



WAGES AND WHITE LION INVESTMENTS, L.L.C.,  
d/b/a TRITON DISTRIBUTION; VAPETASIA, *Petitioners*

v.

FOOD AND DRUG ADMINISTRATION, *Respondent*

Nos. 21-60766, 21-60800, Decided July 18, 2022

*U.S. Court of Appeals for the Fifth Circuit*

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

**Opinion Topic:** Was FDA's denial of premarket tobacco product application APA-compliant?

## Introduction:

Petitioners seek review of FDA's marketing denial orders (MDO) for flavored nicotine-containing e-liquids for use in e-cigarette devices. Petitioners allege that FDA violated the Administrative Procedure Act (APA) and that the agency lacked statutory authority to require evidence that flavored juices are more effective at promoting smoking cessation than tobacco-flavored juices. The Fifth Circuit, per Judge Haynes, rejected both arguments. The majority concluded that FDA's actions in denying Petitioners' applications were "reasoned" and did not fall into the "narrow circumstances" under which a court would declare agency action arbitrary or capricious.

In dissent, Judge Jones strongly objected to the majority's extreme deference to FDA and the agency's conclusion that the decision-making process preceding the MDOs for Triton and Vapetasia complied with the APA. Her dissent advances basic administrative-law principles of fair notice, transparent decision making, and consistent application of publicly announced review standards.

## Opinion Digest:

EDITH H. JONES, *Circuit Judge*, dissenting:

Six judges of this court have reviewed the FDA's "reasons" for removing from the market and destroying the business for these petitioners' electronic nicotine delivery system ("ENDS") products. Four of us have found the agency's decisions seriously inadequate, but at least the debate with my colleagues is founded on known standards. Not so FDA's actions. In a mockery of "reasoned" administrative decision-making, FDA (1) changed the rules for private entities in the middle of their marketing application process, (2) failed to notify the public of the changes in time for compliance, and then (3) rubber-stamped the denial of their marketing applications *because* of the hitherto unknown requirements. *See DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020). Kafka would have understood the FDA all too well. The agency's decisions are arbitrary and capricious. I dissent.

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The **Honorable Edith H. Jones** serves on the U.S. Court of Appeals for the Fifth Circuit. *Judge Jones had no role in WLF's selecting or editing this opinion for our CIRCULATING OPINION feature.*

## I. BACKGROUND

. . . Petitioners had to submit a premarket tobacco product application (“PMTA”) to the FDA by September 9, 2020. *See* 21 U.S.C. § 387j; *Vapor Tech. Ass’n v. FDA*, 97 F.3d 496, 498-501 (6th Cir. 2020). If the FDA issues a marketing denial order (“MDO”) in response to a PMTA, sales of the products become unlawful. Given that ENDS product companies’ very existence depended on securing marketing approval, petitioners had significant incentives to get the applications right. Recognizing this, the FDA put an extensive amount of information out to the public about what was relevant to a successful application, and what was not.

. . . In relaying the types of studies that could support a PMTA, an FDA representative stated: “*No specific studies are required for a PMTA*; it may be possible to support a marketing order for an ENDS product without conducting new nonclinical or clinical studies given *other data sources* can support the PMTA.” Premarket Tobacco Product Application Content Overview: lilun Murphy – OS/Division of Individual Health Science (October 23, 2018) (emphasis added).

In June 2019, the FDA issued final guidance on PMTAs for ENDS products, the purpose of which was to “assist persons submitting [PMTAs] for [ENDS]” products and to “enable ENDS manufacturers to consider and strengthen their applications.” FDA, Guidance for Industry, Premarket Tobacco Applications for Electronic Nicotine Delivery Systems (June 2019); Triton-FDA2-004408, 004411. The FDA’s guidance made four salient points. First, “in general, *FDA does not expect that applicants will need to conduct long-term studies to support an application.*” Triton FDA2-004423 (emphasis added) . . . Third, FDA intended to review each PMTA and weigh all the benefits and risks from the product. Fourth, FDA would specifically pay attention to marketing restrictions that could restrict distribution to underage users.

In September 2019, FDA’s proposed rule governing PMTAs reinforced all of these points. In particular, the agency stated once again that long-term studies were *not* expected. In addition, the FDA re-emphasized that marketing plans *were* critical:

*“[t]he applicant’s marketing plans will help FDA determine whether permitting the marketing of the new tobacco product would be [appropriate for the protection of the public health] . . . FDA will review the marketing plan to evaluate potential youth access to, and youth exposure to the labeling, advertising, marketing, or promotion of, a new tobacco product.”*

84 Fed. Reg. 50566, 50581 (Sept. 25, 2019) (emphasis added).

Petitioners . . . accordingly prepared applications that emphasized their restrictive marketing but did not include long-term studies on smoking cessation behavior . . .

### 1. The New Rules.

Ten months later, when FDA was inundated by literally millions of PMTAs, the agency circulated an internal memorandum providing a new “standard of evidence” for some PMTAs for flavored ENDS products. *See* Triton-FDA2-005144-005155 (July 9, 2021). This memo was not publicly released, though its intent was to facilitate “final action on as many applications as possible by September 10, 2021.” *See* Triton-FDA2-005144. Given the “large number of applications that remain[ed] to be reviewed by September 9, 2021,” the memo explained that in lieu of reviewing applications on an individualized basis, the FDA would “conduct a Fatal Flaw review”. . . Triton-FDA2-005145. The “fatal flaw” would be the absence of . . . long-term studies that the agency previously stated were neither necessary nor expected. Triton-FDA2- 005144 - 45. Put bluntly, the memo ensured that even if an applicant followed FDA’s pre-deadline public statements and proposed rule, the FDA would nonetheless deny a PMTA because it failed to satisfy the internal non-public requirement for “the necessary type of studies” crafted in July 2021. FDA asserts that the Fatal Flaw memo was rescinded, but 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.

Similarly, FDA changed its mind about reviewing marketing plans and decided not to do so “for the sake of efficiency.” Significant sections of that internal memo, though also claimed by FDA to be rescinded, are copied word-for-word in the [Technical Project Leads (TPLs)] for petitioners’ products.

## 2. The Late Notice.

The FDA revealed its new *modus operandi* concerning long-term studies on August 26, 2021 in a press release when it denied 55,000 ENDS products PMTAs in one day. Thus, nearly a year after the PMTA deadline, FDA announced that it would authorize the flavored ENDS products only if the PMTAs included previously purely optional studies, . . .

. . . In an attempt to adjust to the new requirement, petitioners submitted a letter to the FDA on September 1, 2021, stating that they intended to conduct additional behavioral studies on adult smoking cessation and long-term studies of their products to supplement their PMTAs.

## 3. Rubber-stamped denials.

Their prompt reaction was in vain. On September 14, FDA issued MDOs denying them the right to sell their flavored liquids in the United States. The MDOs refused to consider, much less evaluate the petitioners’ marketing plans “for the sake of efficiency.”<sup>1</sup> TRITON-FDA 1–000279. Petitioners were denied any attempt to comply with the new rule, FDA informed them, because the September 1, 2021 letter was “received near the completion of scientific review.” Triton-FDA1-000123. \*\*\*

## 4. The Post Mortem Rule.

FDA published its final PMTA Rule on October 4, 2021, a rule consistent with its prior pre-August 2021 policies but inconsistent with the process described in petitioners’ MDOs. FDA, Premarket Tobacco Product Applications and Recordkeeping Requirements, Final Rule, 86 Fed. Reg. 55300. The Final Rule, yet again, states that the FDA does “not expect that applicants will need to conduct long-term clinical studies to support an application.” 86 Fed. Reg. 55300, 55387. Contrary to the fatal flaw approach, the final rule states that the “FDA declines to create a series of criteria that either all products or a specific subset of products must meet in order for marketing of such products to be considered as part of this rule.” *Id.* at 55386. Instead, FDA assured that it would “consider many factors,” *id.* at 55314, would not rely on “one static set of requirements,” *id.* at 55385, does not assign weight to different types of evidence, *id.* at 55335, and carefully “balances” risks and benefits, *id.* at 55384.

Concerning marketing plans, the FDA’s Final Rule repeatedly contradicts the MDOs’ flat refusal to consider them, as it explains that “FDA has rationally concluded that the required descriptions of marketing plans will directly inform its assessment of who may be exposed to the [marketing processes] and, as a result, its consideration of the potential impact on youth initiation and use. *Id.* at 55324.

## II. Discussion

. . . The Supreme Court has succinctly explained that “[t]he 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); *see also Motor Vehicle Mfgs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983).

. . . Agency action may not be justified to a court based on *post hoc* rationalization; the agency must “defend its actions based on the reasons it gave when it acted.” *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891,

<sup>1</sup> This MDO also states that “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.” Because FDA had not seen a successful marketing plan on past applications, it generalized, all future applications must lack worthwhile marketing plans. So much for individualized consideration of marketing plans.

1909 (2020). Nor may an agency wholly fail to consider “relevant factors” and “important aspect[s] of the problem.” *Michigan v. EPA*, 576 U.S. 743 (2015). Nor may an agency thwart legitimate reliance interests by pulling a “surprise switcheroo” by changing its requirements too late for the petitioners to respond. See *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).

The majority’s analysis of these MDOs looks almost exclusively at the bottom-line result of FDA’s decisions and finds nothing to criticize. But the facts recited above speak for themselves. FDA refused to review petitioners’ marketing restrictions, which it had repeatedly stated were key to discouraging youthful use of the products and were thus critical components of the PMTAs. FDA repeatedly counselled applicants that long term studies were likely unnecessary and it said nothing about comparative efficacy studies—until the PMTA deadline was long gone; and then it refused petitioners the opportunity to conduct such studies. Finally, FDA’s defense against petitioners on the merits of their applications is loaded with *post hoc* rationalizations. Any of these errors is a “fatal flaw.” Taken together, they are mortal wounds.

The MDOs should be vacated, and the case remanded to FDA with instructions to allow these petitioners to develop and offer further evidence in support of the PMTAs.

### A. Marketing Plans

\*\*\* First, the majority accepts FDA’s assertion that it had not in the past evaluated a marketing plan that discouraged youth from using ENDS products. This is not a “reason” for refusing to even look at these petitioners’ MDOs. As the stay panel noted, this excuse is akin to a judge’s saying, “she stopped reading briefs because she previously found them unhelpful.” *Wages & White Lion*, 16 F.4th at 1137. It is obviously illogical and unreasonable to infer from the general to the particular, especially when FDA acknowledged its duty to consider each PMTA individually and holistically. . . . The agency’s failure to meaningfully consider an aspect of the petitioners’ PMTAs that it had previously deemed essential is quintessentially arbitrary and capricious. *Univ. of Texas M.D. Anderson Cancer Ctr. v HHS*, 985 F.3d 472, 475 (5th Cir. 2021).

\*\*\* Fourth, and most objectionably, the majority blames *petitioners* for not knowing that “marketing plans on their own are not particularly useful.” That statement stands the requirement of reasoned *agency* decision making on its head. Every single statement by the agency, until it issued its MDOs to these petitioners, reasonably led petitioners to believe that if they devised marketing arrangements that would prevent underage persons from purchasing their flavored e-liquids for open systems, they would have surmounted a significant requirement for marketing approval.

\*\*\* For all these reasons, the agency cannot run away from individually reviewing petitioners’ marketing plans when, for two years, it assured the public that properly tailored marketing of flavored ENDS products could protect youth from exposure and abuse while the products also helped those who need to stop smoking. It is the epitome of agency hubris to pull the rug out from entities whose very existence depends on the agency’s careful balancing of all factors relevant to this public health issue.

### B. Notice and Reliance Interests

\*\*\* [P]etitioners were only advised in the TPLs underlying their MDOs<sup>2</sup>—when it was too late—that [comparative efficacy studies] are “most likely” to provide reliable and robust evidence to satisfy the APPh standard. And only then were they advised that studies “over time” should have been included. From October 2018 through the September 2020 PMTA deadline, and until August 2021, the FDA continually repeated that such studies were neither necessary nor expected.<sup>3</sup> Instead, FDA stated that other forms of evidence, including observational and consumer-perception studies, as well as scientific literature reviews, could be

<sup>2</sup> Petitioners did not receive TPLs automatically; they obtained them only through FOIA requests.

<sup>3</sup> As has been explained, FDA also steadfastly represented the critical importance of marketing plans that would prevent underage youth from obtaining petitioners’ products—until it backtracked on that requirement in the TPLs.

acceptable. In August 2021, contrary to those pronouncements, FDA announced that it had denied 55,000 PMTAs precisely because they lacked “the evidence of benefits to adult smokers for such products [that] would likely be in the form of a randomized controlled trial or longitudinal cohort study....”

If this meandering administrative course is not an “administrative switcheroo,” it is hard to know what is. For one thing, from FDA’s denials of 55,000 PMTAs one might reasonably infer that other manufacturers besides these petitioners were fooled by FDA’s previous instructions. And that legitimate reliance interests were built into the previous FDA announcements is attested by an affidavit of petitioners’ executive in charge of filing their PMTAs. Moreover, petitioners’ business was generating \$15 to 20 million annual revenues. Petitioners invested a half million dollars to complete their PMTAs and filed 9 gigabytes of information, including hundreds of files, with FDA in seeking marketing approval. They had every reason to file PMTAs most conscientiously and comprehensively because the existence of the company depended on agency approval of their products.

In light of all the circumstances, there are two ways to look at the MDOs in this case. Under one scenario, FDA changed its policies: from individualized consideration of PMTAs and flexibility as to the type of scientific evidence it would hold acceptable, to perfunctory disapproval of PMTAs lacking longitudinal studies . . .

Viewed as a policy change, FDA acted arbitrarily and capriciously by failing to inform petitioners and by failing to consider their legitimate reliance interests. After all, “[t]hose regulated by an administrative agency are entitled to know the rules by which the game will be played.” (citation omitted) Agencies must provide fair warning of conduct the agency “prohibits or requires” and cannot “unfair[ly] 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 (2012). . . . FDA’s disregard for the principles of fair notice and consideration of reliance interests is exacerbated here by its refusal to allow petitioners to supplement their applications according to the new requirements.

\*\*\* The MDOs rested on rejecting the types of evidence the agency had previously found likely sufficient, while requiring product-specific studies conducted “over time” that it had previously found unnecessary. But laying that aside, the Supreme Court holds that “[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*, 579 U.S. 211, 136 S. Ct. 2117, 2125-26 (2016) (quotation omitted). 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 (quotation omitted). FDA’s migration from stating that “in general, FDA does not expect that applicants will need to conduct long-term studies to support an application” to denying petitioners’ MDOs because they lacked long-term studies of comparative efficacy is “unexplained” and “inconsistent” and therefore arbitrary and capricious.

FDA, in sum, sealed the petitioners’ doom by changing its evaluation rules without giving them notice and by ignoring individualized consideration of their plan for marketing restrictions to prevent underage youth access. Even with the noblest of motives in mind, a federal agency does not have license to run companies out of business without adhering to fixed rules of fair procedure. I respectfully dissent.