NO. 23-40076

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

R.J. REYNOLDS TOBACCO CO.; SANTA FE NATURAL TOBACCO CO., INC.; ITG BRANDS LLC; LIGGETT GROUP LLC; NEOCOM, INC.; RANGILA ENTERPRISES, INC.; RANGILA LLC; SAHIL ISMAIL, INC.; IS LIKE YOU, INC.,

Plaintiffs-Appellees,

v.

FOOD AND DRUG ADMINISTRATION; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT M. CALIFF, COMMISSIONER OF FOOD AND DRUGS; XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants-Appellants.

On Appeal from the United States District Court for the Eastern District of Texas
(Case No. 6:20-cv-176) (District Judge J. Campbell Barker)

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE SUPPORTING APPELLEES AND AFFIRMANCE

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July 17, 2023

CERTIFICATE OF INTERESTED PERSONS

I certify that the following listed persons and entities have an interest in this case's outcome as described in the fourth sentence of Fifth Circuit Rule 28.2.1. These representations are made so that the judges of this Court may evaluate possible disqualification or recusal.

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INTEREST OF AMICUS CURIAE*

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as an amicus curiae in important compelled-speech cases. *See, e.g.*, *United States v. United Foods, Inc.*, 533 U.S. 405 (2001); *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1 (1986); *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled in part by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

WLF's Legal Studies Division, its publishing arm, regularly distributes papers about First Amendment limits on government-compelled speech. *See, e.g.*, Howard L. Dorfman, *CMS's DTC Drug Ad Price-Disclosure Mandate: An Ill-Conceived & Illegal Proposal*, WLF Legal Opinion Letter (Jan. 25, 2019), https://bit.ly/3SQZW5Q; Bert W. Rein & Megan L. Brown, *Two First Amendment Appeals Will Test Impact*

* No party's counsel authored any part of this brief. No one, apart from WLF and its counsel, contributed money intended to fund the brief's preparation or submission. All parties consented to the filing of WLF's brief.

of NIFLA v. Becerra *On Commercial Speech Regulation,* WLF Legal Backgrounder (Sep. 7, 2018), https://bit.ly/3SUhb63.

INTRODUCTION

The Food and Drug Administration relies on *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985), to justify forcing cigarette makers and retailers to disseminate the government's tendentious messages and images. But *Zauderer* does not hold, and this Court has never suggested, that a commercial speaker's First Amendment rights are minimal any time the government wants to force it to parrot the government's views.

On the contrary, a law compelling speech is no less pernicious than one banning it; the State as ventriloquist is no better than the State as censor. *See Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 797 (1988) (the First Amendment's guarantee of "freedom of speech" protects "the decision of both what to say and what *not* to say"). Applying this constitutional tenet, the District Court rightly found that FDA violated Plaintiffs' free-speech rights by foisting controversial and factually ambiguous warnings on cigarette makers and retailers.

By forcing Plaintiffs "to speak a particular message" against their will, FDA's compelled warnings "alte[r] the content of [their] speech." *Nat'l Inst. of Fam. & Life Advocs. (NIFLA) v. Becerra*, 138 S. Ct. 2361, 2371 (2018) (quoting *Riley*, 487 U.S. at 795). Nothing in *Zauderer* remotely suggests that the government may commandeer a business into serving as an involuntary mouthpiece for controversial viewpoints it opposes—much less as a billboard for discouraging consumers from buying its goods. Because that is a grave constitutional violation under any level of constitutional scrutiny, this Court should affirm.

STATEMENT OF THE CASE

In the Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 1776, Congress granted FDA limited authority to regulate tobacco products and marketing. Among other things, the TCA amends § 4 of the Fair Packaging and Labeling Act to require nine new textual warnings, or "label statements," that must be displayed on a rotating basis with the same frequency. 15 U.S.C. §§ 1333(a)(1), (b)(2), (c)(2). A label statement must occupy the top 50 percent of the front and back panels of all cigarette packaging and at least the top 20 percent of all cigarette advertising. *Id.* § 1333(b)(2). The

TCA also directs the Secretary of Health and Human Services to ensure, by rulemaking, that every label statement includes "color graphics depicting the negative health consequences of smoking." *Id.* § 1333(d).

In 2011, FDA issued a final rule specifying nine graphic warnings to accompany the label statements. *See* FDA, *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36,628 (June 22, 2011). The graphic warnings featured sensational images ostensibly depicting the consequences of smoking, such as diseased lungs or a cadaver on an autopsy table. *Id.* Five tobacco companies challenged the rule on First Amendment grounds. Finding not a "shred of evidence" that the new warnings would further FDA's stated interest in reducing smoking, the D.C. Circuit in 2012 vacated that rule as an unconstitutional compulsion of the tobacco companies' speech. *R.J. Reynolds*, 696 F.3d at 1221–22.

Years later, in March 2020, FDA issued the new Rule. *See* FDA, *Required Warnings for Cigarette Packaging and Advertisements*, 85 Fed. Reg. 15,638 (Mar. 18, 2020). The Rule omits seven of the TCA's textual warnings, adds nine FDA-created label statements, and imposes eleven corresponding graphic images. ROA.189–ROA.90. Aimed at

manufacturers and retailers alike, the Rule makes it a crime to make, package, sell, advertise, or offer for sale cigarettes without the mandated warnings. 21 C.F.R. §§ 1140.10(c), (d). Failure to include these warnings on all cigarette packaging and advertising renders cigarettes "misbranded" under the Rule, which permits the government to seize them. 85 Fed. Reg. at 15,709; 21 U.S.C. § 334(a)(2), (g).

FDA abandons its earlier interest in reducing smoking to justify the new Rule. Unable to prove that graphic warnings will have any real-world impact on smoking behavior, FDA now asserts a purely informational interest—fostering "greater public understanding" of the risks of smoking—as its sole justification for commandeering private speech. 85 Fed. Reg. at 15,650.

Plaintiffs—four cigarette manufacturers and five cigarette retailers—challenged the Rule's compelled-warnings regime on First Amendment grounds. After granting the parties' joint motion to postpone the Rule's effective date, the District Court ultimately granted summary judgment for Plaintiffs on their First Amendment claim.

First, the District Court concluded that the Rule's warnings do not qualify for relaxed First Amendment scrutiny under *Zauderer* because

they are not purely factual and uncontroversial. FDA presented no evidence that "each image-and-text pairing conveys only one, unambiguous meaning that is factually correct." ROA.205. Given their "capacity for multiple reasonable interpretations," the Rule's warnings were not "objectively 'accurate'" as *Zauderer* requires. ROA.208.

Second, the District Court held that the Rule's warnings cannot survive intermediate scrutiny under *Central Hudson Gas & Electric v. Public Service Commission*, 447 U.S. 557 (1980), because they are not narrowly tailored. ROA.210. FDA failed to show that "compelling these large, graphic warnings is necessary in light of other options." *Id.* Other measures, like increased government funding for anti-smoking education, would be more narrowly drawn to achieve the Rule's stated aim without abridging Plaintiffs' freedom of speech. *Id.*

The District Court entered judgment declaring the Rule unconstitutional under the First Amendment and vacating it. ROA.178–ROA.220. FDA now appeals.

SUMMARY OF ARGUMENT

In *Zauderer*, the Supreme Court clarified that "free flow of commercial information is valuable enough to justify imposing on would-

be regulators the costs of distinguishing . . . the harmless from the harmful." 471 U.S. at 646. Yet FDA badly mangles *Zauderer*, ignoring just how much the Court's modest compelled-speech holding hinges on the case's unique facts. At bottom, commandeering private speakers to spread the government's message allows the government to promote its own agenda at the expense of First Amendment rights. FDA's watered-down take on *Zauderer* ignores this threat to free speech.

If anything, *Zauderer* further exposes the constitutional defect in FDA's position. To advance a purely informational interest in "fostering greater public understanding" of smoking risks, 85 Fed. Reg. at 15,650, FDA invokes *Zauderer* to justify compelling manufacturer and retailer speech. But the Supreme Court has never applied *Zauderer* outside the narrow confines of requiring a business to prevent consumer deception by curing false or misleading advertisements. Although this Court has never considered the question, it should do so now. By expanding *Zauderer*'s scope and sweep, FDA drastically erodes the First Amendment's prohibition against compelled speech.

While the Rule's warnings are impermissible compelled speech subject to strict scrutiny, the Rule also fails to satisfy the government's

evidentiary burden under either *Zauderer* or *Central Hudson*. First, even if *Zauderer* applies, FDA may not mandate a disclosure if it is "unjustified." *Zauderer*, 471 U.S. at 651. Here the Rule is unjustified because FDA has not shown that it will materially improve the public's understanding of the risks of smoking. Likewise, under *Central Hudson*, the Rule "must directly advance" FDA's stated interest in improving public understanding of the risks of smoking "in a material way." *Cent. Hudson*, 477 U.S. at 566; *Edenfield v. Fane*, 507 U.S. 761, 774 (1993). Yet again, FDA's shaky record evidence cannot satisfy its burden.

FDA's studies are deeply flawed. As the Office of Management and Budget concluded, FDA selectively recruited its study participants using convenience sampling whose outcomes are not nationally representative. Even worse, FDA's cost-benefit analysis failed even to quantify the Rule's supposed benefits. No surprise, then, that FDA hid crucial data from the public, which had no opportunity to comment on its peer-review report or FDA's response to it. And without explanation, FDA failed to seriously consider several alternatives.

Even if taken at face value, however, FDA's studies undercut the Rule's effectiveness. The main takeaway from FDA's data is that the

public overwhelmingly understands that smoking is harmful. As FDA's own PATH survey shows, 99.5% of individuals believe that cigarette smoking endangers health, with 91% believing that it is "very or extremely harmful." What's more, FDA ignored its own study's findings that participants simply did not believe FDA's sensational new warnings. And FDA ignored, downplayed, and misrepresented its own peer-review feedback, which identified core defects in FDA's studies. In sum, because no credible empirical evidence links the Rule's mandated warnings to FDA's only stated goal, the Rule cannot survive any level of scrutiny.

ARGUMENT

I. FDA ADVANCES A DEEPLY FLAWED READING OF *ZAUDERER*.

A. *Zauderer* confirms that the First Amendment accords commercial speakers equally broad rights to speak and not to speak.

FDA views *Zauderer* as a low bar the government can easily clear whenever it seeks to compel speech from commercial entities. That reading is wide of the mark. A consumer's interest in commercial speech "may be as keen, if not keener by far, than his interest in the day's most urgent political debate." *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 763 (1976). That is why, *Zauderer*

says, it is always preferable to cure deceptive or misleading commercial speech with a clarifying disclosure, rather than to ban it altogether. 471 U.S. at 650. But that rationale simply does not apply here.

To begin, *Zauderer* was a mostly successful First Amendment challenge to Ohio's restrictions on truthful attorney advertising. Applying *Central Hudson*'s four-part test, the Supreme Court invalidated Ohio's ban on soliciting clients through ads tied to "specific legal problems," 471 U.S. 639–47, as well as its ban on using illustrations in attorney ads, *id*. at 647–49.

FDA relies on four pages in *Zauderer* that upheld Ohio's right to discipline an attorney who advertised his services for a contingency fee without also disclosing that his clients must pay all costs if they lost their suit. 471 U.S. at 650–54. In upholding Ohio's mandated disclosure, the Supreme Court—at least thirteen times—underscored the need to correct deceptive advertising as its only rationale. *Id*.

The Court found that Ohio, by disciplining the attorney, was directly advancing its "substantial interest" in "preventing deception of consumers." *Id.* at 651. Without a clarifying disclaimer about court costs, the Court explained, it was "self-evident" that some consumers would

mistakenly assume that hiring an attorney for a contingency fee was a no-cost proposition. *Id*. at 652–53.

Yet *Zauderer* also stressed that government compulsion of speech is always subject to meaningful First Amendment scrutiny. 471 U.S. at 650. If anything, the Court suggested, some speech compulsions may merit *more* exacting First Amendment scrutiny than traditional speech restrictions. *Zauderer* recalled that, in *West Virginia Board of Education v. Barnette*, 319 U.S. 624 (1943), the Court declared that "'involuntary affirmation could be commanded only on *even more immediate and urgent grounds* than silence.'" *Zauderer*, 471 U.S. at 650 (quoting *Barnette*, 319 U.S. at 633) (emphasis added).

Zauderer allows the government to prevent consumer deception by compelling advertisers to include in their ads purely factual and uncontroversial information about themselves and their goods or services. But nothing in *Zauderer* remotely suggests that the government may commandeer a business into serving as an involuntary mouthpiece for controversial viewpoints it opposes—much less as a billboard for discouraging consumers from buying its goods. On the contrary, the "right to speak and the right to refrain from speaking are complementary

components" of the freedom of speech. *Wooley v. Maynard*, 430 U.S. 705, 714 (1977).

B. *Zauderer* governs only disclosures aimed at protecting consumers from false or deceptive advertising.

FDA insists that *Zauderer* allows it to commandeer private speech to further its interest in "fostering greater public understanding," 85 Fed. Reg. at 15,650. But *Zauderer* strictly limits its holding to curing speech that is "false or deceptive." *Zauderer*, 471 U.S. at 638. The government may mandate speech only "to dissipate the possibility of consumer confusion or deception." *Id.* at 651. Indeed, the Court upheld the state's advertising disclaimer only after finding that the possibility of deception was "self-evident" and that "substantial numbers of potential clients would be so misled" without Ohio's disclosure rule. *Id.* at 652.

Even in the commercial-speech context, then, *Zauderer* recognizes that "an advertiser's rights are adequately protected" only so long as "disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Id.* at 651. Outside that narrow context of supplementing misleading ads with disclosures to prevent consumer deception, *Zauderer* simply does not apply.

The Supreme Court has never wavered from this rule. In *Ibanez v. Florida Department of Business & Professional Regulation*, 512 U.S. 136, 146 (1994), for example, the Court relied on *Zauderer* to invalidate a Florida regulation mandating a disclaimer on any ad that (truthfully) held out a professional as a Certified Financial Planner. The Court held that Florida's compelled-speech mandate could not survive First Amendment scrutiny without evidence of "potentially real, not purely hypothetical" consumer deception. *Id.* If the "protections afforded commercial speech are to retain their force," *Ibanez* explained, courts "cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden." *Id.* (quoting *Zauderer*, 471 U.S. at 648–49). Had the Court shared FDA's elastic view of *Zauderer*, then *Ibanez* would have upheld Florida's compelled-speech mandate without evidence of consumer deception.

Likewise, in *Milavetz, Gallop & Milavetz, P.A. v. United States*, the Court considered a First Amendment challenge to a federal law requiring attorneys and other debt-relief professionals to include disclosures in their advertisements. 559 U.S. 229, 232–33 (2010). Congress required those disclosures to prevent consumers from being misled about the

services being offered. *Id*. Deciding that *Zauderer* supplied the proper First Amendment test, the Court reiterated that the "essential feature[]" of the disclosures upheld in *Zauderer* was that they were aimed at "inherently misleading commercial advertisements." *Id.* at 250 (quoting *Zauderer*, 471 U.S. at 651). Because that prong was satisfied—a showing FDA has not made here—the Court upheld the disclosure under *Zauderer*.

FDA's position also contravenes *United Foods*. There, the Court invalidated a federal law forcing mushroom growers to finance a government-run advertising campaign for mushrooms. 533 U.S. at 413–16. The Court refused to apply *Zauderer*. *Id*. at 416. Ohio had compelled speech in *Zauderer* to prevent consumer deception, *United Foods* explained, but there was no suggestion "that the mandatory assessments" were "somehow necessary to make voluntary advertisements nonmisleading for consumers." *Id.* Again, under FDA's expansive reading of *Zauderer*, *United Foods* would have come out the other way.

As Justice Souter noted more than twenty years ago, "however long the pedigree of [compelled-speech] mandates may be, and however broad

the government's authority to impose them, *Zauderer* carries no authority for a mandate unrelated to the interest in avoiding misleading or incomplete commercial messages." *Glickman v. Wileman Bros. & Elliott*, 521 U.S. 457, 490 (1997) (Souter, J., dissenting); *see Milavetz*, 559 U.S. at 257 (Thomas, J., concurring). FDA has ignored this important limit of *Zauderer*'s scope; this Court should enforce it.

C. This Court should clarify *Zauderer*'s limited scope.

As shown, FDA seeks to empty *Zauderer* of a crucial prong that the Supreme Court has steadfastly retained: a permissible disclosure must be "an appropriately tailored check against deception or confusion." *Ibanez*, 512 U.S. at 146. Here, FDA disclaims any interest in preventing consumers from being deceived by Plaintiffs' speech. And it is undisputed that Plaintiffs' relevant commercial speech is neither false nor misleading. After all, Plaintiffs are prohibited by law from making false or misleading claims through cigarette packaging or advertising. That alone suffices to disqualify *Zauderer* as the appropriate standard of First Amendment review.

In its opening brief, FDA lackadaisically suggests (at 28) that the Rule's warnings meet this test because they are "intended in part to

correct consumer misperceptions regarding the risk posed by cigarettes." But "consumer misperceptions" are constitutionally relevant only if they spring, or are likely to spring, from the very commercial speech the government wants to correct. That is the whole point of a disclosure: to cure the misleading or deceptive speech at issue. *See Test Masters Educ. Servs., Inc. v. Robin Singh Educ. Servs., Inc.*, 799 F.3d 437, 453 (5th Cir. 2015). Again, FDA points to nothing in manufacturers' packaging or retailers' advertising that fits that bill. Nor can it.

Although it has not yet squarely answered the threshold question of *Zauderer*'s scope, this Court has understood *Zauderer* as a way "to gauge" laws and regulations "directed at deceptive or misleading commercial speech [that] requires a disclosure." *TestMasters, Inc.*, 799 F.3d at 453. And when confronted with compelled disclosures unrelated to preventing consumer deception, the Court has applied heightened scrutiny. *See Hersh v. U.S. ex rel. Mukasey*, 553 F.3d 743, 764–68 (5th Cir. 2008); *Allstate Ins. Co. v. Abbott*, 495 F.3d 151, 164–65 (5th Cir. 2007). Here, FDA does not even claim that Plaintiffs' commercial speech *might be* misleading.

True, this Court has denied pre-enforcement facial relief from a Texas-mandated disclosure aimed at "enabl[ing internet platform] users to make an informed choice." *NetChoice, LLC v. Paxton*, 49 F.4th 439, 485–88 (5th Cir. 2022). But no party there disputed the adequacy of the state's interest, so this Court never considered the question. *Id.* at 485. And while this Court can easily dispense with *Zauderer* as the District Court did—because the Rule's warnings are neither "purely factual" nor "uncontroversial"—the Court should reach the logically prior question about *Zauderer*'s threshold scope. That question is far too important to ignore any longer.

By expanding the universe of acceptable justifications for government-compelled speech, FDA's position undermines the Supreme Court's historical rationale for giving commercial advertising somewhat reduced, but still considerable, First Amendment protection. The "greater 'objectivity' of commercial speech," the Court has said, "justifies affording the State more freedom to distinguish false advertisements from true ones." *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 499–500 (1996) (quoting *Va. State Bd.*, 425 U.S. at 771 n.24). Put differently,

truthful commercial speech receives greater constitutional protection than false or misleading commercial speech.

But that rationale collapses as a justification for *compelling* speech when the mandatory disclosure is *not* aimed at preventing consumer deception. When, as here, the government seeks to compel speech for some other reason, "the greater objectivity of commercial speech" cannot justify treating commercial and noncommercial speakers differently. As the Supreme Court has recently reiterated, Philip Zauderer's statements "would have been 'fully protected' if they were made in a context other than advertising." *NIFLA*, 138 S. Ct. at 2374 (quoting *Zauderer*, 471 U.S. at 637 n.7).

As the District Court rightly found, *Zauderer* applies only to purely factual and uncontroversial disclosures that have nothing in common with the Rule's incendiary warnings. ROA.205–ROA.08. Affirming on that basis would be easy. But to ensure the coherence of the Fifth Circuit's compelled-speech jurisprudence, this Court should reinforce *Zauderer*'s bright line threshold. It should hold explicitly that because the Rule's mandated warnings are not reasonably related to consumer deception, *Zauderer* does not apply.

II. NO CREDIBLE EMPIRICAL EVIDENCE LINKS THE RULE'S MANDATED WARNINGS TO FDA'S STATED GOAL.

The Rule also fails to satisfy either *Zauderer*'s or *Central Hudson*'s required evidentiary showing. First, even if *Zauderer* supplies the right test, FDA may not mandate a disclosure if it is "unjustified." *Zauderer*, 471 U.S. at 651. Here the Rule is unjustified because it will not materially improve the public's understanding of the risks of smoking, which is FDA's only stated goal.

Likewise, under *Central Hudson*, the Rule "must directly advance" FDA's stated interest in improving public understanding of the risks of smoking "in a material way." *Edenfield*, 507 U.S. at 774. It is not enough that the Rule "provides only ineffective or remote support for the government's purposes," or that it has "little chance" of advancing the FDA's goal. *Id.* at 770–71. FDA's record evidence simply cannot clear that hurdle.

A. FDA's studies are deeply flawed.

Facts are stubborn things, but studies are pliable. Bent on reaching its predetermined conclusions no matter what, FDA placed a heavy thumb on the scales for its various studies. These methodological flaws make FDA's underlying studies unreliable.

FDA relied on two quantitative studies to justify the Rule. The first study tested whether the Rule's textual warnings produced a statistically significant change in participants' beliefs about smoking risks. *See* RTI Int'l, *Experimental Study on Warning Statements for Cigarette Graphic Health Warnings: Study 1 Report* (Apr. 2018), https://bit.ly/3HD3zbh. The second study tested whether the Rule's graphic warnings had that same effect. *See* RTI Int'l, *Experimental Study of Cigarette Warnings: Study 2 Report* (May 2019), https://bit.ly/41KNvMr. Both studies were deeply flawed from the outset. As the Office of Management and Budget concluded, FDA selectively recruited the participants for both studies "using convenience sampling methods" with no "known probability of selection." OMB, *Notice of Office of Management and Budget Action, Experimental Study on Warning Statements for Cigarette Graphic Health Warnings*, Ref. No. 201708-0910-011 (Jan. 29, 2018), https://bit.ly/41SOwl9. As a result, FDA's quantitative studies are "not intended to generate nationally representative outcomes." *Id.* As the saying goes: garbage in, garbage out.

FDA also relied on three qualitative studies. But FDA did not design those studies to test the accuracy of the Rule's warnings or the

messages they convey to consumers. Rather, FDA focused merely on whether the warnings conveyed new information, grabbed participants' attention, or were believed or understood by participants. *See* RTI Int'l, *Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions* at 6–7 (July 2015), https://bit.ly/3oF4YqV; Siegel+Gale, *FDA Graphic Health Warning Image Concept Testing* at 11–13 (June 2016), https://bit.ly/3L3od5b; RTI Int'l, *Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images* at 3 (Apr. 2018), https://bit.ly/3NfVY66. But none of those variables fairly measures the Rule's effectiveness at *improving* the public's understanding of the *true risks* of smoking.

Nor is that all. "[W]hen an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable." *Idaho Conservation League v. Wheeler*, 930 F.3d 494, 507 (D.C. Cir. 2019) (cleaned up). Here, FDA's cost-benefit analysis failed even to quantify the Rule's benefits. *See* FDA, *Preliminary Regulatory Impact Analysis* at 2 (Aug. 2019), https://bit.ly/3NyeS8r ("[T]here is a high level of uncertainty around quantitative economic benefits at this time, so we describe them

qualitatively."); FDA, *Final Regulatory Impact Analysis* at 17 (Mar. 2020), https://bit.ly/40GRJDp ("[T]here is a high level of uncertainty around quantified economic benefits at this time[,] and we therefore apply a break-even analysis.").

Even worse, FDA hid crucial data from the public during the rulemaking. "[S]tudies upon which an agency relies in promulgating a rule must be made available during the rulemaking in order to afford interested persons meaningful notice and an opportunity for comment." *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008). Yet, despite repeated requests, FDA refused to release the final data sets from its two quantitative studies. *See, e.g.*, Letter from A. Klingler, Docket No. FDA-2019-N-3065-0001 (Sept. 9, 2019); Letter from Altria Client Services, Docket No. FDA-2019-N-3065-0001 (Sept. 5, 2019).

FDA also failed, at first, to release the underlying data, or even the study reports, for its three qualitative studies. 84 Fed. Reg. at 42,767, 42,771. When—nearly a month after the comment period closed—FDA finally placed the qualitative study reports on the docket, it gave the public only fifteen days to comment. *See Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Additional*

Materials; Reopening of the Comment Period, 84 Fed. Reg. 60,966 (Nov. 12, 2019).

This Court need not guess why FDA hid its data from stakeholders during the rulemaking. In a revealing "Memo to File" included in the administrative record, FDA openly worried that disclosure would "allow third party attempts to analyze the data in different and potentially selective, biased or misleading ways other than what FDA pre-specified in the statistical analysis plan." AR 236863.2. But the entire assumption behind rulemaking is that FDA's "pre-specified" methodological assumptions will be scrutinized, challenged, and even criticized by stakeholders. FDA has no right to obstruct that process.

FDA also failed to seriously consider alternative approaches. It ignored several less-restrictive alternatives suggested by stakeholders—public-education campaigns, differently placed and differently sized warnings, or revised textual warnings. *See* Comment Letter of RAI Services Co. at 31–32, Docket No. FDA-2019-N-3065 (Oct. 11, 2019). And even when it considered more cost-effective alternatives, FDA supplied no rational explanation for rejecting them. For example, when FDA considered mandating only nine warnings instead of eleven, it concluded

that nine warnings would be less costly. FDA, *Preliminary Regulatory Impact Analysis*, *supra*, at 51–54. But FDA stuck with eleven warnings and has never shown that the greater costs imposed by those eleven warnings are offset by any greater benefits.

B. Even if reliable, FDA's own evidence undercuts its position.

Even if FDA's evidence is accepted as reliable, it undermines the notion that the Rule effectively enhances the public's understanding of smoking risks. FDA papers over these defects, but this Court should scrutinize them.

FDA's own studies reveal that most of the Rule's warnings describe already well-known smoking risks. *See* RTI Int'l, *Qualitative Study on Cigarettes and Smoking*, *supra*, at 20, 33, 35; Comment Letter of RAI Services Co., *supra*, Ex. C, Stmt. of J. Klick ¶¶ 5.43, 5.45, 5.48, 5.50, 5.58, 5.59, 5.60; Dannielle E. Kelley et al., *Effective Message Elements for Disclosures About Chemicals in Cigarette Smoke*, 20 Nicotine & Tobacco Rsch. 1047, 1051 (2018). Indeed, Americans overwhelmingly understand that smoking is harmful. As FDA's own PATH survey shows, 99.5% of individuals believe that cigarette smoking harms health, with 91% believing that it is "very or extremely harmful." Stmt. of J. Klick ¶ 5.20.

Simply put, FDA does not "educate" the public by merely repeating information the public already knows.

Again, FDA's first quantitative study tested whether the textual warnings led to a statistically significant change in participants' beliefs about smoking risks. But when compared to the TCA's textual warnings, seven of the nine FDA-created warnings—for "head-and-neck cancer," "bladder cancer," "erectile dysfunction," "amputation," "diabetes," "macular degeneration," and "cataracts"—did not increase the participants' belief that smoking has the negative health outcome tied to that warning. *See* RTI Int'l, *Study 1 Report*, *supra*, at 40–42. On the contrary, participants found that the FDA-created statements were "less believable." *Id.* at 40. Rather than address these defects, FDA nixed questions on "believability" from its second quantitative study. As FDA's own peer-review report pointedly asked, "What happened to believability?" *Final Summary Report: External Letter Peer Review of FDA's Quantitative Consumer Research on Cigarette Health Warnings Required by the Family Smoking Prevention and Tobacco Control Act* at 34 (Nov. 19, 2019), https://bit.ly/3ApCDrf. FDA has never answered that question.

Likewise, FDA's second quantitative study tested whether the Rule's graphic warnings led to any statistically significant change in views about smoking risks. Yet it showed that five of the Rule's eleven graphic warnings had no significant effect on participants' views, and that five more had only a small effect that quickly dissipated. RTI Int'l, *Study 2 Report*, *supra*, at 42–45.

What's more, FDA ignored its own study's findings that participants simply did not believe the FDA-created textual warnings. For example, the first qualitative study's "most prevalent" finding was that participants had a "widespread negative reaction" to warnings that smoking "causes" a disease, rather than "can cause," "may cause," or "increases the risk of" a disease. RTI Int'l, *Qualitative Study on Cigarettes and Smoking*, *supra*, at 7, 52; *see also id.* at 15, 17, 19, 26, 27, 31, 33, 34, 35, 36, 38, 45, 46. Despite these valid concerns, FDA simply ignored their own study participants' feedback. Indeed, nearly all the Rule's FDA-created warnings say that smoking "causes" the specific negative health outcome.

FDA's study participants also "expressed a desire for more information about the relationship between the amount and duration of

smoking . . . to the health effects of smoking." *Id.* at 7; *see also id.* at 38, 52. Although this was one of the study's "key findings," FDA never included this clarifying information on the warnings. Participants were also dubious of warnings about certain smoking risks—like erectile dysfunction or diabetes—without more detail about how smoking "causes" them. *See id.* at 23–24, 45, 53. Yet despite its supposed goal of fostering "greater public understanding" of the risks of smoking, 85 Fed. Reg. at 15,650, FDA ignored this finding in the final Rule.

FDA has also ignored, downplayed, and misrepresented its own peer-review feedback. FDA portrayed its peer-review report as overwhelmingly favorable. *See* 85 Fed. Reg. at 15,661. Yet peer reviewers identified core weaknesses with FDA's studies, which were based on a conceptual model that is "undetermined and never clearly defined." *Final Summary Report*, *supra*, at 14. FDA's sole reliance on "self-reported learning" and "new information," for example, lacked "convincing validity" as measures of the Rule's effectiveness. *Id.* at 14; *see also* 27–28, 33.

As peer reviewers explained, neither criteria—"self-reported learning" nor "new information"—can tell us whether the Rule's

warnings would improve public understanding of smoking risks; they are non-standard measures of questionable validity. *Id.* at 14, 18, 28. No surprise, then, that FDA gave the public no opportunity to comment on the peer-review report or FDA's response to it. *See* RTI Int'l, *Study 1 Report*, *supra*, at 4–5; RTI Int'l, *Study 2 Report*, *supra*, at 1–2. This is typical for FDA, which displayed a curious tendency to downplay and even hide the underlying data for its own studies throughout the rulemaking.

WLF urges this Court to doggedly follow each of the FDA's evidentiary claims to their ultimate source. If it does, it will find that none of FDA's evidence supports FDA's flimsy justification for the Rule. This is just one more reason, among many, to affirm the judgment below.

CONCLUSION

This Court should affirm.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limits of Federal Rule of Appellate Procedure 29(a)(5) because it contains 5,160 words, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f).

I also certify that this brief complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5) and (6) because it uses 14-point Century Schoolbook font.

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CERTIFICATE OF SERVICE

I hereby certify that, on July 17, 2023, I served all counsel of record via the Court's CM/ECF system.

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