IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

R.J. REYNOLDS TOBACCO COMPANY, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

Civil Action No. 6:20-CV-00176

BRIEF FOR *AMICI CURIAE* AMERICAN ACADEMY OF PEDIATRICS, AMERICAN CANCER SOCIETY, AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, AMERICAN HEART ASSOCIATION, AMERICAN LUNG ASSOCIATION, AMERICAN MEDICAL ASSOCIATION, CAMPAIGN FOR TOBACCO-FREE KIDS, CHILDREN'S HOSPITAL ASSOCIATION OF TEXAS, NATIONAL ASSOCIATION OF HISPANIC NURSES, TEXAS ACADEMY OF FAMILY PHYSICIANS, TEXAS HOSPITAL ASSOCIATION, TEXAS MEDICAL ASSOCIATION, TEXAS NURSES ASSOCIATION, TEXAS PEDIATRIC SOCIETY, TEXAS PTA, THE COOPER INSTITUTE, TRUTH INITATIVE FOUNDATION, BRUCE C. CARTER, M.D., AND DAVID LAKEY, M.D. IN SUPPORT OF DEFENDANTS

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Public health, medical and community organizations, along with individual public health and medical experts, from Texas and across the nation, submit this brief as *amici curiae* in support of the Defendants' Cross-Motion for Summary Judgment and in opposition to Plaintiffs' Motion for Summary Judgment and for Preliminary Injunction. The parties have consented to the filing of this brief.

STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici groups and individuals are described in the Exhibit to this brief. *Amici* here include the following national, state, and local public health, medical and community organizations, and individual public health and medical experts from the State of Texas:

1. **AMERICAN ACADEMY OF PEDIATRICS**
2. **AMERICAN CANCER SOCIETY**
3. **AMERICAN CANCER SOCIETY CANCER ACTION NETWORK**
4. **AMERICAN HEART ASSOCIATION**
5. **AMERICAN LUNG ASSOCIATION**
6. **AMERICAN MEDICAL ASSOCIATION**
7. **CAMPAIGN FOR TOBACCO-FREE KIDS**
8. **CHILDREN'S HOSPITAL ASSOCIATION OF TEXAS**
9. **NATIONAL ASSOCIATION OF HISPANIC NURSES**
10. **TEXAS ACADEMY OF FAMILY PHYSICIANS**
11. **TEXAS HOSPITAL ASSOCIATION**
12. **TEXAS MEDICAL ASSOCIATION**
13. **TEXAS NURSES ASSOCIATION**
14. **TEXAS PEDIATRIC SOCIETY**
15. **TEXAS PTA**

16. **THE COOPER INSTITUTE**

17. **TRUTH INITATIVE FOUNDATION**

18. **BRUCE C. CARTER, M.D.**

19. **DAVID LAKEY, M.D.**

Each of the *amici* has 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 the effective communication to the public of the extraordinary range of health harms from smoking. Indeed, the absence of effective health warnings on cigarette packages and advertising makes it much more difficult for the *amici* to educate the public about the health harms of smoking, implement effective programs to help smokers quit and, in the case of medical organizations and physicians, to effectively communicate to patients the health harms of smoking. Given their expertise, these *amici* are particularly well suited to provide the Court with valuable perspectives on the core issues raised by Plaintiffs.

INTRODUCTION: THE FIRST AMENDMENT FRAMEWORK

Since the Supreme Court's decision in *Zauderer v. Office of Disciplinary Counsel,* 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 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,* 447 U.S. 557 (1980). *Zauderer,* 471 U.S. at 651.

Under *Zauderer*, requiring 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.[1] *Id.* As demonstrated below, the Final Rule warnings clearly satisfy the *Zauderer* test. Moreover, even under the "intermediate scrutiny" test applied in *Central Hudson*, 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.[2] *See Cent. 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 of the hazards of cigarettes are consistent with the First Amendment.*

ARGUMENT

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

As addressed more fully below, the administrative record strongly supports the conclusion that the Final Rule warnings will significantly promote greater public understanding of the negative

[1] The circuit courts have unanimously rejected Plaintiffs' view, Pls.' Mot. for Summ. J. & Prelim. Inj. ("Pls.' Br.") at 20, that *Zauderer* is applicable only when government-compelled speech prevents or corrects deceptive speech. 85 Fed. Reg. at 15,644-45 (citing relevant cases). In any event, as demonstrated *infra* Part I.C., the challenged warnings are necessary to correct the consequences of many decades of deceptive speech by the Plaintiffs.

[2] 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, Plaintiffs' contention that the Final Rule should be subject to strict scrutiny review, Pls.' Br. at 45, should be rejected.

health consequences of cigarette smoking. Plaintiffs argue, however, that even if that were true, the Final Rule would violate the First Amendment because "the government has no substantial interest in improving the public's understanding" of the health harms of smoking, absent evidence that such improved understanding will affect consumer behavior and diminish smoking. Pls.' Br. at 3. Otherwise, according to Plaintiffs, the warnings serve only the "purely academic interest" of providing consumers information. *Id.* at 46.

Contrary to Plaintiffs' mischaracterization, *see id.* at 3, in no sense has the government "conceded" that greater public knowledge of the health harms of smoking will not improve public health by affecting consumer behavior and diminishing smoking. But that is not the issue here. Rather, the issue is whether increasing public knowledge of the full range of harmful effects of smoking on the human body is itself a legitimate and substantial governmental objective [3] Representing the public health and medical community in Texas and elsewhere, the *amici* strongly urge the Court to find that ensuring that the public has a more complete understanding of the debilitating and deadly damage cigarettes do to the human body is, standing alone, a vital governmental public health objective.

A. The Health Harms of Smoking Are Uniquely Significant.

The devastating effects of cigarettes on the public health make a mockery of Plaintiffs' assertion that information about those harms serves only a "purely academic interest" of consumers. Pls.' Br. at 46. Twenty years ago, the Supreme Court recognized that "tobacco use, particularly among

[3] That FDA here is maintaining that increasing public knowledge of the health harms of tobacco can stand alone as a legitimate and substantial government interest distinguishes the Final Rule here from the Rule struck down in *R.J. Reynolds Tobacco Co. v. FDA,* in which, as the D.C. Circuit characterized it, the interest in "effectively communicating health information" was conceded by FDA to describe "only the *means* by which FDA is attempting to reduce smoking rates." 696 F.3d 1205, 1221 (D.C. Cir. 2012) (emphasis in original).

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 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." 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.* In addition, over 16 million Americans live with diseases and health conditions caused by smoking, including not only lung cancer, heart disease and chronic obstructive pulmonary disease (COPD), but 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.* We now know that smoking attacks nearly every organ in the human body, causing premature death in half of long-term smokers.[4]

There can be no doubt that the government's interest in ensuring that consumers are fully informed about the health risks of a product that kills half of its users is not merely to satisfy "consumer curiosity." *See Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 n.6 (2d Cir. 2001). Rather,

[4] U.S. Dept. of Health and Human Services (HHS), *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General* 69, 847 (2014). All reports and studies cited in this brief either appear as references in the Proposed Rule or Final Rule or are included in the Comments on the Proposed Rule filed by the Campaign for Tobacco-Free Kids and 37 other public health and medical organizations in Docket No. FDA-2019-N-3065, Required Warnings for Cigarette Packages and Advertisements, Oct. 15, 2019 or in the Comments on the Proposed Rule filed by Dr. David Hammond in that Docket, Oct. 15, 2019.

the government's interest is in giving consumers the tools to make informed decisions about smoking that could profoundly affect their health and well-being.

B. Enhancing Public Understanding of the Full Range of Health Hazards Associated with Cigarettes is a Vital Governmental Interest Regardless of the Impact on Smoking Prevalence.

In upholding the mandate in the Family Smoking Prevention and Tobacco Control Act ("TCA") for graphic health warnings against First Amendment attack by the tobacco industry, the Sixth Circuit found that "[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." *Disc. Tobacco City & Lottery Inc. v. United States*, 674 F.3d 509, 567 (6th Cir. 2012). 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." 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.[5]

[5] The recent decision of the D.C. Circuit in *Cigar Association of America v. FDA,* No. 18-5195 (D.C. Cir., July 7, 2020), striking down an FDA rule requiring larger health warnings for cigars, whatever its merit, is not to the contrary. That case addressed an FDA rule that was issued under the authority given the agency in Section 906(d)(1) of the Food, Drug & Cosmetic Act, as amended by the TCA. In contrast, the Final Rule at issue here was promulgated pursuant to the statutory provisions in the Federal Cigarette Labeling and Advertising Act (FCLAA), as amended by Sections 201(a) and 202(b) of the TCA, mandating FDA to require graphic health warnings on cigarette packs and in cigarette advertising. As part of the determination whether a rule is "appropriate for the protection of the public health" under Section 906(d)(1), FDA must take into account whether a warning label has a particular impact: "the increased or decreased likelihood that existing users of

"[T]here is no question that [the government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial." *Edenfield v. Fane*, 507 U.S. 761, 769 (1993). In a variety of contexts, courts have found that the government has a "substantial" interest in providing information to consumers to enable them to make informed decisions that may impact their health. For example, courts have found a substantial interest in cases involving country-of-origin labels for meat, *Am. Meat Inst. v. USDA*, 760 F.3d 18, 23 (D.C. Cir. 2014), warning label requirements for products containing mercury, *Nat'l Elec. Mfrs. Ass'n*, 272 F.3d at 115, compelled disclosure requirements for genetically engineered foods, *Grocery Mfrs. Ass'n v. Sorrell*, 102 F. Supp. 3d 583, 631 (D. Vt. 2015), and disclosure requirements for cell phones regarding radio frequency radiation, *CTIA – The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 846 (9th Cir. 2019). FDA's goal here is no different.

In striking down FDA's 2011 cigarette warnings, the *R.J. Reynolds* court found, not that the government's interest in effectively communicating the health harms of smoking could not be substantial,[6] 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." *See R.J. 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. FDA established that the warnings showed statistically significant

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tobacco products will stop using such products" and "the increased or decreased likelihood that those who do not use tobacco products will start using such products." In contrast, the provisions of the FCLAA under which the Final Rule at issue here was promulgated do not require FDA to take into account the potential impact of its graphic warnings rule on the likelihood of cessation or initiation of cigarette use.

[6] Indeed, the *R.J. Reynolds* court recognized that "the government can certainly require that consumers be fully informed about the dangers of hazardous products." 696 F.3d at 1212.

improvements in the key outcomes of "new information" and "self-reported learning" – metrics that are, according to the relevant scientific literature, predictive of whether the warnings will promote greater public understanding of the risks of cigarette smoking. *See infra* at II.C.3.

FDA's stated justification for the Final Rule 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 production methods).

By contrast, FDA's goal of promoting greater public knowledge of the extraordinary range of health harms of smoking is, standing alone, a substantial government interest.

C. 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 tobacco companies designed to conceal those harms. Plaintiffs argue that the public has received information about the health harms of smoking from various sources (including the public education efforts of many of the *amici* here). *See* Pls.' Br. at 30. However, to tell the truth about cigarettes, these efforts must overcome over fifty years of industry lies. 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), a federal district court found R.J. Reynolds and other cigarette companies liable for 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.[7] *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 dangerousness of those products, but also to counter decades of fraudulent misrepresentations by their purveyors. Although, contrary to Plaintiffs' contention, the Supreme Court's *Zauderer* analysis is applicable to governmental interests beyond correcting deceptive speech,[8] the Final Rule warnings are certainly justified by that interest alone. In any event, the industry's past and continuing fraud surely makes the effective communication of smoking's profoundly adverse health effects a particularly vital governmental interest.

II. THE GRAPHIC WARNINGS MANDATED BY THE FINAL RULE DIRECTLY ADVANCE THE GOVERNMENTAL INTEREST IN ENHANCING PUBLIC KNOWLEDGE OF THE HEALTH HAZARDS OF SMOKING.

The Final Rule warnings directly advance the government's vital interest in promoting greater public understanding of cigarette smoking's many, all-too-real harms. Despite public education campaigns and other public health efforts seeking to overcome decades of industry deception,

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[7] Plaintiffs ignore the court's findings in *Philip Morris,* even as they assert that "FDA makes no attempt to show that any previous misrepresentations by tobacco companies continue to mislead consumers today . . . ." *See* Pls.' Br. at 22. *But see* 85 Fed. Reg. at 15,645 (FDA referencing court's finding of cigarette companies' "long history of deception").

[8] *See supra* note 1.

consumers remain unaware of the full range of deleterious health effects caused by cigarettes. 85 Fed. Reg. at 15,650. FDA's graphic warnings effectively remedy many of these critical knowledge gaps.

A. The Current Surgeon General's Warnings Are Routinely Ignored by Consumers and Do Not Address Many of the Significant, but Lesser Known, Health Harms of Smoking.

The current health warnings on cigarette packs are wholly inadequate because they have been unchanged for nearly 35 years, are small and inconspicuous, and do not contain a color image. 84 Fed. Reg. at 42,759-61. As FDA found, the current warnings do not effectively inform the public or promote greater understanding 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. *Id.* For years, researchers have shown that the frequency with which smokers notice, read and think about health warnings lessens over time as smokers become desensitized to those warnings.[9]

Recent research supports the conclusion that these decades-old warnings are ineffective. For example, FDA describes research from Wave 4 (2016-2017) of the Population Assessment of Tobacco and Health (PATH) Study, which found that nearly three-quarters (73.5%) of the U.S. population "never" or "rarely" noticed health warnings on cigarette packs. 84 Fed. Reg. at 42,760. Given that 88% of long-term smokers begin smoking before the age of 18,[10] and that youth have long been a critical target of industry marketing, *Philip Morris*, 449 F. Supp. 2d at 565, the ineffectiveness of the current cigarette warnings is particularly consequential for young people. Each day in the United

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[9] Environics Research Group, *Health Warning Testing: Final Report* (1999) (prepared for Health Canada). *See also* Informa Market Research Co. Ltd., *Focus Group Research on New Health Warnings on Tobacco Packages* (1999); International Agency for Research on Cancer, *Measures to Evaluate the Effectiveness of Tobacco Product Labeling Policies,* 12 *IARC Handbook II: Evaluating the Effectiveness of Population Based Tobacco Control: Methods for Evaluating Tobacco Control Policies* 292 (2007).

[10] HHS, CDC, Office on Smoking and Health, *Preventing Tobacco Use among Youth and Young Adults: A Report of the Surgeon General* 3 (2012).

States 1,600 youth ages 12-17 smoke their first cigarette, and 170 become daily cigarette smokers. 85 Fed. Reg. at 15,652. Yet studies repeatedly show that "adolescents . . . do not see or read, and do not remember," the current warnings. 84 Fed. Reg. at 42,761.

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 warnings. *Id.* 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. Despite Multiple Efforts to Educate the Public About the Health Hazards of Cigarettes, There Remain Significant Gaps in Public Understanding.

Plaintiffs ignore the overwhelming evidence of gaps in consumer knowledge about smoking, and instead argue that the government's interest is a "purely hypothetical" problem because the public already knows that smoking is harmful. *See* Pls.' Br. at 29. But this argument improperly conflates consumers' general awareness that smoking is harmful with an informed understanding of many specific risks of smoking.

1. Contrary to Plaintiffs' representations, large gaps remain even as to the general harms addressed by the existing Surgeon General's warnings.

In claiming that the public already knows smoking is harmful, Pls.' Br. at 29-34, Plaintiffs disregard overwhelming evidence demonstrating that a large number of smokers have inadequate knowledge of the health effects of smoking, even as to general smoking-related harms addressed in

the existing Surgeon General's warnings. *See* 84 Fed. Reg. at 42,760.[11] This gap in knowledge exists despite the numerous public reports and public education campaigns on the risks of smoking. Even though many smokers are aware that smoking causes lung cancer, knowledge of other smoking-caused illnesses is much lower. 84 Fed. Reg. at 42,761. For example, 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.* Moreover, although some smokers generally know that tobacco use is harmful, they underestimate the severity and magnitude of the health risks and tend to perceive other smokers to be at greater risk for disease than themselves.[12] These findings demonstrate that there remain significant gaps in public understanding about the harms addressed by the current Surgeon General warnings.

2. Contrary to Plaintiffs' representations, large gaps remain about the particular harms addressed by the warnings mandated by the Final Rule.

Plaintiffs' assertion that there is universal knowledge about smoking-related harms is contradicted by FDA's experimental studies and by the survey performed by Plaintiffs' own expert, Dr. Iyengar. *See* Pls.' Br. at 31; Pls.' Compl. at Ex. No. 5, Ex. E, at App'x 3.1 ("Iyengar Report"). In both studies, more than half of all respondents indicated they had never heard about the health effects depicted in the Final Rule warnings. *See* 84 Fed. Reg. at 42,767-772; Iyengar Report, App'x 3.1.

Plaintiffs rely on selective data points from the PATH study cited in Professor Jonathan Klick's report (prepared for Plaintiff R.J. Reynolds) showing that 94% of respondents indicated that

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[11] *See also* Lila Rutten, et al., *Smoking knowledge and behavior in the United States: Sociodemographic, Smoking Status, and Geographic Patterns*, 10 Nicotine & Tobacco Research 1559 (2008).
[12] Neil Weinstein, et al., *Smokers' Unrealistic Optimism About Their Risk*, 14 Tobacco Control 55 (2005).

cigarette smoking causes lung cancer and 88% believe that smoking causes heart disease. Pls.' Br. at 31. But Plaintiffs ignore Professor Klick's additional findings showing that public awareness of the hazards covered in FDA's warnings ranges from 46% to 94%. *See* Pls.' Compl. at Ex. No. 5, Ex. C, at 27, 5.62, tbl. 21 ("Klick Report"). Professor Klick's own report establishes that, with the singular exception of lung cancer, there is nowhere near universal awareness of the health risks featured in FDA Final Rule warnings.[13] *See* Klick Report at tbl. 21.

Professor Klick's cherry-picking of the data is evident in his use of a study by Dr. David Hammond and others ("Hammond Study") to show that awareness of the link between lung cancer and smoking is as prevalent in the U.S., without graphic warnings, as in Canada, where such warnings are in effect. *See* Klick Report at 29, 5.65.1. In fact, the Hammond Study concluded that "warnings that are graphic, larger, and more comprehensive in content are more effective in communicating the health risks of smoking."[14] Specifically, the study makes the following findings, unmentioned by Professor Klick, regarding the U.S., which the paper noted was the country in this study with "the weakest health warnings":

- 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.
- Only 73% of U.S. smokers agreed that smoking causes stroke, only 68% agreed that smoking causes lung cancer in non-smokers, and only 34% agreed that smoking causes impotence.
- Only 47% of U.S. smokers reported noticing information about the dangers of smoking 'often' on cigarette packages, compared to 84% in Canada.[15]

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[13] It should also be noted that, in the PATH study, participants were provided with various health effects of smoking and were asked if they agree or not. Measures of agreement drastically overestimate the "awareness" of a health effect, given that many respondents simply say "yes" or "agree" with the question due to social desirability bias. *See* Neil Weinstein et al., *Public Understanding of the Illnesses Caused by Cigarette Smoking*, 6 Nicotine Tobacco Res. 349 (2004).

[14] 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).

[15] *See id.* at iii21 tbl. 2.

In short, Plaintiffs, and the experts on which they rely, mischaracterize the relevant data, which support FDA's conclusion that there are serious gaps in public understanding of the particular health harms addressed by the warnings mandated by the Final Rule.

C. Large, Graphic Health Warnings Will Substantially Enhance Public Understanding of the Full Scope of the Health Hazards of Smoking.

A substantial body of scientific research, including evidence from countries where comparable warnings have been in place for many years, demonstrate the effectiveness of large, graphic warnings in enhancing public understanding about smoking-related harms.

1. Larger Warnings Are More Effective.

In upholding the TCA mandate for larger cigarette warnings in *Discount Tobacco*, the Sixth Circuit 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 once again 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.[16] 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. Thus, 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), where the city's own expert conceded that a warning one-half the size of the challenged warning would be

[16] *See also* David Hammond, *Tobacco Labelling & Packaging Toolkit, A Guide to FCTC Article 11*, (February 2009), http://www.tobaccolabels.ca/toolkit.

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.

2. Graphic Warnings Enhance Consumer Knowledge.

a. International experience with graphic health warnings supports their importance in increasing the communicative effectiveness of textual warnings.

Plaintiffs outright ignore the compelling scientific evidence provided by FDA that graphic health warnings are more effective than text-only warnings at increasing knowledge and public understanding of the health effects of smoking. The Final Rule points to multiple studies showing that graphic health warnings increase attention, noticeability, recall, information processing and understanding of warnings. 84 Fed. Reg. at 42,762-65. As noted in the Proposed Rule, "visual depictions of smoking-related disease in pictorial cigarette warnings help address gaps in public understanding of the negative health consequences of smoking by providing new information beyond what is in the text of the warnings through reinforcing and helping to depict and explain the health effect described in the text." *Id.* at 42,763

This conclusion is confirmed by real world experience in countries that have implemented graphic health warnings on cigarette packs. Smokers in countries where a graphic warning depicts a particular health hazard of smoking were much more likely to know about that hazard, and smokers

who reported noticing warnings were 1.5 to 3.0 times more likely to believe in each health hazard. 84 Fed. Reg. at 42,762.[17]

b. The impact of graphic elements is particularly important for consumers with low literacy and adolescents.

Pictures measurably increase the understanding of health warnings among people with low levels of literacy. 84 Fed. Reg. at 42,765.[18] Knowledge of the health risks of smoking is lower among people with lower income and fewer years of education because of lower health literacy and limited access to information about the hazards of smoking.[19] According to research from the International Tobacco Control (ITC) 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."[20] The effectiveness of graphic warnings across the globe reflects their ability to effectively communicate information to diverse populations. Similarly, research establishes that exposure to graphic warnings leads to knowledge gains about the harms of smoking among adolescents, the age group, as noted *supra* at section III.A, in which virtually all smoking initiation occurs. 84 Fed. Reg. at 42,763.

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[17] *See also* Hammond et al., *supra* note 14.
[18] *See also* Hammond, *supra* note 16; CRÉATEC + Market Studies, *Effectiveness of Health Warning Messages on Cigarette Packages in Informing Less-literate Smokers, Final Report* (2003) (prepared for Communications Canada); WJ Millar, *Reaching Smokers with Lower Educational Attainment*, 8 Health Rep 11 (1996); Mohammud Siahpush et al., *Socioeconomic and Country Variations in Knowledge of Health Risks of Tobacco Smoking and Toxic Constituents of Smoke: Results from the 2002 International Tobacco Control Policy Evaluation Survey*, 15 Tobacco Control iii65 (2006).
[19] Rutten et al., *supra* note 11; Siahpush et al., *supra* note 18.
[20] David Hammond et al., *Text and Graphic Warnings on Cigarette Packages: Findings from the International Tobacco Control Four Country Study*, 32 Am. J. of Preventive Med. 202 (2007).

Thus, under either *Zauderer* or *Central Hudson*, the warnings mandated by the Final Rule are fully consistent with the First Amendment, given the unique effectiveness of graphic images in addressing the gaps in public understanding about the negative health consequences of smoking. The inclusion of graphic images is no more extensive than necessary to advance a substantial governmental interest.

3. FDA's studies establish that the specific warnings mandated by the Final Rule will increase public knowledge of the health hazards of smoking.

In addition to the real world evidence showing the effectiveness of graphic cigarette warnings across the globe, 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.

Plaintiffs' characterization of the results of FDA studies as "dismal," Pls.' Br. at 35, misrepresents the key results. Much of Plaintiffs' critique 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. This pivotal study produced results that validate the effectiveness of the combined warnings to increase consumer understanding.[21] 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

[21] In its second quantitative study, FDA tested 16 potential warnings. FDA rejected three because the survey revealed they were relatively ineffective. 84 Fed. Reg. at 42,772.

warnings outperformed the Surgeon General 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," helpful in understanding health effects of smoking, and recall. 85 Fed. Reg. at 15,658.

Although Plaintiffs suggest that the impact on health beliefs was insignificant because it "quickly began wearing off," Pls' Br. at 35, in fact all of the tested warnings were more likely than the Surgeon General warnings to be recalled after approximately 14 days, which is notable given the brief exposure to the warnings in the study. 84 Fed. Reg. at 42,772. Whereas participants in FDA's study saw the warnings for the first time for only several seconds, in the real world regular smokers will be exposed to the warnings thousands of times per year on their packs and in retail stores and thus will be more likely to recall the information.[22]

Finally, although Plaintiffs make much of the fact that most of the tested warnings were perceived as lower than the existing Surgeon General warnings in "perceived factualness," Pls.' Br. 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. In no way does this imply that the Final Rule warnings will not be believed when they are implemented in the marketplace. FDA's reliance on the results of its second quantitative study was well-justified and in no way arbitrary or capricious.

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[22] *See* David Hammond, et al., *Impact of the Graphic Canadian Warning Labels on Adult Smoking Behavior*, 20 Tobacco Control 391 (2003).

4. The graphic elements of the warnings do not make them any less factual or uncontroversial under the *Zauderer* test.

According to Plaintiffs, the graphic elements of the health warnings mandated by the Final Rule inherently render the warnings not "purely factual and uncontroversial," but rather demonstrate that the warnings are intended to "shock the viewer" and "to convey an ideological message that consumers should not smoke." Pls.' Br. at 22. Invoking the D.C. Circuit's opinion in *R.J. Reynolds*, Plaintiffs assert that the warnings required by the Final Rule here cannot possibly meet the *Zauderer* test. Pls.' Br. at 23. Plaintiffs' arguments are misleading and unjustified and were explicitly rejected by the Sixth Circuit in *Discount Tobacco*. 674 F.3d at 559-60.

a. Plaintiffs misleadingly portray the graphic warnings as if they were separate from the textual warnings.

Plaintiffs make the fundamental error of analyzing the graphic elements of the Final Rule warnings as if they were entirely separate from the textual warnings they accompany. For example, Plaintiffs assert that "it will be difficult for the government to prove that, in fact, the public consistently understands a given image as conveying a specific, purely factual proposition." Pls.' Br. at 23. They cite various examples, from FDA's Qualitative Studies, of study participants who were unsure what facts were being portrayed by an image, including the "erectile dysfunction" image and the "sick child" image, *id.* at 34, *but in each case the image was being shown to participants without the accompanying text*. None of these participant reactions were to the combined textual and graphic warnings as they actually will appear on cigarette packages and advertising. FDA repeatedly makes the point that consumers will encounter the textual and graphic elements together as complementary elements communicating the same warning. For example, as FDA commented about the warning "Tobacco smoke can harm your children," paired with the image of a young boy receiving a nebulizer treatment for asthma, "[b]ecause the required warning contains the textual warning statement and image paired together, the image aids

in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa." 85 Fed. Reg. at 15,672.

When Plaintiffs do acknowledge that the images ultimately will appear with the accompanying text, they assert that "the images are necessarily serving a purpose other than communicating purely factual information," allowing the "natural inference . . . that the images are being used not to *convey facts,* but to scare consumers." Pls.' Br. at 23 (emphasis in original). Plaintiffs can draw that inference only by ignoring the scientific evidence that graphic health warnings for cigarettes in use across the globe have been shown to increase public understanding of the facts about the health effects of cigarettes (*supra* at Section II.C.2.a) and by misrepresenting FDA's studies of the warnings at issue here that demonstrate a similar effect (*supra* at Section II.C.3). At bottom, Plaintiffs' position is that the inclusion of *any* graphics renders a demonstrably true textual warning no longer "factual and uncontroversial," a position expressly rejected by the Sixth Circuit in *Discount Tobacco.* 674 F.3d at 559.[23]

b. That the warnings may evoke emotional responses does not render them less factual and uncontroversial.

The health effects of smoking are inherently frightening. Thus, the fact that the combined textual and graphic warnings may elicit emotional responses from viewers does not make them any less factual and uncontroversial. For example, there is little doubt that cancer is a widely-feared disease in the general population and it is now known that smoking causes at least 14 different types of

[23] 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.

cancer.[24] Beyond mortality, the medical treatments for these cancers – including surgery, radiation and chemotherapy – can be terribly painful and difficult. Other health effects from smoking are frightening because of their effects on loved ones, including the risks to babies and small children. FDA's goal is clear: these warnings were developed and tested based on their efficacy in communicating information, not on their capacity to elicit an emotional response. The fact that the Final Rule warnings may possibly in some people elicit negative emotions is an indication that they are effectively communicating factual information about the health effects of smoking. As FDA concluded:

> To be sure, some viewers may experience the information contained in the images – which appropriately convey the serious health consequences in a factually accurate, realistic manner – as concerning; but to the extent this occurs, it will be because the severe, life-threatening and sometimes disfiguring health effect of smoking are indeed concerning.

85 Fed. Reg. at 15,670.

Moreover, FDA's explanation for how the warnings were selected makes clear that they were not chosen because of evidence they were "shocking." 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.[25] The qualitative findings from FDA studies indicate that most of the warnings that were perceived as most shocking were not selected for subsequent testing, including images tested for cancer, blindness, impotence, heart disease, and fetal

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[24] HHS, *supra* note 4, at 2.

[25] *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 Research 93 (2013).

effects.[26] 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," (e.g. the image of a diseased lung) or "a picture or drawing of a person suffering from a smoking-related medical condition . . . ." (e.g. images of persons suffering from cataracts, reduced blood flow, heart disease, erectile dysfunction, respiratory problems, head and neck cancer, and COPD). 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 the factual information conveyed in the texts. *Id.* at 559; 85 Fed. Reg. at 15,646.

Therefore, there is no basis to conclude that the Final Rule warnings cannot be "factual and uncontroversial" simply because they include graphic elements or because they may evoke strong emotional reactions.

c. Contrary to Plaintiffs' assertion, the graphic elements of the required warnings are not extreme or misleading.

Plaintiffs claim that the Final Rule warnings are "controversial" and "misleading" because the graphics "exaggerate" smoking risks by portraying "relatively rare" consequences of smoking. Pls.' Br. at 26-27. This argument misunderstands the point of health warnings and mischaracterizes the Final Rule warnings.

As an initial matter, Plaintiffs' characterization of the warnings as "exaggerated" 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

[26] FDA, *FDA Graphic Health Warning Image Concept Testing, Qualitative Study of Perceptions and Knowledge of Visually Depicted Health Conditions* (June 2016) (OMB control number 091—0796).

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."[27] That many users of a product may not experience its most harmful effects that are the subject of the warning certainly does not render it "misleading," "exaggerated," or "controversial."

Plaintiffs claim, for example, that the effects of secondhand smoke are "exaggerated" by the image of a child in a hospital gown receiving a nebulizer treatment, accompanying the textual warnings that "Tobacco smoke can harm your children." Pls.' Br. at 26. Yet FDA cites studies showing that "children with asthma and secondhand smoke exposure are nearly twice as likely to be hospitalized with asthma exacerbations as asthmatic children without secondhand smoke exposure." 85 Fed. Reg. at 15,672. Moreover, as FDA noted, "acute asthma exacerbations can be severe and may necessitate treatment, including nebulizer treatment, in an emergency department or an inpatient setting." *Id.* Thus, as FDA found, it is not "rare or atypical" for children with chronic asthma resulting from secondhand smoke exposure to receive nebulizer treatment in a hospital setting. *Id.*

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 "exaggerated" 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.

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

III. THE MANDATED WARNINGS DO NOT UNDULY BURDEN PLAINTIFFS' COMMERCIAL SPEECH.

In no sense will the warnings chill protected speech. *See Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 250 (2010). The tobacco industry undeniably retains the ability, and has the resources, to convey its own message. *See Nat'l Inst. of Family & Life Advoc. v. Becerra*, 138 S. Ct. 2361, 2378 (2018) (explaining that protected speech could have been "drown[ed] out" by a disclosure order of magnitudes larger); *Ibanez v. Fla. Dep't. of Bus. & Prof'l Reg.*, 512 U.S. 136, 146-47 (1994) (holding that a disclosure chilled commercial speech when it was *physically impossible* for attorneys to state their qualifications on business cards). Plaintiffs will have 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, cigarette companies have successfully advertised their cigarettes with their logos and other design features.[28] That ability will not be limited by the mandated warnings.

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 they have "few remaining avenues for communicating with adult consumers," Pls.' Br. at 41, cannot be taken seriously.

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[28] Tobacco Labelling Resource Centre, Canada Cigarette Package Images, https://tobaccolabels.ca/pack-images/country/?n=Canada (last visited July 17, 2020).

Therefore, the mandated warnings will not unduly burden or chill Plaintiffs' commercial speech.

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.

Dated: July 17, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Federal Rule Civil Procedure 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email on July 17, 2020.

/s/ Andrew M. Johnson
Andrew M. Johnson

EXHIBIT TO BRIEF *AMICUS CURIAE*

Description of *Amici*

1. American Academy of Pediatrics

American Academy of Pediatrics (AAP), founded in 1930, is a national, not-for-profit organization dedicated to furthering the interests of children's health and the pediatric specialty. Since its inception, the membership of the AAP has grown from the original group of 60 physicians specializing in children's health to 67,000 pediatricians. Over the past 90 years, the AAP has become a powerful voice for children's health through education, research, advocacy, and expert advice and has demonstrated a continuing commitment to protect the wellbeing of America's children. The AAP has engaged in broad and continuous efforts to prevent harm to the health of children and adolescents caused by the use of tobacco products and exposure to secondhand tobacco smoke.

2. American Cancer Society

The American Cancer Society (the Society)'s mission is to save lives, celebrate lives, and lead the fight for a world without cancer. Smoking accounts for about 30% of all cancer deaths in the United States, including about 80% of all lung cancer deaths. Lung cancer is the leading cause of cancer death in both men and women, and is one of the hardest cancers to treat. Not only does smoking increase the risk for lung cancer, it's also a risk factor for cancers of the mouth, larynx, pharynx, esophagus, kidney, cervix, liver, bladder, pancreas, stomach, and colon. Thus, the Society works for tobacco control.

3. American Cancer Society Cancer Action Network

The American Cancer Society Cancer Action Network (ACS CAN) is the nation's leading voice advocating for public policies that are helping to defeat cancer. As the advocacy affiliate of the American Cancer Society, ACS CAN works to encourage government officials to make cancer a top priority, including supporting comprehensive tobacco control.

4. American Heart Association

The American Heart Association (AHA) is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke. Founded in 1924, the Dallas-based organization now includes more than 40 million volunteers and supporters with offices nationwide. The association funds innovative research, advocates for the public's health, and shares lifesaving resources. AHA has long been active before Congress and regulatory agencies on tobacco and other health-related matters and has petitioned the Food and Drug Administration on several occasions seeking regulation of cigarettes and other tobacco products under the Federal Food, Drug, and Cosmetic Act.

5. American Lung Association

The American Lung Association is the nation's oldest voluntary health organization. The American Lung Association has long been active in research, education and public policy advocacy regarding the adverse health effects caused by tobacco use, including placing graphic health warning labels on cigarettes.

6. American Medical Association

The American Medical Association ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty and in every state, including Texas. The AMA supports requiring more explicit and effective health warnings regarding the use of tobacco products.

The AMA and TMA join this brief on their own behalves and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state and the District of Columbia. Its purpose is to represent the viewpoint of organized medicine in the courts.

7. Campaign for Tobacco-Free Kids

The Campaign for Tobacco-Free Kids is a leading force in the fight to reduce tobacco use and its deadly toll in the United States and around the world. The Campaign envisions a future free of the death and disease caused by tobacco, and it works to save lives by advocating for public policies that educate the public about the dangers of smoking, prevent kids from smoking, help smokers quit and protect everyone from secondhand smoke.

8. Children's Hospital Association of Texas

The Children's Hospital Association of Texas (CHAT) is a non-profit association whose mission is to advance children's health and well-being by advocating for policies and funding that promote children's access to high-quality, comprehensive health care. CHAT represents eight free-standing, not-for-profit children's hospitals located in the state of Texas. Children's hospitals are unique resources that benefit all children through clinical care, research, pediatric medical education and advocacy and provide specialized care for the most severe and complex medical problems.

9. National Association of Hispanic Nurses

Since 1975 the National Association of Hispanic Nurses (NAHN) is the nation's leading professional society for Latino nurses. With a growing membership in 47 local chapters, NAHN, a 501(c) (3) non-profit, represents the voices of Latino nurses in our country. NAHN is committed to advancing the health in Hispanic communities and to lead, promote and advocate the educational, professional, and leadership opportunities for Hispanic nurses.

10. Texas Academy of Family Physicians

The Texas Academy of Family Physicians is the state's largest medical specialty organization, with more than 9,500 member physicians, residents and medical students. TAFP serves the family medicine community and provides a unified voice for family medicine as it continues to be one of the most patient-oriented public health groups in Texas. The mission of the Texas Academy of Family Physicians is to promote the health of all Texans by serving the needs of members and advancing the specialty of family medicine.

11. Texas Hospital Association

The Texas Hospital Association ("THA"), a non-profit trade association, represents approximately 470 Texas hospitals. Among other efforts, THA advocates for legislative, regulatory, and judicial means to improve public health. THA supported the recent change to Texas' legal age for the purchase and consumption of tobacco products and the issues addressed in this brief are of interest to THA and its member hospitals.

12. Texas Medical Association

With more than 53,000 members, the Texas Medical Association (TMA) is the nation's largest state medical society. TMA is a private, voluntary, non-profit association of Texas physicians and medical students. It was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health. Today, its vision is to "Improve the health of all Texans." TMA supports policies to assure that tobacco consumers are aware of the hazards of tobacco use and its impact on Texans.

13. Texas Nurses Association

The Texas Nurses Association is a membership association representing the 300,000 professional nurses in Texas. We participate on the steering committee of the Texas Public Health Coalition and support efforts to promote healthy communities.

14. Texas Pediatric Society

The Texas Pediatric Society (TPS), the state chapter of the American Academy of Pediatrics, represents more than 4,600 primary care and subspecialist pediatricians and medical students in Texas. Our mission is to ensure that the children in Texas are safe and healthy, that its members are well informed and supported, and that the practice of pediatrics in Texas is both fulfilling and economically viable. TPS advocates for decreasing youth access to all forms of tobacco and nicotine products to ensure children never grow up addicted and burdened by health complications associated with smoking.

15. **Texas PTA**

Texas PTA is the largest child advocacy association in the state and second largest state PTA in the nation with over 523,000 members who champion for Texas students and schools. Texas PTA has advocated for tobacco control policies at the state and local level so that all children may reach their full potential.

16. **The Cooper Institute**

The Cooper Institute, a Dallas-based organization, is dedicated to promoting life-long health and wellness through research and education. The Cooper Institute supports programs and efforts focused on reducing the harmful effects caused by the use and addiction to tobacco.

17. **Truth Initiative Foundation**

Truth Initiative Foundation, d/b/a Truth Initiative (Truth Initiative) is a 501(c)(3) Delaware corporation created in 1999 out of a 1998 master settlement agreement that resolved litigation brought by 46 states, five U.S. territories, and the District of Columbia against the major U.S. cigarette companies. Headquartered in Washington, D.C., Truth Initiative studies and supports programs in the United States to reduce youth smoking, vaping and nicotine use and to prevent diseases associated with tobacco products. Its nationally recognized truth® campaign has educated hundreds of millions of young people about the health effects and social costs of tobacco.

18. **Bruce C. Carter, M.D.,** Diagnostic Radiology (Tyler, Texas).

19. **David Lakey, M.D.,** Former Commissioner of the Texas Department of State Health Services (2007-2015).