No. 21-3902

IN THE UNITED STATES COURT OF
APPEALS FOR THE SIXTH CIRCUIT

BREEZE SMOKE, LLC,

Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

ON PETITION FOR REVIEW OF A FINAL MARKETING DENIAL ORDER
BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION
FDA Submission No. PM0000983

UNOPPOSED BRIEF OF *AMICI CURIAE* MEDICAL AND PUBLIC HEALTH GROUPS IN SUPPORT OF RESPONDENT

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DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1(a) and 6th Cir. R. 26.1, *amici curiae* are all non-profit organizations committed to advancing the public health. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

Dated: December 17, 2021

/s/ Jacquelyn A. Klima
Jacquelyn A. Klima (P69403)
Lead counsel for *Amici Curiae*

Amici medical, public health, and community organizations submit this brief in support of Respondent United States Food and Drug Administration ("FDA") and urge the Court to uphold the Final Marketing Denial Order ("MDO") issued to Petitioner Breeze Smoke, LLC ("Petitioner" or "Breeze Smoke") because the MDO was not arbitrary and capricious, FDA did not adopt a product standard requiring notice-and-comment rulemaking, and vacatur of the MDO would harm public health.

STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici are the following state and national medical, public health, and community organizations: American Academy of Family Physicians, American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, American Medical Association, Campaign for Tobacco-Free Kids, Ohio State Medical Association, Parents Against Vaping e-cigarettes and Truth Initiative (collectively, "*amici*" or "medical and public health groups"). From physicians who counsel their young patients and their parents about the hazards of tobacco use, to organizations with formal programs to help users quit, to groups representing parents and families struggling to free young people from nicotine addiction, each of these organizations works on a daily basis to reduce the devastating health harms of tobacco products,

including electronic nicotine delivery system ("ENDS" or "e-cigarette") products.[1] Accordingly, *amici* have a direct and immediate interest in ensuring that Petitioner's highly-addictive and kid-appealing flavored disposable e-cigarettes not be permitted on the market, which can only be assured by upholding the MDO.

Amici also have a special interest in this case because many of the groups were plaintiffs in *American Academy of Pediatrics v. FDA*, in which they obtained a federal court order (1) establishing new deadlines for the required submission of premarket applications for e-cigarette products, and (2) limiting the time period that e-cigarettes may remain on the market without the required premarket orders. 379 F. Supp. 3d 461 (D. Md. 2019); 399 F. Supp. 3d 479 (D. Md. 2019), *appeal dismissed sub nom. In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020). *Amici* therefore have a strong interest in ensuring that the premarket review process now functions to protect the public health by taking off the market flavored e-cigarette products, like Petitioner's, that threaten the health and well-being of young people, with little evidence of any countervailing benefit to adult cigarette smokers.

STATEMENT OF COMPLIANCE WITH RULE 29(a)

Amici represent that no party's counsel authored this brief in whole or in part, neither the parties nor their counsel contributed money intended to fund preparing or submitting this brief, and no person—other than *amici*, their members, or their

[1] This brief uses the terms "e-cigarette" and "ENDS" interchangeably.

counsel—contributed money that was intended to fund preparing or submitting this brief. This brief is filed with the consent of the parties.

INTRODUCTION AND SUMMARY OF ARGUMENT

Petitioner exclusively manufactures flavored, disposable e-cigarettes, *see* Corrected Opening Brief of Petitioner, ECF No. 30 (Nov. 16, 2021) ("Pet'r Br.), at 15—the very type of e-cigarette product that is now most popular among youth. FDA denied Petitioner's application to market its youth-appealing e-cigarettes because the applications lacked sufficient evidence demonstrating that Petitioner's products—available in flavors such as Blueberry Lemon and Strawberry Cream—provide a benefit in helping adult smokers to stop smoking cigarettes that would be adequate to outweigh the known risks to youth. *See* Petitioner's Appendix, ECF No. 26 (Nov. 12, 2021) ("App."), at 1, 5-6.

I.A. In light of the mountain of evidence of youth attraction to flavored e-cigarettes, it was entirely reasonable for FDA to require Petitioner to submit robust, product-specific evidence—in the form of a randomized control trial, longitudinal cohort study, or other similarly rigorous evidence—of the benefit of its products vs. unflavored (i.e., tobacco-flavored) products in aiding smokers to stop smoking. It was not arbitrary and capricious for FDA to then issue an MDO once it determined that Petitioner failed to provide such evidence.

I.B. Moreover, contrary to Petitioner's assertion, FDA carefully considered the public health impact of its decision on applications submitted by Petitioner and other flavored ENDS manufacturers—in fact, such impact was central to its decision to deny Petitioner's application.

I.C. It also was not arbitrary and capricious for FDA to conclude that youth access and marketing restrictions would be insufficient to adequately reduce the risk of youth initiation of Petitioner's products given (1) FDA's own experience with these types of restrictions and (2) other real-world data showing that, with respect to flavored e-cigarettes, these restrictions are, by their nature, insufficient to prevent youth usage of these products, given their intense appeal to young people.

II. Contrary to Petitioner's argument, FDA—in denying Petitioner's application for failure to provide rigorous studies showing that its flavored e-cigarettes help smokers stop smoking—did not adopt a product standard requiring notice-and-comment rulemaking. Rather, the agency set forth the types of evidence that may be sufficient to market new, flavored products in the absence of a product standard prohibiting such flavors.

III. Finally, Petitioner asks the Court to order FDA to allow its products to remain on the market while it conducts the required studies. Allowing Petitioner's flavored, disposable e-cigarettes to remain on the market for even one more day

poses a significant risk to our children with no countervailing public health benefit. Therefore, Petitioner's requested relief, if granted, would harm public health.

ARGUMENT

I. The MDO Was Not Arbitrary and Capricious.

A. Given the overwhelming evidence of youth attraction to flavored e-cigarettes, it was reasonable for FDA to require robust and product-specific evidence that Petitioner's flavored products help smokers to stop smoking more effectively than unflavored e-cigarettes.

In determining if an e-cigarette is "appropriate for the protection of the public health" ("APPH")—the standard for a marketing order under the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 et. seq. ("TCA")—FDA must weigh two competing factors: (1) the likelihood that the product will help existing users stop using tobacco products vs. (2) the likelihood that the product will lead non-tobacco users, including youth, to begin using tobacco products. *See* 21 U.S.C. § 387j(c)(4). When one factor weighs heavily against a certain finding, the only way to overcome it is if the competing factor weighs even more strongly in favor of the finding. Applying this to e-cigarettes, FDA found the evidence overwhelming that flavors appeal to youth more than tobacco-flavored products—and the evidence is even stronger with respect to disposable flavored e-cigarettes, the only type of product subject to the MDO issued to Petitioner. Given this unequivocal evidence that

flavors pose a greater degree of risk of youth uptake compared to tobacco-flavored products, it was entirely reasonable for FDA to require "the strongest types of evidence" demonstrating that, compared to tobacco-flavored products, flavored products like Petitioner's benefit smokers by helping them to stop smoking cigarettes and to issue an MDO for failure to furnish such evidence. App. 9.

The impact of a product on youth initiation is particularly critical because, as FDA noted, "use of tobacco products, no matter what type, is almost always started and established during adolescence when the developing brain is most vulnerable to nicotine addiction." App. 11-12. Whereas "almost 90% of adult daily smokers started smoking by the age of 18…youth and young adults who reach the age of 26 without ever starting to use cigarettes will most likely never become a daily smoker." App. 12. As FDA reasonably concluded, "[b]ecause of the lifelong implications of nicotine dependence that can be established in youth, preventing tobacco use initiation in young people is a central priority for protecting population health." *Id.*

1. FDA found "robust and consistent" evidence that flavored e-cigarettes, like Petitioner's, are particularly attractive to youth.

As FDA explained in the Technical Project Lead Review ("TPL Review") for Petitioner's products, e-cigarettes are the most popular tobacco product among youth, with more than 3.6 million young people reporting current use in 2020, according to the National Youth Tobacco Survey ("NYTS"). *Id.* Nearly one in five (19.6%) U.S. high school students were current e-cigarette users in 2020—about the

same level as in 2018 when the U.S. Surgeon General first declared youth e-cigarette use an "epidemic." App. 11-12.[2]

Flavors, as FDA correctly found, are driving this youth vaping epidemic. *See* App. 12 ("The evidence shows that the availability of a broad range of flavors is one of the primary reasons for the popularity of ENDS among youth."). "[T]he flavoring[s] in tobacco products (including ENDS) make them more palatable for novice youth and young adults, which can lead to initiation, more frequent and repeated use, and eventually established regular use." App. 13. In 2020, 84.7% of high school e-cigarette users reported using a flavored product. App. 12. And according to data from the FDA and National Institutes of Health's Population Assessment of Tobacco and Health ("PATH") Study,[3] over 93% of youth reported

[2] Since the time that FDA issued the challenged MDO, the 2021 NYTS data has become available. *See* Eunice Park-Lee et al., Notes from the Field: *E-Cigarette Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021*, 70 MORBIDITY & MORTALITY WKLY. REP. 1387, 1387 (2021), https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039a4-H.pdf. Even during the midst of the COVID-19 pandemic, over 2 million high school and middle school students reported current e-cigarette use. *Id.* at 1387. The Centers for Disease Control and Prevention has cautioned against comparing this data to previous survey years due to methodology changes. *Id.* Whereas previous years' surveys were conducted entirely in-school, the 2021 survey included both in-school and at-home responses; students who completed surveys in school reported higher e-cigarette use, suggesting that rates may have been much higher had the survey been conducted entirely in schools as with previous surveys.

[3] *See FDA and NIH Study: Population Assessment of Tobacco and Health*, FDA, https://www.fda.gov/tobacco-products/research/fda-and-nih-study-population-assessment-tobacco-and-health (last updated Oct. 1, 2021).

that their first e-cigarette product was flavored and 71% of current youth e-cigarette users reported using e-cigarettes "because they come in flavors I like." App. 12-13. As this Court found in denying Petitioner's motion for an emergency stay of the MDO, "[f]lavored ENDS products especially appeal to children." *Breeze Smoke, LLC v. FDA*, 18 F.4th 499, 505 (6th Cir. 2021).

Petitioner's products are not only flavored, but disposable, making them even more appealing to young people. Indeed, use of disposable e-cigarettes by youth has surged in recent years. Between 2019 and 2020, "there was a ten-fold increase (from 2.4% to 26.5%) among high school current e-cigarette users" reporting using disposable products. App. 14. By 2021, disposables had become the most commonly used type of e-cigarette among youth, used by over half (55.8%) of youth e-cigarette users.[4]

Petitioner suggests that its products are not used by minors because the average age of the respondents in a customer survey it conducted was 34.1 years. Pet'r Br. 17. Not only does this finding leave open the possibility that a substantial percentage of its customers are below the legal age of 21, but it is unlikely that young people were proportionately represented among those surveyed, since responses were solicited by request from customers in retail stores. *See* App. 161-62. In

[4] Park-Lee et al., *supra* note 2, at 1387.

denying a stay of the MDO, this Court found Petitioner's survey "suggests biased respondents." *Breeze Smoke*, 18 F.4th at 506.

More fundamentally, the salient point is not whether a particular brand of flavored e-cigarette, or even a particular kind of flavored e-cigarette device, is popular among youth at a specific point in time—youth preference for particular brands and types of e-cigarettes is fluid, as FDA found. App. 14. But while youth preference for brand and device type is fluid, youth preference for flavors is not. Simply put, it has been consistently true that flavored e-cigarettes attract youth. *See id.* ("[W]hen FDA changed its enforcement policy to prioritize pod-based flavored ENDS, which were most appealing to youth at the time, we subsequently observed a substantial rise in use of disposable flavored ENDS…underscoring the fundamental role of flavor in driving appeal."). It is undeniable that Petitioner's flavored disposable products—which come in flavors like Blueberry Lemon, Pomegranate Berry Mint, and Strawberry Cream, App. 5-6—have the features that make e-cigarettes attractive to youth.

The data leaves little doubt that flavored e-cigarettes, and especially disposable flavored e-cigarettes, appeal to youth more than unflavored products. The "published literature" showing "the substantial appeal to youth of flavored ENDS…is robust and consistent" and this youth preference for flavored products "is

consistently demonstrated across large, national surveys and longitudinal cohort studies." App. 13.

2. As FDA found, flavored e-cigarettes pose a direct threat of addiction and other health harms to young people.

Petitioner's products contain nicotine, which is "among the most addictive substances used by humans." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 270 (D.C. Cir. 2019). In its TPL Review of Petitioner's products, FDA noted the factors making "[y]outh and young adult brains . . . more vulnerable to nicotine's effect than the adult brain due to ongoing neural development." App. 14. According to the Surgeon General, adolescents are more likely to experience nicotine dependence at lower levels of exposure than adults and can feel dependent after just minimal exposure and within a relatively short period of time. *See* FDA-BREEZESMOKE-000399.[5] FDA also found that the high prevalence of youth e-cigarette use was increasing nicotine dependence among young people. App. 14. In 2019, as FDA noted, an estimated 30.4% of middle and high school e-cigarette users reported frequent use (i.e., use on more than 20 of the previous 30 days), and even more alarming, 21.4% of high school users and 8.8% of middle school users reported *daily*

[5] Although this report is part of the administrative record, *see* Administrative Record Index, ECF No. 15 (Oct. 21, 2021), at 2, Doc. 5, it was not included in Petitioner's Appendix. Full citation: OFFICE OF THE SURGEON GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS 24 (2012), https://www.ncbi.nlm.nih.gov/books/NBK99237/pdf/Bookshelf_NBK99237.pdf.

use, a strong indication of deep nicotine addiction. *Id.* Both frequent and daily use prevalence among high school students were even higher in both 2020[6] and 2021, with 43.6% of high school e-cigarette users reporting frequent use and 27.6% reporting daily use in 2021.[7] In addition to the risk of addiction, FDA found that youth exposure to nicotine "can induce short and long-term deficits in attention, learning, and memory." App. 14. FDA cited other health harms from e-cigarettes as well, including "associations between ENDS use and self-reported history of asthma, chronic bronchitis, emphysema, or chronic obstructive pulmonary disease with increased ENDS use (i.e., daily use) relating to increased odds of disease." App. 15.

FDA also noted the data documenting a risk of progression from e-cigarettes to other tobacco products. In the TPL Review of Petitioner's products, FDA cites a "systematic review and meta-analysis that summarized nine prospective cohort studies" finding "significantly higher odds of smoking initiation . . . and past 30-day combusted cigarette use . . . among youth who had used ENDS as compared to youth who had not used ENDS." *Id.* A 2018 report by the National Academies of Sciences, Engineering, and Medicine found "substantial evidence that ENDS use

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[6] Teresa W. Wang et al., *E-cigarette Use Among Middle and High School Students – United States, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1310, 1310 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf.

[7] Park-Lee et al., *supra* note 3, at 1388 tbl.

increases [the] risk of ever using combusted tobacco cigarettes among youth and young adults." *Id.* A nationally representative analysis also found that from 2013 to 2016, youth e-cigarette use was associated with more than four times the odds of trying combustible cigarettes and nearly three times the odds of current combustible cigarette use. *See* FDA-BREEZESMOKE-003360.[8] Thus, the threat of flavored e-cigarettes is not just to the health of youth today; it also is a threat to their future health by increasing the risk that they will progress to a lifetime of addiction to even more hazardous tobacco products.

3. FDA acted reasonably in requiring robust evidence showing that flavored e-cigarettes help smokers stop smoking more effectively than unflavored products.

Precisely because the evidence that flavored tobacco products appeal to youth is so "robust and consistent," App. 13, it was entirely reasonable for FDA to require similarly "robust and reliable" evidence showing that flavored e-cigarettes are more effective in helping smokers stop smoking than unflavored products, and that this benefit "is significant enough to overcome the risk to youth." App. 17. Both the publicly available evidence, as well as the data submitted by Petitioner, fall woefully short.

[8] This study is part of the administrative record, *see* Administrative Record Index at 6, Doc. 48, but was not included in Petitioner's Appendix. Full citation: Kaitlin M. Berry et al., *Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in US Youths*, 2 JAMA NETWORK OPEN 1, 7 (2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425.

"[I]n contrast to the evidence related to youth initiation—which shows clear and consistent patterns of real-world use that support strong conclusions—the evidence regarding the role of flavors in promoting switching among adult smokers is far from conclusive." App. 17-18. For example, a systematic review that examined consumer preference for various e-cigarette attributes found "inconclusive evidence" as to whether flavored e-cigarettes assisted smokers in quitting smoking.[9] As FDA accurately concluded, "the literature does not establish that flavors differentially promote switching amongst ENDS users in general." App. 18. This Court's own assessment was that Petitioner's own review of the scientific literature "offers mixed findings on flavored ENDS products." *Breeze Smoke*, 18 F.4th at 506. Thus, it was entirely reasonable for the FDA to require Petitioner to demonstrate the effectiveness of its flavored products in helping smokers stop smoking through randomized control trials, longitudinal cohort studies, or other similarly rigorous studies.

Instead of doing rigorous scientific studies, Petitioner conducted a customer survey showing that 92% of those surveyed "stated that flavored e-liquids were important to them in choosing to vape instead of smoke cigarettes." App. 164; *see also* Pet'r Br. 18. This survey suffers from at least two critical deficiencies. First,

[9] Samane Zare et al., *A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type*, 13 PLoS ONE 1, 12 (2018), https://pubmed.ncbi.nlm.nih.gov/29543907/.

as this Court recognized in its Order Denying a Stay, the survey, submitted via a Google Form, likely contained "biased respondents" because responses were solicited from customers in retail stores. *Breeze Smoke*, 18 F.4th at 506. Second, such surveys measure only users' beliefs about their experience with flavored products; they prove nothing about whether the use of flavors actually affects smoking behavior when compared to unflavored products. *See* App. 19 ("Consumer perception studies (surveys or experiments) typically assess outcomes believed to be precursors to behavior, such as preferences or intentions related to new products, but are not designed to directly assess actual product use behavior."). Petitioner presented no studies showing that users of their flavored products were more likely to stop smoking cigarettes than users of tobacco-flavored products. Only the kinds of rigorous studies required by FDA—measuring the extent to which smokers actually stop smoking cigarettes using flavored products vs. using tobacco-flavored products—can establish the link between flavors and smoking behavior.

4. FDA's requirement for product-specific evidence showing the comparative benefit of flavored vs unflavored e-cigarettes in helping smokers to stop smoking was reasonable.

In its Order Denying a Stay, this Court correctly rejected Petitioner's argument that FDA unreasonably imposed different evidentiary standards for assessing risks versus benefits of flavored products. *Breeze Smoke*, 18 F.4th at 508.

FDA reasonably relied on general scientific literature to show the special appeal of flavored e-cigarettes to youths because, in the Court's words, "those risks are understood as a matter of scientific consensus." *Id.* Thus, there is no question that each of Petitioner's products has the primary characteristic—flavors—that, according to the scientific consensus, is attracting young people to e-cigarettes. As discussed, *supra* p. 9, the popularity of certain brands and devices among youth may vary over time, but the presence of flavors is the constant factor in youth appeal. FDA also found that no such scientific consensus exists on whether flavors help cigarette smokers stop smoking to a greater degree than tobacco-flavored e-cigarettes. *See* App. 17-18. It was, therefore, entirely reasonable for FDA to require product-specific evidence to support this claim.

Given the overwhelming evidence that flavored e-cigarettes have addicted millions of young people to nicotine and the relative absence of evidence that flavored e-cigarettes confer any advantage over tobacco-flavored products in helping people to stop smoking cigarettes, there was nothing arbitrary and capricious about FDA's requirement of scientifically-valid and product-specific studies to demonstrate that Petitioner's flavored products help cigarette smokers stop smoking so substantially as to outweigh their indisputable risks to youth.

B. FDA considered the impact that its MDOs would have on public health.

Petitioner claims that FDA failed to consider the impact that its MDOs of flavored e-cigarettes—both as to Petitioner's products and as to other e-cigarettes subject to MDOs—would have on public health. Pet'r Br. 49. According to Petitioner, FDA did not consider the risk that taking e-cigarettes off the market would cause millions of smokers to migrate back to smoking cigarettes. *Id.* Contrary to Petitioner's account, the impact of taking flavored products like Petitioner's off the market was at the core of the agency's entire analysis, and in fact, the primary reason for denying Petitioner's application. Indeed, this Court has recognized that "the FDA likely properly concluded that [Petitioner] failed to show that its products adequately protected the public health . . . ." *Breeze Smoke*, 18 F.4th at 508.

Petitioner's argument assumes that flavored products confer an advantage over tobacco-flavored products in helping smokers stop smoking which was not considered by FDA, but this is precisely the proposition that FDA found unproven by the general scientific literature and by Petitioner's failure to do the kind of studies necessary to demonstrate such a benefit from its flavored products. The MDO is based on the agency's entirely reasonable conclusion that it does not benefit public health to allow the marketing of products that have a common characteristic—flavors—that drives youth appeal but has no countervailing public health benefit in

aiding cigarette smokers to stop smoking. *See, e.g.*, App. 9 ("[T]obacco-flavored ENDS may offer the same type of public health benefit as flavored ENDS, i.e., increased switching and/or significant reduction in smoking, but do not pose the same degree of youth uptake."). Furthermore, "the literature does not establish that flavors differentially promote switching amongst ENDS users in general." App. 18.

Petitioner points specifically to "former adult smokers who have switched to less-harmful e-cigarettes" as a group that FDA failed to consider in rendering its decision. Pet'r Br. 50. However, FDA did consider these adult e-cigarette users, comparing their use of flavored products with that of youth. The data show that "[y]outh users are more likely to use flavored ENDS than adult ENDS users." App. 15; *see also* App. 12. This finding suggests that the availability of flavors—or lack thereof—likely has a greater impact on usage by youth ENDS users than adult ENDS users. Petitioner presented no reliable evidence to suggest that the presence of flavors in ENDS is necessary to prevent former cigarette smokers from relapsing.

C. FDA's determination that access and marketing restrictions are insufficient to reduce youth initiation of flavored products was not arbitrary and capricious.

Petitioner argues that FDA failed to consider its marketing plan, which it says "delineated the measures that Breeze Smoke takes to deter minors from accessing its products." Pet'r Br. 42. As is apparent from the TPL Review of Petitioner's products, FDA gave due consideration to the role of access restrictions on youth

usage of e-cigarettes and, based on the agency's experience with such restrictions and other real-world data, reached the reasonable conclusion that those restrictions, by their nature, are insufficient to prevent youth usage of flavored and highly-addictive products that are so intensely appealing to young consumers. *See* App. 17 n.xix. While access and marketing restrictions are important and indeed necessary, as FDA has emphasized time and again, *see* Pet'r Br. 43-44, they are not sufficient when it comes to flavored e-cigarettes.[10]

The core problem with flavored e-cigarettes is the product itself—namely its appeal to youth and its addictiveness—not simply youth access or the marketing of these products. FDA's experience confirms this. In March 2019, in response to the youth vaping epidemic, FDA issued Draft Guidance which "proposed to focus its enforcement priorities of flavored ENDS products on how the product was sold…." App. 121. However, in 2020, FDA—armed with more data—announced in its Final Guidance that these access restrictions had been insufficient to protect youth from flavored e-cigarettes. "The reality," FDA found, "is that youth have continued

[10] The specific measures proposed by Petitioner are certainly insufficient to prevent youth access to its disposable flavored e-cigarettes. Petitioner does not itself sell directly to consumers, but sells only to retail stores and authorized distributors. Pet'r Br. 16. Thus, Petitioner's measures largely consist of informing retailers of the requirements of the law. *See* Haddad Decl., at A352-53 ¶ 5 (The Haddad Declaration was previously filed as part of Petitioner's addendum to its motion for a stay pending review, ECF No. 8-2, at A351). Moreover, stating on the packaging that "this product is only for people above the age of 21," accomplishes little when the product itself has all the features that make it attractive to youth. App. 165.

access to [e-cigarette] products in the face of legal prohibitions and even after voluntary actions by some manufacturers." *Id.* "[A]fter considering the comments, the public health threats, and the new evidence described above, FDA determined that focusing on how the product was sold would not appropriately address youth use of the products that are most popular among youth…." *Id.*

FDA's conclusion—in both its 2020 Guidance and the TPL Review it issued to Petitioner—is also supported by other data indicating that youth are able to obtain e-cigarettes with relative ease. According to the 2020 Monitoring the Future Survey, about 60% of 10th grade students reported that it was easy to get vaping devices and e-liquids.[11] Moreover, according to the 2020 NYTS, 22.2% of high school e-cigarette users report obtaining e-cigarettes from a gas station or convenience store in the past month and 17.5% from a vape shop.[12] Finally, most youth e-cigarette users obtain e-cigarettes through social sources, such as older friends or relatives—an avenue of access unlikely to be significantly affected by access restrictions.[13]

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[11] Lloyd D. Johnston et al., MONITORING THE FUTURE: 2020 OVERVIEW: KEY FINDINGS ON ADOLESCENT DRUG USE 131 TBL.17 (2021), https://files.eric.ed.gov/fulltext/ED611736.pdf.

[12] Teresa W. Wang et al., *Characteristics of e-Cigarette Use Behaviors Among US Youth, 2020*, 4 JAMA NETWORK OPEN 1, 5 (published online June 7, 2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780705.

[13] *Id.* (57.1% of high school e-cigarette users reported getting e-cigarettes from a friend).

Given the shocking level of continued youth usage of flavored e-cigarettes, FDA can hardly be criticized for observing that "we are not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use ENDS." App. 17 n.xix. It was entirely reasonable for FDA to rely on its own experience—bolstered by other real-world data—to conclude that marketing and access restrictions are inherently insufficient to adequately reduce the risk of youth initiation of these flavored products that are so appealing to the young.

II. In Denying a Marketing Order to Petitioner, FDA Did Not Adopt a Product Standard Requiring Notice-and-Comment Rulemaking.

According to Petitioner, FDA's requirement of strong evidence that flavored products help smokers to stop smoking cigarettes more effectively than unflavored products is itself a product standard, requiring notice-and-comment rulemaking. Pet'r Br. 46. This simply misunderstands the nature of a product standard under the TCA.

Under Section 907 of the TCA (21 U.S.C. § 387g), FDA has the authority to set product standards if the agency can demonstrate that they are APPH, 21 U.S.C. § 387g(a)(3)(A), a required showing that parallels the showing companies generally must make to market new tobacco products under Section 910 (21 U.S.C. § 387j). Section 907 makes clear that a product standard is necessarily a rule that restricts the manufacture of products with certain properties, whether those products are "new"

products (first marketed after February 15, 2007) or not. This is apparent throughout Section 907. That section itself establishes a product standard (the "Special Rule for Cigarettes") prohibiting flavors in cigarettes providing that they "shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice . . . that is a characterizing flavor of the tobacco product or tobacco smoke." 21 U.S.C. § 387g(a)(1)(A). Section 907 then grants FDA the authority to "adopt tobacco product standards in addition to" the cigarette "Special Rule" if shown to be "appropriate for the protection of the public health." 21 U.S.C § 387g(a)(3)(A). It provides that a product standard "shall…include," where APPH, "provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product." 21 U.S.C § 387g(a)(4)(B); *see also U.S. Smokeless Tobacco Manufacturing Co. LLC v. City of New York,* 708 F.3d 428, 433 (2d Cir. 2013) (In Section 907, Congress "banned the use of flavoring additives in cigarettes and authorized the FDA to prohibit the use of other ingredients in tobacco products if it deems them particularly harmful to the public health.")

In requiring particularly probative evidence of a benefit of non tobacco-flavored products in helping cigarette smokers stop smoking for purposes of a marketing order under Section 910, FDA has not prohibited the manufacture of e-cigarettes with such flavors, as would a product standard; indeed, it has set forth the

kind of evidence that may be sufficient to market new, flavored products in the absence of a product standard prohibiting those flavors.[14] Petitioner makes much of the fact that Section 907 states that product standards shall include, where appropriate, provisions for the "testing" of the tobacco product that is subject to the standard, *see* Pet'r Br. 46, but the context shows that this is a reference to tests that may be needed to determine if the product has the prohibited ingredient, constituent or property. *See* 21 U.S.C. § 387g(a)(4)(B). The reference to "testing" in Section 907 cannot be read to convert an MDO into a product standard where the required evidence was insufficiently probative of a public health benefit, even if FDA, in the interest of consistency, is imposing the same evidentiary requirement on all such flavored products.[15]

Therefore, FDA's requirement of rigorous studies showing that specific e-cigarette products help smokers stop smoking cigarettes for purposes of product

[14] Under Section 910, FDA is required to deny a marketing order if the tobacco product "is not shown to conform in all respects to a product standard in effect under section 387g of this title [Section 907], and there is a lack of adequate information to justify the deviation from such standard." 21 U.S.C. § 387j(c)(2)(D).

[15] In this regard, it is revealing that Petitioner relies on a dictionary definition of the word "standard," quoted by the Supreme Court in *Engine Mgrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.,* 541 U.S. 246, 252-53 (2004) to interpret "standard" as used in an entirely different statute, the federal Clean Air Act, instead of relying on the meaning of "tobacco product standard" under the TCA. *See* Pet'r Br. 47.

review under Section 910 has nothing to do with product standard rulemaking under Section 907.

III. Vacating the MDO Would Harm Public Health.

Petitioner asks the Court to vacate the challenged MDO and to require FDA to allow Petitioner to keep its products on the market while it conducts the studies necessary to secure approval. Pet'r Br. 55-56. Such relief, if granted, would be profoundly contrary to public health.

As discussed, *supra* Sections I.A.1 & 2, Petitioner's products are precisely the types of ENDS products—flavored and disposable—that are most attractive to youth and that have driven the youth vaping epidemic. *See, e.g.*, App. 12-14. Petitioner has offered insufficiently probative evidence that its products provide a countervailing public health benefit that would justify allowing their continued marketing despite having failed to satisfy the APPH standard. *See Breeze Smoke*, 18 F.4th at 508 ("FDA likely properly concluded that Breeze Smoke failed to show that its products adequately protected the public health….").

Under the TCA, manufacturers may only market their tobacco products if they have first demonstrated that their products are APPH—they have no inherent right to market their products. *See* 21 U.S.C. § 387j(c)(2)(A). Indeed, because they have no marketing order, Petitioner's products have been on the market only through the enforcement forbearance of the FDA. *See generally*, *American Academy of*

Pediatrics v. FDA, 379 F. Supp. 3d 461, 469 (D. Md. 2019), *appeal dismissed sub nom. In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020). Should the Court uphold the challenged MDO, Petitioner would have the opportunity to perform the required studies and re-submit its application. If the Court were to allow Petitioner to keep its products on the market during this period, it would effectively place the burden of Petitioner's failure to meet the APPH standard on the young people who have already suffered so much at the hands of flavored e-cigarette manufacturers. Vacatur of the challenged MDO would have profound negative public health consequences and should be denied by this Court.

CONCLUSION

For these reasons, and those presented by the government, *amici* urge the Court to uphold the MDO.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT, TYPEFACE REQUIREMENTS, AND TYPE-STYLE REQUIREMENTS

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CERTIFICATE OF CONFERENCE

I hereby certify under Fed. R. App. P. 29(a)(2) that on December 15, 2021 I contacted counsel for Petitioner and Respondent by electronic mail and that Petitioner and Respondent each consented to the filing of the Brief of *Amici Curiae*.

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CERTIFICATE OF SERVICE

I hereby certify that on December 17, 2021, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

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