

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF ALBANY

In the Matter of

VAPOR TECHNOLOGY ASSOCIATION,
BENEVOLENT ELIQUIDS INC., and PERFECTION
VAPES, INC.,

Petitioners,

- against -

ANDREW M. CUOMO, Governor of the State of New
York, NEW YORK STATE DEPARTMENT OF
HEALTH, HOWARD ZUCKER, M.D., Commissioner of
New York State Department of Health, THE PUBLIC
HEALTH AND HEALTH PLANNING COUNCIL, and
NEW YORK STATE POLICE,

Respondents.

Index No.: 906514-19

**BRIEF OF AMICI CURIAE IN OPPOSITION TO THE MOTION
FOR A PRELIMINARY INJUNCTION**

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Introduction and Statement of Interest of Amici Curiae

Amici curiae are filing this brief in opposition to the petitioners' motion for a preliminary injunction against Respondent State of New York's Prohibition on the Sale of Electronic Liquids with Characterizing Flavors ("Emergency Rule"). The amici are the following public health, medical and community organizations: American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, Healthy Capital District Initiative, March of Dimes, Medical Society of the State of New York, NAACP New York State Conference, New York School-Based Health Alliance, New York State Academy of Family Physicians, New York State American Academy of Pediatrics, New York State Association of County Health Officials, New York State Association for Health, Physical Education, Recreation, and Dance, New York State Association for Rural Health, New York State Osteopathic Medical Society, New York State Public Health Association, New York State Society of Anesthesiologists, New York State PTA, PAVe, (Parents Against Vaping e-cigarettes), St. Joseph's Health, St. Peter's Health Partners, The Children's Agenda, Trinity Health, and Truth Initiative. A description of each organization is provided in Appendix A to this brief.

By this filing, amici seek to demonstrate that the balance of equities weighs heavily against a preliminary injunction. This is because an injunction would deprive residents of the state, and particularly its young people, of the demonstrable public health benefits of the Emergency Rule prohibiting the sale of flavored e-cigarettes.¹

As organizations working every day in communities in New York State and around the nation to reduce the death and disease caused by tobacco products, the amici have a strong interest

¹ This brief uses the term "e-cigarette" to include e-cigarettes, electronic cigarettes, electronic liquids, and e-liquids as those terms are defined in Subpart 9-2 of Section 225 of the Public Health Law.

in the implementation of tobacco control policies that will prevent the initiation of tobacco use by young people and save lives. Reducing the availability of flavored e-cigarettes that are especially appealing to young people is one such policy. Flavored e-cigarettes are addicting a new generation of kids to nicotine and threaten to reverse decades of progress in reducing youth tobacco use. The amici have an interest in enhancing this Court's understanding of the public health benefits of the Emergency Rule under attack and in assuring its timely implementation.

Summary of Argument

In determining whether to issue a preliminary injunction against the enforcement of a regulation or statute, courts must determine whether the injunction would have a balance of equities in its favor. *See Rural Comm. Coal., Inc. v. Vill. of Bloomingburg*, 118 A.D.3d 1092, 1095 (3d Dep't 2014) (stating that a preliminary injunction should be issued cautiously); *F.F. on behalf of Y.F. v. State*, 2019 WL 4050472, 2019 N.Y.S Slip Op. 29261 (Sup. Ct., Alb. Cty. Aug. 23, 2019) (finding balance of equities did not favor preliminary injunction in light of increase risk of disease that injunction would cause). In this case, the balance of the equities does not support a preliminary injunction against the Emergency Rule because the rule represents a science-based policy that is critical to curbing the youth e-cigarette epidemic facing New York State.

Youth e-cigarette use in the United States has skyrocketed to what the U.S. Surgeon General and the U.S. Food and Drug Administration (FDA) have called "epidemic" levels. It is a public health crisis and *it is getting worse*. Newly released data from the 2019 National Youth Tobacco Survey (NYTS) shows that e-cigarette use among high school students more than doubled from 2017 to 2019, to 27.5 percent of students, or more than 1 in 4 high schoolers.² Altogether,

² FDA, *Trump Administration Combating Epidemic of Youth E-cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-cigarette Products*, September 11, 2019, <https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized->

5 million middle and high school students used e-cigarettes in 2019—an increase of nearly 3 million users in two years.³ Moreover, there is little doubt that flavored products are driving this epidemic by contributing to the powerful appeal of these products to youth. The existence of the epidemic makes self-evident the inadequacy of existing age restrictions for e-cigarettes. Contrary to the suggestion in petitioners’ brief, flavored e-cigarettes have not been proven to help smokers quit; indeed, no e-cigarette has been approved by FDA for smoking cessation. Also contrary to petitioners’ argument, the existence of federal regulatory authority over e-cigarettes in no way diminishes the authority of the State of New York to prohibit the sale of flavored e-cigarettes, nor the importance of doing so in the interest of public health. The Emergency Rule thus constitutes a proper and appropriate use of the State’s emergency authority to protect the health of New York’s children by ending the sale of flavored e-cigarettes and thereby reducing the use of these highly-addictive products by New York youth. In this case, the balance of equities tips strongly in favor of the State’s interest in protecting public health, particularly the health of New York’s children.

Argument

I. The State of New York faces a vaping crisis among youth.

The Emergency Rule responds to an epidemic of youth usage of flavored e-cigarettes by ending the sale of flavored e-cigarettes in New York (except tobacco flavored products).⁴ The

non?utm_source=CTPEblast&utm_medium=email&utm_term=stratout&utm_content=pressrelease&utm_campaign=ctp-vaping.

³ Edney, A., et al., *Vaping Furor Intensifies as Trump Vows Tough U.S. Scrutiny*, Bloomberg, September 11, 2019, <https://www.bloomberg.com/news/articles/2019-09-11/trump-to-hold-meeting-on-vaping-after-reports-of-u-s-illness>.

⁴ Although the Emergency Rule as originally issued did not include menthol and mint flavored e-cigarettes, the Governor has announced that it will be revised to include those flavors. *See* Press Release, Governor Cuomo Accepts Recommendation from State Health Commissioner to Ban the Sale of Menthol Flavored E-cigarettes, September 26, 2019,

severity of this epidemic cannot be overstated. E-cigarettes have become by far the most commonly used tobacco products among U.S. youth. Whereas the 2019 NYTS showed that 5.8% of high school students smoked regular cigarettes, the use of e-cigarettes by high school students soared to 27.5% in 2019, up from 20.8% in 2018 and 11.7% in 2017.⁵ Kids are not just experimenting with e-cigarettes, but are using them frequently. More than a quarter (27.7%) of high school e-cigarette users are frequent users, using e-cigarettes on at least 20 of the preceding 30 days.⁶ Alarming, 1 in 9 of all high school seniors (11.7%) report that they vaped nicotine nearly daily, a strong indication of deep addiction.⁷

Trends in e-cigarette use in New York mirror the epidemic levels that are seen nationwide. According to the most recent New York State Youth Tobacco Survey (NYS-YTS), between 2014 and 2018, the rate of e-cigarette use among high school youth in New York increased 160%, from 10.5% in 2015 to 27.4% in 2018.⁸ Furthermore, newly released data indicates that an alarming 36.7% of 12th grade students in New York State reported current e-cigarette use in 2018.⁹

<https://www.governor.ny.gov/news/governor-cuomo-accepts-recommendation-state-health-commissioner-ban-sale-menthol-flavored-e>.

⁵ *Supra* note 2.

⁶ CDC, *Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011-2018*, Morbidity and Mortality Weekly Report (MMWR), 67(45): 1276-1277.

⁷ Miech, R, et al., *Trends in Adolescent Vaping, 2017-2019*, N. Engl.J. Med., Oct. 10, 2019.

⁸ NYS DOH, Bureau to Tobacco Control, StatShot Vol. 12, No. 1, Jan. 2019, https://www.health.ny.gov/prevention/tobacco_control/reports/statshots/volume12/n1_electronic_sig_use_increase.pdf.

⁹ NYS DOH, Bureau of Tobacco Control, StatShot Vol. 12, No. 4, Oct. 2019, https://www.health.ny.gov/prevention/tobacco_control/reports/statshots/volume12/n4_ecig_trends.pdf

E-cigarettes remain the most commonly used tobacco product among New York youth, surpassing cigarettes, cigars, smokeless tobacco, and hookahs.¹⁰

Both the Commissioner of the FDA and the Surgeon General of the United States have recognized that youth usage of e-cigarettes has reached epidemic proportions. According to Norman E. “Ned” Sharpless, Acting Commissioner of the FDA, “Years of progress to combat youth use of tobacco—to prevent lifetimes of addiction to nicotine—is now threatened by an epidemic of e-cigarette use by kids.”¹¹ In December 2018, Surgeon General Jerome Adams issued an advisory on e-cigarette use among youth, declaring the growing problem an “epidemic.” The Surgeon General called for “aggressive steps to protect our children from these highly potent products that risk exposing a new generation of young people to nicotine.”¹²

The increasing number of vaping related pulmonary illnesses around the country only heightens the concern about initiation of vaping by youth.¹³ Doctors report that the lung damage in some people who have become ill after vaping resemble a chemical burn. Speaking about the pattern of injuries observed in the lungs, a surgical pathologist recently noted, “To be honest, they look like the kind of change you would expect to see in an unfortunate worker in an industrial

¹⁰ *Supra* note 8.

¹¹ FDA, *Statement on the agency’s actions to tackle the epidemic of youth vaping and court ruling on application submission deadlines for certain tobacco products, including e-cigarettes*, Statement from Acting Commissioner of Food and Drug Administration, July 15, 2019, <https://www.fda.gov/news-events/press-announcements/statement-agencys-actions-tackle-epidemic-youth-vaping-and-court-ruling-application-submission>.

¹² Office of the Surgeon General, *Surgeon General’s Advisory on E-cigarette Use Among Youth*, December 18, 2018, <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>.

¹³ Abbot, B., *What We Know About Vaping-Related Lung Illness*, The Wall Street Journal, Oct. 3 2019.

accident where a big barrel of toxic chemicals spills, and that person is exposed to toxic fumes and there is a chemical burn in the airways.”¹⁴

Indeed, as of October 8, 2019, there were 1,299 confirmed or probable cases of acute lung illness associated with the use of e-cigarette or vaping products reported to CDC and 26 deaths confirmed in 21 states.¹⁵ As of October 9, 2019, New York State has reported 114 vaping-related lung illnesses from across the state.¹⁶ The known vaping associated illnesses in New York have afflicted teens and other young people, with the youngest victim being 14 years old.¹⁷ On October 8, 2019, Governor Cuomo announced the first vaping-related death in New York State—the victim was only 17 and is the youngest vaping fatality in the U.S.¹⁸

These statistics establish that New York, like other states across the nation, faces a vaping crisis among youth demanding immediate action. As explained more fully below, any injunction delaying implementation of the Emergency Rule would deprive this State of a vital tool to bring this epidemic under control.

¹⁴ Grady, D., *Lung Damage From Vaping Resembles Chemical Burns, Report Says*, The New York Times, Oct. 2, 2019.

¹⁵ CDC, Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html (last updated October 10, 2019).

¹⁶ NYS DOH, Pulmonary Illnesses Associated with Black Market Vaping Products, https://www.health.ny.gov/prevention/tobacco_control/campaign/e-cigarettes/ (last updated Oct. 7, 2019).

¹⁷ *Id.*

¹⁸ Shanahan, E and Paybarah, A., Bronx Teenager’s Death Is the Youngest Vaping Fatality in U.S., The New York Times, Oct. 8, 2019.

II. E-cigarettes available in thousands of flavors increase youth usage and pose serious health risks to youth.

In recent years, tobacco companies have significantly stepped up their introduction and marketing of flavored non-cigarette tobacco products, especially e-cigarettes. Flavored e-cigarettes are undermining the nation's overall efforts to reduce youth tobacco use and putting a new generation of kids at risk of addiction and the serious health harms that result from it.

Internal tobacco industry documents show that tobacco companies have a long history of using flavors to reduce the harshness of their products and to make them more appealing to new users, almost all of whom are under age 18.¹⁹ In recent years, companies have extended this strategy of using flavored products to attract kids to the emerging market for e-cigarettes. As of 2017, researchers had identified more than 15,500 unique e-cigarette flavors available online.²⁰ An earlier study of e-cigarette flavors found that among the more than 400 brands available online in 2014, 84% offered fruit flavors and 80% offered candy and dessert flavors.²¹ In addition to the more conventional candy and fruit flavors like mint and mango, e-liquids are also being sold in such kid-friendly options as cotton candy and gummy bear. These products are widely available through convenience stores, other retail outlets and online retailers.

News stories across the country have documented the popularity of flavored e-cigarettes like JUUL. According to one high school student, "It [JUUL] spread like wildfire for two reasons

¹⁹ HHS, *Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012, <http://www.cdc.gov/Features/YouthTobaccoUse/>.

²⁰ Zhu, S-H, et al., *Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-2017: Analysis of Brand Websites*, *Journal of Medical Internet Research*, 20(3), J Med Internet Res 2018;20(3):e80, <https://www.jmir.org/2018/3/e80/>.

²¹ Zhu, S-H, et al., *Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation*, *Tobacco Control*, 23(Suppl 3):iii3-iii9, 2014.

... the first reason is the flashy flavors like crème brûlée. The flavors are responsible for bringing the kids in, the nicotine keeps them.”²²

The data confirms that flavors play a major role in youth initiation and the continued use of e-cigarettes. The 2016 Surgeon General Report on e-cigarettes concluded that flavors are among the most commonly cited reasons for using e-cigarettes among youth and young adults.²³ Data from the 2016–17 wave of the government’s Population Assessment of Tobacco and Health (PATH) study found that 70.3% of current youth e-cigarette users say they use e-cigarettes “because they come in flavors I like.”²⁴ The PATH study also found that 97% of current youth e-cigarette users had used a flavored e-cigarette in the past month.²⁵ The 2019 NYTS found that 63.9% of high school e-cigarette users vaped mint or menthol flavors, an increase from 51.2% in 2018.²⁶ Mint and menthol flavors are about as popular as fruit flavors among high school e-cigarette users.²⁷

²² Ramanathan, L, *We killed the cigarette. What we got in return is mango-flavored nicotine in ‘party mode,’* Washington Post, August 8, 2018, https://www.washingtonpost.com/lifestyle/style/we-killed-the-cigarette-what-we-got-in-return-is-mango-flavored-nicotine-in-party-mode/2018/08/08/bf4db3a8-8b8a-11e8-8aea-86e88ae760d8_story.html?noredirect=on&utm_term=.2a6418f461f3

²³ HHS, *E-cigarette Use Among Youth and Young Adults. A Report of the Surgeon General.* Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

²⁴ FDA, *Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance*, at 9, March 13, 2019, <https://www.fda.gov/media/121384/download>.

²⁵ *Id.*

²⁶ *Supra* note 2.

²⁷ *Id.*

Flavored tobacco products play a key role in enticing new users, particularly kids, to a lifetime of addiction. There is growing concern that use of e-cigarettes may function as a gateway to the use of conventional cigarettes and other combustible tobacco products, thereby undermining decades of progress in curbing youth smoking. A 2018 report by the National Academies of Science, Engineering and Medicine (NASEM) concluded that, “There is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.”²⁸ 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 cigarettes and nearly three times the odds of current cigarette use. The researchers estimate that this translates to over 43,000 current youth cigarette smokers who might not have become smokers without e-cigarettes.²⁹ Use of e-cigarettes is not limited to youth who are likely to become cigarette smokers. E-cigarette use is associated with trying cigarettes even among youth who are unlikely to smoke. Several studies have found that the link between e-cigarette use and smoking initiation is stronger for youth who had lower risk factors for smoking.³⁰

E-cigarettes and refill liquids contain widely varying levels of nicotine, and the nicotine delivered through the aerosol can also vary depending on the device characteristics and user practices.³¹ While e-cigarettes can be used for non-nicotine products, including marijuana, more

²⁸ National Academies of Sciences, Engineering, and Medicine (NASEM), *Public health consequences of e-cigarettes*, 2018, Washington, DC: The National Academies Press, <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx>.

²⁹ Berry, KM, et al., *Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in U.S. Youths*, JAMA Network Open, 2(2), published online Feb. 1, 2019.

³⁰ *Id.* See also Barrington-Trimis, JL, et al., *E-cigarettes and Future Cigarette Use*, *Pediatrics*, 138(1), July 2016; Wills, TA, et al., *E-cigarette use is differentially related to smoking onset among lower risk adolescents*, Tobacco Control, published online August 19, 2016.

³¹ NASEM, *supra* note 28.

than two-thirds of youth e-cigarette users report using e-cigarettes exclusively for nicotine-containing products.³² Nicotine is a highly addictive drug that can have lasting damaging effects on adolescent brain development.³³ As the Surgeon General’s Advisory warned, “Nicotine exposure during adolescence can impact learning, memory and attention.”³⁴ Nicotine also impacts the cardiovascular system.³⁵ The Surgeon General concluded that, “The use of products containing nicotine poses dangers to youth, pregnant women, and fetuses. The use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.”³⁶

Flavorings in e-cigarettes can pose additional health hazards. According to the Surgeon General, “while some of the flavorings used in e-cigarettes are generally recognized as safe for ingestion as food, the health effects of their inhalation are generally unknown” and noted that some of the flavorings found in e-cigarettes have been shown to cause serious lung disease when

³² CDC, *Characteristics of Electronic Cigarette Use Among Middle and High School Students—United States, 2015*, MMWR, 65(50-51): 1425-1429, <https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm655051a2.pdf>.

³³ HHS, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*, CDC, Office of Smoking and Health (OSH), 2014, <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html>. See also, CDC Office on Smoking and Health, *Electronic Nicotine Delivery Systems: Key Facts*, July 2015.

³⁴ Surgeon General’s Advisory on E-cigarette Use Among Youth, December, 2018, at 1, <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>.

³⁵ HHS, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*, Centers for Disease Control and Prevention, Office on Smoking and Health, 2010 <http://www.ncbi.nlm.nih.gov/books/NBK53017/>.

³⁶ HHS, *E-cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016, at 5, https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf.

inhaled.³⁷ An article in the *Journal of the American Medical Association* raised concerns that the chemical flavorings found in some e-cigarettes and e-liquids could cause respiratory damage when the e-cigarette aerosol is inhaled deeply into the lungs.³⁸

Thus, given the fast-spreading epidemic of youth e-cigarette use, caused in large part by the appeal of flavored products, the Emergency Rule is critical to the State's efforts to protect its young people from the addictive and other harmful effects of e-cigarettes.

III. New York's Emergency Rule is necessary because other existing tobacco regulations are insufficient to address the epidemic of e-cigarette use among kids.

Although New York's age restrictions on the sale of tobacco products are important and necessary to restrict access, they are insufficient on their own to combat the e-cigarette epidemic among youth. Young people entering stores cannot avoid being accosted by an array of e-cigarettes—virtually all with flavors designed to enhance their appeal to youth. The youth vaping epidemic itself makes it self-evident that, because flavored e-cigarettes have such a powerful appeal to youth, laws prohibiting sales to minors are simply not enough.

According to the 2018 Monitoring the Future Survey, more than 60% of 10th grade students say it is easy to get vaping devices and e-liquids.³⁹ Indeed, it is clear that, despite age restrictions, retailers continue to sell these products to minors. In the summer of 2018, FDA's undercover enforcement efforts resulted in over 1,300 warning letters and fines to brick-and-

³⁷ *Id.*

³⁸ Barrington-Trimis, JL, Samet, JM, & McConnell, R, *Flavorings in Electronic Cigarettes: An Unrecognized Respiratory Health Hazard?*, The Journal of the American Medical Association, doi:10.1001/jama.2014.14830, published online November 10, 2014.

³⁹ University of Michigan, Monitoring the Future Study, *Trends in Availability – Tables 15-17*, 2018, <http://monitoringthefuture.org/data/18data/18drtbl15.pdf> and <http://monitoringthefuture.org/data/18data/18drtbl16.pdf>.

mortar and online retailers for illegally selling e-cigarettes to minors.⁴⁰ A study in JAMA Pediatrics found that in California, where the tobacco sales age is 21, over 44% of tobacco and vape shops sold e-cigarettes to underage decoys.⁴¹

Given the obvious insufficiency of age restrictions alone, the Emergency Rule prohibiting the sale of flavored e-cigarettes is absolutely necessary to reduce the use of e-cigarettes by New York kids.

IV. E-cigarettes have not been approved as a smoking cessation drug or device in the U.S.

Although petitioners assert that flavored e-cigarettes facilitate smoking cessation,⁴² no e-cigarette has been approved, or even reviewed, as a smoking cessation drug or device by FDA. The U.S. Preventive Services Task Force concluded that “the current evidence is insufficient to recommend electronic nicotine delivery systems for tobacco cessation”⁴³ The same NASEM report cited by petitioners also concluded, “Overall, there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation.”⁴⁴ According to CDC researchers, “There is currently no conclusive scientific evidence that e-cigarettes promote long-term cessation, and

⁴⁰ FDA, *Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance*, March 13, 2019.

⁴¹ Roeseler, A, et al., *Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops*, JAMA Pediatrics, June 24, 2019.

⁴² Pl.’s Mem. in Support of Verified Petition and Motion for Temporary, Preliminary and Permanent Injunctive Relief, Sep. 25, 2019, NYSEF No. 22, at 4.

⁴³ U.S. Preventive Services Task Force, *Behavioral and Pharmacotherapy Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Women*: U.S. Preventive Services Task Force Recommendation Statement, *Annals of Internal Medicine*, Vol. 163, No. 8, October 2015, <http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1>.

⁴⁴ *Supra* note 28.

e-cigarettes are not included as a recommended smoking cessation method by the U.S. Public Health Service.”⁴⁵ A 2018 systematic review of 66 articles published on consumer preference for e-cigarettes has supported these conclusions and also found inconclusive evidence as to whether e-cigarettes assist smoking cessation.⁴⁶

Furthermore, according to CDC data, most adult smokers do not switch completely to e-cigarettes; rather, they use both e-cigarettes and cigarettes (dual use).⁴⁷ NASEM found that dual use of cigarettes and e-cigarettes “is not a proven method for combustible tobacco cigarette cessation.”⁴⁸ FDA reached the same conclusion and stated, “[T]here is not sufficient evidence to conclude that youth and young adults are using [e-cigarettes] as a means to quit smoking.” *See* 81 Fed. Reg. 29,028. According to FDA, “systematic reviews found insufficient evidence to conclude that e-cigarettes aid smoking cessation.” *Id.* at 29,037.

Moreover, there is no evidence that flavors in e-cigarettes play any role in smoking cessation. While there are surveys showing that many adults enjoy using flavored products, and anecdotal reports of smokers who say flavored e-cigarettes helped them quit, there is no evidence

⁴⁵ King, BA, et al., *Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011*, Nicotine & Tobacco Research, 15(9):1623-7, 2013. See also, King, BA, et al., *Trends in Awareness and Use of Electronic Cigarettes among U.S. Adults, 2010-2013*, Nicotine & Tobacco Research, first published online September 19, 2014.

⁴⁶ Zare, S, et al., “A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type,” *PLoS One*. 2018 Mar 15;13(3):e0194145. doi: 10.1371/journal.pone.0194145

⁴⁷ CDC, “QuickStats: Cigarette Smoking Status Among Current Adult E-cigarette Users, by Age Group — National Health Interview Survey, United States, 2015,” *MMWR* 65(42):1177, October 28, 2016, <https://www.cdc.gov/mmwr/volumes/65/wr/mm6542a7.htm>. See also CDC, “About Electronic Cigarettes (E-cigarettes),” Last reviewed November 15, 2018, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html#who-is-using-e-cigarettes

⁴⁸ *Supra* note 28, at 18-24.

that smokers could not have quit without non-tobacco flavors. There has not been a single randomized controlled trial to assess the impact of flavored versus non-flavored or tobacco-flavored e-cigarettes on smoking cessation outcomes.

V. FDA’s regulatory authority over e-cigarettes has been largely unused and states retain broad authority to issue regulations like the Emergency Rule to protect public health in their communities.

Petitioners vastly distort reality when they claim that “nicotine-containing vapor products, including flavored e-liquids, are heavily regulated by the Food and Drug Administration.”⁴⁹ Although Congress gave FDA broad regulatory authority over tobacco products in the Family Smoking Prevention and Tobacco Control Act of 2009, the agency has largely failed to use that authority to regulate e-cigarettes. Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. §§ 387–387u). Moreover, the Tobacco Control Act expressly preserves the power of each state to regulate, and even prohibit, the sale of tobacco products. Thus, the existence of FDA regulatory authority in no way diminishes the public health importance of measures like the Emergency Rule.

E-cigarettes were entirely unregulated by FDA until the 2016 issuance of a final rule “deeming” e-cigarettes subject to FDA regulation. *See* Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974 (May 10, 2016) (“Deeming Rule”). Even after the Deeming Rule was issued, FDA’s regulatory power has been severely underutilized. For example, although petitioners note that FDA now has the authority to “regulate the methods used in manufacturing and testing vapor products and to mandate new product standards regarding the composition and characteristics of vapor products,”⁵⁰ the agency has issued no regulations requiring good manufacturing practices for e-cigarettes, nor has it issued a single

⁴⁹ *Supra* note 42 at 5.

⁵⁰ *Id.* at 6.

product standard for e-cigarettes. In addition, although petitioners note that e-cigarette manufacturers are under an obligation to provide FDA all documents in their possession relating to the “health, toxicological, behavioral, or physiologic effects” of their products,⁵¹ FDA is enforcing that mandate only as to documents generated by companies before December 31, 2009.⁵² This means that virtually no such “health documents” have been provided for e-cigarettes, most of which were not even on the market until after 2009.

Most significantly as to e-cigarettes, FDA has failed to implement the required premarket review of “new tobacco products” (i.e., products marketed after February 15, 2007), in which manufacturers generally would be required to demonstrate that their products are “appropriate for the protection of the public health” in order to stay on the market or enter the market. 21 U.S.C. § 387(j). At the time it issued the Deeming Rule in August 2016, FDA exercised its enforcement discretion as to e-cigarettes already on the market, to give their manufacturers a two-year period, until August 2018, to file applications for premarket review. 81 Fed. Reg. 28,978. Then, in an August 2017 Guidance, FDA announced it would further defer enforcement of the premarket review requirements for e-cigarettes four additional years, until 2022.⁵³ Thus, FDA allowed thousands of flavored e-cigarettes to remain on the market until 2022 without having to even submit an application demonstrating that they met the public health standard in the statute.

As the result of a lawsuit brought against FDA by several of the amici here, a federal court held that FDA had abdicated its statutory duty to subject new tobacco products like e-cigarettes to

⁵¹ *Id.*

⁵² FDA, Guidance for Industry, “Health Document Submission Requirements for Tobacco Products (Revised) (October, 2017), at 14.

⁵³ FDA, Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry (Revised) (August 2017 Guidance), at 8.

premarket review. After noting that “youth use of e-cigarettes has reached epidemic proportions,” the court found that FDA’s “wholesale suspension” of premarket review had given manufacturers a “safe-harbor” that “has allowed the manufacturers enough time to attract new young users and get them addicted to nicotine before any of their products, labels, or flavors are pulled from the market” *See Am. Acad. of Peds., et al. v. FDA*, 379 F. Supp. 3d 461, 494 (D. Md. 2019). In a subsequent order, the Court established a ten-month deadline (until May 2020) for industry submissions and a one-year deadline for completion of FDA review.⁵⁴ Thus, the premarket review process has been revived, but only by court order. Far from being “heavily regulated,” e-cigarette manufacturers have not been required to submit a single product for FDA public health review.⁵⁵

Moreover, even if FDA had more fully utilized its regulatory authority, nothing in the Tobacco Control Act would prohibit New York from issuing the Emergency Rule. Section 916 of the Tobacco Control Act specifically preserves broad state and local authority with respect to tobacco products. 21 U.S.C. § 387(p). Section 916(a)(2)(B), the provision’s “saving clause,” specifically states that the limited preemption provision in Subparagraph (A) does not apply to the “sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age” *Id.*; *see also U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428, 435 (2d Cir. 2013) (upholding New York City’s restriction on sales of flavored tobacco products under “saving clause” of Section 916). Thus, in no sense does the existence of federal regulatory authority over

⁵⁴ *Am. Acad. of Peds., et al. v. FDA*, No. PWG-18-883, 2019 WL 3067492 (D. Md. 2019).

⁵⁵ FDA recently has indicated its intent to “finalize a compliance policy in the coming weeks” that would subject non-tobacco flavored e-cigarettes that lack premarket orders to enforcement actions 30 days after a final Guidance is issued. *See FDA, supra* note 2. Even if this policy becomes final, tobacco-flavored e-cigarettes on the market when the Deeming Rule became final would still be subject to the court order.

e-cigarettes affect the authority of the State of New York to prohibit the sale of non-tobacco flavored e-cigarettes, nor does it diminish the public health importance of doing so.

Conclusion

In response to the youth vaping epidemic, New York and six other states have prohibited the sale of flavored e-cigarettes. At least 200 localities also have passed restrictions or complete prohibitions on the sale of flavored e-cigarettes.⁵⁶ New York children and families should not be deprived of the benefits of this necessary and appropriate response to the current epidemic. In this case, the equities tip decisively in favor of the State, as it seeks to protect the health of New York's families, and especially New York children. Injunctive relief should be denied.

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Respectfully submitted,

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⁵⁶ Campaign for Tobacco-Free Kids, *States & Localities That Have Restricted the Sale of Flavored Tobacco Products*, <https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>.

APPENDIX A

Description of Amici Curiae

1. American Cancer Society Cancer Action Network

The American Cancer Society Cancer Action Network (ACS CAN) is working to make cancer a top priority for public officials and candidates at the federal, state and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden.

2. American Heart Association

The American Heart Association (AHA) is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke. In New York State, AHA has successfully advocated for critical tobacco control and prevention policies including the Clean Indoor Air Act, the inclusion of e-cigarettes in the Clean Indoor Air Act, increased funding for the Tobacco Control Program, a substantial tobacco tax as an effective prevention measure, and most recently, a raise in the age for tobacco purchase to 21.

3. American Lung Association

The American Lung Association is the nation's oldest voluntary health organization. The American Lung Association has long been active in research, education and public policy advocacy regarding the adverse health effects caused by tobacco use, including supporting eliminating the sale of all flavored tobacco products.

4. Campaign for Tobacco-Free Kids

The Campaign for Tobacco-Free Kids is a leading force in the fight to reduce tobacco use and its deadly toll in the United States and around the world. The Campaign envisions a future free of the death and disease caused by tobacco, and it works to save lives by advocating for public policies that prevent kids from smoking, help smokers quit and protect everyone from secondhand smoke. Tobacco-Free Kids has a strong interest in ensuring the timely enforcement of New York's Emergency Rule because it is essential to curbing the dramatically increasing incidence of youth usage of e-cigarettes in New York that threatens to addict a new generation of young people to nicotine and undermine the progress made over decades in curbing tobacco use by adolescents in New York and elsewhere.

5. Healthy Capital District Initiative

The Healthy Capital District Initiative is a partnership of the hospitals, public health departments, Federally Qualified Health Centers, health insurers, and community based organizations which collaborate to improve access to coverage and care, provide health planning expertise, and support health prevention programs across six counties of the Capital Region.

6. March of Dimes

March of Dimes leads the fight for the health of all mothers and babies and advocates for policies that prioritize their health and improve the care they receive. March of Dimes also pioneers research to find solutions to the biggest health threats to mothers and babies.

7. Medical Society of the State of New York

The Medical Society of the State of New York is the largest omnibus advocacy organization for physicians in New York State, representing over 20,000 physicians, residents and student members of every specialty and region. MSSNY's key priorities include enhancing the ability of patients to receive timely needed care and improving public health, such as expanding vaccination availability and reducing availability of known harmful substances such as nicotine.

8. NAACP New York State Conference

The NAACP New York State Conference has been a vital programmatic component of the National Association for the Advancement of Colored People for 80 of the 108-year history of the oldest, most effective and most respected civil rights organization in the nation. The New York State Conference has played a pivotal role in moving the agenda for freedom and equality forward in New York throughout its history and has worked to address the disproportionate impact that flavored tobacco products of all types have had on African American and other minority communities.

9. New York School-Based Health Alliance

The New York School-Based Health Alliance is a statewide organization representing school-based health centers in New York State. Its mission is to create access to comprehensive, high-quality physical and mental health care for all children and youth statewide. These efforts include advocacy and promoting practices that prevent students from using and/or becoming addicted to tobacco products.

10. New York State Academy of Family Physicians

The New York State Academy of Family Physicians (NYSAFP) annually advocates for an increase in state funding for New York's Tobacco Control Program and has worked with others to successfully expand the program to include electronic cigarettes. Over the last few years, NYSAFP supported efforts to regulate electronic cigarettes like tobacco, to raise tobacco purchase age to 21 and to ban sale of tobacco in pharmacies.

11. New York State American Academy of Pediatrics

The New York State American Academy of Pediatrics (AAP) is the voice for children and adolescents in New York State and advocates for policies which will allow them to grow and thrive in a healthy environment to maximize their potential. AAP advocates for mitigating health risks to children and adolescents caused by tobacco and has strongly advocated for

critical tobacco legislation including the statewide Tobacco 21 policy. It recognizes that there is more work to be done and will continue to advocate for the well-being of all children.

12. New York State Association of County Health Officials

The New York State Association of County Health Officials (NYSACHO) is a 501(c)(3) non-profit organization representing the 58 local health departments in New York State. NYSACHO supports, advocates for, and empowers local health departments in their work to promote health and wellness and prevent disease, disability and injury throughout New York State. NYSACHO strongly supports and advocates for policy and programmatic actions to further NYS Prevention Agenda goals around tobacco use and vaping to reduce the morbidity and mortality caused by tobacco and vaping products.

13. New York State Association for Health, Physical Education, Recreation, and Dance

Since its inception in 1924, the mission of the New York State Association for Health, Physical Education, Recreation and Dance has been to support, encourage, facilitate, advocate, and promote physically active and healthy lifestyles through school and community programs in Health Education, Physical Education, recreation, and dance.

14. New York State Association for Rural Health

The New York State Association for Rural Health (NYSARH) is a not-for-profit, non-partisan, grassroots membership organization working to preserve and improve health and human services in rural New York State. NYSARH has advocated for policies that would raise the age for tobacco purchase to 21 at both the state and local level.

15. New York State Osteopathic Medical Society

New York State has more than 6,000 licensed osteopathic physicians, representing the fourth largest osteopathic physician population in the country. Many osteopathic physicians in New York State practice primary care; many also practice in rural and urban medically underserved regions. Preventing tobacco product use among youth is critical to ending the tobacco epidemic in the United States because once addicted, it is very difficult to quit. The New York State Osteopathic Medical Society believes that it is important to protect New York's adolescents from tobacco addiction and strongly supports efforts to prohibit the sale of flavored e-cigarettes to help eradicate the vaping crisis among our youth.

16. New York State Public Health Association

The New York State Public Health Association is a membership organization of public health professionals working in health departments, community organizations, academia and other settings across New York. Combating youth tobacco and e-cigarette use has been a long-term goal of the Association because of the large adverse health impact use of these products have on youth.

17. New York State Society of Anesthesiologists

The New York State Society of Anesthesiologists, Inc. is an organization of physicians and scientists dedicated to advancing the specialty of anesthesiology and providing the safest and highest quality patient care to the citizens of New York State.

18. NYS PTA

The New York State PTA strives to be a powerful voice for children and a strong advocate for the education and well-being of every child. The NYS PTA has advocated for tobacco control policies at the state and local level so that children may reach their full potential.

19. PAVe

PAVe (Parents Against Vaping e-cigarettes) is a grassroots organization founded by three concerned New York City mothers as a response to the current youth vaping epidemic, the most serious adolescent public-health crisis our country has faced in decades. PAVe's volunteer parent advocates operate in multiple states, working in partnership with other stakeholders including public-health groups and community-based organizations. PAVe believes that regulatory and legislative change at the federal/national and/or state and local levels (e.g., a ban on all e-cigarette flavors including mint and menthol and Tobacco 21 Laws without exceptions) are key to slowing the explosive growth of teen vaping and will prevent younger kids from starting to use flavored e-cigarettes. In cities and states where PAVe works as part of a broader anti-tobacco coalition—such as in New York City, its home base—it fully supports a ban on all flavored tobacco products including menthol cigarettes.

20. St. Joseph's Health Partners

St. Joseph's Health is a regional non-profit health care system based in Syracuse, New York. St. Joseph's has been an innovative leader in health care since its founding in 1869 as the first hospital open to the public in the city of Syracuse. Offering primary, specialty and home care, a Magnet-recognized hospital, and collaboration with community partners, St. Joseph's Health advances the well-being of the communities it serves through an expanding range of services to ensure its patients achieve optimum long-term health. St. Joseph's is ranked by Consumer Reports among the top 15 heart surgery centers in the country, a designated Stroke Center and a U.S. News "Best Regional Hospital." St. Joseph's Health is a member of Trinity Health.

21. St. Peter's Health Partners

St. Peter's Health Partners is the Capital Region's largest and most comprehensive not-for-profit network of high-quality, advanced medical care, primary care, rehabilitation and senior services, with nearly 12,000 employees in more than 170 locations. Presently, these state-of-the-art services and programs are provided through Albany Memorial, St. Peter's, Samaritan and Sunnyview Rehabilitation Hospitals, as well as The Eddy system of continuing care and The Community Hospice. Peter's Health Partners is a member of Trinity Health, one of the nation's largest Catholic health systems.

22. The Children's Agenda

The Children's Agenda is a 15-year-old non-profit organization in Rochester, New York that advocates at the local, state and federal level for effective policies and evidence-based solutions for the health, education and success of children. It improves children's lives by engaging leaders in systemic change through research, collaboration and advocacy.

23. Trinity Health

Trinity Health is committed to reducing tobacco use in every community it serves, as it knows tobacco use is the leading cause of preventable death in our country. It does this by ensuring its patients who screen positive for tobacco use are referred to cessation services and through advancing community level policy change to reduce access to tobacco products, particularly for youth. It applauds the State of New York for passing tobacco 21 and support New York's Emergency Rule. One in four high school students use e-cigarettes and this public health epidemic must be addressed. A ban on flavors will significantly reduce the appeal of vaping. Addressing youth vaping is only one of many important policy changes needed to significantly reduce tobacco use in the United States.

24. Truth Initiative

Truth Initiative Foundation, d/b/a Truth Initiative ("Truth Initiative") is a 501(c)(3) Delaware corporation created in 1999 out the 1998 Tobacco Master Settlement Agreement that resolved litigation brought by 46 states, five U.S. territories, and the District of Columbia against the major U.S. cigarette companies. Headquartered in Washington, D.C., Truth Initiative studies and supports programs in the United States to reduce youth tobacco use and to prevent diseases associated with tobacco use. Its nationally recognized truth campaign has educated hundreds of millions of young people about the health effects and social costs of tobacco.