United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit

FILED
August 19, 2026

Lyle W. Cayce
Clerk

No. 24-60272

NicQuid, L.L.C.; Wood Creek Vapory,

Petitioners,

versus

Food & Drug Administration; Marty Makary, *Commissioner, U.S. Food and Drug Administration*; Robert F. Kennedy, Jr., *Secretary, U.S. Department of Health and Human Services*,

Respondents,

consolidated with

No. 24-60304

Breeze Smoke, L.L.C.; Texas Wholesale,

Petitioners,

versus

Food & Drug Administration; United States Department of Health and Human Services; Robert F. Kennedy, Jr., *Secretary, U.S. Department of Health and Human Services*; Marty Makary, *Commissioner, U.S. Food and Drug Administration*,

Respondents,

CONSOLIDATED WITH

No. 24-60332

VERTIGO VAPOR, L.L.C., *doing business as* BATON VAPOR; MAX & ZACH'S VAPOR SHOPS INCORPORATED,

Petitioners,

versus

FOOD & DRUG ADMINISTRATION; MARTY MAKARY, *Commissioner, U.S. Food and Drug Administration*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., *Secretary, U.S. Department of Health and Human Services*,

Respondents,

CONSOLIDATED WITH

No. 24-60424

LEAD BY SALES, L.L.C., *doing business as* WHITE CLOUD CIGARETTES; JP-MAXX, L.L.C., *doing business as* JAIL PUFF MAX,

Petitioners,

versus

FOOD & DRUG ADMINISTRATION; MARTY MAKARY, *Commissioner, U.S. Food and Drug Administration*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., *Secretary, U.S. Department of Health and Human Services*,

Respondents,

CONSOLIDATED WITH

No. 24-60628

VAPERMATE, L.L.C.; VAPE AWAY, L.L.C.,

Petitioners,

versus

FOOD & DRUG ADMINISTRATION; MARTY MAKARY, *Commissioner, U.S. Food and Drug Administration*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., *Secretary, U.S. Department of Health and Human Services*,

Respondents,

CONSOLIDATED WITH

No. 25-60098

ELITE BROTHERS, L.L.C.; CLOUDS VAPORS, L.L.C.,

Petitioners,

versus

U.S. FOOD & DRUG ADMINISTRATION; MARTY MAKARY, *Commissioner, U.S. Food and Drug Administration*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., *Secretary, U.S. Department of Health and Human Services*,

Respondents,

CONSOLIDATED WITH

No. 25-60369

AMERICAN VAPOR COMPANY, L.L.C.,

Petitioner,

versus

FOOD & DRUG ADMINISTRATION; MARTY MAKARY, *Commissioner, U.S. Food and Drug Administration*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., *Secretary, U.S. Department of Health and Human Services*,

Respondents.

Petitions for Review of an Order of
the Food and Drug Administration
Agency No. PM0003712PD1
Agency No. PM0003303.PD1
Agency No. PM0000975.PD21
Agency No. PM0003477
Agency No. PM0003735
Agency No. PM0002354.PD27-PD28
Agency No. PM0004614.PD01-PD43, PD48-PD95

Before HIGGINBOTHAM, SMITH, and OLDHAM, *Circuit Judges*.

JERRY E. SMITH, *Circuit Judge*:

These petitioners petition for review of a marketing denial order of the Food and Drug Administration ("FDA"). For the reasons explained, we grant review, vacate the order, and remand.

The Family Smoking Prevention and Tobacco Control Act ("TCA") prohibits marketing new tobacco products without authorization from the FDA and provides that the agency "shall deny" a new premarket tobacco product application ("PMTA") unless the applicant shows that its product would be "appropriate for the protection of the public health" (the "APPH" standard). 21 U.S.C. § 387j(c)(2)(A). The TCA defines "tobacco product" as "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product." *Id.* § 321(rr)(1).

To identify whether a tobacco product is APPH, the FDA must evaluate "the risks and benefits to the population as a whole," taking into account both the "likelihood that those who do not use tobacco products will start using such products" and the "likelihood that existing users of tobacco products will stop." *Id.* § 387j(c)(4). For cessation-oriented products such as e-cigarettes, the APPH standard introduces a calculus comparing initiation of new users with cessation by old users, which FDA calculates based on "well-controlled investigations" or other "valid scientific evidence" that is "sufficient to evaluate the tobacco product."[1]

Petitioner NicQuid, LLC, is a maker of electronic nicotine delivery systems ("ENDS"), while co-petitioner Wood Creek Vapory sells various vaporized-nicotine related products.[2] NicQuid submitted a PMTA applica-

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[1] 21 U.S.C. 387j(c)(5); *FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 572 (2025).

[2] NicQuid manufactures nicotine salt liquids, which are used in "open-system" ENDS, as distinguished from the pre-filled cartridges that are combined with delivery devices in "closed-system" ENDS. For consistency across the several consolidated cases, we use ENDS throughout, while acknowledging that NicQuid makes an ENDS-related tobacco product regulated under the same law. The consolidated cases all present substantially equivalent fact-patterns and legal claims, including No. 24-60304, *Breeze Smoke,*

tion, which the FDA denied under its "comparative-efficacy standard"[3] on May 3, 2024, through a marketing denial order ("MDO" or "the Order"). Petitioners timely petitioned for review per 21 U.S.C. § 387*l*(a)(1)(B).

FDA centrally contends that its denial of the company's application complies with *FDA v. Wages & White Lion Investments, L.L.C.*, 604 U.S. 542 (2025) ("*Wages*"), reversing *Wages and White Lion Invs., L.L.C. v. FDA*, 90 F.4th 357 (5th Cir. 2024) (en banc).

Petitioners primarily assert that FDA's application of the comparative efficacy standard, as shown in the MDO itself and two internal agency memoranda that allegedly mandated FDA employees to apply the "comparative efficacy study requirement" to all PMTAs and thereby forced denial of any application lacking such a study, was arbitrary and capricious or otherwise violated due process. Petitioners posit that the comparative efficacy standard counts as a substantive standard under governing principles of administrative law and was adopted in circumvention of the statutory notice-and-comment rulemaking procedure in the TCA or in violation of the foundational notice-and-comment rulemaking requirements of the Administrative Procedure Act ("APA"). Petitioners further maintain that FDA failed to give NicQuid fair notice of its change in position regarding the comparative efficacy analysis and regarding its enforcement policy specifically with respect to menthol-flavored products.

Petitioners' contention that application of the comparative efficacy standard was arbitrary and capricious is foreclosed by *Wages*,[4] where the Court held that FDA did not unlawfully change its position regarding what

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L.L.C. v. FDA, under which heading petitioners previously consolidated their briefing.

[3] *VDX Distro, Inc. v. FDA*, 179 F.4th 356, 360 (5th Cir. 2026).

[4] *Wages*, 604 U.S. at 571–72; *id.* at 578–79.

information must be included in a PMTA when applying the comparative efficacy standard to PMTAs for non-tobacco flavored vapes (fruit, candy, and dessert-flavored products). The question whether the comparative efficacy standard amounts to a "tobacco product standard" within the statutory definition of the TCA—and therefore whether it would need to be adopted under the TCA's notice-and-comment rulemaking procedure—is likewise foreclosed by *VDX Distro*.

Nevertheless, we credit petitioners' APA argument regarding the notice-and-comment requirement under this circuit's doctrine that a substantive rule binding an agency to one course of action and prospectively applying to an unbounded set of parties triggers APA requirements and due process concerns.[5] *A fortiori*, we observe that both the Supreme Court in *Wages* and this court in *VDX Distro* specifically reserved rulings on APA notice-and-comment rulemaking, in each case refusing to rule on those grounds.[6] We take up those courts' invitations and hold that the comparative

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[5] *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 192–94 (5th Cir. 2023) (quoting T*exas 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))); *id.* at 193 ("[A] substantive rule 'affects the rights of broad classes of unspecified individuals.'") (quoting *City of Arlington v. FCC*, 668 F.3d 229, 242 (5th Cir. 2012) (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"))); *see also Texas v. United States*, 809 F.3d 134, 171 (5th Cir. 2015) ("While mindful but suspicious of the agency's own characterization, we . . . focus[] primarily on whether the rule has binding effect on agency discretion or severely restricts it.") (citation omitted)), *aff'd by an equally divided Court*, 136 S. Ct. 2271 (2016); *Phillips Petroleum Co. v. Johnson*, 22 F.3d 616, 619 (5th Cir. 1994) ("This court, however, must determine the category into which the rule falls: '[T]he label that the particular agency puts upon its given exercise of administrative power is not, for our purposes, conclusive; rather it is what the agency does in fact.'" (citation omitted) (alteration in original)).

[6] *Wages*, 604 U.S. at 565 (("[T]heir brief also suggests that the FDA's decision to issue denials based on standards developed in adjudication violated other provisions of the APA and TCA that . . . required notice-and-comment rulemaking . . . . We did not grant certiorari on that question . . . . Accordingly, we do not reach that question and express no

efficacy standard is a substantive rule that needed to be adopted under the APA's notice-and-comment requirements so as not to imperil the due-process-protected interests of bound parties.[7] We direct the FDA, on remand, either to rethink the rule, to re-adopt it consistently with the APA's information-forcing procedure that permits the many bound parties to have their say and contribute to rational and sound policy, or to undertake other appropriate proceedings consistent with this opinion.

I.

Under the TCA's framework for balancing free market interests in tobacco production and sale with the public health effects and widely recognized addictive potential of vaporized tobacco, FDA has provided significant guidance on the APPH standard:

> If such products result in minimal initiation by children and adolescents while significant numbers of smokers quit, then there is a potential for the net impact at the population level to

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view on its merits.") (citation omitted); *VDX Distro*, 179 F.4th at 367 n.9 ("Petitioners' TCA notice-and-comment attack on the comparative efficacy standard is distinct from a claim based on the APA's notice-and-comment provisions . . . . We therefore leave for another day the merits of an APA notice-and-comment argument."). Depending upon how broadly one reads the *ratio decidendi* of the Supreme Court's reversal, this court's en banc suggestion that FDA failed to follow notice-and-comment rulemaking procedures is still convincing. *See Wages*, 90 F.4th at 384 n.5.

[7] *R.J. Reynolds*, 65 F.4th at 193–94. That opinion has not been vacated, and though its holding on change-in-position is abrogated by the intervening *Wages* decision, its holding that identifies what is essentially the comparative efficacy standard survives and binds this panel. *See id.* at 191–92 (discussing the FDA's internal 2021 memorandum, since rescinded, showing 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.'") (quoting Alex Norcia, *Memos Show FDA Overruled Science-Office Call to OK Menthol Vapes*, FILTER MAGAZINE (Dec. 14, 2022), https://bit.ly/3JjjcVi), and declaring the comparative efficacy standard a substantive rule, *id.* at 193 (citing *City of Arlington*, 668 F.3d at 242).

> be positive . . . . If, on the other hand, there is significant initiation by young people, minimal quitting, or significant dual use of combustible and non-combustible products, then the public health impact could be negative.[8]

Following the adoption and implementation of this proposed rule in August, 2016, it became unlawful to market all new ENDS without FDA authorization. *Wages*, 604 U.S. at 555. For those products already on the market, the agency announced that it would not take enforcement action based on a product's lack of premarket authorization for two to three years, ultimately leading to a September 2020 deadline for applications. *Id.* at 555–56.

In the face of rising youth initiation, FDA's 2020 enforcement policy prioritized action on cartridge-based e-cigarettes with flavors other than tobacco or menthol, such as fruit, candy, and dessert flavors.[9] FDA maintains that "[t]he evidence shows that the availability of a broad range of flavors is one of the primary reasons for the popularity of [e-cigarettes] among youth." The agency also warned that the crackdown on cartridge-based e-cigarettes in sweet and appealing flavors, such as Juuls, led to a substantial offsetting rise in youth use of fully-disposable models in the same flavors, such as Elf Bars, "underscoring the fundamental role of flavor in driving appeal."

FDA received a large number of PMTAs at the time of the 2020 deadline and authorized more than three dozen e-cigarette products, most of which are tobacco flavored.[10] The agency determined that those products pose a comparatively low risk of initiation because "interest in tobacco flavor

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[8] 79 Fed. Reg. 23,142, 23,147 (Apr. 25, 2014) (FDA proposed rule).

[9] FDA, FDA ENDS PMTA Enforcement Guidance (Apr. 2020).

[10] FDA, *E-Cigarettes Authorized by the FDA* (July 2025) (Tobacco Product Marketing Orders).

is low among youth," while the same products can benefit "established cigarette smokers" who often identify tobacco as their "flavor of interest" and could switch to e-cigarettes "as a way to stop or reduce smoking."[11] While generally finding that e-cigarettes with flavors other than tobacco pose greater risks to youth, FDA has granted marketing authorization to six menthol-flavored e-cigarettes for which the "evidence submitted by the applicant showed that these menthol-flavored products provided a benefit for adults who smoke cigarettes relative to that of the applicant's previously authorized tobacco-flavored products."[12] FDA generally submits PMTAs to an APPH analysis that "considers many factors," including overall population health, individual health risk, effects on vulnerable populations, consumer understanding and perception, and liability for abuse.[13] At the same time, FDA has refused "to create a series of criteria" that all products must meet to satisfy the APPH standard, while maintaining its intent to conduct an "individualized" assessment of "the risks and benefits of a specific tobacco product . . . based on all of the contents of [the] application."[14]

In guidance, FDA suggested that new long-term clinical or nonclinical studies would likely not be required to support a PMTA, while also recommending that applicants include evidence on the comparative health risks of their ENDS products versus existing products on the market. FDA guidance on flavored products added that "[t]he term flavored ENDS in this review refers to any ENDS other than tobacco-flavored and menthol-flavored

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[11] FDA, *Technical Project Lead (TPL) Review of PMTAs* 27–32 (May 12, 2022).

[12] FDA, *FDA Authorizes Marketing of Four Menthol-Flavored E-Cigarette Products After Extensive Scientific Review* (June 21, 2024); FDA, *FDA Authorizes Marketing of Tobacco- and Menthol-Flavored JUUL E-Cigarette Products* (July 17, 2025).

[13] 86 Fed. Reg. 55,300; 55,314.

[14] *Id.* at 55,320; 55,390; 55,386.

ENDS . . . . Applications for menthol-flavored ENDS will be addressed separately. When it comes to evaluating the risks and benefits of a marketing authorization, the assessment for menthol ENDS, as compared to other non-tobacco flavored ENDS, raises unique considerations."

In 2020, NicQuid submitted PMTAs for e-liquids in flavors including Menthol Blend, Strawberry-Peach, Spearmint, and Sweet Leaf. All included flavors other than tobacco, while the latter three included sweet flavorings addressed in *Wages*.[15] NicQuid also submitted an application for a product called "NicQuid Added Burst," available only in a 00 mg/mL nicotine concentration.

In May 2024, FDA issued a marketing denial order ("MDO"), finding that NicQuid's products were not APPH because its PMTA "lack[ed] sufficient evidence demonstrating that your flavored ENDS will provide a benefit to adult users that would be adequate to outweigh the risks to youth." FDA explained that tobacco use "is almost always started and established during adolescence . . . [and] preventing tobacco use initiation in young people is a central priority for protecting public health." FDA stated the available evidence showed that "flavored [e-cigarettes], including menthol" present "a known and substantial risk of youth initiation and use."

The agency observed that the rate of youth e-cigarette use had declined from its peak in 2019, coinciding with increased enforcement.

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[15] *Wages*, 604 U.S. at 578–79. Though petitioners describe Sweet Leaf as a tobacco-flavored product, FDA claims "the record does not support that assertion." Instead, the agency contends that it found sufficient substantial evidence in the record to evaluate Sweet Leaf as a characterized product—that is, any product containing flavors other than tobacco—citing petitioners' descriptions of Sweet Leaf as "[a] sweet turn on your favorite bold tobacco flavor," that "will excite your taste buds" due to its "undertone of sweet and spice." FDA's finding "is supported by 'substantial evidence' in the 'existing administrative record.'" *Id.* at 586 (quoting *Biestek v. Berryhill*, 587 U.S. 97, 102 (2019)).

Despite that decline, FDA still saw e-cigarettes as the most widely used tobacco product among youth, with as many as 2.55 million youth users in 2022, adding that "[t]he evidence shows that the availability of a broad range of flavors is one of the primary reasons for the popularity of [e-cigarettes] among youth" and that "flavors not only facilitate initiation but also promote established regular [e-cigarette] use." FDA added that studies over time indicated that use of flavored e-cigarettes, as compared to tobacco e-cigarettes, is "associated with progression . . . as well as escalation in the number of days [e-cigarettes] were used."

FDA also rejected NicQuid's voluntary marketing restrictions, stating that in its experience, such efforts fail to "mitigate the high risk to youth posted by flavored [e-cigarettes]" and that "youth have been able to obtain products, including flavored [e-cigarettes], despite sales restrictions." The agency discounted NicQuid's proposed sale restrictions methods as non-novel and inadequate.

FDA also considered the evidence of benefits from NicQuid's flavored e-cigarettes and found that the applications "lack[ed] sufficient evidence demonstrating that [the] flavored [products] will provide a benefit to adult users that would be adequate to outweigh the risks to youth." The agency noted that the PMTAs lacked any Randomized Control Trial, longitudinal cohort study, or "other evidence that reliably and robustly evaluated the impact of the new flavored vs. tobacco-flavored products on complete switching or significant cigarettes reduction over time among adults who used combustible cigarettes." FDA stated that the PMTA contained "cross-sectional surveys," but rejected those as not "evaluat[ing] the specific products in the application" or "evaluat[ing] these outcomes based on flavor type to enable comparisons between tobacco and other flavors."

Finally, after FDA's original submission of a certified administrative

record index in this matter, it filed an amended certified list including two internal agency memoranda.[16] Petitioners claim those memos clearly required FDA employees to deny any PMTA lacking a comparative efficacy study, discussed *infra*.[17]

II.

Although the Supreme Court's and this court's recent decisions have reduced the number of issues, discounting petitioners' arguments on fair notice and change-in-position for all flavored products other than menthol, as well as denying their TCA statutory argument, petitioners' positions on the APA remain viable. We therefore take up the APA argument and do not reach the question of whether the FDA was arbitrary and capricious in applying the comparative efficacy standard to NicQuid's menthol, tobacco-flavored or zero-nicotine products.

A.

As a preliminary matter, NicQuid properly petitioned for review in this court, even though its principal place of business is outside the Fifth Circuit. Respondent challenges NicQuid's choice of venue, despite that co-

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[16] FDA, *Memorandum to File from Brian A. King, PhD, MPH: Process for Evaluating Menthol-Flavored ENDS PMTAs* (Oct. 25, 2022); FDA, *Memorandum to File from Benjamin Apelberg, PhD: Development of the Approach to Evaluating Menthol-Flavored ENDS PMTAs* (Oct. 25, 2022). This court is also aware of the 2021 rescinded memo, which a previous panel has criticized as "followed in a check-box 'scientific review' form that indicated only whether a PMTA included a randomized controlled trial or longitudinal cohort study." *R.J. Reynolds*, 65 F.4th at 193 n.9.

[17] For one procedural point, NicQuid and Wood Creek Vapory's petition was filed before the Supreme Court's decision in *Wages*. This court stayed FDA's marketing denial order under our then-controlling opinion in *Wages*. The Supreme Court's decision has led to petitioners' amending their briefing and waiving their claims with respect to fruit, candy, and dessert-flavored products. Only claims on menthol, tobacco-flavored, and zero-nicotine products remain.

petitioner Wood Creek Vapory has its principal place of business in the Fifth Circuit. FDA posits that the statute governing judicial-review jurisdiction for the TCA, 21 U.S.C. § 387*l*(a)(1), "any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business," denies venue to an out-of-circuit co-petitioner. FDA acknowledges that in *FDA v. R.J. Reynolds Vapor Co.*, 606 U.S. 226 (2025), the Court held that a retailer can be sufficiently injured by a marketing denial order to support a petition for review, but that that Court reserved the question whether "each petitioner in a joint petition for review must independently establish venue" under the TCA for this Court to resolve its petition in the first instance. *Id.* at 240–41. FDA also analogizes to *Trump v. CASA*, 606 U.S. 831 (2025), suggesting that the equitable relief of APA vacatur and remand should be limited to that necessary to redress a plaintiff's injury. *See id. at* 839–47, 851–54.

Petitioners insist that venue is proper as to NicQuid and that NicQuid may rely upon Wood Creek Vapory's residence and principal place of business in Texas. Petitioners point to several of this court's decisions, including *National Association of Private Fund Managers v. SEC*, 103 F.4th 1097 (5th Cir. 2024). There, interpreting an essentially identical jurisdiction and venue statute, 15 U.S.C. § 80b-13(a), this court held that venue was appropriate for all petitioners even though no petitioner apart from the organizational lead petitioner resided within this circuit. *Id.* at 1109. NicQuid also cites *Global Van Lines, Inc. v. ICC*, 691 F.2d 773, 774 n.1 (5th Cir. 1982), in which this court approved venue where only one of the petitioners was organized in Texas. Applied here, the analogous reasoning is that if venue is appropriate for Wood Creek Vapory, it works as well for NicQuid.

Because these cases were decided pre-*CASA*, it is worth considering

whether that decision unsettles this conclusion. It does not. *CASA* stands for the proposition that the Judiciary Act of 1789 does not authorize equitable or injunctive relief for parties that are virtually represented but not actually present.[18] The Court specifically distinguished between the "traditional[]" practice whereby "courts issued injunctions prohibiting executive officials from enforcing a challenged law or policy only against the plaintiffs in the lawsuit" and novel "injunctions—known as 'universal injunctions'" which "prohibit enforcement of a law or policy against *anyone*."[19] NicQuid is an actually present party in an administrative action seeking vacatur and remand, which are equitable remedies authorized under the APA.[20]

NicQuid's participation in this case might still turn on the propriety of joinder, but such argument is unbriefed and therefore forfeited—as well as obvious where a party shares a common demand for relief, as distinguished from making any virtual demand for equitable relief barred by *CASA*. In sum, *National Association*, 103 F.4th at 1109, controls this situation, where one of two co-petitioners is appropriately venued in this court.

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[18] *CASA*, 606 U.S. at 841 ("A universal injunction can be justified only as an exercise of equitable authority, yet Congress has granted federal courts no such power.").

[19] *Id.* at 837.

[20] 5 U.S.C. § 706(2) ("The reviewing court shall . . . hold unlawful and set aside agency action found to be [variously unlawful]"). We view this as an equitable remedy. *See Acheson Hotels, LLC v. Laufer*, 601 U.S. 1, 16 (2023) (Jackson, J., concurring) ("As an equitable remedy, vacatur 'is not granted as a matter of course.' (quoting *Salazar v. Buono*, 559 U.S. 700, 714 (2010))); *see also* Aditya Bamzai, *The Path of Administrative Law Remedies*, 98 NOTRE DAME L. REV. 2037, 2041 (2023) ("By the time of the APA's adoption in 1946, the 'set aside' remedy had come to be equated in many . . . respects with the equitable remedies that formed the backdrop to the APA's adoption."); *but see* T. Elliot Gaiser, Mathura Sridharan & Nicholas Cordova, *The Truth of Erasure: Universal Remedies for Universal Agency Actions*, U. CHI. L. REV. (Online) (2024) ("Universal remedies under the APA, however, remain within Article III limits because they are legal, not equitable, remedies created by Congress and available only to resolve true cases or controversies.").

B.

Next, we consider whether the FDA violated the APA's notice-and-comment rulemaking procedure in developing and applying the comparative efficacy standard to PMTAs. We hold that, in using informal adjudication to promulgate a substantive rule that binds the agency to its enforcement position, prospectively applies to an unbounded set of applicants, and amounts to a *de facto* ban, the FDA sidestepped the notice-and-comment rulemaking requirement of the APA.

Although, as a policy matter, one might agree with the FDA's decision severely to police youth access to e-cigarettes, the procedural safeguards of the APA serve to promote informed, rational decisionmaking by administrative agencies.[21] Those safeguards cannot be so easily evaded by saying that the agency's free choice under *Chenery II* to use adjudication[22] empowers it to make a prospective decision behind closed doors, adopting a standard that will apply to numerous non-present parties without affording them the due process appropriate to protect their extant and vested commercial interests.

1.

Pre-*Wages*, petitioners claimed that FDA had instituted a *de facto* restriction or ban on non-tobacco flavored ENDS in violation of the TCA's notice-and-comment rulemaking procedure. Although petitioners' theory that the comparative efficacy standard amounts to a statutorily defined

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[21] *See Michigan v. EPA*, 576 U.S. 743, 750 (2015) ("Federal administrative agencies are required to engage in 'reasoned decisionmaking.'") (quoting *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998)).

[22] *Wages*, 604 U.S. at 565 ("Unless Congress has specified otherwise, agencies are generally free to develop regulatory standards 'either by general [legislative] rule or by individual order' in an adjudication") (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 202–03 (1947) (*Chenery II*)).

"tobacco product standard" has recently been rejected in *VDX Distro*, 179 F.4th at 364, petitioners continue to press their APA arguments in supplemental letter briefs.

Petitioners centrally argue that the comparative efficacy standard, as applied, amounts to a substantive rule requiring notice-and-comment rulemaking, citing *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 193 (5th Cir. 2023)). Petitioners adduce evidence that the FDA has issued MDOs for over 1.2 million flavored ENDS, while only approving four menthol-flavored closed-system ENDS, about 0.000333%.[23] In total, FDA has received applications for more than six million ENDS products, while only approving 45 total ENDS of any variety.[24]

Petitioners allege that the agency reviewers were required to deny any PMTA that did not contain comparative efficacy data—binding the FDA to that position—and petitioners add that, while a 2021 internal memo was rescinded, this court has found it "has remained in full effect for all non-tobacco flavored" ENDS (citing *R.J. Reynolds*, *id.*). Petitioners therefore demand that the order be set aside under 5 U.S.C. § 706(2)'s provision allowing courts to review agency actions "found to be . . . without observance of procedure required by law."

Post-*Wages*, petitioners additionally point to the two late-filed FDA

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[23] The FDA's subsequent approval of four additional e-cigarette products in menthol, mango, and blueberry flavors does not upset this point. *See* FDA, *Marketing Granted Orders for Glas Inc.* (May 5, 2026), https://perma.cc/B4YK-6KBN; FDA Press Release, *FDA Expands Market Access, Authorizes New ENDS Products* (May 5, 2026), https://perma.cc/4GKB-749T (Press Release). Four more products raise this percentage to only 0.000666%, which this court still considers a low rate of approval suggesting a *de facto* ban.

[24] FDA, *E-Cigarettes, "Vapes" and Other Electronic Nicotine Delivery Systems (ENDS) Authorized by the FDA* (May 5, 2026), https://perma.cc/YSP4-AJ2M.

internal memoranda[25] as violations of the APA's notice-and-comment requirement. They insist that the memos corroborate the alleged *de facto* ban and imposed a binding standard on FDA staff, to be applied rigidly and across-the-board in all PMTA reviews of menthol-flavored ENDS. Petitioners focus on the Supreme Court's implication that some statutes may require rulemaking despite the general amphibious approach of *Chenery II*, while narrowing the *Wages* holding to reflect only a ruling on change-of-position by an administrative agency, rather than any holding on rulemaking versus adjudication.[26]

FDA responds that it did not violate any procedural requirement in using the comparative efficacy standard, which the Supreme Court referred to in *Wages* as a "comparative-efficacy requirement," 604 U.S. at 578, and which FDA contends is a permissible development of a point of law through adjudication under *Chenery II*. FDA notes that the Court stated that the Act "expressly contemplates comparisons of different tobacco products," *id.*, thereby covering the FDA's use of cross-sectional survey data to assess comparative risks. FDA insists that its choice to resolve PMTAs through informal adjudication was not a sufficient departure from prior guidance (which had generally been phrased in conditional language) to amount to an abuse of discretion through change-in-position.[27] FDA also points out that it conducted an individualized assessment of NicQuid's application, evaluating

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[25] The Dr. King and Dr. Apelberg memos, *supra*.

[26] While we read *dictum* from our reversed case with caution, we acknowledge petitioners' argument that our old footnote in *Wages*, 90 F.4th at 384 n.5, is an independent holding.

[27] *See Tearney v. NTSB*, 868 F.2d 1451, 1453 (5th Cir. 1989) ("[I]n order to constitute . . . an abuse [of discretion], an adjudicative rule must be 'such a new departure [from prior policy] that [it] could not reasonably have been foreseen.") (further parentheticals omitted)).

the relevant evidence and denying it as not APPH. Finally, in a supplemental letter, the agency adds that *VDX Distro* forecloses petitioners' APA argument by suggesting that it permissibly chose adjudication (while only ruling on TCA statutory grounds).

In *VDX Distro*, 179 F.4th at 364–67, this court confronted a similar set of facts and legal issues and held that the comparative efficacy standard does not constitute a "tobacco product standard" within the specific statutory definition of the TCA. We reasoned that the existing statutory examples of tobacco product standards, as well as a couple of proposed regulatory examples in the Federal Register, were united by rigid bans or limiting requirements for marketable tobacco products, as distinguished from a more flexible criterion such as comparative efficacy, which conceivably could be satisfied in multiple ways.[28] This distinction make sense in part because, applying the *ejusdem generis* canon[29] to the TCA's examples of statutorily-defined tobacco product standards, comparative efficacy does not neatly fit next to (A) banning flavored tobacco, and (B) banning pesticide-tainted tobacco. 21 U.S.C. § 387g(a)(1). But the *VDX Distro* panel expressly renounced any

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[28] *Id.* The Supreme Court also suggests that the APPH standard invites a cost-benefit analysis, rather than delineating between two different categories of rigid-versus discretionary-standards: "[T]he FDA's determination that a new tobacco product is 'appropriate for the protection of the public health' is an inherently comparative judgment . . . [and] calls out for various types of comparisons, including comparisons between new tobacco products and those that are already available, as well as between different types of new tobacco products that may attract new smokers." *Wages*, 604 U.S. at 578–79.

[29] *See generally United States v. Buluc*, 930 F.3d 383, 389 (5th Cir. 2019) (explaining that "ejusdem generis relies on the 'familiar semantic structure' in which an enumeration of specific terms imparts a restrictive meaning to a generic 'follow-on phrase.'") (internal citation omitted); *see generally* ANTONIN SCALIA & BRYAN GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 199 (2012) ("Scalia & Garner") (stating that *ejusdem generis* signifies "[w]here general words follow an enumeration of two or more things, they apply only to persons or things of the same general kind or class specifically mentioned.").

wider holding beyond interpreting the statutory language of "tobacco product standard," including on the possible substantive-rule character of the comparative efficacy standard.[30]

2.

The APA defines a "rule" as "an agency statement of general or particular applicability *and future effect* designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4) (emphasis added). The APA requires agencies to undertake notice-and-comment rulemaking whenever they adopt substantive rules (as opposed to mere interpretive rules or general policy statements). *See* 5 U.S.C. § 553.[31]

Whether a rule is "substantive" partly "turns on whether an agency

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[30] 179 F.4th at 367 n.9 ("Petitioners' TCA notice-and-comment attack on the comparative-efficacy standard is distinct from a claim based on the APA's notice-and-comment provisions. Amici curiae in support of Petitioners lodge both arguments, but Petitioners make only the former. We therefore leave for another day the merits of an APA notice-and-comment argument . . . . [T]he TCA's particular statutory framework and context drive our analysis of the TCA notice-and-comment issue before us.") (citing *R.J. Reynolds*, 65 F.4th at 192–94)). Today, it turns out, is "another day."

[31] *City of Arlington v. FCC*, 668 F.3d 229, 240 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013). *See also St. Mary's Hosp., Inc. v. Harris*, 604 F.2d 407, 408 (5th Cir. 1979) (substantive rules, also known as legislative rules, are "promulgated pursuant to legislative authority delegated to the agency by Congress"); *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95 (D.C. Cir. 1997) (a substantive rule "modifies or adds to a legal norm based on the agency's own authority"); *see generally* Richard J. Pierce, Jr., *Distinguishing Legislative Rules from Interpretive Rules*, 52 ADMIN. L. REV. 547, 552 (2000) (substantive rules "bind the public and courts in a manner indistinguishable from a statute." (quotation omitted)); *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) ("[T]he critical feature of interpretive rules is that they are 'issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers.' The absence of a notice-and-comment obligation makes the process of issuing interpretive rules comparatively easier for agencies than issuing legislative rules. But that convenience comes at a price: Interpretive rules 'do not have the force and effect of law and are not accorded that weight in the adjudicatory process.'") (quoting *Shalala v. Guernsey Mem. Hosp.*, 514 U.S. 87, 99 (1995)).

intends to bind itself to a particular legal position." *Texas v. EEOC*, 933 F.3d at 441. To identify the line between policy statements and substantive rules, we ask "whether the rule (1) imposes any rights and obligations and (2) genuinely leaves the agency and its decision-makers free to exercise discretion." *Texas v. United States*, 809 F.3d at 171 (cleaned up). For background, whether the generation of a particular point of law is an act of rulemaking or an act of adjudication turns on whether it is an "order" within the meaning of the APA.[32]

Under this Circuit's precedent, we know, for several reasons, that the comparative efficacy standard constitutes a substantive rule.[33]

First, the comparative efficacy standard "affects the rights of broad classes of unspecified individuals," *City of Arlington*, 668 F.3d at 242, applying not only to thousands of existing applicants but to an infinite future stream of similarly situated applicants, many of which already exercise property rights in the e-cigarette business.[34] The numerosity of over one million MDOs' applying to more than six million products is persuasive.

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[32] *See* 5 U.S.C. § 551(7) "'adjudication' means agency process for the formulation of an order"; *id.* § 551(6) "'order' means the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making." Given that we know that rulemaking is of "future effect," anything that is of current or retroactive effect inclines towards the order category. Indeed, one fundamental hallmark of rulemaking is prospectivity. Another is that an order is a "final disposition" in a particular matter applying to a particular set of parties, as distinguished from rulemaking's "general . . . applicability . . . designed to implement . . . law or policy." *Id.* § 551(4).

[33] In *R.J. Reynolds*, 65 F.4th at 194, we held it was "not a close call" that FDA violated the APA's notice-and-comment procedures in adopting a substantive rule—and this point of law has *not been overturned* by any court.

[34] "FDA employs that interpretation across-the-board in its evaluation of applications for non-tobacco-flavored e-cigarette products. That uniformity may be tantamount to FDA's application of a rule." *VDX Distro*, 179 F.4th at 366.

While admittedly, a *first* adjudication can then analogically influence later orders, validly creating a point of law that is applied to materially indistinguishable facts (not unlike the development of any body of law), it is implausible that more than one million MDOs could have materially indistinguishable facts.[35] The opposite view—that those applications are denied under a check-the-box exercise applied to every PMTA for non-tobacco flavored ENDS (if it lacks an RCT, automatically deny)—is a more accurate reading of the record.[36]

In the few cases where the FDA has approved a flavored ENDS, the manufacturer provided comparative-efficacy evidence.[37] This contrast, between the FDA granting applications that satisfy the comparative efficacy standard but denying many thousands that lack such a study, underscores the point that it uses comparative efficacy to determine the rights and obligations of parties. *See Texas v. EEOC*, 933 F.3d at 441; *Syncor*, 127 F.3d at 95. Relat-

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[35] *See NLRB v. Bell Aerospace Co. Div. of Textron, Inc.*, 416 U.S. 267, 294 (1974) ("The views expressed in *Chenery-II* . . . make plain that the Board is not precluded from announcing new principles in an adjudicative proceeding and that the choice between rulemaking and adjudication lies in the first instance within the Board's discretion . . . [as] duties of buyers vary widely depending on the company or industry[,] it is doubtful whether any generalized standard could be framed which would have more than marginal utility. The Board thus has reason to proceed with caution, developing its standards in a case-by-case manner with attention to the specific character of the buyers' authority and duties in each company."); *see also Brown-Forman Corp. v. NLRB*, 169 F.4th 646, 662–63 (6th Cir. 2026) (finding that a purely prospective rule of general application could not be developed through adjudication). This Sixth Circuit case is persuasive insofar as the FDA did not develop the comparative efficacy standard as a case-specific means to provide a remedy to the parties, but instead to implement policy in an open-ended way.

[36] *R.J. Reynolds*, 65 F.4th at 193–94 (stating that the 2021 memo "took away the FDA reviewers' former discretion to consider individual PMTAs solely on their merits and instead requires a cursory, box-checking review").

[37] *See* NJOY TPL Review at 7–8, https://perma.cc/2AS7-D5X4; JUUL TPL Review at 8–10, https://perma.cc/Y8ST-K7DT.

edly, the application of the comparative efficacy standard "imposes" a novel "obligation" on PMTA applicants to produce an RCT. *Texas v. United States*, 809 F.3d at 171.

This breadth of application also implicates due process concerns for the expansive and unbounded set of future applicants that will have their property rights and commercial interests determined in a forum to which they have no access.[38] Due process requires agencies to "provide regulated parties fair warning" of what the agency "prohibits or requires" before taking adverse action.[39]

Second, "[a]n 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 law."[40] The comparative efficacy standard, as revealed in the 2021 memo, corroborated by the Dr. King and Dr. Apelberg Memos, and lately raised again in draft guidance,[41] appears to be binding on FDA staff, has been applied in more than

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[38] *See Ohio v. EPA*, 603 U.S. 279, 293–94 (2024) (holding that EPA failed to offered a reasoned response to the regulated parties, contrary to its statutory notice-and-comment obligations); *see generally Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) ("This Court consistently has held that some form of hearing is required before an individual is finally deprived of a property interest.") (citation omitted); *Board of Regents of State Colls. v. Roth*, 408 U.S. 564, 569-70 (1972) ("The requirements of procedural due process apply only to the deprivation of interests encompassed by the Fourteenth Amendment's protection of liberty and property. When protected interests are implicated, the right to some kind of prior hearing is paramount.") (citation omitted).

[39] *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012) (quotation omitted).

[40] *R.J. Reynolds*, 65 F.4th at 193 (cleaned up) (citation omitted); *accord Texas v. United States*, 809 F.3d at 171 (citing *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 382 (D.C. Cir. 2002) (quoting *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1320 (D.C. Cir. 1988)).

[41] FDA, *Flavored Electronic Nicotine Delivery System (ENDS) Premarket Applications – Considerations Related to Youth Risk (Draft Guidance)* *4 (March 2026), https://tinyurl.com/452cp63s (stating the comparative efficacy standard "is the approach

one million MDOs for non-tobacco flavored ENDS as though it is binding, and has impacted the rights of numerous applicants.[42] It clearly constrains the FDA's reviewers from considering individual PMTAs on their merits and thereby adopting any different view of law.[43] Can we credibly say that FDA and its staff are free to exercise discretion in adjudicating applications and issuing orders outside, around, or despite the comparative efficacy standard? No.[44]

Third, we know that this policy was developed and applied prospectively, given the 2021 rescinded memo and the Dr. King and Dr. Apelberg memos.[45] The FDA did not develop its adjudicatory position in the course of resolving, for its purposes, a 'case or controversy' in a PMTA—meaning a current adjudication. Neither did it retroactively determine that a party had violated one of its policies (another posture of order). Instead, the 2022 internal memoranda developed a prospective policy behind closed doors,

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that the FDA has long applied in reviewing PMTAs for flavored ENDS products . . . [and] [t]hat approach remains unchanged and is not affected by this guidance").

[42] *Cf. Texas v. United States*, 809 F.3d at 171–73 (holding that the DAPA policy was a binding substantive rule requiring notice and comment where it was applied and led to the same outcome in 95% of thousands of immigration applications).

[43] *Cf. R.J. Reynolds*, 65 F.4th at 193–94.

[44] On this point, we distinguish the Glas, Inc., approval as a genuine adjudication determining the rights of a single party on a present or retroactive basis, taking the form of an order rather than a rule for APA purposes. *See supra*.

[45] *See also R.J. Reynolds*, 65 F.4th at 187 ("In June 2019, the FDA issued a 'how-to' guide for submitting e-cigarette PMTAs.") (citing FDA, *Guidance for Industry, Premarket Tobacco Applications for Electronic Nicotine Delivery Systems* (June 2019) ("PMTA Guidance"), https://bit.ly/2R5TyYj); *id.* at 192 ("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.'") (citation omitted).

with heavy-handed experts far away from the *hoi polloi*, which FDA then began to apply in adjudications.[46] Instead of originating in a specific adjudication or order, it is most plausible to say that the comparative efficacy standard was born in internal agency policymaking and was then publicly debuted in an adjudication rather than through notice-and-comment.

We therefore hold that FDA's application of the comparative efficacy standard in denying NicQuid's PMTA constituted the development of a substantive rule in circumvention of the APA's notice-and-comment requirement. The nominal process of adjudication cannot conceal or excuse the secretive development of a prospective policy: We agree with the prior panel that "[t]his is not a close call." *R.J. Reynolds*, 65 F.4th at 194.

3.

FDA's primary response is to appeal to an agency's discretion to choose between rulemaking and adjudication. We doubt, however, whether (a) the agency can use adjudication to promulgate a rigid across-the-board requirement, or (b) use *informal* adjudication to promulgate a substantive rule.

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[46] King Memo at 3 ("[I]n light of the risk to youth and the lack of robust evidence of actual differential use of menthol-flavored ENDS to quit or significantly reduce cigarettes per day, the approach to menthol-flavored ENDS should be the same as with other flavored ENDS with respect to the evidence of adult benefit . . . . In reaching this conclusion [that menthol ENDS should be subject to the comparative efficacy standard], CTP leadership, supported by FDA leadership, has tried to maintain a balanced, appropriate, and science-driven focus."); Apelberg Memo at 3 ("OS, on its own initiative, then reassessed and decided it was reasonable and consistent to treat menthol-flavored ENDS PMTAs in the same way as other non-tobacco-flavored ENDS PMTAs regarding the evidence needed to show a potential benefit to adult smokers."). Observe that it is the Office of Science, Center for Tobacco Products, and FDA's leadership—and not the targets of the regulation—that were deliberating this consequential decision.

a.

Agencies cannot use adjudication to promulgate rigid rules applying across the board in all situations regardless of material differences in facts. While FDA cites *Chenery II* for the classic principle that agencies may choose between adjudication and rulemaking, the Supreme Court's *Chenery II* decision turns out to be unhelpful to FDA.

In *Chenery II*, the Court articulated why agencies need discretion to maneuver between adjudication and rulemaking:

> [P]roblems may arise in a case which the administrative agency could not reasonably foresee, problems which must be solved despite the absence of a relevant general rule. Or the agency may not have had sufficient experience with a particular problem to warrant rigidifying its tentative judgment into a hard and fast rule. Or the problem may be so specialized and varying in nature as to be impossible of capture within the boundaries of a general rule.

Id. at 202–03. None of these three rationales supports FDA's use of adjudicative fiat here—to the contrary, each counsels against using adjudication to impose the comparative efficacy rule.

To begin, the risk of flavored ENDS to youth is not a problem FDA "could not reasonably foresee." *Id.* at 202. The fact that FDA cites a wealth of data demonstrating the risk of flavored ENDS to youth and that this evidence became the basis for the comparative efficacy standard shows that this risk is obvious and central to each of the more than one million MDOs.

Next, the comparative efficacy rule does not fix a "problem[] which must be solved despite the absence of a relevant general rule." *Id.* Perhaps the first time FDA dealt with a PMTA for a flavored ENDS, FDA lacked "sufficient experience" with such products and was disinclined to "rigidify[]" the comparative-efficacy rule "into a hard and fast rule." *Id.* FDA

cannot possibly claim inexperience now: It has received over six million applications to market flavored ENDS and has issued at least one million MDOs, suggesting that the comparative efficacy problem does not respond to "the absence of a relevant general rule," but prescribes a general rule of decision at too high a level of generality. FDA has also approved forty-five ENDS, which suggests adequate experience in calculating the risks to youth. And whatever inexperience FDA may once have had, the comparative-efficacy rule is now a "hard and fast rule"—the antithesis of the flexible and fluid "tentative judgment" contemplated by *Chenery II*. 332 U.S. at 202.

Perhaps FDA thinks the problem of flavored ENDS is "so specialized and varying in nature as to be impossible of capture within the boundaries of a general rule"? *Id.* at 203. Again, the uniform use of the comparative efficacy rule to assess millions of applications belies any notion that the problem here is "impossible of capture within the boundaries of a general rule." *Id.* All to say, adjudication provides "a very definite place for the case-by-case evolution of statutory standards." *Id.* A rigid rule that FDA applies with the consistency and predictability of a metronome is the antithesis of an evolving, case-by case standard.

This application of *Chenery II* is consistent with that of the Sixth Circuit in *Brown-Forman Corp. v. NLRB*, 169 F.4th 646 (6th Cir. 2026). Surveying *Chenery II* and its progeny, the Sixth Circuit articulated two limitations on agencies' adjudicatory authority: If an agency uses adjudication to promulgate a standard, then the agency must derive that standard from "case-specific facts" and implement the standard "to resolve the parties' dispute." *Id.* at 665–67. Applying those limitations to the case before it, the *Brown-Forman* court found that NLRB exceeded its authority by using adjudication to promulgate "a new rule of general applicability" that "provide[d] a rigid" and "widely applicable base." *Id.* at 667. The court criticized the NLRB for deriving the rule "not from the facts of the adjudication before it,

but from decades of experience." *Id.* (citation modified). In other words, the rule was not inductive, but deductive—as the court put it, "[t]he intended flexibility of adjudication-based policymaking [was] lost" with "a non-case-specific hard-and-fast rule." *Id.* (citing *Chenery II*, 332 U.S. at 202–03).

The *Brown-Forman* court's analysis easily maps onto the facts of this case: The comparative efficacy rule is not "derived from case-specific facts." *Id.* at 665. FDA derived it from non-product-specific literature regarding the general risk of flavored ENDS to youth. It also was not created to "resolve the parties' dispute." *Id.* at 666. Instead, it applies every time FDA adjudicates a PMTA and constitutes a "rigid," "widely applicable," "non-case-specific," and "hard-and-fast" requirement. *Id.* at 667.

b.

Even if *Chenery II* allows FDA to adopt the comparative efficacy rule via adjudication, the agency still could not adopt it via *informal* adjudication. The APA outlines a series of procedures to be used "in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing." 5 U.S.C. § 554(a). These trial-like, on-the-record hearings are known as "formal adjudication." But administrative agencies also engage in informal adjudication, from licensing to any other agency action resulting in "final disposition . . . in a matter other than rule making." *Id.* § 551(6). In the latter category of decisions, agencies do "not have any legal obligation to hold an evidentiary hearing—that is, do[] not have to have a structured interchange that develops a formal record that is the basis for decision."[47] The agency action at issue here—FDA's marketing denial orders—deny a license to market a particular product and are therefore a

[47] Todd D. Rakoff et al., Administrative Law 594 (13th ed. 2023).

quintessential example of informal adjudication.

It makes little sense that agencies could use informal adjudication (marketing denial orders) to promulgate substantive policy (the comparative efficacy rule). Start with the premise that formal adjudication mirrors notice-and-comment rulemaking. In each instance, agencies give regulated entities notice of proposed action, an opportunity to submit facts and present reasoned arguments, as well as the ability to engage in back-and-forth dialogue. These back-and-forth procedures are what give substantive rulemaking the force and effect of law. If and only if an agency has gone through the required dialogue with the regulated party may it take an action that determines the rights and obligations of the American public.

By analogy, an agency may promulgate a substantive standard via adjudication only if that adjudication has sufficient procedural formality to be akin to notice-and-comment rulemaking. It would be utterly nonsensical to make agencies go through the rigor of notice-and-comment for substantive rules but then allow them *carte blanche* to take the same action without those procedures via informal adjudication. Moreover, it would render a 'dead letter' or surplusage the several heads of the APA that provide for formal adjudication. *See* 5 U.S.C. §§ 554, 556, 557.

As the Court has put it, "[i]t is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force." *United States v. Mead Corp.*, 533 U.S. 218, 230, (2001). In other words, if an agency is going to act with the force and effect of law, it must use notice-and-comment rulemaking or formal adjudication, not one-off informal adjudi-

cations native to the facts on the ground.[48]

Consistent with this understanding, the Court has never given agencies the go-ahead to use informal adjudication to promulgate a substantive rule. In *Bell Aerospace*, the Court held that an agency "is not precluded from announcing new principles in an adjudicative proceeding and that the choice between rulemaking and adjudication lies in the first instance within the Board's discretion." *NLRB v. Bell Aerospace Co. Div. of Textron*, 416 U.S. 267, 294 (1974). But the Court approved NLRB's use of adjudication rather than rulemaking because, through NLRB's *formal* adjudicative process, "[t]hose most immediately affected, the buyers and the company in the particular case, are accorded a full opportunity to be heard before the Board makes its determination." *Id.* at 295. The NLRB's adjudicatory process (at least theoretically) allows for "mature and fair consideration of the issues," including through formal hearings and live testimony. *See* 29 U.S.C. § 160.

Contrast NLRB's formal adjudication with the paltry procedure FDA offered to ENDS manufacturers here. Manufacturers were not informed of the comparative-efficacy rule before they submitted their PMTAs. Manufacturers were given no input into the closed-door development of the comparative efficacy rule. And manufacturers were given no opportunity to cure any deficiency in their PMTAs in light of the comparative efficacy rule. Manufacturers heard about the comparative-efficacy rule only when FDA denied their PMTAs with no ifs, ands, or buts. Thus, while FDA is correct that an agency enjoys discretion to choose between rulemaking and adjudication, the promulgation of a substantive rule through wholly informal adjudication smacks of a "situation[] where the [agency's] reliance on adjudication

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[48] *See generally* Lon L. Fuller and Kenneth I. Winston, *The Forms and Limits of Adjudication*, 92 HARV. L. REV. 353, 362–73 (1978).

would amount to an abuse of discretion." *Bell Aerospace*, 416 U.S. at 294.

Likewise, the D.C. Circuit has distinguished between using informal adjudication to apply existing statutory standards versus advancing substantive rules: In *Neustar*, the petitioner sought review of an FCC Order naming another company to replace the petitioner as the Local Number Portability Administrator, in charge of managing the central database to route ported phone numbers. *Neustar, Inc. v. FCC*, 857 F.3d 886, 888–89 (D.C. Cir. 2017). There, the petitioner argued that FCC had to appoint the new Administrator through notice-and-comment rulemaking rather than informal adjudicatory order. *Id.* at 894. The court disagreed, reasoning that the FCC could proceed via informal adjudication because selecting an Administrator "does not have any of the distinctions of legislative rulemaking." *Id.* at 894. Indeed, picking an Administrator is precisely the kind of polycentric problem related to ever-changing facts that is ill-fitted to formal adjudication.[49] Here, in keeping with *Neustar*, FDA could not promulgate the new evidentiary burden of the comparative efficacy rule via informal adjudication.

III.

Applying the existing and undisturbed law of *R.J. Renyolds* within the self-confessed carveouts of the Supreme Court in *Wages* and this court in *VDX Distro*, we hold that FDA's comparative efficacy standard amounts to a substantive rule, and that its adoption through informal adjudication contravenes the APA's notice-and-comment rulemaking requirement. Notice-and-comment rulemaking promotes reasoned decisionmaking, such that good procedure is generally—though not always—associated with good policy.

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[49] Fuller & Winston, *supra* note 48, at 394–404.

The petitions for review are GRANTED, the order is VACATED, and these matters are REMANDED for appropriate proceedings. We express no view on what actions FDA or the petitioners should take on remand.