FDA's Graphic Warnings Rule for Cigarette Packaging Remains on Hold After Fifth Circuit Affirms Texas Federal Court's Decision

Aug 31, 2026

Categories:
Publications

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On August 18, 2026, the U.S. Court of Appeals for the Fifth Circuit affirmed the Eastern District of Texas's order postponing the effective date of the Food and Drug Administration's (FDA) cigarette graphic-warning rule under Section 705 of the Administrative Procedure Act in *R.J. Reynolds Tobacco Co. v. FDA*, No. 25-40137 (5th Cir. Aug. 18, 2026)

The court held that the plaintiffs demonstrated a substantial likelihood of success on their claim that the FDA exceeded its statutory authority by requiring 11 warning labels instead of the nine prescribed by Congress in the Family Smoking Prevention and Tobacco Control Act (TCA). Writing for the panel, Judge Willett concluded that the statutory text, structure, and surrounding provisions establish a closed set of nine warnings and that the FDA's "adjust" authority does not encompass the power to add new warnings.

I. Parties and Procedural Posture

Plaintiffs-appellees: R.J. Reynolds Tobacco Company, Santa Fe Natural Tobacco Company, Inc., ITG Brands LLC, Liggett Group LLC, Neocom, Inc., Rangila Enterprises, Inc., Rangila LLC, Sahil Ismail, Inc., and Is Like You, Inc. — a group of cigarette manufacturers and retailers.

Defendants-appellants: U.S. Food & Drug Administration, U.S. Department of Health and Human Services, Kyle Diamantas (Acting FDA Commissioner), and Robert F. Kennedy, Jr. (Secretary of HHS).

Procedural history: The plaintiffs originally filed suit in the Eastern District of Texas, challenging the FDA's 2020 graphic-warning rule under the First Amendment and the APA. The district court initially granted summary judgment on First Amendment grounds without

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reaching the APA claims. On appeal, the Fifth Circuit reversed the First Amendment ruling, holding that the warnings are factual and uncontroversial under *Zauderer* scrutiny, and remanded for consideration of the APA claims. After the U.S. Supreme Court denied certiorari, the plaintiffs moved on remand for a postponement of the rule's effective date under APA § 705. The district court granted that motion, finding a substantial likelihood of success on the plaintiffs' statutory-authority claims. The FDA appealed that interim-relief order, which the Fifth Circuit has now affirmed.

Panel: Circuit Judges Southwick, Willett, and Ho. Judge Ho joined all but Part III.C.1–2 (addressing the universal scope of § 705 relief and the effect of *Trump v. CASA, Inc.*).

II. Key Facts and Legal Issues

Regulatory framework: The TCA, enacted in 2009, specifies nine textual warning statements that must appear on cigarette packages and advertisements, paired with color graphics depicting the negative health consequences of smoking. Congress granted the FDA limited authority under § 1333(d)(2) to "adjust the format, type size, color graphics, and text" of the label requirements upon finding that such a change would "promote greater public understanding" of tobacco-related health risks.

Challenged rule: In 2020, the FDA promulgated its final graphic-warning rule. Unlike the vacated 2011 rule, the FDA disclaimed any behavioral purpose. According to the FDA, it was not intended to reduce smoking rates but to "promote greater public understanding" of smoking's health consequences. Critically, the 2020 rule discarded all but two of Congress' nine statutory warnings, substituting FDA-drafted statements, resulting in a regime of 11 rotating warnings instead of nine.

Legal issues presented: The primary question was whether the district court abused its discretion in concluding that the plaintiffs were substantially likely to prevail on their claim that the FDA exceeded its statutory authority under the TCA by increasing the number of required warnings from nine to 11.

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III. The Fifth Circuit's Holding and Reasoning

Statutory text establishes a closed set of nine warnings. The court held that the phrase "one of the following labels," proceeded by a specific enumeration of nine warnings, reads as exclusive and exhaustive. Congress used no language such as "including" or "such as" to signal an open or illustrative list. The court noted that multiple cross-referencing provisions in §§ 1333(a)(2), (b), and (c) repeatedly reference the labels "specified in subsection (a)(1)," confirming that the nine statements anchor the entire labeling regime. The rotation-and-display requirements assume a fixed and finite set of warnings, and permitting a "default" set that the FDA could expand at will would disrupt the coherence of the rotation scheme Congress enacted.

"Adjust" does not authorize adding new warnings. The FDA relied on § 1333(d)(2)'s authority to "adjust the … text" of label requirements. The court rejected this reading, reasoning that "to adjust is to modify something that already exists — not to conjure something new." The word "number" does not appear anywhere in the provisions addressing the FDA's adjustment authority. Had Congress intended to authorize the FDA to expand the warning set, it could have said so expressly.

Preemption clause is not an independent delegation. The FDA further argued that § 1334(a), which contains an exception permitting "additional or different statements" to the extent required by the FDA pursuant to federal law, functioned as independent authority. The court held that § 1334(a) is a preemption provision, not an affirmative grant of regulatory authority; it presupposes valid authority conferred elsewhere in the statute. Reading § 1334(a) as an independent license to require any number of warnings would render § 1333(d)(2)'s carefully drawn limitations superfluous.

Equitable factors favored the plaintiffs. The court found that the remaining interim-relief factors favored the plaintiffs. Irreparable harm was established through unrecoverable compliance costs, including redesigning packaging, retooling printing and distribution systems, and coordinating nationwide supply chain changes, that

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could not be recovered from the government due to sovereign immunity. The balance of equities favored the plaintiffs because the FDA identified no comparable hardship from a temporary postponement, particularly given the rule's informational (rather than behavioral) purpose. The public interest was not disserved because existing Surgeon General text warnings remain in effect, and no graphic-warning rule has taken effect in the 17 years since the TCA's enactment.

Relief granted on rule-wide basis. The court held that § 705 authorizes rule-wide postponement rather than party-specific relief because the statutory remedy is action-centric, not party-centric. The court distinguished *Trump v. CASA, Inc.*, reasoning that *CASA* addressed equitable injunctions, not statutory APA remedies. The court also declined to require severance of the FDA's rule, holding that the severability clause does not apply at the interim stage since the rule has not been "held to be invalid," and severance cannot manufacture authority the agency never possessed.

Court applied four-factor standard. The court reviewed the district court's interim-relief order for abuse of discretion, applying de novo review to legal conclusions and clear-error review to factual findings. It applied the four-factor interim-relief test: (1) likelihood of success on the merits, (2) substantial threat of irreparable harm, (3) balance of hardships favoring the movant, and (4) consistency with the public interest, with the last two merging when the government is a party.

IV. Concurring and Dissenting Opinions

No formal dissenting or concurring opinion was published with the decision. However, Judge Ho joined all of the opinion except Part III.C.1–2, which addresses whether § 705 authorizes universal relief and the applicability of *Trump v. CASA, Inc.* Judge Ho's partial non-joinder suggests a reservation regarding the scope-of-remedy analysis, though the document does not include a separate statement of his reasoning. His agreement with the remainder of the opinion, including the statutory-authority analysis, the irreparable-harm finding, and the ultimate affirmance, is unqualified.

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V. Practical Implications for Cigarette Manufacturers

Immediate effect: The FDA's 11-warning graphic-label rule remains postponed on a rule-wide basis. Manufacturers and retailers are not required to comply with the rule while the district court resolves the merits. This means manufacturers need not, for now, undertake the substantial compliance measures, including package redesign, printing retooling, and supply chain coordination, that the rule would require.

Statutory-authority constraint: The Fifth Circuit's analysis strongly signals that the FDA's authority under the TCA is limited to requiring the nine specific warnings Congress prescribed. The word "adjust" does not encompass expanding the number of warnings. This interpretation limits future FDA rulemaking to modifications of existing warning attributes (format, type size, color graphics, and text of the nine existing labels) rather than the substantive addition of new warning categories.

Parallel litigation: A separate challenge in the Southern District of Georgia (*Philip Morris USA Inc. v. FDA*) resulted in vacatur of the same rule on different grounds. The court there found that the FDA failed to disclose key underlying data during notice-and-comment rulemaking. That ruling is on appeal before the U.S. Court of Appeals for the Eleventh Circuit. The two rulings rest on independent grounds, meaning the rule is currently subject to both a postponement and a vacatur.

Not a final merits decision: The Fifth Circuit's opinion addresses only the interim-relief standard, which is whether the district court abused its discretion in finding a substantial likelihood of success. Final merits proceedings remain pending in the Eastern District of Texas. Additional APA claims (e.g., that the FDA improperly rewrote warning text) were not resolved and may provide alternative grounds for relief.

First Amendment status: The prior Fifth Circuit panel decision, *R.J. Reynolds Tobacco Co. v. FDA*, 96 F.4th 863 (5th Cir. 2024), held that the graphic warnings satisfy *Zauderer* scrutiny and do not violate the First Amendment. That ruling is law of the case and is not

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disturbed by the current opinion. Manufacturers should therefore not rely on First Amendment arguments against the graphic-warning concept itself; the current victory rests solely on the FDA's statutory overreach in expanding the warnings beyond Congress's nine.

For guidance on the implications of this ruling and how it may impact your operations, compliance planning, and regulatory strategy, please contact the author or any member of FBT Gibbons' Consumables Goods team.

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