No. 22-1123

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

JUUL LABS, INC,

Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

ON PETITION FOR REVIEW OF A FINAL MARKETING DENIAL ORDER BYTHE UNITED STATES FOOD AND DRUG ADMINISTRATION

UNOPPOSED BRIEF OF DR. DAVID B. ABRAMS, Ph.D., SCOTT D. BALLIN, J.D., CLIVE D. BATES, M.Sc., PROFESSOR MARTIN J. JARVIS D.Sc., AND PROFESSOR DAVID T. SWEANOR, J.D. AS *AMICI CURIAE* IN SUPPORT OF PETITIONER'S EMERGENCY MOTION FOR STAY PENDING REVIEW

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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.

The proposed *amici* are independent health experts with extensive experience related to tobacco and public health policy who want to collectively share their views and perspectives regarding the electronic nicotine delivery systems industry as such pertains to the issues that are paramount in the present case. Every effort has been made to consolidate the views of these public health *amici* for this purpose.

At the present time, the proposed *amici* are aware that (i) thirty-eight national and state Electronic Nicotine Delivery System Product Advocacy Associations and (ii) the National Association of Convenience Stores, have filed motions for leave to file *amici* briefs in support of Petitioner. The proposed *amici* are also aware that the Vapor Technology Association, a national trade association, intends to file an *amicus* brief on behalf of its industry members.

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.

While no case has been filed either in this United States Court of Appeals or in other United States Court of Appeals having identical issues to those presented in this case, there are several cases that *amici* are familiar with having issues similar to this case. They are as follows:

Magellan Technology, Inc., v. U.S. Food and Drug Administration, No. 21-2426

Liquid Labs, LLC v. U.S. Food and Drug Administration, No. 21-2883

Avail Vapor, LLC v. U.S. Food and Drug Administration, No. 21-2077

Wages & White Lion Investments, LLC, DBA Triton Distribution v. U.S. Food and Drug Administration, No. 21-60766

Gripum v. U.S. Food and Drug Administration, No. 21-2840

My Vape Order v. U.S. Food and Drug Administration, No. 21-71302

Lotus Vaping Technology v. U.S. Food and Drug Administration, No. 21-71328

Bidi Vapor, LLC v. U.S. Food and Drug Administration, No. 21-13340

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. R. 26.1 and D.C. Circuit Rule 26.1, the undersigned counsel of record certifies that the following *Amici Curiae* are individual persons: Dr. David B. Abrams, Ph.D.; Scott D. Ballin, J.D.; Clive D. Bates, M.Sc.; Professor Martin J. Jarvis, D.Sc.; and Professor David T. Sweanor, J.D.

Accordingly, there are no parent corporations or any publicly held corporation which owns 10% or more of relevant corporate stock required to be disclosed pursuant to Federal and Local Rules.

Dated: July 5, 2022

/s/ Mary G. Bielaska
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INTEREST OF *AMICI CURIAE*

The *Amici Curiae*[1] are public health experts with extensive experience related to tobacco and public health policy.

Dr. David B. Abrams, Ph.D. is Professor, Department of Social and Behavioral Science at New York University School of Global Public Health; he has published over 300 peer-reviewed articles.

Scott D. Ballin, J.D. has spent more than forty years in tobacco and public health policy; he served as the American Heart Association's vice president and legislative counsel for ten years.

Clive D. Bates, M.Sc. is Director of Counterfactual, a consultancy focused on sustainability. He was previously Director of Action on Smoking and Health (UK).

Professor Martin J. Jarvis, D.Sc. is Emeritus Professor of Health Psychology at University College London and author of 200 peer-reviewed publications.

Professor David T. Sweanor, J.D. is Adjunct Professor of Law and Chair of the Advisory Board of the Centre for Health Law, Policy and Ethics at the University of Ottawa.

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[1] This brief is accompanied by a Motion for Leave as required by Federal Rule of Appellate Procedure 29(b). Pursuant to Fed. R. App. P. 29(a)(4)(E), *amici* certify that no counsel for a party authored this brief in whole or in part, and no person other than *amici* or their counsel made a monetary contribution intended to fund the preparation or submission of this brief. The parties have consented to its filing under Fed. R. App. P. 29(a)(2).

SUMMARY OF ARGUMENT

Amici are concerned that abrupt, disruptive and unjustified action taken by the Food and Drug Administration (FDA) will have unpredictable and negative consequences for the three million Americans who use JUUL vaping products.

On June 23, 2022, FDA issued marketing denial orders (MDOs) under the Tobacco Control Act[2] for all vaping products currently available in the United States made by Juul Labs Inc. (JLI).[3] As a result, the company and its retailers were ordered to stop selling JUUL products immediately.

Amici wish to make three points. First, without any specific finding to the contrary, there is no reasonable scientific doubt that using vaping products, including JUUL, is far safer than cigarette smoking. FDA's determination does not rest on any known hazard with the JUUL products but on what it describes in its press release as "*insufficient and conflicting data […] that precluded the FDA from completing a full toxicological risk assessment*". FDA also appears not to have drawn any conclusions from the extensive evidence it has received.

Second, the alleged deficiency in the evidence provided by JLI should have been the basis for further communication between FDA and the applicant over the many

[2] Family Smoking Prevention and Tobacco Control Act (codified at 21 U.S.C. §387j).
[3] Food and Drug Administration, Press Release, *FDA Denies Authorization to Market JUUL Products*, June 23, 2022. https://bit.ly/3HTqKgi.

months that the review has taken. It should not be a pretext for hostile communications and a reckless intervention to remove JLI products from the market.

Third, *amici* estimate that about three million Americans use JUUL products. Removing these products could have adverse public health effects on today's JUUL users if they are driven back to smoking or unregulated, illegal, or counterfeit vaping products. By disrupting the anti-smoking strategies of millions of Americans, FDA's action poses its own threat to public health.

Despite political concerns about a "youth vaping epidemic", FDA has not based its MDO on risks related to adolescent vaping. Youth vaping has fallen sharply since 2019, and the use of JUUL among youth is now low in absolute terms (0.6% of high school students) and low compared to other brands.[4] It is not considered further in this brief.

[4] Park-Lee, E, Ren C, Sawdey MD, *et al*., *Notes from the Field: E-Cigarette Use Among Middle and High School Students* — National Youth Tobacco Survey, United States, 2021. *MMWR* MORB. & MORTAL WKLY. REP. 70:1387-1389 (2021). https://bit.ly/3OyZfeo (High school past-30-day vaping peaked at 27.5% in 2019 but fell back to 11.3% in 2021. JUUL was used by 5.7% of high school e-cigarette users compared to 26.1% for Puff Bar.)

ARGUMENT

A. Cigarette Smoking Remains a Major Cause of Disease and Death in the United States and All Vaping is a Much Safer Alternative to Smoking.

1. Cigarettes Kill More Americans Than Illegal Drugs, Alcohol, Road Accidents, HIV, and Guns Combined.

According to the Centers for Disease Control and Prevention (CDC), smoking in the United States causes 480,000 premature deaths annually. Sixteen million Americans live with smoking-induced disease:[5]

> *Smoking causes cancer, heart disease, stroke, lung diseases, diabetes, and chronic obstructive pulmonary disease (COPD), which includes emphysema and chronic bronchitis. Smoking also increases risk for tuberculosis, certain eye diseases, and problems of the immune system, including rheumatoid arthritis.*

2. People Use Nicotine to Obtain a Range of Psychological Benefits, But This Also Makes Smoking Hard to Quit.

Nicotine is the active stimulant in tobacco and the main reason people smoke. For some, nicotine provides pleasure and functional benefits. According to Professor Neal Benowitz, a global authority on nicotine[6]:

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[5] Centers for Disease Control and Prevention, *Health Effects of Cigarette Smoking* (2020). https://bit.ly/3QO8jxr.

[6] Benowitz, NL. *Pharmacology of nicotine: addiction, smoking-induced disease, and therapeutics*. ANNU. REV. OF PHARMACOL. AND TOXICOL. (2009). https://bit.ly/3ONxrmn.

> *In humans, nicotine from tobacco induces stimulation and pleasure, and reduces stress and anxiety. Smokers come to use nicotine to modulate their level of arousal and for mood control in daily life. Smoking may improve concentration, reaction time, and performance of certain tasks.*

These "rewards" are the reason why people use nicotine. They also explain how smokers become dependent and, therefore, why many find quitting difficult.

3. Switching From Cigarettes to Smoke-Free Products is an Effective Way to Reduce Health Risks.

The former FDA Commissioner and former Director of the Center for Tobacco Products have provided an elegant basis for "tobacco harm reduction"[7]:

> *Nicotine, though not benign, is not directly responsible for the tobacco-caused cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year.*

CDC identifies over 7,000 chemicals in cigarette smoke, of which at least 250 are harmful to health.[8] The Surgeon General's 2010 report shows that harms associated with smoking are overwhelmingly attributable to the complex chemical mix that forms cigarette smoke, *but not to nicotine*.[9]

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[7] Gottlieb, S., & Zeller, M. *A nicotine-focused framework for Public Health*. NEW ENGLAND JOURNAL OF MED., 111-114 (2017). https://bit.ly/3y5NyVl.
[8] Centers for Disease Control and Prevention, *National Biomonitoring Program: Tobacco*. (2021). https://bit.ly/3bqDpep.
[9] U.S. Department of Health and Human Services *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease:*

Tobacco harm reduction helps people who cannot or do not wish to quit using nicotine by reducing the user's exposure to toxicants. The most effective way to achieve this is to switch to smoke-free nicotine products. It is an important public health strategy for reducing the risks to America's thirty-one million smokers.[10]

4. Vaping Products Eliminate Tobacco Combustion and Work as a Popular Alternative to Cigarettes.

Vaping products, including JUUL, do not involve combustion and therefore do not create the complex toxic mixtures found in tobacco smoke. They significantly reduce the harms associated with smoking by displacing cigarettes for people who continue to use nicotine.

Vaping products work by electrically heating a liquid to form a fine mist of liquid droplets (aerosol) that the user inhales. The liquid comprises a base, pharmaceutical-grade nicotine, and flavorings. Vaping products typically operate below 250°C, which compares to the burning tip of a cigarette at 800-900°C.

The simpler chemistry and lower temperatures involved mean there are no combustion products, and vaping aerosol is *inherently* less complex and toxic than tobacco smoke. One study comparing cigarette smoke and JUUL aerosol showed an

A Report of the Surgeon General (2010). https://bit.ly/3NpBUub.

[10] Centers for Disease Control and Prevention, *Current cigarette smoking in the United States*. (2020). https://bit.ly/3y0dlOX.

approximately 50-fold decrease in chemical complexity.[11] Many toxicological studies of vape aerosol and measurements of toxicants found in users' blood, saliva, or urine ("biomarkers of exposure") show greatly reduced risk.

5. Major Assessments Confirm Vaping is Much Safer Than Smoking.

This fundamental difference in the physics and chemistry, supported by extensive experimental data, explains why many authoritative assessments have concluded that vaping is likely much safer than smoking.

According to the United States National Academies of Sciences, Engineering, and Medicine (NASEM), in a report commissioned by FDA:[12]

> *Laboratory tests of e-cigarette ingredients, in vitro toxicological tests, and short-term human studies suggest that e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes.*

This is consistent with other major assessments,[13] including, for example, by the Royal College of Physicians (London):[14]

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[11] Crosswhite, MR. *et al., Non-Targeted Chemical Characterization of JUUL Virginia Tobacco Flavored Aerosols Using Liquid and Gas Chromatography*. Separations (2021) https://bit.ly/3ubNt1w.

[12] National Academies of Sciences, Engineering, and Medicine. *Public Health Consequences of E-Cigarettes*. Washington, DC (2018). https://bit.ly/3y0U9R0.

[13] Abrams, DB. *et al., Managing nicotine without smoke to save lives now: Evidence for harm minimization*. PREVENT. MED. (2018). https://bit.ly/3AftQJO.

[14] Royal College of Physicians. *Nicotine without smoke: tobacco harm reduction*. London (2016). https://bit.ly/3br3Alb.

> *the hazard to health arising from long-term vapour inhalation from the e-cigarettes available today is unlikely to exceed* ***5% of the harm from smoking tobacco****. (Original emphasis)*

In a 2021 review, fifteen past presidents of the Society for Research on Nicotine and Tobacco summarized the evidence suggesting that vaping is far safer than smoking. As one example, the authors refer to biomarkers of exposure:[15]

> *Biomarkers reflecting exposure to toxic substances are present at much higher levels in exclusive cigarette smokers than in exclusive vapers, and studies of smokers who switch to e-cigarettes find decreases in toxicant exposures.*

Specific research on the JUUL products confirms these generalized biomarker findings. Two studies showed switching from cigarettes to JUUL reduced multiple exposure biomarkers by almost as much (90-100%) as quitting altogether.[16],[17] It remains unclear why FDA has not relied more on such compelling biomarker data.

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[15] Balfour, D. *et al., Balancing Consideration of the Risks and Benefits of E-Cigarettes*. AM. J. OF PUBLIC HEALTH (2021). https://bit.ly/39RLc4J.

[16] Cohen, G. *et al., Changes in Biomarkers of Cigarette Smoke Exposure After 6 Days of Switching Exclusively or Partially to Use of the JUUL System with Two Nicotine Concentrations: A Randomized Controlled Confinement Study in Adult Smokers*. NICOTINE & TOB. RESEARCH (2021). https://bit.ly/3QS8k3u.

[17] Jay, J. *et al., Five-Day Changes in Biomarkers of Exposure Among Adult Smokers After Completely Switching from Combustible Cigarettes to a Nicotine-Salt Pod System*. NICOTINE & TOB. RESEARCH. (2020). https://bit.ly/3u9TNq5.

6. FDA Should Not Use Vague Uncertainties About Evidence to Pull Valuable Anti-Smoking Products from the Market.

Beyond reasonable scientific doubt, vaping products are far safer than smoking products. This insight should guide the regulatory practice of FDA. It means that FDA should be looking for concrete reasons to depart from this general assessment when it conducts its product-specific pre-market reviews.

It is conceivable that FDA could discover novel hazards during a product-specific review. But this is not the reason FDA has denied the JLI applications. In its June 23 press release, FDA stated that it has "*not received clinical information to suggest an immediate hazard associated with the use of the JUUL device or JUUL pods*". It has merely stated that it has insufficient data to complete its toxicology assessment.

The JLI products were removed from the market on a slender pretext without evidence of a hazard or a good faith attempt to resolve alleged deficiencies in the evidence JLI provided. Yet around 3,000 cigarette products remain available on the U.S. market.

B. FDA's Approach is Unreasonable and Disproportionate, and Its Decision-Making is Unaccountable.

1. FDA Does Not Find Any Material Risk with the JUUL Products.

There would be a case to abruptly remove anti-smoking products used by millions of people if there was imminent danger or a novel risk to health. But that is not the case

here. JLI's products have been on the market since 2015, and there is no sign of any material hazard to health, and FDA has not reported any.

2. FDA's Approach to JUUL Was Alarming.

FDA made high-profile public statements evoking concerns over genotoxicity and leaching, which on closer examination were not statements about health risks, but about the interpretation of evidence. FDA also encouraged JUUL users "*to report any unexpected health problems or product problems [..] and to seek medical attention as necessary*", even though it has no specific basis to recommend this to JUUL users any more than users of any other product, including and especially cigarettes.

3. Legitimate Doubts About Evidence Should Be Settled by Communication Between FDA and the Applicant.

FDA's requirements for evidence are quite opaque. However, the review process builds in the option for FDA to seek more clarity via deficiency letters or other engagement. This back and forth between applicant and agency is the proper way to address alleged deficiencies in evidence. It is, for example, evident in the Modified Risk Tobacco Product application made by Philip Morris International for its iQOS heated tobacco product. Thirty-four incremental amendments were made to the application over three years.[18]

[18] Food and Drug Administration, *Modified Risk Tobacco Product Application, Technical Project Lead Decision summary (IQOS System Holder and Charger)*, 14 (July 7, 2020). https://bit.ly/3I01kNP.

4. FDA's Conduct Raises Serious Concerns About Its Accountability.

In contrast, there was a gap of more than one year between JLI responding to FDA's first and only deficiency letter and FDA issuing its devastating MDO. The intervening year should have been used to address any concerns about evidence.

There are profound accountability problems with this manner of decision-making. A regulator that acts arbitrarily, capriciously, or vindictively can erect evidential hurdles invisible to the applicant or exaggerate doubts or ambiguities about evidence but then offer no practical way for the applicant to resolve or challenge such concerns.

C. The Reaction of Three Million JUUL Users to FDA's Disruptive Action is Unpredictable and May Be Detrimental to Health.

1. The Three Million Users of JUUL Are Mostly Current or Former Smokers.

Without a stay, the three million users of JUUL products will be unable to access these products lawfully.[19] Nearly all these users will be smokers or former smokers using JUUL as an alternative to smoking or to cut down their cigarette use. JLI's own comprehensive survey shows that over 90% of its customers reported a history of smoking.[20]

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[19] Three million users: adult population (258m), survey of adult vaping prevalence (4.7%), and the proportion of adult vapers who use JUUL products (~25%).

[20] Shiffman, S. *et al., The adult JUUL switching and smoking trajectories (ADJUSST) study: Methods and analysis of loss-to-follow-up*. AM. JOURNAL of HEALTH BEHAV. (2021). https://bit.ly/39UCuCK.

2. FDA's Disproportionate Action May Drive Vapers Back to Smoking or to Unregulated or Illicit Vaping Products.

The abrupt removal of JUUL products and FDA's alarming messaging are of considerable concern because the behavioral response is unpredictable. Some users may follow FDA's advice and switch to other vaping products that have been authorized. But others may switch to unregulated counterfeit JUUL products, illegal disposables, or move to the thousands of vaping products that FDA has not yet reviewed but remain on the market.

American adults already have severe misperceptions of the relative risks of vaping and smoking, with a majority (62%) incorrectly believing that vaping is as harmful or more harmful than smoking.[21] Following FDA's communications, it is likely that some JUUL users, and possibly other vapers, will conclude that vaping is prone to unexpected hazards and switch back to smoking on a "better the devil you know" principle.

Many foreseeable responses to FDA's action will *increase* risks to users.

CONCLUSION

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

Dated: July 5, 2022

Respectfully submitted,

/s/ Mary G. Bielaska
Mary G. Bielaska

[21] National Cancer Institute, HINTS survey (2020). https://bit.ly/39UEJ9b.

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume requirement setforth in Fed. R. App. P. 32(a)(7)(B) because, excluding the parts of the brief exempted by Fed. R. App. R. 32(f), this brief contains 2,592 words.
2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5)and the type-style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, size 14.

CERTIFICATE OF CONFERENCE

I hereby certify under Fed. R. App. P. 29(a)(2) that I contacted counsel for both the Petitioner and the Respondent on June 30, 2022 by electronic mail seeking consent to file the subject Brief of *Amici Curiae*, and again on July 1, 2022, seeking consent to file on July 5, 2022, and that counsel for both Petitioner and Respondent articulated their consent.

/s/ Mary G. Bielaska
Mary G. Bielaska

Counsel for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that on July 5, 2022, a true and correct copy of the foregoing **UNOPPOSED BRIEF OF DR. DAVID B. ABRAMS, Ph.D., SCOTT D. BALLIN, J.D., CLIVE D. BATES, M.Sc., PROFESSOR MARTIN J. JARVIS, D.Sc., AND PROFESSOR DAVID T. SWEANOR, J.D., AS *AMICI CURIAE* IN SUPPORT OF PETITIONER'S EMERGENCY MOTION FOR STAY PENDING REVIEW** was filed with the Clerk's Office for the United States Court of Appeals for the District of Columbia Circuit using the CM/ECF system and was served by electronic mail upon the following persons:

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