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Legal Sidebar

Circuit Split over the Food and Drug Administration's Denial of Applications Seeking to Market Flavored E-Cigarettes, Part 2 of 2

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This two-part Sidebar examines the circuit split over certain electronic nicotine delivery system (ENDS) products—that is, products with many common names, such as e-cigarettes and vape pens—that come in flavors like fruit, candy, and other sweets ("flavored ENDS products"). In particular, the Sidebar focuses on circuit court decisions that have considered challenges to the Food and Drug Administration's (FDA's) denial of applications seeking to market flavored ENDS products. Of the courts that have considered these petitions, the Second, Third, Fourth, Sixth, Seventh, Ninth, Tenth, and the D.C. Circuits have sided with FDA and denied the petitions or requests to stay the agency's marketing denial orders (MDOs). The Eleventh and Fifth Circuits, on the other hand, have sided with the ENDS manufacturers and vacated FDA's MDOs, remanding the applications to FDA for reconsideration. Part I of the Sidebar provides an overview of the relevant statutory and regulatory background. This part provides an overview of the litigation challenging FDA's MDOs and certain preliminary observations for consideration by Congress.

Overview of Flavored ENDS PMTA Litigation

As discussed in Part I, up to and through the September 9, 2020, premarket tobacco product application (PMTA) deadline, FDA received more than 6 million applications. To date, FDA has not authorized any flavored ENDS products for lawful marketing and has issued MDOs on many applications involving these products. In many of these MDOs, FDA concluded that the applications generally did not show that authorizing the products would be "appropriate for the protection of the public health," or APPH, under the Family Smoking Prevention and Tobacco Control Act (TCA). In particular, in some MDOs, FDA found that the applications lacked sufficient evidence demonstrating that the flavored ENDS products at issue have a benefit to adult smokers—that is, that they are *better than* tobacco-flavored ENDS products at promoting smoking cessation or switching from combustible cigarettes for such smokers—that is sufficient to overcome the products' "well-documented, alarming levels" of risk of initiating youth use.

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Many applicants that received an MDO filed petitions in circuit courts seeking judicial review of the orders pursuant to TCA Section 912 (21 U.S.C. § 387*l*(a)(1)(B)). This provision permits "any person adversely affected" by a denial of a PMTA to file a petition for review of an MDO with the D.C. Circuit or the circuit in which "such person resides or has their principal place of business."

The types of health risk data included in the relevant PMTAs typically included literature reviews showing the public health benefits of tobacco-flavored ENDS product use by cigarette smokers and short-term (often small) surveys, studies, or focus groups that measured behavior or attitudes about smoking cessation at a single point in time. In general, FDA concluded that this evidence did not provide sufficient reliable data demonstrating that the flavored ENDS product at issue would promote the relevant behavior change (e.g., switching from combustible cigarettes) in adult smokers over time or be better than tobacco-flavored ENDS products at promoting such behavior change.

Petitioners challenged the MDOs on various grounds. Several petitioners argued that FDA lacked statutory authority to require applicants to demonstrate that their flavored products better promote smoking cessation than comparable tobacco-flavored products—a standard some petitioners refer to as the "comparative efficacy" standard. Many petitioners also argued that FDA acted arbitrarily and capriciously in issuing the MDOs because the agency imposed the comparative efficacy standard without notice. They asserted that FDA's pre-submission-deadline guidance documents stated that no long-term studies were expected, but the agency, in issuing the MDOs, pulled "a surprise switcheroo" by both requiring evidence of comparative efficacy and requiring such evidence to be in the form of "a randomized controlled trial, longitudinal study, or other long-term study." Additionally, many petitioners also argued that the MDOs were arbitrary and capricious because FDA failed to consider their marketing and sales-access-restrictions plans—information FDA had advised was relevant to the APPH determination.

Courts Affirming or Declining to Stay FDA's MDOs

To date, eight of the ten circuits that have considered petitions challenging FDA's MDOs for flavored ENDS products have upheld or declined to stay the orders. Several of these courts, for instance, concluded that the TCA "expressly authorizes the FDA to consider comparative evidence" and that FDA "acted well within [Congress's] statutory directive when it compared the claimed cessation benefits of flavored and non-flavored products." In these courts' view, the statutory APPH consideration is "inherently comparative," directing FDA to "weigh the risk of hooking new users on tobacco products against a product's potential to help existing users switch from unhealthier forms of tobacco—i.e., combustible cigarettes." Given that FDA has found, based on a robust array of literature, that flavored products present greater risks of attracting youth to initiate use, the comparative efficacy standard demanded a greater showing of benefit to adult users. This analysis, these courts found, "is precisely the type of analysis the statute calls for."

These courts generally rejected the petitioners' argument that "the term 'risk,'" as used in TCA's PMTA provision, "refers only to 'physiological *health* risks' and 'not some broader concept of risk that encompasses initiation and cessation behaviors.'" In these courts' view, "[t]he degree to which a harmful product entices and addicts new users is inarguably a component of the 'health risk' it poses."

Courts that have affirmed the MDOs also generally concluded that the orders were not arbitrary and capricious. While the courts acknowledged that FDA's pre-submission-deadline guidance documents, discussed in Part I, stated that the agency did not expect the applicants to conduct long-term studies to support an application, the courts generally concluded that reading the documents in context, the agency "consistently required evidence that evaluated the impacts of flavored versus non-flavored products on initiation and cessation." The need for this comparative showing, in the courts' view, was not unfairly

surprising because it flowed directly from the statute, which asks for valid scientific evidence concerning whether an applicant's tobacco product presents less risk than other tobacco products.

Moreover, under these courts' reading of the guidance documents, "FDA never guaranteed that manufacturers could carry their evidentiary burden under the TCA without providing long-term data." FDA instead, these courts found, maintained the position that "it might accept evidence other than long-term studies to demonstrate that an ENDS product was [APPH] *if* that evidence had sufficient scientific underpinnings." In these courts' view, FDA applied this standard and reasonably concluded that the PMTAs at issue—typically supported by literature reviews and single-point-in-time behavioral studies—did not provide reliable data demonstrating the relevant behavioral changes (e.g., switching from combustible cigarettes) in adult smokers. Accordingly, these courts generally concluded that FDA reasonably denied the applications "due to a lack of *any* 'valid scientific evidence' substantial enough to outweigh the known risks to youth of flavored products."

Several of these courts also concluded that FDA's failure to review petitioners' marketing and sales-access restrictions plans did not warrant remand of the applications. While some courts found that petitioners plausibly argued that FDA erred in declining to review the plans or reasonably explain its failure to do so, the courts generally concluded that, assuming the agency had erred, that error was harmless. The marketing plans at issue, the courts found, described measures "materially identical . . . to those that . . . FDA had already described as insufficient," such as age verification measures, mystery shopper programs, and contractual penalties for retailers. As a result, the courts concluded that even if FDA had reviewed the plans, it would not have changed its decisions on the applications.

Petitioners in four of these cases have sought review by the Supreme Court, which has rejected two of the petitions for certiorari. The two more recently filed petitions, seeking review of the Second and Ninth Circuits' decisions, are still pending.

Courts Vacating FDA's MDOs

Two of the ten circuits that have considered petitions challenging FDA's MDOs for flavored ENDS products agreed with the petitioners that the orders were arbitrary and capricious, and remanded the applications for FDA's reconsideration.

The Eleventh Circuit concluded that FDA arbitrarily and capriciously denied certain PMTAs because the agency refused to consider the petitioners' marketing plans designed to minimize youth exposure and access. Because FDA had consistently recognized such marketing plans as a "critical" and "necessary" part of the APPH determination in its pre-submission-deadline guidance documents, the agency's refusal to consider the plans for efficiency reasons, in the court's view, meant that it failed to consider an "important aspect of the problem." This error, the court continued, also was not harmless because the PMTAs at issue included measures not mentioned in FDA's April 2020 enforcement guidance, such as "Trace/Verify technology" and an authentication system designed to prevent counterfeit products from becoming accessible to youth. Because the agency *may* reach a different result upon considering the marketing plans, the court concluded that the error was not harmless. The court, however, also acknowledged that FDA is not required to reach a different substantive result on remand.

In an en banc decision, the Fifth Circuit held that the MDOs at issue were arbitrary and capricious. First, the court agreed with the Eleventh Circuit that the MDOs were arbitrary and capricious because FDA failed to consider the petitioners' marketing plans.

Second, the court held that the MDOs were also arbitrary and capricious because they imposed new requirements on petitioners to provide long-term comparative efficacy studies without adequate notice or justification for this change in position. In the court's view, FDA's pre-submission-deadline guidance documents expressly stated that long-term studies were not expected and invited petitioners to rely on

both (1) "existing data (including studies of smokers and users of unflavored ENDS products) to make inferences about flavored ENDS products" and (2) "observational studies" that "could include surveys." However, when FDA reviewed the applications, according to the court, the agency "flip-flopped," denying the "petitioners' applications because they did not perform 'a randomized controlled trial and/or longitudinal cohort study' or other comparably robust evidence that directly measured the behaviors of those who use their flavored products." In the court's view, FDA effectively "categorically banned flavored-product manufacturers from relying on any study that did not focus on the specific flavored product mentioned in the PMTA." This "about-face," according to the court, carried "drastic" consequences for manufacturers, who "will unquestionably [be] put . . . out of business."

Moreover, even if FDA's pre-submission-deadline guidance documents could be reasonably read to put manufacturers on notice of their obligations to perform long-term scientific studies, the court continued, petitioners reasonably read and relied upon the documents' statements that long-term studies were not necessary. According to the court, in issuing the MDOs, FDA arbitrarily and capriciously ignored petitioner's "serious reliance interests" based on their good-faith reading of the relevant guidance documents.

The Fifth Circuit further held that it cannot avoid sending the applications back to FDA for reconsideration by considering whether the agency's errors were harmless. According to the court, the "ordinary" rule is that a federal court must remand to the agency as soon as it identifies a legal error in the agency's decision, and the harmless-error exception applies only "where the agency would be *required* to take the same action no matter what." Where, as here, the adjudicatory standards are discretionary and highly fact-specific, and turn on FDA's "ever-evolving understanding of what 'public health' requires," the court continued, the harmless-error rule does not apply.

The government did not seek further review of the Eleventh Circuit's decision but filed a petition for certiorari on March 19, 2024, seeking review of the Fifth Circuit's decision.

Court Orders on Proper Venue for Petitions

In the context of a petition challenging an MDO issued for certain menthol-flavored ENDS products, filed by two manufacturer and two retailers, the Fifth Circuit also granted a motion to stay the MDO. In addition to concluding that the petitioners were likely to succeed on the merits of their claims that FDA acted arbitrarily and capriciously when it denied their PMTAs, the court also held, as a threshold matter, that venue was proper in that circuit because the *retailers*, who did not file PMTAs but have been selling the ENDS products subject to the MDOs, have their principal place of business there.

The manufacturers who received the MDOs are based in North Carolina, which is in the Fourth Circuit. Had the manufacturers petitioned for review alone, TCA's venue provision would have limited the petition to be filed either in the D.C. Circuit or in the Fourth Circuit, and the petitioners in fact also filed timely petitions for review in the D.C. Circuit. In concluding that venue was proper, the Fifth Circuit did not elaborate on its reasoning, and FDA later filed a motion seeking to dismiss or transfer the petition to the D.C. Circuit. A divided panel denied the motion, concluding that the retailers are "person[s] adversely affected" for purposes of TCA's venue and statutory standing provision. In the court's view, the retailers are adversely affected by the MDO because one of them asserted in a declaration that it would cease operations if it could not sell the products at issue. This potential closure was sufficient injury for purposes of establishing statutory standing, according to the court, even though petitioners "could not lawfully have been selling the e-cigarettes without prior approval." The Fifth Circuit appears to be the only circuit that has interpreted TCA's venue provision to date.

Preliminary Observations

The circuit split over whether FDA reasonably denied applications seeking to lawfully market flavored ENDS products raises several legal questions, including interpretive questions concerning the TCA and courts' application of certain administrative law principles that may be of interest to Congress.

First, while the Eleventh and Fifth Circuits both ruled in favor of petitioners and vacated the applicable MDOs, only the Fifth Circuit held that FDA acted arbitrarily and capriciously because the agency described a different review standard in its pre-submission-deadline guidance documents than the one it ultimately applied. Unlike other courts that have addressed the issue, the Fifth Circuit concluded that the guidance documents did not adequately convey that for flavored ENDS products, applicants should submit a randomized controlled trial, a longitudinal cohort study, or other comparably robust evidence showing that the flavored ENDS product at issue is better than tobacco-flavored ENDS products at promoting switching from combustible cigarettes for adult smokers. Instead, the court appears to read the guidance documents as advising the submission of a combination of short-term behavioral studies, including surveys, plus other studies—including peer-reviewed studies, long-term randomized controlled trials, and longitudinal cohort studies of *tobacco-flavored* ENDS products—that show that ENDS products are generally less harmful than combustible cigarettes. This reading would also appear to generally subject tobacco-flavored and other flavored ENDS products to similar standards of review.

This reading of the relevant guidance documents raises a question: for products that have been shown to present higher risks of youth initiation, like flavored ENDS products, would this level of evidence meet the statutory APPH standard? To the extent the Fifth Circuit implicitly answered this question in the affirmative, the circuit split may reflect a disagreement over what the statute requires. The statutory standard directs FDA to consider "the increased or decreased likelihood that existing users of tobacco products will stop using such products" and "the increased or decreased likelihood that those who do not use tobacco products will start using such products," based on "clinical investigations" and other "valid scientific evidence." For courts that have upheld FDA's MDOs, this statutory standard "explicitly contemplates that FDA must embark on a comparative inquiry" between the flavored ENDS product and unflavored products because the former carries a greater risk of youth initiation. Put another way, in these courts' view, for a product that presents a greater risk of prompting nonsmokers to begin smoking, the APPH balancing analysis demands a showing that the product carries "overmatching greater benefits" at promoting smoking cessation by current smokers. This aspect of the balancing analysis required by the statute, according to these courts, calls for—and gives notice to applicants of—the need to submit sufficiently robust comparative efficacy studies for applications involving flavored ENDS products. Some petitioners, in fact, appeared to recognize the need for these studies by describing in their PMTA such studies—in the form of randomized trials—that were proposed or under way but not yet completed.

Second, inasmuch as the Fifth Circuit's reading of the relevant guidance documents raises questions regarding what the statutory standard requires, its separate decision on venue has the potential to compound those questions. As discussed above, the Fifth Circuit concluded that it is the proper venue for a petition because the PMTA applicant, whose principal place of business is outside of the Fifth Circuit, included retailers located in the circuit as petitioners. Practically, this interpretation of TCA's venue provision may have the effect of prompting other applicants receiving MDOs to strategically join certain retailers in order to file their petitions in the Fifth Circuit. This forum selection may be especially likely if an applicant is otherwise headquartered in a state located in one of the eight circuits that have upheld FDA's MDOs.

To the extent the circuit split regarding the review standard reflects a disagreement about the requirements of the statutory APPH standard—including the circumstances under which comparative effectiveness studies may be required—Congress, if it determines appropriate, may further modify or clarify the standard. Similarly, to the extent Congress determines that the scope of TCA's venue provisions should be

clarified, it may also modify or further specify who may seek to petition review of an MDO or where such petitions may be brought.

Finally, the Fifth Circuit's decision also raises several questions regarding the application of several administrative law principles. In many of the cases relied upon by the Fifth Circuit in its application of the fair notice, change-in-position, and good-faith reliance doctrines, the courts had applied these doctrines to reject as arbitrary or capricious agency rules or interpretations that precluded applicants from submitting an application at all (i.e., "cut off a right" to apply) or imposed certain liability on regulated entities. In contrast, the Fifth Circuit applied these doctrines to limit how FDA can conduct case-by-case determinations in an application process for which the applications have been reviewed on the merits and where applicants are allowed to resubmit their applications with new information that address the deficiencies identified in the MDOs. This application of these doctrines raises an open legal question: whether these principles apply with equal force to views expressed by FDA in guidance regarding how it intends to conduct case-by-case discretionary determination that is, as the Fifth Circuit described, "highly fact-specific" and "turns on FDA's ever-evolving understanding of what 'public health' requires." Alternatively stated, where case-by-case determination is involved, even where an agency may be applying a "new policy" in a pending proceeding, the question is whether these principles demand only that the agency "explain its actions in a way that coheres with the rest of its [regulatory] scheme" or, put another way, "provide a reasoned explanation that treats like cases alike."

One concern that appears to underlie the Fifth Circuit's decisions involving the MDO petitions is the view that the review standard FDA applied unfairly impinged on certain vested interests of the applicants and other entities to continue to market products they have been selling, in many cases, for years, and in some cases, products upon which their business operations depend. Given TCA's premarket approval regime, however, each flavored ENDS product applicant and seller likely knew or should have known, when they entered the market, that any authorized products remained on the market through FDA's exercise of enforcement discretion and that it is uncertain whether their products will ultimately receive FDA marketing authorization. These circumstances raise a question regarding what, if any, legally cognizable right or reliance interest the applicants have. To the extent litigation continues before either the Supreme Court or other appellate courts, the courts may clarify the answers to some of these questions.

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