United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
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August 18, 2026
Lyle W. Cayce
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No. 25-40137

R J Reynolds Tobacco Company; Santa Fe Natural Tobacco Company, Incorporated; ITG Brands LLC; Liggett Group LLC; Neocom, Incorporated; Rangila Enterprises, Incorporated; Rangila LLC; Sahil Ismail, Incorporated; Is Like You, Incorporated,

Plaintiffs—Appellees,

versus

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

Defendants—Appellants.

Appeal from the United States District Court
for the Eastern District of Texas
USDC No. 6:20-CV-176

Before Southwick, Willett, and Ho[*], *Circuit Judges*.

Don R. Willett, *Circuit Judge*:

[*] Judge Ho joins all but Part III.C.1–2.

When Congress legislates in broad strokes, constitutional trouble sometimes follows. This case presents the opposite problem: Congress legislated with precision, and an agency treated that precision as optional. In the Family Smoking Prevention and Tobacco Control Act (TCA), Congress provided a detailed framework with nine prescribed warning statements that must appear on cigarette packages and advertising, while granting the Food and Drug Administration (FDA) only limited, conditional authority to adjust it. The FDA's rule, however, requires the display of eleven warnings, prompting multiple cigarette manufacturers and retailers (Plaintiffs) to challenge it.

At this preliminary stage, the statutory text points one way: the FDA may require the nine warnings Congress prescribed—no more. The district court agreed and temporarily postponed the Rule's effective date after finding that Plaintiffs had shown a substantial likelihood of success on their claim that the FDA exceeded its statutory authority. Because that interim relief was no abuse of discretion, we AFFIRM.

I

This appeal sits against an intricate statutory scheme, a long regulatory history, and a parallel case in another circuit.

A

After decades of federal regulation of cigarette labeling and advertising,[1] Congress enacted the Family Smoking Prevention and Tobacco Control Act (TCA) in 2009.[2] The TCA amended the Federal Cigarette

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[1] *See R.J. Reynolds Tobacco Co. v. FDA*, 96 F.4th 863, 868–74 (5th Cir. 2024) (detailing the lengthy history of such regulation).

[2] Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as amended in scattered sections of Titles 15 and 21). Tobacco companies quickly challenged the TCA's

Labeling and Advertising Act (FCLAA)[3] and transferred primary regulatory authority over tobacco products to the FDA.[4] Two provisions of the TCA—§ 201(a) and § 201(b)—were codified at 15 U.S.C. § 1333(d). To avoid confusion, we adopt the same nomenclature as the parties and the district court: § 1333(d)[1] and § 1333(d)[2].

Relevant here, the TCA made it "unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution" cigarettes if the package "fails to bear . . . one of the following labels[.]"[5] The statute then enumerates nine warning labels addressing specific health risks associated with smoking:

- WARNING: Cigarettes are addictive.
- WARNING: Tobacco smoke can harm your children.
- WARNING: Cigarettes cause fatal lung disease.
- WARNING: Cigarettes cause cancer.
- WARNING: Cigarettes cause strokes and heart disease.
- WARNING: Smoking during pregnancy can harm your baby.
- WARNING: Smoking can kill you.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

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constitutionality, but the Sixth Circuit upheld it in 2012. *See Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 569 (6th Cir. 2012) (controlling opinion by STRANCH, J.).

[3] 15 U.S.C. §§ 1331 *et seq.*

[4] *Id.* § 1333(d)[1].

[5] *Id.* § 1333(a)(1).

- WARNING: Quitting smoking now greatly reduces serious risks to your health.[6]

Congress further directed the FDA to "issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1)."[7] These text-and-graphic pairings must appear on the top 50 percent of the front and rear panels of cigarette packages and at least 20 percent of cigarette advertisements.[8] The warning statements must also comply with detailed placement, rotation, and formatting requirements.[9]

Despite the TCA's intricate specifications, it grants the FDA modest authority to adjust the warnings in two limited ways. First, in § 1333(d)[1], the FDA may visually "adjust the type size, text and format of the label statements . . . so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area."[10] Second, under § 1333(d)[2], the FDA may "adjust the format, type size, color graphics, and text of any of the label requirements" or "establish the format, type size, and text of any other disclosures required under the Food, Drug, and Cosmetic Act [(FDCA)] . . . if the [FDA] finds that such

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[6] *Id.*

[7] *Id.* § 1333(d)[1].

[8] *Id.* § 1333(a)(2), (b)(2).

[9] *Id.*

[10] *Id.* § 1333(d)[1]. The FDA initially acknowledged the modest nature of its authority to "adjust the text" in (d)[1], explaining that it was limited to "changes that go to the visual presentation of cigarette warnings," such as "placement, typography, clarity, conspicuousness, and legibility." *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15,638, 15,642 (Mar. 18, 2020).

a change would promote greater public understanding of the risks associated with the use of tobacco products."[11]

The TCA also imposes marketing requirements to ensure that the warning statements are evenly displayed on cigarette packages. Manufacturers must "randomly display[]" "[t]he label statements specified in subsection (a)(1) . . . in as equal a number of times as possible" annually.[12] For advertisements, manufacturers must likewise "rotate[] quarterly in alternating sequence" the specified "label statements."[13]

The TCA amended the FCLAA's preemption provision, 15 U.S.C. § 1334. Section 1334(a) originally provided that "no statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package."[14] It now opens with the phrase, "[e]xcept to the extent [the FDA] requires additional or different statements on any cigarette package" pursuant to the TCA or certain provisions of the FDCA.[15]

B

The FDA first tried to implement the TCA's graphic-warning mandate in 2011.[16] Aiming to "reduc[e] the number of Americans . . . who

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[11] 15 U.S.C. § 1333(d)[2]. While the FDA considers this subsection as supplying "broader authority" to make adjustments, its own description of the additional authority notably excludes any mention of increasing the number of warnings. 85 Fed. Reg. at 15,642.

[12] 15 U.S.C. § 1333(c)(1).

[13] *Id.* § 1333(c)(2).

[14] *Id.* § 1334(a) (2009).

[15] *Id.* § 1334(a) (2026).

[16] *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36,628 (June 22, 2011).

use cigarettes," the 2011 rule required cigarette packaging and advertisements to bear one of nine graphic images corresponding to the nine statutory warning statements.[17] The 2011 rule also required a prominent "1-800-QUIT-NOW" message alongside those text-and-image pairings to encourage consumers to contact a smoking-cessation hotline.[18] Before the 2011 rule could take effect, the D.C. Circuit vacated it on First Amendment grounds, holding that the FDA had not demonstrated that the compelled graphics would directly advance its asserted interest in reducing smoking rates.[19]

After the 2011 rule was vacated, the FDA began a new rulemaking process. On August 16, 2019—following a delay of seven-and-a-half years—the FDA again issued a proposed graphic-warnings rule.[20] The proposal followed significant testing, including three qualitative studies[21] and two quantitative studies.[22] After receiving extensive public comments, the FDA promulgated the final rule at issue here (Rule).[23] Unlike in 2011, the FDA emphasized that "increased smoking cessation and decreased initiation are

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[17] *Id.* at 36,628–29.

[18] *Id.* at 36,681.

[19] *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1219, 1222 (D.C. Cir. 2012), *overruled by Am. Meat Inst. v. USDA*, 760 F.3d 18, 21–23 (D.C. Cir. 2014) (en banc) (overruling on the point that *Zauderer* review applies to "factual and uncontroversial" compelled disclosures that serve government interests other than preventing consumer deception).

[20] *Required Warnings for Cigarette Packages and Advertisements*, 84 Fed. Reg. 42,754 (Aug. 16, 2019).

[21] *Id.* at 42,765–72, 42,777–78; 85 Fed. Reg. at 15,645, 15,648–52.

[22] 85 Fed. Reg. at 15,651. The FDA, however, stated that it did not rely on qualitative studies. *Id.*

[23] *Id.* at 15,638.

not the purpose[s] of this rule."[24] Its stated goal, instead, was to "promote greater public understanding of the negative health consequences of cigarette smoking."[25]

The Rule broke from its predecessor in another, more consequential way: it discarded all but two of Congress's nine statutory warnings and substituted statements of the FDA's own drafting.[26] As a result, the Rule requires cigarette manufacturers and retailers to display a rotating total of eleven warning statements—rather than the nine enumerated in § 1333(a)(1)—each paired with a graphic image depicting a smoking-related health harm.[27] Those pairings comprise the following graphic labels:

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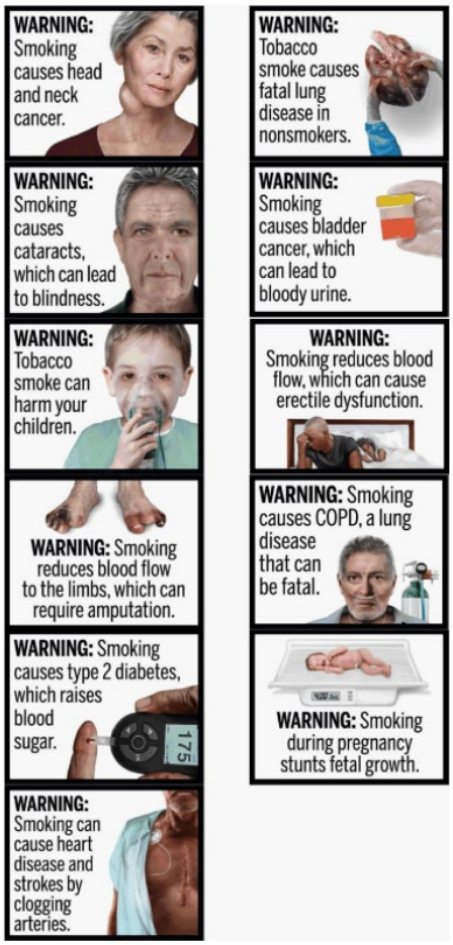
[24] *Id.* at 15,650; *see also id.* at 15,660, 15,665 (providing other purposes).

[25] *Id.* at 15,640.

[26] *Id.* at 15,685, 15,708–09.

[27] *Id.* at 15,709.



C

Immediately following issuance of the Rule, Plaintiffs filed this action in the Eastern District of Texas. Plaintiffs primarily challenged the Rule under the First Amendment and Administrative Procedure Act (APA). The district court granted summary judgment to Plaintiffs and enjoined enforcement of the Rule based on the First Amendment claim without addressing the APA claims.[28]

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[28] *R.J. Reynolds Tobacco Co. v. FDA*, No. 6:20-cv-00176, 2022 WL 17489170, at *21 (E.D. Tex. Dec. 7, 2022), *rev'd*, 96 F.4th 863 (5th Cir. 2024).

The FDA appealed, and we reversed, holding that the Rule did not violate the First Amendment and remanding for consideration of Plaintiffs' APA claims in the first instance.[29] After we denied en banc review[30] and the Supreme Court denied certiorari,[31] Plaintiffs moved for an interim postponement of the Rule's effective date under § 705 of the APA. The FDA opposed the motion and moved for summary judgment.

Following a hearing, the district court granted Plaintiffs' motion for interim relief. The court concluded that Plaintiffs established a substantial likelihood of success on two of their APA claims: (1) the FDA lacks statutory authority to increase the number of required warnings from nine to eleven, and (2) the FDA lacks statutory authority to substantively rewrite the required warnings. The court also found that irreparable harm would occur absent interim relief, emphasizing substantial compliance costs and the impossibility of recouping those costs if the Rule were later invalidated. Because "the equities strongly tilt in [P]laintiffs' favor," the court postponed the Rule's effective date. The FDA appealed.

While this appeal was pending, a separate challenge to the same Rule was filed in the Southern District of Georgia. In *Philip Morris USA Inc. v. FDA*, a Georgia district court granted summary judgment to different plaintiffs (also tobacco companies) and vacated the Rule in its entirety.[32] The Georgia court held that the FDA violated the APA's notice-and-comment requirements by failing to disclose key underlying data during the rulemaking

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[29] *R.J. Reynolds*, 96 F.4th at 887 n.77, 888.

[30] *R.J. Reynolds Tobacco Co. v. FDA*, No. 23-40076, ECF No. 162 (5th Cir. May 21, 2024).

[31] *R.J. Reynolds Tobacco Co. v. FDA*, 145 S. Ct. 592 (2024) (mem.).

[32] 801 F. Supp. 3d 1353, 1367–68, 1381 (S.D. Ga. 2025).

process, thereby depriving the public of a meaningful opportunity to participate.[33] The court justified its vacatur of the Rule because it was promulgated "without observance of procedure required by law."[34] Notably, however, that court rejected all other challenges to the FDA's authority and decisionmaking.[35] This decision is now pending before the Eleventh Circuit.[36] As matters stand, two orders affect the Rule: the Texas district court's postponement of its effective date and the Georgia district court's vacatur. The two rest on independent grounds—ours on the statute's numerical limit, the Georgia court's on a procedural defect in the rulemaking—so neither leans on the other's reasoning to stand.

II

The APA requires courts to "hold unlawful and set aside agency action" found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[37] While a court evaluates the lawfulness of agency action, it "may issue all necessary and appropriate process to postpone the effective date of an agency action."[38]

"Motions to stay [or postpone] agency action pursuant to [section 705] are reviewed under the same standards used to evaluate requests for

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[33] *Id.* at 1375–80.

[34] *Id.* at 1381; *see also id.* at 1380–81 (rejecting remand without vacatur).

[35] *Id.* at 1365–75.

[36] Notice of Appeal, *Philip Morris USA Inc. v. FDA*, No. 25-13863 (11th Cir. Oct. 27, 2025).

[37] 5 U.S.C. § 706(2)(c).

[38] *Id.* § 705.

interim injunctive relief."[39] A movant must show (1) a likelihood of success on the merits; (2) a substantial threat of irreparable harm; (3) that the balance of hardships weighs in the movant's favor; and (4) that the interim relief will not disserve the public interest.[40] The last two factors merge when the government is a party.[41] We review the grant of interim relief for abuse of discretion.[42] In doing so, we review the district court's legal conclusions *de novo* and factual findings for clear error.[43]

III

We affirm for three related reasons. First, the district court did not abuse its discretion in concluding that Plaintiffs are substantially likely to succeed on their claim that § 1333(a)(1) establishes a closed set of nine warning statements. Second, the remaining equitable factors favor preserving the status quo while the district court resolves the merits. Third, the district court did not exceed its remedial authority in postponing the Rule's effective date.

A

The question before us is narrow. It is not whether Plaintiffs have won on the merits, but whether the district court abused its discretion in concluding that Plaintiffs were substantially likely to win on their claim that

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[39] *Affinity Healthcare Servs. v. Sebelius*, 720 F. Supp. 2d 12, 15 n.4 (D.D.C. 2010); *see also Texas v. EPA*, 829 F.3d 405, 435 (5th Cir. 2016) (applying the preliminary injunction factors).

[40] *Rest. L. Ctr. v. U.S. Dep't of Lab.*, 66 F.4th 593, 597 (5th Cir. 2023).

[41] *Nken v. Holder*, 556 U.S. 418, 435 (2009).

[42] *Texas v. United States*, 809 F.3d 134, 150 (5th Cir. 2015).

[43] *Speaks v. Kruse*, 445 F.3d 396, 399 (5th Cir. 2006); *Anibowei v. Morgan*, 70 F.4th 898, 902 (5th Cir. 2023).

the FDA overstepped its statutory authority. The TCA supplies a carefully calibrated framework with nine prescribed warning statements that must appear on cigarette packages and advertising, while granting the FDA only limited and conditional authority to adjust that regime. The Rule departs from this framework by requiring eleven warnings instead of nine.[44] Because Plaintiffs made the requisite showing that the FDA likely lacks authority to increase the number of warning statements, the district court did not abuse its discretion in finding the first interim-relief factor satisfied.[45]

1

As always, we begin with the statutory text[46]—"the alpha and the omega of the interpretive process."[47] The operative provision here, § 1333(a)(1), makes it unlawful to sell or distribute cigarettes whose package "fails to bear, in accordance with the requirements of this section, *one of the following labels*."[48] It then immediately prescribes the labels to use.[49] Rarely is statutory text this crisp. The command requires a package to bear "one of the following labels," and then lists nine of them—yet the FDA would read nine as eleven. Nine is not a placeholder for eleven.

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[44] Although Plaintiffs raised additional APA claims, we need not address them to uphold the district court's postponement of the Rule. *See Mock v. Garland*, 75 F.4th 563, 578 (5th Cir. 2023) (concluding that plaintiffs established a substantial likelihood of success on one claim while declining to address the other claims). We express no view on their merits.

[45] *See Kruse*, 445 F.3d at 399.

[46] *Duncan v. Walker,* 533 U.S. 167, 172 (2001) ("We begin, as always, with the language of the statute.").

[47] *United States v. Maturino*, 887 F.3d 716, 723 (5th Cir. 2018).

[48] 15 U.S.C. § 1333(a)(1) (emphasis added).

[49] *Id.*

"One of the following labels," trailed by nine specific labels, reads as exclusive—a closed set of exactly those nine.[50] No phrase like "including" or "such as" signals an open list; nothing marks the nine as illustrative or default; and nothing hints that the FDA may add to them. The better reading is the plain one: Congress specified nine warnings—and only nine—that the FDA may require.

Consider a familiar analogy: If a restaurant menu says a customer may choose "one of the following sides" followed by a list of nine choices, no ordinary diner reads that as license to order an unlisted tenth. Trendy eateries may keep a secret menu; the United States Code does not. Congress supplied a list of nine labels and required sellers and manufacturers to use one of them on rotation. But the Rule departs from that command. It instead requires packages and advertisements to rotate among eleven warnings—two more than Congress listed. A package bearing one of the extra labels is thus not bearing "one of the following labels" Congress enumerated. That straightforward reading suffices here.

Even if the ordinary meaning were unclear, the surrounding statutory structure reinforces our interpretation. The statute repeatedly refers back to the label statements specified in subsection (a)(1). For instance, subsections (a)(2) and (b)(2) impose detailed typographical, placement, and formatting requirements for "each label statement required by paragraph (1)."[51] Subsection (b)(1) similarly requires advertisements to display "one of the labels specified in subsection (a)."[52] Throughout these provisions, Congress

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[50] *See* Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 132 (2012) (discussing the presumption of nonexclusive "include").

[51] 15 U.S.C. § 1333(a)(2), (b)(2).

[52] *Id.* § 1333(b)(1).

cross-references the warnings already "specified" in subsection (a)(1), confirming that the nine statements anchor the entire labeling regime.

The TCA's rotation-and-display requirements point in the same direction. Section 1333(c) requires manufacturers to randomly display and rotate "[t]he label statements specified in subsection (a)(1)" and to ensure that "all of the labels required under this section" are displayed at the same time across different products and locations.[53] These provisions assume a fixed and finite set of warnings. Reading them to permit a "default" set of warnings, as the FDA urges, would disrupt the coherence of the rotation scheme Congress enacted.

Despite this fixed set of nine, the Rule compels the rotating use of one of "*11* required warnings."[54] The FDA contends that adding two extra labels is permissible because the statute nowhere says "exactly nine." But Congress need not use the word "exactly" to prescribe a finite set; it may do so through semantic devices and negative implication.[55] When (a)(1) directs a regulated entity to choose "one of the following" and then provides an enumerated list with no textual indicators that the list is merely exemplary or suggestive, the phrase should be read as exhaustive.[56] That reading is reinforced by the statute's command that it is "unlawful" for a package or

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[53] *Id.* § 1333(c)(1), (c)(3)(B).

[54] 85 Fed. Reg. at 15,670 (emphasis added).

[55] *See* SCALIA & GARNER, *supra*, at 107–11 (negative-implication canon); *id.* at 233 (discussing ways statutory language excludes the negative-implication canon); *see also id.* at 132–33, 210, 227 (explaining that "to include" introduces examples rather than an exhaustive list).

[56] *See Henson v. Santander Consumer USA Inc.*, 582 U.S. 79, 83–84 (2017) (recognizing that courts interpret statutory phrases based on ordinary meaning).

advertisement not to use one of the specifically enumerated labels.[57] By imposing additional warnings beyond the list of nine, some cigarette packages and advertisements will necessarily be unlawful by failing to carry one of the required nine. The district court thus acted well within its discretion in refusing to treat Congress's nine warnings as a mere starting point.

2

Because the FDA cannot identify any provision that expressly authorizes more than nine warning statements, it then relies on § 1333(d)[2], which permits the Secretary to "adjust the format, type size, color graphics, and text of any of the label requirements" upon making a specified finding about improved public understanding.[58] According to the FDA, because § 1333(d)[2] authorizes it to "adjust the . . . text," this authority implicitly includes the power to add new warnings or eliminate old ones. But that reading loads more onto "adjust" than the word can carry, and it ignores the context around it. To adjust is to modify something that already exists—not to conjure something new.[59] It does not naturally encompass the broad power to create additional items—such as new warning statements—or to increase the number Congress selected. Had Congress intended to authorize the FDA to expand the warning set, it could have said so directly or otherwise indicated that the list was not exhaustive.[60] Congress did neither. At a

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[57] 15 U.S.C. § 1333(a)(1).

[58] *Id.* § 1333(d)[2].

[59] *Adjust*, COLLINS ENGLISH DICTIONARY (7th ed. 2005); *see also Adjust*, THE NEW OXFORD AMERICAN DICTIONARY (2d ed. 2005) ("[A]lter or move (something) slightly in order to achieve the desired fit, appearance, or result"); *Adjust*, CAMBRIDGE DICTIONARY OF AMERICAN ENGLISH (2d ed. 2008) ("[T]o change something slightly to make it fit, work better, or be more suitable").

[60] *See* SCALIA & GARNER, *supra*, at 132–33, 210, 227.

minimum, the district court did not abuse its discretion in concluding that "adjust" is too modest a verb to bear the weight the FDA places on it.

Situating § 1333(d)[2] within the broader statutory framework is further instructive. Section 1333(d)[2] presupposes the existence of the prescribed "label requirements" and permits the FDA to adjust specified attributes—format, type size, color graphics, and text. Nothing in that language suggests Congress broadly empowered the FDA to increase the number of warning statements beyond those listed in § 1333(a)(1). Indeed, the word "number" (or a synonym) does not even appear in the provisions discussing the FDA's adjustment authority. If Congress intended to confer such authority, it could have done so expressly, as it has in other regulatory schemes.[61] Because Congress did not do so here, the district court did not abuse its discretion when it concluded that expanding the number of warnings demonstrates that the FDA exceeded its authority.

3

The district court rested on § 1333 alone. The FDA counters that a different provision—the FCLAA's preemption clause, § 1334—hands it broad power to change the warnings' number and content. That argument fares no better. Section 1334(a) is a preemption provision designed to prohibit state and local governments from imposing additional smoking-and-health statements beyond those required by federal law.[62] It is not an independent

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[61] *See U.S. ex rel. Polansky v. Exec. Health Res. Inc.*, 599 U.S. 419, 436 (2023) (explaining that courts do not infer sweeping authority from silence); *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 668–69 (2007) (same); *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000) (SCALIA, J.) ("Congress says in a statute what it means and means in a statute what it says there.").

[62] 15 U.S.C. § 1334 (titled "Preemption"); *id.* § 1334(a) ("[N]o statement relating to smoking and health, other than the statement required by section 1333 of this title, shall

grant of regulatory authority. Its opening clause—permitting "additional or different statements" to the extent the Secretary requires them pursuant to federal law[63]—presupposes valid authority conferred elsewhere; it does not create that authority itself.

Reading § 1334(a) as an independent grant of power would invert the statute's structure and render § 1333(d)[2]'s limitations largely superfluous.[64] Properly read, § 1334(a) does not expand the FDA's authority to change the number of warnings. It merely clarifies that, when the FDA lawfully acts under another provision, such as § 1333, its actions are not preempted. That narrower reading preserves the statute's structure: § 1333 supplies the substantive authority and its limits; § 1334 ensures that otherwise authorized federal warnings are not preempted.

The text confirms as much at every turn. Section 1334 is titled "Preemption," and it addresses which additional warning statements may be required, and by whom.[65] Subsection (a) is framed in prohibitory terms: "no statement relating to smoking and health . . . shall be required."[66] It is also subject to express exceptions: "to the extent the Secretary requires" such statements and "pursuant to" the TCA and the related FDCA provisions.[67]

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be required on any cigarette package."); *id.* § 1334(b) (prohibiting state-law prohibitions or requirements).

[63] *Id.* § 1334(a).

[64] *See* SCALIA & GARNER, *supra*, at 174–79 (canon against surplusage).

[65] 15 U.S.C. § 1334; *see also* SCALIA & GARNER, *supra*, at 222 (title-and-headings canon).

[66] 15 U.S.C. § 1334(a).

[67] Section 1334(a) expressly creates a preemption exception only for "additional or different statements" required "by a regulation, by an order, by a standard, by an authorization to market a product, or by a condition of marketing a product, pursuant to [the TCA]" *or* "as required under section 387c(a)(2) . . . or section 387t(a) of [the

In other words, § 1334's title, structure, and prohibitory phrasing all point the same way. The provision begins from a baseline of no additional statements and then carves out statements otherwise authorized by federal law.

Section 1334's language must also be harmonized with § 1333's operative scheme. The "except to the extent" clause does not supply an independent font of authority to impose any warning regime the FDA chooses. Rather, it clarifies the preemptive effect of federal law when the FDA acts pursuant to the delegations contained in the TCA (including § 1333(d)[2]). On that reading, the FDA's authority to require "additional or different statements" remains bounded by § 1333(d)[2]'s conditions and by the structure and text of § 1333(a). This construction preserves coherence across the TCA's integrated amendments to §§ 1333 and 1334 without converting a preemption clause into a backdoor delegation that nullifies the statute's carefully drawn limits.

The "pursuant to" phrase is likewise informative. Congress did not write an open-ended authorization that the agency "may require" any additional statements. To the contrary, it wrote a preemption provision recognizing that additional statements may be required when the agency acts under the substantive authority conferred elsewhere in federal law. Along with the "except to the extent" phrase, this language presupposes a valid FDA action elsewhere. The amendment's most natural function, then, is to ensure that the FCLAA's preemption rule does not bar the agency from requiring

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FDCA]"—a different federal statute. *Id.* Section 387c(a)(2) of the FDCA concerns statements about modified-risk claims or other marketing terms that the FDA can require. 21 U.S.C. § 387c(a)(2). And § 387t(a) concerns origin-labeling statements, such as "sale only allowed in the United States." *Id.* § 387t(a)(1). Both are "additional or different statements" that may appear on cigarette packaging or advertising *in addition to* the TCA's nine prescribed warnings.

additional or different statements when it acts under the TCA's newly granted regulatory powers.

The FDA's broadest reading founders on a basic canon: no construction should render a neighboring provision inoperative.[68] Read § 1334(a) as an independent license to require any number of warnings, and § 1333(d)[2]'s carefully drawn predicate—that the FDA may adjust the labels only upon finding that a change would "promote greater public understanding"—collapses into surplusage, a hoop the agency could sidestep at will. Congress does not bury a sweeping delegation in a preemption clause and then erect detailed conditions next door for the agency to vault over. The FDA presses the point all the same, urging that "additional or different statements" in § 1334(a) frees it from § 1333's limits altogether—and at least one court has agreed. The Southern District of Georgia read the phrase as an "affirmative statutory authorization," concluding that "changing the number of warnings is authorized by section 1334."[69] But that reading works only by looking past the surrounding text and draining § 1333(d)[2] of force. Congress did not say the agency may require "additional or different statements" whenever it wishes; it tied any adjustment of the label requirements—"format" and "text" included—to a prerequisite finding that the change would "promote greater public understanding."[70] A construction that lets the agency slip that finding cannot be the better one. In any event, the competing reading does not undermine the district court's conclusion that Plaintiffs are substantially likely to succeed on their narrower reading of the statute.

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[68] *See* SCALIA & GARNER, *supra*, at 174–79 (canon against surplusage).

[69] *Philip Morris*, 801 F. Supp. 3d at 1367.

[70] 15 U.S.C. § 1333(d)[2].

Finally, standard interpretive practice disfavors a reading that allows a general clause to swallow a specific one.[71] With this in mind, the more coherent interpretation is that § 1334(a)'s carveout recognizes that additional or different statements may be required elsewhere, but *only* "to the extent" the agency does so as required by the two FDCA provisions or pursuant to the TCA's substantive grants—which include § 1333(d)[2]'s limits and predicates.[72] Under this view, § 1334(a) and § 1333(d)[2] fit together harmoniously,[73] with § 1333(d)[2] defining when and how the FDA may alter warning content and § 1334(a) ensuring that FCLAA preemption does not forbid otherwise authorized warnings. The same cannot be said for the FDA's interpretation.

For these reasons, the far better reading treats § 1334(a) as a narrow preemption carveout tied to valid exercises of authority under § 1333 or elsewhere in federal law—not as an independent enlargement of the FDA's authority. Treating § 1334(a) as a freestanding delegation of the power to increase the number of warnings would let a preemption clause override the detailed limits Congress placed in § 1333's affirmative delegation. Although the district court did not address § 1334(a), the questions raised by the amended preemption provision do not undermine its conclusion that the

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[71] *See RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) ("[I]t is a commonplace of statutory construction that the specific governs the general." (quoting *Morales v. Trans World Airlines, Inc.,* 504 U.S. 374, 384 (1992)); *HCSC-Laundry v. United States*, 450 U.S. 1, 6 (1981) (per curiam) (explaining that the specific governs the general, "particularly when the two are interrelated and closely positioned, both in fact being parts of [the same statutory scheme]"); *see also* SCALIA & GARNER, *supra*, at 183–88 ("If there is a conflict between a general provision and a specific provision, the specific provision prevails.").

[72] When referring to authority conferred elsewhere, we gesture not to some undefined future statute but instead to § 1334(a)'s specific referents.

[73] *See* SCALIA & GARNER, *supra*, at 180–82 (harmonious-reading canon).

FDA exceeded the authority Congress conferred when it expanded the number of warnings from nine to eleven. At the very least, § 1334(a) does not so clearly enlarge the FDA's authority as to make the district court's contrary reading an abuse of discretion.

* * *

In sum, Plaintiffs established a substantial likelihood of success on the merits of their claim that the Rule contravenes § 1333(a)(1) by mandating more than nine warnings. Congress pursued its public-health aims with specificity and with limits. We must honor both, whether or not some other reading might serve the statute's purpose more fully.[74] Plaintiffs demonstrated a substantial likelihood of success on the merits of at least one claim, and we conclude that the district court did not abuse its discretion in postponing the Rule's effective date. Because interim relief may rest on a substantial likelihood of success on even one claim, we need not address Plaintiffs' remaining theories.

B

Most of the district court's analysis focused on whether Plaintiffs raised a substantial likelihood of success on the merits of their APA claims. But the district court also noted that the remaining interim-relief factors weigh heavily in Plaintiffs' favor. Although the district court addressed those factors briefly, the record adequately supports its conclusion that they favor interim relief.[75]

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[74] *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 392 (2024) (holding "that agency interpretations of statutes—like agency interpretations of the Constitution—are *not* entitled to deference"); *West Virginia v. EPA*, 597 U.S. 697, 723–24 (2022) (recognizing that agencies may not rewrite statutes in the name of policy goals).

[75] *ICEE Distributors, Inc. v. J&J Snack Foods Corp.*, 325 F.3d 586, 594 (5th Cir. 2003) (explaining that, in "the absence of findings" in support of the injunction, "[i]t calls

The district court reasonably found that, without interim relief, the Rule's looming effective date would inflict irreparable harm. In reaching this conclusion, the court credited Plaintiffs' evidence that manufacturers and retailers will incur substantial compliance costs that cannot be recovered if Plaintiffs ultimately prevail. Those costs include redesigning packaging and advertising, retooling printing and distribution systems, and coordinating supply-chain changes across nationwide markets. Because sovereign immunity protects federal agencies like the FDA, any such expenditures are unrecoverable.[76] That is enough. Unrecoverable compliance costs imposed by allegedly unlawful agency action ordinarily qualify as irreparable harm.

The district court's finding also accords with settled precedent recognizing that unrecoverable compliance costs imposed by allegedly unlawful agency action constitute irreparable injury.[77] The FDA failed to meaningfully dispute that Plaintiffs would incur these costs before final judgment. Reviewing the uncontested record evidence reveals that compliance planning must begin well in advance of the Rule's effective date and that manufacturers cannot delay action without risking regulatory noncompliance. Irreparable harm occurs where a plaintiff faces a Hobson's choice between violating a regulation or absorbing unrecoverable costs under

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on [the appellate court] to 'examin[e] the record to determine if . . . sufficient evidence supports the issuance of injunctive relief'" (quoting *Sampson v. Murray*, 415 U.S. 61, 86 n.58 (1974))).

[76] *See Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130, 1142 (5th Cir. 2021) (recognizing that irreparable harm is generally satisfied when costs are unrecoverable because of the government defendant's sovereign immunity from monetary damages).

[77] *See, e.g.*, *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 765 (2021) (per curiam); *Rest. L. Ctr.*, 66 F.4th at 597; *see also Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220–21 (1994) (SCALIA, J., concurring in part and concurring in the judgment).

a potentially unlawful regulation.[78] The district court did not clearly err in so finding here.

2

The district court also reasonably concluded that the balance of equities tips decisively in Plaintiffs' favor. On one side of the ledger are the concrete, imminent, and unrecoverable costs that Plaintiffs would incur absent interim relief. On the other, the FDA identified no comparable hardship arising from a temporary postponement of the Rule's effective date. With no comparable countervailing interest, the district court did not abuse its discretion in concluding that the equities favor Plaintiffs.

That conclusion is reinforced by the Rule's stated objective. The FDA expressly disclaimed any immediate behavioral aim and instead framed the Rule as promoting public understanding of smoking risks "in the abstract,"[79] not producing a measurable reduction in smoking rates or other near-term public-health outcomes.[80] A temporary postponement pending judicial review therefore does not meaningfully frustrate any time-sensitive regulatory goal.

Perhaps recognizing the need to identify such an interest, the FDA contends in its reply brief that postponing the Rule subverts its important mandate to counter public misunderstandings about smoking risks. That overstates matters. The Surgeon General's textual warnings have appeared

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[78] *See Texas v. EPA*, 829 F.3d at 433 ("[C]omplying with a regulation later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs." (citation omitted)); *id.* (recognizing that such compliances "almost *always* produces the irreparable harm of nonrecoverable costs").

[79] 85 Fed. Reg. at 15,657.

[80] *Id.* at 15,655.

on cigarette packaging for decades, and they remain in force throughout this litigation.[81] Additionally, the Rule's postponement merely preserves the longstanding status quo rather than creating a regulatory vacuum. No text-and-graphic warning has taken effect since the TCA's enactment in 2009. Against this seventeen-year history, preserving that status quo for a bit longer while the district court resolves substantial statutory questions does not meaningfully impair the TCA's operation.

For largely the same reasons, the district court did not abuse its discretion in finding that interim relief is in the public's interest. The public is not served by a court enforcing a rule that may exceed an agency's statutory authority.[82] Rather, the public has an interest in agencies acting within the bounds set by Congress and in avoiding regulatory disruption caused by rules later found unlawful.[83] That interest is especially weighty where, as here, the challenged regulation would impose significant costs across a nationwide industry before judicial review is complete. Nor is there evidence that a temporary delay will cause concrete public-health harm while existing warnings remain in place, especially given that the Rule's only goal is achieving more information in the abstract, not achieving a real-world change in behavior. Balancing these considerations, the district court reasonably concluded that the public interest does not outweigh the irreparable harm to Plaintiffs.

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[81] *See R.J. Reynolds*, 96 F.4th at 868 (surveying the evolution of cigarette labeling requirements).

[82] *State v. Biden*, 10 F.4th 538, 560 (5th Cir. 2021) ("[T]here is generally no public interest in the perpetuation of unlawful agency action." (quoting *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016)).

[83] *BST Holdings, L.L.C. v. OSHA*, 17 F.4th 604, 618 (5th Cir. 2021) (recognizing that an injunction preventing an unlawful agency action does not disserve the public interest).

* * *

In sum, the district court considered each of the remaining factors and reasonably concluded that there is a "strong tilt of the equitable factors in [P]laintiffs' favor." That tilt reflects both the existence of "costs that cannot be reimbursed" and the postponement's limited effect, if any, on the public interest when the Rule's goal is informative rather than behavioral.[84] Because the equities weigh heavily in Plaintiffs' favor, the district court did not abuse its discretion in concluding that Plaintiffs satisfied the remaining interim-relief factors.

C

The FDA's last line of defense is the remedy. It says the district court should have confirmed the postponement to Plaintiffs alone, or severed the Rule's invalid parts and let the rest take effect. We disagree.

1

The FDA first argues that any relief should be limited to Plaintiffs alone. But that contention is incompatible with the APA's text. Section 705 authorizes a "reviewing court" to "postpone the effective date of an *agency action* . . . to preserve status or rights pending conclusion of the review proceedings."[85] Congress framed the remedy in action-centric rather than

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[84] The FDA's opening brief does not challenge this conclusion that the remaining factors also weigh in Plaintiffs' favor. Even if we credit the FDA's post-hoc challenge in its reply brief, that effort amounts to mere disagreement with the district court's weighing of the remaining factors rather than showing that the court applied an incorrect legal standard or relied on clearly erroneous factual findings.

[85] 5 U.S.C. § 705 (emphasis added).

party-centric terms.[86] Recognizing this distinction, we have previously held that § 705 relief is "not party-restricted" and that "limit[ing] any relief to the named parties . . . do[es] not hold water."[87] As a result, a postponement or other interim stay of an agency rule "affects persons in all judicial districts equally," just as vacatur does.[88] Under both the APA's text and our precedent, party-restricted relief is neither authorized nor appropriate here. The district court therefore did not err in declining to postpone the Rule's effective date only as to Plaintiffs.

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[86] *See id.* (authorizing courts to "postpone the effective date of *an agency action*" (emphasis added)); *see also id.* § 706 (authorizing courts to "set aside *agency action*") (emphasis added)).

[87] *Career Colls. & Schs. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024) (citing 5 U.S.C. § 705); *see also In re Clark*, 94 F.4th 502, 512 (5th Cir. 2024) (construing "set aside" in § 706 as having "nationwide effect"); Jonathan Mitchell, *The Writ-of-Erasure Fallacy*, 104 VA. L. REV. 933, 1012–13 (2018) ("Unlike judicial review of statutes, in which courts enter judgments and decrees only against litigants, the APA . . . go[es] further by empowering the judiciary to act directly against the challenged agency action. This statutory power to 'set aside' agency action is more than a mere non-enforcement remedy." (footnote omitted)); Mila Sohoni, *The Power to Vacate a Rule*, 88 GEO. WASH. L. REV. 1121, 1173 (2020) ("The term 'set aside' means invalidation—and an invalid rule may not be applied to anyone." (footnote omitted)). Because "the scope of preliminary relief under Section 705 aligns with the scope of ultimate relief under Section 706," *Career Colls.*, 98 F.4th at 255, it follows, then, that if "[v]acatur is intrinsically universal, because it affects the regulation itself," the same is true for its preliminary counterpart. *See* John Harrison, *Vacatur of Rules Under the Administrative Procedure Act*, 40 YALE J. ON REGUL. 119, 122 (2023).

[88] *In re Clark*, 94 F.4th at 512; *see also Career Colls.*, 98 F.4th at 255 (recognizing that "the scope of preliminary relief under Section 705 aligns with the scope of ultimate relief under Section 706"); *Cargill v. Garland*, 57 F.4th 447, 472 (5th Cir. 2023) (en banc) ("[A]s an initial matter, [§ 706] vacatur of an agency action is the default rule in this Circuit.") (collecting cases).

The FDA next argues that *Trump v. CASA, Inc.*[89] constrains the district court's authority to grant rule-wide relief. Once again, that argument misunderstands the nature of the § 705 remedy. It also overreads *CASA*. The Supreme Court in *CASA* addressed only the scope of equitable injunctions—specifically, when courts may issue broad injunctions extending beyond the parties before them.[90] It did *not* involve either of the APA's remedies.[91] Nor did *CASA* restrict remedies that Congress expressly authorizes by statute.[92] Instead, *CASA*'s reasoning is rooted wholly in equitable principles and therefore does not foreclose the statutory relief granted here.[93]

That said, the district court's remedial language references *both* a preliminary injunction and a § 705 postponement. But this overlap does not require us to disturb the bottom-line relief the district court granted. Best understood, the preliminary injunction implements and reinforces the § 705

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[89] 606 U.S. 831 (2025).

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

[91] *Id.* at 847 n.10 (expressly carving out questions regarding the APA's remedial equivalents).

[92] *Id.* ("Nothing we say today resolves the distinct question whether the Administrative Procedure Act authorizes federal courts to vacate federal agency action."); *see also id.* at 873 (KAVANAUGH, J., concurring) ("Going forward, . . . district courts will grant or deny the functional equivalent of a universal injunction . . . by preliminarily setting aside or declining to set aside an agency rule under the APA.").

[93] *Id.* at 847 (majority opinion) ("Because the universal injunction lacks a historical pedigree, it falls outside the bounds of a federal court's equitable authority[.]" (citations omitted)).

postponement without expanding beyond what § 705 already authorizes.[94] As a result, the injunction is, at most, coextensive with the § 705 postponement and imposes no independent substantive restraints. Even if the injunction's association with a universal postponement is necessarily problematic under *CASA*, the district court justified the remedy's broad scope when it found that party-specific relief would mislead consumers and destabilize the cigarette marketplace. That finding supports rule-wide relief as "necessary to provide complete relief to . . . [P]laintiff[s]," [95] particularly when limiting relief to specific parties would risk creating a patchwork of inconsistent legal regimes. Without this universal scope, certain Plaintiffs will almost certainly suffer direct economic harm if retailers stop stocking and selling *any* noncompliant cigarettes. We therefore conclude that the district court's postponement properly carries a universal scope.[96]

3

Finally, the FDA contends that even if some aspects of the Rule exceed its statutory authority or contain defects, the district court should have severed the invalid portions so that the remainder could take effect. The district court did not err in declining to do so.

To begin, it is not clear that the severability provision even applies. We have previously explained that "the possibility of severance does not preclude preliminary . . . relief." [97] Presumably, that is because it makes little

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[94] Alternatively, the injunction could be viewed as a limited fallback remedy that prevents the FDA from enforcing the Rule against Plaintiffs.

[95] *CASA*, 606 U.S. at 861 (emphasis omitted).

[96] *See BST Holdings*, 17 F.4th at 618; *Career Colls.*, 98 F.4th at 241.

[97] *Space Exploration Techs. Corp. v. NLRB*, 151 F.4th 761, 773 (5th Cir. 2025) ("*SpaceX*").

sense for a severability provision to be invoked at a preliminary stage. The TCA's severability clause states that, "[i]f any provision . . . or the application of any such provision . . . is *held to be invalid*, the remainder . . . shall not be affected and *shall continue to be enforced* to the fullest extent possible."[98] Importantly, the district court's postponement does not actually invalidate any provision of the statute or Rule—it merely delays when the Rule could become effective. As the district court explained, "[i]f the court's final judgment departs from this analysis and ultimately favors [the FDA], the final judgment will specify *the remaining time until the effectiveness* of the [R]ule and the associated [TCA] provisions." Because the Rule has yet to exist in a manner that would allow for any invalidation, the severability provision, by its own terms, does not yet apply.[99] At least for present purposes, that is enough to distinguish this case from one requiring severance after a final holding of invalidity.

Regardless, severance cannot manufacture authority the agency never had.[100] And even if excision were possible, the FDA has never told us which of its eleven warnings would survive it. Courts may not rewrite an agency rule or make policy choices on the agency's behalf.[101] Absent the FDA's input, severability here would amount to judicial policymaking.

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[98] 21 U.S.C. § 387 note (codifying § 5 of the TCA) (emphases added); 85 Fed. Reg. at 15,695; *see also SpaceX*, 151 F.4th at 772 & n.40 (involving a nearly identical severability provision and the absence of any other provision "held to be invalid" (citation omitted)).

[99] *See* 21 U.S.C. § 387 note.

[100] *See George v. McDonough*, 596 U.S. 740, 751 (2022) (emphasizing that "an unauthorized regulation is a 'nullity,'" (quoting *Dixon v. United States*, 381 U.S. 68, 74 (1965)); *see also FG Hemisphere Assocs., LLC v. Republique du Congo*, 455 F.3d 575, 591 (5th Cir. 2006) ("This kind of error cannot be cured by subsequent modification because the order was void *ab initio*.").

[101] *See SEC v. Chenery Corp.*, 318 U.S. 80, 87–88 (1943).

* * *

Reviewing for abuse of discretion, we conclude that the district court did not err in postponing the Rule's effective date.[102] Section 705 authorizes universal relief as to the rule, not just to the parties. *CASA* does not apply to statutory remedies. Even if *CASA* applies to the overlapping injunction, that remedy merely implements the postponement without expanding its scope. And the severability clause is inapplicable and does not bar rule-wide interim relief. Accordingly, we need not address Plaintiffs' alternative request to "restore the status quo by providing for a 15-month compliance period."

IV

Congress sometimes speaks in gauzy generalities. But Congress steered clear of any concerns attendant to doing so in the TCA. And when Congress opts for precision, agencies must respect that choice, not revise it. Precision in legislation leaves no room for improvisation in execution. Because the district court did not abuse its discretion in concluding that Plaintiffs showed a substantial likelihood of success on their claim that the FDA exceeded its statutory authority by requiring more than the nine prescribed labels,[103] and because the equities favor interim relief, we AFFIRM the district court's postponement of the Rule's effective date pending a final decision on the merits.[104]

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[102] *See Career Colls.*, 98 F.4th at 237; *see also BST Holdings*, 17 F.4th at 618–19.

[103] *See Kruse*, 445 F.3d at 399.

[104] *See id.*

United States Court of Appeals

FIFTH CIRCUIT
OFFICE OF THE CLERK

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August 18, 2026

MEMORANDUM TO COUNSEL OR PARTIES LISTED BELOW

Regarding: Fifth Circuit Statement on Petitions for Rehearing or Rehearing En Banc

No. 25-40137 R J Reynolds Tobacco Company v. FDA
USDC No. 6:20-CV-176

Enclosed is a copy of the court's decision. The court has entered judgment under Fed. R. App. P. 36. (However, the opinion may yet contain typographical or printing errors which are subject to correction.)

Fed. R. App. P. 39 through 41, and Fed. R. App. P. 39, 40, and 41 govern costs, rehearings, and mandates. **Fed. R. App. P. 40 require you to attach to your petition for panel rehearing or rehearing en banc an unmarked copy of the court's opinion or order.** Please read carefully the Internal Operating Procedures (IOP's) following Fed. R. App. P. 40 for a discussion of when a rehearing may be appropriate, the legal standards applied and sanctions which may be imposed if you make a nonmeritorious petition for rehearing en banc.

Direct Criminal Appeals. Fed. R. App. P. 41 provides that a motion for a stay of mandate under Fed. R. App. P. 41 will not be granted simply upon request. The petition must set forth good cause for a stay or clearly demonstrate that a substantial question will be presented to the Supreme Court. Otherwise, this court may deny the motion and issue the mandate immediately.

Pro Se Cases. If you were unsuccessful in the district court and/or on appeal, and are considering filing a petition for certiorari in the United States Supreme Court, you do not need to file a motion for stay of mandate under Fed. R. App. P. 41. The issuance of the mandate does not affect the time, or your right, to file with the Supreme Court.

Court Appointed Counsel. Court appointed counsel is responsible for filing petition(s) for rehearing(s) (panel and/or en banc) and writ(s) of certiorari to the U.S. Supreme Court, unless relieved of your obligation by court order. If it is your intention to file a motion to withdraw as counsel, you should notify your client promptly, **and advise them of the time limits for filing for rehearing and certiorari**. Additionally, you MUST confirm that this information was given to your client, within the body of your motion to withdraw as counsel.

The judgment entered provides that each party bear its own costs on appeal.

Sincerely,

LYLE W. CAYCE, Clerk

By: Rebecca Andry
Rebecca Andry, Deputy Clerk
504-310-7638

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