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SECOND CIRCUIT REVIEW

Upholding the FDA on E-Cigarette Marketing

By Martin Flumenbaum and Brad S. Karp
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In *Magellan Technology v. United States Food and Drug Administration,* the U.S. Court of Appeals for the Second Circuit reviewed the FDA's decision to deny an application by a manufacturer of electronic nicotine delivery systems to market its fruit-and dessert-flavored replaceable cartridges or "pods." In a unanimous opinion authored by Circuit Judge Myrna Pérez and joined by Circuit Judges Dennis Jacobs and Sarah Merriam, the court denied the petition for review, agreeing with the FDA that there was insufficient evidence that marketing the flavored pods would appropriately protect public health. 70 F.4th 622 (2d Cir. 2023). The Second Circuit decision is another decision in a line of recent decisions from circuit courts, including the Third, Fourth, Seventh, and District of Columba Circuit, denying petitions for review of FDA decisions regarding e-cigarette products.

Statutory Background

The Family Smoking Prevention and Tobacco Control Act (the TCA), which was enacted in 2009 to combat the public's use and dependence on tobacco, authorizes the FDA to regulate the manufacture, marketing, and distribution of tobacco products and requires the FDA to conduct a premarket review of "new tobacco products." To obtain FDA approval, an applicant must show that allowing its product to be marketed would be "appropriate for the public health." In making this determination, the FDA weighs the benefits of the new tobacco product in promoting smoking cessation against the risk of the product contributing to smoking initiation, which the FDA bases on "well-controlled investigations" or other "existing valid scientific evidence." The regulatory framework also provides that e-cigarette products already on the market prior to 2009 are subject to the TCA's premarket authorization framework, and required applicants to submit premarket tobacco applications

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(PMTAs) for all such products by Sept. 9, 2020.

FDA's Pre-Deadline Preparation

Prior to the Sept. 9, 2020, deadline for filing PMTAs, the FDA published several guidance documents to assist manufacturers of e-cigarette products with filing their PMTAs. In its June 2019 guidance, the FDA acknowledged the dearth of scientific studies and analyses into e-cigarette products given their recent entrance into the U.S. market and previewed that it would not limit its review to "well-controlled investigations." The FDA also released two memoranda in July and August 2021. The July 2021 memorandum stated that the FDA would engage in a preliminary "fatal flaw review" of flavored e-cigarette PMTAs, meaning that any application lacking a randomized-control trial (RCT) or longitudinal cohort study would likely receive a marketing denial order (MDO). The August 2021 memorandum, which, superseded the July 2021 memorandum, stated that, in addition to RCTs and longitudinal studies, the FDA would consider evidence from other study types, provided that those studies "could reliably and robustly assess behavior change (product switching or cigarette reduction) over time, comparing users of flavored products with those of tobacco-flavored products."

The FDA's Denial

Magellan submitted a PMTA for its e-cigarette pods on Sept. 8, 2020. In support of its application, Magellan submitted four nonclinical studies and a marketing plan that outlined its strat-

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egy to restrict youth access and exposure to its products. On Sept. 8, 2021, the FDA issued a marketing denial order to Magellan for its flavored pods, concluding that the PMTAs "lacked sufficient evidence demonstrating that [its] flavored [pods] will provide a benefit to adult users that would be adequate to outweigh the risks to youth." See Magellan Technology, 70 F.4th at 628. The FDA specifically determined that Magellan had failed to show the comparative efficacy of its flavored pods over tobacco-flavored pods in helping smokers completely switch to e-cigarettes or quit smoking altogether. Because the FDA found Magellan's evidence to be insufficient, it did not proceed to other aspects of the application, including reviewing the marketing plan.

The Second Circuit's Review

The Second Circuit affirmed the FDA's denial of Magellan's PMTA for its flavored pods. Magellan argued that the FDA's denial of its PMTA was arbitrary and capricious in violation of the Administrative Procedure Act (APA) because the FDA departed from its stated standard of review without providing notice to or considering the reliance interests of applicants; and failed to consider Magellan's marketing plan despite previously emphasizing its importance. Magellan further argued that the FDA exceeded its statutory authority under the TCA by requiring applicants to demonstrate that their flavored pods are more effective than tobacco-flavored pods at promoting cessation or switching from combustible cigarettes to e-cigarettes. The panel considered and dismissed each of these arguments.

The panel first rejected Magellan's argument that the FDA acted arbitrarily and capriciously by imposing a new evidentiary standard on Magellan by conducting a "fatal flaw" analysis for the absence of an RCT or longitudinal cohort study without providing notice or considering its reliance interests, as required by the APA. The panel responded that even if the July 2021 Memorandum heightened the standard of review, as contended by Magellan, it was explicitly superseded by the August 2021 memorandum, which contemplated consideration of other types of studies. Magellan Technology, 70 F.4th at 630. The panel also found no evidence for Magellan's allegation that the FDA "surreptitiously" applied the July 2021 memorandum's "fatal flaw" analysis to its application; the record plainly showed the FDA considering Magellan's nonclinical evidence and concluding that it was "not adequate," an analysis that would not have been necessary had the FDA engaged in a fatal flaw review. Therefore, because the FDA did not depart from its stated standard of review, it was not obligated to notify Magellan or consider its reliance interests.

The panel next considered Magellan's argument that the FDA acted arbitrarily and capriciously by not evaluating Magellan's marketing plan as part of its review. Although the panel agreed with Magellan that the FDA should have considered its marketing plan—"given that the FDA itself identified the marketing plan as a relevant factor to its determination of whether Magellan's flavored pods would be marketed"—it determined that the error was harmless because consideration of the plan would not have resulted in a different outcome.

Finally, the panel confirmed that the FDA had statutory authority under the TCA to require that e-cigarette applicants demonstrate their flavored products are more effective than tobacco-flavored products at promoting cessation or switching from combustible cigarettes to e-cigarettes. The panel determined that because the TCA expressly contemplates a comparative analysis among tobacco products in evaluating product appropriateness (PMTAs must include "full reports of ... the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products"), the FDA was within its rights to require applicants to submit information comparing the efficacy of flavored and non-flavored e-cigarette products.

A ruling in favor of the e-cigarette manufacturer may cement a circuit split and could lead to the Supreme Court's review of the FDA's PMTA regime.

Conclusion

In affirming the FDA's denial order, the Second Circuit joined the Third, Fourth, Seventh and District of Columbia Circuits in upholding the manner in which the FDA reviews PMTAs for flavored e-cigarette products. See *Liquid Labs v. U.S. Food and Drug Administration,* 52 F.4th 533 (3d Cir. 2022); *Avil Vapor v. U.S. Food and Drug Administration,* 55 F.4th 409 (4th Cir. 2022); *Grippum v. U.S. Food and Drug Administration,* 47 F.4th 553 (7th Cir. 2022); *Prohibition Juice v. U.S. Food and Drug Administration*, 45 F.4th 8 (D.C. Cir. 2022). The Eleventh Circuit stands alone in disagreement, determining in August 2022 that the FDA acted arbitrarily and capriciously in refusing to consider six e-cigarette manufacturers' marketing plans before denying their applications. See *Bidi Vapor v. U.S. Food and Drug Administration,* 47 F.4th 1191 (11th Cir. 2022). Regulators and consumers of e-cigarettes alike will now turn their eyes to the Fifth Circuit, which this year granted en banc review after one panel ruled in favor of the FDA's PMTA regime. See *Wages and White Lion Investments v. U.S. Food and Drug Administration,* 58 F.4th 223 (5th Cir. 2023). A ruling in favor of the e-cigarette manufacturer may cement a circuit split and could lead to the Supreme Court's review of the FDA's PMTA regime.