United States Court of Appeals for the Fifth Circuit

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Fifth Circuit
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Lyle W. Cayce
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No. 21-60766

WAGES AND WHITE LION INVESTMENTS, L.L.C., *doing business as* TRITON DISTRIBUTION,

Petitioner,

versus

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

Petition for Review of an Order of the
Food and Drug Administration

Before ELROD, OLDHAM, and WILSON, *Circuit Judges*.

ANDREW S. OLDHAM, *Circuit Judge*:

The Food and Drug Administration denied Triton's application to market flavored e-cigarettes. Triton moved for a stay pending disposition of its petition for review. We grant the stay.

I.

A.

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act ("TCA") to regulate tobacco products. Pub. L. No. 111-31, 123 Stat. 1776 (2009). The TCA authorizes the Secretary of Health

and Human Services to implement the Act through the Food and Drug Administration ("FDA"). *See* 21 U.S.C. §§ 387a(b), 393(d)(2). The TCA prohibits manufacturers from selling any "new tobacco product" without authorization. *See id.* § 387j(a). In 2016, the FDA deemed electronic nicotine delivery systems ("ENDS")—colloquially called "electronic cigarettes" or "e-cigarettes"—a "new tobacco product." 81 Fed. Reg. 28,973 (May 10, 2016) ("Deeming Rule"); *see also Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 443 (5th Cir. 2020) ("In the TCA, Congress delegated to the Secretary the power to 'deem' which tobacco products should be subject to the Act's mandates."). Thus, the TCA and the Deeming Rule generally prohibited the marketing of e-cigarettes.

This created a serious and obvious problem because, by the time the FDA got around to issuing the Deeming Rule, manufacturers were widely marketing e-cigarettes throughout the United States. To avoid an overnight shutdown of the entire e-cigarette industry, the FDA delayed enforcement of the Deeming Rule. Then the FDA forced e-cigarette makers to meet a series of requirements and staggered deadlines to keep their products on the market.

As relevant here, the FDA required e-cigarette manufacturers to submit premarket tobacco applications ("PMTAs"). The PMTA process is "onerous," to put it mildly. *See Big Time Vapes*, 963 F.3d at 439 ("The PMTA process is onerous, requiring manufacturers to gather significant amounts of information."). A manufacturer must submit to the FDA information on the product's health risks, ingredients, and manufacturing process. The manufacturer also must include samples of the product and its proposed labeling. 21 U.S.C. § 387j(b)–(c).

In the months and years following the Deeming Rule, the FDA moved its regulatory goalposts in at least two important ways. First, it moved the

PMTA deadline. Originally, the FDA demanded that all PMTAs must be filed within 24 months of the Deeming Rule—*i.e.*, by 2018. The FDA later purported to extend the PMTA deadline to 2022. But then, in response to litigation from anti-smoking groups, the FDA moved the deadline up to September 9, 2020. Second, and crucial to this case, the FDA changed the regulatory requirements for PMTAs. Initially, the FDA's guidance stated that "in general, FDA does not expect that applicants will need to conduct long-term studies to support an application." A.74; *see also* A.92 (same). As Triton's case illustrates, however, the FDA later changed its mind and required the very thing it said it would not—namely, long-term studies of e-cigarettes.

B.

Wages and White Lion Investments, LLC, doing business as Triton Distribution ("Triton"), is a Texas-based manufacturer of e-cigarettes. Some of its e-cigarette products have been on the market since August 4, 2016—before the Deeming Rule's effective date. Triton submitted a timely PMTA for certain flavored e-cigarettes. So did many other e-cigarette manufacturers.

On August 26, 2021, the FDA announced that it would deny the PMTAs for 55,000 flavored e-cigarettes. In its press release, the FDA explained that it would do so because it "likely" needed evidence from long-term studies to grant a PMTA for flavored e-cigarettes. Less than a week after the FDA changed its regulatory requirements, Triton submitted a letter stating that it intended to conduct long-term studies of its products.

About two weeks later, on September 14, the FDA issued a marketing denial order ("Order") to Triton. *See* 21 U.S.C. § 387j(c)(2). The FDA acknowledged that it did not consider Triton's letter in its determination because the FDA "received [the letter] near the completion of scientific

review." A.14–15. The "key basis" for the denial, wrote the FDA, was that Triton's PMTA lacked "robust and reliable evidence" from long-term studies, such as a "randomized controlled trial," a "longitudinal cohort study," or "other evidence . . . evaluat[ing] the impact of the new flavored vs. Tobacco-flavored products on adult smokers' switching or cigarette reduction over time." A.49.

Triton then petitioned for review and moved to stay the Order pending that review.[1] We granted a temporary administrative stay to prevent the FDA from shutting down Triton's business. Now we enter a full stay pending disposition of Triton's petition.

II.

For a stay pending review, we must consider four factors: (1) whether the requester makes a strong showing that it's likely to succeed on the merits; (2) whether the requester will be irreparably injured without a stay; (3) whether other interested parties will be irreparably injured by a stay; and (4) where the public interest lies. *Nken v. Holder*, 556 U.S. 418, 426 (2009). "The first two factors are the most critical." *Valentine v. Collier*, 956 F.3d 797, 801 (5th Cir. 2020) (per curiam). "'The party seeking the stay bears the burden of showing its need.'" *Tex. League of United Latin Am. Citizens v. Hughs*, 978 F.3d 136, 143 (5th Cir. 2020) (quoting *Clinton v. Jones*, 520 U.S. 681, 708 (1997)); *see also Nken*, 556 U.S. at 433–34 ("The party requesting a stay bears the burden of showing that the circumstances justify an exercise of that discretion."). Triton has met its burden: The first three factors support a stay, while the fourth is at worst neutral.

[1] Triton did not first ask the FDA for a stay. But it's common ground that it would have been "impracticable" for Triton to do so. *See* FED. R. APP. P. 18(a)(2)(i).

A.

First, likelihood of success. The Administrative Procedure Act ("APA") directs courts to "hold unlawful and set aside agency action[s]" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). "The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). We must not "substitute" our "own policy judgment for that of the agency." *Ibid.* Still, we must ensure that "the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Ibid.*; *see also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962))). "Put simply, we must set aside any action premised on reasoning that fails to account for 'relevant factors' or evinces 'a clear error of judgment.'" *Univ. of Tex. M.D. Anderson Cancer Ctr. v. HHS*, 985 F.3d 472, 475 (5th Cir. 2021) (quoting *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 378 (1989)).

In reviewing an agency's action, we may consider only the reasoning "articulated by the agency itself"; we cannot consider *post hoc* rationalizations. *State Farm*, 463 U.S. at 50; *see also DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020) ("An agency must defend its actions based on the reasons it gave when it acted."). Our review is "not toothless." *Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1013 (5th Cir. 2019). In fact, after *Regents*, it has serious bite. *See* 140 S. Ct. at 1907–15; *see also, e.g.*, *Texas v. Biden*, 10 F.4th 538, 552–57 (5th Cir. 2021) (per curiam); *Biden v. Texas*, No. 21A21, 2021 WL 3732667, at *1 (U.S. Aug. 24, 2021).

Triton has shown a strong likelihood of success on the merits. That's because the FDA failed to "reasonably consider[] the relevant issues and reasonably explain[]" the Order. *Prometheus*, 141 S. Ct. at 1158; *see also Michigan v. EPA*, 576 U.S. 743, 750, 752 (2015) ("[A]gency action is lawful only if it rests on a consideration of the relevant factors" and "important aspect[s] of the problem." (quotation omitted)). The relevant factors the FDA inadequately addressed or explained include: (1) Triton's marketing plan; (2) Triton's reliance interests; (3) less disruptive alternatives; (4) device-type preferences; and (5) evidence on the potential benefits of flavored e-cigarettes. The FDA's counterarguments (6) are unavailing.

1.

The FDA failed to reasonably consider Triton's proposed marketing plan. The FDA repeatedly stated that a marketing plan is "a critical factor in[] FDA's statutorily required determination." Premarket Tobacco Product Applications and Recordkeeping Requirements, 86 Fed. Reg. 55,300, 55,324 (Oct. 5, 2021) ("Final Rule"); *see also* 84 Fed. Reg. 50,566, 50,581 (Sept. 25, 2019) ("Proposed 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." (emphasis added)); A.45 n.xix ("Limiting youth access and exposure to marketing is a *critical* aspect of product regulation." (emphasis added)); A.45 (Premarket "assessment includes evaluating the appropriateness of the proposed marketing plan."). Here, however, the FDA simply ignored Triton's plan. It stated: "[F]or the sake of efficiency, the evaluation of the marketing plan in applications will not occur at this stage of review, and we have not evaluated any marketing plans submitted with these applications." A.45 n.xix.

The FDA's excuses for ignoring the "critical factor" of Triton's marketing plan are unpersuasive. First, the FDA says it didn't evaluate Triton's plan for "the sake of efficiency." *Ibid.* But "efficiency" is no substitute for "reasoned decisionmaking." *Michigan*, 576 U.S. at 750; *see also Judulang v. Holder*, 565 U.S. 42, 64 (2011) (emphasizing that "cheapness alone cannot save an arbitrary agency policy").

Second, the FDA claimed that its purported expertise and experience showed that no marketing plan would be sufficient, so it stopped looking:

> It is theoretically possible that significant mitigation efforts could adequately reduce youth access and appeal such that the risk for youth initiation would be reduced. However, to date, none of the ENDS PMTAs that FDA has evaluated have proposed advertising and promotion restrictions that would decrease appeal to youth to a degree significant enough to address and counter-balance the substantial concerns, and supporting evidence, discussed above regarding youth use. Similarly, we are not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use ENDS.

A.45 n.xix. This statement is insufficient. For one thing, it's unreasonable for the FDA to stop looking at proposed plans because past ones have been unpersuasive. That's like an Article III judge saying that she stopped reading briefs because she previously found them unhelpful.

For another, reliance on expertise and experience, like efficiency, is no substitute for "reasoned decisionmaking." *Michigan*, 576 U.S. at 750. Of course, "[a]gencies . . . have expertise and experience in administering their statutes that no court can properly ignore." *Judulang*, 565 U.S. at 53. But here that hurts, not helps, the FDA. That's because experience and expertise bring responsibility:

> [A]n agency's "experience and expertise" presumably enable the agency to provide the required explanation, but they do not substitute for the explanation, any more than an expert witness's credentials substitute for the substantive requirements applicable to the expert's testimony under [Federal Rule of Evidence] 702. The requirement of explanation presumes the expertise and experience of the agency and still demands an adequate explanation in the particular matter.

CS Wind Viet. Co., Ltd. v. United States, 832 F.3d 1367, 1377 (Fed. Cir. 2016) (citations omitted).

The FDA did not meet its obligation. Its statement on marketing plans is conclusory, unsupported, and thus wholly insufficient. *See, e.g.*, *United Techs. Corp. v. U.S. Dep't of Def.*, 601 F.3d 557, 562 (D.C. Cir. 2010) ("We do not defer to the agency's conclusory or unsupported suppositions." (quotation omitted)); *Texas v. Biden*, 10 F.4th at 556 (collecting cases).[2] This "omission alone [likely] renders [the FDA's] decision arbitrary and capricious." *Regents*, 140 S. Ct. at 1913.

2.

The FDA also failed to reasonably consider Triton's legitimate reliance interests. Between the Deeming Rule's effective date and the deadline for PMTAs, the FDA held public meetings and issued guidance on

[2] The FDA's failure to meaningfully consider Triton's marketing plan is even more unreasonable because part of Triton's plan was endorsed by a former FDA commissioner. *See* Statement from FDA Commissioner Scott Gottlieb, M.D., On Proposed New Steps to Protect Youth by Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes (Nov. 15, 2018) ("The changes I seek would protect kids by having all flavored ENDS products (other than tobacco, mint and menthol flavors or non-flavored products) sold in age-restricted, in-person locations and, if sold online, under heightened practices for age verification."); *ibid.* (calling some of Triton's proposed marketing restrictions "best practices").

how e-cigarette manufacturers could get premarket authorization. In its "final guidance," the FDA stated that it did not "expect" that tobacco manufacturers would need to conduct long-term studies to support their PMTA. *See, e.g.*, A.73–74; A.92; *see also Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 282 (D.C. Cir. 2019) ("The FDA has expressed willingness to accept scientific literature reviews instead of commissioned studies in support of e-cigarette applications in appropriate circumstances."). The FDA's expectation did not deviate in its Proposed Rule issued before the Order or the Final Rule issued a couple weeks after the Order. *See* Final Rule, 86 Fed. Reg. at 55,387 ("FDA 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."); Proposed Rule, 84 Fed. Reg. at 50,619 (similar). Many e-cigarette companies relied on the FDA's repeated insistence that it did "not expect that applicants will have to conduct long-term studies to support an application" and did not perform or submit such evidence. A.74.

Then the FDA "pull[ed] a surprise switcheroo on regulated entities." *Env't Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (Sentelle, J.); *accord Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1810 (2019) (citing the "surprise switcheroo" doctrine). Almost a year after the PMTA deadline, the FDA issued its first marketing denial orders for various flavored e-cigarettes and announced that it required the very studies it originally expected it didn't need. *See* Press 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). It explained: "[T]he evidence of benefits to adult smokers for such products would likely be in the form of a randomized controlled trial or longitudinal cohort study, although the agency does not foreclose the possibility that other types of evidence could be adequate if sufficiently robust and reliable" and

performed over time. *Ibid.* About two weeks later, the FDA maintained its long-term-study requirement in the Order denying Triton premarket authorization. *See* A.49; A.37 (materially identical language to Press Release). Despite the radical difference, the FDA never mentioned, let alone reasonably considered, whether e-cigarette manufacturers, like Triton, could've reasonably relied on the FDA's prior meetings and guidance.

The law requires more. "When an agency changes course, . . . it must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." *Regents*, 140 S. Ct. at 1913 (quotation omitted). This does not mean that the FDA could not have "determine[d], in the particular context before it, that other interests and policy concerns outweigh any reliance interests. Making that difficult decision was the agency's job, but the agency failed to do it." *Id.* at 1914. This reinforces that the Order was likely arbitrary, capricious, or otherwise unlawful.

3.

The FDA insufficiently addressed alternatives to issuing the Order as well. "[W]hen an agency rescinds [or alters] a prior policy[,] its reasoned analysis must consider the alternatives that are *within the ambit of the existing policy*." *Regents*, 140 S. Ct. at 1913 (emphasis added) (quotation omitted). While considering less disruptive alternatives, the FDA "was required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Id.* at 1915. The FDA did not consider alternatives when changing from its no-long-term-studies-necessary policy to its apparent long-term-studies-required policy.

And even if the FDA did, it failed to adequately assess reliance interests. "So it would be impossible for the [Order] to properly weigh the

relevant interests against competing policy concerns while considering alternatives." *Texas v. Biden*, 10 F.4th at 555.

4.

The FDA also failed to adequately address Triton's contention that its reusable e-cigarette will reduce youth popularity compared to disposable e-cigarettes. In January 2020 guidance, the FDA found that "youth overwhelmingly prefer [disposable] ENDS products" because they "are easy to conceal" and "can be used discreetly." Enforcement Priorities for Electronic Nicotine Delivery Systems and Other Deemed Products on the Market Without Premarket Authorization; Guidance for Industry; Availability, 85 Fed. Reg. 720, 722 (Jan. 7, 2020). By contrast, the FDA found in the Order that the type of system didn't matter. Specifically, the FDA found that "preference for device types and popularity of certain styles is likely fluid and affected by the marketplace" and "that the removal of one flavored product option prompted youth to migrate to another ENDS type that offered the desired flavor option, underscoring the fundamental role of flavor in driving appeal." A.42.

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 (2009). The FDA initially said that *disposable* e-cigarettes pose risks to youths. When Triton said that concern doesn't apply to its *reusable* e-cigarettes, the FDA turned around and ignored its prior disposable-reusable distinction. The FDA failed to adequately explain this change. This further reinforces that the Order is likely arbitrary, capricious, or otherwise unlawful.

5.

In announcing its rule that the manufacturer must provide long-term studies to get approval for flavored e-cigarettes, the FDA resorted entirely to

experience and expertise from reviewing applications other than Triton's PMTA. *See* A.45. In so doing, the FDA used "generalized language to reject" Triton's PMTA. *See Siddiqui v. Holder*, 670 F.3d 736, 744 (7th Cir. 2012) ("Where, as here, the agency uses only generalized language to reject the evidence, we cannot conclude that the decisions rest on proper grounds."). The consequence is that the FDA failed to reasonably consider relevant issues that *Triton* brought up in its PMTA but that others might not have.

The FDA responded to much of Triton's evidence for the first time before our court. But "[i]t is a fundamental precept of administrative law that an administrative agency cannot make its decision first and explain it later." *Texas v. Biden*, 10 F.4th at 558–59; *see also Sherley v. Sebelius*, 689 F.3d 776, 784 (D.C. Cir. 2012) (Sentelle, C.J.) ("The failure to respond to comments is significant only insofar as it demonstrates that the agency's decision was not based on a consideration of the relevant factors." (quotation omitted)); *Circus Circus Casinos, Inc. v. NLRB*, 961 F.3d 469, 476 (D.C. Cir. 2020) ("New rules set through adjudication must meet the same standard of reasonableness as notice and comment rulemaking." (citing *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998))).

For example, Triton urged the FDA to consider a 2015 survey of 20,000 e-cigarette users showing that nearly a third of the respondents "started out using tobacco or menthol flavors" and then began using other flavored e-cigarettes. A.296. Similarly, Triton asserted that flavored e-cigarettes "could serve an important role in transitioning existing adult users away from more harmful, combustible cigarette products." *Ibid.* But in the Order, the FDA ignored the first point altogether and gave the second short shrift. The FDA cannot cure those deficiencies by offering *post hoc* rationalizations before our court. The very fact that the FDA perceived the need to rehabilitate its Order with new and different arguments before our

court underscores that the Order itself omitted a reasoned justification for the agency's action. This further confirms that the Order is likely arbitrary, capricious, or otherwise unlawful.

6.

The FDA makes four other counterarguments. They fail.

First, the FDA argues that its consistency "in reviewing other manufacturers' similar applications to market flavored e-cigarette products is a hallmark of good government, not a reason to fault the agency." Opp. at 23 (citation omitted). Consistency is great—but only when the agency is consistently following the law. As the Supreme Court has made clear: "Arbitrary agency action becomes no less so by simple dint of repetition." *Judulang*, 565 U.S. at 61; *see also ibid.* ("[L]ongstanding capriciousness receives no special exemption from the APA.").

Second, the FDA insists that the reasoning in the Order is consistent with its prior guidance. According to the FDA, it didn't make a rule requiring long-term studies because it left open that "other types of evidence could be adequate[] and will be evaluated on a case-by-case basis." A.37.

But the administrative record makes clear that the FDA now requires direct evidence through studies performed "over time" for flavored e-cigarettes. A.46; *see also, e.g.*, A.37 n.vi; A.47 n.xxiii. And it's clear the FDA expressly rejected reliance on evidence it approved of in its pre-Order guidance, such as observational and consumer-perception studies. *Compare* A.46–47, *with* A.99. The FDA did not have to completely flip flop for there to be a change in position. *Cf. Sw. Airlines Co. v. Fed. Energy Regul. Comm'n*, 926 F.3d 851, 856 (D.C. Cir. 2019) ("A full and rational explanation becomes especially important when, as here, an agency elects to shift its policy or depart from its typical manner of administering a program." (quotation omitted)). It is enough that the FDA's guidance indicated long-term studies

were likely unnecessary, while the FDA's Order at the very least created a strong presumption that such evidence is required.

Plus, if we accepted the FDA's current position that it did not acknowledge a change in policy in the Order, then the Order would obviously be arbitrary and capricious. That's because "[w]hen an agency changes its existing position, it . . . must at least display awareness that it is changing position and show that there are good reasons for the new policy." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125–26 (2016) (quotation omitted); *see also id.* at 2126 (explaining that an "unexplained inconsistency in agency policy is a reason for holding an [action] to be an arbitrary and capricious change from agency practice" (quotation omitted)); *Fox*, 556 U.S. at 515 ("[T]he requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it *is* changing position. An agency may not . . . depart from a prior policy *sub silentio*."). It would be impossible for the FDA to display awareness that it was changing position if it believed it wasn't.

Third, the FDA argues that Triton should not have relied on the agency's pre-Order guidance. This is because, the FDA claims, 21 U.S.C. § 387j(c)(5) "directs FDA to make that finding based on 'clinical investigations by experts qualified by training and experience to evaluate the tobacco product' or other 'valid scientific evidence' that FDA determines is sufficient." Opp. at 19; *see also id.* at 20 (The "2019 guidance does not and could not relax the statute's requirements."). Of course, an agency cannot issue guidance on the meaning of a statute, encourage its regulated entities to rely on the guidance, and then blame *the statute* for pulling the rug out from under the entities. And in any event, the FDA mischaracterizes § 387j(c)(5). Paragraph (5) does not require the FDA to base *all* of its appropriate-for-the-protection-of-the-public-health findings on long-term studies; instead, it requires the FDA to base its decision on "well-controlled investigations"

"*when appropriate*" and provides that those investigations "*may* include 1 or more *clinical* investigations." 21 U.S.C. § 387j(c)(5)(A) (emphases added). And the consideration of other "valid scientific evidence" is likewise discretionary. *See id.* § 387j(c)(5)(B) ("may authorize"). The FDA's "final guidance" reflected its "expect[ation]" that, at the time, it would not deem it "appropriate" to base its decision on long-term studies. A.74; A.92. The guidance also stated that the FDA would consider the type of evidence Triton presented "valid scientific evidence." So of course, the statute might have *permitted* the FDA to demand the evidence it ultimately did. But it does not follow that the statute *required* the FDA to jettison the guidance it previously offered regulated entities.

Fourth and last, the FDA argues that Triton's reliance interests shouldn't matter because Triton has been breaking the law and the FDA's non-enforcement was entirely discretionary. *Regents* squarely forecloses this argument. There, the Department of Homeland Security ("DHS") tried to rescind the Deferred Action for Childhood Arrivals ("DACA") program because of "the Attorney General's conclusion that DACA was unlawful." *Regents*, 140 S. Ct. at 1910. The United States argued that justified ignoring potential reliance interests. *Id.* at 1913–14. The Supreme Court rejected that argument. *Ibid.* The Court instead required reasonable consideration of the relevant issues and the "important aspects of the problem." *Id.* at 1910 (quotation omitted). That was because, the Court explained, "deciding how best to address a finding of illegality moving forward can involve important policy choices." *Ibid.* The same is true here. The FDA was free to make that policy choice, but it had to address Triton's reliance interests in a reasonable and reasonably explained decision.

For these reasons, Triton has shown a likelihood of success based on its APA challenge. So this critical factor favors granting a stay. We therefore need not address Triton's argument that the FDA violated the Due Process

Clause for not giving "fair warning" of its change in position on what evidence would be required in its PMTA.

B.

Next, irreparable injury. Triton alleges that because of the Order, it "has stopped production of all of its flavored ENDS products, representing 90 percent of its annual revenue, thereby requiring the company to make plans to lay off its employees within approximately two weeks and threatening the company's very existence." Stay Mot. at 21; *see also* A.15–16 (Declaration of Triton's General Manager). The FDA does not contest that allegation.

Triton's alleged injury is irreparable for two independent reasons. First, we've explained that "substantial financial injury" may be "sufficient to show irreparable injury." *Texas v. EPA*, 829 F.3d 405, 433 (5th Cir. 2016). Triton's alleged financial injury "threatens the very existence of [its] business." *Id.* at 434. Even assuming the financial costs are recoverable, this suffices to show irreparable injury. *See id.* at 434 n.41 ("Even recoverable costs may constitute irreparable harm where the loss threatens the very existence of the movant's business." (quotation omitted)).

Second, the costs are likely unrecoverable. "Indeed, complying with [an agency order] later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs." *Id.* at 433 (quotation omitted). The FDA does not contend that Triton has an avenue to recover costs from complying with the Order. That's probably because federal agencies generally enjoy sovereign immunity for any monetary damages. *See, e.g.*, *Alabama-Coushatta Tribe of Texas v. United States*, 757 F.3d 484, 488 (5th Cir. 2014); *Louisiana v. United States*, 948 F.3d 317, 320 (5th Cir. 2020); *Muniz-Muniz v. U.S. Border Patrol*, 741 F.3d 668, 671 (6th Cir. 2013) ("Sovereign immunity extends to agencies of the United States." (quotation omitted)).

At bottom, Triton's lack of a "guarantee of eventual recovery" is another reason that its alleged harm is irreparable. *Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021).

The FDA makes no developed argument contesting irreparable harm. *See* Opp. at 11, 13 (mentioning "irreparable injury" in passing). So such arguments are forfeited. *See, e.g.*, *DeVoss v. Sw. Airlines Co.*, 903 F.3d 487, 490 n.1 (5th Cir. 2018) (concluding that an argument was "forfeited" because it wasn't "structured"); *Texas v. EPA*, 829 F.3d at 435 ("Because EPA offers nothing beyond this cursory comment, it has waived any argument about the scope of the stay.").

In these circumstances, given Triton's uncontested allegations of injury and the FDA's failure to make a developed argument challenging this factor, we conclude that Triton has met its burden of showing irreparable harm. Thus, the two most critical factors favor granting a stay.

C.

Now, the balance of harms and public interest.

The balance of the harms favors a stay. We've explained that "the maintenance of the *status quo* is an important consideration in granting a stay." *Barber v. Bryant*, 833 F.3d 510, 511 (5th Cir. 2016) (quotation omitted). And staying the Order will preserve the *status quo ante*. *Cf. Turning Point Brands, Inc. v. FDA*, No. 21-3855, ECF No. 19 at 9–10 (6th Cir. Oct. 8, 2021) (FDA letter rescinding a marketing denial order and stating the "FDA has no intention of initiating an enforcement action against any of your tobacco products identified in" the relevant PMTA). "Given the great likelihood that [Triton] will ultimately succeed on the merits, combined with the undeniable, irreparable harm that [the Order] would inflict on" Triton and the FDA's failure to make a developed argument on this factor, we conclude,

in these circumstances, "that the balance of harms weighs in favor of" Triton. *Tex. Democratic Party v. Abbott*, 961 F.3d 389, 412 (5th Cir. 2020).

The public-interest factor is at worst neutral. The "public interest is in having governmental agencies abide by the federal laws that govern their existence and operations." *Texas v. Biden*, 10 F.4th at 559 (quotation omitted). "And 'there is generally no public interest in the perpetuation of unlawful agency action.'" *Id.* at 560 (alteration omitted) (quoting *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016)). Although the FDA fails to argue this factor, *amici curiae* do. They argue that the public interest cuts against a stay because continued sale of flavored e-cigarettes will endanger the youth much more than it might help adults. "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. So we conclude that this factor is at best neutral, or, in all events, outweighed by the three other factors favoring a stay.

III.

Finally, the FDA argues that Triton requests relief we cannot give. We have no authority, says the FDA, to permit Triton to continue marketing and selling the products denied in the Order. But again, the APA says otherwise. Under 5 U.S.C. § 705, we may, under certain "conditions[,] . . . and to the extent necessary to prevent irreparable injury, . . . issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings."

The immigration context is instructive. Consider an alien that is unlawfully present in the United States. Suppose the Government attempts to remove the alien. Then the alien argues that he should not be removed because he deserves asylum, and he asks us to stay the removal pending our

review of his petition. Under the FDA's logic, we couldn't do anything. After all, we couldn't order the Board of Immigration Appeals to grant the alien asylum or otherwise adjust his immigration status to make his presence lawful. But of course, we could grant a stay of the removal, giving the alien interim relief. *See generally Tesfamichael v. Gonzales*, 411 F.3d 169 (5th Cir. 2005) (granting a stay of removal pending the court of appeals' consideration of the party's petition for review); *see also Nken*, 556 U.S. at 429 ("An alien seeking a stay of removal pending adjudication of a petition for review does not ask for a coercive order against the Government, but rather for the temporary setting aside of the source of the Government's authority to remove. Although such a stay acts to bar Executive Branch officials from removing the applicant from the country, it does so by returning to the *status quo*—the state of affairs before the removal order was entered." (quotation omitted)).

Triton's request is not materially different. It merely seeks to preserve the *status quo ante*, before the FDA issued the Order. In other words, "the relief sought here would simply suspend *administrative* alteration of the *status quo*." *Nken*, 556 U.S. at 430 n.1. So we reject the FDA's argument that we lack authority to grant a stay that provides interim relief.

* * *

Three factors—including the two most critical—favor granting a stay, while one factor is at worst neutral. Triton has thus met its burden. Contrary to the FDA's suggestion, we have the authority to give Triton relief pending review. For the foregoing reasons, Triton's motion for a stay pending review of its petition is GRANTED.