Nos. 19-2130, -2132, -2198 & -2242

In the United States Court of Appeals for the Fourth Circuit

AMERICAN ACADEMY OF PEDIATRICS, et al.,
Plaintiffs-Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,
Defendants-Appellants,

E-LIQUID MANUFACTURING STANDARDS ASSOCIATION, et al.,
Intervenors-Appellants

CIGAR ASSOCIATION OF AMERICA, et al.,
Appellants,

On Appeal from the United States District Court
for the District of Maryland

BRIEF OF AMICI CURIAE PUBLIC HEALTH LAW CENTER, ACTION ON SMOKING AND HEALTH, AMERICAN ACADEMY OF ALLERGY, ASTHMA AND IMMUNOLOGY, AMERICAN COLLEGE OF CHEST PHYSICIANS, AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE, AMERICANS FOR NONSMOKERS' RIGHTS, AMERICAN MEDICAL ASSOCIATION, AMERICAN PUBLIC HEALTH ASSOCIATION, AMERICAN THORACIC SOCIETY, NAATPN, INC., NATIONAL ASSOCIATION FOR THE MEDICAL DIRECTION OF RESPIRATORY CARE, AND NATIONAL MEDICAL ASSOCIATION IN SUPPORT OF APPELLEES AND AFFIRMANCE

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DISCLOSURE STATEMENT

Pursuant to FRAP 26.1 and Local Rule 26.1, Public Health Law Center, Action on Smoking and Health, American Academy of Allergy, Asthma and Immunology, American College of Chest Physicians, American College of Occupational and Environmental Medicine, Americans for Nonsmokers' Rights, American Medical Association, American Public Health Association, American Thoracic Society, NAATPN, Inc., National Association for the Medical Direction of Respiratory Care, and National Medical Association, who are amici curiae, make the following disclosures:

1. No amicus is a publicly held corporation or other publicly held entity.
2. No amicus has any parent corporation.
3. No amicus issues any stock, therefore no publicly held corporation or other publicly held entity owns 10% or more of the stock of any amicus.
4. No publicly held corporation or other publicly held entity has a direct financial interest in the outcome of the litigation.
5. (n/a)
6. This case does not arise out of a bankruptcy proceeding.

/s/ Rachel Bloomekatz
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INTRODUCTION AND STATEMENT OF INTEREST[1]

Have you ever heard of a "Puff Bar"? It is a new precharged, prefilled, disposable e-cigarette catching on with teenagers across the country.[2] Like other e-cigarettes, it heats up a nicotine liquid, creating a vapor the user inhales. Teachers find discarded bars in flavors like banana ice, sour apple, and cool mint in classroom trashcans. You can buy one in orange, mango, and guava—called O.M.G. for short—for between $6 and $10, and it has enough battery and liquid to last all day.[3] Puff Bars are just the latest "fad" sweeping through high schools. These products—and many like them—represent an entirely new generation of tobacco products. They often come in sweet flavors, designed to look like juice boxes or candy, and small enough to be hidden in a teenager's palm or pocket. They are getting a new generation addicted to nicotine.

For the past few years, the hot trend was JUUL—an e-cigarette that looks just like a USB flash drive. After much outrage—and after five million high school and middle school students reported using e-cigarettes—the Food and Drug Administration (FDA) finally took action on JUUL, requiring a pause in flavored JUUL sales (though

[1] No counsel of any party to this proceeding authored any part of this brief. No party or party's counsel, or person other than *amici* and their members, contributed money to the preparation or submission of this brief. Descriptions of each individual *amicus* are included in the Addendum.

[2] Sheila Kaplan, *Teens Find a Big Loophole in the New Flavored Vaping Ban*, N.Y. Times (Jan. 31, 2020), https://perma.cc/LUS8-Z447.

[3] *Id.*; RJ Frometa, *What Are the Main Benefits of Puff Bar Disposable?*, Vents Mag. (Feb. 7, 2020), https://perma.cc/PN6V-KDGN.

not for the tobacco or menthol flavors) starting just this month.[4] But closing the door on JUUL has "merely opened the door to an array of competing brands that produce disposables, like Puff Bars, blu, Posh and Stig," that come in all the fancy flavors now banned for JUUL; they even have more nicotine than a JUUL pod and are cheaper. Teens are also moving to "highly concentrated, refillable nicotine vape products" (so called "open-tank" products) called "Smok" and "Suorin Drops" that also remain unregulated. As teens report: "Juul's so yesterday, we've moved on."[5]

E-cigarettes are not the only new tobacco product catching on with youth, even if they are getting the most attention. Skirting regulations for conventional cigarettes, which cannot come in flavors, cigar manufacturers now make little cigars and cigarillos, (some of which even resemble cigarettes) in flavors, like a "Da Bomb Blueberry."[6] The proliferation of new cigars means that high school students are now more likely to smoke cigars than cigarettes.[7]

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[4] *See* Ctr. for Tobacco Prods., Food & Drug Admin., *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization: Guidance for Industry* (2020), https://perma.cc/BUH7-BNWQ (hereinafter "2020 Guidance").

[5] Kaplan, *supra* note 2; Erika Edwards, *Federal Flavor Ban Goes into Effect Thursday, But Many Flavored Vape Products Will Still Be Available*, NBC News (Feb. 5, 2020, 12:29 PM), https://perma.cc/EG5S-8KZF.

[6] *See* Desmond Jenson, *A Cigarette by Any Other Name Is Still a Cigarette*, Tobacco Control (Feb. 26, 2020), https://perma.cc/VL8S-MHJ6.

[7] Teresa W. Wang et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students—United States, 2019*, 68 Morbidity & Mortality Weekly Report Surveillance Summaries 1, 5 (2019), https://perma.cc/6KBT-LJS3.

The *amici* here see the devastating public health impact of these new tobacco products every day. The *amici* are nonprofit groups of medical professionals and researchers that, based on their scientific expertise and professional experience, are particularly well-suited to explain the health dangers of these products—particularly e-cigarettes and cigars—and their increasing prevalence among youth. The scientific evidence of their dangers, especially to youth, is overwhelming.

To its credit, Congress meant to stop this revolving door of deceptive and devastating tobacco products when it enacted the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776, 1777 (2009) (TCA or Act). Before JUUL was even on the market, Congress mandated that every new tobacco product undergo premarket review *before* it could be sold to the general population. Rather than ban existing products, Congress set a baseline from which the FDA could improve health by restricting new products that would attract youth. Therefore, with the TCA, Congress prohibited tobacco companies from selling new tobacco products unless the manufacturer could prove to the FDA either that each product was "substantially equivalent" to those commercially available in 2007 or that allowing its sale would be "appropriate for the protection of the public health" under the statute's standards. *See* 21 U.S.C. § 387j. The FDA, with its 2016 Deeming Rule, deemed e-

cigarettes, cigars, and other tobacco products within the scope of the Act's mandates, including these "premarket" review requirements.[8]

So how did all these new harmful products get on the market? The answer is simple: the FDA violated Congress's mandate to conduct premarket review. At the outset, the Deeming Rule required premarket review applications to be filed by August 2018. But the FDA's 2017 Guidance at issue in this case delayed the deadline for combustibles like cigars to 2021 and non-combustibles like e-cigarettes to 2022, so not a single manufacturer was required to file an application until twelve years after Congress enacted the TCA.[9] That means that many addictive nicotine products enjoyed years of unfettered access to the market.

Heeding Congress's mandate, the lower court's order (incorporated in the FDA's 2020 Guidance) now requires manufacturers to file premarket applications by May 2020.[10] As the District Court recognized, it is neither lawful nor reasonable for the FDA to abdicate its statutory obligations. The public health consequences alone reflect why. Accordingly, *amici* respectfully request that the Court affirm the lower court's decision.

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[8] Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,973, 28,977 (May 10, 2016) (hereinafter "DR").

[9] Center for Tobacco Prods., Food & Drug Admin., *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, Guidance for Industry (Revised)* (4th Ed., Nov. 2017), https://perma.cc/DT2Z-X4FK (hereinafter "2017 Guidance").

[10] *See* 2020 Guidance, *supra* note 4, at 27.

ARGUMENT

I. The vape and cigar industries should not be allowed to evade the product-by-product review system Congress established in the TCA to protect public health from emerging tobacco products.

With the enactment of the TCA, Congress established a product-by-product review process to ensure that new tobacco products entering the market would not exacerbate the existing public health crisis. *See* 123 Stat. at 1779. Understanding this process not only highlights why the District Court correctly held that the FDA's 2017 Guidance is *ultra vires*, but also underscores why this Court should reject the e-cigarette and cigar industries' attempt to evade premarket review.

A. Congress recognized that its existing approach was inadequate to curb youth tobacco use.

The TCA's enactment reflects Congress's understanding of three key aspects of the tobacco crisis. *First* and foremost, Congress recognized that even decades after the harms of tobacco use and nicotine addiction had been revealed, the public health crisis continued. "Based on extensive evidence of tobacco's widespread use and nicotine's addictive character and harmful effects, Congress found that the 'use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco dependent children and adults." *Nicopure Labs LLC v. Food & Drug Admin.*, 944 F.3d 267, 271 (D.C. Cir. 2019) (quoting 123 Stat. at 1777).

Second, Congress understood that the tobacco crisis is driven by an industry that depends on addicting new, young users. "Virtually all new users of tobacco products are under the minimum legal age to purchase such products." 123 Stat. at 1777. To keep attracting new users, the industry continued its longstanding pattern of deception even after tobacco was a known public health crisis. Whether through introducing new products like "light" cigarettes meant to seem healthier (they weren't), creating advertising campaigns targeting youth, or using flavors, giveaways, and other gimmicks to attract youth, the industry had proven its resilience in continuing its deception and targeting of youth. *Id.* at 1780-81, 1784, 1831.

Third, the TCA grew out of Congress's recognition that its earlier attempts to curb tobacco use, including by adolescents, had been unsuccessful. *Nicopure*, 944 F.3d at 272 (citing 123 Stat. at 1777). The Master Settlement Agreement and existing legislative efforts were no match for the industry's tactics. By the time that federal or state governments (or the private bar) realized the devastating health effects of a new product (e.g., "light" cigarettes) or ad campaign, it was too late—more young people were already addicted. The game of whack-a-mole was not working.

B. Congress mandated that the FDA review every new tobacco product before it is marketed to the public.

So Congress decided to act. With the TCA, it insisted on a "comprehensive" scheme that, at a minimum, was meant to hold the line on new tobacco products detrimental to public health entering the market. 123 Stat. at 1777; *Nicopure*, 944 F.3d at

276-77. So it took the "then-current tobacco product market as a baseline from which to ratchet down tobacco products' harms to public health." 944 F.3d at 271. Tobacco products on the market as of February 15, 2007 were grandfathered in. *Id.* at 276. But beyond that existing baseline, Congress prohibited any new tobacco product from entering the market unless the manufacturer first proves that, at least, its "product's public health harms do not exceed its benefits." *Id.* at 281.

To effectuate this goal, the TCA requires *all* new products to go through review or prove substantial equivalence *before* entering the market to ensure they do not exacerbate the public health crisis. New products must be "appropriate for the protection of the public health" under statutory standards. *See* 21 U.S.C. § 387j. And if manufacturers claim that their products are safer than other tobacco products they must meet even more stringent standards. *See id.* § 387k. Premarket review includes an evaluation not just of a product's ingredients, but also of its proposed labeling and advertising. *See id.* §§ 387j(b)(1), 387j(c)(2), 387k(b)(2)(A).

Congress, of course, could have developed a different scheme, varying the process's stringency by product type or giving the FDA the power to declare classes of products safe and exempt from review. But it didn't. *See Nicopure*, 944 F.3d at 281. Congress had learned its lesson from past failures, and in the TCA required the FDA to determine that "each new tobacco product's risks not outweigh its benefits to the public health" before being introduced to the public en masse. It mandated a product-by-product review neither the FDA nor industry can evade. *See id.*

Upon the TCA's enactment in 2009, the FDA's review did not include e-cigarettes or cigars because Congress deferred to the FDA's expertise as to whether these products should be "deemed" tobacco products under the Act. Given the overwhelming research about their harms, the FDA answered in the affirmative.[11] The result: *all* products, including e-cigarettes and cigars, are subject to premarket review to ensure that any new product will "not be a step backward for the public health." *Nicopure*, 944 F.3d at 282. Or so Congress intended.

The FDA's 2017 Guidance and the industry's arguments upended this statutory scheme. Under its 2017 Guidance, premarket review was delayed for more than four years after little cigars and e-cigarettes were deemed subject to the TCA. While the 2020 Guidance moves up premarket review for some products, including JUUL, for other products, the FDA still would continue to delay premarket review, and has only stated that such premarket review applications must be filed earlier to comply with the lower court's decision. Many new products will have been on the market for over a decade without review. And other new products, like O.M.G. Puff Bars, have emerged without scrutiny—and are getting the next generation addicted to nicotine. That is precisely what Congress sought to avoid.

For its part, the e-cigarette industry argues it should be given an easier path because its products are safer. It acknowledges that some "pod-based" e-cigarettes have

[11] DR at 29,020-25, 29,029-35.

caused a teen vaping epidemic, but argues that because its "open tank" products are not (yet) at the heart of the problem and are arguably safer than conventional cigarettes, it should be able to bypass (or delay) review. Appellants' Br. 10, 15. But, as the D.C. Circuit held, this argument "impermissibly assumes the very public health conclusions that premarket authorization requires be substantiated before a product may be sold." *Nicopure*, 944 F.3d at 281. Even if the Vape Appellants' products have not caught on at same rate as JUUL and pod-based systems, the same premarket review system they seek to dissolve is the system needed to evaluate both those products and even newer ones—like Puff Bars. Their argument about their products' safety is, in short, appropriate for the premarket review process itself. It should not be used to dismantle it.

Unfortunately, as discussed below, because the FDA has not adhered to Congress's mandate to review each new product before marketing, *amici* have already seen the devastating effects on public health, particularly among youth. The Court should affirm, and not let the FDA and the industry evade the TCA any further.

II. In the absence of premarket review, e-cigarettes and kid-friendly cigars have caused a public health crisis.

Without premarket review, new tobacco products—in particular e-cigarettes and little cigars[12]—have flooded the market in sweet flavors and with catchy advertising

[12] Wang et al., *supra* note 7, at 5.

directly targeting youth. The result: While cigarette use has fallen among adolescents,[13] the popularity of other products and the "skyrocketing growth" of e-cigarette use "threatens to erase progress made in reducing youth tobacco use."[14] Despite the claims of the profit-driven industries behind them, these products are not safe. Like cigarettes, e-cigarette use leads to nicotine addiction, which interferes with brain development, and cigar smoking causes cancer, heart disease, lung disease, stroke, and death. The FDA violated Congress's mandate to hold the line at the pre-TCA baseline, with devastating impacts for public health.

A. The increasing prevalence of e-cigarettes and other electronic nicotine delivery systems continues to threaten public health.

In 2018, the Surgeon General declared the use of e-cigarettes among U.S. youth and young adults an "epidemic"—one demanding "action now to protect the health of our nation's young people."[15] That is because nicotine addiction is dangerous, particularly for youth. If that weren't enough, other health harms associated with e-cigarette use are beginning to emerge.

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[13] Lloyd D. Johnston et al., *Monitoring the Future National Survey Results on Drug Use, 1975−2018*, at 2 (2019), https://perma.cc/PQG2-3539.

[14] Press Release, Centers for Disease Control, Progress Erased: Youth Tobacco Use Increased During 2017-2018 (Feb. 11, 2019) (quoting CDC Director Robert Redfield), https://perma.cc/D6BF-L6MF.

[15] U.S. Dep't of Health & Human Servs., Surgeon General's Advisory on E-Cigarette Use Among Youth (Dec. 18, 2018), https://perma.cc/4JC8-Q5XA.

1. E-cigarette use among youth has now reached "epidemic" proportions.

"E-cigarette use is rampant and climbing sharply among middle and high school students." *Nicopure*, 944 F.3d at 275. Between 2017 and 2019, the proportion of high school students nationally who reported e-cigarette use in the past 30 days more than doubled (increasing from 11.7% to 27.5%). For middle school students, it more than tripled (increasing from 3.3% to 10.5%).[16] That means that, in the past month, more than one in four high schoolers and nearly one in ten middle schoolers used e-cigarettes. Of those, 21% of high school users and nearly 9% of middle school users reported daily use.[17] In total, researchers now estimate that 5.3 million youth in the United States used e-cigarettes in 2019, and nearly a million are daily users.[18] These products are now "the most commonly used form of tobacco among youth in the United States"—surpassing cigarettes.[19]

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[16] Karen A. Cullen et al., *E-Cigarette Use Among Youth in the United States, 2019*, 322 J. Am. Med. Ass'n 2095, 2095-96 (2019), published online Nov. 5, 2019, https://perma.cc/LDY8-66FV; Andrea S. Gentzke et al., *Vital Signs: Tobacco Product Use Among Middle and High School Students—United States, 2011-2018*, 68 Morbidity & Mortality Weekly Report 157, 160 (2019), published online Feb. 11, 2019, https://perma.cc/Q92C-VCDM. *See also* Richard Miech et al., Correspondence, *Trends in Adolescent Vaping, 2017-2019*, 381 New Engl. J. Med. 1490 (2019), https://perma.cc/7Q8E-JHAH.

[17] Cullen et al., *supra* note 16, at 2098.

[18] *Id.* at 2100.

[19] Office on Smoking & Health, U.S. Dep't of Health & Human Servs., *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, at vii (2016), https://perma.cc/5A7W-YUAN (hereinafter "SGR 2016"). *See also* Wang et al., *supra* note 7, at 1 (noting that "[e]-cigarettes were the most common cited tobacco product"

The growing prevalence of e-cigarette use among youth is unsurprising, given the industry's intentional campaign to use flavors and marketing to attract them. The vape industry would like to think that the new federal law raising the tobacco sales age to 21 (which applies to e-cigarettes too) erases any concerns about youth, Appellants' Br. 49, as if the legal purchase age ever prevented tobacco companies from targeting young people. Not so. Although sales to those under 21 are now illegal, companies nonetheless have strong economic incentives to maximize their products' attractiveness to youth, just as cigarette companies (many of which now sell e-cigarettes) did in the past.[20] E-cigarette companies are using the same playbook: deploying flavors and marketing techniques to target kids. Without premarket review, they evaded the regulation Congress thought necessary to stem (and prevent a replay of) the public health crisis caused by "Big Tobacco."

Since the lower court's decision, the FDA has issued new Guidance and will now require e-cigarette manufactures to submit premarket review applications in May 2020. That 2020 Guidance, however, did little to change the availability of flavors appealing to adolescent users right now. Although in September 2019 the FDA proposed

among youth in 2019, "followed in order by cigars, cigarettes, smokeless tobacco, hookahs, and pipe tobacco").

[20] Campaign for Tobacco Free Kids, *Tobacco Company Marketing to Kids* (Apr. 10, 2018), https://perma.cc/3KW5-756Q.

"clear[ing] the market" of flavored e-cigarettes pending premarket review,[21] the final Guidance only requires a sales pause for cartridge-based e-cigarette flavors beyond tobacco or menthol.[22] It was announced after JUUL had already removed all its flavors besides tobacco and menthol from the market.[23] And it does not extend to disposable systems, like Puff Bars, that have quickly become a JUUL substitute.[24]

At a minimum, this Court should reject the industry's attempt to undermine the new May 2020 deadline for e-cigarette premarket review applications. There is no reason to overlook the threat of so-called "open tank" systems, as the vape industry and its *amici* would like. Although cartridge-based systems like JUUL have driven the surge in youth e-cigarette use,[25] devices that can be refilled with flavored liquids ("open-tank" systems) may be gaining ground. Consider these examples:

[21] Laurie McGinley, *Trump Moves to Ban Flavored E-Cigarettes*, Wash. Post (Sept. 11, 2019, 2:19 PM), https://perma.cc/3D9Y-2M5G.

[22] 2020 Guidance, *supra* note 4, at 19; Laurie McGinley, *Flavored E-Cigarette Pod Ban Starts Thursday: What It Means for Vapers, Kids and Parents*, Wash. Post (Feb. 5, 2020, 6:00 AM), https://perma.cc/46DB-BAH7.

[23] Angelica LaVito, *E-Cigarette Giant Juul Suspends Sales of All Fruity Flavors Ahead of Looming US Ban*, CNBC (Oct. 17 2019, 1:00 PM), https://perma.cc/3VZ3-DN2M.

[24] Kaplan, *supra* note 2.

[25] *Id.*

These are flavored liquids to be used in open-tank systems, and it does not take an expert or study to see they target young people. Even so, in 2019, the National Youth Tobacco Survey found that two refillable/open-tank e-cigarettes—Suorin and Smok—were the second and third most popular brands, behind JUUL.[26] Particularly as flavored cartridges disappear from the market, still-unregulated and unreviewed open-tank systems may gain popularity among the increasingly addicted youth market.[27] As former FDA Commissioner Scott Gottlieb reflected following the publication of the 2020 Guidance: "the new rules appear to have overlooked different devices that are gaining popularity with kids."[28]

In addition to using flavors to attract youth, e-cigarette advertising appears to target youth, "mimicking," in the Department of Justice's own words, "the strategies previously used by 'Big Tobacco'—to devastating effect—and thus banned for conventional cigarettes."[29] As the Surgeon General noted, these recycled techniques include advertisements on radio, television, and social media with themes "reprised from the most memorable cigarette advertising, including those focused on freedom,

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[26] Cullen et al., *supra* note 16, at 2099; Scott Gottlieb, Opinion, *The FDA Got It Partially Right on E-Cigs. Here's What Else Needs to be Done.*, Wash. Post (Jan. 4, 2020, 4:38 PM), https://perma.cc/AWN6-FULE.

[27] *See* Edwards, *supra* note 5.

[28] Gottlieb, *supra* note 26.

[29] Memorandum in Opposition to Plaintiffs' Motions for Summary Judgement and in Support of Defendants' Cross-Motion for Summary Judgment, *Nicopure Labs, LLC v. FDA* and *Right to be Smoke-Free Coalition v. FDA (consolidated),* CA Nos. 16-878, 16-1210, at 15 (D.D.C. filed Aug. 16, 2016).

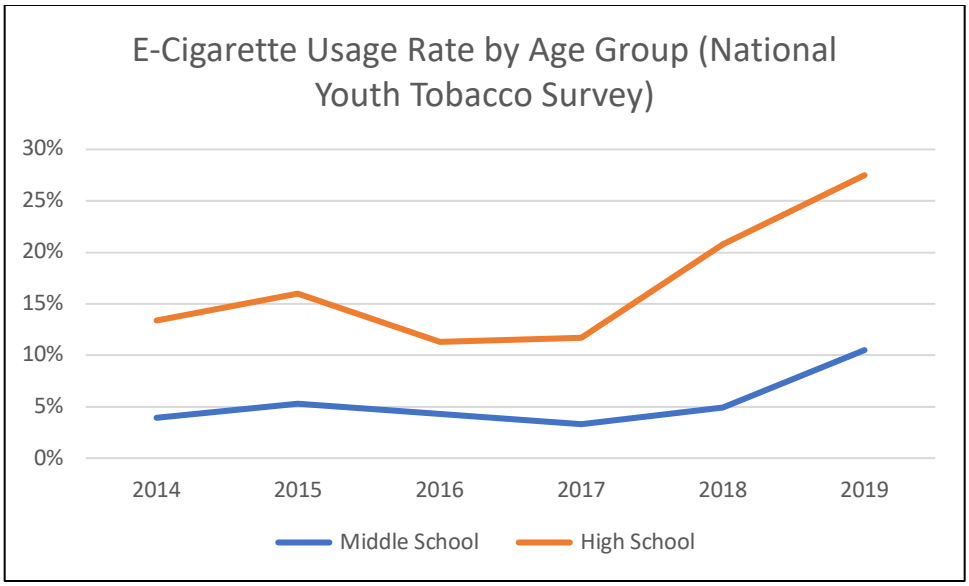
rebellion, and glamor."[30] Unfortunately, the industry's targeting of youth has worked and "put[] a new generation at risk for nicotine addiction."[31]

Premarket review could have prevented, or at least mitigated, this epidemic. The FDA deemed e-cigarettes within the Act's purview (hence subject to premarket review) in 2016, before the crisis escalated. But then it delayed review, contravening Congress's mandate to hold the line and evaluate products before release. Then, after 2017, e-cigarette rates skyrocketed. (*See* chart below.)[32] The consequence is what Congress feared: a new product got a new generation hooked.

[30] SGR 2016, *supra* note 19, at 15, 159, 168.

[31] Press Release, Progress Erased, *supra* note 14.

[32] This chart was created with data from the National Youth Tobacco Survey. *See* René A. Arrazola et al., *Tobacco Use Among Middle and High School Students — United States, 2011-2014*, 64 Morbidity & Mortality Weekly Report 381 (2015), https://perma.cc/FX4P-S4SB; Tushar Singh et al., *Tobacco Use Among Middle and High School Students — United States, 2011-2015*, 65 Morbidity & Mortality Weekly Report 361 (2016), https://perma.cc/3KRX-WUSQ; Ahmed Jamal et al., *Tobacco Use Among Middle and High School Students — United States, 2011-2016*, 66 Morbidity & Mortality Weekly Report 597 (2017), https://perma.cc/AE36-V46M; Teresa W. Wang et al., *Tobacco Product Use Among Middle and High School Students — United States, 2011-2017*, 67 Morbidity & Mortality Weekly Report 629 (2018), https://perma.cc/6QR5-26QJ; Gentzke et al., *supra* note 16.



2. E-cigarette use is a crisis for public health.

Despite the claims of the vaping industry, e-cigarettes are not safe, particularly for youth. And there is no credible evidence that they lead to smoking cessation; instead, they provide an "on ramp" for cigarette use, undermining the progress made in reducing conventional cigarette smoking.

a. The full scope of the health harms associated with e-cigarette use is still unknown.

Although the full scope of the health harms associated with e-cigarette use is still unknown, existing research sets off alarms. Among the most concerning health effects of the growing youth e-cigarette epidemic is the potential to impair brain development for a whole new addicted generation. Nicotine exposure at a young age "may have lasting adverse consequences for brain development."[33] Neuroscience research has

[33] DR at 28,981.

shown that, contrary to earlier assumptions, brain development continues into one's twenties (when it is legal to purchase e-cigarettes).[34] Because nicotine exposure at this younger age induces structural changes in the brain, those who begin to use tobacco as adolescents are more likely to use into adulthood, have more difficulty quitting, and experience deeper levels of addiction.[35]

That is just the beginning of the potential health problems. Although "[t]here has been very little rigorous or sustained research on the effects of e-cigarettes," *Nicopure*, 944 F.3d at 275, the existing evidence raises serious concerns. These include dangerously poor product quality (leading to fires and explosions),[36] child poisonings from nicotine exposure,[37] the use of ingredients (particularly flavorants) that are

[34] *See* Elizabeth S. Scott & Laurence Steinberg, *Rethinking Juvenile Justice* 44 (2010) ("Scientists have found clear evidence that the brain continues to mature through adolescence and into the early twenties, with large-scale structural change taking place during this period.").

[35] SGR 2016, *supra* note 19, at 105.

[36] Between 2015 and 2017, U.S. hospital emergency departments saw an estimated 2035 e-cigarette explosion and burn injuries. *See* Matthew E. Rossheim et al., *Electronic Cigarette Explosion and Burn Injuries, US Emergency Departments 2015-2017*, 28 Tobacco Control 472, 472 (2019), https://perma.cc/LK69-B48M.

[37] Alisha Kamboj et al., *Pediatric Exposure to E-Cigarettes, Nicotine, and Tobacco Products in the United States*, Pediatrics (May 2016), https://perma.cc/SKK4-KQ4Q (the monthly number of calls to the National Poison Data System relating to e-cigarette exposures increased by nearly 1500% between 2012 and 2015).

dangerous to inhale,[38] the ability of users to modify the product in hazardous ways,[39] and more. The outbreak of vaping-related pulmonary illnesses around the country only heightens the concern about youth vaping. As of February 18, 2020, 2,807 confirmed or probable cases of acute lung illness associated with e-cigarette products were reported to the CDC, and 68 deaths have been confirmed.[40]

As the D.C. Circuit concluded, reviewing the evidence just a few months ago: "E-cigarettes are indisputably highly addictive and pose health risks, especially to youth, that are not well understood." *Nicopure*, 944 F.3d at 271. Without premarket review, the FDA cannot assess—much less address—the public health effects of these products.

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[38] Many e-liquids contain chemicals with known risks, including formaldehyde, diacetyl and acetyl propionyl, and various aldehydes. DR at 29,029-31. Even for chemical flavorings that have been "generally recognized as safe for ingestion as food, the health effects of inhalation are generally unknown." SGR 2016, *supra* note 19, at 184. *See also* Scott Gottlieb & Amy Abernethy, *Understanding the Health Impact and Dangers of Smoke and 'Vapor'*, FDA Voices: Perspectives from FDA Leadership and Experts (Apr. 3, 2019), https://perma.cc/DA8Z-5NCA. Rather, "recent research has highlighted the potential toxicity of flavor additives." Jack Bozier et al., *The Evolving Landscape of Electronic Cigarettes: A Systematic Review of Recent Evidence*, CHEST (2020), accepted for publication Dec. 16, 2019. *See, e.g.*, Jessica L. Barrington-Trimis et al., *Flavorings in Electronic Cigarettes: An Unrecognized Respiratory Health Hazard?*, 312 J. Am. Medical Ass'n 2493 (2014), https://perma.cc/6U9F-6MHB (raising concerns about deep inhalation of chemical flavorings).

[39] Suchitra Krishnan-Sarin et al., *E-cigarettes and 'Dripping' Among High-School Youth*, Pediatrics (Feb. 2017), https://perma.cc/KAT7-E4SN.

[40] Centers for Disease Control & Prevention, Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping (last visited Feb. 26, 2020), https://perma.cc/QER3-NBM4 (hereinafter "CDC Outbreak"). Appellants disclaim responsibility, arguing that recent outbreak was "driven" by illicit THC products containing vitamin E acetate. *See* Appellants' Br. 11 n.5. But nearly a fifth of patients did not report using THC-containing products. CDC Outbreak, *supra* note 40.

b. The e-cigarette industry's safety claims are controverted by established research.

The vaping industry and its *amici* argue that the FDA should further delay premarket review because their products are safer than conventional cigarettes. *See* Appellants' Br. 1; CASAA Br. 3. The proper place to raise those claims is with the FDA *during premarket review*. Likely, the vaping industry is attempting to evade that congressionally-mandated process because there is, in fact, little reliable evidence supporting the industry's claims that their products are, on the whole, "appropriate for public health."

For instance, Amicus Michael Siegel claims that "switching from smoking to e-cigarettes improves both respiratory and cardiovascular health." Siegel Br. 6. But as to the respiratory effects, a National Academy of Sciences (NAS) review found only limited evidence for improvement in lung function or reduction of chronic obstructive pulmonary disease exacerbations among adult smokers who switched to e-cigarettes completely or in part.[41] Also, it is simply too soon to tell what the longer-term health effects will be, given the "[d]ecades of chronic smoking . . . needed for development of lung diseases."[42] The industry's claims of comparative cardiovascular benefits are

[41] National Academies of Sciences Engineering & Medicine, *Public Health Consequences of E-Cigarettes* 8 (Jan. 23, 2018), https://perma.cc/U8TH-P5LL (hereinafter "NAS").

[42] Jeffrey E. Gotts et al., *What Are the Respiratory Effects of E-Cigarettes?*, 366 Brit. Med. J. (2019), https://perma.cc/7KNR-T74D.

likewise contested; recent studies have found that use of e-cigarettes or dual use may be associated with *higher* cardiovascular risks.[43]

Moreover, the industry *amici*'s safety and benefits claims are predicated on the false assumption that smokers will switch completely from conventional cigarettes to vape products. Siegel Br. 6; *see also id.* at 4 (reporting benefits for those who "switched completely to e-cigarettes"), 5 (same), 6 (same). In fact, studies demonstrate that the majority of adult e-cigarette users are "dual users."[44] Dr. Siegel and the other industry *amici*, unsurprisingly, do not claim health effects from this use pattern. Additionally, even if safer than cigarettes, "[p]eople addicted to nicotine . . . may be misled into turning to e-cigarettes over evidence-based nicotine reduction therapies." *Nicopure*, 944 F.3d at 275 (citing 79 Fed. Reg. at 29,039).

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[43] *See, e.g.*, Tarang Parekh et al., *Risk of Stroke With E-Cigarette and Combustible Cigarette Use in Young Adults*, Am. J. Preventive Med. (2019), https://perma.cc/VJR2-MERL (finding dual use associated with 1.83 times higher odds of stroke, compared with combustible cigarette smokers); Klaas Frederik Franzen et al., *E-Cigarettes and Cigarettes Worsen Peripheral and Central Hemodynamics as Well as Arterial Stiffness: A Randomized, Double-Blinded Pilot Study*, 23 Vascular Medicine 419 (2018), https://perma.cc/3NNS-SMZ7 (finding acute effects of vaping that suggest a link to increased cardiovascular risk); Talal Alzahrani et al., *Association Between Electronic Cigarette Use and Myocardial Infarction*, 55 Am. J. Prev. Med. 455 (2018), https://perma.cc/J3AN-UBB8 (finding daily e-cigarette use independently associated with increased odds of heart attack).

[44] *See* Office on Smoking & Health, U.S. Dep't of Health & Human Servs., *Smoking Cessation: A Report of the Surgeon General* 541 (2020) (hereinafter "SGR 2020"), https://perma.cc/RBN6-ZYFA.

Instead, "while e-cigarettes have been touted as less risky than combustible cigarettes," as the D.C. Circuit concluded just a few months ago, "those claims remain unproved." *Nicopure*, 944 F.3d at 275.

Furthermore, the Vape Appellants claim that their products may help current smokers quit. Yet the Surgeon General Report on Smoking Cessation, released just last month (January 2020), determined that "there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation."[45] Reviews of research by the FDA, the NAS, and the U.S. Preventive Services Task Force—which sets the standards for which smoking cessation services the Affordable Care Act covers—have likewise found insufficient evidence to support the industry's cessation claims.[46] If anything, there is growing evidence that e-cigarettes may inhibit cessation. Several studies and meta-analyses have found that the odds of quitting were lower for smokers using e-cigarettes. In fact, the FDA itself noted several studies that found statistically significantly worse quit rates for smokers who used e-cigarettes than for those who did not.[47] The industry's position would have the Court disregard the findings of the Surgeon General, reputable scientific institutions, and the FDA itself.

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[45] *Id.* at 7.

[46] *See* DR at 29,037; NAS, *supra* note 41, at 10; U.S. Preventive Task Force, *Final Recommendation Statement: Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions* (Sept. 2017), https://perma.cc/9TCL-2DFP.

[47] *See* DR at 29,028, 29,037.

c. E-cigarettes provide a trendy "on ramp" for youth tobacco use.

Rather than fostering transition away from combustibles products or smoking cessation, existing and growing evidence demonstrates that youth e-cigarette use is a gateway into other tobacco products. "[K]ids who start on e-cigarettes are actually more likely than non-user peers to migrate to smoking tobacco,"[48] according to evidence from the NAS and the Surgeon General.[49] A growing body of evidence[50] raises the specter that the proliferation of youth e-cigarette use could, over time, undermine our nation's progress in reducing smoking rates. As the Surgeon General has cautioned, "the potential benefit of e-cigarettes for cessation among adult smokers cannot come at the

[48] Alex M. Azar & Scott Gottlieb, Opinion, *We Cannot Let E-Cigarettes Become an On-Ramp for Teenage Addiction*, Wash. Post (Oct. 11, 2018, 8:05 AM), https://perma.cc/XLT4-TM4P.

[49] *See* NAS, *supra* note 41, at 10; SGR 2016, *supra* note 19, at 56.

[50] Kaitlyn M. Berry, *Association of Electronic Cigarette Use With Subsequent Initiation of Tobacco Cigarettes in US Youths*, 2 JAMA Network Open (Feb. 1, 2019), https://perma.cc/76UX-UH92 (finding youth who used e-cigarettes were more than four times more likely to subsequently try cigarettes); Jessica L. Barrington-Trimis et al., *E-Cigarettes and Future Cigarette Use*, Pediatrics 138(1) (2019), https://perma.cc/37QB-MG3L (reporting that e-cigarette users were more than six times likely to initiate cigarettes as never e-cigarette users, and that associations were *stronger* in adolescents with no intention of smoking at initial evaluation); Samir Soneji et al., *Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Youth Adults: A Systematic Review and Meta-analysis*, 171 JAMA Pediatrics 788 (Aug. 2017), https://perma.cc/8W4H-HVK2 (meta-analysis finding "consistent and strong evidence" associating e-cigarette use with increased odds of subsequent cigarette smoking initiation and current cigarette smoking).

expense of escalating rates of use of these products by youth."[51] But by delaying premarket review, that is exactly what the FDA has let happen.

B. Cigar smoking increases the risk of devastating health conditions and death, and it has particularly troubling medical consequences for youth.

While the district court and *amici* have focused considerable attention on e-cigarettes, the FDA has also allowed new variants of cigars to enter the market without review—and has delayed review of them until 2021, six years after they were deemed within the purview of the TCA. These cigars are not subject to the strict controls on cigarettes and have been manufactured in flavors and marketed to target youth. Given the devastating health consequences of cigar smoking, the FDA's violation of the TCA in failing to require cigar industry premarket review cannot be ignored.

1. New little cigars and cigarillos are designed and marketed to attract youth, causing a spike in use among young people.

Cigar use is conventionally thought of as largely confined to older men smoking in lounges or for celebratory occasions. But the current cigar landscape looks quite different. New candy and fruit-flavored cigars have entered the market, acting as a workaround for the tobacco industry, which under the TCA cannot sell flavored cigarettes in the U.S. (except menthol). 21 U.S.C. § 387g. Because there is no prohibition on flavored cigars, tobacco manufacturers have been quick to modify cigars to imitate

[51] SGR 2020, *supra* note 44, at 25.

cigarettes in size and appearances—and then add flavorings. These PrimeTime "wild berry" little cigars are one example:

Like cigarettes (and now e-cigarettes), cigar companies target youth with flavors and marketing. Since 2008, the number of unique cigar flavors on the market has more than doubled from 108 to 250.[52] Tobacco industry documents show "that tobacco companies marketed flavored little cigars and cigarillos to youth and to African Americans to facilitate their uptake of cigarettes."[53] The modern cigar industry's efforts were well summed up by one FDA-cited study: according to a focus group of 14- to 18-year-olds, "cigars were easy to obtain," "new brands were targeting youth," and "the products were prominent in rap videos." 79 Fed. Reg. 23,141, 23,158 (Apr. 25, 2014).

[52] Cristine D. Delnevo et al., *Changes in the Mass-Merchandise Cigar Market since the Tobacco Control Act*, 3 Tob. Regul. Sci. S8 (Apr. 2017), https://perma.cc/KDR8-CREE. *See also* Campaign for Tobacco Free Kids, *The Flavor Trap: How Tobacco Companies Are Luring Kids with Candy-Flavored E-Cigarettes and Cigars* (Mar. 15, 2017), https://perma.cc/5844-XQ67.

[53] SGR 2016, *supra* note 19, at 11.

The tobacco industry evidently hopes that smaller and cheaper flavored cigarillos will lead to greater tobacco use over time.

The strategy has paid off—all to the detriment of public health. Flavored cigar sales skyrocketed by 50 percent between 2008 and 2015, taking over half of the entire cigar market.[54] More and more young people are smoking cigars each day the FDA does not act. Cigarillo popularity has exploded in particular communities.[55] According to the 2019 National Youth Tobacco Survey, 12.3% of African American high school students reported smoking cigars in the past thirty days—more than one-and-a-half times the proportion of white high school students who did.[56]

While particularly prevalent among African American youth, cigar use has now overtaken conventional cigarette use among all high school students. High school boys and girls are now more likely to smoke cigars than cigarettes.[57] Each year without premarket review, more than two million youth try this deadly product, potentially starting on the path to a deadly addiction.[58] For young people, cigars are no longer an "alternative" to cigarettes, but a preferred tobacco product.

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[54] Delnevo et al., *supra* note 52.

[55] Amy L. Nyman et al., *Little Cigars and Cigarillos: Users, Perceptions, and Reasons for Use*, 2 Tobacco Regul. Sci. 239 (2016), https://perma.cc/NR8D-JHLS.

[56] Wang et al., *supra* note 7, 13 tbl. 2.

[57] *Id.*

[58] U.S. Dep't Health & Human Servs., Substance Abuse & Mental Health Servs. Admin., *2018 National Survey on Drug Use and Health: Detailed Tables*, at tbl. 4.4B (2019), https://perma.cc/5BRY-GKJE.

2. Cigar smoking has devastating health consequences.

The devastating health consequences of cigar smoking are well-established. "All cigar smokers have an increased risk of oral, esophageal, laryngeal, and lung cancer compared to non-tobacco users."[59] Users also experience an "increased risk of heart and pulmonary disease," particularly chronic obstructive pulmonary disease.[60] Compared to nonsmokers, cigar smokers face increased risk of both fatal and nonfatal strokes.[61] All told, cigar smoking is "responsible for approximately 9,000 premature deaths"—or the loss of "almost 140,000 years of potential life"—every year.[62]

Given what is known about the health effects of smoking cigarettes, the devastating health effects of smoking cigars is no surprise. Just like cigarettes, cigars contain tobacco and nicotine, and burning them creates an array of dangerous chemicals.[63] The FDA reported that a single "cigar can contain as much tobacco as a whole pack of cigarettes, and nicotine yields from smoking a cigar can be up to eight times higher than yields from smoking a cigarette."[64]

The cigar industry dismisses these health concerns, assuming that many of its products will be considered "substantially equivalent" to existing cigars, and that cigar

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[59] DR at 29,020.
[60] *Id.*
[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] *Id.* at 29,022.

manufacturers will therefore not have to prove that they are "appropriate for the protection of the public health." But that is no excuse for the FDA to absolve cigar companies of their obligations to file such applications. Indeed, if the issue were so clear, then the cigar industry would have already filed such applications and would not be seeking more delay. With the new designs and marketing of cigar products, proving "substantial equivalence" might not be so easy. That is exactly why the FDA must require review. Congress required the FDA to be its watchdog. And although they may not have gained the attention that e-cigarettes have, little cigars and cigarillos likewise threaten to reduce the gains made on reducing tobacco use.

CONCLUSION

Amici respectfully request that the Court affirm the District Court's decision.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 29(a)(5) because it contains 6,476 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f). This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in 14-point Garamond font, a proportionally spaced typeface.

/s/ Rachel Bloomekatz
Rachel Bloomekatz

CERTIFICATE OF SERVICE

I hereby certify that on February 27, 2020, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the appellate CM/ECF system. All participants are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Rachel Bloomekatz
Rachel Bloomekatz

ADDENDUM: IDENTITY OF *AMICI CURIAE*

Public Health Law Center

The Public Health Law Center is a public interest legal resource center dedicated to improving health through the power of law and policy, grounded in the belief that everyone deserves to be healthy. Located at the Mitchell Hamline School of Law in Saint Paul, Minnesota, the Center helps local, state, national, Tribal, and global leaders promote health by strengthening public policies. For twenty years, the Center has worked with public officials and community leaders to develop, implement, and defend effective public health laws and policies, including those designed to reduce commercial tobacco use, improve the nation's diet, encourage physical activity, protect the nation's public health infrastructure, and promote health equity. The Center has been involved with more than sixty briefs as amicus curiae filed in the highest courts in the United States and before international bodies. Having worked for two decades to ensure that the public is protected from the dangers of tobacco use and nicotine addiction, the Center is particularly well-suited to address the importance of the FDA's premarket of tobacco products.

Action on Smoking and Health

Action on Smoking and Health (ASH) is the nation's oldest anti-tobacco organization. ASH is dedicated to ending the global death, disease, and damage caused by tobacco consumption and nicotine addiction through public policy, litigation, and public education. The marketing and sale of tobacco products is a violation of basic human rights, and ASH works to end the tobacco epidemic by attacking its root—the tobacco industry.

American Academy of Allergy, Asthma and Immunology

The American Academy of Allergy, Asthma & Immunology (AAAAI) is a professional organization with over 7,000 members in the United States, Canada, and 72 other countries dedicated to the advancement of the knowledge and practice of allergy, asthma, and immunology for optimal patient care. As such, AAAAI is dedicated to reducing and/or preventing the effects of tobacco on allergy, asthma, and immunology patients, and safeguarding the public from the deleterious effects of tobacco products.

American College of Chest Physicians

The American College of Chest Physicians is the global leader in advancing best patient outcomes through innovative chest medicine education, clinical research, and team-based care. With more than 19,000 members representing 100+ countries around the world, its mission is to champion the prevention, diagnosis, and treatment of chest diseases through education, communication, and research. As such, CHEST is dedicated to the prevention of tobacco-related diseases.

American College of Occupational and Environmental Medicine
Established in 1916, the American College of Occupational and Environmental Medicine (ACOEM) is an international society of 4,500 occupational and environmental medicine (OEM) physicians. The OEM physician has the knowledge and skills to provide evidence-based clinical evaluation and treatment of injuries and illnesses that are occupationally and/or environmentally related. In addition, the OEM physician's skill and expertise includes understanding health risks, clinical practice guidelines for chronic disease management, and current practices in disease detection, prevention, and treatment. Members of ACOEM have the ability to assess the causes and occupational impact of respiratory disorders and pulmonary impairment.

Americans for Nonsmokers' Rights
Americans for Nonsmokers' Rights is a member-supported national advocacy organization which promotes the protection of everyone's right to breathe smokefree air, educates the public and policy-makers regarding the dangers of secondhand smoke, works to prevent youth tobacco addiction, and tracks and reports on the adversarial effects of the tobacco industry.

American Medical Association
The American Medical Association (AMA) is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policy making process. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every state and in every medical specialty.

American Public Health Association
The American Public Health Association (APHA) champions the health of all people and all communities, strengthens the profession of public health, shares the latest research and information, promotes best practices, and advocates for public health policies grounded in research. APHA represents over 20,000 individual members and is the only organization that combines a nearly 150-year perspective and a broad-based member community with an interest in improving the public's health. APHA advocates for tobacco control measures to protect the public's health from the adverse effects of tobacco products.

American Thoracic Society
Founded in the 1905, the American Thoracic Society is a medical professional society comprised of over 16,000 physicians, scientists, nurses, respiratory therapists, and allied

health professionals dedicated to the prevention, detection, treatment, cure, and research of pulmonary disease, critical care illness, and sleep disordered breathing. Our members seek to improve health through research, education, clinical care, and advocacy. As respiratory experts, our members are all too familiar with disease, death, and emotional destruction caused by tobacco products.

NAATPN, Inc.

NAATPN, Inc. works to address the health impact of tobacco products on African Americans through education and advocacy. It is the parent organization of the National African American Tobacco Prevention Network, a Centers for Disease Control and Prevention-funded network that focuses on assessing the impact of tobacco within disparate populations, identifying gaps in data, crafting interventions, and conducting research involving African Americans and tobacco use.

National Association for the Medical Direction of Respiratory Care

The primary mission of the National Association for the Medical Direction of Respiratory Care (NAMDRC) is to improve access to quality care for patients with respiratory disease by removing regulatory and legislative barriers to appropriate treatment. NAMDRC supports efforts to reduce tobacco-related disease and addiction through effective regulation of all tobacco products.

National Medical Association

As the nation's oldest and largest organization representing African American physicians and health professionals in the United States, the National Medical Association (NMA) has led the fight for better medical care and opportunities for all Americans, with a strong focus on health issues related to communities of color and the medically underserved, including the targeting of young people of color with tobacco advertising and increased availability of flavored tobacco products. The NMA is dedicated to reducing and eliminating disparities in health and improving the lives of our patients, their families, and their communities.