

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF GEORGIA  
BRUNSWICK DIVISION

PHILIP MORRIS USA INC., et al.,

*Plaintiffs,*

v.

UNITED STATES FOOD AND DRUG  
ADMINISTRATION, et al.,

*Defendants.*

Case No. 2-24-cv-00143-LGW-BWC

**BRIEF OF *AMICI CURIAE* MEDICAL AND PUBLIC HEALTH  
ORGANIZATIONS IN SUPPORT OF DEFENDANTS’ COMBINED MOTION  
FOR SUMMARY JUDGMENT, PARTIAL MOTION TO DISMISS FOR  
LACK OF SUBJECT-MATTER JURISDICTION, AND OPPOSITION TO  
PLAINTIFFS’ MOTION FOR PRELIMINARY INJUNCTION**

**TABLE OF CONTENTS**

STATEMENT OF INTEREST OF *AMICI CURIAE* ..... 3

THE FIRST AMENDMENT FRAMEWORK..... 4

ARGUMENT..... 5

I. INCREASING PUBLIC UNDERSTANDING OF THE HEALTH HAZARDS OF  
SMOKING IS A UNIQUELY SUBSTANTIAL GOVERNMENTAL PUBLIC HEALTH  
INTEREST..... 5

    A. The Health Harms of Smoking Are Uniquely Significant..... 5

    B. Decades of Industry Deception About the Health Harms of Smoking Underscore the  
        Government’s Interest in Increasing Public Knowledge of Those Harms. .... 7

    C. Increasing Public Understanding of the Full Range of Health Hazards of Cigarettes Is a  
        Vital Governmental Interest Standing Alone, Regardless of the Impact on Consumer  
        Behavior..... 9

II. THE HEALTH WARNINGS MANDATED BY THE FINAL RULE DIRECTLY  
ADVANCE THE GOVERNMENTAL INTEREST IN INCREASING PUBLIC  
UNDERSTANDING OF THE HEALTH HARMES OF SMOKING AND ARE NO MORE  
EXTENSIVE THAN NECESSARY TO ADVANCE THAT INTEREST..... 11

    A. The Administrative Record Established Widespread Public Ignorance of the Full Range

of Health Harms of Smoking. .... 11

B. Extensive International Experience Demonstrates That Large, Graphic Health Warnings for Cigarettes Promote Greater Public Understanding of the Health Harms of Smoking. 13

1. The size of the Final Rule warnings promotes greater public understanding of cigarette smoking, while allowing cigarette companies to communicate with consumers. .... 13

2. There is extensive evidence that graphic warnings in effect internationally increase consumer understanding of the health harms of smoking. .... 16

C. FDA’s Studies Confirm that the Final Rule Warnings Will Increase Public Understanding of the Health Hazards of Smoking..... 17

III. AN EMOTIONAL RESPONSE DOES NOT MAKE THE GRAPHIC WARNINGS LESS FACTUAL AND UNCONTROVERSIAL. .... 20

CONCLUSION..... 25

**INTRODUCTION**

In asking this Court to postpone the effective date of FDA’s graphic warnings rule, Plaintiffs make the remarkable claim that FDA has not “identified any public health rationale warranting immediate implementation after four-plus years of delay.” Pls.’ Mot. For Summ. Judg., Postponement, & Prelim. Inj., & Br. in Supp. 65, ECF No. 23-2 [hereinafter “Pls.’ Mot.”]. FDA identified the “substantial Government interest” served by the required warnings in the Final Rule itself: as “[p]roviding relevant, truthful and non-misleading information” about the health risks of smoking that “provides consumers with a better opportunity to make informed choices.” *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15,638, 15,643 (Mar. 18, 2020) (to be codified at 21 C.F.R. pt. 1141) (“Final Rule”). As developed more fully below, it is difficult to imagine a public health rationale more compelling than ensuring that the public—including people who smoke or may initiate smoking—have a more complete and deeper understanding of the extraordinarily broad range of health hazards posed by cigarettes.

It has been 15 years since Congress ordered FDA to issue a rule within 24 months requiring large, graphic health warnings on cigarettes to replace the unnoticed and stale Surgeon General’s

warnings on the sides of cigarette packs. In each of those 15 years, almost 500,000 Americans have perished from smoking-related diseases. *See* Final Rule, 85 Fed. Reg. at 15,652. The tobacco industry’s First Amendment attack on the Final Rule’s graphic warnings has been rejected by a unanimous panel of the U.S. Court of Appeals for the Fifth Circuit, *R.J. Reynolds Tobacco Co. v. FDA*, 96 F.4th 864 (5th Cir. 2024), rehearing *en banc* was denied by that court with no dissent, No. 23-40076, ECF No. 162-2 (5th Cir. May 21, 2024) and the U.S. Supreme Court has denied *certiorari* with no noted dissent, 2024 WL 4874678 (Nov. 25, 2025) (“*Reynolds II*”). It is long past time for the Congressional mandate for greater public understanding of the dangers of Plaintiffs’ products to be implemented. There is no First Amendment barrier to effective cigarette warnings, as mandated by the Final Rule. For the reasons given below, and those advanced by the government, any further delays would be deeply harmful to public health. Plaintiffs’ Motion for Summary Judgment, Postponement, and a Preliminary Injunction should be denied, and Defendants’ Cross-Motion for Summary Judgment should be granted.

#### **STATEMENT OF INTEREST OF *AMICI CURIAE***

This *amicus curiae* brief is submitted by the following national medical and public health organizations: American Academy of Family Physicians, American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Truth Initiative. Each of the *amici* works on a daily basis to prevent the disease and death caused by cigarettes and other tobacco products. Therefore, they have a direct and continuing interest in implementation of the health warnings mandated by the Final Rule. They are united in the conviction that the large, graphic health warnings mandated by the Final Rule are essential for the effective communication to the public of the extraordinary range of health harms from smoking.

In addition, given their expertise, these *amici* are particularly well suited to provide the Court with valuable perspectives on the core First Amendment issues raised by Plaintiffs, including the importance of the Government’s interest in increasing public knowledge of the health harms of smoking, the unique breadth of those harms justifying the Final Rule warnings and distinguishing cigarettes from other dangerous products, the validity of FDA’s conclusion that the Final Rule warnings will increase public knowledge of those harms, the factual and uncontroversial nature of those warnings, and the harms that will result from any further delay in implementing the Final Rule.

### **THE FIRST AMENDMENT FRAMEWORK**

Since the Supreme Court’s decision in *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985), mandatory *disclosures* of “purely factual and uncontroversial” information about products and services have been subject to less exacting First Amendment judicial scrutiny than *limitations* on commercial speech. This distinction is grounded in the Supreme Court’s observation that “the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides . . . .” *Id.* As the Supreme Court concluded, the “constitutionally protected interest in *not* providing any particular factual information in . . . advertising is minimal.” *Id.* (emphasis in original). Thus, in *Zauderer*, the Supreme Court rejected the application to mandatory factual disclosures of the “intermediate scrutiny” test that it applied to restrictions on commercial speech in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). *Id.*

In *Reynolds II*, the Fifth Circuit recently found *Zauderer* applicable to the Final Rule warnings and upheld them against the identical First Amendment challenge brought in the present case. The Fifth Circuit held that, consistent with *Zauderer*, the Final Rule requires disclosure of “purely factual” and “uncontroversial” information about a product and that information

“reasonably relate[s]” to a legitimate governmental interest and does not unduly burden protected speech. *Reynolds II*, 96 F.4th at 885-887. As demonstrated below, this Court should reach the same conclusion against Plaintiffs’ First Amendment challenge. Moreover, even under the “intermediate scrutiny” applied in *Central Hudson* to restrictions on commercial speech, the mandated warnings do not violate the First Amendment because they directly advance a substantial governmental interest and are no more extensive than necessary to serve that interest. *See Central Hudson*, 447 U.S. at 564.<sup>1</sup> Thus, as this brief will demonstrate, *under any constitutional standard applicable to mandatory disclosure requirements in the commercial context, the Final Rule warnings on the hazards of cigarettes are consistent with the First Amendment.*

## **ARGUMENT**

### **I. INCREASING PUBLIC UNDERSTANDING OF THE HEALTH HAZARDS OF SMOKING IS A UNIQUELY SUBSTANTIAL GOVERNMENTAL PUBLIC HEALTH INTEREST.**

Contrary to Plaintiffs’ argument, (Pls.’ Mot. 59-61), there should be little doubt that, under either *Zauderer* or *Central Hudson*, the government’s interest in increasing public understanding of the myriad health harms of smoking is sufficiently substantial to justify the Final Rule warnings. Indeed, the unique breadth and seriousness of the impact of smoking on the human body makes cigarettes a product for which public understanding of the full range of health hazards is a uniquely substantial governmental and public health imperative.

#### **A. The Health Harms of Smoking Are Uniquely Significant.**

The devastating effects of cigarettes on the public health make a mockery of Plaintiffs’ comparison of the health risks of cigarettes to the risks of lawnmowers, swimming pools, ladders,

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<sup>1</sup> Given that the Supreme Court has recognized that restrictions on commercial speech are subject to less exacting judicial scrutiny than restrictions on other forms of speech, *Central Hudson*, 447 U.S. at 562-63, there can be no argument that the Final Rule should be subject to strict scrutiny review.

chain saws, and trampolines. *See* Pls’. Mot. 54-55. Almost a quarter-century ago, the Supreme Court wrote that “tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States.” *FDA v. Brown & Williamson Tobacco Co.*, 529 U.S. 120, 161 (2000). It remains so today. As the FDA has noted, citing the 2014 Surgeon General’s Report on the Health Consequences of Smoking, “[c]igarette smoking is the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year.” *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 84 Fed. Reg. 42,754, 42,756 (proposed Aug. 16, 2019) (to be codified at 21 C.F.R. pt. 1141) (“Proposed Rule”). Indeed, “[s]moking causes more deaths each year than human immunodeficiency virus, illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents combined.” *Id.* at 42,756. In addition, over 16 million Americans live with diseases and health conditions caused by smoking. *Id.* These include not only lung cancer, heart disease and chronic obstructive pulmonary disease (“COPD”), but also other lesser known effects, including many other types of cancer, premature birth, low birth weight, sudden infant death syndrome, respiratory illnesses, clogged arteries, reduced blood flow, diabetes, rheumatoid arthritis, and vision conditions such as age-related macular degeneration and cataracts. *Id.* It is now known that smoking attacks nearly every organ in the human body, causing premature death in half of long-term smokers.<sup>2</sup>

As FDA has noted in another context, the disease and death caused by smoking is “ultimately the result of addiction to the nicotine contained in combustible cigarettes, leading to repeated exposure to toxicants from such cigarettes.” *Tobacco Product Standard for Nicotine*

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<sup>2</sup> OFFICE OF THE SURGEON GENERAL, U.S. DEP’T OF HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS 69, 847 (2014), [https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf\\_NBK179276.pdf](https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf).

*Level of Combusted Cigarettes*, Advance notice of proposed rulemaking, 83 Fed. Reg. 11,818, 11,820 (Mar. 16, 2018). “Nicotine is powerfully addictive,” according to the FDA, which is especially significant because “87 percent of adult smokers start smoking before the age of 18 and half of adult smokers become addicted before the age of 18 . . . .” *Id.* at 11,821. Not only are these young people largely unaware of the addictiveness of nicotine, but the “adolescent brain is more vulnerable to developing nicotine dependence than the adult brain . . . .” *Id.*

There is no other consumer product that both causes such egregious damage to the human body and is so highly addictive, particularly to those most vulnerable to promotional tactics— young people. Thus, contrary to Plaintiffs’ suggestion (Pls’. Mot. 54-55), large, graphic health warnings on cigarettes do not necessarily justify similar warnings on other dangerous products. There may be no “tobacco exception” to the First Amendment (*id.*), but the First Amendment permits distinctions between the nature and importance of the governmental interests at stake in product warnings cases, allowing differences between the kinds of warnings that satisfy the First Amendment. Certainly, the First Amendment does not dictate that the warnings for a highly addictive product that kills half of its long-term users are comparable to the warnings appropriate on a ladder.

**B. Decades of Industry Deception About the Health Harms of Smoking Underscore the Government’s Interest in Increasing Public Knowledge of Those Harms.**

The importance of effectively communicating the staggering range of health harms of smoking is underscored by the decades of deception by the cigarette companies—including Plaintiff Philip Morris USA Inc.—about the adverse health effects of smoking. Indeed, in *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff’d in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S. Ct. 3501 (2010), the court found Philip Morris

and other cigarette companies liable for violating federal racketeering laws by engaging in a 50-year conspiracy to misrepresent the truth about the health effects of smoking. The court wrote:

[This case] is about an industry, and in particular these Defendants, that survives, and profits, from selling a highly addictive product which causes diseases that lead to a staggering number of deaths per year, an immeasurable amount of human suffering and economic loss, and a profound burden on our national health care system. Defendants have known many of these facts for at least 50 years or more. *Despite that knowledge, they have consistently, repeatedly and with enormous skill and sophistication, denied these facts to the public, the Government, and to the public health community.*

*Id.* at 28. (emphasis added). The court further found that “[d]efendants have not ceased engaging in unlawful activity” and that their deception was likely to continue into the future. *Id.* at 909-10.

The government has a substantial interest in increasing public knowledge of the health hazards of cigarettes, not only because of the unique danger these products pose, but also to overcome decades of fraudulent misrepresentations made by their purveyors. Although the Eleventh Circuit has never adopted Plaintiffs’ view (Pls’. Mot. 42-43, 56-57) that *Zauderer* is applicable only when government-compelled speech prevents or corrects deceptive speech,<sup>3</sup> a reading of *Zauderer* that has been rejected by the First, Second, Fifth, Sixth, Ninth and D.C. Circuits,<sup>4</sup> the Final Rule warnings are certainly justified by that interest alone. In any event, the industry’s fraud makes the effective communication of the profoundly adverse health effects of smoking a particularly vital governmental interest. To this day, significant gaps remain in public

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<sup>3</sup> Contrary to Plaintiffs’ misleading suggestion (Pls’. Mot. 43), the court in *NetChoice, LLC v. Attorney General*, 34 F.4th 1196, 1227 (11th Cir. 2022), *vacated and remanded on other grounds sub nom. Moody v. NetChoice, LLC*, 144 S. Ct. 2383 (2024), did not hold that preventing consumer deception was the only possible governmental interest that would suffice under *Zauderer*, but only that the governmental interest “in ensuring that users—consumers who engage in commercial transactions with platforms by providing them with a user and data for advertising in exchange for access to a forum – are fully informed about the terms of that transaction and aren’t misled about platforms’ content-moderation policies” is “likely legitimate” under *Zauderer*. *NetChoice*, 34 F.4th at 1230.

<sup>4</sup> See *Reynolds II*, 96 F.4th at 882 (collecting cases).



knowledge of the full range of health harms from smoking cigarettes, the direct result of the industry's decades-long misrepresentations of the truth about its products. Proposed Rule, 84 Fed. Reg. at 42,761. This unprecedented fraud further distinguishes cigarettes from other dangerous products, justifying large, graphic health warnings on cigarette packages and advertising to ensure that the truth is finally communicated in the most effective way. As the Fifth Circuit concluded, “[i]ncreasing public understanding of the risks of smoking, *particularly given the ‘long history of deception concerning consumer health risks in the cigarette industry,’* is a legitimate state interest, meeting that [Zauderer] standard.” *Reynolds II*, 96 F.4th at 884 (emphasis added by Fifth Circuit) (quoting Final Rule, 85 Fed. Reg. at 15,645).

**C. Increasing Public Understanding of the Full Range of Health Hazards of Cigarettes Is a Vital Governmental Interest Standing Alone, Regardless of the Impact on Consumer Behavior.**

Invoking the decision in *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled in part*, *American Meat Institute v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (“*Reynolds I*”), Plaintiffs argue that FDA’s asserted interest in increasing public knowledge of the health harms of smoking is “circular” and unable to stand on its own as a valid and substantial governmental interest for First Amendment purposes, without a further showing that the warnings would cause consumers to make different choices and stop smoking. Pls’. Mot. 59-60.

But the *Reynolds I* Court itself recognized that “the government can certainly require that consumers be fully informed about the dangers of hazardous products.” 696 F.3d at 1212. In striking down the FDA’s 2011 cigarette warnings, the D.C. Circuit found that “[t]he *only* explicitly asserted interest in either the Proposed or Final Rule is an interest in reducing smoking rates,” and that FDA conceded that its interest in effective communication of health information “describes only the *means* by which FDA is attempting to reduce smoking rates . . . .” *Id.* at 1218, 1221 (emphasis in original). The *Reynolds I* court did not find that the government’s interest in

effectively communicating the health harms of smoking was insubstantial, but rather that it was “too vague to stand on its own,” because FDA had offered no “barometer” for assessing the effectiveness of the graphic warnings other than whether “they encourage current smokers to quit and dissuade would-be smokers from taking up the habit.” *Id.* at 1221. Unlike the 2011 Rule, however, the Final Rule here sets out several “barometers” to measure the effectiveness of the mandated warnings in promoting understanding of the health harms of smoking and tested the warnings against those metrics. FDA found that the warnings showed statistically significant improvements in the key outcomes of “new information” and “self-reported learning,” and that those metrics were predictive of whether the warnings would promote greater public understanding of the risks of cigarette smoking. *See infra* at II.C.

That greater public knowledge of the health harms of smoking can stand alone as a vital governmental interest was recognized in *Discount Tobacco City & Lottery, Inc. v. United States*, where the Sixth Circuit upheld, against First Amendment challenge, the statutory mandate for graphic health warnings in the Tobacco Control Act (“TCA”). 674 F.3d 509 (6th Cir. 2012). The court wrote, “[w]hat matters in our review of the required warnings is not how many consumers ultimately choose to buy tobacco products, but that the warnings effectively communicate the associated health risks so that consumers possess accurate, factual information when deciding whether to buy tobacco products.” *Id.* at 567. Indeed, in enacting the TCA, Congress explicitly upheld that greater public understanding of the health hazards of smoking is itself a substantial governmental interest. Not only did Congress include, as one of the expressed statutory purposes, “to ensure that consumers are better informed,” but this purpose is also embedded in the provision giving FDA the authority to revise the cigarette warnings upon a finding that “such a change would promote greater public understanding of the risks associated with the use of tobacco products.”

See TCA, Pub. L. No. 111-31, §§ 3(6), 202(d), 123 Stat. 1777, 1782, 1845-46 (2009). No showing of an impact on smoking cessation or initiation is required. Moreover, Congress recognized the urgency of requiring new health warnings that more effectively enhanced public understanding of those risks, when it directed FDA to issue a graphic warnings rule within 24 months of enactment, TCA §201(d) and limited the implementation period for the warnings to 15 months from the date of the rule's issuance. 15 U.S.C. § 1333 note.

Plaintiffs disavow the urgency felt by Congress, minimizing the interest asserted as simply “giving consumers information.” Pls.’ Mot. 59-60. But health warnings on cigarettes do not simply convey more information for its own sake. They convey information about a highly addictive product that kills half of its long-term users. The justification for the Final Rule warnings bears no resemblance to the cases, cited by Plaintiffs (*id.* at 60), in which the government’s stated interest is merely improving consumer knowledge without any connection to public health or safety.

## **II. THE HEALTH WARNINGS MANDATED BY THE FINAL RULE DIRECTLY ADVANCE THE GOVERNMENTAL INTEREST IN INCREASING PUBLIC UNDERSTANDING OF THE HEALTH HARMS OF SMOKING AND ARE NO MORE EXTENSIVE THAN NECESSARY TO ADVANCE THAT INTEREST.**

The mandated warnings in the Final Rule directly advance the government’s vital interest in promoting greater public understanding of the all-too-real negative health effects of smoking and are no more extensive than necessary to advance the government’s interest. As such, the Final Rule is entirely consistent with the First Amendment under either *Zauderer* or *Central Hudson*.

### **A. The Administrative Record Established Widespread Public Ignorance of the Full Range of Health Harms of Smoking.**

Despite extensive efforts to educate the public about the health hazards of cigarettes, there remain significant gaps in public understanding about the general harms of cigarette smoking

addressed by the current text of the Surgeon General's health warnings, as well as the particular harms addressed by the warnings mandated by the Final Rule.

In *Reynolds II*, the Fifth Circuit relied on "FDA's significant evidence that consumers do not notice, much less internalize, the text-only warnings in the *status quo*." 96 F.4th at 884. The existing Surgeon General's health warnings, which have been unchanged for over three decades, are routinely ignored by consumers. For the entirety of that time, the warnings have been printed in small text on the side of cigarette packs. As the FDA found, the current warnings do not effectively inform the public of the negative health effects of smoking because they do not attract attention, are not remembered, and do not prompt thoughts about the risks of smoking. Proposed Rule, 84 Fed. Reg. at 42,759-61. A significant portion of respondents in studies have failed to identify emphysema as a smoking-related lung disease, have underestimated the percent of people diagnosed with lung cancer who would die from the condition, incorrectly believe that cigarettes have not been proven to cause cancer, and do not accurately understand the health effects of smoking during pregnancy. *Id.* at 42,761.

Moreover, in the decades during which health warnings on cigarette packs have remained unchanged, medical research has linked additional diseases to smoking. The 2014 Surgeon General's Report added 11 diseases causally linked to smoking to the list of 40 other adverse health consequences of smoking and exposure to secondhand smoke that were already known. *Id.* at 42,756. As FDA found, there is low public awareness of the adverse health consequences of smoking that are not addressed in the Surgeon General's warnings. *Id.* FDA's experimental studies demonstrated that more than half of all respondents indicated that they had never heard about the health effects depicted by the Final Rule warnings. *Id.* at 42,767-772. By focusing on

some of these lesser-known health effects, the warnings required by the Final Rule will increase the public’s knowledge and understanding of the full range of smoking’s health consequences.

**B. Extensive International Experience Demonstrates That Large, Graphic Health Warnings for Cigarettes Promote Greater Public Understanding of the Health Harms of Smoking.**

The requirement of large, pictorial warnings is supported by remarkably broad real-world experience. Canada was the first country to implement picture warnings in 2001.<sup>5</sup> Today, 127 countries require graphic warnings to cover at least 50% of the package.<sup>6</sup> The impact of those warnings has been extensively studied and they have been shown to measurably increase public understanding of the dangers of smoking.

**1. The size of the Final Rule warnings promotes greater public understanding of cigarette smoking, while allowing cigarette companies to communicate with consumers.**

Research shows that size plays a key role in the effectiveness of graphic warnings—larger graphic health warnings are more effective. The size of the mandated warnings in the Final Rule is no more extensive than reasonably necessary to advance the government’s interest in promoting greater public understanding of the health harms of cigarettes. In upholding the TCA mandate for larger cigarette warnings, the Sixth Circuit in *Discount Tobacco* found “abundant evidence” that “larger warnings incorporating graphics promote a greater understanding of tobacco-related health risks . . . .” 674 F.3d at 565. In support of the Final Rule, FDA has provided substantial evidence to demonstrate that the effectiveness of a warning to communicate health information increases with size. *See* 84 Fed. Reg. at 42,759-60, 42,763, 42,779. Warnings must be large enough to be

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<sup>5</sup> Canadian Cancer Society, *Cigarette Package Health Warnings: International Status Report 2* (8th ed. 2023), <http://bit.ly/3BYkB3X>.

<sup>6</sup> *Id.*

easily noticed and read. *Id.* at 42,779.<sup>7</sup> A major multi-country study that compared health warnings in four high-income countries (Australia, Canada, the United Kingdom, and the United States) found that larger, more comprehensive health warnings were more likely to be noticed and rated as effective by individuals who smoke. 84 Fed. Reg. at 42,760, 42,762.

The warnings at issue here are unlike the sugar-sweetened beverage warnings found unduly burdensome in *American Beverage Association v. City & County of San Francisco*, 916 F.3d 749, 757 (9th Cir. 2019) (en banc), where the city’s own expert conceded that a warning one-half the size of the challenged warning would be just as effective. Here, FDA found that the “scientific literature strongly supports that larger warnings, such as those of the size proposed in this rule, are necessary to ensure that consumers notice, attend to, and read the messages conveyed by the warnings, which leads to improved understanding of the specific health consequences that are the subject of those warnings.” 84 Fed. Reg. at 42,779.

Plaintiffs suggest that “less-invasive” methods exist to increase public understanding, like FDA’s own successful public-information campaigns. Pls.’ Mot. 62. *Amici* recognize the effectiveness of such public education campaigns, but effective health warnings on cigarette packs and advertising have unique advantages over other means of communicating the harms of smoking.<sup>8</sup> The Final Rule warnings are particularly well-suited to serve the government’s interest because they are “paired” with the product itself. This ensures that all potential cigarette

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<sup>7</sup> See also David Hammond, *Tobacco Labelling & Packaging Toolkit, A Guide to FCTC Article 11* (Feb. 2009), <http://www.tobaccolabels.ca/toolkit>.

<sup>8</sup> *Amici* have particular credibility on this point, as many of them have been involved for decades in sponsoring and supporting public education campaigns on the dangers of tobacco products and are thus well aware of the effectiveness of those campaigns. See, e.g., *1960’s American Cancer Society PSAs*, AM. CANCER SOC’Y, <https://www.youtube.com/watch?v=hHRcw3NPMD0>; *Quit Smoking, Vaping and Tobacco Use*, AM. HEART ASS’N, <https://www.heart.org/en/healthy-living/healthy-lifestyle/quit-smoking-tobacco>; *Quit Smoking*, AM. LUNG ASS’N, <https://www.lung.org/quit-smoking>; *Youth Smoking and Vaping Prevention*, TRUTH INITIATIVE, <https://truthinitiative.org/what-we-do/youth-smoking-prevention-education>.

consumers are repeatedly exposed to the warnings at the point of sale, and prior to use. These health warnings provide assurance that potential consumers, particularly young people, have accurate health information before using a highly addictive and lethal product. The combined text and graphic warnings required by the Final Rule are no more extensive than necessary to ensure the effective communication of the health risks of cigarettes to every consumer at the point where purchase and use decisions are made. Thus, even under the *Central Hudson* test, the Final Rule warnings pass muster, as they are no more extensive than necessary to serve the government's substantial interest in promoting greater public understanding of the hazards of smoking.<sup>9</sup>

Moreover, in no sense will the warnings chill protected speech. The tobacco industry undeniably retains the ability, and has the resources, to convey its own message. Plaintiffs will retain 50% of the space on the front and back panels of cigarette packs and 80% of the space for cigarette advertisements to feature their logos, brand names, and other information. *Disc. Tobacco*, 674 F.3d at 524 (citing 15 U.S.C. §§ 1333, 4402(2)(A)). They also will have the additional package space now occupied by the current health warnings. In countries where graphic warnings have been in place for years, cigarette companies have successfully advertised their cigarettes with their logos and other design features.<sup>10</sup> According to the Fifth Circuit's opinion in *Reynolds II*, unlike the warnings struck down in *National Inst. Of Family & Life Advocs. v.*

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<sup>9</sup> Contrary to Plaintiffs' suggestion, (Pls.' Mot. 48), the fact that Congress has mandated textual warnings covering only 30% of the area on smokeless tobacco packages hardly establishes that smaller, text-only cigarette warnings would be just as effective as the Final Rule warnings. Rather, it may simply represent a Congressional recognition that more prominent warnings are needed on cigarettes, given that industry spending on the promotion of cigarettes far exceeds spending to promote smokeless tobacco. See Fed. Trade Comm'n, *FTC Releases Reports on Cigarette and Smokeless Tobacco Sales and Marketing Expenditures for 2022* (Oct. 30, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/10/ftc-releases-reports-cigarette-smokeless-tobacco-sales-marketing-expenditures-2022>.

<sup>10</sup> Tobacco Labelling Resource Centre, *Canada Cigarette Package Images*, <https://tobaccolabels.ca/pack-images/country/?n=Canada> (last visited Jan. 15, 2025).

*Becerra*, 585 U.S. 755 (2018) (“*NIFLA*”), the Final Rule warnings “do not impose a disproportionate requirement that would ‘effectively rule[] out’ the possibility of having [an advertisement] in the first place.” 96 F.4th at 887 (quoting *NIFLA*, 585 U.S. 755, 778 (2018)).

Despite the restrictions on cigarette advertising in the United States, cigarette companies’ annual expenditures for advertising and promotion in the United States totaled \$1.3 billion in 2017. Proposed Rule, 84 Fed. Reg. at 42,759. Smokers and nonsmokers in the United States, including adolescents, are constantly exposed to cigarette advertising through a range of market channels, including print and digital media, outdoor locations, and in and around retail establishments. *Id.* None of these channels will be foreclosed by the mandated warnings. Plaintiffs’ assertion that FDA’s Final Rule “would seize virtually the only means of communication that cigarette manufacturers have left” (Pls.’ Mot. 44) cannot be taken seriously.

**2. There is extensive evidence that graphic warnings in effect internationally increase consumer understanding of the health harms of smoking.**

FDA points to multiple studies from various countries showing that graphic health warnings increase attention, noticeability, recall, information processing and understanding of warnings. Proposed Rule, 84 Fed. Reg. at 42,762-65. As one such study concluded, “warnings that are graphic, larger, and more comprehensive in content are more effective in communicating the health risks of smoking.”<sup>11</sup> It found that smokers in the U.S. reported the lowest level of health knowledge among all countries in the study, both overall and for individual health effects of smoking.<sup>12</sup> It also found that only 47% of U.S. smokers reported noticing information about the

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<sup>11</sup> David Hammond et al., *Effectiveness of Cigarette Warning Labels in Informing Smokers About the Risks of Smoking: Findings from the International Tobacco Control (ITC) Four Country Survey*, 15 TOBACCO CONTROL iii19, iii 19 (2006), [https://tobaccocontrol.bmj.com/content/tobaccocontrol/15/suppl\\_3/iii19.full.pdf](https://tobaccocontrol.bmj.com/content/tobaccocontrol/15/suppl_3/iii19.full.pdf).

<sup>12</sup> *Id.* at iii21, tbl 2.



dangers of smoking “often” on cigarette packages, compared to 84% in Canada.<sup>13</sup> Another study comparing the impact of text-only cigarette warnings in Mexico with pictorial warnings in Canada showed that Canadian adult smokers were more likely to notice the warning label and think about the harms of smoking. *See* Proposed Rule, 84 Fed. Reg. at 42,762.

Plaintiffs seek to minimize the significance of these foreign studies by noting that they involve “different countries with different demographics” (Pls.’ Mot. 61), but as FDA noted in the Final Rule, the “consistency of findings on the effectiveness of pictorial cigarette warnings across countries supports both the scientific validity and reliability of the effect of pictorial cigarette warnings, irrespective of country-specific contexts.” 85 Fed. Reg. at 15,657.

**C. FDA’s Studies Confirm that the Final Rule Warnings Will Increase Public Understanding of the Health Hazards of Smoking.**

FDA’s own experimental studies of the specific pairings of text and graphics in the Final Rule establish that these warnings will increase public knowledge of the health hazards of smoking.

Much of Plaintiffs’ critique of FDA’s development of the Final Rule warnings focuses on FDA’s qualitative studies and first quantitative study, in which earlier versions or partial components of the warnings were tested in isolation to inform the development of the final warnings. *See* Pls.’ Mot. 33-39. FDA’s *second* quantitative study, in contrast, tested the images and texts when they are presented together—as they will be when the Final Rule goes into effect. FDA’s carefully-constructed, randomized trial collected data on ten measures of the impact of the combined warnings, including the two measures FDA had pre-selected as the best predictors of improved understanding—whether a warning was “new information” and whether participants learned something (“self-reported learning”). Proposed Rule, 84 Fed. Reg. at 42,768-69. *Every*

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<sup>13</sup> *Id.* at iii23.

Final Rule warning outperformed the existing Surgeon General’s warnings, not only as “new information,” and “self-reported learning,” but also as “more likely to grab attention,” “easier to understand,” “more informative,” more likely to make participants “think about the health risks of smoking,” helpfulness in understanding health effects of smoking, and recall. Final Rule, 85 Fed. Reg. at 15,658. Plaintiffs’ attack largely ignores the significance of these findings and instead focuses on various decisions made by FDA as to which diseases to feature in the warnings and how to portray them. In doing so, Plaintiffs lose the forest for the trees by obfuscating the key conclusion supported by FDA’s studies: that these specific warnings will increase public understanding of the health harms of cigarettes as compared to the current Surgeon General’s warnings.

First, Plaintiffs charge that FDA’s “choices of which health risks to feature” in the warnings was “irrational.” Pls.’ Mot. 31. But FDA’s choices are justified by a consistently applied principle: that increases in public understanding of health risks are more likely if the warnings convey new, lesser-known information. Although some of the Final Rule warnings address some of the health risks that have long been the subject of the Surgeon General’s warnings, they provide new, specific information about those risks. For example, the original TCA statement, “Cigarettes cause cancer” was replaced with two separate messages, “Smoking causes bladder cancer, which can lead to bloody urine,” and “Smoking causes head and neck cancer.” All of the revised text statements in the Final Rule were more likely to be perceived as “new information” than a corresponding TCA statement.<sup>14</sup>

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<sup>14</sup> Jessica K. Pepper et al., *Impact of Pictorial Cigarette Warnings Compared With Surgeon General’s Warnings on Understanding of the Negative Health Consequences of Smoking*, 22 NICOTINE TOBACCO RESEARCH 5 (2020), <https://pmc.ncbi.nlm.nih.gov/articles/PMC10557086/>.

Although Plaintiffs acknowledge that the Surgeon General's 2014 Report identified 51 diseases and conditions caused by their products, they "question why FDA bypassed many" conditions and picked others. Pls.' Mot. 33. Of course, any difficulty facing FDA in choosing what smoking-related diseases to feature in the warnings arises from the sheer number and seriousness of the diseases caused by cigarettes. But there was nothing irrational about FDA's choices. FDA supported each new warning with evidence that the warning is factually true and scored higher than the current Surgeon General's warnings on both providing new information and self-reported learning, as well as other relevant measures. *See* Final Rule, 85 Fed. Reg. at 15,667-84. The fact that warnings could have been developed and tested to address other health harms from smoking in no way establishes that the choices made were "arbitrary," or that the Final Rule warnings will fail to materially enhance the public's understanding of the devastating health consequences of cigarettes.<sup>15</sup>

Second, Plaintiffs suggest that FDA's qualitative studies provide evidence that the warnings are "unclear" and "confusing." Pls.' Mot. 36. But the images referenced by Plaintiffs refer to the initial concept drawings tested in the early stage of development, not the images in the Final Rule warnings. *See e.g.* AR23452, AR23468, AR23512. Moreover, none of the examples identified by Plaintiffs as "confusing" were the subjects of later studies that tested both the image and the accompanying text statement together, as did FDA's pivotal second quantitative study.

Third, although Plaintiffs make much of the fact that most of the tested warnings were lower in perceived factualness than the existing Surgeon General's warnings, *see* Pls.' Mot. 35, 37-39, this finding is entirely consistent with the fact that the tested warnings were providing new information. It is unsurprising that, when initially exposed to new information about the health

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<sup>15</sup> Of course, FDA may at some point revise the Final Rule warnings to address different disease risks caused by smoking, under the authority given it by section 202 of the TCA.

risks of smoking, many study participants questioned if it was true, especially when compared to the Surgeon General’s warnings, which have appeared on cigarette packages for more than three decades. *See* Final Rule, 85 Fed. Reg. at 15,660. It does not imply that the Final Rule warnings will not improve consumer understanding when they are implemented and seen repeatedly.

Finally, it is revealing that Plaintiffs cite the negative reaction of some qualitative study participants to the causal language in the Final Rule textual warnings. Pls.’ Mot. 36-37. As explained in depth by FDA, the language used in each of the Final Rule warnings, “Smoking causes [health consequence],” is entirely consistent with the epidemiological evidence and the conclusions of the Surgeon General’s Report. *See* Proposed Rule, 84 Fed. Reg. at 42,773-77. Plaintiffs’ objection to definitive causal language is the latest of the longstanding efforts of cigarette companies to sow doubt among consumers as to the health effects of their products. If some participants in the FDA’s studies questioned the believability of strong, causal statements, it evidences the industry’s decades of deception.

Therefore, Plaintiffs’ determined search for flaws in the process by which FDA developed and tested its warnings fails to throw doubt on the decisive proposition: that the Final Rule warnings will enhance public understanding of the devastating health effects of cigarettes.

### **III. AN EMOTIONAL RESPONSE DOES NOT MAKE THE GRAPHIC WARNINGS LESS FACTUAL AND UNCONTROVERSIAL.**

Plaintiffs argue that because the Final Rule warnings provoked “expressive responses” and “trigger emotion” from participants in FDA’s qualitative studies, they cannot be “purely factual” disclosures under *Zauderer*. Pls’ Mot. 51-52. This is a transparent fallacy.

**The fact is that the health effects of smoking are inherently frightening.** For example, there is little doubt that cancer is a widely-feared disease in the general population and that

smoking causes at least 14 different types of cancer.<sup>16</sup> Beyond mortality, the medical treatments for these cancers—including surgery, radiation and chemotherapy—can be terribly painful and difficult. That the Final Rule warnings may elicit negative emotions is an indication that they are effectively communicating factual information about the health effects of smoking. *See* 85 Fed. Reg. at 15,670 (“[T]he severe, life-threatening and sometimes disfiguring health effect of smoking are indeed concerning.”). In *Discount Tobacco*, the Sixth Circuit exposed the flaw in Plaintiffs’ reasoning:

[W]e vigorously disagree with the underlying premise that a disclosure that provokes a visceral response must fall outside *Zauderer*’s ambit. Facts can disconcert, displease, provoke an emotional response, spark controversy, and even overwhelm reason, but that does not magically turn such facts into opinions . . . [W]hether a disclosure is scrutinized under *Zauderer* turns on whether the disclosure conveys factual information or an opinion, not on whether the disclosure emotionally affects its audience or incites controversy.

674 F.3d at 569 (emphasis added).

Moreover, if FDA had sought to prioritize “shocking” images, it would have selected images that depicted actual images of “real people” suffering the health effects of smoking. Instead, the agency opted for photorealistic images, which are considerably less graphic and less likely to elicit strong negative emotions.<sup>17</sup> Indeed, some of the graphics chosen by FDA match the examples given by the court in *Discount Tobacco* in rejecting the contention that graphic warnings are inherently non-factual or controversial, including “a picture or drawing of the internal anatomy of a person suffering from a smoking-related medical condition,” or “a picture or drawing of a person suffering from a smoking-related medical condition . . . .” 674 F.3d at 559-60. As the

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<sup>16</sup> Nat’l Insts. of Health, *Harms of Cigarette Smoking and Health Benefits of Quitting* (Dec. 19, 2017), <https://www.cancer.gov/about-cancer/causes-prevention/risk/tobacco/cessation-fact-sheet#r1>.

<sup>17</sup> David Hammond et al., *Pictorial Health Warnings on Cigarette Packs in the United States: An Experimental Evaluation of the Proposed FDA Warnings* 15 NICOTINE & TOBACCO RESEARCH 93 (2013), <https://pmc.ncbi.nlm.nih.gov/articles/PMC3524059/>.

Sixth Circuit also noted, such images are typically used in medical textbooks precisely because they are accurate renditions of factual information. *Id.* at 559; *see* Final Rule, 85 Fed. Reg. at 15,646.<sup>18</sup> In upholding the Final Rule warnings against First Amendment challenge, the Fifth Circuit found the Sixth’s Circuit’s reasoning persuasive, concluding that the textual warnings are entirely supported by factual findings and the “addition of images to the textual warnings makes no difference to the constitutional analysis of factuality.” *Reynolds II*, 96 F.4th at 879. As the Fifth Circuit explained, “at most, the emotional response of viewers is incidental to their retention of information about the health risks.” *Id.* at 880. Thus, “the emotional impact of the Warnings does not abrogate their factual nature.” *Id.*

Contrary to Plaintiffs’ suggestion (Pls.’ Mot. 51-52, 53-54), the D.C. Circuit’s *Reynolds I* decision does not suggest in any way that the Final Rule warnings here cannot be regarded as “factual and uncontroversial” under *Zauderer*. As noted above, the D.C. Circuit found that FDA’s only asserted governmental interest supporting the 2011 cigarette warnings was to reduce smoking rates. The court further held that, consistent with that purpose, the 2011 cigarette warnings were not efforts to convey factual information, but rather “were unabashed attempts to evoke emotion . . . and browbeat consumers into quitting.” 696 F.3d at 1217. The court also noted that some of the images “do not convey *any* warnings information at all,” citing one image of a man wearing a T-shirt with the words “I QUIT,” but offering no information about the health effects of smoking. *Id.* at 1216-17 (emphasis in original). Moreover, the court relied heavily on the inclusion, in all

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<sup>18</sup> As the Sixth Circuit also noted, although *Zauderer* did not address graphic health warnings, the *Zauderer* opinion itself “eviscerates the argument that a picture or drawing cannot be accurate or factual.” *Disc. Tobacco*, 674 F.3d at 560. In striking down a state rule banning all illustrations in attorney advertising, the *Zauderer* Court wrote that “the use of illustrations or pictures in advertisements serves important communicative functions: it attracts the attention of the audience to the advertiser’s message, and it may also serve to impart information directly.” 471 U.S. at 647; *accord Reynolds II*, 96 F.4th at 884.

the 2011 warnings, of a 1-800-QUIT NOW hotline number. *Id.* All these factors led the *Reynolds I* court to conclude that FDA had crossed the line from factual disclosures to efforts “to compel a product’s manufacturer to convey the state’s subjective—and perhaps even ideological—view that consumers should reject the other legal, but disfavored, product [.]” *Id.* at 1212.

FDA’s rulemaking leading to the Final Rule warnings here demonstrates that the agency carefully accounted for the *Reynolds I* decision and did not cross the line between factual disclosure and ideology. The administrative record shows that, unlike the 2011 warnings, the Final Rule warnings were never assessed for their capacity to induce emotional responses and discourage smoking, but only for their capacity to enhance consumer understanding of the health dangers of smoking. FDA’s carefully constructed randomized trial collected data on ten measures of the impact of the warnings, including the two measures FDA had pre-selected as the best predictors of improved understanding. Proposed Rule, 84 Fed. Reg. at 42,768-69. As explained above, FDA also relied on a plethora of studies of large, graphic warnings on cigarettes in other countries showing that such warnings have increased consumer understanding. Moreover, unlike the 2011 warnings, every warning mandated by the Final Rule features information about the health dangers of cigarettes and none feature anything remotely similar to the advocacy message of “1-800-QUIT NOW.” Thus, as with the warning upheld in *Zauderer*, FDA here “has not attempted to prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to express by word or act their faith therein.” *Zauderer*, 471 U.S. at 651 (internal citations omitted).

Nor does the Supreme Court’s decision in *NIFLA* show that FDA’s warnings are not “factual and uncontroversial” disclosures properly analyzed under *Zauderer*. In *NIFLA*, the Court struck down a California statute directed at “crisis pregnancy centers” that offer a range of free

pregnancy options but clearly are aimed at discouraging women from seeking abortions. In finding *Zauderer* inapplicable, the Court noted that the required notice was not limited to factual and uncontroversial information related to the services that the clinic provided, but rather required those clinics to disclose information about the availability of abortion services elsewhere. *NIFLA*, 585 U.S. at 767-68. These notices are not remotely analogous to the Final Rule warnings, which relate specifically to factual and uncontroversial health harms from use of the products on which the warnings appear. As the Ninth Circuit observed, the compelled statement in *NIFLA* “took sides in a heated political controversy.” *CTIA – The Wireless Ass’n v. City of Berkeley*, 928 F.3d 832, 846 (9th Cir. 2019). The same cannot be said for the health warnings mandated by the Final Rule. Indeed, the Court in *NIFLA* itself distinguished the mandatory notices at issue in that case from health and safety warnings: “[W]e do not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products.” *NIFLA*, 585 U.S. at 775.

Finally, Plaintiffs’ assertion that the Final Rule warnings are “misleading” (Pls.’ Mot. 49) is groundless. The charge is largely based on the failure of the warnings to provide *more* information—specifically, information about the *relative* risk of suffering various diseases from smoking, where certain diseases like lung disease are more likely than other diseases like bladder cancer. Plaintiffs never explain why warnings of health hazards that are otherwise factual and uncontroversial are somehow rendered suspect under the First Amendment because they fail to address the comparative risk of being victimized by the myriad of diseases caused by cigarettes. Moreover, Plaintiffs’ characterization of the graphic elements as “misleading” because they may not depict the “typical” consequences of smoking, or of the diseases caused by smoking (Pls.’ Mot. 51), ignores the fundamental purpose of effective health warnings, whether on cigarette packaging,



workplace machinery, or pharmaceutical products: to communicate the risk of serious harm to those who may use the product. Indeed, the more serious the harm, the more prominent the warning, as demonstrated, for instance, by the “Black Box” warnings on some pharmaceuticals, which convey only “serious or life-threatening risks.”<sup>19</sup> That many users of a product may not experience the most harmful effects that are the subject of the warning certainly does not render it “misleading.” As the Fifth Circuit observed in upholding the Final Rule warnings, “we uncover no caselaw requiring the government to choose only the most common side-effect or consequence of the disease or injury discussed in a warning.” *Reynolds II*, 96 F.4th at 881.

For each of the warnings, FDA cites evidence from the Surgeon General’s Report and other highly credible sources establishing that the textual warnings are factual and uncontroversial, and that the graphics accurately portray a serious consequence of the disease that is the subject of the text. Final Rule, 85 Fed. Reg. at 15,671-84. Plaintiffs’ suggestion that the graphics are “misleading” is nothing more than the latest chapter in the decades-long story of the tobacco industry’s efforts to minimize the risks of smoking by denying what the science plainly shows.

### **CONCLUSION**

As expressed by the Supreme Court in *Zauderer*, the core of the First Amendment protection of commercial speech is “the value to consumers of the information such speech provides.” 471 U.S. at 651. Far from impeding the communication of valuable factual information to consumers, the Final Rule warnings will advance the government’s vital public health interest in promoting greater public understanding of the devastating health harms of smoking cigarettes. For this reason, and for the reasons asserted in the government’s brief, the Court should grant

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<sup>19</sup> FDA, *Glossary of Terms*, <https://bit.ly/3C5wzJ3> (Apr. 19, 2019).

Defendants' Combined Motion for Summary Judgment (Dkt. 39) and deny Plaintiffs' Motion for Summary Judgment, Postponement, and a Preliminary Injunction (Dkt. 23-2).

Respectfully Submitted,

/s/ Theresa D. Beaton

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### **CERTIFICATE OF SERVICE**

Pursuant to Local Rule 5.1, the *amici* certify that they effected service of this filing on all parties to this action by filing it with the Court's electronic filing system.

Dated: January 23, 2025

/s/ Theresa D. Beaton