# No. 21-2426

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE SECOND CIRCUIT**

MAGELLAN TECHNOLOGY, INC.,

Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

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On Petition for Review of a Final Marketing Denial Order
by the United States Food and Drug Administration

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

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*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 Marketing Denial Order ("MDO") issued to Petitioner Magellan Technology, Inc. By issuing an MDO for Petitioner's mango-, pretzel graham-, and blue raspberry-flavored e-cigarette cartridges (referred to as "Juno Pods" by Petitioner), FDA has acted to protect the public health by removing from the market the very type of e-cigarette products—flavored cartridges—that have fueled an epidemic of youth usage of highly addictive and harmful e-cigarettes, with no demonstrated countervailing benefit in helping adult smokers to stop smoking cigarettes. This brief is filed with the consent of the parties.[1]

## STATEMENT OF INTEREST OF *AMICI CURIAE*

*Amici* are the following national and state 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, Medical Society of the State of New York, Parents Against Vaping e-cigarettes and Truth Initiative. From physicians

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E) and L.R. 29.1(b), *amici* affirm that no party's counsel authored this brief, 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 counsel—contributed money that was intended to fund preparing or submitting this brief.

who counsel their young patients and their parents about the hazards of tobacco use, to organizations with formal programs to urge users to 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.[2] Accordingly, *amici* have a direct and immediate interest in ensuring that Petitioner's highly addictive and youth-appealing flavored e-cigarette cartridges 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 *amici* 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 tobacco product 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 functions to protect the public health by removing from the market flavored e-cigarette products, like Petitioner's cartridges, that threaten the health and

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

well-being of young people without sufficient countervailing evidence of any benefit to adult cigarette smokers.

## INTRODUCTION AND SUMMARY OF ARGUMENT

Petitioner distributes flavored e-cigarette cartridges[3]—a highly addictive and harmful product that has consistently been shown to appeal to youth. FDA denied Petitioner's application to market its mango-, pretzel graham-, and blue raspberry-flavored cartridges because its application lacked sufficient evidence that such products are more effective than unflavored (i.e., tobacco-flavored) products in helping adult smokers stop smoking cigarettes, and therefore did not demonstrate any benefits that outweigh the known risks to youth posed by these products. Magellan-FDA1-000044-45.

**I.A**. In light of the mountain of evidence of youth attraction to flavored e-cigarettes, particularly the cartridge-based products that Petitioner distributes, and the addictiveness and health harms to young people from those products, it was both reasonable and appropriate for FDA to require Petitioner to submit robust, product-specific evidence of the benefit of its products compared to tobacco-flavored products in aiding smokers to stop smoking. It was not arbitrary and capricious for FDA to issue an MDO based on Petitioner's failure to provide such evidence.

[3] Petitioner's tobacco- and menthol-flavored cartridges are not subject to the challenged MDO. *See* Petr's Br. 19.

**I.B.** It also was not arbitrary and capricious for FDA to conclude that youth access and marketing restrictions would be insufficient to reduce the risk of youth initiation of Petitioner's products in light of: (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 inherently inadequate to prevent youth usage of such products, given their intense appeal to young people.

**I.C.** Moreover, contrary to Petitioner's assertion, under the Federal Food, Drug and Cosmetic Act ("FFDCA"), as amended by the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 ("TCA"), FDA's authority to require post-market surveillance and review of Petitioner's products is immaterial to FDA's determination of whether a product satisfies the statutory standard for a marketing order. Reliance on such authority would also be inadequate to protect the public health.

**II.** There is no merit to Petitioner's argument that FDA lacks the statutory authority to require Petitioner to submit reliable evidence that its flavored products confer a greater benefit in helping cigarette smokers stop smoking than tobacco-flavored products. Such a requirement is at the core of the TCA's public health standard. It does not improperly import, into the premarket review of new tobacco products, the "safe and effective" standard for new drug approval under the FFDCA.

**III.** FDA's requirement of reliable evidence that Petitioner's flavored products confer a greater benefit in helping smokers stop smoking than tobacco-flavored products is not a product standard that required notice-and-comment rulemaking.

**IV.** Finally, having enjoyed a lengthy period of marketing its products without the statutorily-required marketing order, the Court should reject Petitioner's request that its flavored products be allowed to remain on the market for an additional period while Petitioner conducts the studies necessary to demonstrate a public health benefit from such products. Petitioner's requested relief, if granted, would be inconsistent with the TCA and 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, FDA reasonably denied Petitioner's application for failure to provide robust evidence that its flavored cartridges help smokers stop smoking more effectively than unflavored products.

In determining if the marketing of an e-cigarette is "appropriate for the protection of the public health"—the standard for a marketing order under the TCA—FDA must weigh two factors: (1) the likelihood that the product will help existing tobacco users stop using tobacco products, and (2) the likelihood that the product will lead non-tobacco users, including youth, to begin using such products. 21 U.S.C. § 387j(c)(4). Applying this framework to e-cigarettes, FDA found the

evidence overwhelming that flavors appeal to youth more than tobacco-flavored products—and the evidence is particularly strong with respect to flavored cartridge-based e-cigarettes, the product type at issue here. Magellan-FDA1-000047-49. Given this unequivocal evidence, it was entirely reasonable, and certainly not arbitrary and capricious, for FDA to require Petitioner to submit "the strongest types of evidence" demonstrating that, compared to tobacco-flavored products, its flavored products benefit smokers by helping them to stop smoking cigarettes and to issue an MDO based on Petitioner's failure to furnish such evidence. *Id.* at 000044.

The impact of a product on youth initiation is particularly critical because, as FDA noted in its Technical Project Lead Review ("TPL Review") of Petitioner's products, "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." *Id.* at 000046-47. Whereas "almost 90 percent 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." *Id.* at 000047. As FDA 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 demonstrating that flavored e-cigarettes, like Petitioner's, are particularly attractive to youth.

As FDA explained in its TPL Review, 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." *Id.* at 000046-47.[4]

Flavors are driving this youth vaping epidemic. *Id.* at 000047 ("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 in tobacco products (including ENDS) make them more palatable for novice youth and young adults,

[4] Since the time 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 (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.*—a warning Petitioner disregards. Petr's Br. 46. 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. Park-Lee, *supra* note 4, at 1387-89.

which can lead to initiation, more frequent and repeated use, and eventually established regular use." *Id.* at 000048. In 2020, 84.7% of high school e-cigarette users reported using a flavored product. *Id.* at 000047. And according to data from the federal government, over 93% of youth users reported 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." *Id.* at 000047-48. As the Sixth Circuit found in denying an emergency stay of an MDO in a similar case, "[f]lavored ENDS products especially appeal to children." *Breeze Smoke, LLC v. FDA*, 18 F.4th 499, 505 (6th Cir. 2021).[5]

Petitioner's products are not only flavored, they are the cartridge-based products that drove youth e-cigarette use rates to historically high levels and led FDA, in 2020, to revise its enforcement priorities to attach the highest priority to enforcement against cartridge-based e-cigarettes in flavors other than tobacco or menthol. *See* FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)* (Apr. 2020), Magellan-FDA2-000288 ("2020 Guidance").[6] In 2019, just before FDA's revised enforcement policy took effect, 27.5% of high school students reported current e-cigarette use, with most youth e-cigarette users

[5] The Supreme Court denied a stay of the MDO on December 10, 2021. *Breeze Smoke, LLC v. FDA*, 142 S. Ct. 638 (2021).

[6] https://www.fda.gov/media/133880/download.

reporting a cartridge-based product, such as Juul, as their usual brand.[7] FDA determined that the "evidence shows that youth are particularly attracted to flavored, cartridge-based ENDS products," precisely the types of products at issue here. 2020 Guidance at 19. FDA noted that the "design features" of such products contribute to their youth appeal. *Id.* at 16. As can be seen in the photo below, the small size of Petitioner's e-cigarette device, which is roughly the size of a USB flash drive[8] and designed to be used with the flavored cartridges at issue in this litigation, Petr's Br. 11, "allows for easy concealability" and "may allow youth to use the product in circumstances where use of tobacco products is prohibited, such as a school." *Id.* These products also possess "intuitive and convenient features that facilitate ease of use, including draw activation, prefilled cartridges or pods, and USB rechargeability." *Id.*

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

[8] Petitioner's e-cigarette device measures 109 x 18.5 x 10 millimeters (or 4.29 x 0.73 x 0.39 inches). *See Juno Vape Review – Personalize Vaping Experience*, VAPING DAILY (last updated Jan. 21, 2021), https://vapingdaily.com/best-electronic-cigarettes/juno-vape-review/.


Figure 1: Juno e-cigarette.[9]

The data leave no doubt that flavored e-cigarettes, and especially flavored cartridge-based 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." Magellan-FDA1-000048.

**2. As FDA found, flavored e-cigarettes, such as Petitioner's, pose a direct threat of addiction and other health harms to young people.**

The vast majority of Petitioner's flavored cartridges contain nicotine, Petr's Br. 12, 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, FDA

[9] *JUNO,* BUFFALO VAPOR, https://www.buffalovapor.com/juno (last visited Apr. 20, 2022).

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." Magellan-FDA1-000049. FDA found that the high prevalence of youth e-cigarette use was increasing nicotine dependence among young people. *Id.* And FDA noted that in 2019, an estimated 30.4% of middle and high school e-cigarette users reported frequent use (i.e., use on 20 or more of the previous 30 days), and even more alarming, 21.4% of high school users and 8.8% of middle school users reported *daily* use. *Id.* Frequent and daily use prevalence among high school students were even higher in 2020[10] and then again in 2021, when 43.6% of high school e-cigarette users reported frequent use and 27.6% reported daily use.[11]

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." Magellan-FDA1-000049. 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." *Id.* at 000050.

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[10] 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.

[11] Park-Lee et al., *supra* note 4, at 1388 tbl.

FDA also noted the data documenting a risk of progression from e-cigarettes to other tobacco products. *Id.* In its TPL Review, FDA cited 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…." *Id.* A 2018 report by the National Academies of Sciences, Engineering, and Medicine, cited in the TPL Review, found "substantial evidence that ENDS use increases [the] risk of ever using combusted tobacco cigarettes among youth and young adults." *Id.* Thus, the threat of flavored e-cigarettes is not just a short-term health threat; it also is a threat to a young person's future health by increasing the risk of progression 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 tobacco-flavored products.

Precisely because the evidence that flavored tobacco products appeal to youth is so "robust and consistent," Magellan-FDA1-000048, it was entirely reasonable, and certainly not arbitrary and capricious, for FDA to require similarly "robust and reliable" evidence showing that Petitioner's flavored e-cigarettes help smokers stop smoking more effectively than tobacco-flavored products, and that such a benefit be "substantial enough to overcome the significant risk of youth uptake and use posed

by the flavored ENDS product." *Id.* at 000051-52. Both the publicly available evidence of such benefits to adult smokers, as well as the data submitted by Petitioner, fall woefully short.

FDA found that "in 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." *Id.* at 000052-53. 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 to stop smoking.[12] As FDA concluded, "the literature does not establish that flavors differentially promote switching amongst ENDS users in general." Magellan-FDA1-000053. Thus, it was both reasonable and appropriate for FDA to require Petitioner to demonstrate the effectiveness of its flavored products in helping smokers to stop smoking through randomized controlled trials, longitudinal cohort studies, or other similarly rigorous studies.

Instead of submitting any such studies, Petitioner offered "cross-sectional perception and intent studies and surveys, focus groups, [and] diary studies." Petr's Br. 43. These studies are insufficient to demonstrate that Petitioner's flavored

[12] 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/.

products better enable cigarette smokers to stop smoking than tobacco-flavored products for at least two independent reasons. First, such studies don't compare tobacco-flavored ENDS versus flavored ENDS (let alone Petitioner's specific flavored ENDS) in terms of their impact on helping smokers stop smoking. *See* Petr's Br. 43-44. Second, as FDA found, such studies 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* Magellan-FDA1-000054 ("Consumer perception studies (surveys or experiments) typically assess outcomes believed to be precursors to behavior…but are not designed to directly assess actual product use behavior.").

In short, Petitioner presented no studies showing that users of its flavored products were more likely to stop smoking cigarettes than users of tobacco-flavored products. In its TPL Review, FDA explained in detail why it is necessary to perform studies that "enable direct assessment of behavioral outcomes associated with actual product use over time," *id.*, which the studies offered by Petitioner did not do.

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

Contrary to Petitioner's claim (Petr's Br. 45-47), the MDO was not arbitrary and capricious because it relied on general evidence of the impact of flavors on youth e-cigarette use, while requiring product-specific evidence to assess any benefits to

smokers from use of Petitioner's products. The Sixth Circuit rejected a similar argument in *Breeze Smoke*. 18 F.4th at 508 (concluding that FDA acted lawfully in "considering literature that supported the thesis that flavored ENDS products pose special health risks to children[, while] requiring [Petitioner] present more than literature reviews to justify its products' public health benefits.").

FDA relied on general scientific literature to show the special appeal of flavored e-cigarettes to youth because, in the Sixth Circuit's words, "those risks are understood as a matter of scientific consensus." *Id.* In contrast, FDA found that no scientific consensus exists on whether flavors help cigarette smokers stop smoking to a greater degree than tobacco-flavored e-cigarettes. Magellan-FDA1-000052-53. FDA further concluded that product-specific evidence is necessary because the effectiveness of a product in "promoting switching among smokers arises from a combination of its product features—including labeled characteristics like flavor and nicotine concentration—as well as the sensory and subjective experience of use (taste, throat hit, nicotine delivery), and can also be influenced by how the device itself looks and feels to the use[r]." *Id.* at 000054. It was thus appropriate for FDA to require product-specific evidence to support this claim.

### B. FDA's determination that access and marketing restrictions are insufficient to reduce youth initiation of flavored products was reasonable.

Petitioner also argues that FDA failed to consider its marketing plan, which it claims "would limit youth access and exposure" to its flavored cartridges. Petr's Br. 38. As is apparent from the TPL Review, FDA gave due consideration to the role of access and marketing restrictions on youth usage of e-cigarettes and, based on the agency's experience with those restrictions and other real-world data, concluded that they are, by their nature, insufficient to prevent youth usage of flavored and highly addictive products that are so intensely appealing to young consumers. *See* Magellan-FDA1-000052 n.xix. While access and marketing restrictions are important and indeed necessary to support a premarket tobacco product application, as FDA has emphasized time and again, *see* Petr's Br. 39-40, they are not sufficient when it comes to flavored e-cigarettes.

The specific measures proposed by Petitioner would be insufficient to prevent youth access to its flavored cartridges. For example, Petitioner claims that its marketing plan called for "restricting sales to age-gated vape and specialty tobacco shops." Petr's Br. 38. But Petitioner ignores the fact that more youth report buying e-cigarettes from vape or tobacco shops (22.2%) than from gas stations or

convenience stores (17.7%), according to the 2021 NYTS.[13] A 2019 study found that in California, e-cigarette sales to minors violations are significantly higher in tobacco and vape shops than in any other type of retailer, with 44.7% selling to underage buyers.[14] Similarly, Petitioner's claim that it only allows a customer to purchase twenty cartridges ("five four-packs") in a single transaction so as "to minimize the potential for 'strawman' sales" Petr's Br. 39, is unlikely to have any effect on access to its products by youth. Twenty cartridges of Petitioner's 4.8% or 3.6% nicotine strength products can contain more nicotine than twenty packs of cigarettes[15]—an extremely high "limit." Moreover, because the quantity limit is imposed on a per-transaction basis, nothing would prevent a consumer from making multiple twenty-cartridge purchases each day. Petitioner's other measures, such as "[n]ot engaging third-party influencers or promoters[,]…[n]ot using models who

[13] Andrea S. Gentzke et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021*, 71 MORBIDITY & MORTALITY WKLY. REP. 1, 23 tbl.7 (2022), https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf.

[14] April Roeseler et al., *Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops*, 173 JAMA PEDIATRICS 795, 796 (2019), https://jamanetwork.com/journals/jamapediatrics/fullarticle/2735684.

[15] Robert K. Jackler & Divya Ramamurthi, *Nicotine arms race: JUUL and the high-nicotine product market*, 28 TOBACCO CONTROL 1, 3 (2019), https://tobaccocontrol.bmj.com/content/28/6/623 (noting that Juul asserted that its 0.7 mL cartridges of 5% nicotine strength e-liquid "are equivalent in nicotine delivery to a pack of 20 traditional cigarettes"). Petitioner's cartridges each contain 1.6mL of e-liquid. *See* Pet. Review, Ex. A at 4.

appear to be under 25 years of age," and not "depicting Juno products as 'cool' or rebellious," Petr's Br. 38-39, can be expected to have minimal impact given that Petitioner's products themselves have all the features that make e-cigarettes attractive to youth.

The core problem is that youth access and marketing restrictions are insufficient to protect youth from the inherent hazards of these flavored products. FDA's experience confirms this. In March 2019, in response to the youth vaping epidemic, FDA issued Draft Guidance[16] which "proposed to focus its enforcement priorities of flavored ENDS products on how the product was sold…." 2020 Guidance at 21 (describing 2019 Draft Guidance). 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, particularly flavored cartridges. "The reality," FDA found, "is that youth have continued access to these products in the face of legal prohibitions and even after voluntary actions by some manufacturers." *Id.* "[A]fter considering…comments, the public health threats, and the new evidence…FDA determined that focusing on how the product was sold would not appropriately address youth use of the products that are the most popular among youth—*i.e.*, flavored cartridge-based products." *Id.* Petitioner cites the

[16] FDA, *Modifications to Compliance Policy for Certain Deemed Tobacco Products; Draft Guidance for Industry; Availability*, 84 Fed. Reg. 9,345 (Mar. 14, 2019), https://www.govinfo.gov/content/pkg/FR-2019-03-14/pdf/2019-04765.pdf.

provision in its marketing plan that requires retailers to abide by the existing legal requirements for age verification, Petr's Br. 38, but it is precisely those legal requirements that FDA determined, based on its experience, are insufficient to protect against youth usage of flavored products. 2020 Guidance at 6-8, 44 ("FDA believes that age verification alone is not sufficient to address this issue, given…that youth use of ENDS products continues to increase.").

FDA's conclusion—in both its 2020 Guidance and TPL Review—is also supported by data indicating that youth obtain e-cigarettes with relative ease. According to the 2021 Monitoring the Future Survey, 54.6% of 10th grade students reported that it would be easy to get vaping devices and 48.5% reported it would be easy to get the nicotine-containing e-liquids used in such devices.[17] As FDA recognized in its 2020 Guidance (at 28-29), many 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 youth access restrictions.

Given the alarming level of continued youth usage of flavored e-cigarettes, FDA reasonably concluded 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." Magellan-FDA1-000052 n.xix. It was similarly appropriate for FDA to

[17] *Table 16: Trends in Availability of Drugs as Perceived by 10th Graders*, MONITORING THE FUTURE, http://monitoringthefuture.org/data/21data/table16.pdf.

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 cartridge-based products that are so appealing to the young.

### C. FDA's authority to require post-market surveillance and review of Petitioner's products is immaterial to the determination of whether those products are appropriate for the protection of the public health.

Petitioner asserts that the MDO was also arbitrary and capricious because FDA "failed to consider other approaches" to address youth initiation, such as by exercising its authority to require post-market reporting and review of "labeling, advertising, marketing, promotional materials, and marketing plans that were not previously submitted." Petr's Br. 47-48. Petitioner also contends FDA could use its post-market authority "to later revoke or suspend a marketing order should it determine that [Petitioner's] products are no longer appropriate for the protection of the public health." *Id.* at 48. Contrary to Petitioner's argument, not only does the TCA make the availability of such post-market FDA action immaterial to the statutory public health determination; reliance on post-market surveillance and action would be inadequate to protect the public health.

Section 910 of the FFDCA requires FDA to deny a premarket application if "there is a lack of a showing that *permitting such tobacco product to be marketed* would be appropriate for the protection of the public health." 21 U.S.C. §

387j(c)(2)(A) (emphasis added). By its plain terms, an applicant's new products must be appropriate for the protection of the public health *before* they can be marketed. The fact that FDA may exercise its authority to require extensive post-market information from a successful applicant,[18] and can withdraw a marketing order or take other post-market action based on that information, cannot itself be a basis for granting a marketing order for a product that is not appropriate for the protection of the public health based on premarket information. Thus, as important as FDA's post-market authority is to protect the public health, the exercise of that authority is not a factor that FDA may consider in determining, in the first place, whether a product is appropriate for the protection of the public health.

Moreover, the nation's experience with the public health consequences of flavored e-cigarettes demonstrates that the availability of post-market surveillance may not be sufficient to protect the public health in the absence of rigorous premarket review. Largely because of flavored cartridges, like those sold by Petitioner, youth use of e-cigarettes quickly reached epidemic levels, increasing an astounding 78% in a single year (from 2017 to 2018) and catching FDA by surprise.[19] In the words of then-Commissioner Gottlieb, "[w]hat I did not predict

[18] *See* 21 C.F.R. §§ 1114.39 & 1114.41.

[19] *See* FDA, Press Release, *Statement from FDA Commissioner Scott Gottlieb, M.D. on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes* (Nov. 15, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-

was that, in 2018, youth use of e-cigarettes…would become an epidemic."[20] The lesson here is that by the time FDA determines that a new tobacco product has become a threat, substantial harm may already have occurred, and the patterns of addiction may be difficult to reverse. To sufficiently protect public health, the availability of post-market surveillance is not an adequate substitute for the rigorous premarket review mandated by Section 910.

## II. FDA's Requirement of Reliable Evidence that Petitioner's Flavored Products Confer a Greater Benefit in Helping Smokers to Stop Smoking than Tobacco-Flavored Products Is Well Within the Agency's Statutory Authority.

### A. FDA's evidentiary requirement is at the core of the TCA's public health standard.

In addition to arguing that the MDO was arbitrary and capricious, Petitioner asserts that FDA lacks any authority under Section 910 of the FFDCA to impose a requirement that Petitioner's flavored products are more effective in helping smokers stop smoking than a comparable tobacco-flavored product. Petr's Br. 48-55. Petitioner's argument ignores the relevant statutory language. As noted, under Section 910, whether the marketing of a new tobacco product is appropriate for the protection of the public health requires a determination of whether non-users of

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commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access.

[20] *Id.*

tobacco products "will start using such products" and whether "existing users of tobacco products will stop using such products." 21 U.S.C. § 387j(c)(4). FDA expressly made these determinations when it found overwhelming evidence that non-tobacco flavors drive youth initiation to a greater degree than tobacco-flavored products, and further required Petitioner to marshal robust evidence that its flavored cartridges produce a countervailing benefit in helping smokers stop smoking greater than whatever such benefit may be conferred by tobacco-flavored products.[21]

If flavored products yield no greater benefit than unflavored products in helping smokers stop smoking, but have the serious added harm of enticing children to begin using ENDS, then there can be no net public health benefit from authorizing flavored products. Rather, the increased youth initiation from flavored products would be a clear public health detriment. Not only does Section 910 give FDA the authority to engage in such a risk-benefit assessment of flavored versus tobacco-flavored products, that assessment is ***required*** by Section 910 because it is at the core of the public health standard.

[21] *Amici* do not read the MDO or TPL Review as concluding that tobacco-flavored ENDS help smokers stop smoking; rather these documents reflect the conclusion that a higher level of evidence of such a benefit is necessary for flavored products, given their intense appeal to youth.

### B. FDA did not evaluate Petitioner's application under the drug approval standard.

Contrary to Petitioner's suggestion (Petr's Br. 27, 50-52), FDA's approach does not import the standards for drug approval under the FFDCA into Section 910; the drug approval standard is entirely different from the standard in Section 910, and the issue here is whether FDA applied the requirements of Section 910 in evaluating Petitioner's application.

In contrast to Section 910, which requires FDA to decide whether a new product meets the public health standard considering "the risks and benefits to the population as a whole," 21 U.S.C. § 387j(c)(4), drug approval in Section 505 of the FFDCA requires FDA to decide whether a drug is safe and effective for its intended use. The requirement to demonstrate safety involves weighing a drug's risks against its benefits. *See id.* § 355(b)(1)(A).

While Petitioner is correct that products "marketed with [tobacco] cessation claims," such as nicotine replacement therapies, must meet the "safe and effective" drug standard (Petr's Br. 51 & n.4), that standard has no application to tobacco products which, as here, do not make such therapeutic claims and are inherently unsafe. Petitioner applied to market its products as tobacco products and does not claim that they can be used in the "diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B). Thus, Petitioner's application

was properly assessed under Section 910's new tobacco product authorization standards.

## III. FDA's Requirement of Strong Evidence that Petitioner's Flavored Products Confer a Greater Benefit in Helping Smokers Stop Smoking than Tobacco-Flavored Products Is Not a Product Standard Requiring Notice-and-Comment Rulemaking.

According to Petitioner, FDA's requirement of strong evidence that flavored products help smokers stop smoking cigarettes more effectively than tobacco-flavored products is itself a product standard, requiring notice-and-comment rulemaking. Petr's Br. 53-55. This argument simply misunderstands the nature of a product standard under the TCA.

Under Section 907 of the FFDCA, FDA has the authority to set product standards if the agency can demonstrate that they are appropriate for the protection of the public health, a required showing that parallels the showing companies generally must make to market new tobacco products under Section 910.[22] Under Section 907, a product standard is 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. That Section itself establishes a product standard

[22] *Compare* 21 U.S.C. § 387g(a)(3)(A) ("The Secretary may adopt tobacco product standards…if…appropriate for the protection of the public health"), *with id.* § 387j(c)(2) ("The Secretary shall deny an application…if…there is a lack of showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health.").

(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 grants FDA the authority to "adopt product standards in addition to" the cigarette "Special Rule" if shown to be appropriate for the protection of the public health. *Id.* § 387g(a)(3)(A). It provides that a product standard "shall, where appropriate for the protection of the public health, include provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product." *Id.* § 387g(a)(4)(B); *see also U.S. Smokeless Tobacco Mfg. 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.").

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

Therefore, FDA's requirement of rigorous studies showing that specific flavored e-cigarette products help smokers stop smoking for purposes of product review under Section 910 has nothing to do with product standard rulemaking under Section 907.

## IV. Petitioner's Requested Relief Would Be Contrary to the TCA and Harm Public Health.

Petitioner asserts that, if the Court vacates the MDO but determines that FDA acted within its statutory authority, the Court should grant a myriad of alternative additional relief, all of which appears to boil down to allowing Petitioner to keep its products on the market while it conducts the studies necessary to secure approval. Petr's Br. 55-59. The Court should reject this argument because such relief, if granted, would be contrary to the TCA and profoundly harmful to public health.

As discussed *supra* Section I.A., Petitioner's addictive, flavored products are highly attractive to youth, and Petitioner has not offered evidence sufficient to show that its products provide a countervailing public health benefit to justify allowing their continued marketing. Under the TCA, manufacturers may only market tobacco products if they have first demonstrated that their products are appropriate for the protection of the public health; they have no inherent right to market tobacco products that do not meet that standard. *See* 21 U.S.C. § 387j(c)(2). Indeed, because

they have no marketing order, Petitioner's products have been on the market only through the enforcement forbearance of FDA. *See generally*, *Am. Academy of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 468, 493 (D. Md. 2019) (noting that e-cigarette manufacturers have enjoyed "a holiday from meeting the obligations of the law").

Should the Court vacate the MDO, but recognize FDA's authority to require the kinds of studies necessary to show a benefit to adult smokers, any further relief to Petitioner allowing it to keep its products on the market while it conducts the required studies would turn the TCA on its head by allowing Petitioner to market its products despite having failed to satisfy the statutory public health standard, a showing the TCA expressly requires applicants to demonstrate *before* marketing a tobacco product. 21 U.S.C. § 387j(c)(2).

Importantly, further relief would also effectively place the burden of Petitioner's continuing failure to meet the public health standard on the young people who have already suffered at the hands of flavored e-cigarette manufacturers, rather than on the companies that have enjoyed the benefit of a years-long regulatory "holiday." If granted, Petitioner's requested relief would run counter to the TCA and have profoundly negative public health consequences. It therefore should be denied.

## 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

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## CERTIFICATE OF CONFERENCE

I hereby certify under Fed. R. App. P. 29(a)(2) that on April 20, 2022, my partner Andrew Goldfarb 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*.

*/s/ Shawn Naunton*
Shawn Naunton
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**CERTIFICATE OF SERVICE**

I hereby certify that on May 12, 2022, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

*/s/ Shawn Naunton*
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