United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
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Lyle W. Cayce
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No. 23-60037

R.J. Reynolds Vapor Company; RJR Vapor Company, L.L.C.; Avail Vapor Texas, L.L.C.; Mississippi Petroleum Marketers and Convenience Stores Association,

Petitioners,

versus

Food & Drug Administration; Robert Califf, *in his official capacity as Commissioner of the United States Food & Drug Administration*; United States Department of Health and Human Services; Xavier Becerra, *in his official capacity as Secretary of the United States Department of Health and Human Services*,

Respondents,

CONSOLIDATED WITH

No. 23-60128

R.J. Reynolds Vapor Company; RJR Vapor Company, L.L.C.; Avail Vapor Texas, L.L.C.; Mississippi Petroleum Marketers and Convenience Stores Association,

Petitioners,

versus

UNITED STATES FOOD & DRUG ADMINISTRATION; ROBERT M. CALIFF, *Commissioner of Food and Drugs*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, *Secretary, U.S. Department of Health and Human Services*,

Respondents.

Appeal from the Food & Drug Administration
Agency Nos. PM0000637, PM0000713,
PM0000554, PM0000561

Before KING, JONES, and SMITH, *Circuit Judges*.

EDITH H. JONES, *Circuit Judge*:

The Food and Drug Administration denied petitioners' application to market menthol-flavored e-cigarettes. Petitioners seek a stay pending review of the denial order on the merits. We grant the stay.

I. BACKGROUND

This court has become quite familiar with the legal and regulatory framework underpinning this case. *See Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 437 (5th Cir. 2020); *Wages & White Lion Invs. v. FDA*, 16 F.4th 1130 5th Cir. 2021) (stay order); *Wages & White Lion Invs. v. FDA*, 41 F.4th 427 (5th Cir. 2022) (merits decision), *vacated* 58 F.4th 233 (5th Cir. 2023). And the material facts resemble those in *Wages & White Lion*, with some notable differences.

The Food and Drug Administration ("FDA") has been regulating tobacco products since 2009 under the Family Smoking Prevention and Tobacco Control Act ("TCA"). Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387, *et seq.*). And since 2016, the FDA has been in

the business of regulating e-cigarettes,[1] including those containing no tobacco flavoring. *See* 81 Fed. Reg. 28,974, 28,976 (May 10, 2016). In order to continue marketing e-cigarettes, manufacturers must submit to the FDA a premarket tobacco product application ("PMTA"). 21 U.S.C. § 387j.

In June 2019, the FDA issued a "how-to" guide for submitting e-cigarette PMTAs. FDA, *Guidance for Industry, Premarket Tobacco Applications for Electronic Nicotine Delivery Systems* (June 2019) ("PMTA Guidance"), https://bit.ly/2R5TyYj. In it, the agency stated that it "does not expect that applicants will need to conduct long-term studies to support an application." *Id.* at 13. The Proposed and Final Rules repeated this expectation. *See* Premarket Tobacco Product Applications and Recordkeeping Requirements, 86 Fed. Reg. 55,300, 55,387 (October 4, 2021); 84 Fed. Reg. 50,566, 50,619 (Sept. 25, 2019). The FDA also recommended that applicants use "products that consumers are most likely to consider[] interchangeable" when submitting "comparative health risk data." PMTA Guidance at 13.

With this guidance in mind, Petitioner R.J. Reynolds Vapor Company ("RJRV") submitted a PMTA for its menthol-flavored Vuse Vibe e-cigarette on March 31, 2020,[2] well ahead of the September 9, 2020, deadline. *See* 21 U.S.C. § 387j; *Wages*, 16 F.4th at 1135. On December 18, 2020, the FDA sent RJRV a deficiency letter regarding several other pending PMTAs for RJRV's flavored ENDS. The FDA instructed RJRV to "provide evidence to demonstrate that the use of these flavored products (*other than menthol*)

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[1] Known more technically as electronic nicotine delivery systems ("ENDS").

[2] Vuse Vibe is a cartridge-based, closed system e-cigarette, which is distinct from "open system" and disposable e-cigarettes. In contrast, the products at issue in *Wages & White Lion* are flavored liquids used in "open system" e-cigarettes. 41 F.4th at 443 n.1 (Jones, J., dissenting).

increases the likelihood of complete switching among adult smokers relative to tobacco or menthol-flavored products." (emphasis added). Because this advice expressly excluded its menthol-flavored products, RJRV did not supplement its menthol Vuse Vibe PMTA.[3]

Over two years later, on January 24, 2023, the FDA denied RJRV's PMTA in a marketing denial order ("Denial Order"). A stated basis for the denial was that RJRV's long-term studies "were not brand- or product-specific," and, as such, "did not demonstrate that [RJRV's] menthol-flavored new products are more likely to promote complete switching or significant cigarette reduction compared to tobacco-flavored products." Additionally, the FDA stated that the "marketing restrictions and other mitigation measures that [RJRV] proposed cannot mitigate . . . risks to youth sufficiently." RJRV petitioned the FDA for a stay, which was denied. RJRV and three other companies then petitioned this court for review and moved to stay the Denial Order.[4] We granted an administrative stay, and now we enter a full stay pending resolution of RJRV's petition on the merits.

II. Discussion

As a preliminary matter, venue is proper in this circuit because a petitioner has its "principal place of business" here.[5] 21 U.S.C. § 387l(a)(1)(B). Also, because it is undisputed that "at least one" petitioner—namely, RJRV—has standing, Article III's case-or-controversy

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[3] RJRV's application for Vuse Vibe already spanned over 150,000 pages.

[4] The FDA also denied a PMTA for menthol Vuse Ciro. Petitioners no longer sell that product, and so do not seek a stay as to the denial of its marketing application.

[5] Petitioner Mississippi Petroleum Marketers and Convenience Stores Association is incorporated in and has its principal place of business in Mississippi.

requirement is satisfied. *Town of Chester v. Laroe Estates, Inc.*, 581 U.S. 433, 439, 137 S. Ct. 1645, 1651 (2017).

The "issuance of a stay is left to the court's discretion." *Nken v. Holder*, 556 U.S. 418, 433, 129 S. Ct. 1749, 1760 (2009). Our judgment is "guided by sound legal principles" that "have been distilled into consideration of four factors: (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Id.* at 434, 129 S. Ct. at 1761 (internal quotation marks omitted). "The first two factors . . . are the most critical." *Id.*

RJRV has made the strong showing of its likely success on the merits, irreparable injury, and the balance of harms and public interest weigh in favor of granting the stay. Thus, RJRV has met its "burden of showing that the circumstances justify an exercise of [our] discretion." *Id.*

A. Likelihood of success

The FDA's order is reviewed under the Administrative Procedure Act's ("APA") "arbitrary and capricious" standard, 5 U.S.C. § 706(2)(A), and will pass muster so long as it is "reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). To begin with, this means an "agency must defend its actions based on the reasons it gave when it acted"; we will not let the agency cut corners by entertaining *post hoc* rationalizations. *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020). Further, when an agency changes course, it must take into account "serious reliance interests" its "longstanding policies may have engendered" along with "alternatives that are within the ambit of the existing policy." *Id.* at 1913 (internal quotation marks omitted and alterations

adopted).[6] Additionally, failure to consider "relevant factors" will render "an agency's decreed result" unlawful. *Michigan v. EPA*, 576 U.S. 743, 750, 135 S. Ct. 2699, 2706 (2015). The above requirements ensure that an agency has engaged in "reasoned decisionmaking." *Id.*

Specifically, RJRV demonstrates that the FDA failed to reasonably consider the company's legitimate reliance interests concerning the need for longitudinal studies and marketing plans; failed to consider relevant evidence, *inter alia*, that youthful users do not like menthol-flavored e-cigarettes; and has created a *de facto* rule banning all non-tobacco-flavored e-cigarettes without following APA notice and comment requirements.

1. Legitimate reliance interests

The FDA did not reasonably consider RJRV's legitimate reliance interests before changing its position on the types of comparative studies and marketing plans critical to a compliant and complete PMTA. Dealing with administrative agencies is all too often a complicated and expensive game, and players like RJRV "are entitled to know the rules." *Alaska Prof'l Hunters Ass'n v. FFA*, 177 F.3d 1030, 1035 (D.C. Cir. 1999), *abrogated on other grounds by Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 135 S. Ct. 1199 (2015). To keep things fair, agencies must give notice of conduct the agency "prohibits or requires" and cannot "surprise" a party by penalizing it for "good-faith reliance" on the agency's prior positions. *Christopher v. Smithkline Beecham Corp.*, 567 U.S. 142, 156–57, 132 S. Ct. 2156, 2167–68 (2012). At a bare minimum, "[w]hen an agency changes its existing position, it . . . must at least display awareness that it is changing position and show that there are

[6] Colloquially, this is known as the "surprise switcheroo" doctrine. *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1810 (2019); *Env't Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005).

good reasons for the new policy." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 136 S. Ct. 2117, 2125–26 (2016). It follows that "unexplained inconsistency in agency policy is a reason for holding an [action] to be an arbitrary and capricious change from agency practice." *Id.* at 2126 (internal quotation marks omitted).

The FDA inexplicably switched its position on menthol-flavored e-cigarettes in at least two crucial ways. First, before the application deadline, the FDA represented that long-term studies were likely unnecessary and that applicants had discretion to use "products that consumers are most likely to consider[] interchangeable" when submitting "comparative health risk data." PMTA Guidance at 13. The FDA then notified RJRV directly that for its "flavored products (*other than menthol*)," it should submit evidence that those products "increase[d] the likelihood of complete switching among adult smokers relative to tobacco or menthol-flavored products." (emphasis added) The FDA never told RJRV that similar evidence would be required for its menthol Vuse Vibe PMTA. RJRV relied upon these representations when crafting its PMTAs and supplemental filings.

Despite its representations, the FDA's subsequent Denial Order stated that RJRV's "studies were not brand- or product-specific, and thus did not demonstrate that [RJRV's] menthol-flavored new products are more likely to promote complete switching or significant cigarette reduction compared to tobacco-flavored products." In the same vein, the accompanying Technical Project Lead ("TPL") faulted RJRV's studies for failing to "assess the impact of menthol-flavored ENDS . . . on cigarette smoking switching behavior" or "complete switching or significant cigarette reduction *over time*." (emphasis added) And again, nearly parroting FDA's earlier instruction, the TPL stated that RJRV "did not submit evidence from a [randomized controlled trial] or cohort study showing that its menthol-

flavored ENDS provide an added benefit to adult smokers in terms of complete switching or significant cigarette reduction over tobacco-flavored ENDS." In other words, the FDA's prior representations were that RJRV need not submit long-term studies showing that its menthol-flavored e-cigarette was more likely than a tobacco-flavored e-cigarette to cause smokers to quit. Yet the lack of that evidence became the very basis on which the FDA denied RJRV's application.

The FDA's second unexplained switch was from the policy on marketing plans it announced in its April 2020 Final Guidance ("2020 Guidance").[7] The 2020 Guidance enumerated "adequate measures" manufactures could take "to prevent minors' access" to ENDS products. FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (Revised): Guidance for Industry*, 21–22, https://bit.ly/3ZPRkPx. These included: (1) age-verification barriers for retail websites; (2) enforcement monitoring programs with retailers; (3) a limit on the number of ENDS that can be purchased at once or over a period of time; and (4) a mystery shopper program. *Id.* at 22. The guidance also listed common ways manufacturers improperly target minors, such as advertising with "social media influencers," "popular children's characters," and kid-friendly "cartoon or animated characters." *Id.* at 26–27. RJRV's proposed marketing plan accounted specifically for these and many more measures.

The FDA changed positions on this front as well, cursorily stating in its Denial Order that RJRV's "marketing restrictions and other mitigation measures" were insufficient. Remarkably, the TPL recounted the same

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[7] *See* 85 Fed. Reg. ¶ 23,973 (Apr. 30, 2020). The 2020 Guidance revised an earlier edition, published in January 2020, in which the FDA first described the marketing restrictions manufacturers could implement to restrict youth use. *Enforcement Priorities for Electronic Nicotine Delivery Systems: Guidance for Industry*, 85 Fed. Reg. ¶ 720 (Jan. 7, 2020).

"restrictions on advertising and promotion" and "restrictions on sales access" that the FDA had earlier hailed as "adequate measures," but concluded that none of them actually worked to a sufficient degree. In fact, the only measures described as potentially effective were "age-gating technologies that require user identification by fingerprint or other biometric parameters in order to unlock and use a tobacco product or geo-fencing technologies." These extreme measures were not listed in the 2020 Guidance. The TPL concluded that "only the most stringent mitigation measures could provide sufficient assurance" against the risks to youth from flavored ENDS.

The FDA's Denial Order wholly failed to explain both of these "about face" maneuvers. Of course, the FDA could have *formally* changed its requirements, but it did not. *Regents*, 140 S. Ct. at 1914 ("Making that difficult decision was the agency's job, but the agency failed to do it."). These "unexplained" and "inconsistent" positions are likely arbitrary and capricious. *See Encino Motorcars*, 579 U.S. at 222, 136 S. Ct. at 2126.

The FDA's disregard for the principles of fair notice and consideration of reliance interests is exacerbated by its failure to consider alternatives to denial. When an agency changes course, as the FDA did here, it must take into account "alternatives that are within the ambit of the existing policy." *Regents*, 140 S. Ct. at 1913 (internal quotation marks omitted and alterations adopted). For example, the FDA could have invited RJRV to submit supplemental filings to shore up its menthol Vuse Vibe application, as it had done for RJRV's non-tobacco-flavored e-cigarette PMTAs. Apparently, the FDA accepted as many as 13 amendments for RJRV's other applications. FDA, *TPL Review of PMTA, PM0000491, PM0000492* 11–14 (Dec. 4, 2018), https://tinyurl.com/2p83ymvb. The FDA gave RJRV no such opportunity for its menthol PMTA.

2. Failure to consider relevant factors

The FDA did not adequately address RJRV's evidence that substantial health benefits would accrue to adult and youth cigarette smokers alike who switched to menthol Vuse, while popularity among youth would remain low overall. For example, RJRV's application contained studies that "switching from smoking to use of menthol Vuse Vibe substantially reduces toxicant exposure in a manner similar to smoking abstinence." RJRV also submitted evidence of low popularity among youth relative to other flavored ENDS.

This evidence was overlooked even though it comports with the FDA's own findings published at the time RJRV filed its PMTA. In its 2020 Guidance, in response to the concern over a growing level of youth vaping, the FDA cited evidence that "youth use of menthol-flavored products is not as high as that for mint- and fruit-flavored products," *id.* at 15, and that "youth overwhelmingly prefer certain flavors . . . such as fruit, mint, and candy," *id.* at 24. Specifically, a survey of 8th, 10th, and 12th graders found that mango, mint, and fruit were the most popular flavors, together accounting for 75% of responses, while menthol and tobacco ranked among the least popular with between 2% and 6% each. *Id.* Further, the guidance noted menthol's unique status as "the only characterizing flavor available in cigarettes." *Id.* at 23.

This is where the plot thickens. Internal memoranda circulated among the FDA's Center for Tobacco Products ("CTP") and CTP's Office of Science ("OS") emerged in December 2022. *See* Alex Norcia, *Memos Show FDA Overruled Science-Office Call to OK Menthol Vapes*, Filter Magazine (Dec. 14, 2022) ("Norcia"), https://bit.ly/3JjjcVi. These reveal that OS, well into reviewing a PMTA for a menthol-flavored e-cigarette, recommended in late 2021 that the PMTA be granted because benefits to

smokers likely outweighed the "known risks to youth from the marketing of the products." Then in July 2022, a new CTP director appeared on the scene and told OS that "the approach to menthol-flavored ENDS should be the same as for other flavored ENDS, i.e., the products could be found [appropriate for the protection of the public health] only if the evidence showed that the benefits of the menthol-flavored ENDS were greater than tobacco-flavored ENDS, which pose lower risk to youth." OS then changed its position. These memoranda are strong evidence that CTP developed and internally circulated new criteria for evaluating PMTAs for menthol-flavored ENDS in Summer 2022, long after RJRV had filed its application.

When rejecting RJRV's evidence in the Denial Order, the FDA brushed over its prior statements about the low popularity of menthol-flavored e-cigarettes among youth and substantial benefits for cigarette smokers who make the switch. Because its "new policy rest[ed] upon factual findings that contradict those which underlay its prior policy," the FDA had to provide "a more detailed justification." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515, 129 S. Ct. 1800, 1811 (2009). It did not do so. This sudden turnabout further reinforces that the Order is likely arbitrary, capricious, or otherwise unlawful.

3. "Tobacco product standard"

RJRV has adduced evidence that the FDA has effectively banned all non-tobacco-flavored e-cigarettes, pursuant to its new and secret heightened evidentiary standard, without affording affected persons any notice or the opportunity for public comment. There is no dispute that the TCA requires the FDA to abide by notice-and-comment rulemaking procedures before

establishing a "tobacco product standard."[8] 21 U.S.C. § 387g(c)–(d). Similarly, it is clear that a ban on all but tobacco-flavored e-cigarettes would constitute a "tobacco product standard." *See id.* § 387g(a)(1)(A); *id.* § 387g(a)(2); *id.* § 387g(a)(3). The FDA admits that it "has yet to grant" a single application to market non-tobacco-flavored e-cigarettes. This means it has denied over 355,000 such applications, which amount to 99% of all timely-filed PMTAs. FDA, Press Release, *FDA Denies Marketing to Two Vuse Menthol E-Cigarette Products* (Jan. 24, 2023), https://bit.ly/3YRYWzB; Jim McDonald, *FDA Denies PMTAs for 300,000 More Flavored E-Liquids*, Vaping 360 (Sept. 3, 2021), https://bit.ly/3Fu08SS. *Cf.* FDA, *Premarket Tobacco Product Marketing Granted Orders* (Feb. 7, 2023), https://bit.ly/3lbNEIV. The only question, then, is whether the FDA has instituted a *de facto* ban on non-tobacco-flavored e-cigarettes. If so, then it has violated the APA by failing to provide those regulated with notice or an opportunity for public comment.

The alleged ban stems in part from the "Fatal Flaw" memorandum. It is common knowledge that by Summer 2021, the FDA unexpectedly found itself inundated with millions of PMTAs. To speed up application processing, the agency circulated an internal memorandum providing a new "standard of evidence" for some PMTAs for flavored e-cigarettes. The standard should sound familiar: PMTAs now require evidence from a randomized controlled trial or long-term study, along with "strong evidence that the flavored products have an added benefit relative to that of tobacco-flavored ENDS in facilitating smokers completely switching away from or

[8] Some argue Congress impermissibly delegated authority to the FDA in violation of the "major questions" doctrine by permitting the agency to determine what constitutes a new "tobacco product." *See, e.g.*, En Banc Brief for 38 Nat'l and State Elec. Nicotine Delivery Sys. Prod. Advoc. Ass'ns as Amici Curiae Supporting Petitioners, *Wages & White Lion Invs. v. FDA* (No. 21-60766) at 20–24. We do not consider that argument here.

significantly reducing their smoking."[9] FDA, *PMTA Review: Evidence to Demonstrate Benefit of Flavored ENDS to Adult Smokers* (Aug. 17, 2021); *see also* Timothy Donahue, *Lawsuits Focus on FDA's 'Fatal Flaw' Review for PMTAs*, Vapor Voice (Nov. 19, 2021), https://bit.ly/3lil0Wt (linking to "fatal flaw" memoranda); Alex Norcia, *FDA Memos Reveals Its "Fatal Flaw" Rejection plan for Flavored Vapes*, Filter (Nov. 3, 2021), https://bit.ly/3mY6T9m. Every PMTA that did not include the requisite new evidence was denied. The result: not a single PMTA for non-tobacco-flavored e-cigarettes has been granted.[10]

We thus must consider whether this heightened evidentiary standard may avoid the APA's notice-and-comment requirements because the Fatal Flaw memo and its progeny were general statements of policy rather than substantive rules. This question "turns on whether an agency intends to bind *itself* to a particular legal position." *Texas v. EEOC*, 933 F.3d 433, 441 (5th Cir. 2019) (quoting *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 94 (D.C. Cir. 1997)). An action is binding "if it appears on its face to be binding," "is applied by the agency in a way that indicates it is binding," or "retracts an agency's discretion to adopt a different view of the law." *Id.* at 441–42

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[9] The dissenting judge in the now-vacated *Wages & White Lion* merits opinion noted that although the Fatal Flaw memo was rescinded at the end of August 2021, "its approach appears to have been followed in a check-box 'scientific review' form that indicated only whether a PMTA included a randomized controlled trial or longitudinal cohort study." *Wages*, 41 F.4th at 444 (Jones, J. dissenting). The deficiency letter FDA sent RJRV in 2021 and the internal memoranda between CTP and OS are additional evidence that this standard remained in full effect for all non-tobacco-flavored e-cigarette PMTAs.

[10] It is worth noting that when this standard was expanded to menthol-flavored e-cigarette PMTAs, OS employees expressed their concern to CTP that the standard would "result in the removal of all ENDS from the U.S. market except for tobacco-flavored ENDS." *See* memo attached in Norcia at 3. n.3 (FDA-LOGICTECHNOLOGY-000171). They had good foresight.

(internal quotation marks omitted and alteration adopted). Further, a substantive rule "affects the rights of broad classes of unspecified individuals." *City of Arlington v. FCC*, 668 F.3d 229, 242 (5th Cir. 2012); *see also id.* (citing *MacLean v. DHS*, 543 F.3d 1145, 1161 (9th Cir. 2008) (agency action constituting "de facto rulemaking" "may require a notice and comment period")); *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 381–85 (D.C. Cir. 2002 (an EPA guidance document was a legislative rule that should have been issued following notice and an opportunity for public comment).

We conclude that the Fatal Flaw memo's heightened evidentiary standard "bears all the hallmarks" of a substantive rule. *City of Arlington*, 668 F.3d at 242. First, the memo is binding on its face by mandating that applications contain "the *necessary* type of studies." Second, it has been applied in a way that indicates it is binding; indeed, the subsequent, myriad Denial Orders refer to the same deficiencies identified as "fatal" in the memo. Third, it took away the FDA reviewers' former discretion to consider individual PMTAs solely on their merits and instead requires a cursory, box-checking review. Finally, it affected the rights of literally hundreds of thousands of applicants whose PMTAs were denied. This is not a close call. *See Iowa League of Cities v. EPA*, 711 F.3d 844, 872–76 (8th Cir. 2013) (vacating two letters sent by the EPA to Senator Charles Grassley as containing new legislative rules without satisfying notice and comment procedures); *Safari Club Int'l v. Zinke*, 878 F.3d 316, 333–34 (D.C. Cir. 2017) (setting aside a press release issued by the U.S. Fish and Wildlife Service for creating an industry ban without going through notice and comment); *Batterton v. Marshall*, 648 F.2d 694, 710 (D.C. Cir. 1980) (holding unlawful a new methodology for collecting and computing unemployment statistics never published or announced by the Department of Labor).

In sum, the FDA has articulated reasons to be concerned about youth vaping. But "[r]egardless of how serious the problem an administrative

agency seeks to address, . . . it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'" *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125, 120 S. Ct. 1291, 1297 (2000) (holding that Congress had not yet empowered the FDA to regulate tobacco products). Here, RJRV is likely to show that the FDA has instituted a *de facto* ban on non-tobacco-flavored e-cigarettes without going through notice-and-comment. Such action would be held unlawful and set aside as promulgated "without observance of procedures required by law." 5 U.S.C. § 706(2)(D).[11]

B. Irreparable injury

RJRV submits allegations, unchallenged by FDA, that because of the Order, it will incur substantial financial losses in annual revenue as well as reputational harm. It will also have to pay a hefty sum to remove the product from the market and subsequently dispose of it. "[S]ubstantial financial injury" may be "sufficient to show irreparable injury," especially when there is "no guarantee of eventual recovery." *Texas v. EPA*, 829 F.3d 405, 433 (5th Cir. 2016); *Alabama Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2015). Further, "complying with a regulation later held invalid almost *always* produces irreparable harm of nonrecoverable compliance costs." *Texas v. EPA*, 829 F.3d at 433. There is no suggestion, for instance, that RJRV could

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[11] The Seventh and Eleventh Circuits granted motions to stay FDA Denial Orders for other non-tobacco flavored e-cigarette PMTAs. *See Gripum LLC v. FDA*, No. 21-2840, 2021 WL 8874972 (7th Cir. Nov. 4, 2021); *Bidi Vapor LLC v. FDA*, 47 F.4th 1191 (11th Cir. 2022). The Sixth Circuit has denied a motion to stay. *Breeze Smoke, LLC v. FDA*, 18 F.4th 499 (6th Cir. 2021). And this court granted a motion to stay in *Wages*, 16 F.4th 1130.

Ruling on the merits, court decisions have denied e-cigarette manufacturers' petitions for review. *See Avail Vapor, LLC v. FDA*, 55 F.4th 409 (4th Cir. 2022); *Liquid Labs LLC v. FDA*, 52 F.4th 533 (3d Cir. 2022); *Gripum, LLC v. FDA*, 47 F.4th 553 (7th Cir. 2022); *Prohibition Juice Co. v. FDA*, 45 F.4th 8 (D.C. Cir. 2022). Those decisions are unpersuasive on the facts before us.

overcome the FDA's sovereign immunity to recover costs. *See Wages*, 16 F.4th at 1142. Given RJRV's uncontested allegations and legal arguments, we conclude that it has met its burden of showing irreparable harm if denied a stay pending appeal. "Thus, the two most critical factors favor granting a stay." *Id.* at 1143.

C. Balance of harms and public interest

"[T]he maintenance of the status quo is an important consideration in granting a stay." *Barber v. Bryant*, 833 F.3d 510, 511 (5th Cir. 2016). Here, RJRV's menthol Vuse Vibe has been lawfully sold for almost seven years, three of which the FDA spent reviewing its application. RJRV contends that a "a small delay of this one denial order will not harm FDA." The FDA does not argue otherwise. "Given the great likelihood that [RJRV] will ultimately succeed on the merits," we agree that this factor favors a stay. *Texas Democratic Party v. Abbott*, 961 F.3d 389, 412 (5th Cir. 2020).

It is of highest public importance that federal agencies follow the law. *See Texas v. Biden*, 10 F.4th 538, 559 (5th Cir. 2021) (per curiam). The FDA argues that we should defer to "Congress's policy choice" "that it is in the public interest to prohibit the marketing of a new tobacco product until FDA finds that it will produce, on balance, a benefit to the public health." This argument is obviously colored by the FDA's view of the merits. "But our system does not permit agencies to act unlawfully even in pursuit of desirable ends." *Alabama Ass'n of Realtors*, 141 S. Ct. at 2490. In sum, "there is generally no public interest in the perpetuation of unlawful agency action," *Texas v. Biden*, 10 F.4th at 560. And there is no evidence that "Congress's policy choice" included an exemption from mandatory federal administrative procedures.

III. Conclusion

All four factors favor granting a stay pending appeal. RJRV has easily met its burden. For the foregoing reasons, RJRV's motion for a stay pending review of its petition is GRANTED.