No. 22-3030

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

LOGIC TECHNOLOGY DEVELOPMENT LLC,

Petitioner,

v.

U.S. FOOD & DRUG ADMINISTRATION,

Respondent.

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

MOTION OF MEDICAL, PUBLIC HEALTH, CIVIL RIGHTS, AND COMMUNITY GROUPS FOR LEAVE TO FILE AMICUS BRIEF IN SUPPORT OF RESPONDENT'S OPPOSITION TO PETITIONER'S MOTION FOR A STAY

William B. Schultz
Margaret M. Dotzel
Andrew N. Goldfarb
ZUCKERMAN SPAEDER LLP
1800 M. Street NW, Suite 1000
Washington, DC 20036-5807
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
agoldfarb@zuckerman.com

Attorneys for Amici Curiae

Of Counsel:
Dennis A. Henigan
Connor Fuchs
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 Eye Street, NW, Suite 1200
Washington, DC. 2005
Tel: (202) 296-5469
Fax: (202) 296-5427
dhenigan@tobaccofreekids.org
cfuchs@tobaccofreekids.org

Pursuant to Rule 29(a)(2) of the Federal Rules of Appellate Procedure and L.A.R. 29.1(a), proposed *amici* 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, American Medical Association, Campaign for Tobacco-Free Kids, National Medical Association, Parents Against Vaping e-cigarettes (PAVe), Pennsylvania Medical Society, and Truth Initiative (the "medical, public health, civil rights, and community groups") move for leave to file a brief urging the Court to deny the Motion for a Stay filed by Petitioner Logic Technology Development LLC. Petitioner takes no position on the motion; Respondent consents to the participation of the medical, public health, civil rights, and community groups as *amici*. The proposed brief is attached.

Each of the medical, public health, civil rights, and community groups works daily to reduce the devastating health harms of tobacco products, including menthol and other electronic nicotine delivery system ("ENDS" or "e-cigarette") products. Consistent with those efforts, they have an acute interest in whether Petitioner is allowed to continue to sell its menthol products while its appeal of the marketing denial orders ("MDO") issued by the Food and Drug Administration ("FDA") proceeds.

In addition, the medical, public health, civil rights, and community groups are particularly well suited to inform the Court of the substantial public health harm from the continued availability of Petitioner's menthol e-cigarettes that would result from the requested stay. Many of these groups have participated actively, in a similar capacity, as *amici* in several Courts of Appeals, including this Circuit, in proceedings by other e-cigarette manufacturers challenging MDOs issued by FDA. *E.g.*, Br. of *Amici Curiae* Medical and Pub. Health Grps. in Supp. of Resp., *Liquid Labs LLC v. FDA*, No. 21-2883 (3d. Cir.) (filed Mar. 23, 2022).

Accordingly, the medical, public health, civil rights, and community groups respectfully ask the Court to grant the instant motion and allow them to participate as *amici* through the attached brief.

Dated: November 15, 2022

Respectfully submitted,

/s/ William B. Schultz

William B. Schultz
Margaret M. Dotzel
Andrew N. Goldfarb
ZUCKERMAN SPAEDER LLP
1800 M. Street NW, Suite 1000
Washington, DC 20036-5807
Tel: (202) 778-1800
Fax: (202) 822-8106
Email: wschultz@zuckerman.com
Email: mdotzel@zuckerman.com
Email: agoldfarb@zuckerman.com

Dennis A. Henigan (Of Counsel)
Connor Fuchs (Of Counsel)
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 I St. NW, Suite 1200
Washington, DC 20005
Tel: (202) 481-9366
Fax: (202) 296-5427
Email: dhenigan@tobaccofreekids.org
Email: cfuchs@tobaccofreekids.org

Attorneys for Proposed Amici Curiae

CERTIFICATE OF ADMISSION TO THE BAR

I certify that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit. *See* 3d Cir. R. 28.3(d) & 46.1(e).

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

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

CERTIFICATE OF SERVICE

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/s/ William B. Schultz
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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

William B. Schultz
Margaret M. Dotzel
Andrew N. Goldfarb
ZUCKERMAN SPAEDER LLP
1800 M. Street NW, Suite 1000
Washington, DC 20036-5807
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
agoldfarb@zuckerman.com

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Dennis A. Henigan
Connor Fuchs
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 Eye Street, NW, Suite 1200
Washington, DC. 2005
Tel: (202) 296-5469
Fax: (202) 296-5427
dhenigan@tobaccofreekids.org
cfuchs@tobaccofreekids.org

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* 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, American Medical Association, Campaign for Tobacco-Free Kids, National Medical Association, Parents Against Vaping e-cigarettes (PAVe), Pennsylvania Medical Society, and Truth Initiative ("medical, public health, civil rights, and community groups") 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: November 15, 2022

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

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Cases

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Other Authorities

Amici medical, public health, civil rights, and community organizations submit this brief urging the Court to deny the Motion for a Stay filed by Petitioner Logic Technology Development LLC because a stay would be contrary to the public interest, given the (1) substantial risk of youth usage of Petitioner's menthol-flavored e-cigarette cartridges and (2) insufficient evidence of any potential benefit of those products in helping smokers to stop smoking that would outweigh the demonstrated risk to youth. The U.S. Supreme Court has previously denied an emergency stay of a marketing denial order ("MDO") for flavored e-cigarettes, *Breeze Smoke, LLC v. FDA*, 142 S. Ct. 638 (2021), and this Court has upheld, on the merits, an MDO for flavored e-cigarettes. *Liquid Labs LLC v. FDA*, -- F.4th --, 2022 WL 15090594 (3d Cir. Oct. 27, 2022).

STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici are the following national and state medical, public health, civil rights, and community organizations: 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, American

[1] 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.

Medical Association, Campaign for Tobacco-Free Kids, National Medical Association, Parents Against Vaping e-cigarettes (PAVe), Pennsylvania Medical Society, and Truth Initiative. Each group works daily to reduce the devastating health harms of tobacco products, including menthol and other electronic nicotine delivery system ("ENDS" or "e-cigarette") products, and thus are particularly well suited to inform the Court of the substantial public health harm from the continued availability of Petitioner's menthol e-cigarettes that would result from the requested stay.

INTRODUCTION

E-cigarettes are the most popular tobacco products among youth, with more than 2.5 million young people reporting current e-cigarette use in 2022.[2] The tobacco industry has long understood that almost all new tobacco users begin their addiction before the age of 18[3] and that flavored products, including menthol products, are essential to successfully market their products to young people.[4] Here,

[2] Maria Cooper et al., *Notes from the Field: E-Cigarette Use Among Middle and High School Students –United States, 2022*, 71 MORBIDITY & MORTALITY WKLY. REP. 1283, 1283-84 (2022), https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7140a3-H.pdf.

[3] OFFICE OF THE SURGEON GENERAL ("OSG"), U.S. DEP'T OF HEALTH & HUMAN SERVICES ("HHS"), PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS 508 (2012), https://www.ncbi.nlm.nih.gov/books/NBK99237/pdf/Bookshelf_NBK99237.pdf.

[4] *Id.* at 535-539.

the products at issue are menthol-flavored e-cigarette cartridges. Pet. for Review, Doc. No. 1-1, Ex. A ("MDO") at 4 (Oct. 27, 2022). In 2022, almost 85% of youth e-cigarette users used a flavored product, and among them, 26.6% used a menthol product.[5] Among youth users of flavored e-cigarette cartridges, like Petitioner's products, over half (53.9%) reported using a menthol product in 2022.[6] Flavored cartridge-based e-cigarettes were the products that ignited an epidemic of youth vaping,[7] and remain popular with young people today.[8]

The risk of youth initiation and use posed by menthol e-cigarettes, particularly cartridges, is well documented, but there is little evidence that these products have any role in helping cigarette smokers to stop smoking. Accordingly, allowing Petitioner's menthol cartridges to remain on the market while the Court considers the Petition poses a significant risk to youth with no countervailing public health benefit. Therefore, the stay sought by Petitioner is entirely contrary to the public

[5] Cooper et al., *supra* note 2, at 1283.

[6] *Id.*

[7] FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)* (Apr. 2020), https://www.fda.gov/media/133880/download ("FDA Enforcement Priorities").

[8] Cooper et al., *supra* note 2, at 1284 tbl. (cartridges were the second most common e-cigarette device type used by youth in 2022).

interest, a key factor in the Court's consideration of a stay motion. *See Nken v. Holder*, 556 U.S. 418, 426 (2009).

ARGUMENT

I. A Stay Is Contrary to the Public Interest Because There Is a Substantial Risk of Youth Usage of Petitioner's Products.

A. Youth use of e-cigarettes, particularly flavored products including menthol, is an on-going public health crisis.

E-cigarettes have been the most commonly used tobacco product among youth since 2014.[9] According to the National Youth Tobacco Survey ("NYTS"), in 2022, over 2.5 million youth, including 14.1% of high schoolers, reported current e-cigarette use.[10] Young people are not just experimenting with e-cigarettes—they are using them frequently. In 2022, 46% of high school e-cigarette users reported using them on at least 20 of the preceding 30 days.[11] Even more alarming, 30.1% of high school e-cigarette users reported *daily* use, a strong indication of nicotine addiction.[12] Roughly 700,000 middle and high school students are vaping on a daily basis.[13]

[9] Cooper et al., *supra* note 2, at 1283.

[10] *Id.* at 1283, 1285.

[11] *Id.* at 1284 tbl.

[12] *Id.*

[13] *Id.*

Flavored products, including menthol, are especially appealing to youth and are largely driving the alarming rates of youth e-cigarette use. According to a 2020 Surgeon General Report, "the role of flavors in promoting initiation of tobacco product use among youth is well established . . . and appealing flavor is cited by youth as one of the main reasons for using e-cigarettes."[14] Data from the 2022 NYTS show that 84.9% of middle and high school e-cigarette users had used a flavored product in the past month.[15]

Petitioner's cartridges contain nicotine, MDO at 4, a highly addictive substance that can have lasting damaging effects on adolescent brain development.[16] According to the Surgeon General, "Nicotine exposure during adolescence can impact learning, memory and attention," and "can also increase risk for future addiction to other drugs."[17] The Surgeon General has warned that "[t]he use of products containing nicotine in any form among youth, including in e-cigarettes, is

[14] OSG, HHS, SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL 611 (2020), https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf ("OSG Smoking Cessation").

[15] Cooper et al., *supra* note 2, at 1283.

[16] OSG, HHS, SURGEON GENERAL'S ADVISORY ON E-CIGARETTE USE AMONG YOUTH 1 (2018), https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf ("OSG Advisory").

[17] *Id.*

unsafe."[18] In upholding an MDO for flavored e-cigarettes, the U.S. Court of Appeals for the D.C. Circuit succinctly summarized the evidence on flavors, nicotine, and youth: "A vast body of scientific evidence shows that flavors encourage youth to try e-cigarettes, and together with the nicotine, keep them coming back." *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 11 (D.C. Cir. 2022).

Petitioner's cartridges also contain menthol, MDO at 4, which FDA has found can enhance the addictive effects of nicotine in the brain, including in young people.[19] In its proposed rule to prohibit menthol as a characterizing flavor in cigarettes, FDA concluded that the combination of menthol and nicotine increases youth initiation, increases youth progression to regular cigarette smoking, and increases the intensity of addiction among both youth and adults, making it harder to stop.[20] Although the evidence FDA discussed in the proposed rule was largely drawn from experience with cigarette smokers, there is no scientific basis to suggest that menthol does not similarly enhance the addictiveness of the nicotine in e-cigarettes.

Finally, use of e-cigarettes may function as a gateway to the use of

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[18] OSG, HHS, E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS, A REPORT OF THE SURGEON GENERAL 5 (2016), https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf.

[19] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, 26,464 (proposed May 4, 2022).

[20] *Id.*

conventional cigarettes and other combustible tobacco products, thereby undermining decades of progress in curbing youth smoking. A 2018 report by the National Academies of Sciences, Engineering, and Medicine ("NASEM") found "substantial evidence that e-cigarette use increases [the] risk of ever using combustible tobacco cigarettes among youth and young adults."[21] Additionally, a nationally representative analysis found that from 2013 to 2016, youth e-cigarette use was associated with more than four times the odds of trying combustible cigarettes and nearly three times the odds of current combustible cigarette use.[22]

B. There is a significant risk of youth usage of Petitioner's menthol cartridges.

Petitioner's products have two features that make them particularly appealing to youth. First, they are mentholated. Second, they are cartridges, the type of e-cigarette most responsible for igniting the youth vaping epidemic.

There is overwhelming evidence that menthol e-cigarettes are highly appealing to youth, and that youth will gravitate to these products if they are left on the market. *See* MDO at 2 ("There is substantial evidence that the use of menthol

[21] NASEM, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 10 (2018), https://nap.nationalacademies.org/catalog/24952/public-health-consequences-of-e-cigarettes.

[22] Kaitlin M. Berry et al., *Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in US Youths*, 2 JAMA NETWORK OPEN 1, 7 (2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425.

flavors in tobacco products, like the menthol flavors in the new products, has significant appeal to youth and is associated with youth initiation of such products."). When FDA restricted the sale of cartridge-based e-cigarettes in flavors other than menthol and tobacco in February 2020,[23] youth shifted to using menthol e-cigarettes.[24] In 2020, over one million high school and middle school youth used menthol e-cigarettes.[25] High levels of youth menthol e-cigarette use persist today. In 2022, 26.6% of all youth flavored e-cigarette users reported using a menthol product.[26] The rates are even higher among youth users of flavored cartridge-based products, like Petitioner's, with 53.9% reporting use of a menthol product.[27] In total, over half a million middle and high schoolers reported current use of a menthol e-cigarette in 2022.[28]

Petitioner's products are not only mentholated, they are the cartridge-based products that drove youth e-cigarette use rates to historically high levels and led FDA, in 2020, to revise its enforcement priorities to attach the highest priority to

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[23] FDA Enforcement Priorities, *supra* note 7, at 18.

[24] See Teresa W. Wang et al., *Characteristics of e-Cigarette Use Behaviors Among US Youth, 2020*, 4 JAMA NETWORK OPEN 1, 9 (published online June 7, 2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780705.

[25] *Id.* at 7 tbl.3.

[26] Cooper et al., *supra* note 2, at 1283.

[27] *Id.*

[28] *Id.* at 1284 tbl.

enforcement against cartridge-based e-cigarettes in flavors other than tobacco or menthol.[29] In 2019, before FDA's revised enforcement policy took effect, 27.5% of high school students reported current e-cigarette use, with most youth e-cigarette users reporting a cartridge-based product, such as Juul, as their usual brand.[30] FDA found that the "design features" of cartridge-based e-cigarettes contribute to their youth appeal.[31] Petitioner's devices, with which its menthol cartridges are designed to be used, are roughly the size of an ink pen,[32] which "allows for easy concealability" and "may allow youth to use the product in circumstances where use of tobacco products is prohibited, such as a school."[33]

The risk that youth will use Petitioner's products is not just theoretical. Contrary to Petitioner's assertion that its "menthol-flavored products are not frequently used by youth," Mot. for Stay at 15, roughly 100,000 middle and high schoolers (or 4.3% of current youth e-cigarette users) reported using a Logic product

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[29] FDA Enforcement Priorities, *supra* note 7.

[30] Karen A. Cullen et al., *e-Cigarette Use Among Youth in the United States, 2019*, 322 J. AM. MED. ASS'N 2095, 2097-2098 (2019), https://jamanetwork.com/journals/jama/fullarticle/2755265.

[31] FDA Enforcement Priorities, *supra* note 7, at 16.

[32] Petitioner's Logic Power device measures 9.2 mm in diameter and 82.6 mm in length (0.36 x 3.25 inches); its Logic Pro device measures 14.1 mm in diameter and 78.2 mm in length (0.56 x 3.08 inches). *See* FDA, Marketing Granted Orders for certain Logic Technology Development LLC products at 6 (Mar. 24, 2022), https://www.fda.gov/media/158752/download.

[33] FDA Enforcement Priorities, *supra* note 7, at 16.

in the past month in 2022.[34] Every day that Petitioner's menthol cartridges remain on the market, they contribute to the risk of nicotine addiction and other health harms to young people. Allowing these products to remain on the market while the Court considers the Petition is decidedly not in the public interest.

II. A Stay Is Contrary to the Public Interest Because Any Potential Benefit of Petitioner's Products in Helping Smokers Stop Smoking Is Outweighed by the Known Risk of Menthol E-Cigarettes to Youth.

Given the overwhelming evidence that menthol e-cigarette cartridges attract young people, it is entirely reasonable for FDA to require "robust and reliable evidence" demonstrating that, in comparison to unflavored (i.e., tobacco-flavored) products, Petitioner's menthol cartridges benefit smokers by helping them to stop smoking cigarettes and to issue an MDO for failure to furnish such evidence. MDO at 2.

The publicly available evidence does not convincingly show that e-cigarettes help smokers stop smoking—and the evidence is just as unclear that flavors, including menthol, play a beneficial role for people who currently smoke. Studies of adult smokers have found that while many adult e-cigarette users use flavored e-cigarettes, there is still limited evidence to suggest that flavored e-cigarette use is associated with successfully stopping smoking cigarettes.[35] The leading public

[34] Cooper et al., *supra* note 2, at 1284 tbl.

[35] *E.g.*, Lin Li et al., *How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking? Findings From the 2016 and 2018 ITC*

health authorities in the U.S., including the Surgeon General, the U.S. Preventive Services Task Force ("USPSTF"), the CDC, and NASEM, have all concluded that there is insufficient evidence to recommend any e-cigarettes for smoking cessation.[36] In a 2020 report, the Surgeon General stated that "there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation."[37]

Indeed, the evidence that *menthol* e-cigarettes are more effective than tobacco-flavored e-cigarettes at helping people who smoke cigarettes to stop smoking is similarly unpersuasive. As FDA observed, "the published literature on the role of menthol-flavored ENDS and smoking cessation or reduction is limited and does not demonstrate that menthol-flavored ENDS are more effective in promoting complete switching or significant cigarette reduction relative to tobacco-flavored ENDS." MDO at 2. Thus, it was entirely reasonable for FDA to require

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4CV, 23 NICOTINE & TOBACCO RESEARCH 1490 (2021), https://pubmed.ncbi.nlm.nih.gov/33631007/; Samane Zare et al., *A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type*, 13 PLoS ONE 1, 12 (2018), https://pubmed.ncbi.nlm.nih.gov/29543907/.

[36] OSG Smoking Cessation, *supra* note 14; USPSTF, *Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: USPSTF Recommendation Statement*, 325 J. AM. MED. ASS'N 265 (2021), https://jamanetwork.com/journals/jama/fullarticle/2775287; CDC, *Adult Smoking Cessation – The Use of E-Cigarettes*, https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html (Jan. 23, 2020); NASEM, *supra* note 21, at 10.

[37] OSG Smoking Cessation, *supra* note 14, at 7.

Petitioner to provide evidence that its menthol products "are more likely to promote complete switching or significant cigarette reduction compared to tobacco-flavored products," and to deny authorization for failure to provide such evidence. *Id.*

CONCLUSION

For these reasons, and those presented by the government, *amici* urge the Court to deny Petitioner's Motion for a Stay.

Dated: November 15, 2022

Respectfully submitted,

/s/ William B. Schultz

William B. Schultz
Margaret M. Dotzel
Andrew N. Goldfarb
ZUCKERMAN SPAEDER LLP
1800 M. Street NW, Suite 1000
Washington, DC 20036-5807
Tel: (202) 778-1800
Fax: (202) 822-8106
Email: wschultz@zuckerman.com
Email: mdotzel@zuckerman.com
Email: agoldfarb@zuckerman.com

Dennis A. Henigan (Of Counsel)
Connor Fuchs (Of Counsel)
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 I St. NW, Suite 1200
Washington, DC 20005
Tel: (202) 481-9366
Fax: (202) 296-5427
Email: dhenigan@tobaccofreekids.org
Email: cfuchs@tobaccofreekids.org

Attorneys for *Amici Curiae*

CERTIFICATE OF ADMISSION TO THE BAR

I certify that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit. *See* 3d Cir. R. 28.3(d) & 46.1(e).

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

CERTIFICATE OF SERVICE

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