Congressional Research Service
Informing the legislative debate since 1914

Legal Sidebar

Circuit Split over the Food and Drug Administration's Denial of Applications Seeking to Market Flavored E-Cigarettes, Part 1 of 2

April 5, 2024

Electronic nicotine delivery system (ENDS) products—products that go by many common names, such as e-cigarettes and vape pens—are generally required to receive prior authorization from the Food and Drug Administration (FDA) before they can be lawfully marketed in the United States. Before FDA issued regulations in 2016 to subject these products to the premarket review process, however, many of them were already being sold on the U.S. market and were allowed to remain there while FDA implemented the application and review process. These products come in a variety of forms and flavors, from tobacco and menthol flavors based on the flavors of traditional combustible cigarettes to other flavors based on the flavors of fruit, candy, and other sweets ("flavored ENDS products"). While limited studies of certain ENDS products show that they contain substantially lower levels of toxins than combustible cigarettes, indicating a benefit to current adult smokers who switch completely to using ENDS products, flavored ENDS products have been shown to be particularly attractive to youth. In a 2016-2017 study, for instance, 93.2% of youth ENDS product users reported that their first use was with a flavored product. In 2018, the Surgeon General issued an advisory on the "e-cigarette epidemic among youth."

Since the initial deadline in September 2020 for ENDS product manufacturers to submit their premarket tobacco product applications (PMTAs), FDA has received millions of applications for ENDS products. To date, the agency has authorized 23 tobacco-flavored ENDS products for lawful marketing and has not authorized any flavored ENDS products. Many applicants that have received a marketing denial order (MDO) for their flavored ENDS products have filed petitions in U.S. Courts of Appeals throughout the country to challenge the denial of their PMTAs. Of the courts that have considered these petitions, the Second, Third, Fourth, Sixth, Seventh, Ninth, Tenth, and D.C. Circuits have sided with FDA and denied the petitions or requests to stay the agency's 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. This circuit split sets the stage for potential Supreme Court review regarding what information FDA may require applicants seeking to market flavored ENDS products to provide as part of

Congressional Research Service
https://crsreports.congress.gov
LSB11141

their PMTAs. This two-part Sidebar examines the circuit split. Part I provides an overview of the Family Smoking Prevention and Tobacco Control Act (TCA) regulatory framework, relevant FDA actions related to ENDS products, and the agency's review and denial of the PMTAs involving flavored ENDS products. Part II provides an overview of the litigation challenging those FDA orders, the court decisions to date, and certain preliminary observations for consideration by Congress.

Background on TCA's Statutory Framework

In 2009, Congress enacted the TCA, which established the central federal regulatory regime for the manufacture, marketing, and distribution of tobacco products. Among other things, the TCA required all new tobacco products—that is, those not commercially marketed in the United States prior to February 15, 2007—to receive prior authorization from FDA before they can be marketed to the public. In establishing this regulatory regime, the TCA aims to balance competing interests in protecting the public's health against the harmful effects of smoking and youth tobacco use, while preserving access to lawfully marketed tobacco products for adult consumers. To further this goal, the TCA grants FDA "primary Federal regulatory authority" over tobacco products and establishes a premarket review process for new tobacco products. Such products generally may not be marketed until the manufacturer submits a PMTA and receives a marketing granted order (MGO) from the Center for Tobacco Products, established within FDA to implement the TCA.

The TCA permits FDA to issue an MGO only upon certain findings, including a conclusion that "permitting such tobacco product to be marketed would be appropriate for the protection of the public health," or APPH. This APPH determination must be made "with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product," taking into account the likelihood that existing users of tobacco products will stop using such products and the likelihood that those who do not use such products will start using them. The TCA directs FDA, in making this evaluation, to consult a range of evidence, including "information submitted to the Secretary as part of the [PMTA] and any other information before the Secretary with respect to such tobacco product." Such information may include "when appropriate . . . well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product," as well as other "valid scientific evidence" determined by the Secretary to be sufficient to evaluate the tobacco product.

While the TCA explicitly applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, the statute also authorizes FDA to deem other tobacco products subject to the law. In 2016, FDA invoked this authority and promulgated what is known as the Deeming Rule, which subjected ENDS products to the TCA's regulatory regime.

Background on Relevant FDA Actions

Early Regulatory Efforts and the Promulgation of the Deeming Rule

Modern ENDS products deliver nicotine to their users by heating an "e-liquid"—which usually contains nicotine derived from tobacco, flavorings, and other additives—to create an inhalable aerosol. These products—which were initially largely manufactured in China—began appearing on the U.S. market during the mid-2000s, with rising sales beginning in 2007. In response, and prior to the enactment of the TCA, FDA declared these products to be unapproved drug-device combination products under the federal Food, Drug, and Cosmetic Act (FD&C Act) and began ordering that imported ENDS products be denied entry into the United States.

A few months prior to the enactment of the TCA, these FDA actions drew legal challenges from importers and distributors of ENDS products. They argued that under *FDA v. Brown & Williamson*, in which the Supreme Court rejected FDA's claimed authority to regulate combustible cigarettes and smokeless tobacco products as "drugs" under the FD&C Act, FDA lacked the authority to regulate ENDS products as combination devices under the FD&C Act. In 2010, the D.C. Circuit agreed in *Sottera, Inc. v. FDA*, holding that these products, unless marketed for therapeutic purposes, generally must be regulated under the newly enacted TCA.

While FDA worked to promulgate regulations to deem certain new tobacco products subject to the TCA, marketing of ENDS products became widespread in the United States. Sales of these products increased rapidly in the 2010s, including to youth, who reported in several surveys high use of flavored ENDS products. By 2015, ENDS products surpassed combustible cigarettes as the nicotine product of choice among U.S. high school students. Around the same time, however, limited testing of certain ENDS products showed that they contained substantially lower levels of toxins than combustible cigarettes, indicating their potential to reduce health risks to individuals who completely switch from using combustible cigarettes to using ENDS products.

In 2016, FDA finalized and promulgated the Deeming Rule, designating—among other products—ENDS products and their component e-liquids as "new tobacco products" under the TCA, subjecting them to premarket review. Entities seeking to legally market ENDS products that were on the market as of August 8, 2016, were generally required to submit a PMTA. Under the Rule, however, FDA also stated that it was exercising enforcement discretion and deferring enforcement against new products on the market for staggered two- to three-year periods to allow manufacturers to prepare the PMTAs and for FDA to review the applications. While the Deeming Rule generally set August 8, 2018, as the submission deadline for PMTAs, FDA later issued August 2017 guidance that sought to extend the compliance period and associated deadlines by up to six years. The American Academy of Pediatrics and other public health organizations and practitioners sued to challenge the extension. The suit resulted in a court-imposed deadline that ultimately fell on September 9, 2020.

FDA Guidance on PMTA Submissions

Before the PMTA submission deadline, FDA issued a number of documents that provided guidance to applicants on their submissions. FDA first issued guidance in June 2019 that outlined its then-current "thinking on the types of information an applicant should include in a PMTA" to help the agency make the APPH determination. Among other things, the guidance advised that such information included "well-controlled investigations" and "other 'valid scientific evidence' if found sufficient to evaluate the tobacco product." FDA noted, for example, that it intended to review "information on other products (e.g., published literature, marketing information)" if applicants provided "appropriate bridging studies" to show that those data apply to the product at issue in the application. The agency also cautioned that literature reviews "are considered a less robust form" of evidence and that "[n]onclinical studies alone are generally not sufficient to support" marketing authorization. At the same time, FDA also stated that, given the relative newness of the products, it did "not expect that applicants [would] need to conduct long-term studies to support an application."

In September 2019, FDA issued a proposed rule that would, among other things, "interpret and set forth requirements related to the content and format of PMTAs," including health risk investigations. FDA explained that the proposed rule did "not set requirements for specific studies that must be contained in every single PMTA" and recognized that "long-term data is not available for all categories of products and [that FDA] does not expect that long-term clinical studies . . . will need to be conducted for each PMTA." At the same time, FDA reiterated that it would rely upon "only valid scientific evidence to determine whether the marketing of the new tobacco product would be APPH" and recommended that applicants "compare the health risks of its product to both products within the same category and

subcategory, as well as products in different categories as appropriate." This comparative data, FDA noted, "is an important part of the evaluation of the health effects of product switching." The proposed rule would also require PMTAs to include other information, such as a marketing plan "concerning at least the first year of marketing after an applicant receives a marketing order," to help the agency "consider how an applicant will target the marketing of its new tobacco product."

In April 2020, FDA issued guidance describing its enforcement priorities. Among other things, FDA stated that it would prioritize enforcement against "flavored, cartridge-based ENDS products" and any ENDS product that is marketed in a manner that is likely to promote use by minors. These priorities are intended to address "an alarming increase in the use of ENDS products by middle and high school students," who are "particularly attracted to flavored ENDS products." The guidance described examples of safeguards proposed by manufacturers to limit youth access to ENDS products, including age verification requirements and technology, contractual penalties for retailers that sell products to minors, and "mystery shopper" programs to monitor retailer compliance with age verification and sales restrictions. Despite these voluntary measures, however, FDA observed that youth e-cigarette use continued to increase, leading the agency to conclude that "focusing on how the product was sold would not appropriately address youth use of . . . flavored, cartridge-based products." Thus, in response to comments that stricter enforcement of current age verification rules would be effective at curbing youth use, FDA stated that while the agency continues to "vigorously enforce[] the age verification requirements," it believes that "age verification alone is not sufficient to address this issue . . . given the many sources of products available for youth access."

FDA's Review and Denial of Flavored ENDS PMTAs

Up to and through the September 9, 2020, PMTA deadline, FDA received applications for more than 6 million products. In July 2021, FDA circulated an internal memorandum that described "a new plan to effectively manage" a subset of applications for flavored ENDS products and to "take final action on as many applications as possible by September 10, 2021." Under this plan, "the agency would conduct a 'simple' fatal flaw review to identify whether the application contained 'either a randomized controlled trial (RCT) or longitudinal cohort study." If an application lacks those studies, it would "likely receive a marketing denial order." In August 2021, FDA issued a superseding memorandum that explained that the agency would broaden its review to consider other types of studies if they "reliably and robustly assess behavior change (product switching or cigarette reduction) over time, comparing users of flavored products with those of tobacco-flavored products."

In late August 2021, FDA announced that it had issued the first MDOs for ENDS products after determining the applications for about 55,000 flavored ENDS products. In a September 9, 2021, statement, FDA noted that it had taken action on more than 90% of the PMTAs that had been submitted, including issuing MDOs "for more than 946,000 flavored ENDS products." FDA noted that these applications generally did not show that authorizing the products would be APPH because they "lacked sufficient evidence that they have a benefit to adult smokers sufficient to overcome the public health threat posed by the well-documented, alarming levels of youth use of such products." More specifically, in some MDOs, FDA stated that the applications at issue generally lacked sufficient evidence demonstrating "the benefit of [the flavored ENDS product at issue] over an appropriate comparator tobacco-flavored ENDS," that is, that the flavored ENDS product at issue is *better than* tobacco-flavored ENDS products at promoting smoking cessation or switching from combustible cigarettes for adult smokers. Where this "key evidence" was missing, FDA generally issued an MDO without "assess[ing] other aspects of the applications," including an applicant's marketing plans for their ENDS products. An MDO, unless vacated by a court upon a petition for review, generally requires an applicant to stop marketing the products subject to the MDO.

Part II of this Sidebar examines the litigation challenging these FDA MDOs for flavored ENDS products.

Author Information

Wen W. Shen
Legislative Attorney

Disclaimer