No. 21-13340

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BIDI VAPOR LLC,

Petitioner,

v.

U.S. FOOD AND DRUG ADMINISTRATION; JANET WOODCOCK, M.D., in her official capacity as Acting Commissioner of the FDA; and the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondents.

On Petition for Review of a Final Marketing Denial Order Issued by the U.S. Food and Drug Administration Under the Federal Tobacco Control Act

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rule 26.1-1, Petitioner hereby certifies that the following have an interest in the outcome of this petition for review:

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United States Department of Health & Human Services (Respondent)

United States Department of Justice

United States Food & Drug Administration (Respondent)

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Woodcock, Janet M.D. (Respondent)

Zeller, Mitch (Director, Center for Tobacco Products, U.S. Food and Drug Administration)

Pursuant to Federal Rule of Appellate Procedure 26.1 and Eleventh Circuit Rule 26.1-3, Petitioner certifies that none of the corporate entities listed

above are public traded. Further, pursuant to Eleventh Circuit Rule 26.1-C, Petitioner certifies that this Certificate of Interested Persons is complete and accurate at the time of filing.

/s/ Eric P. Gotting
Eric P. Gotting

STATEMENT REGARDING ORAL ARGUMENT

Petitioner Bidi Vapor LLC ("Bidi") requests oral argument in this matter. This case involves novel legal questions under the Family Smoking Prevention and Tobacco Control Act ("TCA"), and in particular the nature and scope of the TCA's "appropriate for the protection of the public health" ("APPH") standard as applied by the U.S. Food and Drug Administration ("FDA") to determine whether electronic nicotine delivery systems ("ENDS") may be sold and marketed in the United States. 21 U.S.C. §387*l*(a). This matter also involves an extensive administrative record containing scientific and technical data submitted to FDA by Bidi in support of its request for market authorization through Pre-Market Tobacco Product Applications ("PMTA") covering Bidi's eleven flavored ENDS products. Therefore, Bidi believes oral argument will assist the Court in resolving the issues raised on appeal.

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STATEMENT OF JURISDICTION

This Court has jurisdiction under Section 912, 21 U.S.C. §387*l*(a), of the Family Smoking Prevention and Tobacco Control Act ("TCA") to review the U.S. Food and Drug Administration's ("FDA") marketing denial order ("MDO") issued to Petitioner Bidi Vapor LLC ("Bidi") on September 7, 2021. The MDO denied marketing authorization sought by Bidi in Pre-Market Tobacco Product Applications ("PMTA") filed under Section 910 of the TCA, 21 U.S.C. §387j, for eleven electronic nicotine delivery products ("ENDS"). The MDO fully and finally decided Bidi's PMTAs at the administrative level. *See* 21 U.S.C. §§387j, 387*l*. Bidi filed a timely Petition for Review with this Court on September 29, 2021 pursuant to the 30-day deadline set forth in 21 U.S.C. §387*l*(a). Venue is proper in this circuit under 21 U.S.C. §387*l*(a) as Bidi is headquartered in Grant-Valkaria, Florida.

GLOSSARY

APA	Administrative Procedure Act
APPH	Appropriate for the Protection of the Public Health
ENDS	Electronic Nicotine Delivery Systems
FDA	Food and Drug Administration
MDO	Marketing Denial Order
PATH	Population Assessment of Tobacco Health
PMTA	Pre-Marketing Tobacco Product Application
RCT	Randomized Controlled Trial
TCA	Family Smoking Prevention and Tobacco Control Act
TPPI	Tobacco Product Perception and Intention Studies

STATEMENT OF THE ISSUES

Petitioner Bidi Vapor LLC ("Bidi") filed extensive Pre-Market Tobacco Product Applications ("PMTA") with the U.S. Food and Drug Administration ("FDA") pursuant to the Family Smoking Prevention and Tobacco Control Act ("TCA") seeking FDA's approval to market and sell eleven flavored electronic nicotine delivery system ("ENDS") products (*i.e.*, electronic cigarettes). FDA denied the PMTAs because they did not contain specific types of studies – a randomized controlled trial ("RCT"), a longitudinal cohort study, or unspecified similar scientific evidence (collectively "RCT/longitudinal study") – showing that Bidi's non-tobacco flavored ENDS are more effective than Bidi's tobacco flavored ENDS in helping adult smokers switch from traditional cigarettes. FDA did not otherwise review the contents of Bidi's PMTAs and instead only claimed that an RCT/longitudinal study was needed to demonstrate under the TCA that Bidi's non-tobacco flavored products are "appropriate for the protection of the public health" ("APPH"). This case raises the following issues:

1. Did FDA violate the TCA and act *ultra vires* when it engaged in a box-checking exercise to determine whether Bidi's PMTAs contained an RCT/longitudinal study, rather than conducting a full scientific review of the PMTAs to determine whether Bidi's products satisfy the APPH standard?

2. Did FDA violate the Administrative Procedure Act ("APA") and otherwise proceed in an arbitrary and capricious manner when it denied Bidi's PMTAs based on the mere absence of an RCT/longitudinal study instead of reviewing the extensive information and data contained in the PMTAs demonstrating that Bidi's products are APPH?

3. Did FDA violate the APA and the Due Process Clause of the Fifth Amendment by failing to give Bidi fair notice of this box-checking approach after it had repeatedly told Bidi and the ENDS industry that RCT/longitudinal studies would not be required to satisfy the APPH standard?

4. Did FDA violate the APA when it failed to engage in notice and comment rulemaking when adopting the box-checking approach and applying it across-the-board to Bidi's PMTAs and virtually all other applications submitted by ENDS manufacturers for non-tobacco flavored ENDS?

5. Should this Court give FDA's box-checking approach *Skidmore* deference where it conflicts with the broad definitions of APPH and extensive scientific review requirements appearing in the TCA, as well as FDA's regulations, guidance, and public statements?

STATEMENT OF THE CASE

I. Nature of the Case

This case challenges the U.S. Food and Drug Administration's ("FDA") denial of marketing authorization for eleven electronic nicotine delivery systems ("ENDS"), manufactured and sold by Petitioner Bidi Vapor LLC ("Bidi"), as unlawful under the Family Smoking Prevention and Tobacco Control Act ("TCA"), the Administrative Procedure Act ("APA"), and the Due Process Clause of the Fifth Amendment. As required by the TCA, Bidi submitted to FDA extensive Pre-Market Tobacco Product Applications ("PMTA") containing information and data demonstrating that its ENDS products meet the TCA's "appropriate for the protection of the public health" ("APPH") standard.

On September 7, 2021, FDA issued Bidi a marketing denial order ("MDO") prohibiting the continued marketing and sale of Bidi's ENDS products in the United States. FDA did so without substantively reviewing the contents of Bidi's PMTAs; instead, FDA undertook a box-checking exercise and determined that the PMTAs did not contain a single, discrete type of study and denied the applications solely on that basis.[1]

[1] On October 22, 2021, FDA entered a temporary administrative stay pursuant to 21 C.F.R. §10.35. The stay was put in place in response to a request filed by Bidi that FDA re-review the MDO to determine whether Bidi's PMTAs, in

II. The Tobacco Control Act And FDA's Deeming Rule

In 2009, Congress enacted the TCA, amending the Food, Drug and Cosmetic Act ("FDCA"), to give FDA regulatory authority over the marketing and sale of "tobacco products." 21 U.S.C. §387, *et seq.* Six years later, on August 8, 2016, FDA's "Deeming Rule" went into effect, which applied the TCA to ENDS and other tobacco products that had not been initially regulated under the TCA. 21 U.S.C. §387a(a); 81 Fed. Reg. 28974 (May 10, 2016).

Consequently, ENDS were immediately subject to numerous TCA provisions, including a requirement that ENDS manufacturers, including Bidi, obtain premarket authorization from FDA before continuing to market and sell their products. 21 U.S.C. §387j. A manufacturer must submit a PMTA which, as discussed below, entails a time-consuming and costly process of compiling extensive scientific, technical, and marketing data that FDA must review before granting market authorization.

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fact, contain the type of information and data that the MDO otherwise claims are missing. According to FDA, the temporary administrative stay will be lifted once the re-review is completed, which FDA estimates will be in early-December 2021. Importantly, this re-review focuses on only the narrow issue raised in the MDO (*i.e.*, the presence or absence of certain studies) and is not a full substantive, scientific review of the PMTAs, which is what Bidi maintains on appeal FDA is required to conduct under the TCA. *See* Bidi Stay Mot. at 23 n.7 (Oct. 25, 2021) & Bidi Stay Reply at 2-11 (Nov. 12, 2021).

III. FDA's PMTA Filing Deadlines

Because the sudden retroactive application of the TCA's premarket requirements to ENDS would abruptly force them off the marketplace, FDA established an enforcement policy permitting existing ENDS to remain on the market until PMTAs were due. The Deeming Rule set an August 8, 2018 deadline; if a timely PMTA was filed, the product could remain on the market for up to an additional year pending FDA review. 81 Fed. Reg. at 28,978. FDA said this approach balanced concerns regarding underage use and providing access to products adult smokers may be using to move away from more dangerous cigarettes. *Id.* at 28,977-78.

FDA changed the deadline several times in the ensuing years, finally landing on August 8, 2021.[2] Again, in each instance, FDA balanced competing interests involving preventing underage use and adult interests in transitioning away from combustible cigarettes. *Id.* Then, in response to a lawsuit filed by anti-ENDS groups, a federal district court in Maryland vacated the prior dates and, in a remedies decision, shortened the deadline to May 2020, which was subsequently extended to September 9, 2020 due to the

[2] FDA News Release, *FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death* (July 27, 2017), https://tinyurl.com/vrubw8tz; FDA, *Modification to Compliance Policy for Certain Deemed Tobacco Products* (March 2019), https://tinyurl.com/vr6ph8.

COVID-19 pandemic. *Am. Academy of Pediatrics, et al. v. FDA*, 8:18-cv-00883-PWG (D. Md.) (Dkt. Nos. 127 & 182). Any ENDS subject to a timely filed PMTA could remain on the market until September 9, 2021 while FDA considered the application. *Id.* The court's decision, however, did not order FDA to complete its PMTA reviews by that date; rather, it indicated that products for pending PMTAs would be "subject to" FDA's enforcement absent a case-by-case exemption.

Although FDA anticipated receiving about 6,800 PMTAs, applications covering 6.7 *million* products were submitted.[3] Mitch Zeller, Director, FDA Center for Tobacco Products ("CTP"), admitted in February 2021 that this unexpected number would present "challenges" due to the "size, complexity and diversity" of the PMTAs. FDA-BIDIVAPOR-005261-62.

IV. Three Phases Of PMTA Review

Overall, the PMTA review process consists of up to three phases – acceptance, filing, and substantive (or scientific) review. The acceptance phase is governed by a 2016 regulation (21 C.F.R. §1105.10) and the filing phase by a

[3] FDA, News Release: *FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health* (Aug. 26, 2021), https://tinyurl.com/n9c9rwu8; *Am. Academy of Pediatrics*, Zeller Decl., Dkt. No. 120-1 at 15.

2014 FDA memo posted on its website,[4] with each phase formalized in the recently adopted PMTA Final Rule (21 C.F.R. §1114.27).[5] Bidi's PMTAs, as did all PMTAs filed by September 9, 2020, followed this process.

FDA first screens an application for acceptance to ensure that it contains basic information and satisfies various technical elements (*e.g.*, the application includes product information, contains required FDA forms, is written in English, etc.). 21 C.F.R. §1105.10, §1114.27(a).

FDA next "make[s] a threshold determination of whether the application contains sufficient information to permit a substantive review." 21 C.F.R. §1114.27(b) (*e.g.*, published literature, bridging information, product health risk comparisons, abuse liability data, actual use data, data regarding the impacts of labeling and advertising on use behavior, etc.).[6]

Finally, after filing, FDA "begin[s] substantive review of the application." 21 C.F.R. §1114.27(c). Within 180 days of receiving a PMTA

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[4] *See* https://tinyurl.com/2wax428w.

[5] The final pre-publication version was issued on January 19, 2021 at the end of President Trump's term. *See* PMTA-Rule-2021-01212-1, https://tinyurl.com/37dsystt. The Biden Administration halted publication in the Federal Register, https://tinyurl.com/3us7xta3, so it could review the rule and re-published it in virtually identical form on October 5, 2021. 86 Fed. Reg. 55300. The effective date was November 4, 2021. *Id.*

[6] *See also supra* note 4.

"meeting the filing requirements set out in 1114.27(b), FDA will complete its review of the PMTA and act on the application." *Id.*

V. The TCA's "Appropriate For The Protection Of The Public Health" ("APPH") Standard

The TCA requires FDA to conduct a complex, science-based evaluation based on all contents in a PMTA to determine whether a product is "appropriate for the protection of the public health" ("APPH"). The TCA directs FDA to make that determination "with respect to the risks and benefits to the population *as a whole*, including users and nonusers of the tobacco product, and taking into account – (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products." 21 U.S.C. §387j(c)(4) (emphasis added). Accordingly, FDA has repeatedly described APPH as a multi-factored and multi-disciplinary standard.

For instance, FDA noted in the PMTA Final rule that APPH involves a "complex determination," 86 Fed. Reg. at 55335, that FDA "considers many factors," *id.* at 55314, and that FDA does not make a "determination on one static set of requirements," *id*. at 55385. FDA further declined "to assign weight to different types of evidence," *id.,* emphasizing APPH "requires a balancing" of risks and benefits. *Id.* at 55384. FDA also refused "to create a

series of criteria" that all products must meet for APPH, stated that an APPH "determination would involve consideration of many factors," and noted it "will be made with respect to…the population as a whole, rather than whether a product meets each item in a series of specific criteria." *Id.* at 55386. FDA committed to determining APPH on an "individualized" basis, the "risks and benefits of a specific tobacco product," and "based on *all* of the contents of the application." *Id.* at 55320, 55390 (emphasis added).

During the rulemaking, FDA also rejected a comment demanding that an APPH evaluation focus on population segments most likely to be affected by ENDS and "require applications to show a public health benefit for those specific groups." FDA concluded FDA does not require applicants to show a public health benefit for specific population segments. *Id* at 55385. Further, in response to comments asking FDA to impose specific requirements on flavored tobacco products before issuing a marketing order, FDA again "declin[ed] to create a series of criteria that either all products or a specific subset of products must meet…to be considered APPH." *Id.* at 55386.

Similarly, in June 2019, FDA issued final PMTA Guidance "intended to assist persons submitting" PMTAs which also discussed APPH. FDA-BIDIVAPOR-004493. Specifically, FDA said it "weighs all of the potential benefits and risks from information contained in the PMTA" to make an

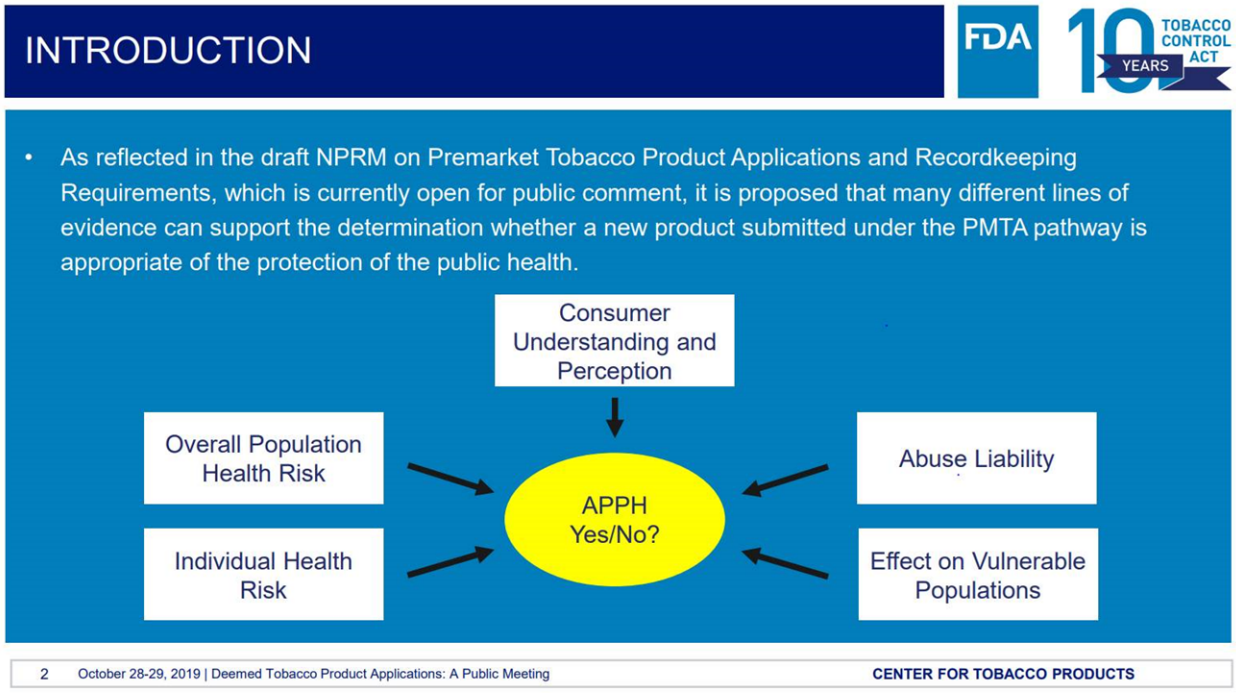
APPH determination. FDA-BIDIVAPOR-004504. During an October 2018 public meeting, FDA also described a PMTA review as a "multi-disciplinary approach,"[7] and likewise during an October 2019 public meeting FDA reiterated the "multi-disciplinary" characterization and then described APPH by citing to numerous factors that must be considered (*e.g.*, health risks, marketing plans). FDA-BIDIVAPOR-004667-68, -4814-15, -4913. And Director Zeller noted the "complexity of those applications and the scientific review process" during the *Am. Academy of Pediatrics* litigation when asking the court to set a reasonable PMTA filing deadline. *Supra* at 6 n.3.

The 2019 PMTA Guidance, which runs over 50 pages, also identifies numerous types of information and data that are considered by FDA as being supportive of an APPH finding. These include, *inter alia*, sales restrictions guarding against underage use, label warnings, health risk studies, toxicological and pharmacological testing, public literature reviews, pharmacokinetic evaluations, and consumer perception and intention studies. FDA-BIDIVAPOR-004504, -4515, -004520-21, -004526-27, 004530-32. *See* 86

[7] FDA, Tobacco Product Application Review Public Meeting, at 119 (Oct. 22, 2018), https://tinyurl.com/w6k59jka.

Fed. Reg. at 55414-32 (21 C.F.R. §1114.7 listing of extensive information and data required for PMTAs).[8]

For the court's convenience, presented below is an FDA diagram depicting some of the many APPH factors that FDA considers as part of a complete APPH analysis.[9]



[8] *See also* 84 Fed. Reg. 50566, 50,619 (Sept. 25, 2019) (proposed Final PMTA Rule) ("The applicant's marketing plans…will provide input that is critical to FDA's determination of the likelihood of changes in tobacco product use behavior, especially when considered in conjunction with other information contained in the application.").

[9] *See* https://tinyurl.com/98jc36hc.

VI. FDA's Instructions To ENDS Manufacturers Regarding APPH

Before the September 9, 2020 filing deadline, FDA identified which forms of scientific evidence would be required in a PMTA to demonstrate APPH. FDA maintained that an RCT/longitudinal study or similar evidence would *not* be necessary. In the 2019 PMTA Guidance, FDA stated "in general, FDA does not expect that applicants will need to conduct long-term studies to support an application" and said it considers long term studies to last six months or longer. FDA-BIDIVAPOR-004505; *see* FDA-BIDIVAPOR-004523. Instead, FDA suggested ENDS manufacturers could rely on other sources of information, such as "existing longer duration studies in published literature [on similar products]…and extrapolating from short-term studies." FDA-BIDIVAPOR-004505. And regarding data showing potential cessation benefits, FDA concluded that "[a]though randomized clinical trials could address cessation behavior of users of tobacco products, FDA believes this would also be true for observational studies (perception, actual use, or both) examining cessation behaviors." FDA-BIDIVAPOR-004530.

Likewise, during an October 2019 public meeting, FDA advised that "[i]t may be possible to support a marketing order for a[n] ENDS product without conducting new, non-clinical or clinical studies given other data sources can support this PMTA." FDA-BIDIVAPOR-004789; *supra* at 10 n.7

at 133-34 (similar statement from October 2018 public meeting). In the PMTA Final Rule, FDA again said it "does not expect that long-term clinical studies will need to be conducted for each PMTA; instead, it expects that it should be able to rely on other valid scientific evidence to evaluate some PMTAs." 86 Fed. Reg. at 55387.

Indeed, FDA made these same representations directly to Bidi as it was preparing the PMTAs. In response to a February 2020 meeting request by Bidi to discuss clinical testing requirements, including how to conduct testing on comparator products, FDA sent a May 8, 2020 letter to Bidi explicitly stating there are no requirements "for applicants to conduct clinical studies or trials to support a PMTA" and there are no "specific requirements for evaluating comparator products." FDA-BIDIVAPOR-005276-77. FDA then referred Bidi to the 2019 PMTA Guidance, the then-proposed PMTA Rule, and the 2018 and 2019 public meetings for further information, all of which indicate that clinical studies may not be needed to support APPH. FDA-BIDIVAPOR-005274-75.[10]

[10] *See also* 84 Fed. Reg. at 50,619 (proposed PMTA Final Rule rule). FDA's response also painted APPH as a broad concept involving evaluation of numerous sources of information and data. FDA-BIDIVAPOR- 005274-75 (stating PMTAs should "use different types of studies, methods, instruments, and analyses" to demonstrate APPH and citing as examples perception and behavioral studies, constituent testing, and literature reviews).

At no time since the Deeming Rule was promulgated did FDA state that an ENDS manufacturer must conduct the specific type of clinical or long-term study identified in the MDO, let alone indicate its absence would prevent an application from receiving a full substantive, scientific review and *automatically* result in a marketing denial.

VII. Bidi Vapor LLC

Bidi Vapor was founded by Niraj Patel, a former smoker who quit by using ENDS. FDA-BIDIVAPOR-005263-64.[11] Having witnessed first-hand the deleterious impact of combustible tobacco, Mr. Patel left his family's tobacco business in India to start his own venture developing combustible cigarette alternatives for adult smokers. *Id.* Using his degrees in chemistry and pharmacology, he developed various ENDS technologies culminating in the BIDI® Stick – a high-quality, tamper-resistant, UL-certified disposable ENDS that contains pre-filled, flavored e-liquid and uses an innovative sensitivity control system to ensure consistent nicotine delivery. *Id.*[12]

[11] Alex Soderstrom, *Melbourne e-cigarette manufacturer to move operations from China to Florida*, Orlando Business Journal, Feb. 26, 2021. FDA-BIDIVAPOR-005265-70; Bidi Stay Mot. (Oct. 25, 2021), Patel Aff. at ¶7.

[12] Associated Press, *Bidi Vapor Submits Premarket Application to FDA*, September 8, 2020, https://tinyurl.com/84cxspnx; *see generally* Bidi Stay Mot. (Oct. 25, 2021), Patel Aff. at ¶¶7-8, 23.

The BIDI® Stick comes in 11 varieties – nine non-tobacco flavors (Dawn, Gold, Marigold, Regal, Summer, Tropic, Winter, Zest, and Solar), one menthol (Arctic) and one tobacco (Classic). FDA-BIDIVAPOR-005307. From its inception, Bidi Vapor recognized the legitimate public health concerns over underage ENDS use, and made youth-access prevention, adult-focused marketing, and regulatory compliance its top priorities. *Supra* at 14 n.11, n.12; *infra* at 21-24. Bidi spent over $6.6 million compiling its PMTAs and submitted them by the court-ordered deadline on September 8, 2020. *Supra* note 12.[13]

VIII. Bidi Vapor LLC's PMTAs

Bidi Vapor submitted comprehensive and scientifically rigorous PMTAs based on FDA's most current recommendations, the PMTA Final Rule (as proposed and first finalized in January 2021), various guidance, and in FDA's correspondence with Bidi in response to a meeting request. The applications included, among other things, *in vitro* toxicity testing, e-liquid and aerosol analysis of harmful and potentially harmful chemicals, comprehensive literature reviews, comparisons to other tobacco products, hardware safety and battery certification information, manufacturing and quality control details, independent and validated consumer insight surveys, environmental

[13] *See generally* Bidi Stay Mot. (Oct. 25, 2021), Patel Aff. at ¶5.

assessments and stability data, as well as details about the company's stringent youth-access prevention measures, adult-focused marketing practices, post-market surveillance strategies and unique recycling program. FDA-BIDIVAPOR-005278-96. The submitted PMTAs spanned over 285,000 pages combined.[14]

Bidi's PMTAs demonstrated that its products meet the APPH standard, including that BIDI® Sticks offer adults substantial benefits in terms of lower relative health risks and an effective means to move away from more traditional cigarettes. For example, the comprehensive literature review evaluated hundreds of scientific articles on ENDS, covering *in vitro* and *in vivo* toxicology, health effects, human factors, initiation, cessation, transition, biomarkers of harm and exposure, topography, pharmacokinetics, and abuse liability. FDA-BIDIVAPOR-005278-96. The review summarized key information from nationally representative cross-sectional surveys and studies used to evaluate the population impact of ENDS.[15]

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[14] *Supra* note 12.

[15] These included the Monitoring the Future, the National Youth Tobacco Survey (as conducted by FDA and the Centers for Disease Control), the National Adult Tobacco Survey, the Youth Risk Behavior Survey, the National Health Interview Survey, and the Tobacco Use Supplement of the Current Population Survey. FDA-BIDIVAPOR-005297-99.

The literature review included the types of studies – RCTs and longitudinal cohort studies – referenced by the MDO. For instance, the following RCTs which evaluated the impact of ENDS on adult smoking cessation were considered:

- Carpenter, M.J., B.W. Heckman, A.E. Wahlquist, T.L. Wagener, M.L. Goniewicz, K.M. Gray, B. Froeliger and K.M. Cummings. 2017. A Naturalistic, Randomized Pilot Trial of E-Cigarettes: Uptake, Exposure, and Behavioral Effects. Cancer Epidemiol Biomarkers Prev 26(12): 1795-1803.
- Baldassarri, S.R., S.L. Bernstein, G.L. Chupp, M.D. Slade, L.M. Fucito and B.A. Toll. 2018. Electronic cigarettes for adults with tobacco dependence enrolled in tobacco treatment program: A pilot study. Addict Behav 80: 1-5.
- Halpern, S.D., M.O. Harhay, K. Saulsgiver, C. Brophy, A.B. Troxel and K.G. Volpp. 2018. A Pragmatic Trial of E-Cigarettes, Incentives, and Drugs for Smoking Cessation. N Engl J Med 378(24): 2302-2310.
- Lee, S.M., R. Tenney, A.W. Wallace and M. Arjomandi. 2018a. E-cigarettes versus nicotine patches for perioperative smoking cessation: a pilot randomized trial. PeerJ 6: e5609.
- Masiero, M., C. Lucchiari, K. Mazzocco, G. Veronesi, P. Maisonneuve, C. Jemos, E.O. Sale, S. Spina, R. Bertolotti and G. Pravettoni. 2018. E-cigarettes May Support Smokers With High Smoking-Related Risk Awareness to Stop Smoking in the Short Run: Preliminary Results by Randomized Controlled Trial. Nicotine Tob Res.
- Hajek, P., A. Phillips-Waller, D. Przulj, F. Pesola, K. Myers Smith, N. Bisal, J. Li, S. Parrott, P. Sasieni, L. Dawkins, L. Ross, M. Goniewicz, Q. Wu and H.J. McRobbie. 2019. A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy. N Engl J Med 380(7): 629-637.
- Holliday, R., P.M. Preshaw, V. Ryan, F.F. Sniehotta, S. McDonald, L. Bauld and E. McColl. 2019. A feasibility study with embedded pilot randomised controlled trial and process evaluation of electronic cigarettes for smoking cessation in patients with periodontitis. Pilot Feasibility Stud 5: 74.
- Lee, S., H.J. Ahn and C.K. Cheong. 2019b. Effect of Electronic Cigarettes on Smoking Reduction and Cessation in Korean Male Smokers: A Randomized Controlled Study. J Am Board Fam Med 32(4): 567-574.

FDA-BIDIVAPOR-005367-69.

Further, the literature review included studies evaluating data from FDA's own Population Assessment of Tobacco Health ("PATH"), an on-going longitudinal cohort study assessing tobacco use behavior, attitudes and beliefs, and tobacco-related health outcomes launched in 2013. FDA-BIDIVAPOR-005300-01.

With respect to adult use of ENDS, the literature review concluded adults report using ENDS to aid with cessation of combustible cigarettes in part because they are available in appealing flavors. In fact, adult former smokers who reported using ENDS because of the appealing flavors were statistically less likely to relapse to smoking. FDA-BIDIVAPOR-005303. As to the overall impact of ENDS on the population health, the literature review concluded that "studies consistently found improvements in years of life lost or overall mortality for adults indicating that e-cigarettes provide a health benefit to the population." FDA-BIDIVAPOR-005304.[16]

[16] FDA is also aware that approximately 9 million U.S. adults currently use ENDS and has acknowledged that "[s]tudies have shown that the majority of adult e-cigarette users use flavored e-cigarettes and there is some evidence to suggest that flavored e-cigarettes may improve switching from cigarette smoking to using e-cigarettes, compared to non-flavored e-cigarettes." FDA-BIDIVAPOR-000384; s*ee* 81 Fed. Reg. at 28977 (stating FDA seeks to balance concerns regarding risks to youth with "emerging evidence that some adults may potentially use certain flavored tobacco products to transition away from combusted tobacco use.").

FDA conducted its acceptance review of Bidi's PMTAs on February 4, 2021 and issued an acceptance letter to Bidi on February 5, 2021. FDA-BIDIVAPOR-000019-23, -000038-44. FDA then undertook the filing review on February 23, 2021 and Bidi received a filing letter the same day. FDA-BIDIVAPOR-000024-30, -000045-51. Accordingly, FDA deemed Bidi's PMTAs ready for scientific review as of February 2021 (*see* filing letter stating Bidi's PMTAs "are sufficiently complete to enter [the] substantive review phase"). FDA-BIDIVAPOR-000024. On August 20, 2021, Bidi received an email notification from FDA stating that Bidi's "non-tobacco flavored ENDS products have entered scientific review." FDA-BIDIVAPOR-005271-72.

IX. Bidi Vapor LLC's PMTA Amendments

After FDA accepted Bidi's PMTAs for full scientific review, Bidi continued to update the applications at FDA's request with three amendments before the MDO issued.[17] The stated purpose of each amendment was to

[17] In its initial PMTAs, Bidi informed FDA of delayed studies due to COVID-19 (*e.g.*, inability to secure laboratory space). FDA-BIDIVAPOR-005320. FDA then indicated it would account for COVID-19 delays as companies continued to supplement applications prior to September 2021. FDA, Response to Citizen Petition Docket No. FDA-2020-P-1797 (Feb. 12, 2021), https://tinyurl.com/2edb5d5u. FDA also stated during a June 11, 2021 webinar that it expected applicants to submit amendments to PMTAs so FDA had all relevant evidence for scientific review. FDA, June 2021 Webinar Transcript, at 32, https://tinyurl.com/4jbhayuu.

further inform FDA's APPH determination. FDA-BIDIVAPOR-005305-06; -005307-14; -005315-19.

The first amendment was submitted on October 13, 2020 and contained the results of a Consumer Insight Survey, which surveyed over 1,000 adult ENDS users. The survey assessed the impact of flavored ENDS and concluded that these products significantly reduce the use of traditional cigarettes and play a key role in helping adult smokers transition away from combustible products. FDA-BIDIVAPOR-005305-06.

The second amendment was filed on March 23, 2021 and provided to FDA the results of a Disposable Vape User Insights Study, which surveyed over 1,000 ENDS users. The survey examined consumer decision drivers (*e.g.*, why consumers select a particular device or brand) and was based on FDA's guidance for Tobacco Product Perception and Intention Studies ("TPPI").[18] The results showed almost a quarter of the respondents say ENDS help them use fewer conventional cigarettes. FDA-BIDIVAPOR-005309-10. Moreover, Bidi notified FDA it is conducting three additional studies – two TPPI studies and an abuse liability (pharmacokinetic or "PK") study. Bidi indicated that

[18] FDA, *Draft Guidance for Industry: Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies* (October 2020), https://tinyurl.com/2w7afvpz.

the results of these studies would likely be available by the end of 2021. FDA-BIDIVAPOR-005310-11.

The third amendment was submitted on April 20, 2021 and provided an update on the TPPI and PK studies. In particular, the first behavioral study is examining the impact of BIDI® Sticks on consumers' likelihood of changing their usage behavior, including relative to traditional cigarettes. The second one is assessing the impact of flavors on usage, switching potential, and relative health risks. Finally, the PK study is considering comparative usage patterns based on varying flavors and nicotine levels among BIDI® Sticks, JUULs, and combustible cigarettes in a randomized, crossover manner. FDA-BIDIVAPOR-005315-19.

X. Bidi Vapor LLC's Underage Prevention Measures

Bidi strongly opposes underage use. FDA-BIDIVAPOR-005321. As FDA repeatedly stated that underage preventions measures were key to any APPH showing, Bidi has taken aggressive steps to prevent access by minors and discussed those at length in the PMTAs and amendments.

First, Bidi discontinued (as of February 22, 2021) online, direct-to-consumer sales ("DTC") through its website. Instead, Bidi moved exclusively to adult-only brick-and-mortar stores and a single, online delivery service (www.goPuff.com), both of which require face-to-face, age-verified

transactions (goPuff also requires an adult signature upon delivery). All Bidi partners are required to sign a Wholesaler and Direct Retailer Agreement and a Retailer Pledge requiring them to comply with all federal, state, and local restrictions (including home delivery requirements), employ valid-ID checks, furnish an anonymous hotline to report violations, adopt a policy of notifying FDA of violations, and submit to internal compliance checks. Bidi also screens partners for age verification policies before establishing or renewing relationships and terminates them for non-compliance. FDA-BIDIVAPOR-005322; -005323-27; -005328-30; -005336.

Second, in Fall 2020, Bidi halted production of BIDI® Sticks for two months to revise its packaging and labeling to align with FDA's Enforcement Priorities Guidance.[19] Bidi adopted single-word, non-characterizing product names (like Dawn and Summer) so that its branding and advertising do not resemble kid-friendly foods or employ youth-appealing cartoons or graphics. FDA-BIDIVAPOR-005328; -005341-42; -005324; -005335. BIDI® Stick labels also contain notifications on age restrictions, nicotine warnings in compliance with 21 C.F.R. §1143.3, and California Proposition 65 warnings. FDA-BIDIVAPOR-005343-45; -005335.

[19] *See* FDA-BIDIVAPOR-000360-411.

Third, Bidi has adopted a marketing strategy that minimizes exposure of its products to minors. Bidi does not use celebrities, bloggers, sponsors, influencers, or youthful-looking models, nor does its marketing appear aspirational or appeal to youth culture or lifestyle. FDA-BIDIVAPOR-005323-24; -005355-56; -005345-46; -005357-46; -005341; -005358; -005337. Bidi also does not directly advertise to consumers; rather it focuses on retailers and distributors through trade press and other online industry sites with a 21+ audience. FDA-BIDIVAPOR-005324; -005363-65; -005342; -005337. Bidi's social media accounts follow each platform's age-gating requirements, its social media managers verify that followers are 21-years old or older, and any postings routinely remind viewers of 21+ age restrictions. FDA-BIDIVAPOR-005345-53; -005358-62.

Fourth, Bidi has taken additional measures to protect underage consumers, including ensuring through regular monitoring that any advertising by wholesale and retail partners is done responsibly, restricting any advertising in brick-and-mortar stores to areas that cannot be viewed from outside the premises, producing training videos for partners regarding underage prevention, and foregoing any marketing or advertising on radio or television

or sponsorship of sporting or entertainment events. FDA-BIDIVAPOR-005322; -005354; -005326; -005337.[20]

XI. FDA's Marketing Denial Order

The MDO, issued by FDA on September 7, 2021, was not based on a full scientific review of Bidi's filed PMTAs; rather, it was the product of a literal box-checking exercise, which an internal FDA memorandum called the "Fatal Flaw" review, that apparently took only a half day to complete. FDA-BIDIVAPOR-000031-37, -000052-61, -005226-27.[21]

FDA cited only one reason for denying market authorization – because the PMTAs did not contain a single, highly-specific study designed to elicit a discrete datapoint – *i.e.*, an RCT/longitudinal cohort study or similar data comparing the cessation benefits of Bidi's flavored ENDS to Bidi's tobacco-

[20] *See* 86 Fed. Reg. at 55320, 55395, 55396 (PMTA Final Rule) (noting sales and marketing restrictions, including age-gating on social media, not using celebrities or influencers, and other youth access restrictions, are all particularly relevant to FDA's APPH determination, and reserving FDA's right to further impose such restrictions to ensure a product is APPH).

[21] FDA's certified Administrative Record Index indicates, without explanation, that the Fatal Flaw memorandum has been "Superseded." *See* FDA-BIDIVAPOR-005226-27. However, the index does not cite to any document formally withdrawing the memorandum, does not state on what date the memorandum was purportedly superseded, and the memorandum itself does not indicate that it has, in fact, been superseded. In any event, FDA clearly implemented the Fatal Flaw approach, as the box-checking exercise that ultimately led to Bidi's MDO (and MDOs for over one million other products) is entirely consistent with that memorandum. FDA-BIDIVAPOR-000052-61.

flavored product. FDA-BIDIVAPOR-000031-32. On the morning of September 7, 2021, the day the MDO issued, an FDA reviewer completed a check-list indicating the required study was absent, with another staffer concurring only minutes later. FDA-BIDIVAPOR-000053, -000058. Then, early that afternoon, the MDO was signed by the Director, Office of Science, Center for Tobacco Products. FDA-BIDIVAPOR-000033.

FDA did not review any other information or data contained in Bidi's PMTAs or conduct any scientific review. The MDO, the checklists, and the Fatal Flaw memorandum indicate FDA did not consider any other aspect of Bidi's 285,000-page PMTAs. FDA-BIDIVAPOR-000032 ("scientific review did not proceed to assess other aspects of the applications"); FDA-BIDIVAPOR-000054, -000059; FDA-BIDIVAPOR-005227 ("The Fatal Flaw review is a simple review in which the reviewer examines the submission to identify whether or not it contains the necessary type of studies. The Fatal Flaw review will be limited to determining presence or absence of such studies; it will not evaluate the merits of the studies."). As FDA stated, the "absence of these studies is considered a fatal flaw, meaning any application lacking this evidence will likely receive a marketing denial order." *Id.*

This holds true even though the technical project lead review (called a "TPL"), the main document supporting Bidi's MDO, repeatedly states that

PMTAs require a full scientific review and that all data must be considered to determine whether a product is APPH. FDA-BIDIVAPOR-000066 (FDA will conduct a "science-based evaluation" to determine APPH); *id.* ("FDA's scientific review is not limited to considering only information in a PMTA, but also extends to any other information before the Agency, including relevant scientific literature (See Section 910(c)(2))"; *id.* (indicating that potential switching benefits to adult smokers of flavored ENDS is only one of many issues considered); FDA-BIDIVAPOR-000070 (FDA required to "balance" benefits and risks of all users and nonusers "as a whole"); FDA-BIDIVAPOR-000072 (stating applications are evaluated in their "totality").

Consistent with prior FDA guidance and the PMTA Final Rule, the TPL also identifies information that is relevant to APPH in addition to adult cessation issues discussed in the MDO. For instance, it highlights the importance of underage prevention measures. FDA-BIDIVAPOR-000071 (FDA must take into "account all relevant evidence and circumstances, including whether there are effective limitations on youth access"); FDA-BIDIVAPOR-000072 n.xix (APPH looks to "evaluating the appropriateness of the proposed marketing plan") ("Limiting youth access and exposure is a

critical aspect of product regulation.").[22] But the TPL never cites to Bidi's own, comprehensive underage prevention measures.

Further, the TPL cites to data on health risks, as well as behavioral, perception, and PK studies, as being relevant. FDA-BIDIVAPOR-000071 (stating potential health risks are relevant and must be evaluated on a "case-by-case" basis, and that benefits to adult consumers must be considered using "behavioral," "intention," and "pharmacological" studies). It points to data showing lower exposures to hazardous substances or dual use where a consumer is using fewer cigarettes as highly germane. *Id*. The TPL supporting Bidi's MDO, however, never mentions these data contained in Bidi's PMTAs.

In addition, while the TPL discusses studies on youth and the potential for initiation, it dedicates only a few sentences to adults when finding that flavored products may not provide sufficient cessation benefits. FDA-BIDIVAPOR-000072 (stating that research on adults is "far from conclusive" and "mixed"). There is no mention, however, of the published literature review and other studies presented in Bidi's applications showing definite switching benefits to adults. And the TPL takes the same approach regarding youth prevention measures. In a footnote, it concludes that, in general, such

[22] *See* 86 Fed. Reg. at 55324 (PMTA Final Rule) (stating marketing plans are a "critical factor in…FDA's statutorily required determination").

efforts do not sufficiently reduce underage exposure, but it also concedes FDA did not consider Bidi's extensive efforts to minimize access by minors. FDA-BIDIVAPOR-000072 n.xix ("we have not evaluated any marketing plans submitted with these applications").

FDA also emphasized quickly dealing with the unprecedented number of PMTAs filed by ENDS manufacturers by September 9, 2021. The Fatal Flaw memorandum states that the Office of Science had "been tasked with developing a new plan to effectively manage the remaining non-tobacco flavored ENDS PMTAs." FDA-BIDIVAPOR-005226. It then says "[c]onsidering the large number of applications that remain to be reviewed by the September 9, 2021 deadline, [FDA] will conduct a Fatal Flaw review of PMTAs not in [scientific review] for non-tobacco flavored ENDS products." FDA-BIDIVAPOR-005227.

Without explanation, FDA also set a goal to "take final action on as many applications as possible by the September 10, 2021" cutoff even though the federal district court in Maryland imposed no such deadline (only a date after which products with pending PMTAs become subject to enforcement). FDA-BIDIVAPOR-005226. The Fatal Flaw memorandum is dated the same day that Bidi's MDO issued, and is time-stamped less than two hours before the MDO was signed. The TPL, also dated the same day, is almost an

identical, cookie-cutter version of an exemplar TPL published by FDA on its website and issued to other applicants covering millions of ENDS.[23] [24] [25]

Finally, leading up to the MDO, during a highly anticipated June 11, 2021 virtual meeting, FDA reiterated to ENDS manufacturers that it would issue at least one "deficiency letter" giving the manufacturer a chance to correct any shortcomings in the PMTA. "As part of our preparations for the influx of the large volume of PMTAs we received…we did streamline the review process to generally issue just one deficiency letter to promote efficiency…[O]nce we get a substantial scientific review…our intent is to issue a single deficiency letter."[26] Indeed, the issuance of a deficiency letter remains

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[23] FDA, Tobacco Products Marketing Orders: FDA Sample Decision Summary Document, https://tinyurl.com/npn2x4ec.

[24] FDA, What You Should Know About FDA Regulation of E-Cigarettes, https://tinyurl.com/b6upm9s, at slide 3 (Oct. 2021).

[25] The MDO also includes Bidi's menthol ENDS product – *i.e.*, the Arctic BIDI® Stick – even though FDA otherwise did not intend to deny marketing authorization to ENDS with menthol-characterizing flavors. FDA-BIDIVAPOR-000036. The TPL explicitly states that menthol ENDS "raise[] unique considerations" and will be "addressed separately." FDA-BIDIVAPOR-000064; *supra* note 3. On September 21, 2021, Bidi filed a request for supervisory review pursuant to 21 C.F.R. §10.75 and requested the MDO be rescinded as to the Arctic BIDI® Stick only. On October 27, 2021, FDA indicated in correspondence to Bidi's counsel that it would make a decision by January 19, 2022.

[26] FDA, June 2021 Webinar Transcript, at 28, 35, https://tinyurl.com/4jbhayuu.

listed on FDA's webpage as one of two types of "output" during the substantive, scientific review phase.[27] But FDA abandoned that approach as its perceived review deadline neared, believing that applicants would not be able to conduct an RCT/longitudinal study or otherwise adequately respond within a short amount of time. FDA-BIDIVAPOR-005366. Bidi never received a deficiency letter.

The MDO concludes Bidi Vapor's products are misbranded and adulterated (*citing* 21 U.S.C. §§387b, 387c) and that continued sale may result in civil penalties, seizure, and/or an injunction. FDA-BIDIVAPOR-000032 (citing 21 U.S.C. §§331, 333).[28]

STANDARD OF REVIEW

When an ENDS manufacturer challenges an MDO, the TCA requires this Court's review be conducted pursuant to the APA, 5 U.S.C. §706(2)(A). Specifically, the Court must evaluate whether the MDO was "arbitrary,

[27] *See* https://tinyurl.com/y2p2zwwk.

[28] On October 14, 2021, Bidi submitted a request to FDA asking that the MDO be rescinded. Importantly, the request is not based on the same grounds as Bidi's Petition for Review. Instead, it is based on the fact that FDA had rescinded an MDO for another applicant, Turning Point Brands (TPBs), whose PMTAs do not appear to have contained product specific, RCTs/longitudinal studies. Instead, like Bidi's applications (*supra* at 17), TPB's PMTAs contained relevant, third party RCTs/longitudinal studies. On October 21, 2021, FDA issued an administrative stay pursuant to 21 U.S.C. §10.35 pending its review of the MDO on these limited grounds.

capricious, an abuse of discretion, or otherwise not in accordance with the law." *Id.* Because Bidi also challenges the lawfulness of the MDO under the TCA itself and the Due Process Clause of the Fifth Amendment, the Court must also determine whether the MDO is: (i) contrary to constitutional right, power, privilege, or immunity; (ii) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; or (iii) without observance of procedure required by law. 5 U.S.C. §§706(2)(B)-(D).

SUMMARY OF THE ARGUMENT

1. This appeal challenges as unlawful a U.S. Food and Drug Administration ("FDA") marketing denial order ("MDO") issued to Petitioner Bidi Vapor LLC ("Bidi") which prohibits Bidi from selling its non-tobacco flavored electronic nicotine device systems ("ENDS") (*i.e.*, electronic cigarettes) in the United States. Under the Family Smoking Prevention and Tobacco Control Act ("TCA"), ENDS manufacturers must submit detailed Pre-Market Tobacco Product Applications ("PMTA") to FDA and secure pre-market approval before entering or continuing to operate in the marketplace.

2. Under the TCA, each ENDS manufacturer must demonstrate its products are "appropriate for the protection of the public health" or "APPH." In the years leading up to the deadline for submitting PMTAs, FDA provided substantial guidance and direction on the extensive information and data that

would be relevant to an APPH determination and should be included in any PMTA. But at the last minute, FDA jettisoned all of that. For Bidi and over one million other products, FDA never conducted a substantive, scientific review of each ENDS application.

3. Instead, citing a need to efficiently resolve the unprecedented number of applications and products filed with FDA, it hastily developed what it called the "Fatal Flaw" analysis. FDA staff were directed to conduct a literal box-checking exercise in which they determined whether a PMTA contained a specific type of study – *i.e.,* a randomized controlled trial, a longitudinal cohort study, or similar (but unspecified) scientific evidence – that addressed a discrete issue – *i.e.*, whether Bidi's non-tobacco flavored ENDs are better at helping adult smokers quit smoking than Bidi's tobacco flavored products. If such a study was absent, the PMTA was automatically denied.

4. The MDO violates the TCA and is thus *ultra vires*. The TCA defines APPH in broad and sweeping terms, and requires FDA to grant marketing authorization if it determines the subject product is APPH. Under the statute, information and data relevant to any APPH determination includes "risks and benefits" of the product to the "population as a whole" (*i.e.*, adults, minors, users, non-users, etc.). It explicitly requires each PMTA to include data on numerous issues like health risks, product constituents, marketing

plans (including steps taken to protect against underage access and use), and a product's impact on tobacco use initiation and cessation. The TCA then instructs FDA to make an APPH determination "on the basis of information submitted to FDA" and any other data FDA deems relevant. Accordingly, the TCA envisions a holistic, multi-factored APPH analysis that demands a full substantive, scientific review of an application. The TCA does not allow FDA to skip entirely any scientific review and instead proceed on the mere absence of a single study addressing an extremely narrow issue .

5. The MDO violates the Administrative Procedure Act ("APA") as it is the epitome of arbitrary and capricious decision-making. FDA has long characterized APPH as involving a "complex determination" consisting of "many factors." In regulations, guidance, and public statements, FDA has described APPH as requiring an "individualized" or case-by-case analysis, a weighing of "all" risks and benefits, and consideration of "all" contents of a PMTA. FDA has directed ENDS manufacturers to include in their applications wide-ranging information and data on countless issues relevant to the APPH determination. Not surprisingly, FDA has branded APPH a "multi-disciplinary" approach whose resolution depends on how the relative benefits and risks of a particular product "balance" against each other. Yet FDA did not look at, let alone reasonably consider, any of the information or

data submitted by Bidi which FDA had previously regarded as relevant to an APPH finding. And FDA never explained how, given the 285,000 pages of materials contained in Bidi's PMTAs, the Fatal Flaw approach was in any way appropriate as to Bidi's products. It merely concluded that Bidi failed to meet a requirement that it could not know existed and denied the applications.

6. The MDO violates the APA and the Due Process Clause of the Fifth Amendment as FDA failed to give Bidi and the ENDS industry fair notice that the absence of a specific type of study would be a deal-breaker. For years, FDA had consistently represented to manufacturers, including in correspondence directly with Bidi, that clinical or long-term studies would likely not be required to demonstrate APPH. It was not until the first MDOs were issued, well after Bidi's PMTAs had been filed, did Bidi and others realize FDA had not only moved the goal posts, but was playing on a completely different field.

7. The MDO is based on a Fatal Flaw memorandum that was required to go through APA notice and comment rulemaking. The memorandum gives FDA staff virtually no discretion to reject a PMTA if the requisite long-term clinical or longitudinal study is missing. It also is not based on any language or provision contained in the TCA. As a result, the Fatal Flaw approach imposes a new legal norm on ENDS manufacturers, constitutes

a legally binding policy, and represents a legislative rule that must comply with proper administrative rulemaking procedures.

8. Even if the Fatal Flaw memorandum is not a rule, it deserves no *Skidmore* deference from this Court because it is, as discussed above, unlawful on multiple grounds.[29]

ARGUMENT

I. The MDO Violates The TCA And Is *Ultra Vires*

By refusing to conduct a full scientific review of Bidi's PMTAs, FDA violated the TCA. 5 U.S.C. §§706(2)(A), (2)(C), (2)(D); *see City of Arlington, Tex. v. FCC*, 569 U.S. 290, 297 (2013) (when agency exceeds power delegated by Congress it acts *ultra vires*). Under the statute, once FDA receives a complete PMTA, it must do more than a cursory evaluation; it must review and evaluate the application's contents in its entirety.

The TCA's plain language provides that a PMTA shall be denied if "*upon the basis of information submitted* to [FDA]…and any other information before [FDA]" the applicant has not demonstrated APPH. 21 U.S.C.

[29] The 5th Circuit recently granted another ENDS manufacturer a stay pending appeal in a suit challenging a similar MDO, holding the manufacturer was likely to succeed on the merits as FDA failed to give fair notice of the Fatal Flaw approach and the MDO was otherwise arbitrary and capricious. *Wages and White Lion Invs. L.L.C., d/b/a Triton Distribution v. FDA*, 2021 WL 4955257 (5th Cir. Oct. 26, 2021) ("*Triton*"); *but see Breeze Smoke, LLC v. FDA*, No. 21-3902 (Doc. 24-2) (Nov. 12, 2021).

§387j(c)(2) (emphasis added). The statute defines APPH in broad terms with respect to "risks and benefits to the population *as a whole*," including "users and nonusers of tobacco products." 21 U.S.C. §387j(c)(2) (emphasis added). In this context, the statute enumerates numerous forms of evidence that must be in any PMTA, including data on health risks, ingredient and additive information, manufacturing practices, product samples, labeling specimens, and any other information required by FDA. 21 U.S.C. §387j(b)(1).

Congress, therefore, intended that any APPH determination be based on a multi-faceted analysis weighing all data and information in a PMTA. FDA must consider the *whole* population, including not only underage nonusers and adult users, as the MDO purports to, but also any other demographics that might be impacted by an ENDS product (*e.g.*, adult non-users, underage cigarette smokers, etc.).

Moreover, FDA must gauge not only the relative cessation benefits to adult smokers, which is the MDO's focus, but also all other *risks and benefits* of a given product, including health factors, such as the extent to which a product results in relatively less or more exposure to hazardous constituents. *See also* 21 U.S.C. §387g(a)(4) (defining APPH in context of tobacco control standards as including reduction or elimination of harmful constituents). Indeed, as

discussed *supra* at 8-11 and *infra* at 40-41, this is how FDA has interpreted APPH in PMTA regulations and guidance.

Further, along with the other types of evidence the TCA says must be included in any PMTA, the statute explicitly envisions that FDA consider the impact that restrictions on the sale or distribution of a product could have on the APPH determination. 21 U.S.C. §387j(c)(1)(B). These may include constraints on access to a given product, and advertising and marketing limitations, aimed at reducing underage use (*e.g.*, only allowing face-to-face transactions in adult-only facilities). *Id.* (referencing examples of restrictions identified in 21 U.S.C. §387f(d)).

All of this is consistent with Congress's choice of words adopting the APPH standard. Congress did not employ any words or terms of limitation. Rather, they used the word "appropriate"—"the classic broad and all-encompassing term that naturally and traditionally includes consideration of all the relevant factors." *Michigan v. EPA*, 576 U.S. 743, 752 (2015) (citation omitted). Further, common definitions of "public health" are broad and refer to protecting the "community" as a whole; they are not otherwise restricted to certain persons or population demographics.[30] And of course, nowhere in the

[30] Merriam-Webster Dictionary, https://tinyurl.com/55p876pn ("the art and science dealing with the protection and improvement of community health");

TCA is there any indication that FDA was authorized to abandon all scientific review and instead deny a PMTA (and, in fact, PMTAs covering over one million products) based on nothing more than the mere absence of one, single-issue study.[31]

A PMTA might be so deficient on its face that FDA should not have to spend resources on any further review. But that is not the case here. FDA conducted two screening exercises of Bidi's applications and determined that the PMTAs are "sufficiently complete to enter [the] substantive review phase." FDA-BIDIVAPOR-000024-30 (filing letter); FDA-BIDIVAPOR-000019-23 (acceptance letter); *see supra* at 19. At this point, FDA was statutorily obligated to provide a full scientific review, and in fact notified Bidi that its PMTAs had been accepted for scientific review. FDA-BIDIVAPOR-005271-72. But it then adopted the Fatal Flaw approach and did nothing of the sort.

Because FDA did not follow the TCA in issuing the MDO, it acted contrary to law and its illegal actions must be set aside. *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 691 (9th Cir. 2021) (failure of agency to

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American Heritage Dictionary, https://tinyurl.com/ywxdthby ("The science and practice of protecting and improving the health of a community").

[31] As discussed *supra* at 24 and *infra* at 43, both the 2019 PMTA guidance and the PMTA Final Rule indicate that FDA reserves the right to impose sales and marketing restrictions on a given product to meet the APPH standard.

conduct safety review of pesticide was *ultra vires* when citizen petition contained "sufficient evidence to undertake" such review).

II. The MDO Is Arbitrary And Capricious

FDA also failed to adequately evaluate Bidi's PMTAs and thus engaged in arbitrary and capricious decision-making. 5 U.S.C. §706(2)(A); *Sierra Club v. U.S. Army Corps Of Eng'rs*, 295 F.3d 1209, 1216 (11th Cir. 2002) (agencies must take a "hard look" at the record). Agency action must be overturned where it did not rely on factors Congress said must be evaluated or consider an important aspect of the problem. *Id.*; *Marquez-Martinez v. U.S. Attorney General*, 752 Fed. Appx. 832, 835 (11th Cir. 2018) (same); *Triton Distribution*, 2021 WL 4955257, at *3 (same). An "agency cannot ignore evidence that undercuts its judgment; and it may not minimize such evidence without adequate explanation." *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018); *see Dep't of Homeland Security v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1910 (2020) (agency must consider important aspects of the problem); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (agency must examine relevant evidence and articulate a satisfactory explanation).

A. FDA Ignored The Comprehensive And Multi-Factored PMTA Review Process Set Forth In The TCA And In FDA Regulations, Guidance, and Public Statements

To begin, by relying on a truncated Fatal Flaw review, FDA ignored the all-encompassing PMTA review process set out by Congress in the TCA and FDA's own, long-standing interpretation of APPH. As discussed above, Congress used an expansive term in the word "appropriate," set forth relevant factors to consider under the APPH standard, and directed FDA to weigh the "risks and benefits to the population *as a whole*." *Supra* at 35-39. Congress did not limit APPH to only one issue, in stark contrast to the MDO's sole focus on potential cessation benefits of non-tobacco flavored ENDS for adult smokers.

Likewise, in interpreting the TCA, FDA has said it must consider "all" information in a PMTA, consider the application in its "totality," and evaluate the PMTA on a "case-by-case" basis. 86 Fed. Reg. at 55320; FDA-BIDIVAPOR-000071-72. Specifically, FDA has characterized APPH broadly, using descriptors like "complex," depicting it as a "multi-disciplinary" or "balancing" process, noting FDA must "consider[] many factors" and "weigh[] all of the potential benefits and risks" in a PMTA, and maintaining APPH is not limited to a specific or static set of criteria. *Supra* at 8-10. Indeed, even the TPL, which underlies the MDO itself, describes the PMTA review process in equally sweeping terms. *Supra* at 25-26. But with the Fatal Flaw

review, implemented *en masse* across over one million product PMTAs, FDA completely abandoned this approach.

And contrary to the MDO, FDA has otherwise refused demands that APPH turn on whether public health benefits have been shown for selected population segments or products. 86 Fed. Reg. at 55385; FDA-BIDIVAPOR-000031-32; *supra* at 9. Indeed, as the TPL states, whether non-tobacco flavored ENDS provide a certain level of cessation benefits to adult smokers is only one of many issues that are relevant to the APPH determination. FDA-BIDIVAPOR-00066. But again, FDA neglected its own advice and instead issued an MDO simply because there was no RCT/longitudinal study or other data showing that one product – non-tobacco flavored ENDS – provides "added benefits" to one population demographic – adult smokers – when compared to any similar benefits of tobacco flavored products.

B. FDA Failed To Conduct A Substantive, Scientific Review Of Bidi's PMTAs And Instead Denied The PMTAs Based On A Cursory Box-Checking Exercise (Called The "Fatal Flaw" Review) Which Focused On A Single Study And Datapoint

By relying on a mere box-checking exercise and failing to review over 285,000 pages of data and information, the MDO also disregarded *all* of the evidence submitted by Bidi that FDA has otherwise said would be relevant to an APPH determination. Bidi's PMTAs are based on detailed instructions,

laid out by FDA in various guidance, regulations, and other public statements, as well as FDA's responses to Bidi's specific PMTA questions, on how ENDS manufacturers can successfully demonstrate that their products are APPH. *Supra* at 15-24. The 2019 PMTA Guidance alone spends over 50 pages advising manufacturers to submit studies and other data on a broad range of issues, from toxicological and pharmacological testing, consumer perception and use surveys, and public scientific literature reviews, to strict underage prevention measures and warning labels. *Supra* at 10-11.

Yet by its own admission, FDA did not review any of this material. FDA-BIDIVAPOR-000032; -000054; -000059; -005227. FDA did not engage in any scientific review – despite notifying the company that the subject PMTAs had officially entered scientific review – and, instead, spent a mere few hours flipping through Bidi's PMTAs and then indicating on a check-list that they did not contain the aforementioned RCT/longitudinal study. *Id.* Indeed, the amount of APPH-related information and data contained in Bidi's PMTAs that went unreviewed is substantial, including the following:

- Product ingredients and BIDI® Stick design details;
- Toxicological and pharmacological testing;
- Aerosol analyses of potentially harmful constituents;
- Comprehensive scientific public literature reviews containing clinical, cross-sectional, and longitudinal studies evaluating the population effects of ENDS;

- Studies considering the relative health risks of BIDI® Sticks and other tobacco products;
- Manufacturing and quality control details;
- Product-specific behavioral, perception, and intention surveys;
- Consumer insight and product use surveys;
- Environmental assessments and product stability (shelf-life) studies;
- Hardware safety and battery certification information (UL-8139);
- Youth access prevention measures;
- Adult-focused marketing plan; and
- Proposed post-marketing monitoring plan.

Supra at 15-24.

Of particular note, FDA concedes it never evaluated information related to issues it has repeatedly identified as being especially important to any APPH determination. For example, the TPL reflects other FDA statements when it claims that underage prevention measures are "critical" to any APPH analysis. *Supra* at 10; 26-27.[32] Indeed, Bidi implemented an aggressive program guarding against access and use by minors. Among other things, Bidi only distributes products to business partners (*i.e.*, not directly to consumers) who employ strict age-restriction protections (*e.g.*, face-to-face deliveries); requires

[32] FDA-BIDIVAPOR-004504 (2019 PMTA Guidance) (noting "restrictions on sale and distribution…can help support a showing" that a product is APPH, and stating that FDA reserves the right to impose additional restrictions); 86 Fed. Reg. at 55320, 55388, 55394, 55396 (PMTA Final Rule) (FDA maintaining repeatedly that marketing plans will help inform and play an "important role" in any APPH determination, and noting FDA has authority to impose its own sales restrictions to ensure a product continues to be APPH).

wholesalers and distributors to implement comprehensive age-verification procedures; screens partners for continuing compliance; does not employ online influencers, brand ambassadors, or the like; does not sponsor sporting or music events; only advertises to potential business partners through trade press and industry websites; does not market using kid-friendly imagery or messaging; employs aggressive age-gating measures on social media sites; and includes extensive age-related warnings on its products. *Supra* at 21-24.[33] The MDO never weighs this evidence or even mentions these efforts. *Triton*, 2021 WL 4955257, at *3-4 (vacating MDO, in part, because FDA did not consider applicant's marketing plan).

Similarly, FDA highlighted in the TPL and other guidance the need for data on potential health risks and the significance of consumer behavioral/perception/intention studies. *Supra* at 10-11; 26-27. But even though all of these were contained in Bidi's PMTAs, FDA did not analyze, or even acknowledge, such information. *Supra* at 24-30.

Perhaps even more concerning, FDA turned a blind eye to evidence going directly to the issue raised in the MDO – whether non-tobacco flavored

[33] The PMTA Final Rule specifically notes that age-gating on social media, not using celebrities, and other access restrictions are relevant to an APPH determination. 86 Fed. Reg. at 55395.

ENDS help adult smokers move away from more dangerous cigarettes. For instance, Bidi's comprehensive literature review evaluated the types of studies – RCTs/longitudinal cohort studies – the MDO claimed were missing. This includes third party evaluations of FDA's own PATH data, which has been collected since 2013 as part of a longitudinal cohort study looking at tobacco consumer (including ENDS users) behavior and use patterns. Yet nowhere in the MDO or the supporting TPL did FDA discuss, even in passing, the literature review, which concluded that non-tobacco flavored ENDS do, in fact, help adult smokers quit smoking and overall result in added health benefits to the population as a whole. *Supra* at 16-18.

And the same can be said as to the PMTA amendments submitted by Bidi before the MDO was issued, which contain product-specific data further supporting an APPH determination in this case. Bidi provided the results of a Consumer Insight Survey and a Disposable Vape User Survey, both of which involved over 1,000 adult BIDI® Sticks users. The results showed that flavored BIDI® Sticks significantly reduce cigarette use. *Supra* at 19-21. But again, FDA did not review, let alone evaluate, this evidence.

In fact, FDA was motivated by at least one factor in the MDO that is wholly irrelevant to the APPH standard. Specifically, the Fatal Flaw memorandum set forth a plan to "effectively" process the millions of product

PMTAs before September 9, 2021. FDA-BIDIVAPOR-005226-27.[34] This concern is immaterial to APPH. Efficiency goals "cannot save an arbitrary agency policy." *Judulang v. Holder*, 565 U.S. 42, 63-64 (2011) (holding irrelevant agency goal to save time and money); *Michigan*, 576 U.S. at 750 ("efficiency" is no substitute for "reasoned decision-making"); *Triton*, 2021 WL 4955257, at *3 (same). Indeed, lost in FDA's rush to issue as many MDOs as possible by the self-imposed deadline were FDA's promises to issue one deficiency letter to each applicant and entertain PMTA amendments filed after September 9, 2020 due to COVID-19 delays, both of which would help ensure FDA had all pertinent APPH-related information. *Supra* at 19, 29.[35]

FDA deemed Bidi's PMTAs sufficiently complete for scientific review. FDA-BIDIVAPOR-000024. And, in fact, just a few weeks before issuing the MDO, FDA notified Bidi that the subject PMTAs were officially entering

[34] FDA did so even though the federal district court in Maryland did not require FDA to complete its PMTA reviews by that date; rather, it only required that ENDS being sold after the cutoff are subject to enforcement absent a case-by-case exemption. *Am. Academy of Pediatrics,* Doc. 127 at 12.

[35] FDA also pressed ahead with the MDO despite having been put on notice in Bidi's third amendment that FDA would receive by close of 2021 additional information from two consumer perception and intention ("TPPI") studies that would further inform whether adult consumers are using flavored BIDI® Sticks to switch away from conventional cigarettes, as well as a pharmacokinetic (or "PK") study also going to comparative usage patterns among various ENDS products. *Supra* at 21.

scientific review. FDA-BIDIVAPOR-005271. But FDA's Fatal Flaw strategy completely abandoned this approach; rather, the MDO represents a wholesale failure to consider any submitted evidence relevant to the APPH standard. *Regan*, 996 F.3d at 696-97 (holding arbitrary and capricious agency action where denial of a citizen petition to ban pesticide use in food was based on finding that petitioners had not submitted sufficient supporting information without actually making a safety determination based on the entire record).

C. FDA Never Justified The Fatal Flaw Approach And Specifically Its Application To Bidi's Extensive PMTAs

FDA never explained its about-face in the context of Bidi's PMTAs. APPH is clearly a relative concept; the absence of a single study cannot be a deal-breaker. Each PMTA will have its strengths and weaknesses. But how each of those elements impacts the others and dictates the quantum of evidence that is needed cannot be known without evaluating an entire application. FDA says as much in the TPL when it concludes that as "known risks increase, so too does the burden of demonstrating a substantial enough benefit." FDA-BIDIVAPOR-000070-71. But the opposite holds true as well. If the evidence in Bidi's PMTAs shows a relatively lower risk, then its burden of proof on APPH should be adjusted accordingly. Indeed, FDA recently characterized APPH in the PMTA Final Rule as requiring an "individualized

determination" based on the "risks and benefits of a *specific* tobacco product." 86 Fed. Reg. at 55390 (emphasis added). But that did not happen here.

Without reference to Bidi's PMTAs, FDA argues that experience with *other* PMTAs indicates a discrete RCT/longitudinal study is *always* needed. FDA-BIDIVAPOR-000072. It maintains that research *in general* shows minors are primarily attracted to flavored products and that age-prevention measures do not work. *Id.* FDA never grapples, however, with specific information and data in Bidi's PMTAs and whether those, *taken as a whole*, might compel a different conclusion. A full scientific review might reveal that Bidi's underage use prevention measures tip the scales in favor of a marketing order; or it might show that BIDI® Sticks are particularly effective at helping adults move away from more dangerous cigarettes.

But we will never know how FDA might come down on all of this because it never did the work. FDA never justified its Fatal Flaw approach as to Bidi. Indeed, FDA's across-the-board issuance of virtually identical, cookie-cutter MDOs and TPLs for millions of flavored ENDS products belies any claims of reasoned decision-making here. *Siddiqui v. Holder*, 670 F.3d 736, 744 (7th Cir. 2012) (vacating deportation order under statutory abuse of discretion standard where agency did not conduct an "individualized analysis" of the

evidence and instead relied on "boilerplate" language applied in hundreds of other immigration decisions).

III. The MDO Violates The APA And The Due Process Clause Of The Fifth Amendment Because FDA Failed To Give Bidi Fair Notice Of The Fatal Flaw Approach And Consider Bidi's Legitimate Reliance Interests

The MDO also violates due process and is arbitrary and capricious as FDA failed to give Bidi fair notice that its PMTAs would be *automatically* denied if they did not contain the specified RCT/longitudinal study. "A fundamental principle in our legal system is that [agencies]…must give fair notice of conduct that is…required." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) (citing due process). This principle applies to informal guidance and thus it is arbitrary and capricious for an agency not to state a regulatory interpretation with "ascertainable certainty" prior to the alleged unlawful conduct. *ExxonMobil Pipeline Co. v. U.S. Dep't of Transp.*, 867 F.3d 564, 578 (5th Cir. 2017); *Georgia Pacific Corp. v. OSHRC*, 25 F.3d 999, 1005-06 (11th Cir. 1994) (same). Through regulations and "other [agency] public statements," an entity should be able to discern what conduct is demanded for compliance. *General Elec. Co. v. EPA*, 53 F.3d 1324, 1329 (D.C. Cir. 1995).

FDA failed in this regard. Before the September 2020 filing deadline, in guidance intended to help ENDS manufacturers file complete PMTAs, as well as during public meetings, FDA consistently stated that applicants could rely

on scientific literature reviews and behavioral/perception studies to demonstrate APPH. It repeatedly maintained that "no specific studies" would be required to support a PMTA and that any form of long-term studies would likely be unnecessary. *Supra* at 12-14. Even after the MDO was issued, FDA maintained in the recently issued PMTA Final Rule that manufacturers would not be expected to conduct long-term studies lasting more than six months. 86 Fed. Reg. at 55387. At no juncture, however, did FDA warn that the mere absence of an RCT/longitudinal study or similar data comparing non-tobacco flavored e-liquids to tobacco-flavored products, without consideration of any other part of the PMTAs, would literally prevent filed applications from receiving any scientific review and doom such PMTAs as a matter of course.

Moreover, FDA's conduct here is particularly egregious given statements it made directly to Bidi. In February 2020, Bidi asked for a meeting with FDA to discuss what clinical studies would be required, including how it should compare its flavored ENDS to other tobacco products.[36] FDA declined to meet face-to-face. But in follow-up correspondence, FDA said there are no clinical study/trial requirements and no specific requirements for evaluating comparator products, and then recommended Bidi "compare the health risks

[36] Bidi Stay Mot. (Oct. 25, 2021), Patel Aff. at ¶¶57-59.

of your tobacco product to both products within the same category and subcategory, as well as products in different categories as appropriate." FDA-BIDIVAPOR-005277. FDA then referred Bidi to the 2019 PMTA guidance and 2019 public meeting for more information on comparator products, the very sources indicating long-term studies generally would not be needed. *Id.* Significantly, FDA never mentioned the key issue in this matter – *i.e.*, that an MDO would undoubtedly issue if no long-term studies were done showing the manufacturer's non-tobacco flavored e-liquids provide an "added [cessation] benefit" over tobacco-flavored products.

Indeed, as discussed above, both the TCA's plain language and FDA's public statements characterize APPH as turning on a full scientific review of numerous factors, not just a single, discrete study or issue. *Supra* at 8-11. Unsurprisingly, Bidi in good faith embraced FDA's advice and submitted extensive PMTAs containing, among other evidence, the very types of literature reviews, survey data, and perception/behavioral studies FDA said would support an APPH finding, but now suddenly maintains are irrelevant. *Supra* at 15-24; *see Regents*, 140 S. Ct. at 1913 ("[w]hen an agency changes course…it must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.") (internal quotations omitted); *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126

(2016) (arbitrary and capricious not to consider reliance interests engendered by past representations); *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156-57 (2012) (agencies should not change interpretations in adjudications where regulated entities have acted in "good-faith" reliance on prior statements); *Triton*, 2021 WL 4955257, at *4-5 (finding MDO arbitrary and capricious where FDA did not consider applicant's reliance interests).

Finally, "when an agency rescinds a prior policy its reasoned analysis must consider the alternative[s] that are within the ambit of the existing policy." *Regents*, 140 S. Ct. at 1913 (citation and internal quotations omitted). Here, FDA could have readily given Bidi and others fair warning before issuing an MDO. In fact, FDA had said it would do so. During a June 2021 webinar, FDA indicated it would issue one deficiency letter to each manufacturer so it could correct any shortcomings in the application. *Supra* at 29-30. But Bidi never received a deficiency letter. FDA cannot now penalize Bidi for following years of guidance only to do a 180-degree turn and rely solely on a rudimentary, box-checking exercise.

IV. The Fatal Flaw Approach Is A Rule And Was Required To Comply With The APA's Notice And Comment Rulemaking Requirements

The MDO – and its *automatic* denial of Bidi's PMTAs because they did not include a discrete type of study – is based on what amounts to a rule in the form of the Fatal Flaw memorandum that was required by the APA to go through notice and comment rulemaking. 5 U.S.C. §§553 (requiring agencies to give public notice and allow interested persons to submit comments), 706(2) (allowing courts to hold unlawful and set aside agency action "found to be…without observance of procedure required by law").

Under APA Section 553, general statements of policy and interpretive rules are exempt from notice and comment rulemaking. 5 U.S.C. §553(b)(3)(A). In this Circuit, "whether a particular agency proceeding announces a rule or a general policy statement depends upon whether the agency action establishes a 'binding norm.'" *Ryder Truck Lines, Inc. v. United States*, 716 F.2d 1369, 1377 (11th Cir. 1983) (citation omitted). Whether a binding norm is established, in turn, depends on:

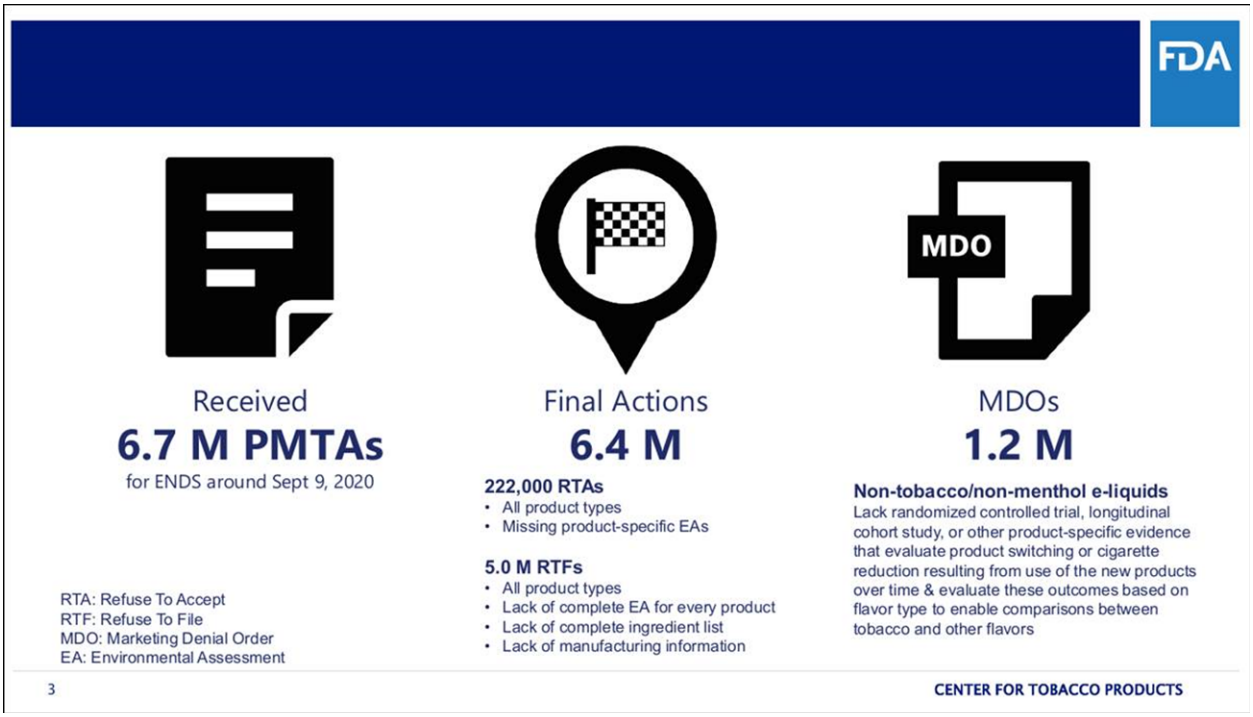
> the extent to which the challenged policy leaves the agency free to exercise its discretion to follow or not to follow that general policy in an individual case, or on the other hand, whether the policy so fills out the statutory scheme that upon application one need only determine whether a given case is within the rule's criterion. As long as the agency remains free to consider the individual facts in the various cases that arise, then the agency action in question has not established a binding norm.

Id.

Here, the Fatal Flaw memorandum clearly imposes a binding norm on FDA staff reviewing the PMTAs. The memorandum requires PMTAs for a non-tobacco flavored ENDS to have a product-specific RCT/longitudinal cohort study or some other similarly "robust and reliable" data showing an incremental cessation benefit to adult smokers associated with a manufacturer's non-tobacco flavored products when compared to a tobacco-flavored product. FDA-BIDIVAPOR-005226-27 (stating PMTA "requires" such evidence). And if such study is missing, FDA has virtually no discretion but to issue an MDO. Indeed, the checklists used to review PMTAs, including Bidi's, require a simple up or down determination before issuing an MDO. FDA-BIDIVAPOR-000052-61. There is no substantive review of an application and the memorandum never mentions additional factors to be considered on a case-by-case basis.

Instead, according to the memorandum, the "absence of these types of studies is considered a fatal flaw, meaning any application lacking this evidence will likely receive a marketing denial order (MDO)." FDA-BIDIVAPOR-005226-27. This memorandum is also intended to be applied across the board to all non-tobacco flavored ENDS. *Id.* (noting that the Fatal Flaw approach is designed to "effectively manage the remaining non-tobacco

flavored ENDS PMTAS not in Phase III, substantive scientific review" and stating that the "objective is to address these applications by applying a standard of evidence" focused on cessation benefits of these products). In fact, as of October 2021, this box-checking exercise has led FDA to deny PMTAs for over 1.2 million flavored products.[37] [38]



Moreover, this Court distinguishes between "legislative rules," which must comply with APA Section 553, and "interpretive rules," which are

[37] *See* FDA, What You Should Know About FDA Regulation of E-Cigarettes, https://tinyurl.com/b6upm9s.

[38] *See* FDA-BIDIVAPOR-000065 (TPL stating the "rationale for FDA's decision for these flavored ENDS applications is consistent with previous decisions for other flavored ENDS and is set forth below").

exempt. *Warshauer v. Solis*, 577 F.3d 1330, 1337 (11th Cir. 2009). While a legislative rule "creates new law, rights, or duties," an interpretive rule "does not modify or add to a legal norm based on the agency's own authority." *Id.* (citation, emphasis, and internal brackets omitted). An interpretive rule "simply states what the administrative agency thinks the statute means, and only reminds affected parties of existing duties." *Id.* (citation and internal quotations omitted).

In this Court, the key "distinction between an interpretative rule and a substantive rule…likely turns on how tightly the agency's interpretation is drawn linguistically from the actual language of the statute." *Id.* (citation omitted). The further an agency statement deviates from the plain language of the statute, the more likely it is a legislative rule. *Id.* at 1338; *Alabama v. Ctrs. For Medicare & Medicaid Servs.*, 780 F. Supp. 2d 1219, 1231 (M.D. Ala. 2011) ("[w]hen an agency exercises its 'delegated powers' and goes 'beyond the text of a statute,' it has created a legislative rule and must first engage in notice and comment rulemaking.") (citation omitted).[39]

[39] Although not dispositive, the "agency's characterization of the rule is relevant to the determination." *Warshauer*, 557 F.3d at 1337 (citation omitted). In this case, the Fatal Flaw memorandum does not claim that it is merely guidance or an interpretive rule.

But nowhere in the TCA does Congress authorize FDA to deny a PMTA because it fails to contain a single type of long-term study. Indeed, the Fatal Flaw memorandum does not cite, because it cannot, to any provision or language in the TCA permitting FDA to require such a study to the exclusion of all else. To the contrary, the TCA requires FDA to conduct a full scientific review considering numerous factors that are relevant to an APPH determination. As such, the Fatal Flaw memorandum does not merely remind manufacturers of their existing obligations; rather, it subjects them to an entirely new legal norm – an additional obligation that had never been articulated by FDA before – and therefore constitutes a rule that required notice and comment rulemaking. *Alabama*, 780 F. Supp. 2d at 1228-31 (finding agency letter dictating state Medicaid reporting requirements to be a legislative rule where letter does not cite to any provision or language in underlying statute for support).

V. This Court Should Not Give The Fatal Flaw Approach Any *Skidmore* Deference

Even if the Fatal Flaw memorandum does not amount to a rule, this Court should not otherwise give any deference to the memorandum's box-checking approach as applied to Bidi's PMTAs. When reviewing informal agency guidance, this Court considers applying a relatively "weaker" form of deference in which an "agency's interpretation [of a statute] is not entitled to

controlling weight." *Rafferty v. Denny's, Inc.*, 13 F.4th 1166, 1179 (11th Cir. 2021). Called "Skidmore" deference, the Court only gives an amount of deference "proportional to the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade." *Id.*; *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944); *Warshauer*, 577 F.3d at 1335 ("an agency's interpretive guidance construing a statute is entitled to deference 'proportional to its power to persuade'") (citation omitted). Nothing about the Fatal Flaw memorandum warrants judicial deference here.

First, there is no analysis on why *every* PMTA for a non-tobacco flavored product should be denied marketing authorization if it does not contain an RCT/longitudinal cohort study or similar data comparing those ENDS to tobacco-flavored products. Aside from generally referring to "information available to date," the memorandum in conclusory fashion maintains these types of discrete studies are required – a position that is literally counter to every other FDA rule, guidance, and public statement regarding PMTA requirements. While it briefly cites to the TCA's PMTA provision, it does not explain how the Fatal Flaw approach is consistent with the statute's broad definition of APPH. *Supra* at 8-11. In fact, the memorandum seems based more on irrelevant efficiency concerns, and a desire to "effectively manage"

the numerous PMTAs filed as of the September 2020 deadline and "to take final actions on as many applications as possible by September 10, 2021." FDA-BIDIVAPOR-005226-27.

Second, the memorandum is entirely inconsistent with prior FDA characterizations of the APPH standard and the more recently adopted PMTA Final Rule. As discussed above, ever since the Deeming Rule was promulgated in 2016, FDA guidance, regulations, and public statements have consistently described APPH in broad terms which requires FDA to evaluate and balance numerous factors in addition to the singular cessation issue discussed in the memorandum. *Supra* at 8-11. Moreover, FDA time and again told ENDS manufacturers that demonstrating APPH would not require long-term clinical or cohort studies, not to mention a study going to the specific product comparison discussed in the memorandum. *Supra* at 12-14. *Rafferty*, 13 F.4th at 1187-88 (court citing agency's prior interpretations and fair notice concerns when refusing to provide any *Skidmore* deference). FDA even stated so in response to Bidi's questions regarding APPH review. *Supra* at 13.

Finally, the Fatal Flaw memorandum simply fails to persuade. Based on extensive direction provided by FDA over the years, Bidi spent $6.6 million compiling PMTAs totaling 285,000 pages of information and data to demonstrate APPH. *Supra* at 15-16. No rational ENDS manufacturer would

have done so if there was any indication that FDA would at the last minute pull the rug out from under ENDS manufacturers and, without any scientific review, issue MDOs *en masse* to over one million products based on nothing more than a contrived Fatal Flaw approach. That is not what Congress envisioned in the TCA. It is not what FDA said it was going to do. It is not what the federal district court in Maryland required FDA to do. And it certainly is not what Bidi was entitled to under the law and what adult smokers relying on Bidi's products to switch away from smoking ultimately deserved.

CONCLUSION

This Court should grant Bidi's Petition for Review, and vacate and remand the MDO for further agency proceedings.

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CERTIFICATE OF COMPLIANCE

I hereby certify the foregoing complies with the length limitations of Federal Rule of Appellate Procedure ("Rule") 27(d)(2)(A) because it is 12,654 words, excluding the parts that are exempted under Rule 32(f). It complies with the typeface and type-style requirements of Rule 32(a)(5) and Rule 32(a)(6) because it is printed in 14-point Calisto MT font, a proportionally spaced typeface with serifs.

Dated: November 19, 2021

/s/ Eric P. Gotting
Eric P. Gotting

Counsel for Petitioner Bidi Vapor, LLC

CERTIFICATE OF SERVICE

I hereby certify that on November 19, 2021, a true and correct copy of the foregoing was filed via the Court's CM/ECF system and served via electronic filing upon all counsel of record in this case.

/s/ *Eric P. Gotting*
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ADDENDUM

21 U.S.C. §387j.....A001

§ 387j. Application for review of certain tobacco products

(a) In general

(1) New tobacco product defined

For purposes of this section the term "new tobacco product" means—

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(2) Premarket review required

(A) New products

An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

(i) the manufacturer has submitted a report under section 387e(j) of this title; and the Secretary has issued an order that the tobacco product—

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this chapter; or

(ii) the tobacco product is exempt from the requirements of section 387e(j) of this title pursuant to a regulation issued under section 387e(j)(3) of this title.

(B) Application to certain post-February 15, 2007, products

Subparagraph (A) shall not apply to a tobacco product—

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009; and

(ii) for which a report was submitted under section 387e(j) of this title within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

(3) Substantially equivalent defined

(A) In general

In this section and section 387e(j) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

(i) has the same characteristics as the predicate tobacco product; or

(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

(B) Characteristics

In subparagraph (A), the term "characteristics" means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

(C) Limitation

A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

(4) Health information

(A) Summary

As part of a submission under section 387e(j) of this title respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

(B) Required information

Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

(b) Application

(1) Contents

An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

(D) an identifying reference to any tobacco product standard under section 387g of this title which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

(F) specimens of the labeling proposed to be used for such tobacco product; and

(G) such other information relevant to the subject matter of the application as the Secretary may require.

(2) Referral to Tobacco Products Scientific Advisory Committee

Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may, on the Secretary's own initiative; or

(B) may, upon the request of an applicant,

refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(c) Action on application

(1) Deadline

(A) In general

As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under subsection (b)(2), shall—

(i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(B) Restrictions on sale and distribution

An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title.

(2) Denial of application

The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

(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;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of this title;

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; 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.

(3) Denial information

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

(4) Basis for finding

For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(5) Basis for action

(A) Investigations

For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

(B) Other evidence

If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

(d) Withdrawal and temporary suspension

(1) In general

The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a tobacco product for which an order was issued under subsection (c)(1)(A)(i), issue an order withdrawing the order if the Secretary finds—

(A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

(B) that the application contained or was accompanied by an untrue statement of a material fact;

(C) that the applicant—

(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 387i of this title;

(ii) has refused to permit access to, or copying or verification of, such records as required by section 374 of this title; or

(iii) has not complied with the requirements of section 387e of this title;

(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 387f(e) of this title and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 387g of this title, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

(2) Appeal

The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A)(i) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 387*l* of this title.

(3) Temporary suspension

If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the authority of the manufacturer to market the product. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

(e) Service of order

An order issued by the Secretary under this section shall be served—

(1) in person by any officer or employee of the department designated by the Secretary; or

(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

(f) Records

(1) Additional information

In the case of any tobacco product for which an order issued pursuant to subsection (c)(1)(A)(i) for an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

(2) Access to records

Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(g) Investigational tobacco product exemption for investigational use

The Secretary may exempt tobacco products intended for investigational use from the provisions of this subchapter under such conditions as the Secretary may by regulation prescribe.

(June 25, 1938, ch. 675, §910, as added Pub. L. 111–31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1807.)

PRIOR PROVISIONS

A prior section 910 of act June 25, 1938, was renumbered section 1010 and is classified to section 399a of this title.

§ 387k. Modified risk tobacco products

(a) In general

No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product.

(b) Definitions

In this section:

(1) Modified risk tobacco product

The term "modified risk tobacco product" means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.