IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHILIP MORRIS USA INC.,

SHERMAN GROUP HOLDINGS, LLC,

Plaintiffs,

v.

Case No.: 20-cv-1181 (KBJ)

UNITED STATES FOOD AND DRUG ADMINISTRATION,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

STEPHEN M. HAHN, in his official capacity as Commissioner of the United States Food and Drug Administration,

ALEX AZAR, in his official capacity as Secretary of the United States Department of Health and Human Services,

Defendants.

BRIEF OF *AMICI CURIAE* MEDICAL AND PUBLIC HEALTH ORGANIZATIONS IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND A PRELIMINARY INJUNCTION

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CORPORATE AND FINANCIAL DISCLOSURE STATEMENT

Amici curiae[1] are non-profit organizations committed to advancing the public health. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

STATEMENT OF COUNSEL PURSUANT TO FEDERAL RULE OF APPELLATE PROCEDURE 29(a)(4)(E) AND LOCAL CIVIL RULE 7(o)(5)

Counsel for *amici curiae* hereby states that no counsel for any party to this litigation authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund, or did fund, the preparation or submissions of this brief; and no person, other than *amici curiae*, contributed money that was intended to fund, or did fund, the preparation or submission of this brief.

[1] *Amici* include the following organizations: American Academy of Otolaryngology – Head and Neck Surgery, American Academy of Pediatrics, American Cancer Society, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, American Medical Association, American Public Health Association, American Thoracic Society, Campaign for Tobacco-Free Kids, COPD Foundation, March of Dimes, Medical Society of the District of Columbia, National Black Nurses Association, National Hispanic Medical Association, Society for Cardiovascular Angiography and Interventions, and Truth Initiative Foundation.

STATEMENT OF INTEREST OF *AMICI CURIAE*

This brief is submitted by the following national organizations: American Academy of Otolaryngology – Head and Neck Surgery, American Academy of Pediatrics, American Cancer Society, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, American Medical Association, American Public Health Association, American Thoracic Society, Campaign for Tobacco-Free Kids, COPD Foundation, March of Dimes, Medical Society of the District of Columbia, National Black Nurses Association, National Hispanic Medical Association, Society for Cardiovascular Angiography and Interventions, and Truth Initiative Foundation. As is evident from the description of these groups in the Exhibit to this brief, each of these *amici curiae* works to prevent the disease and death caused by tobacco. For this reason, they have a direct and continuing interest in implementation of the health warnings mandated by the Food and Drug Administration ("FDA") rule at issue here, Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. 15,638 (March 18, 2020) (to be codified at 21 C.F.R. pt. 1141) ("Final Rule"). They are united in the conviction that the large, graphic health warnings mandated by the Final Rule are essential for effective communication to the public of the extraordinary range of health harms from smoking.

Given their expertise, these *amici* are particularly well suited to provide the Court with valuable perspectives on the core 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 the 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 the health harms of smoking and the factual and uncontroversial nature of the Final Rule warnings.

INTRODUCTION: 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 *Zauderer* 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 applied to restrictions on commercial speech in *Central Hudson Gas & Electric Corp. v. Public Service Commission of N.Y.*, 447 U.S. 557, 573 (1980). *See* 471 U.S. at 651.

Under *Zauderer*, required disclosure of "purely factual and uncontroversial information" about a product or service does not violate the First Amendment if it is "reasonably related" to a governmental interest and does not unduly burden protected speech.[2] *See id.* As demonstrated below, the Final Rule warnings clearly satisfy the *Zauderer* test. 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*

[2] Plaintiffs' assertion that "*Zauderer* is properly limited to disclosures correcting misinformation," (Pls.' Mem. at 52, n.6) is directly contrary to the controlling authority in this jurisdiction. *See Am. Meat Inst. v. USDA*, 760 F.3d 18, 20 (D.C. Cir. 2014) (en banc), *overruling in relevant part, R.J. Reynolds Co. v. FDA*, 696 F.3d 1205, 1214 (D.C. Cir. 2012). ("We now hold that *Zauderer* in fact does reach beyond problems of deception . . . .") In any event, as demonstrated below, *see infra* Section I.B, the challenged warnings are necessary to correct the consequences of many decades of deceptive speech by the Plaintiff Philip Morris and other tobacco companies.

Hudson, 447 U.S. at 564. *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.*[3]

ARGUMENT

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

Contrary to Plaintiffs' argument, Mem. In Supp. Of Pls.' Mot. for Summ. J. & Prelim. Inj. at 55-56, ECF No. 22-1 ("Pls.' Mem."), 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 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 those health hazards is a singularly substantial governmental 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, trampolines, peanut butter, steak knives and even alcohol. (Pls.' Mem. at 3, 51). Twenty years ago, the Supreme Court wrote in *FDA v. Brown & Williamson Tobacco Co.* that "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." 529 U.S. 120, 161 (2000). It remains so today. As FDA has noted, citing the 2014 Surgeon General's Report on the Health Consequences of Smoking,

[3] 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.

"[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." Required Warnings for Cigarette Packages and Advertisements, 84 Fed. Reg. 42,734, 42,756 (proposed August 16, 2019) (to be codified at 21 C.F.R. pt. 1141) ("Proposed Rule"). Indeed, "smoking causes more deaths each year than human immunodeficiency virus, illegal drug use, alcohol use, motor vehicle injuries, and firearm-related injuries combined." *Id.* at 42,756. In addition, over 16 million Americans live with diseases and health conditions caused by smoking and exposure to secondhand smoke, including 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 (SIDS), respiratory illnesses, clogged arteries, reduced blood flow, diabetes, rheumatoid arthritis, and vision conditions such as age-related macular degeneration and cataracts." *Id.* We now know that smoking attacks nearly every organ in the human body, causing premature death in half of long-term smokers. *Id.* at 42,758.[4]

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 Level of Combusted Cigarettes, Advance notice of proposed rulemaking, 83 Fed. Reg. 11,818, 11,820 (March 16, 2018). "Nicotine is powerfully addictive," 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 "[t]he adolescent brain is more vulnerable to developing nicotine dependence than the adult brain . . . ." *Id.*

[4] Office of the Surgeon General, U.S. Dept. of Health and Human Services (HHS), *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General* 691 (2014) (AR55357).

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—adolescents. Thus, contrary to Plaintiffs' suggestion (Pls.' Mem. at 51), requiring large, graphic health warnings on cigarettes does not necessarily justify similar warnings on other less dangerous products. There may be no "tobacco exception" to the First Amendment (*see* Pls.' Mem at 51), but the First Amendment surely permits distinctions based on the nature and importance of the governmental interests at stake in product warnings cases. The First Amendment does not dictate that the warnings for a highly-addictive product that kills half of its users be comparable to the warnings appropriate on a ladder.

B. Decades of Industry Deception Underscore the Government's Interest in Increasing Public Knowledge of The Adverse Health Effects of Smoking.

The importance of effectively communicating the wide 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), Judge Gladys Kessler of this 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 by their purveyors. Although the D.C. Circuit determined in *American Meat Institute v. USDA* that the Supreme Court's *Zauderer* analysis is applicable to governmental interests beyond correcting deceptive speech,[5] the Final Rule warnings are certainly justified by that interest alone. In any event, the industry's fraud makes the effective communication of smoking's profoundly adverse health effects a particularly vital governmental interest. To this day, significant gaps remain in public knowledge of the full range of health harms from smoking cigarettes, the direct result of the confusion sown by the industry's decades-long misrepresentation of the truth about its products. 84 Fed. Reg. at 42,761. This massive 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.

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), 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

[5] *Supra* note 2.

consumers to make different choices and stop smoking. (Pls.' Mem. at 55). Oddly, Plaintiffs contradict their own argument in the first sentence of their brief: "No one questions the government's ability to require tobacco companies to disclose the health risks of their products so consumers can make informed choices." (Pls. Mem.' at 1). Stated this way, the government's interest does not depend on consumers making particular choices, only that the choices be "informed."

Moreover, the *Reynolds* court itself recognized that "the government can certainly require that consumers be fully informed about the dangers of hazardous products." *Reynolds*, 696 F.3d at 1212. In striking down FDA's 2011 cigarette warnings, the court 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* court did not find that the government's interest in effectively communicating the health harms of smoking could not be substantial, 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." *Reynolds*, 696 F.3d 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 properly recognized in *Discount Tobacco City & Lottery, Inc. v. United States*, where the court 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 found 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 was required by Congress.

It is instructive that other provisions of the TCA do expressly require FDA to consider the impact of a regulation on smoking cessation and initiation. FDA's failure to do so was the basis for the recent court of appeals decision striking down FDA's rule requiring larger textual health warnings on *cigars*. *Cigar Ass'n of Am. v. FDA*, 964 F.3d 56 (D.C. Cir. 2020). That rule was issued under the authority given FDA in section 906(d)(1) of the Food, Drug & Cosmetic Act, as amended by the TCA, to "by regulation require restrictions on the sale and distribution of a tobacco product . . . ." *Id.* at 61. The court held FDA's rule arbitrary and capricious under the Administrative Procedure Act because it did not consider the warnings' "likely impact on tobacco

cessation and adoption rates," as required by section 906. *Id.* at 62. The Final Rule cigarette warnings at issue here, in contrast, were issued pursuant to the statutory mandate to FDA to require graphic health warnings on cigarette packs and advertising in sections 201(a) and 202(b) of the TCA, which conspicuously do not require a finding by FDA that such warnings impact smoking cessation or initiation. The *Cigar Association* ruling did not address whether increasing public knowledge of the health hazards of smoking is itself a substantial governmental interest for First Amendment purposes.

Plaintiffs knock down a straw man when they argue that it cannot be enough for the government to claim an interest in providing *any* additional information about a product, regardless of its importance. (Pls.' Mem. at 56). In upholding Judge Kessler's finding that Philip Morris and other cigarette companies had engaged in a massive conspiracy to defraud the American public about the health harms of smoking, the D.C. Circuit observed that "statements about the adverse health effects of smoking [citation omitted] would be a matter of importance to a reasonable person deciding to purchase cigarettes." *United States v. Philip Morris USA, Inc.*, 566 F.3d at 1122. In *American Meat Institute*, the D.C. Circuit determined that the government had a substantial interest in requiring country-of-origin labeling as demonstrated by the history of such labeling "that had made the value of this particular product information to consumers a matter of common sense." 760 F.3d at 24. Surely if the importance to consumers of knowing whether products are American-made is a sufficient government interest for First Amendment purposes, then the importance of information about the debilitating and lethal effects of cigarettes must also qualify. The justification for the Final Rule warnings goes far beyond addressing "consumer curiosity" alone, and thus bears no resemblance to cases in which the government's articulated interest is merely improving consumer knowledge without any connection to public health or safety. *See, e.g., Int'l*

Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73-74 (2d Cir. 1996) (concluding, "reluctantly," that "the demand of [Vermont's] citizenry for . . . information" concerning production methods for dairy farmers was insufficient because FDA itself acknowledged "no human safety or health concerns associated with" those methods). By contrast, FDA's goal of promoting greater public knowledge of the extraordinary range of adverse health effects of smoking is, standing alone, a substantial government interest.

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 cigarettes' all-too-real negative health consequences 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, and Plaintiffs Do Not Dispute, Widespread Public Ignorance of the Full Range of Health Harms of Smoking.

Despite extensive efforts to educate the public about health hazards of cigarettes, there remain significant gaps in public understanding about the general harms of cigarette smoking addressed by the existing Surgeon General's health warnings, as well as the particular harms addressed by the warnings mandated by the Final Rule. Plaintiffs do not argue to the contrary.

The existing Surgeon General's health warnings, which have been unchanged for nearly 35 years, 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 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. 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. 84 Fed. Reg. at 42,761.

Moreover, in the 35 years that 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. 84 Fed. Reg. at 42,766. As FDA found, there is low public awareness of the adverse health consequences of smoking 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. 84 Fed. Reg. at 42,767-72. 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 With Large, Graphic Health Warnings for Cigarettes Demonstrates That They 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.[6] Since then, 107 countries have required graphic warnings to cover at least 50% of the package.[7] The impact of those warnings has been extensively studied and they have been shown to measurably increase public understanding of the dangers of smoking.

[6] Canadian Cancer Society, *Cigarette Package Health Warnings, International Status Report* 3 (2018) (AR29355).
[7] *Id.* at 6 (AR29358).

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 here, 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 easily noticed and read. *Id.* at 42,779. [8] 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 smokers. 84 Fed. Reg. at 42,760, 42,762. The size of the warning required by the Final Rule is consistent with the international standard. The WHO Framework Convention on Tobacco Control ("FCTC") recommends that the warning size be at least 50% of the pack size. Based on a review of the evidence, the Article 11 Guidelines for the FCTC concluded that,

> "Evidence demonstrates that the effectiveness of health warnings and messages increases with their prominence. In comparison with small, text only health warnings, larger warnings with pictures are more likely to be noticed, better communicate health risks… Larger picture warnings are also more likely to retain their effectiveness

[8] *See also* David Hammond, *Tobacco Labelling & Packaging Toolkit, A Guide to FCTC Article 11*, 6, 17 (Feb. 2009), https://tobaccolabels.s3.ca-central-1.amazonaws.com/uploads/2013/12/IUATLD-Tookit-Complete-Mar-3-2009.pdf (AR30903, AR30912).

> over time and are particularly effective in communicating health effects to low-literacy populations, children and young people."[9]

The warnings at issue here are unlike the sugar-sweetened beverage warnings found unduly burdensome in *American Beverage Ass'n 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 "[t]he scientific literature strongly supports that larger warnings, such as those 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. Thus, even under the *Central Hudson* test, the Final Rule warnings are no more extensive than necessary to serve the government's substantial interest in promoting greater public understanding of the hazards of smoking.[10]

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 530. 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,

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[9] World Health Organization Framework Convention on Tobacco Control, *Guidelines for Implementation of Article 11: Packaging and Labelling of Tobacco Products* 3, https://www.who.int /fctc/treaty_instruments/adopted/Guidelines_Article_11_English.pdf?ua=1 (last visited Oct. 12, 2020) (AR29563).

[10] Contrary to Plaintiffs' suggestion, (Pls.' Mem. at 46), 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 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* Press Release, Federal Trade Commission, *FTC Releases Reports on Cigarette and Smokeless Tobacco Sales and Marketing Expenditures for 2018* (Dec. 30, 2019), https://www.ftc.gov/news-events/press-releases/2019/12/ftc-releases-reports-cigarette-smokeless-tobacco-sales-marketing.

cigarette companies have successfully advertised their cigarettes with their logos and other design features.[11]

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. 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, in many instances, drown out manufacturers' speech entirely," (Pls.' Mem. at 58), 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. 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."[12] 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. For example, only 47% of U.S. smokers reported noticing information about the dangers of smoking "often" on cigarette packages, compared to 84% in Canada.[13]

[11] Tobacco Labelling Resource Centre, *Canada Cigarette Package Images*, https://tobaccolabels.ca/pack-images/country/?n=Canada (last visited Oct. 12, 2020).
[12] David Hammond et al., *Effectiveness of Cigarette Warning Labels in Informing Smokers About the Risks of Smoking: Findings from International Tobacco Control (ITC) Four Country Survey*, 15 TOBACCO CONTROL iii19 (2006) (AR31048).
[13] *Id.* at iii21, tbl 2 (AR31050).

Plaintiffs seek to minimize the significance of these foreign studies by noting that they involve "different countries with different demographics," (Pls.' Mem. at 40-41), but as FDA noted, the "consistency of findings 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. Moreover, it is grossly misleading to assert that the D.C. Circuit "rejected" these studies in *Reynolds*. (Pls.' Mem. at 57). In *Reynolds*, the court found that FDA had failed to show, from studies of graphic health warnings in countries such as Canada, that large, graphic health warnings had diminished smoking rates. *See* 696 F.3d at 1219-21. The *Reynolds* court did not address the overwhelming international evidence that such warnings are effective in enhancing public knowledge of smoking's health harms.

3. Graphic warnings are particularly important in communicating health risks to diverse populations, including adolescents and consumers with low literacy.

Graphic warnings are particularly vital to address the knowledge deficit that exists for youth and consumers of low literacy regarding the harms of cigarette smoking. According to FDA "research has shown that being a member of a group with lower socioeconomic status ("SES"), as measured by income and education levels, is associated with having lower knowledge of the negative health consequences of smoking," yet "most smokers in the United States are in this group." 84 Fed. Reg. at 42,765. FDA also documented that the current Surgeon General's warnings are particularly ineffective in communicating health information to adolescents. *Id.* at 42,760-61.

Graphics address this information deficit and measurably increase the understanding of health warnings among people with low levels of literacy and adolescents. *Id.* at 42,763-65. Research establishes that exposure to graphic warnings leads to knowledge gains about the harms

of smoking among adolescents, whereas the current 1984 Surgeon General's warnings do not. *Id.* at 42,763. According to research from the International Tobacco Control project, "[l]arge, graphic warnings on cigarette packages are an effective means of increasing health knowledge among smokers [and] health warnings may also help to reduce the disparities in health knowledge by providing low-income smokers with regular access to health information."[14] Thus, large, graphic health warnings have particularly significant benefits in educating the young, the poor, and the less educated about the health harms of cigarettes—an impact that Plaintiffs choose to ignore.

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

FDA's 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. 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"). 84 Fed. Reg. at 42,768-69. Every single one of the Final Rule warnings outperformed the 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,"

[14] *Id.* at iii24 (AR31053).

helpfulness in understanding health effects of smoking, and recall. 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 what diseases to feature in the warnings and how to portray them. In so doing, 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 "irrationally chose which health risks to feature" in the warnings. (Pls.' Mem. at 30-32). 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 long 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.[15]

Although Plaintiffs acknowledge that the Surgeon General's 2014 report identified 51 diseases and conditions caused by their products, they question "why FDA bypassed so many conditions" and picked others. (Pls.' Mem. at 31). 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

[15] 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 RSCH. 1795, 1802 (2020), https://academic.oup.com/ntr/advance-article/doi/10.1093/ntr/ntaa032/5810483 (FDA supported study).

choices. FDA supported each warning with evidence that the warning is factually true and scored higher on both providing new information and self-reported learning, as well as other relevant measures, than the Surgeon General's warnings. *See* 85 Fed. Reg. at 15,667-84. The fact that warnings could have been developed and tested addressing other health harms from smoking in no way establishes that the choices made were "arbitrary," nor that the Final Rule warnings will fail to materially enhance the public's understanding of the devastating health consequences of cigarettes.[16]

Second, Plaintiffs suggest that FDA's qualitative studies provide evidence that the warnings are "unclear" and "confusing." (Pls.' Mem. at 12). 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 perceived as lower in "perceived factualness" than the existing Surgeon General's warnings, (Pls.' Mem. at 38), this finding is entirely consistent with the fact that the tested warnings were providing new information. It is not surprising that, when initially exposed to new information about the health risks of smoking, many study participants questioned whether it was true, especially when compared to the Surgeon General's warnings, which have appeared on cigarette packages for more than three decades. *See* 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.

[16] 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.

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.' Mem at 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* 84 Fed. Reg. at 42,773-77. Plaintiffs' objection to definitive causal language is the latest iteration of the longstanding efforts of cigarette companies to introduce some degree of doubt among consumers as to the health effects of their products. If some participants in FDA's studies questioned the believability of strong, causal statements, it proves only that the industry's decades of deception continue to have an impact.

In short, 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" from participants in FDA's qualitative studies, they cannot be "purely factual" disclosures under *Zauderer*. (Pls.' Mem. at 47). 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 smoking causes at least 14 different types of cancer.[17] 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

[17] HHS, *supra* note 4, at 4 (AR54606).

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.[18] 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 Sixth Circuit also noted, such images are typically used in medical textbooks precisely because they are accurate renditions of factual information. *See id.* at 559; 85 Fed. Reg. at 15,646.[19]

[18] *See* 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 RSCH. 93, 94 (2013) (AR28790 n.82, AR28792 n.88).

[19] 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.

The *Reynolds* 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 *Reynolds* court 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.* Moreover, the court relied heavily on the inclusion, in all the 2011 warnings, of a 1-800-QUIT NOW hotline number. *Id.* All these factors led the *Reynolds* 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* 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. 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 *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) ("*NIFLA*"), show that FDA's warnings are not "factual and uncontroversial" disclosures properly analyzed under *Zauderer*. In that case, the Court struck down a California statute directed at "crisis pregnancy centers." *Id.* These centers offered various types of assistance to pregnant women but were clearly intended to discourage the women from seeking abortions. *Id.* at 2368. 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*, 138 S. Ct. at 2372. 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: "We do not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products." *NIFLA*, 138 S. Ct. at 2376.

The non-ideological content of the health warnings in the proposed rule also distinguishes them from the mandatory disclosure struck down by the D.C. Circuit in *National Association of Manufacturers v. SEC*, 800 F.3d 518 (D.C. Cir. 2015). At issue in *NAM* was an SEC rule requiring companies that used certain minerals originating in the Democratic Republic of the Congo to disclose whether they were "conflict free," referring to the humanitarian crisis in that country. The court found that the label "not conflict free" was "hardly factual and non-ideological," but rather "conveys moral responsibility for the Congo war," suggesting that the products "are ethically tainted." *Id.* at 529 (quoting court's previous opinion at *NAM*, 748 F.3d 359, 371 (D.C. Cir. 2014)) The health warnings in the proposed rule simply communicate uncontroversial facts about the dangers of smoking, while expressing no moral judgments about the product or advising consumers not to use the product.

Finally, Plaintiffs' assertion that the Final Rule warnings "risk misinforming consumers," (Pls.' Mem. at 58), 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. (Pls.' Mem. at 59). 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 "extreme" because they may not depict the "typical" consequences of smoking, or of the diseases caused by smoking, 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."[20] 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" or "controversial."

For each of the warnings, FDA cites evidence, from Surgeon General's reports 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. 85 Fed. Reg. at 15,671-84. Plaintiffs' suggestion that the graphics are "extreme" and "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, the Court should grant Defendants' cross-motion for summary judgment and deny Plaintiffs' motion for summary judgment and for a preliminary injunction.

[20] Food and Drug Administration, *A Guide to Drug Safety Terms at FDA* (2012), https://www.fda.gov/media/74382/download.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 15, 2020, I caused the foregoing Brief of *Amici Curiae* Medical and Public Health Organizations in Support of Defendants' Cross-Motion for Summary Judgment and in Opposition to Plaintiffs' Motion for Summary Judgment and a Preliminary Injunction to be filed with the Clerk of the Court using the Court's electronic filing system which will electronically serve all counsel of record.

October 15, 2020

/s/ *Dennis A. Henigan*
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