No. 22-3030

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

LOGIC TECHNOLOGY DEVELOPMENT LLC,

Petitioner,

v.

U.S. FOOD & DRUG ADMINISTRATION,

Respondent.

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

BRIEF OF *AMICI CURIAE* MEDICAL, PUBLIC HEALTH, CIVIL RIGHTS, AND COMMUNITY GROUPS IN SUPPORT OF RESPONDENT

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CORPORATE DISCLOSURE STATEMENT AND STATEMENT OF FINANCIAL INTEREST

Pursuant to Fed. R. App. P. 26.1(a) and Third Circuit LAR 26.1, *amici curiae* Action on Smoking and Health, African American Tobacco Control Leadership Council, American Academy of Family Physicians, American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, American Medical Association, Campaign for Tobacco-Free Kids, National Medical Association, Parents Against Vaping e-cigarettes (PAVe), Pennsylvania Medical Society, and Truth Initiative make the following disclosure:

1) For non-governmental corporate parties please list all parent corporations:

   None/not applicable.

2) For non-governmental corporate parties please list all publicly held companies that hold 10% or more of the party's stock:

   None/not applicable.

3) If there is a publicly held corporation which is not a party to the proceeding before this Court but which has a financial interest in the outcome of the proceeding, please identify all such parties and specify the nature of the financial interest or interests:

   None/not applicable.

4) In all bankruptcy appeals counsel for the debtor or trustee of the bankruptcy estate must list: 1) the debtor, if not identified in the case caption; 2) the members of the creditors' committee or the top 20 unsecured creditors; and 3) any entity not named in the caption which is an active participant in the bankruptcy proceeding. If the debtor or trustee is not participating in the appeal this information must be provided by appellant.

None/not applicable.

Dated: February 17, 2023

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

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Amici medical, public health, civil rights, 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 Logic Technology Development LLC. By an issuing an MDO for Petitioner's menthol-flavored e-cigarette cartridges, FDA has acted to protect public health by removing from the market menthol-flavored products that have helped fuel an epidemic of youth use of highly addictive and harmful e-cigarettes, with no demonstrated countervailing benefit in helping adult smokers to stop smoking cigarettes. Respondent consents to the filing of this brief and Petitioner does not oppose provided it has an opportunity to respond. *See* Mot. Medical, Public Health, Civil Rights, and Community Groups to File *Amicus* Br., ECF No. 61, at 1 (Jan. 31, 2023).

STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici are the following national and state medical, public health, civil rights, and community organizations: Action on Smoking and Health, African American Tobacco Control Leadership Council, American Academy of Family Physicians, American Academy of Pediatrics, American Cancer Society Cancer Action

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), *amici* affirm that no party's counsel authored this brief in whole or in part, neither the parties nor their counsel contributed money that was intended to fund preparing or submitting this brief, and no person—other than *amici*, their members, or their counsel—contributed money that was intended to fund preparing or submitting the brief.

Network, American Heart Association, American Lung Association, American Medical Association, Campaign for Tobacco-Free Kids, National Medical Association, Parents Against Vaping e-cigarettes (PAVe), Pennsylvania Medical Society, and Truth Initiative. Including physicians who counsel young patients and their parents about the hazards of tobacco use, organizations with formal programs to urge users to quit, and 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 menthol e-cigarette cartridges not be permitted on the market, and upholding the MDO will serve that interest.

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

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

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 menthol cartridges, that threaten the health and well-being of young people without sufficient countervailing evidence of any benefit to adult cigarette smokers.

The Court previously has granted *amicus* status to these groups by granting their motion to file a brief *amicus curiae* in support of Respondent's opposition to Petitioner's motion for a stay, ECF No. 35 (Dec. 15, 2022), and by granting their motion to file a brief *amicus curiae* in opposition to Petitioner's third motion to seal, ECF No. 60 (Jan. 27, 2023).

INTRODUCTION

This Court has previously upheld FDA's approach to evaluating the premarket tobacco product applications of flavored e-cigarettes. *Liquid Labs LLC v. FDA*, 52 F.4th 533 (3d Cir. 2022). In *Liquid Labs*, this Court found that in light of the known risks to youth posed by flavored e-cigarettes, "FDA permissibly required a comparison of a manufacturer's flavored products with tobacco-flavored ENDS products in their ability to assist adult smokers to quit or switch" and that such evidence had to assess actual "behavioral changes" rather than simply perceptions and intentions. *Id.* at 542 (citations and quotations omitted). Here, FDA has applied that same approach. The only difference is that Logic's e-cigarettes are menthol-

flavored, whereas the products at issue in *Liquid Labs* were in flavors other than tobacco or menthol. *Id.* at 537.

In deciding whether to evaluate Petitioner's menthol e-cigarettes under the same framework, FDA thoroughly reviewed the evidence. Based on that review, FDA concluded that menthol-flavored ENDS hold a similar level of youth appeal as other flavors, *e.g.*, JA946-47, but that menthol-flavored ENDS are not "more effective" than tobacco-flavored ENDS "in promoting complete switching or significant cigarette reduction among current smokers (including menthol smokers)." JA951-52. Therefore, FDA concluded, "the approach to menthol-flavored ENDS should be the same as with other flavored ENDS with respect to the evidence of adult benefit." JA904. Just as in *Liquid Labs*, because of flavored products' known risks to youth, FDA reasonably required Petitioner to submit "robust and reliable evidence . . . regarding the magnitude of the potential benefit to adult smokers" from its flavored products. *See Liquid Labs*, 52 F.4th at 538; JA14. This is precisely the sort of "scientific determination" to which a reviewing court is "most deferential." *New Jersey Envtl. Fed'n v. U.S. Nuclear Regulatory Comm'n*, 645 F.3d 220, 228 (3d Cir. 2011) (quoting *Baltimore Gas v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983)); *see also Coalition for Responsible Regulation, Inc. v. EPA*, 684 F.3d 102,120 (D.C. Cir. 2012) (per curiam) (courts "give an extreme degree of deference to the agency when it is evaluating scientific data within its

technical expertise."). Given this Court's decision in *Liquid Labs*, the reasonableness of FDA's approach, and the deference that FDA is owed, there is no basis to overturn the MDO.

ARGUMENT

I. The MDO Was Not Arbitrary and Capricious.

A. FDA correctly concluded that there is overwhelming evidence of youth attraction to menthol e-cigarettes and that Petitioner had failed to provide robust evidence that its menthol cartridges help smokers stop smoking more effectively than tobacco-flavored 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 under the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 ("Tobacco Control Act" or "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 correctly found substantial evidence that menthol products, like other flavored products, appeal to youth more than tobacco-flavored products—and that the evidence is particularly strong with respect to flavored cartridge-based e-cigarettes, the product type at issue here. JA936. Given this unequivocal evidence,

it was entirely reasonable, and certainly not arbitrary and capricious, for FDA to require Petitioner to submit "robust and reliable evidence" demonstrating that its menthol e-cigarettes, as compared to tobacco-flavored products, benefit smokers by helping them to stop smoking cigarettes. And when Petitioner failed to furnish such evidence, FDA correctly issued an MDO. JA14.[3]

The impact of a product on youth initiation is particularly critical because, as FDA noted in its Technical Project Lead Review of Petitioner's products ("TPL Review"), "[u]se 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." JA944. 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 daily smokers." *Id.* As FDA concluded, "[b]ecause of the lifelong implications of

[3] Petitioner relies on two internal FDA memoranda which reveal that there was disagreement in CTP's Office of Science about the evaluation of menthol e-cigarettes under the public health standard in the TCA and the application of that standard to the Logic menthol products in particular. Pet'r. Op. Br. 20-25; Pet'r Reply Br. 7-9. But this has no bearing on whether FDA's final decision to issue an MDO for the Logic menthol products was arbitrary and capricious under the Administrative Procedure Act. Whatever discussion and debate occurred internally on these issues, the legally relevant point is that FDA's decision to issue an MDO for the Logic menthol products was entirely reasonable in light of the evidence presented.

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 correctly concluded that there is "robust and consistent" evidence demonstrating that Petitioner's menthol e-cigarettes are particularly attractive to youth.

E-cigarettes have been the most commonly used tobacco product among youth since 2014. JA1158. According to the National Youth Tobacco Survey ("NYTS"), in 2022, over 2.5 million youth, including 14.1% of high schoolers, reported current e-cigarette use. JA1158-60.

Flavors, including menthol, drive these high rates of youth e-cigarette usage. JA944. As FDA found in its TPL Review, "the flavoring in tobacco products (including ENDS) make them more palatable for novice users, including youth and young adults, which can lead to initiation, more frequent and repeated use, and eventually established regular use." JA945. In 2022, 85.5% of high school e-cigarette users and 81.5% of middle school users reported using a flavored product. *Id.* Moreover, according to data from the federal government, over 93% of youth users reported that their first e-cigarette product was flavored, JA945, and 71% of current youth e-cigarette users reported using e-cigarettes because of flavors. JA930. As the U.S. Court of Appeals for 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).[4] After quantifying the extent of youth usage of e-cigarettes in upholding an MDO for flavored products, the D.C. Circuit observed that "[f]lavored tobacco products lie at the heart of the problem." *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 11 (D.C. Cir. 2022).

With respect to menthol, FDA found—based on compelling evidence—that "the scientific evidence demonstrates that menthol-flavored ENDS pose a substantial risk of youth appeal and use greater than tobacco flavor and similar to flavors such as candy, desserts, sweets, and mint . . . ." JA946-47. In 2022, 26.6% of current youth flavored e-cigarette users reported use of a menthol product, similar to the rates for mint (29.4%) and candy/desserts/sweets (38.3%). JA947. Among youth users of flavored cartridge-based products, like Petitioner's, the rates of menthol use are even higher—*53.9%*. JA1158. As the MDO noted, "There is substantial evidence that the use of menthol flavors in tobacco products, like the menthol flavors in the new products, has significant appeal to youth and is associated with youth initiation of such products." JA14.

Petitioner's products are not only mentholated, they are the cartridge-based products that drove youth e-cigarette use rates to historically high levels and led

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

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), ("2020 Guidance"),[5] JA1106-1157. In 2019, before FDA's revised enforcement policy took effect, 27.5% of high school students reported current e-cigarette use, with most youth e-cigarette users reporting a cartridge-based product, such as Juul, as their usual brand. JA980-81. Between 2017 and 2019, ENDS use more than doubled among middle and high school students. JA946. At that time, FDA determined that the "evidence shows that youth are particularly attracted to flavored, cartridge-based ENDS products." 2020 Guidance at 19, JA1125. Although, as FDA has learned, "preference for device types . . . is likely fluid and affected by the marketplace, particularly the options, especially flavors, that are available for consumers," JA946, the "[s]leek design, ability to use products discreetly and user-friendly nature make pod-based . . . products [like Petitioner's] appealing among youth," JA 936. Petitioner's devices, with which its menthol cartridges are designed to be used, are roughly the size of an ink pen,[6] which "allows for easy concealability" and "may allow youth to use the

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

[6] Petitioner's Logic Vapeleaf device measures 9.2 mm in diameter and 69.4 mm in length (0.36 x 2.73 inches); its Logic Power device: 9.2 mm in diameter and 82.6

product in circumstances where use of tobacco products is prohibited, such as a school." 2020 Guidance at 16, JA1122; *see also* JA936 (TPL Review concluding that Petitioner's products "are sleek and small in design, user friendly, cartridge-based, and easily rechargeable."

FDA's prioritized enforcement against non-menthol, non-tobacco flavored cartridges, which began in February 2020, also demonstrates that youth will migrate to menthol-flavored e-cigarettes if they are left on the market. As researchers from FDA and the Centers for Disease Control and Prevention described the dire situation, the 2020 NYTS data "suggest prominent use of menthol e-cigarettes among US youth" following the implementation of FDA's enforcement priorities.[7] In 2020, over one million high school and middle school youth used menthol e-cigarettes.[8]

Finally, contrary to Logic's claim that "youth do not use its ENDS products in any appreciable amount," Pet'r Op. Br., ECF No. 70, at 17 (Feb. 3, 2023), roughly

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

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

[8] *Id.* at 7 tbl.3. 2020 was the first year in which the NYTS "inquired about mint and menthol as separate flavor types" making it difficult to compare the use rates of these flavors to prior NYTS surveys. *Id.* at 9.

100,000 middle and high schoolers (4.3% of current youth e-cigarette users) reported using a Logic product in the past month in 2022. JA946; JA1159.

The data leave no doubt that, like other flavored products, menthol e-cigarettes—and particularly cartridges like Petitioner's—appeal to youth more than unflavored products.

2. FDA correctly concluded that Petitioner's menthol e-cigarettes pose a direct threat of addiction and other health harms to young people.

Petitioner's menthol cartridges contain nicotine, JA16, 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 explained that it is "during adolescence . . . [that] the developing brain is most vulnerable to nicotine addiction." JA944. And nicotine's grip over young people is borne out by the numbers. In 2022, 46% of high school e-cigarette users reported using e-cigarettes on at least 20 of the preceding 30 days. JA1159. Even more alarming, 30.1% of high school e-cigarette users reported *daily* use, a strong indication of nicotine addiction. *Id.* Roughly 700,000 middle and high school students are vaping on a daily basis. *Id.*

In its TPL Review, FDA also noted that the "[e]xisting literature" suggests that flavored e-cigarettes in particular, including menthol, "not only facilitate initiation but also promote established regular ENDS use." JA945. Flavors, according to FDA, make e-cigarettes and other tobacco products "more palatable for

novice users, including youth and young adults, which can lead to initiation, more frequent and repeated use, and eventually established regular use." *Id.* "Research also shows that ENDS flavors can increase nicotine exposure by potentially influencing the rate of nicotine absorption through pH effects and by promoting the rewards of ENDS use." JA934. FDA concluded that, in sum, the "evidence suggests flavored ENDS may pose greater addiction risk to tobacco nonusers relative to tobacco flavored ENDS, which increases concerns of addiction in youth." *Id.* As the D.C. Circuit found in *Prohibition Juice*, "[a] vast body of scientific evidence shows that flavors encourage youth to try e-cigarettes and, together with the nicotine, keep them coming back." 45 F.4th at 11.

In addition to the risk of addiction, the Surgeon General has found that "[n]icotine exposure during adolescence can impact learning, memory and attention," and "can also increase risk for future addiction to other drugs."[9] Nicotine also impacts the cardiovascular system.[10] In summary, as the Surgeon General has

[9] OFFICE OF THE SURGEON GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVS., SURGEON GENERAL'S ADVISORY ON E-CIGARETTE USE AMONG YOUTH 1 (2018), https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf.

[10] Office of the Surgeon General, U.S. Dep't of Health & Human Servs., *Cardiovascular System*, *in* HOW TOBACCO SMOKE CAUSES DISEASE: THE BIOLOGY AND BEHAVIORAL BASIS FOR SMOKING-ATTRIBUTABLE DISEASE: A REPORT OF THE SURGEON GENERAL 407 (2010), https://www.ncbi.nlm.nih.gov/books/NBK53017/pdf/Bookshelf_NBK53017.pdf.

warned, "[t]he use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe."[11]

Use of e-cigarettes may also function as a gateway to the use of conventional cigarettes and other combustible tobacco products, thereby undermining decades of progress in curbing youth smoking. A 2018 report by the National Academies of Sciences, Engineering, and Medicine ("NASEM") found "substantial evidence that e-cigarette use increases [the] risk of ever using combustible tobacco cigarettes among youth and young adults."[12] A nationally representative analysis found that from 2013 to 2016, youth e-cigarette use was associated with more than four times the odds of trying combustible cigarettes and nearly three times the odds of current combustible cigarette use, compared with youth who had never used a tobacco product.[13] Thus, the threat of menthol 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.

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[11] OFFICE OF THE SURGEON GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVS., E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS, A REPORT OF THE SURGEON GENERAL 5 (2016), https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf.

[12] NASEM, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 10 (2018), https://www.nap.edu/catalog/24952/public-health-consequences-of-e-cigarettes; *see also* A15.

[13] 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.

3. FDA's requirement of "robust and reliable" evidence showing that menthol e-cigarettes help smokers stop smoking more effectively than tobacco-flavored products was entirely reasonable and consistent with the statute.

Precisely because the risks to youth from menthol e-cigarettes is "known and substantial," it was entirely reasonable and consistent with the TCA for FDA to require "robust and reliable" evidence that Petitioner's menthol e-cigarettes "have an added benefit relative to tobacco-flavored ENDS in facilitating smokers completely switching or significantly reducing their cigarette use" sufficient to "outweigh the new products' risk to youth." JA947. FDA correctly concluded that the data submitted by Petitioner fell short—as does the publicly available evidence on this issue.

FDA did not, as Petitioner repeatedly claims, "categorically reduce[] to zero a known benefit of menthol ENDS—that they can help current menthol cigarette smokers transition away from menthol cigarettes . . . ." Pet'r Op. Br. 30; *see also id.* at 38, 42-43. Instead, FDA assessed the evidence and concluded that "the scientific literature does not demonstrate that menthol-flavored ENDS are more effective in promoting complete switching or significant cigarette reduction relative to tobacco-flavored ENDS among adult smokers (including menthol smokers)." JA953. Although, as FDA acknowledged, some studies suggest that people who smoke menthol cigarettes prefer menthol-flavored e-cigarettes over tobacco-flavored ones, "these studies were not designed to evaluate behavior change and thus

do not directly address the outcomes of complete switching or cigarette reduction." JA951. FDA explained why assessments of actual product use—rather than just perceptions or reported intentions—are so "critical": "the ability of a product to promote 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)." JA951. In sum, FDA correctly concluded that that the published literature does not establish that menthol e-cigarettes are more effective than tobacco-flavored e-cigarettes at helping smokers to stop smoking. JA91-53.[14]

Petitioner's data also failed to make the required showing on this issue. Instead of submitting the necessary data, Petitioner offered studies purporting to show that adult smokers that used Logic's menthol e-cigarettes for 60 days: (1) liked the flavor more than adult smokers that received tobacco-flavored products, and (2) "reported the strongest desire to use the product to reduce and/or quit smoking." Pet'r Op. Br. 15. While Petitioner contends that this "evidence is as strong as any menthol ENDS seller is likely ever to submit," *id.* at 13, notably absent is any data

[14] Contrary to Petitioner's suggestion, Pet'r Op. Br. 37, the mere fact that menthol cigarettes are available on the market, whereas other flavors in cigarettes have been prohibited, hardly establishes that menthol e-cigarettes help menthol cigarette smokers to stop smoking any more effectively than tobacco-flavored e-cigarettes. As discussed below, Petitioner failed to demonstrate that any evidence of benefit to smokers outweighs the overwhelming evidence of youth usage of menthol e-cigarettes and Logic's products in particular.

on actual product use behavior. Petitioner's data specific to adults that smoke menthol cigarettes fares no better. According to Petitioner, "current menthol cigarette smokers had more positive *experiences and perceptions* of Logic's ENDS products when they received the menthol flavor than when they received the tobacco flavor." *Id.* at 15 (emphasis added). In the TPL, FDA explained in detail why these perceptions studies are insufficient. "Consumer perception studies (surveys or experiments) typically assess outcomes believed to be precursors to behavior, such as preferences or intents related to the new products but are not designed to directly assess actual product use behavior." JA951. As FDA noted, "uptake and transition to ENDS use is a behavioral pattern that requires assessment at more than one time point. Therefore, evaluating the behavioral outcomes needed to show any benefit of the product requires observing the actual behavior of users over time." *Id.* Unlike perception studies, a randomized controlled trial or longitudinal cohort study, which Petitioner did not submit, allows this "periodic and repeated measurement of relevant outcomes," such as cigarette use. *Id.*

In short, Petitioner presented no studies showing that its menthol cartridges were more effective than tobacco-flavored e-cigarettes in helping smokers to actually stop smoking or reduce their cigarette consumption. In contrast, the evidence of widespread youth usage of flavored e-cigarettes, including menthol-flavored products, reflects actual youth behavior, not just perception or intent. Given

the patent insufficiency of Petitioner's evidence on this critical issue, FDA correctly issued an MDO.

B. FDA correctly determined that Petitioner's access and marketing restrictions are insufficient to reduce youth initiation of its menthol cartridges.

Petitioner also argues that FDA failed to "articulate a satisfactory explanation . . . for its assertion that Logic's marketing restrictions would not work to limit youth appeal . . . ." Pet'r Op. Br. 54 (internal quotations and citations omitted). As is apparent from the TPL Review, FDA gave due consideration to Petitioner's proposed access and marketing restrictions and explained that Petitioner "did not propose any novel or materially different measures from those that FDA has previously considered and found insufficient" to curb youth use of flavored e-cigarettes. JA941.

In other cases involving flavored e-cigarette products, this and other courts have upheld MDOs in which FDA used the same approach it applied to Petitioner's application. *See, e.g.*, *Liquid Labs*, 52 F.4th at 544 (Petitioner "has not explained how the approaches in its plan differ from ones previously found insufficient . . . "); *Prohibition Juice*, 45 F.4th at 17 ("The measures [Petitioners] highlight in their marketing plans are not materially different from those the FDA had previously found insufficient to stem the surge in youth e-cigarette use.").

The core problem is that youth access and marketing restrictions like the ones Petitioner proposed are insufficient to protect youth from the inherent hazards of these flavored products, given their intense appeal to young people. As explained in the TPL Review (JA940-41), FDA's experience confirms this. In March 2019, in response to the youth vaping epidemic, FDA issued Draft Guidance[15] which "proposed to focus its enforcement priorities of flavored ENDS products on how the product was sold . . . " 2020 Guidance at 21, JA1127 (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.*; *see also* JA940. "[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." 2020 Guidance at 21, JA1127. Given this experience, FDA correctly concluded that Petitioner's proposed measures—"eschewing trendy colors, flavors, and vivid imagery that appeal to

[15] 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.

youth,"[16] not using models under the age of 30 to market its products, not using social media accounts, and not making online sales, Pet'r Op. Br. 19—would have little impact given that Petitioner's menthol cartridges themselves have all the features that make e-cigarettes attractive to youth.[17] JA940-41.

FDA's conclusion is also supported by data indicating that youth obtain e-cigarettes with relative ease. According to the 2022 Monitoring the Future Survey, over half of 10th grade students reported that it would be easy to get vaping devices (51.9%) and nicotine-containing e-liquids (50.8%).[18] As FDA explained in both the TPL Review (JA940) and 2020 Guidance (at 28-29, JA1134-35), the majority of 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. As to youth who attempt to buy e-cigarettes directly from retailers, according to one study discussed in the TPL Review, "[o]nly one-quarter of youth who tried to buy tobacco products were refused sale because of their age." JA940. Given the ease with which youth report obtaining e-cigarettes, the alarming

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[16] It is unclear what Petitioner means when it says it has eschewed "trendy . . . flavors." As discussed, *supra* I.A.1., menthol e-cigarettes, particularly cartridge-based products, are extremely popular among youth.

[17] Petitioner also claims that its products are "specifically designed to avoid concealment during use" but offers no details. Pet'r Op. Br. 19.

[18] *Table 16: Trends in Availability of Drugs as Perceived by 10th Graders*, MONITORING THE FUTURE (2022), https://monitoringthefuture.org/wp-content/uploads/2022/12/mtf2022table16.pdf.

level of continued youth usage of flavored e-cigarettes, and FDA's experience showing that restrictions like the ones Petitioner proposed are insufficient to curb youth access to flavored e-cigarettes, FDA reasonably concluded that Petitioner's "sales access restrictions do not in themselves provide enough assurance of a sufficient reduction in youth use to mitigate the substantial risk flavored ENDS pose to youth." JA940.

C. FDA's authority to withdraw a marketing order is immaterial to whether a product should be authorized in the first instance.

Petitioner argues that because the TCA allows FDA to withdraw a marketing granted order, FDA should have authorized its products and then withdrawn them if youth use of the products increased. Pet'r Op. Br. 53-54. Petitioner's argument not only distorts the TCA, but, if accepted, would also be inadequate to protect public health, as required by the TCA. In fact, Petitioner has already enjoyed years of marketing its product without the premarket authorization contemplated by the TCA. *See generally, Am. Acad. of Pediatrics*, 379 F.Supp.3d at 468, 493 (noting that e-cigarette manufacturers have enjoyed "a holiday from meeting the obligations of the law" due to FDA's exercise of enforcement discretion). And Petitioner took full advantage of its "holiday": In 2022, it was the tenth most popular e-cigarette brand among youth.

The TCA 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 may be marketed. The fact that FDA may exercise its authority to withdraw a marketing order, *see* 21 U.S.C. § 387j(d)(1)(A), is not 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 authority to exercise 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 is not 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

[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-

of then-FDA Commissioner Gottlieb, "[w]hat I did not predict 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 protect public health, as required by the statute, the authority to withdraw a marketing granted order is not an adequate substitute for the rigorous premarket review mandated by Section 910.

II. If Granted, Petitioner's Requested Transition Period Would Be Contrary to FDA's Past Practice, Undermine the Tobacco Control Act, and Harm Public Health.

Petitioner asserts that FDA violated the Administrative Procedure Act by departing from its prior policy because it did not provide Logic a transition period before ordering its menthol cartridges off the market. Pet'r Op. Br. 56. The Court should reject this argument because no such policy exists, and also because a transition period would both be contrary to the TCA and would harm public health.

The examples that Petitioner cites in arguing that FDA has a "policy" of providing transition periods to e-cigarettes that have been denied premarket authorization make it plain that no such policy exists. Petitioner begins by citing

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

[20] *Id.*

three examples from entirely different regulatory contexts, governed by different statutory schemes, and completely unrelated to tobacco products. Pet'r Op. Br. 57-59 (citing transition periods for "electrical simulation devices," "intravenous gout medication," a drug used in "edible cattle and sheep"). Turning to tobacco products, Petitioner acknowledges that no such transition period exists for e-cigarettes, but nonetheless argues that because FDA has stayed a small handful of MDOs after determining that it needed to further review certain evidence, FDA has "at least in substance" granted a transition period. *Id.* at 59. Of course, a stay and a transition period are not the same. Here, Petitioner seeks to compel FDA to allow its products to remain on the market, even though the agency has determined that they may not legally be sold because they are "not appropriate for the protection of public health." Finally, Petitioner invokes FDA's proposed product standard that would prohibit menthol as a characterizing flavor in cigarettes to argue that "FDA even proposes to provide the tobacco industry a one-year transition period prior to potentially removing menthol cigarettes from the market." *Id.* at 61 (citing 87 Fed. Reg. 26,454 26,455-56 (May 4, 2022)). Petitioner fails to mention that the Tobacco Control Act requires a one-year delay in the effective date for regulations that establish a tobacco product standard "unless the Secretary determines that an earlier effective date is necessary for the protection of the public health." 21 U.S.C. § 387g(d)(2). There is no similar provision for tobacco products that have received an MDO.

Petitioner's transition period request, if granted, would turn the TCA on its head and harm public health. Petitioner's products have never been covered by a marketing order and thus have remained on the market without any legal authorization "for the better part of a decade." Pet'r Op. Br. 8. They have only been allowed to remain on the market because of FDA's exercise of enforcement discretion. *See generally*, *Am. Acad. of Pediatrics*, 379 F.Supp.3d at 468.

Should the Court uphold the MDO, any further relief to Petitioner allowing it to keep its products on the market would be contrary to the TCA by allowing Petitioner to market its products despite having failed to satisfy the statutory public health standard. 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." Petitioner's requested relief 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 ADMISSION TO THE BAR

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

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I hereby certify that on February 17, 2023, 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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