, in the only case where FDA has ever invoked its emergency power to suspend a drug's approval in light of "an imminent hazard to the public health," 21 U.S.C. § 355(d), the agency still allowed for a "90-day transition period" to avoid disruption, 44 Fed. Reg. at 45765 (discussing *In re: New Drug Applications for Phenformin, Order of the Secretary Suspending Approval*, at 59 (July 25, 1977)). FDA has provided no analysis, much less a "reasoned analysis," to depart from that common practice here. *Ramaprakash*, 346 F.3d at 1124. Quite the opposite. FDA admits it "has not received clinical information to suggest an immediate hazard associated with the use of the JUUL device or JUULpods." Ex. 3, at 1.

Absent an immediate administrative stay, JLI will also suffer significant irreparable harm. [redacted]

[redacted] *See Morgan Stanley DW Inc. v. Rothe*, 150 F. Supp. 2d 67, 77 (D.D.C. 2001). [redacted] *See Cigar Ass'n of Am. v. FDA*, 317 F. Supp. 3d 189, 195 (D.D.C. 2018); *see also Ala. Ass'n of Realtors v. HHS,* 141 S. Ct. 2485, 2489 (2021) (spending "with no guarantee of eventual recovery" is "irreparable harm").

[redacted]

Finally, the balance of the harms and the public interest also strongly favor an immediate administrative 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) (quoting *Nken*, 556

U.S. at 435). Here, those merged factors weigh decisively in favor of relief.

FDA cannot credibly argue that there is a critical and 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. FDA has taken almost two years—and almost four times the 180-day review period Congress specified, *see* 21 U.S.C. § 387j(c)(1)(A)—to review JLI's application and issue its marketing-denial order. Throughout that time, FDA exercised its enforcement discretion to allow JLI's products to remain on the market. *See* Ex. 6, Enforcement Priorities for Electronic Nicotine Delivery Systems / Guidance for Industry at 27; Ex. 7, Statement from Janet Woodcock, M.D. FDA's leisurely decision-making process and its own press release show that there is no urgent public-health emergency requiring the immediate removal of JLI's products. Moreover, "[t]here is generally no public interest in the perpetuation of unlawful agency action," *Shawnee Tribe*, 984 F.3d at 103, and that is even more true where it is causing chaos in the U.S. ENDS market.

JLI's forthcoming motion to stay will elaborate on these arguments. What matters for present purposes is that an interim administrative stay is warranted pending this Court's disposition of the forthcoming emergency motion to stay that JLI will file early next week.

For the foregoing reasons, JLI respectfully requests that the Court immediately enter an administrative stay of FDA's June 23, 2022 order until the Court resolves JLI's forthcoming emergency motion to stay.

Respectfully submitted,

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June 24, 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 2,237 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 24, 2022

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

**CERTIFICATE OF SERVICE**

I hereby certify that on June 24, 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 electronic and first-class mail on:

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