

No. 22-3030

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**In the United States Court of  
Appeals for the Third Circuit**

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LOGIC TECHNOLOGY DEVELOPMENT, LLC,

*Petitioner,*

v.

UNITED STATES FOOD AND DRUG  
ADMINISTRATION,

*Respondent.*

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

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**AMICUS BRIEF OF MEDICAL, PUBLIC HEALTH, CIVIL  
RIGHTS, AND COMMUNITY GROUPS OPPOSING  
PETITIONER'S THIRD MOTION TO SEAL**

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## **CORPORATE DISCLOSURE STATEMENT AND STATEMENT OF FINANCIAL INTEREST**

Pursuant to Fed. R. App. P. 26.1(a) and Third Circuit LAR 26.1, *amici curiae* make the following disclosure:

- 1) For non-governmental corporate parties please list all parent corporations:

**None/not applicable.**

- 2) For non-governmental corporate parties please list all publicly held companies that hold 10% or more of the party's stock:

**None/not applicable.**

- 3) If there is a publicly held corporation which is not a party to the proceeding before this Court, but which has a financial interest in the outcome of the proceeding, please identify all such parties and specify the nature of the financial interest or interests:

**None/not applicable.**

- 4) In all bankruptcy appeals counsel for the debtor or trustee of the bankruptcy estate must list: 1) the debtor, if not identified in the case caption; 2) the members of the creditors' committee or the top 20 unsecured creditors; and 3) any entity not named in the caption which is an active participant in the bankruptcy proceeding. If the debtor or

trustee is not participating in the appeal this information must be provided by appellant.

**None/not applicable.**

Dated: January 17, 2023

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

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### CASES

<i>Am. Academy of Pediatrics v. FDA</i> , 399 F. Supp. 3d 479 (D. Md. 2019), <i>appeal dismissed sub nom</i> , <i>In re Cigar Assoc. of America</i> , 812 Fed. Appx. 128 (4th Cir. 2020).....	2
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**GLOSSARY**

FDA.....Food and Drug Administration

MDO .....Marketing Denial Order

Action on Smoking and Health, African American Tobacco Control Leadership Council, American Academy of Family Physicians, American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, Parents Against Vaping e-cigarettes (PAVe), Pennsylvania Medical Society, and Truth Initiative (the “medical, public health, civil rights, and community groups”) submit this *amicus* brief urging the Court to deny Petitioner’s Third Motion to Seal, ECF No. 38 (Jan. 5, 2023), which seeks to seal its Opening Brief and Joint Appendix,<sup>1</sup> because large portions of the redacted material and material Petitioner seeks to maintain under seal are not trade secret or confidential business information. Without access to an unredacted and unsealed brief and Joint Appendix, the public will not be sufficiently informed about the basis for the U.S. Food and Drug Administration’s (FDA’s) action denying marketing authorization for Petitioner’s menthol products or the issues raised by the pending Petition, nor will the medical, public health, civil rights, and community organizations be in the position to file an *amicus* brief on the merits of the Petition filed by Logic Technology Development LLC (Logic).

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<sup>1</sup> Petitioner filed Volumes IV through VII of the Joint Appendix under seal and heavily redacted Volumes I through III of the Joint Appendix.

## STATEMENT OF INTEREST OF *AMICI CURIAE*<sup>2</sup>

*Amici* are medical, public health, civil rights, and community groups that work daily to reduce the devastating health harms of tobacco products, including menthol, and other electronic nicotine delivery system (e-cigarette) products. *Amici* also have a special interest in this case because many were plaintiffs in *American Academy of Pediatrics v. FDA*, in which plaintiffs obtained a federal court order (1) establishing new deadlines for the required submission of premarket tobacco product applications (PMTAs) for e-cigarette products, and (2) limiting the time-period that e-cigarettes may remain on the market without the required premarket orders. *Am. Academy of Pediatrics*, 399 F. Supp. 3d 479 (D. Md. 2019), *appeal dismissed sub nom, In re Cigar Assoc. of America*, 812 Fed. Appx. 128 (4th Cir. 2020).

Many of the medical, public health, civil rights, and community groups have filed *amicus* briefs in numerous other cases challenging FDA's decisions to deny marketing authorization to flavored e-cigarette products,<sup>3</sup> and thus are particularly

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<sup>2</sup> Pursuant to Fed. R. App. P. 29(a)(4)(E), *amici* affirm that no party's counsel authored this brief in whole or in part, neither the parties nor their counsel contributed money that was intended to fund preparing or submitting this brief, and no person—other than *amici*, their members, or their counsel—contributed money that was intended to fund preparing or submitting the brief.

<sup>3</sup> To date, by leave of court and/or consent of the parties, many of the *amici* have filed *amicus curiae* briefs in the following marketing denial order appeals: *Prohibition Juice Co. v. FDA*, No. 21-1201 (D.C Cir.) (consolidated with Nos. 21-1203, 21-1205, 21-1207); *Magellan Tech., Inc v. FDA*, No. 21-2426 (2d Cir.); *Liquid Labs, LLC v. FDA*, No. 21-2883 (3d Cir); *Avail Vapor, LLC v. FDA*, No. 21-2077 (4th Cir.); *Wages & White Lion Invs., L.L.C. v. FDA*, No. 21-60766 (5th Cir.); *Breeze*



well suited to inform the Court as to why the Motion to Seal is overly broad under the standards governing public access to judicial records and proceedings.

### ARGUMENT

This is not the first time that Logic has moved this Court to seal its filings. On November 4, 2022, the company filed a Motion to Permanently Seal its Motion for Stay Pending Appeal and supporting declarations. Pet’r’s Motion to Seal, ECF No. 7. On November 7, 2022, this Court temporarily sealed the documents until the Court had an opportunity to rule on the Motion to Seal. It also provisionally ordered Petitioner to file public redacted versions of those filings, which the Court said, “must redact as little information as the petitioner believes possible.” Order, ECF No. 11 (Nov. 7, 2022). The Court further provided that “[i]f the motion to seal is granted and the Court finds the public versions over-redacted, it may order new public versions with fewer redactions.” *Id.*

Petitioner filed public redacted versions of those submissions and, on November 14, 2022, one of the *amici* on this brief, the Campaign for Tobacco-Free Kids (Tobacco-Free Kids), filed an *amicus* brief opposing Logic’s Motion to

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*Smoke, LLC v. FDA*, No. 21-3902 (6th Cir.); *Gripum LLC v. FDA*, No. 21-2840 (7th Cir.); *7 Daze, LLC v. FDA*, No. 21-71319 (9th Cir.); *Lotus Vaping Techs., LLC v. FDA*, No. 21-71328 (9th Cir.); *MH Global LLC v. FDA*, No. 21-71327 (9th Cir.); *Nude Nicotine Inc. v. FDA*, No. 21-71321 (9th Cir.); *Bidi Vapor LLC v. FDA*, No. 21-13340 (11th Cir.); *Diamond Vapor LLC et al. v. FDA*, Nos. 21-13387, 21-13438, 21-13454 (11th Cir.).

Permanently Seal its Motion to Stay Pending Appeal. ECF No. 25. The Court thereafter found that Logic's public version of the Declaration of Bryan M. Haynes and attached exhibits were still "over-redacted" and required Logic to make "a public redacted filing, redacting as little information as possible and not re-sealing the document in its entirety by December 20, 2022." Order, ECF No. 35 (Dec. 15, 2022). On November 17, 2022, Logic also filed a motion to seal its Reply in Support of Its Motion to Stay and simultaneously filed a public redacted version of its Reply that it claims "redact[s] as little information as the petitioner believes possible." ECF No. 29 at 2 (quoting ECF No. 11). Petitioner has not even attempted to file a redacted version of its Opening Brief or Volumes IV through VII of the Joint Appendix.

Rather than repeat the arguments made in the Tobacco-Free Kids' earlier opposition brief, *amici* incorporate all of the arguments made in that brief. *See* ECF No. 25. Twice already, the Court has ordered Petitioner to unseal or un-redact its filings. Order, ECF No. 11 (Nov. 7, 2022); Order, ECF No. 35 (Dec. 15, 2022). Yet, once again, Petitioner has filed an entire brief and extensive portions of the record under seal, and heavily redacted other portions of the record. For the reasons below and the reasons presented in the Tobacco-Free Kids' earlier opposition brief, the Court should, once again, order Petitioner to unseal or un-redact its filings.

Despite the public health impact of Petitioner's products, discussed at length in the Brief of *Amici Curiae* Medical, Public Health, Civil Rights and Community Groups in Support of Respondent's Opposition to Petitioner's Motion for a Stay, ECF 26-1 (Nov. 15, 2022), because Petitioner seeks to file its Opening Brief and the Joint Appendix under seal, FDA's rationale for denying authorization is unavailable to the public, as is the basis for Petitioner's attacks on FDA's decision. Given the enormous public health impact of Petitioner's e-cigarettes, FDA's decision-making is undoubtedly of major public importance, as is Petitioner's attack on the FDA's marketing denial order (MDO). Petitioner, for example, seeks to seal FDA's toxicology review of Petitioner's products. JA2948-3009; JA3114-3136. Even among the portions of the Joint Appendix that Petitioner did not file completely under seal, Petitioner has redacted FDA's evaluation of Logic's clinical studies (JA927-934; JA949-950), most of Petitioner's proposed marketing restrictions (JA941), FDA's determination on the short- and long-term health effects of Petitioner's products (JA959-962), FDA's analysis of the toxicity of Petitioner's products (JA954-955; JA958), and much of the "Adverse Experiences" section of FDA's review (JA961-962). These documents are critical for the public and *amici* to be able to understand the full risks of Petitioner's products and for *amici* to provide

the Court with their perspectives on the relevant public health issues through the filing of an *amicus* brief, as many of them have done in thirteen other MDO appeals.<sup>4</sup>

### CONCLUSION

The Court should deny Petitioner's Third Motion to Seal, which seeks to seal the company's Opening Brief and the Joint Appendix, except for the specific portions that are trade secret or confidential business information, and that Petitioner has demonstrated will cause it harm if disclosed.

Respectfully submitted,

/s/ William B. Schultz

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<sup>4</sup> See *supra* note 3.

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**CERTIFICATE OF BAR MEMBERSHIP**

Pursuant to Local R. 28.3(d) and Local R. 46.1(e), I certify that I, William B. Schultz, am admitted as an attorney and counselor of the United States Court of Appeals for the Third Circuit.

Dated: January 17, 2023

/s/ William B. Schultz  
William B. Schultz

### **CERTIFICATE OF COMPLIANCE**

This motion complies with the type-volume limitations of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) and the rules of this Court, because it contains 1,322 words, excluding the parts of the motion exempted by Federal Rule of Appellate Procedure 32(f).

This motion complies with the typeface requirements of Federal Rule Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this motion has been prepared in a proportionally spaced typeface using Microsoft Word with 14-point Times New Roman font.

*/s/ William B. Schultz*

William B. Schultz

**CERTIFICATE OF SERVICE**

I hereby certify that on January 17, 2023, a true and correct copy of the foregoing was filed electronically with the Clerk of the U.S. Court of Appeals for the Third Circuit and served on counsel via the CM/ECF system.

*/s/ William B. Schultz* \_\_\_\_\_  
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