ORAL ARGUMENT SCHEDULED FOR JANUARY 25, 2023

No. 22-1076

In the United States Court of Appeals for the District of Columbia Circuit

FONTEM US, LLC,

Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

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

MOTION FOR LEAVE TO FILE BRIEF OF MEDICAL, PUBLIC HEALTH, AND PARENT GROUPS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Cir. R. 28(a)(1), proposed *amici curiae* Medical, Public Health, and Parent Groups certify as follows:

A. Parties and Proposed *Amici*

Petitioner:

Fontem US, LLC

Respondent

United States Food and Drug Administration

Proposed *Amici Curiae*

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 District of Columbia

Parents Against Vaping e-cigarettes

Truth Initiative

(collectively, "Medical, Public Health, and Parent Groups")

B. Rulings under Review

References to the rulings at issue appear in the Briefs for Petitioner and Respondent.

C. Related Cases

Related cases are listed in the Briefs for Petitioner and Respondent.

DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1(a) and D.C. Cir. R. 26.1, proposed *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.

MOTION FOR LEAVE

Proposed *amici* hereby move the Court for leave to file the attached Brief of Medical, Public Health, and Parent Groups as *Amici Curiae* in Support of Respondent. Proposed *amici* previously filed a Notice of Intention to Participate as *Amici Curiae*. Doc. No. 1968175 (Oct. 7, 2022). Respondent does not oppose the motion; Petitioner states that "Fontem opposes the motion as untimely, Fed. R. App. P. 29(a)(6), and prejudicial because filing at this stage of the proceedings deprived Fontem of the opportunity to respond in its reply brief."

Each of proposed *amici* works on a daily basis to reduce the devastating health harms of tobacco products, including electronic nicotine delivery system ("e-cigarette") products. Proposed *amici* include physicians who counsel their patients, including young people, 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 has a direct and immediate interest in ensuring that Petitioner's products not be permitted on the market, given the absence of critical product safety data in Petitioner's Premarket Tobacco Product Application and the failure of Petitioner to demonstrate that its flavored products have a public health benefit to people who smoke sufficient to outweigh their demonstrated risk to youth.

Proposed *amici* also have a special interest in this case because many of them 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). Proposed *amici* therefore have a strong interest in ensuring that the premarket review process functions to protect the public health by removing from the market e-cigarettes that fail to meet the statutory public health standard.

This *amicus* brief will assist the Court because proposed *amici* have substantial expertise in the health harms that may result from the use of e-cigarettes, like Petitioner's, which was a key factor in FDA's decision to issue a marketing denial order ("MDO") to Petitioner. They also have expertise in the role that e-cigarettes, particularly flavored products, play in enticing young people to use tobacco, another factor FDA considered in issuing the MDO. Moreover, many of the proposed *amici* have filed *amicus* briefs in numerous other cases, including one

in this Court, that concern challenges by e-cigarette manufacturers to FDA's decisions to deny marketing authorization to their products.[1]

As contemplated under Fed. R. App. P. 29(a)(6), proposed *amici* move to file this brief outside of the normal timeline provided for under that Rule and Cir. R. 29(c). Generally, "[a]n amicus curiae must file its brief . . . no later than 7 days after the principal brief of the party being supported is filed." Fed. R. App. P. 29(a)(6). However, Rule 29 allows a court to "grant leave for later filing" and to "specify[] the time within which an opposing party may answer." *Id.*

Here, proposed *amici* previously filed a Motion to Unseal key documents that Petitioner filed under seal or heavily redacted, including the argument section of its opening brief and the entirety of FDA's MDO and Technical Project Lead Review Memorandum ("TPL Review"). *See* Medical, Public Health and Parent Groups' Motion to Unseal, Doc. No. 1967952 (Oct. 6, 2022). That Motion to Unseal argued,

[1] To date, by leave of court and/or consent of the parties, many of the proposed *amici* have filed *amicus curiae* briefs in the following MDO appeals: *Prohibition Juice Co. v. FDA*, No. 21-1201 (D.C. Cir.) (consolidated with Nos. 21-1203, 21-1205, 21-1207); *Magellan Tech., Inc v. FDA*, No. 21-2426 (2d Cir.); *Liquid Labs, LLC v. FDA*, No. 21-2883 (3d Cir.); *Logic Tech. Dev. LLC v. FDA*, No. 22-3030 (3d Cir.); *Avail Vapor, LLC v. FDA*, No. 21-2077 (4th Cir.); *Wages & White Lion Invs., L.L.C. v. FDA*, No. 21-60766 (5th Cir.); *Breeze Smoke, LLC v. FDA*, No. 21-3902 (6th Cir.); *Gripum LLC v. FDA*, No. 21-2840 (7th Cir.); *7 Daze, LLC v. FDA*, No. 21-71319 (9th Cir.); *Lotus Vaping Techs., LLC v. FDA*, No. 21-71328 (9th Cir.); *MH Global LLC v. FDA*, No. 21-71327 (9th Cir.); *Nude Nicotine Inc. v. FDA*, No. 21-71321 (9th Cir.); *Bidi Vapor LLC v. FDA*, No. 21-13340 (11th Cir); *Diamond Vapor LLC et al. v. FDA*, Nos. 21-13387, 21-13438, 21-13454 (11th Cir.).

in part, that Petitioner's filings under seal or with redactions adversely affected proposed *amici*'s ability to submit a brief that would assist the Court in considering the key issues in this case. *See id.* at 4-5, 10.

In its Response to the Motion to Unseal, Petitioner attached new versions of its opening brief, the MDO, and TPL Review that contained fewer redactions. *See* Fontem US LLC's Response to Motion to Unseal, Doc. No. 1969344 (Oct. 17, 2022). Although the remaining redactions are overly broad[2] and limit the issues that proposed *amici* can address in its brief, Petitioner's revised filings allow proposed *amici* to address certain of the central issues, including the propriety of FDA's determination that Petitioner's products do not meet the standard of being "appropriate for the protection of the public health." Proposed *amici* waited to file its brief until after Petitioner—pursuant to the direction of the Court (Doc. No. 1979296, Dec. 28, 2022)—filed its Surreply to the Motion to Unseal (Doc. No. 1981157, Jan. 11, 2023), so that they could assess whether Petitioner would disclose additional information in the Surreply. Petitioner did not do so. Petitioner will not be prejudiced by the timing of this filing, as it will have an opportunity to respond

[2] As discussed in the Reply in Support of the Motion to Unseal, Doc. No. 1970350 (Oct. 24, 2022), there remain categories of documents with redactions for which Petitioner, despite repeated efforts (including its recently filed Surreply) still has failed to offer sufficient justification.

to the *amicus* brief at, or even prior to, the January 25, 2023 oral argument. *See* Fed. R. App. P. 29(a)(6).

For these reasons, proposed *amici* urge the Court to grant their motion for leave to file the attached brief.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitations of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) and the rules of this Court, because it contains 1,058 words, excluding the parts of the motion exempted by Federal Rule of Appellate Procedure 32(f).

This motion complies with the typeface requirements of Federal Rule Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this it has been prepared in a proportionally spaced typeface using Microsoft Word with 14-point Times New Roman font.

/s/ Andrew N. Goldfarb
Andrew N. Goldfarb
Attorney for Proposed *Amici Curiae*

CERTIFICATE OF SERVICE

I hereby certify that on January 18, 2023, the foregoing motion was filed via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

/s/ Andrew N. Goldfarb
Andrew N. Goldfarb
Attorney for Proposed *Amici Curiae*

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GLOSSARY

APA	Administrative Procedures Act
FDA	United States Food and Drug Administration
ENDS	Electronic Nicotine Delivery System
HPHC	Harmful and Potentially Harmful Constituents
MDO	Marketing Denial Order
PMTA	Premarket Tobacco Product Application
TCA	Tobacco Control Act
TPL Review	Technical Project Lead Review Memorandum

Amici medical, public health, and parent 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 Fontem US, LLC ("Fontem" or "Petitioner") because FDA reasonably found that Petitioner had failed to show that its e-cigarette products were appropriate for the protection of the public health (the "public health standard"), as required by the Family Smoking Protection and Tobacco Control Act (the "Tobacco Control Act" or "TCA").[1]

STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici are the following medical, public health, and parent 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 District of Columbia, Parents Against Vaping e-cigarettes, and Truth Initiative.

[1] *Amici* have also filed a Motion to Unseal documents filed by Petitioner, which is pending before the Court. As discussed in the Reply in Support of the Motion to Unseal, Doc. No. 1970350 (Oct. 24, 2022), there remain categories of documents with redactions for which Petitioner, despite repeated efforts (including its recently filed Surreply) still has failed to offer sufficient justification. Because the remaining redactions limit the issues that *amici* can address in this brief, a*mici* may request permission to supplement this brief if additional information is unsealed.

Each of these groups 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] *Amici* include physicians who counsel their patients, including young people, 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 has a direct and immediate interest in ensuring that Petitioner's products not be permitted on the market, given the absence of critical product safety data in Petitioner's Premarket Tobacco Product Application ("PMTA" or "application") and the failure of Petitioner to demonstrate that its flavored products have a public health benefit to people who smoke sufficient to outweigh their demonstrated risk to youth.

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 PMTAs 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.*

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

In re Cigar Ass'n of Am., 812 F.App'x 128 (4th Cir. 2020) ("*AAP*"). *Amici* therefore have a strong interest in ensuring that the premarket review process functions to protect the public health by removing from the market e-cigarettes that fail to meet the statutory public health standard.

STATEMENT OF COMPLIANCE WITH RULE 29(a)

Amici represent 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.

INTRODUCTION AND SUMMARY OF ARGUMENT

As this Court recognized in *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 276-77 (D.C. Cir. 2019) and *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 11 (D.C. Cir. 2022), a central feature of the Tobacco Control Act is that, with certain exceptions, no new tobacco product (i.e., those not commercially marketed as of February 15, 2007) may enter the market without undergoing FDA review to determine whether the product is "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2). Although the statute authorized the FDA to initially regulate only cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, the TCA also gave FDA the authority to extend its authority, including the premarket review requirement, to other tobacco products by issuing a regulation subjecting

them to its authority. *Id.* § 387a(b). In April 2011, FDA announced that it intended to issue such a rule bringing e-cigarettes and other tobacco products within its authority;[3] it then issued a proposed deeming rule in 2014[4] and a final rule in 2016.[5]

Due to FDA's exercise of "enforcement discretion," until 2022, which was vacated by a federal court in *AAP*, 379 F.Supp.3d at 498, Petitioner did not actually submit a PMTA seeking the required marketing order until April 2020, *nine years after* FDA first announced that e-cigarette companies would be required to undergo premarket review and meet the statutory standard for new products. In vacating the 2017 Guidance that would have extended to 2022 the deadline for e-cigarette companies to file PMTAs, the court in *AAP* determined that e-cigarette companies had enjoyed an unlawful "holiday from meeting the obligations of the law" that allowed them "to advertise and sell products that are addictive and that target a youth market . . . ." 379 F.Supp.3d at 492-493.

[3] Letter from Lawrence Deyton & Janet Woodcock to Stakeholders re: Regulation of E-Cigarettes and Other Tobacco Products (Apr. 25, 2011). https://www.aaphp.org/Determination

[4] Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 79 Fed. Reg. 23,141 (proposed Apr. 25, 2014).

[5] 81 Fed. Reg. 28,974 (May 10, 2016).

Through its issuance of an MDO, FDA finally brought Petitioner's regulatory "holiday" to an end, finding Fontem's PMTA fatally deficient in multiple respects. Petitioner's attacks on the MDO have no merit.

First, Petitioner misreads Section 910 of the TCA when it asserts that, because some of the deficiencies in its PMTA raise issues involving the company's manufacturing process, they cannot be considered in determining whether the public health standard is met. Not only is FDA permitted to consider deficiencies in the manufacturing process, it is required to do so if, as here, those deficiencies have public health implications.

Second, Petitioner also misreads the TCA when it asserts that FDA has improperly issued a product standard banning flavored e-cigarettes under Section 907 through its adjudication of Petitioner's application, instead of employing notice-and-comment rulemaking. While the statute gives FDA authority to issue a product standard, it also gives the agency the authority to act on Petitioner's application through adjudication and, in adjudicating Petitioner's application, to identify the evidence that may be sufficient to market new flavored e-cigarette products. The agency correctly found Petitioner's application deficient in failing to supply that evidence for its flavored products. JA474-75.

Third, Petitioner challenges FDA's denial of the PMTA based on Petitioner's failure to provide six critical pieces of evidence concerning the safety of its products.

While Petitioner claims that the deficiencies do not represent actual health problems, each of the deficiencies directly affects the risk of adverse health consequences to the consumer and others. The fact is that *nine years after FDA informed the manufacturers of e-cigarette products that it intended to require their products to meet the public health standard, and six years after the issuance of a final rule imposing that requirement*, the company still has not presented FDA with evidence demonstrating the safety of its products.

Finally, contrary to Petitioner's allegation that FDA's treatment of its flavored products invoked a new standard, the MDO was based on an analysis similar to the agency's treatment of other flavored e-cigarette products upheld by this Court in *Prohibition Juice* and by other federal circuit courts. Because flavored e-cigarettes pose known and substantial risks to youth, it was reasonable for FDA to require Petitioner and other manufacturers to advance "robust and reliable evidence" of the benefit of such flavored products, as compared to unflavored (i.e., tobacco-flavored) products, in aiding people who smoke to stop smoking. It also was reasonable for FDA to conclude that the access and marketing restrictions proposed by Petitioner would not reduce the risk to youth of the company's flavored products by a sufficient amount to justify lowering the evidentiary showing the company must make with respect to the benefit (if any) its flavored products offer to adult smokers. These determinations were the result of FDA's straightforward application of the TCA's

requirement that, in determining whether a new product meets the public health standard, FDA must weigh the likelihood that the products will lead non-users to initiate use of tobacco products against the likelihood that the product will help existing tobacco users to stop using such products. 21 U.S.C. § 387j(c)(2).

ARGUMENT

I. Petitioner's Critique of the MDO Is Based on a Fundamental Misunderstanding of the Tobacco Control Act.

Petitioner's central argument that the MDO it received is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," under the Administrative Procedure Act ("APA") is based on a fundamental misreading of Section 910 of the TCA, which requires FDA to deny marketing orders to companies unable to meet their burden of showing that their new tobacco products are "appropriate for the protection of the public health." According to Petitioner, the deficiencies in its application identified by FDA are "manufacturing issues" improperly considered under the public health standard or "reflect improper development of a product standard through adjudication." Pet'r Br. 21. The language and structure of Section 910 do not support Petitioner's arguments.

Section 910(c)(2) provides that "[t]he Secretary shall deny an application" for marketing authorization if any one of four conditions are met:

> (A) 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; ["public health standard"];

> (B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not confirm to the requirements of section 387f(e) of this title ["good manufacturing practices provision"];
>
> (C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular ["labeling provision"]; or
>
> (D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of this title, and there is a lack of adequate information to justify the deviation from such standard ["product standard provision"].

21 U.S.C. § 387j(c)(2). As this Court has summarized, to satisfy Section 910, "a new product must be 'appropriate' for the public health, not make false or misleading claims, and conform to existing tobacco product standards." *Nicopure*, 944 F.3d at 277.

FDA denied marketing authorization for both flavored and unflavored Fontem products on the ground that the company failed to make the requisite showing that the marketing of the products would meet the public health standard, citing six "deficiencies" in Petitioner's application that supported this conclusion. JA471-77. Petitioner erroneously contends that because some of the deficiencies concern its manufacturing processes, and FDA has not issued regulations prescribing good manufacturing practices, FDA could not consider those deficiencies when deciding if Petitioner's PMTA met the public health standard. Pet'r Br. 4. But the "good manufacturing practices" provision of Section 910(c)(2) simply provides that the

failure of a company to demonstrate compliance with a regulation requiring good manufacturing practices is itself sufficient to deny marketing authorization for that product, regardless of whether the public health standard is met. Section 910(c)(2) does not state or imply that in the absence of a good manufacturing practices regulation, deficiencies in an application that relate to the manufacturing process cannot be considered as relevant to whether the public health standard is met. The public health standard is broad—whether a product meets the standard "shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product . . . ." 21 U.S.C. § 387j(c)(4). The TCA further requires marketing applications to contain extensive information about product safety and manufacturing, including "a full description of the methods used in, and the facilities and controls used for, the manufacture[] . . . of" the product, *id.* § 387j(b)(1)(C), a requirement not contingent on the existence of separate good manufacturing practices regulations. As demonstrated in Section II *infra*, the deficiencies cited by FDA have important public health implications. As such, not only is FDA permitted to consider them in evaluating Fontem's marketing application under the public health standard, it is *required* by the statute to do so. That requirement is independent of the separate statutory direction that FDA issue a regulation defining good manufacturing practices.

Similarly, the product standard provision of Section 910(c)(2) simply means that a company's failure to establish compliance with an existing product standard under Section 907 (21 U.S.C. § 387g) is itself a sufficient basis to deny a marketing application, regardless of whether the public health standard is met. Here, as Petitioner points out, Pet'r Br. 9, there are no existing product standards applicable to Petitioner's products. Thus, the product standard provision is not relevant to whether Petitioner should be issued a marketing order for those products.

Petitioner tries to build an argument around the premise that somehow FDA has improperly issued a product standard through its adjudication of Petitioner's flavored products. Pet'r Br. 24-27. This argument misapprehends the nature of a product standard under the TCA.

Under Section 907 (21 U.S.C. § 387g), 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.[6] A product standard is a rule that restricts the manufacture of products with certain properties. Section 907 itself establishes a product standard (the "Special Rule for Cigarettes") prohibiting flavors in cigarettes, providing that they "shall not contain, as a

[6] *Compare* 21 U.S.C. § 387g(a)(3)(A), *with id.* § 387j(c)(2).

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 by regulation to "adopt product standards in addition to" the Special Rule for Cigarettes. 21 U.S.C. § 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." 21 U.S.C. § 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.").

The MDO does not state that particular flavorings in e-cigarette products are banned. Rather, in explaining Deficiency #5 in Petitioner's application, concerning Petitioner's flavored products, FDA determined that "in light of the known risks to youth of marketing flavored ENDS, robust and reliable evidence is needed regarding the magnitude of the potential benefit to adult smokers" in helping them to stop smoking. JA475. Such evidence "could be provided using a randomized controlled trial and/or longitudinal cohort study or other evidence demonstrating the benefit of

your new products to adult smokers." *Id.* By requiring 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; rather, 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*. FDA found Petitioner's longitudinal switching study, its cross-sectional survey, and the general literature insufficient to establish any benefit to people who smoke sufficient to outweigh the known risks to youth from flavored products. JA475. This individualized assessment is entirely in accord with the provisions of Section 910.

Petitioner also alleges both that FDA violated the APA by announcing general evidentiary standards through adjudication, instead of through rulemaking, and that it set out those standards unfairly for the first time in the Fontem MDO. Pet'r Br. 28-29, 30. In its responsive brief, FDA sets out, in great detail, the prior notices of the required evidence Fontem received, which include a deficiency letter from FDA, a 2019 guidance document, and the TCA itself. *See generally* Resp't Br. 31-58. In addition, Fontem's argument overlooks Supreme Court and D.C. Circuit precedent establishing that "[an agency] is not precluded from announcing new principles in an adjudicative proceeding and the choice between rulemaking and adjudication lies

in the first instance within the [agency's] discretion." *N.L.R.B. v. Bell Aerospace Co. Div. of Textron, Inc.*, 416 U.S. 267, 294 (1974); *POM Wonderful, LLC v. FTC*, 777 F.3d 478, 497 (D.C Cir. 2015) (same). FDA plainly has authority to develop and articulate—through adjudication of individual PMTAs—its policy on the types of evidence that would be necessary to support a marketing order for e-cigarette products. As the Supreme Court has recognized, "[a]djudicated cases may and do, of course, serve as vehicles for the formulation of agency policies, which are applied and announced therein." *N.L.R.B. v. Wyman-Gordon Co.*, 394 U.S. 759, 765 (1969); *see also Conference Group, LLC v. FCC*, 720 F.3d 957, 966 (D.C. Cir. 2013) ("The fact that an order rendered in an adjudication may affect agency policy and have general prospective application does not make it rulemaking subject to . . . notice and comment.") (citation and internal quotations omitted). There is no basis for Petitioner's argument that FDA violated the APA by determining and applying evidentiary standards in adjudicating marketing applications to ensure that new e-cigarette products meet the TCA's public health standard.

II. Each of the Deficiencies FDA Identified in Petitioner's Application Has Significant Public Health Implications.

FDA denied Petitioners' marketing applications because Petitioner failed to submit five—and for Petitioner's flavored products, six—critical pieces of evidence about its products. JA472-76. Petitioner contends that these deficiencies are merely "data gaps" and do not identify "an actual public health problem with Fontem's

products." Pet'r Br. 3. On the contrary, these deficiencies go directly to the risk of adverse health consequences to the consumer and others.

First, Petitioner failed to provide the quantities of eight harmful and potentially harmful constituents ("HPHC") that may be emitted when Petitioner's device reaches its maximum allowable coil temperature. JA472. Specifically, Petitioner failed to provide this data for the following HPHCs: total nicotine, acetaldehyde, formaldehyde, acrolein, nickel, lead, chromium, and cadmium. *Id.* An HPHC is a chemical that "causes or has the potential to cause direct or indirect harm to users or non-users of tobacco products."[7] Thus, by their very nature, the presence of HPHCs in e-cigarette aerosol present potential health issues for both users and nonusers. It was appropriate for FDA to require the submission of data about HPHC levels when Petitioner's device is used at high temperatures because, as FDA found, "[e]vidence indicates that high coil temperature may cause [the] emission of large quantities of aerosol HPHCs including carbonyls (e.g., acrolein, formaldehyde, acetaldehyde) and toxic metals." JA472. FDA also concluded that Petitioner's products "lack proper coil temperature control, which may cause emission of high levels of nicotine, formaldehyde, acetaldehyde, acrolein, nickel,

[7] FDA, *"Harmful and Potentially Harmful Constituents" in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry and FDA Staff (Revised)* 2 (Aug. 2016), https://www.fda.gov/media/80109/download.

chromium, lead or cadmium." JA355. Therefore, FDA's conclusion that Petitioner could not show that its products meet the public health standard without providing data on the quantities of HPHCs that are emitted at high temperatures was reasonable.

Second, Petitioner failed to provide key information about its thermal test data, including the complete data sets and thermocouple calibration records, which are the instruments used to measure the temperature of the aerosol emitted by Petitioner's products. JA453. As FDA explained, aerosol temperature may affect the level of toxins emitted and the risk of burn injuries, *id.*, information that is directly relevant to whether the product is appropriate for the protection of public health.

Third, Petitioner failed to provide critical information about its manufacturing process, including the names of the laboratories that performed quality control tests on its products, whether those labs were accredited, the temperature and humidity of its manufacturing facilities, and how long its products were stored in certain warehouses. JA453-44. This information similarly bears on issues of public health: without it, FDA is unable to address basic health issues such as whether the products were manufactured in safe conditions and whether Petitioner's data is valid and reliable.

Fourth, Petitioner did not submit adequate post-manufacturing microbial stability data for its products. JA454. This lack of data precluded FDA from determining the levels of certain microbial components and organisms, such as bacteria, yeast, mold, bacterial and fungal spores, and toxins, in Fontem's products. *Id.* As FDA explained, "the presence of microbial components or organisms may result in increased risk to public health because they may be either carcinogenic in nature or associated with the development of respiratory and/or systemic health issues." *Id.*

Fifth, Petitioner's application relied on the submissions of other parties ("tobacco product master files"), submissions that FDA determined lacked certain information the agency needed to decide if Petitioner's products are appropriate for the protection of public health. JA456. However, due to the heavy redactions in the Joint Appendix and the parties' briefs, *amici* are unable to determine—let alone analyze—the deficiencies in the tobacco product master files. In that connection, *amici* urge the Court to grant their pending Motion to Unseal and order disclosure of the redacted material referenced in the Reply in support of that Motion, Doc. No. 1970350 (Oct. 24, 2022).

Finally, FDA denied Petitioner's flavored products for an additional reason—Petitioner failed to submit "sufficient evidence demonstrating that the new [flavored] products have a potential to benefit adult smokers, who switch completely or

significantly reduce cigarette use, that would outweigh the risk to youth." JA455. As discussed, *infra* Part III, flavored e-cigarettes present significant public health concerns and FDA's analysis and denial of Petitioner's flavored products was both reasonable and in accord with the TCA.

Courts "give an *extreme degree of deference* to the agency when it is evaluating scientific data within its technical expertise," which is precisely the case here. *See Am. Farm Bureau Federation v. EPA*, 559 F.3d 512, 519 (D.C. Cir. 2009) (emphasis added) (quotations omitted). Accordingly, the Court should defer to FDA's conclusion, based on its scientific assessment of technical data submitted by Fontem, that the significant gaps and deficiencies in that data prevented the agency from finding that Petitioner's products meet the public health standard.

III. Given the Overwhelming Evidence That Flavored E-Cigarettes Appeal to Youth, FDA Reasonably Denied Authorization to Petitioner's Flavored Products for Failure to Provide Evidence that Such Products' Potential Benefit to People Who Smoke Outweighs the Products' Risk to Youth.

In determining if the marketing of an e-cigarette is "appropriate for the protection of the public health" 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, FDA found that flavored e-cigarettes pose "known and substantial risks to youth" because such

products increase youth initiation and use of tobacco products. JA434. Given this evidence, it was reasonable for FDA to require Petitioner to submit "robust and reliable evidence" demonstrating that its flavored e-cigarette cartridges "have an added benefit relative to tobacco-flavored [e-cigarettes] in facilitating smokers completely switching or significantly reducing their smoking." And when Petitioner failed to provide such evidence, it was similarly appropriate for FDA to issue an MDO. JA437.

The impact of a product on youth initiation is particularly critical because, as FDA noted in its Technical Project Lead Review Memorandum ("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." JA434. 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 nicotine dependence that can be established in youth, preventing tobacco use initiation in young people is a central priority for protecting population health." *Id.*

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

E-cigarettes have been the most commonly used tobacco product among U.S. youth since 2014.[8] As FDA noted, in the 2021 National Youth Tobacco Survey, 11.3% of high school students reported current e-cigarette use. JA434-35. FDA also observed that, because approximately half of the students took the 2021 survey at home, the survey likely underreported youth e-cigarette use. JA435. In the time since FDA issued Petitioner's MDO, the Centers for Disease Control and Prevention has published the 2022 National Youth Tobacco Survey results, which show that 14.1% of high school students and 3.3% of middle school students reported current e-cigarette use.[9] In total, more than 2.5 million youth reported being current e-cigarette users in 2022.[10]

As this Court has found, "*[f]lavored* tobacco products lie at the heart of the [youth e-cigarette] problem. A vast body of scientific evidence shows that flavors encourage youth to try e-cigarettes, and together with the nicotine, keep them coming back." *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 10 (D.C. Cir. 2022)

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[8] Maria Cooper et al., *Notes from the Field: E-Cigarette Use Among Middle and High School Students – United States, 2022*, 71 MORBIDITY & MORTALITY WKLY. REP. 1283, 1283 (2022), https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7140a3-H.pdf.

[9] *Id.*

[10] *Id.* at 1284 tbl.

(emphasis added). FDA made a similar finding in its TPL Review of Petitioner's PMTA, concluding that 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." JA435. In 2021, 85.8% of high school e-cigarette users and 79.2% of middle school e-cigarette users reported using a flavored e-cigarette. *Id.* Over 90% of youth e-cigarette users reported that their first e-cigarette was flavored, compared to 52.9% of adult users 25 years of age and older. JA435.

Petitioner's e-cigarettes are cartridge-based products (also called "pod-based"). Pet'r Br. 14. Flavored cartridges are the product type 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 non-tobacco, non-menthol cartridge-based e-cigarettes. *See* FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)* (Apr. 2020), JA137 ("2020 Guidance").[11] Specifically citing cartridge-based products, in December 2018, the U.S. Surgeon General declared the youth e-cigarette problem

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

an "epidemic."[12] 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 reporting a cartridge-based product as their usual brand.[13] FDA noted that the "design features" of such products contribute to their youth appeal. JA153. Petitioner's e-cigarette device, which it markets as "sleek and compact" and which is designed to be used with Petitioner's cartridges, is roughly the size of a USB flash drive.[14] As FDA recognized in its 2020 Guidance, this small size "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.*

Petitioner is correct that "for years, the market for vaping products flourished unregulated by FDA." Pet'r Br. 7. However, the "flourishing" of the e-cigarette

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[12] Office of the Surgeon General, U.S. Dep't of Health & Human Services, *Surgeon General's Advisory on E-Cigarette Use Among Youth* (2018), https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf.

[13] 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.

[14] *blu® Device*, BLU, https://www.blu.com/en/US/e-cigs-blu-devices (last visited Dec. 20, 2022) (device measures 4.25in x 0.71in).

market was due, in large part, to a "flourishing" youth market, fueled by flavored cartridge-based products.

Petitioner's own data reinforces the youth appeal of its flavored e-cigarettes. Although Petitioner did not include any youth data in its application, it did provide data from a small sample of young adults (ages 18-24), which "indicated that young adults (proxy for youth) had more curiosity towards" Petitioner's flavored products compared to its tobacco-flavored products. JA394. Although FDA identified methodological issues with Petitioner's young adult study, the agency concluded that if such data is generalizable to youth, it suggests that Petitioner's non-tobacco and non-menthol flavored products are most appealing to youth. JA394-95.

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

Petitioner's cartridges contain nicotine, JA478-83, which is "among the most addictive substances used by humans." *Nicopure*, 944 F.3d at 270. As FDA has found, the "adolescent brain is uniquely vulnerable to nicotine compared to the adult brain." JA174. "Adolescent tobacco users who initiated tobacco use at earlier ages were more likely than those initiating at older ages to report symptoms of tobacco dependence, putting them at greater risk for maintaining tobacco product use into adulthood." JA434. In 2022, 42.3% 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, 30.1% of high school users and 11.7% of middle school users reported *daily* use, a strong sign of nicotine addiction.[15]

In its TPL Review, FDA found that flavors, in particular, likely increase nicotine dependence, particularly among people (including youth) who had not previously used tobacco. *E.g.*, JA431, JA435-36. "[F]lavors can increase nicotine exposure by potentially influencing the rate of nicotine absorption through pH effect and by promoting the reward of ENDS use." JA431. Thus, "flavored ENDS may pose greater addiction risk to tobacco non-users relative to tobacco-flavored ENDS, which increases concerns of addiction in youth." *Id.*

In addition to the risk of addiction, FDA has found that "[r]epeated exposure to nicotine during adolescence induces long-lasting structural and functional changes in brain regions involved in addiction, attention, learning, and memory" and "can lead to long-lasting effects on cognitive function." JA174. FDA also noted that, while further research is needed, the published literature suggests that e-cigarette use "may be associated with a higher likelihood of some health outcomes such as cardiovascular disease, respiratory disease, and oral health." JA371.

[15] Cooper et al., *supra* note 8, at 1283.

C. FDA's requirement that Petitioner submit evidence that the benefit to adult smokers of its flavored products outweighs their risk to youth was reasonable and did not announce a new standard.

In evaluating Petitioner's products, and consistent with the statutory standard, FDA assessed whether the products provided "a net benefit to public health based upon the risks and benefits to the population as a whole." JA410. The agency reasonably found that "[a]s the known risks of the product increase or decrease, the burden of demonstrating a substantial enough benefit likewise increases or decreases." *Id*. As applied to flavored e-cigarettes, FDA found that because these products present "known and substantial risks of youth initiation and use," there is a higher burden that Petitioner (and other applicants) must satisfy "to establish that the likely benefits to adult smokers outweigh that risk." JA410. Contrary to Petitioner's assertion, Pet'r Br. 48-49, this is the same standard FDA has applied in its review of other applicants' flavored e-cigarettes. *See e.g.*, *Prohibition Juice*, 45 F.4th at 12 (upholding MDO in which FDA required applicant to "establish that their flavored liquids carry greater public health benefits than unflavored liquids."); *Liquid Labs LLC v. FDA*, 52 F.4th 533, 538 (3d Cir. 2022) ("We also join our sister circuits in concluding that the 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.") (cleaned up). Not only did FDA act reasonably,

but as this Court has recognized, this is "precisely the type of analysis the [TCA] requires." *Prohibition Juice*, 45 F.4th at 19.

In its decisional documents, FDA explained in detail why the two studies Petitioner submitted—a "longitudinal switching study" and "a retrospective analysis of tobacco product use behavior in users of its vaping products," Pet'r Br. 47-48—were insufficient to show that flavored products help adult smokers transition away from smoking cigarettes more than tobacco-flavored products do. For the longitudinal switching study, FDA found that the study "showed no significant correlation in flavor used ('other' vs. tobacco) being helpful in quitting." JA373; *see also* JA429. Moreover, although the sample size of the study has been redacted, FDA concluded that it was "relatively small," which "render[s] the data ineffectual for the purpose of assessing switching behavior among respondents." *Id.*

FDA found Petitioner's "retrospective analysis" similarly deficient. It was an "online survey administered to a cross-sectional convenience sample on a single occasion." JA429. Aside from the fact that this analysis was based on a sample of only 19 respondents, FDA explained why this type of "one-time assessment of self-reported outcomes . . . does not enable reliable evaluation of behavior change over time." JA439. "Consumer perception studies (surveys or experiments) typically assess outcomes believed to be precursors to behavior, such as preferences or intents . . . but are not designed to directly assess actual product use behavior." *Id*; *see*

Prohibition Juice, 45 F.4th at 21 (finding that FDA's conclusion regarding the inadequacy of one-time assessments was not arbitrary and capricious). Petitioner does not even attempt to rebut FDA's conclusions regarding the inadequacy of this evidence.

D. FDA's determination that Petitioner's proposed access and marketing restrictions are insufficient to mitigate the substantial risk to youth posed by flavored e-cigarettes was not arbitrary and capricious.

While access and marketing restrictions are important and indeed necessary to support a PMTA, FDA reasonably concluded that Petitioner's proposed access and marketing restrictions, which mirror restrictions FDA has previously found inadequate for flavored e-cigarettes, "cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce" the evidentiary showing that Petitioner must make with respect to any benefit to adult smokers from its flavored products. JA440.

In reaching this conclusion, FDA drew on its vast experience with access and marketing restrictions and other real-world evidence. As FDA's experience confirms, the core problem with flavored e-cigarettes is the nature of the product itself—in particular, its special appeal to youth and its addictiveness—not simply youth access to or the marketing of these products. In March 2019, in response to

the youth vaping epidemic, FDA issued a Draft Guidance[16] which "proposed to focus its enforcement priorities of flavored [e-cigarettes] on how the product was sold . . . ." JA158 (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. "The reality," FDA found, "is that youth have continued access to these [e-cigarette] 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 most popular among youth . . . ." *Id.*

In other cases involving flavored e-cigarette products, this Court and other circuit courts have upheld MDOs in which FDA used the same approach it applied to Petitioner's PMTA. *See, e.g.*, *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."); *Wages & White Lions Invs, L.L.C. v. FDA*, 41 F.4th 427, 441 (5th

[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.

Cir. 2022) ("FDA determined that traditional marketing schemes do not work and that absent a 'novel or materially different' scheme, youth appeal [of flavored e-cigarettes] would continue.").

FDA's conclusion—in both its 2020 Guidance and TPL Reviews—is also supported by other 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 e-liquids (50.8%) and vaping devices (51.9%).[17]

Given the intense appeal to youth of flavored e-cigarettes, the relative ease with which youth are able to obtain such products, and the limited success of access and marketing restrictions, it was reasonable for FDA to conclude that Petitioner's access and marketing restrictions would not reduce the risk to youth of flavored e-cigarettes sufficiently to lower the evidentiary showing that Petitioner must make with respect to such flavored products' benefit to adult smokers. Far from announcing a new standard, as Petitioner claims, Pet'r Br. 48-49, this is a straightforward application of the public health standard under Section 910, which

[17] *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.

Petitioner itself recognizes is a balancing test that must account for a product's benefits and risks to the whole population. *See id.* at 55.

CONCLUSION

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

Respectfully submitted,

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I hereby certify that on January 17, 2023, the foregoing brief was filed via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

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