No. 23-40076

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

RJ REYNOLDS TOBACCO COMPANY; Santa Fe Natural Tobacco Company, Incorporated, ITG Brands LLC; Liggett Group LLC; Neocom, Incorporated, Rangila Enterprises, Incorporated; Rangila LLC; Sahil Ismail, Incorporated; Is Like You, Incorporated,

Plaintiffs-Appellees,

v.

FOOD & DRUG ADMINISTRATION; United States Department of Health and Human Services; Robert M. Califf, Commissioner of Food and Drugs; Xavier Becerra, Secretary, U.S. Department of Health and Human Services

Defendants-Appellants.

On Appeal from the United States District Court for the Eastern District of Texas
Civil Action No. 6:20-cv-00176-JCB

BRIEF OF *AMICI CURIAE* MEDICAL, PUBLIC HEALTH, AND COMMUNITY GROUPS IN SUPPORT OF DEFENDANTS-APPELLANTS AND REVERSAL

Scott P. Lewis
Austin P. Anderson
ANDERSON & KREIGER LLP
50 Milk Street, 21st Floor
Boston, MA 02109
Tel: (617) 621-6500
Fax: (617) 621-6600
slewis@andersonkreiger.com
aanderson@andersonkreiger.com

Attorneys for Amici Curiae

Of Counsel:
Dennis A. Henigan
Connor Fuchs
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 Eye Street, NW, Suite 1200
Washington, DC. 2005
Tel: (202) 296-5469
Fax: (202) 296-5427
dhenigan@tobaccofreekids.org
cfuchs@tobaccofreekids.org

SUPPLEMENTAL STATEMENT OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rules 29.2 and 28.2.1, the undersigned counsel of record for *amici curiae* certifies that the following persons and entities as described in the fourth sentence of Rule 28.2.1, in addition to those listed in the parties' briefs, have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

1. American Academy of Family Physicians
2. American Academy of Pediatrics
3. American Cancer Society
4. American Cancer Society Cancer Action Network
5. American Heart Association
6. American Lung Association
7. American Medical Association
8. Campaign for Tobacco-Free Kids
9. Texas Medical Association
10. Truth Initiative

Pursuant to Fed. R. App. P. 26.1(a), *amici curiae* are all 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.

Dated: May 18, 2023

/s/ Scott P. Lewis
Scott P. Lewis
Attorney for *Amici Curiae*

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Public health, medical, and community organizations submit this brief as *amici curiae* in support of Appellants, urging reversal of the District Court decision vacating the rule requiring large, graphic health warnings for cigarette packages and advertisements. All parties have consented to the filing of this brief.[1] *See* Fed. R. App. P. 29(a)(2).

STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici here include the following public health, medical, and community organizations: American Academy of Family Physicians, 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, Texas Medical Association, and Truth Initiative.

Each of the *amici* has a direct interest in implementation of the health warnings mandated by the Food and Drug Administration ("FDA") rule at issue here, Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. 15,638 (Mar. 18, 2020) ("2020 Rule"). They are

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), *amici* affirm that no party's counsel authored this brief in whole or in part, neither the parties nor their counsel contributed money that was intended to fund preparing or submitting this brief, and no person—other than *amici*, their members, or their counsel—contributed money that was intended to fund preparing or submitting the brief.

united in the conviction that the large, graphic health warnings mandated by the 2020 Rule are essential for the effective communication to the public of the extraordinary range of adverse health effects from smoking. These organizations have specialized and relevant expertise, particularly in how to effectively communicate the risks of smoking to the public. *Amici* have spent decades designing, implementing, and evaluating public education campaigns to communicate the adverse health effects of smoking. This is particularly relevant experience and expertise given the District Court's conclusion that the effectiveness of public education campaigns about the risks of smoking makes large, graphic warnings on cigarettes unnecessary. Opinion and Order, *R.J. Reynolds Tobacco Co. v. FDA*, No. 6:20-cv-00176, Doc. 106 (Dec. 7, 2022) ("Op."). In fact, large, graphic health warnings on every pack of cigarettes and on all cigarette advertising would materially enhance the efforts of *amici* to educate the public about the health harms of smoking and, in the case of *amici* medical organizations and physicians, to effectively communicate these harms to patients. These groups, among many other public health groups, filed extensive formal comments with FDA supporting the Proposed Rule, 84 Fed. Reg. 42,754 (Aug. 16, 2019),[2] and filed an *amicus curiae* brief in the District Court.

[2] Comments on Tobacco Products, Required Warnings for Cigarette Packages and Advertisements by 39 Public Health Organizations, Docket No. FDA-N-3065 (Oct. 15, 2019), [cont.]

INTRODUCTION AND SUMMARY OF ARGUMENT

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.* The Supreme Court therefore refused to subject mandatory factual disclosures to the "intermediate scrutiny" applied to restrictions on commercial speech in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980). *Id*.

Under *Zauderer*, the 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. *Id.* In deciding that the 2020 Rule warnings did

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https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2019_10_15_required_warrnings_advertisements.pdf.

not convey "purely factual and uncontroversial" information about the health dangers of smoking, and thus declining to apply *Zauderer*, the District Court erred by speculating about various possible interpretations that could be given the *graphic* elements of each warning, standing alone. The District Court pointed to no record evidence that the *combined* textual and graphic elements are subject to differing interpretations and thus would not convey purely factual information. The messages conveyed by the combined text and graphics in the 2020 Rule warnings are entirely factual, and the warnings serve the government's interest because those facts are communicated far more effectively by the larger size of the warnings and by the inclusion of concordant graphic images, when compared to the current, smaller text warnings. Therefore, the 2020 Rule warnings are constitutional under *Zauderer*.

Even under the "intermediate scrutiny" standard applied in *Central Hudson* to restrictions on commercial speech, the 2020 Rule warnings do not violate the First Amendment because they directly advance a substantial governmental interest and are no more extensive than necessary to serve that interest. *See Central Hudson*, 447 U.S. at 564. The government interest on which FDA relies—increasing public understanding of the health hazards of smoking—is vitally important, given the uniquely devastating health consequences of smoking and the decades of lies and deception by the cigarette companies, including plaintiff R.J. Reynolds, in denying those devastating health consequences. Large, graphic health warnings directly

advance the government's interest because (1) the current small, textual health warnings on cigarettes are barely noticed, particularly by youth; (2) there are significant gaps in the public's understanding of the full range of smoking-related diseases; (3) the scientific literature demonstrates that larger warnings, with graphic elements, lead to greater public understanding of the health hazards of smoking, and (4) FDA's own studies demonstrate that the specific 2020 Rule warnings increase consumer understanding of the health harms of smoking.

Finally, the 2020 Rule warnings do not unduly burden the protected speech of the cigarette companies, leaving them with ample opportunities to convey their commercial message. Moreover, because the warnings accompany the products themselves, they have a unique communicative power at the point of sale and prior to use that is not replicated by public education campaigns and other alternative communication avenues suggested by the District Court. Thus, contrary to the District Court's conclusion, the 2020 Rule warnings meet the *Central Hudson* criteria of being no more extensive than necessary to serve the government's interest in enhancing public understanding of the full range of health risks of cigarettes.

Therefore, under either *Zauderer* or *Central Hudson*, the 2020 Rule warnings of the hazards of cigarettes are consistent with the First Amendment.

ARGUMENT

I. THE 2020 RULE'S HEALTH WARNINGS COMMUNICATE FACTUAL AND UNCONTROVERSIAL INFORMATION AND THUS SHOULD BE EVALUATED UNDER *ZAUDERER*.

Contrary to the District Court decision, because the 2020 Rule warnings convey purely factual and uncontroversial information about the health hazards of smoking, their constitutionality under the First Amendment should be governed by the standards set forth in *Zauderer*.

A. In Finding the 2020 Warnings Non-Factual, the District Court Incorrectly Assumed that the Graphic Elements Convey a Message Distinct from the Textual Warnings.

The 2020 Rule mandates eleven textual warnings of the health hazards of smoking, each paired with a concordant, factually accurate image depicting the health hazard described in the textual warnings. For example, one warning consists of the text "WARNING: Smoking causes head and neck cancer" paired with an image accurately depicting neck cancer, with a woman who has a visible tumor protruding from the right side of her neck. FDA carefully marshalled the scientific evidence supporting the accuracy of each textual warning, relying largely on a series of U.S. Surgeon General Reports. Proposed Rule, 84 Fed. Reg. at 42,773-77.

The District Court did not question the factual accuracy of the textual warnings. Instead, it found the *Zauderer* test inapplicable in part because "it is unclear how a court would go about determining whether its graphic aspect is

'accurate' and 'factual' in nature," using the head and neck cancer warning as an example. Op. 28. But this is the wrong inquiry. The lower court assumed that the graphic aspect of the warning label will somehow convey a different message than the textual warning and that this different message may itself not be factual. But the consumer will only see the graphic aspect in conjunction with the textual message. Thus, the appropriate inquiry is whether the *combined* textual and graphic elements will convey a message that is factual and uncontroversial.

The lower court speculated that "[t]he image may convey one thing to one person and a different thing to another." Op. 28. According to the court, as to the head and neck cancer warning, for example, various possible interpretations of the image include (1) viewing it "as showing a typical representation of the sort of neck cancer caused by smoking before a person could seek medical treatment," (2) viewing the image "as showing a stylized, exaggerated representation of neck cancer, perhaps in an effort to provoke repulsion," or (3) expressing the depicted person's "regret at her choice to smoke or the message that smoking is a mistake." *Id.* Missing from the court's analysis is any reason to believe that any of those additional messages will be conveyed by the combined textual and graphic elements of the warning. Put another way, the lower court cites nothing in the record supporting a finding that there is any message being conveyed other than the purely factual and uncontroversial message that "smoking causes head and neck cancer,"

with the graphic element simply an accurate depiction of head and neck cancer. As FDA observed about each of the warnings, "Because 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." 2020 Rule, 85 Fed. Reg. at 15,675. The image reinforces the text; the text explains the image. Together they convey a single factual and uncontroversial message.

Moreover, the fact that there may be many ways to graphically depict a particular health harm from smoking does not detract from the "purely factual" nature of the warning. In upholding the statutory mandate of graphic health warnings for cigarettes in *Discount Tobacco City & Lottery v. U.S.*, 674 F.3d 509 (6th Cir. 2012), the Sixth Circuit analogized fact-based graphic health warnings for cigarettes to the graphics used in medical textbooks:

> Students in biology, human-anatomy, and medical-school courses look at pictures or drawings in textbooks, of both healthy and damaged cells, tissues, organs, organ systems, and humans because those pictures convey factual information about medical conditions and biological systems. The argument that a picture of a specific person or part of a person is opinion because not every person or part of a person with that condition would appear the same way is unpersuasive . . . [A]rguing that a representation of a medical condition becomes an opinion when people could have that medical condition in ways that deviate from the representation would lead to the insupportable conclusion that textual or pictorial descriptions of standard medical conditions must be opinions as well.

674 F.3d at 559. The Court of Appeals suggested multiple graphic representations that would constitute factual disclosures under *Zauderer*, many virtually identical to those adopted by FDA in the 2020 Rule, including "a picture or drawing of a nonsmoker's and smoker's lungs displayed side by side," and "a picture or drawing of a person suffering from a smoking-related medical condition." *Id.*

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." *Id.* 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.

B. Contrary to the District Court's View, the 2020 Warnings Do Not Convey "Value-laden" Opinions.

The District Court also drew a distinction between "purely factual" verbal statements and statements that are "value-laden" opinions. Op. 27. It then observed that consumers may take from the graphic images in the 2020 Rule warnings "a value-laden message that smoking is a mistake." Op. 28-29. According to the court, "For that reason alone, the graphics make all of the warnings here not 'purely factual' and 'uncontroversial' within the meaning of *Zauderer*." Op. 29. But that is a *non sequitur*. The fact that consumers may conclude, based on the facts communicated

by the combined textual and graphic elements of the warnings, that "smoking is a mistake," does not make the warnings themselves less factual or more controversial. Indeed, consumers could reach the conclusion that "smoking is a mistake" from the textual messages alone, with no graphic elements. The opinion that "smoking is a mistake" may follow logically from the entirely factual warnings mandated by the rule, but it is not expressed by those warnings. As with the required disclosure 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 confess by word or act their faith therein.'" *Zauderer,* 471 U.S. at 651 (citation omitted).

The absence of any expression of "value-laden" opinions in the 2020 Rule warnings distinguishes them from the warnings issued by FDA in 2011 and found unconstitutional in *R.J. Reynolds Tobacco Co. v. FDA,* 696 F.3d 1205 (D.C. Cir. 2012), *overruled in part by Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). In finding that that the 2011 warnings "cannot rationally be viewed as pure attempts to convey information to consumers," the D.C. Circuit pointed to the example of a man wearing a T-shirt emblazoned with the words "I QUIT," as well as the appearance of the "1-800-QUIT-NOW" number on each of the warnings. *Id.* at 1216. No such "value-laden" opinions are expressed by the 2020 Rule warnings. Whereas the court in *R.J. Reynolds* found that the graphic warnings in the 2011 rule "are primarily intended to evoke an emotional response," *id.*, nothing in the record

here supports such a conclusion as to the 2020 Rule warnings. The 2011 rule warnings were tested by FDA to determine whether they caused viewers "to feel 'depressed,' 'discouraged,' or 'afraid,' and whether they "increased viewers' intention to quit or refrain from smoking." *Id.* at 1209. In contrast, the 2020 Rule warnings were tested against entirely different criteria which validated the effectiveness of the warnings in increasing consumer understanding of the health dangers of smoking as compared to the current Surgeon General warnings. *See* Proposed Rule, 85 Fed. Reg. at 42,768-69.

Indeed, the qualitative findings from FDA studies supporting the 2020 Rule warnings reinforce that FDA's focus was effectively communicating factual information. Most of the warnings perceived as most shocking were not selected for subsequent testing, including images tested for cancer, blindness, impotence, heart disease, and fetal effects. ROA.1383-1423. The agency also disagreed with comments on the proposed rule that the images should be made more "gross" or "shocking," because "[t]he images are not intended to evoke negative emotions such as fear, shame and disgust, but rather to promote greater public understanding of the negative health consequences of cigarette smoking." 2020 Rule, 85 Fed. Reg. at 15,670.

Of course, the 2020 Rule warnings may well elicit emotional responses from consumers—the health effects of smoking are inherently frightening. But the fact

that warnings of the health effects of smoking may elicit negative emotions does not make those warnings any less factual; indeed, it indicates that the facts are being effectively communicated. The 2011 warnings communicated the government's opinion that people should not smoke and tested their effectiveness in conveying that opinion by assessing their emotional impact. In contrast, the 2020 Rule warnings communicate only facts, and were assessed according to whether those facts were effectively communicated, allowing individuals to reach their own conclusion about whether they should smoke.

Therefore, because the 2020 Rule warnings, with combined textual and graphic elements, convey entirely factual and uncontroversial information about the health effects of smoking, they should be judged under the *Zauderer* standards.

II. THE HEALTH WARNINGS MANDATED BY THE 2020 RULE ARE REASONABLY RELATED TO, AND DIRECTLY ADVANCE, THE SUBSTANTIAL GOVERNMENTAL INTEREST IN INCREASING PUBLIC UNDERSTANDING OF THE HEALTH HAZARDS OF SMOKING.

Beyond any doubt, the 2020 Rule warnings are "reasonably related" to a legitimate governmental interest and thus meet the *Zauderer* standard.[3] Moreover,

[3] Although the governmental interest served by the mandatory disclosures in *Zauderer* was the prevention of consumer deception, no circuit court has adopted the view that preventing deception is the only governmental interest that can sustain the constitutionality of mandatory disclosures under *Zauderer*. *See* 2020 Rule, 85 Fed. Reg. at 15,644-45 (and cases cited therein). This Court also has interpreted *Zauderer* to require only a reasonable relationship to a "legitimate" state interest, "like preventing deception of consumers," *Netchoice, LLC v. Paxton*, 49 F.4th 439,

the government's interest is sufficiently substantial, and the warnings sufficiently advance that interest, to sustain the constitutionality of the warnings, even if they are evaluated under the "intermediate scrutiny" of *Central Hudson*.

A. Increasing Public Knowledge of the Health Hazards of Smoking Is a Vitally Important Governmental Interest.

1. The extraordinary range of adverse health consequences of smoking supports the critical importance of effectively communicating those consequences.

In issuing the 2020 Rule, FDA identified the governmental interest served by the required warnings as "[p]roviding relevant, truthful, and non-misleading information" about the health risks of smoking that "provides consumers with a better opportunity to make informed choices." 2020 Rule, 85 Fed. Reg. at 15,643. Given the prevalence and extraordinary range of serious health harms caused by cigarette smoking, it is difficult to imagine a governmental interest more legitimate and important than increasing public knowledge of the risks of smoking.[4] Over two

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485 (5th Cir. 2022), thus treating that interest as only one example of a "legitimate" governmental interest. In any event, the continuing need to correct the consequences of decades of deception by the cigarette companies, including plaintiff R.J. Reynolds (*see infra* pp. 15-16), would justify the 2020 Rule warnings even if correcting consumer deception were the only legitimate governmental interest under *Zauderer*.

[4] The *Zauderer* opinion does not require a showing that the governmental interest served by the mandatory disclosures is "substantial," as would be required to sustain limitations on commercial speech under *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). Plainly, the administrative record supporting the 2020 Rule demonstrates that the government's interest in increasing

decades ago, the Supreme Court recognized that "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Co.*, 529 U.S. 120, 161 (2000). It remains so today.

In issuing the 2020 Rule, FDA found that "[c]igarette smoking remains the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year among cigarette smokers and those exposed to secondhand smoke." 2020 Rule, 85 Fed. Reg. at 15,652. 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.* Over 16 million Americans today live with smoking-related diseases, including lung cancer, heart disease, and chronic obstructive pulmonary disease (COPD). *Id.* FDA relied on the 2014 Surgeon General's Report in finding that the negative health consequences of cigarette smoking and secondhand smoke had expanded dramatically in the fifty years since the first Surgeon General's Report on smoking in 1964. The 2014 Report added eleven diseases to the more than 40 unique health consequences previously linked to smoking: liver cancer, colorectal cancer, age-

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public understanding of the health harms of smoking is sufficiently important to meet even the *Central Hudson* test.

related macular degeneration, orofacial clefts in newborns from maternal smoking during pregnancy, tuberculosis, stroke (for adults), diabetes, erectile dysfunction, ectopic pregnancy, rheumatoid arthritis, and impaired immune function. *Id.* The sheer scope of the harm cigarettes inflict on the public's health distinguishes cigarettes from other dangerous products and furnishes a uniquely strong justification for large, graphic health warnings.

2. Decades of deception by the cigarette companies increases the importance of effectively communicating the health harms of smoking.

The importance of effectively communicating the staggering range of health risks associated with smoking is increased by the decades of deception by the cigarette companies—including plaintiff R.J. Reynolds—about those harms. Indeed, in *United States v. Philip Morris USA, Inc.*, 449 F. Supp.2d 1 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S. Ct. 3501 (2010), the D.C. District Court found plaintiff R.J. Reynolds 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. Thus, the government has a substantial interest in increasing public knowledge of the health hazards of cigarettes, not only because of the unique danger of these products, but also to overcome decades of fraudulent representations by their purveyors. This massive fraud further distinguishes cigarettes from other dangerous products, justifying large, graphic health warnings to ensure that the truth is finally communicated in the most effective way.

3. Increasing public understanding of the health harms of smoking can stand alone as a vital governmental interest, regardless of its impact on smoking prevalence.

As the FDA has established, increasing public understanding of the health harms of tobacco can stand alone as a legitimate and substantial government interest for First Amendment purposes. In contrast, as the D.C. Circuit characterized the 2011 rule struck down in *R.J. Reynolds*, the interest in "effectively communicating health information" had been conceded by FDA to describe "only the *means* by which FDA is attempting to reduce smoking rates." 696 F.3d at 1221. Indeed, in *R.J. Reynolds*, the court recognized that "the government can certainly require that consumers be fully informed about the dangers of hazardous products." *Id.* at 1212.

That, of course, is exactly what FDA's 2020 Rule does. In striking down FDA's 2011 Rule, the D.C. Circuit did not question that effectively communicating the health harms of smoking could be a legitimate and substantial governmental interest. Instead, the Court of Appeals found that this interest was "too vague to stand on its own" because FDA had offered no "barometer" for assessing the effectiveness of the graphic warnings other than whether "they encourage current smokers to quit and dissuade would-be smokers from taking up the habit." *Id.* at 1221. In response, when FDA developed its 2020 Rule, FDA used several "barometers" to measure the effectiveness of the mandated warnings in promoting understanding of the health harms of smoking, including the key outcomes of "new information" and "self-reported learning"—metrics that are predictive of whether the warnings will promote greater public understanding of the health effects of cigarette smoking. 2020 Rule, 85 Fed. Reg. at 15,658-67.

In enacting the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 (2009) ("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 §§ 3(6), 202(d). No showing of an impact on smoking cessation or initiation is required.[5]

In upholding the statutory requirement for large, graphic health warnings against First Amendment attack, the Sixth Circuit affirmed the intrinsic value of effectively communicating such information, regardless of its impact on smoking rates: "What 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." *Discount Tobacco*, 674 F.3d at 567.

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[5] The decision of the D.C. Circuit in *Cigar Association of America v. FDA*, 964 F.3d 56 (D.C. Cir. 2020), striking down an FDA rule requiring larger health warnings for cigars, is not to the contrary. That case did not address whether increasing public understanding of the health hazards of tobacco products is a substantial governmental interest for First Amendment purposes. Rather, the court held that FDA had issued the rule under the authority of Section 906(d)(1) of the Food, Drug & Cosmetic Act, as amended by the TCA, without considering the impact of the warnings on smoking cessation and initiation, as expressly required by that statutory section. In contrast, the 2020 Rule was promulgated pursuant to 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. The FCLAA does not require FDA to consider the impact of graphic warnings on cessation or initiation of smoking.

Therefore, the government's interest in promoting greater public understanding of the extraordinary range of health harms of smoking is, standing alone, a legitimate—and indeed vital—governmental interest.

B. The 2020 Rule Warnings Are Reasonably Related to and Directly Advance the Governmental Interest in Increasing Public Knowledge of the Health Hazards of Smoking.

1. The current Surgeon General warnings are ineffective.

There are significant gaps in the public's understanding of the full range of smoking-relating diseases, despite decades of government and other reports and public education campaigns about the risks of smoking. Even though many smokers are aware that smoking causes lung cancer, knowledge of other smoking-caused illnesses, including diseases addressed by the current Surgeon General warnings, is much lower. Proposed Rule, 84 Fed. Reg. at 42,761. FDA marshalled substantial evidence that the current Surgeon General's warnings on the sides of cigarette packs do not attract attention, are not noticed, do not prompt consumers to think about the risks of smoking, are not remembered, do not address the breadth of negative health consequences of smoking, and have not been updated in more than 35 years. 2020 Rule, 85 Fed. Reg. at 15,653-57. For example, FDA describes research from Wave 4 (2016-17) 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. Proposed Rule, 84 Fed. Reg. at

42,760. Given that 88% of long-term smokers begin smoking before the age of 18, it is particularly consequential that, as FDA found, studies consistently show that "adolescents . . . do not see or read, and do not remember" the current warnings. Proposed Rule, 84 Fed. Reg. at 42,761.

FDA found that many studies show limited public understanding of smoking's causal link to the diseases and conditions specifically addressed in the 2020 warnings, including bladder cancer, vision impairment, impotence and the impact of secondhand smoke on children and adults. *Id.* Based on this evidence, FDA concluded that "consumers suffer from a pervasive lack of knowledge about and understanding of the many negative health consequences of smoking, and, importantly, the published literature indicates that consumers do not understand the wide *range* of illnesses caused by smoking." 2020 Rule, 85 Fed. Reg. at 15,654 (emphasis in original). By focusing on serious but lesser-known health effects of smoking, the 2020 Rule warnings will enhance the public's understanding of the extraordinarily broad range of serious smoking-related illnesses.

2. Larger warnings with graphic elements will increase public understanding of the health hazards of smoking.

In upholding the statutory mandate for larger, graphic cigarette warnings in *Discount Tobacco*, the Sixth Circuit found that FDA had supplied "abundant evidence establish[ing] that larger warnings incorporating graphics promote a greater understanding of tobacco-related health risks." 674 F.3d at 565. A similar

abundance of evidence, including from the experience of other countries, supports the conclusion that large, graphic warnings like those in the 2020 Rule are reasonably related to, and directly advance, the governmental interest in greater public understanding of the dangers of cigarette smoking.

As FDA reasonably found, warnings must be large enough, and noticeable enough, to get the consumer's attention. Proposed Rule, 84 Fed. Reg. at 42,762. FDA found that the small size of the current Surgeon General warnings was a significant factor in their general ineffectiveness, *id.* at 42,759, concluding that "[t]he scientific literature strongly supports that larger warnings such as those of the size proposed in this rule, are necessary to ensure that consumers notice, attend to, and read the messages conveyed by the warnings, which leads to improved understanding of the specific health consequences that are the subject of those warnings." *Id.* at 42,779.

FDA points to multiple studies in the research literature showing that graphic health warnings increase attention, noticeability, recall, information processing, and understanding of warnings. *Id.* at 42,762-65. These findings include real-world experience in countries that have implemented graphic warnings on cigarette packs. A major, multi-country study that compared cigarette health warnings in four high-income countries (Australia, Canada, the United Kingdom, and the United States) found that larger, more comprehensive warnings were more likely to be noticed and

rated as effective by smokers. Proposed Rule, 84 Fed. Reg. at 42,760, 42,762. Findings from this study showed that less than half (46.7 percent) of U.S. respondents considered cigarette packages as a source of information on the negative health effects of smoking compared to 84.3 percent of respondents in Canada, where pictorial health warnings are required. *Id.* at 42,760. Another study comparing the impact of text-only cigarette warnings in Mexico with pictorial warnings in Canada showed that Canadian adult smokers were more likely to notice the warning label and think about the harms of smoking. *Id.* at 42,762. Data from the four-country study showed that "[s]mokers who reported noticing the cigarette health warnings were more likely to report believing that smoking causes the specific health consequences contained in the warnings, compared to those who did not notice the warnings." *Id.* at 42,762.

Of particular significance is the impact of graphic health warnings on youth. As FDA found:

> Research supports that exposure to pictorial cigarette warnings leads to knowledge gains about the harms of smoking among adolescents, whereas . . . the current 1984 Surgeon General's warnings do not. A report of Canadian warnings indicated that pictorial cigarette warnings improved knowledge of specific negative health effects of smoking among adolescents (e.g., increased knowledge of bladder cancer, impotence in men, mouth cancer, gum or mouth disease, reduced growth in babies during pregnancy, and strokes).

Id. at 42,763.

The vast research literature supporting the relative effectiveness of large, graphic warnings is bolstered by FDA's own studies of the specific warnings adopted in the 2020 Rule. The pivotal study is FDA's second quantitative consumer research study (involving 9,760 participants) in which 16 text and image pairings were tested, according to 10 outcome criteria, against the current Surgeon General's warnings. 2020 Rule, 85 Fed. Reg. at 15,658. The 11 final required pairings outperformed the Surgeon General's warnings on the two outcomes FDA previously determined were most predictive for promoting understanding of the risks associated with cigarette smoking: whether the warning provided new information to participants ("new information") and whether participants learned something from the warning ("self-reported learning"). *Id.* In addition, all 11 final required warnings surpassed the Surgeon General's warnings on six other measures: whether the warnings led to more thinking about risks; perceived informativeness; perceived understandability; perceived helpfulness in understanding health effects; attracted more attention; and were better recalled. *Id.*

Therefore, the rulemaking record includes abundant evidence that the mandated large, graphic warnings directly advance the governmental interest in greater public understanding of the health hazards of cigarettes, sufficient to meet the standards set forth in both *Zauderer* and *Central Hudson*.

III. THE 2020 RULE WARNINGS DO NOT UNDULY BURDEN PROTECTED SPEECH AND ARE NOT MORE EXTENSIVE THAN NECESSARY TO INCREASE PUBLIC UNDERSTANDING OF THE HEALTH HARMS OF SMOKING.

Because the 2020 Rule warnings do not unduly burden protected commercial speech, and because they are not more extensive than necessary to serve the vital governmental interest in increasing public understanding of the health harms of smoking, they are constitutional under the standards in both *Zauderer* and *Central Hudson*.

As explained by this Court, "*Zauderer* does not countenance a broad inquiry into whether disclosure requirements are 'unduly burdensome' in some abstract sense, but instead instructs us to consider whether they unduly burden (or 'chill') protected *speech* and thereby intrude on an entity's First Amendment speech rights." *Netchoice, L.L.C. v. Paxton,* 49 F.4th at 486 (emphasis in original). It is fanciful to suggest that the 2020 Rule warnings chill the ability of the cigarette companies to convey their commercial messages. *See Discount Tobacco,* 674 F.3d at 530. 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 brand names, logos and other promotional content. They also will be able to recapture additional pack space now occupied by the outdated Surgeon General's warnings.

Despite the restrictions on cigarette advertising in the United States, FDA noted that cigarette companies spent $1.3 billion in advertising and promotion in the

U.S. in 2017. Proposed Rule, 84 Fed. Reg. at 42,759. Smokers and nonsmokers, 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 First Amendment channels are foreclosed by the mandated warnings. This is far from a case where protected speech could be "drown[ed] out" by a required disclosure. *See Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S.Ct. 2361, 2378 (2018).

In addition, because the warnings are no more extensive than necessary to serve the substantial governmental interest in greater public understanding of the health harms of smoking, they do not violate the First Amendment even under the intermediate scrutiny test of *Central Hudson*. In incorrectly applying *Central Hudson* instead of *Zauderer* to the 2020 Rule warnings, the District Court relied largely on the availability of "other options" for the government to increase public understanding of the health harms of cigarettes, "such as increasing funding for anti-smoking advertisements in various forms of media, increasing funding for speakers and school instruction, and increasing anti-smoking resources in the government's own communications." Op. 33.

But *Central Hudson* does not require restrictions on commercial speech to be the "least restrictive means" to further the government interest, as would be required under the strict scrutiny standard applied to restrictions on political and other non-

commercial speech. *Greater New Orleans Broadcasting Ass'n, Inc. v. U.S.*, 527 U.S. 173, 188 (1999). The District Court acknowledged that *Central Hudson* review requires only that the commercial speech regulation be "narrowly drawn" to the governmental interest and "not more extensive than is necessary." Op. 32 (quoting *Central Hudson*). But the court's analysis is far closer to strict scrutiny because it suggests that the existence of other means of educating the public itself establishes that product warnings violate the First Amendment.[6]

Amici recognize the importance, and effectiveness, of public education campaigns of the kind suggested by the District Court, but effective health warnings on cigarette packs and advertising have unique advantages over other means of

[6] The District Court's reliance (Op. 33) on the Supreme Court's decision in *National Institute of Family and Life Advocates v. Becerra* ("*NIFLA*"), *supra*, fails to recognize that the factual context in that case bears no resemblance to warnings on dangerous products. In *NIFLA*, the Court struck down a California statute requiring that certain notices be posted at clinics known as "crisis pregnancy centers," which offered various types of assistance to pregnant women, but were clearly intended to discourage the women from seeking abortions. 138 S.Ct. at 2368. The required notices did not concern the services provided by the clinics, but rather disclosed information about the availability of abortion services elsewhere. *Id.* at 2372. As the Ninth Circuit has observed, the compelled disclosures in *NIFLA* "took sides in a heated political controversy." *CTIA – The Wireless Ass'n v. City of Berkeley, Cal.*, 928 F.3d 832, 845 (9th Cir. 2019). 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 . . . ." 138 S.Ct. at 2376.

communicating the harms of smoking.[7] The health warnings required by FDA's 2020 Rule are particularly well-suited to serve the government's interest because they are "paired" with the product itself. This ensures that all potential cigarette consumers are repeatedly exposed to the warnings at the point of sale, and prior to use. These health warnings provide assurance that potential consumers, particularly young people, have accurate health information before beginning to use a highly addictive and lethal product. School-based programs and anti-smoking advertisements—to which young people may or may not be exposed—do not serve this special function. The combined text and graphic warnings required by FDA's 2020 Rule are no more extensive than necessary to ensure the effective communication of the health risks of cigarettes to every consumer at the point where purchase and use decisions are made. Thus, even under the *Central Hudson* standard, the 2020 Rule warnings are consistent with the First Amendment.

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[7] *Amici* have particular credibility on this point, as they have been involved for decades in sponsoring and supporting public education campaigns on the dangers of tobacco products and are thus well aware of the effectiveness of those campaigns. *See, e.g.*, *1960's American Cancer Society PSAs*, AM. CANCER SOC'Y (Oct. 15, 2010), https://www.youtube.com/watch?v=hHRcw3NPMD0; *Quit Smoking, Vaping and Tobacco Use*, AM. HEART ASS'N, https://www.heart.org/en/healthy-living/healthy-lifestyle/quit-smoking-tobacco; *Quit Smoking*, AM. LUNG ASS'N, https://www.lung.org/quit-smoking; *Youth Smoking and Vaping Prevention*, TRUTH INITIATIVE, https://truthinitiative.org/what-we-do/youth-smoking-prevention-education.

CONCLUSION

For these reasons, the District Court decision should be reversed and the injunction against implementation of the 2020 Rule warnings should be dissolved.

Respectfully submitted,

/s/ Scott P. Lewis

Scott P. Lewis
Austin P. Anderson
ANDERSON & KREIGER LLP
50 Milk Street, 21st Floor
Boston, MA 02109
Tel: (617) 621-6500
Fax: (617) 621-6600
Email: slewis@andersonkreiger.com
Email: aanderson@andersonkreiger.com

Dennis A. Henigan (Of Counsel)
Connor Fuchs (Of Counsel)
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 I St. NW, Suite 1200
Washington, DC 20005
Tel: (202) 481-9366
Fax: (202) 296-5427
Email: dhenigan@tobaccofreekids.org
Email: cfuchs@tobaccofreekids.org

Attorneys for *Amici Curiae*

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/s/ Scott P. Lewis
Scott P. Lewis
Attorney for *Amici Curiae*

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I hereby certify that on May 18, 2023, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

/s/ Scott P. Lewis
Scott P. Lewis
Attorney for *Amici Curiae*