ORAL ARGUMENT NOT YET SCHEDULED
No. 18-5195

In the United States Court of Appeals for the District of Columbia Circuit

CIGAR ASSOCIATION OF AMERICA, INTERNATIONAL PREMIUM CIGAR AND PIPE RETAILERS ASSOCIATION, AND CIGAR RIGHTS OF AMERICA,
Plaintiffs-Appellants,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX AZAR II, AND SCOTT GOTTLIEB, M.D.,
Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA
CASE NO. 1:16-CV-01460-APM (THE HON. AMIT P. MEHTA)

BRIEF OF PUBLIC HEALTH LAW CENTER AS AMICUS CURIAE IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE

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COMBINED CERTIFICATES

Certificate as to Parties, Rulings, and Related Cases

A. Parties and Amici. All parties and amici who appeared before the district court appear in the plaintiffs-appellants' brief and the defendants-appellees' brief. The parties appearing in this Court include those listed in plaintiffs-appellants' brief and the amici listed in defendant-appellee's brief, with the addition of the Public Health Law Center, the amicus filing this brief.

B. Rulings under Review. References to the rulings at issue appear in the defendants-appellees' brief.

C. Related Cases. References to any related cases appear in the defendants-appellees' brief.

Certificate of Amicus Curiae Under Circuit Rule 29(d)

The Public Health Law Center is a leading expert on tobacco policy and works with localities, states, and the federal government to implement evidence-based public health interventions. This amicus brief is necessary to explain to the Court why health warnings are often a preferred option among public health tools and to present the Court with the relevant empirical research supporting the efficacy of warning labels in the tobacco context. This brief responds to the amicus brief of Professor Armstrong regarding the empirical evidence on health warnings and

disclosures. As far as the Public Health Law Center is aware, no other amicus brief contains this material.

Corporate Disclosure Statement

Public Health Law Center has no parent corporations. It has no stock, and hence, no publicly held company owns 10% or more of its stock.

s/Rachel Bloomekatz
Rachel Bloomekatz

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GLOSSARY

FDA — U.S. Food and Drug Administration

PHLC or Center — Public Health Law Center (the amicus curiae)

INTEREST OF THE AMICUS CURIAE[1]

The Public Health Law Center is a public interest legal resource center dedicated to improving health through the power of law and policy, grounded in the belief that everyone deserves to be healthy. Located at the Mitchell Hamline School of Law in Saint Paul, Minnesota, the Center helps local, state, national, tribal, and global leaders promote health by strengthening public policies. For almost twenty years, the Center has worked with public officials and community leaders to develop, implement, and defend effective public health laws and policies, including those designed to reduce commercial tobacco use, improve the nation's diet, encourage physical activity, protect the nation's public health infrastructure, and promote health equity. This work is evidence-based, informed by the leading empirical research on policy interventions. As such, the Center is particularly suited to provide its expertise regarding warning labels, why they serve an important role in public health policy, and the empirical evidence supporting their efficacy.

The Center has been involved in more than sixty amicus curiae briefs filed in the highest courts of the land, including many briefs filed by the Center's commercial tobacco control program, the Tobacco Control Legal Consortium.[2] Among the

[1] All parties consent to the filing of this brief, and no counsel for any party authored it in whole or part. Apart from amicus curiae, no person contributed money intended to fund the brief's preparation and submission.

[2] The Consortium's affiliated legal centers include: ChangeLab Solutions, Oakland, California; Legal Resource Center for Tobacco Regulation, Litigation &

Center's briefs are sixteen addressing the regulation of commercial speech. The Center has a strong interest in supporting the government's ability to require companies to warn consumers about the dangers of their products.

INTRODUCTION

Health warnings on hazardous product packaging and advertising are a long-established public health tool. Since 1965, if you've seen a pack of cigarettes, its side panel has contained a Surgeon General's warning. If you watch prime time television, as millions of Americans do each night, you are likely to catch a pharmaceutical ad that drags on long at the end with a detailed script describing the drug's potential side effects. Containers of poisonous materials have carried the skull and crossbones since the 1850s, and many still do today. And step into a chain restaurant in New York City and a salt shaker symbol warns you when a menu item has more than the recommended daily intake of sodium. These are but a few examples of the warning labels that help consumers understand the health risks associated with common daily behaviors that we often take for granted (or used to)—smoking, taking a pill, buying consumer products, and ordering lunch.

Advocacy, at University of Maryland Francis King Carey School of Law, Baltimore, Maryland; Public Health Advocacy Institute and the Center for Public Health and Tobacco Policy, both at Northeastern University School of Law, Boston, Massachusetts; Smoke-Free Environments Law Project, at the University of Michigan, Ann Arbor, Michigan; and Tobacco Control Policy and Legal Resource Center at New Jersey GASP, Summit, New Jersey.

Not only do scientific studies demonstrate that warning labels are effective in conveying health risks, they have a key advantage over other possible public health regulations: they are often a less restrictive alternative to more aggressive regulation, even when such regulations are justified. Rather than banning a product, restricting its sale, or prohibiting its advertisement altogether, adding a warning label is a modest intervention that conveys truthful facts (and often counters misperceptions) about the health consequences of a product so that consumers can make informed decisions. Indeed, espousing support for informed consumer choice is often the cornerstone of the tobacco industry's fight against other sensible regulations and, ironically, its opposition to warning labels runs counter to that argument.

No one can contest (though many do not realize) that smoking cigars leads to nicotine addiction, cancer, heart disease, lung disease, stroke, and death. These health effects were concerning even when use was thought to be largely confined to older men smoking an occasional cigar in backrooms. But that is not what cigar use is like now. There are new, flavored, and often mini or little cigars (or cigarillos) that appeal to youth and new tobacco users because they make the harsh taste of tobacco more palatable.[3] And, unlike cigarettes, they can be purchased one or two at a time for under a dollar.[4] Consequently, consumption of cigars exceeds cigarettes for many

[3] Patti Neighmond, *Sweet Cigarillos and Cigars Lure Youth to Tobacco, Critics Say*, NPR (Aug. 26, 2013), *available at* https://n.pr/2zHowRA.

[4] *Id.*

key youth demographics. Overall, while cigarette use has fallen, cigar use is on the rise.[5,6]

Given the proliferation of cigar use and its attendant grave health consequences, the FDA and other regulators would be more than justified in taking stronger steps to curb cigar use, such as banning flavors, restricting sales locations, or altering the chemical composition of the product to be less addictive. But before taking those measures, the FDA—following-long established precedent—took a less restrictive step: it mandated a warning. *See* 81 Fed. Reg. at 29061 (codified at 21 C.F.R. § 1143.5).[7] At a minimum, consumers should know the risks they are taking, especially in light of well-documented misperceptions about the relative safety of smoking cigars.

But the cigar industry associations want to take this option effectively off the table. Though they agree that the warnings are truthful, they assert (at 38) that a basic black box warning label that is large enough to "draw the eye" of a consumer

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[5] Campaign for Tobacco Free Kids, Fact Sheet: The Rise of Cigars and Cigar-Smoking Harms, *available at* https://perma.cc/FW4L-487M.

[6] The harms and proliferation of cigar use (including misperceptions about its safety) is detailed in the amicus brief of the Campaign for Tobacco Free Kids, et al. PHLC agrees with that brief and does not repeat that information here.

[7] Final Rule, Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,973 et seq. (May 10, 2016).

is unconstitutional. To be effective, however, a warning must be large enough to be noticed and comprehended. As such, the industry's arguments contradict both law and science. *First*, courts nationwide have recognized that (as long as they are truthful) warning labels are a *less* intrusive means of regulation that, because they *enhance* consumer information, are likely to pass First Amendment scrutiny. *Second*, scientific consensus among researchers of warning labels establishes the efficacy of such labels in communicating health risks, particularly when, as here, they are large enough to be noticed and comprehended by consumers. The implications of the industry's arguments to the contrary threaten not only cigar warnings, but other public health warnings attempting to effectively communicate the health risks of consumer products.

ARGUMENT

I. Courts nationwide have recognized that warning labels are a less intrusive form of regulation that survive First Amendment scrutiny.

It is not just regulators that have favored warning labels because they provide a less intrusive public health intervention. When it comes to the First Amendment, courts too have favored mandated health warnings on products and advertisements over speech restrictions, such as a bans or restrictions on media advertising, branded packaging, or product displays.

First, mandated health labels do not prevent or restrict a corporation from conveying any particular message on its packaging or advertisements. And, thus, they "trench much more narrowly on an advertiser's interests than do flat prohibitions on speech." *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985). Indeed, the Supreme Court so prefers warnings and disclaimers above speech restrictions that in striking laws in other contexts it has "suggested that the remedy in the first instance" should not be "a prohibition [on advertising,] but preferably a requirement of disclaimers or explanation." *In re R. M. J.*, 455 U.S. 191, 203 (1982) (citing *Bates v. State Bar of Arizona*, 433 U.S. 350, 375 (1977)).

So too with the warning labels here. For example, unlike the plain packaging requirements adopted in other countries, warning labels do not prevent a cigar manufacturer from advertising its brand or product on the product package.[8] The inclusion of a label does not prevent the manufacturer from highlighting the distinctive qualities of the product—even those that target and attract youth, such as flavors—or from giving its product a "cool" name, like a "Da Bomb Blueberry" cigarillo. That is, with warning labels, the FDA "'has not attempted to prevent [cigar

[8] "Plain packaging" is the policy requiring the "removal of brand imagery on packages," including logos and trademarks. *See* U.S. Department of Health and Human Services, Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General, 532 (2012), *available at* https://perma.cc/YQ4W-RVM2.

makers] from conveying information to the public.'" *Consol. Cigar Corp. v. Reilly*, 218 F.3d 30, 55 (1st Cir. 2000), *aff'd in part and rev'd on other grounds sub nom. Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001). Accordingly, the "First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed." *Zauderer*, 471 U.S. at 651.

Second, mandating factual and accurate health warning labels actually *furthers* the purposes of the First Amendment commercial speech doctrine. The "extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides." *Id.* at 651 n. 14; *see also Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 563 (1980) ("The First Amendment's concern for commercial speech is based on the informational function of advertising."). Because "[p]rotection of the robust and free flow of accurate information is the principal First Amendment justification for protecting commercial speech, . . . requiring disclosure of truthful information promotes that goal." *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 114 (2d Cir. 2001); *see also 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 501 (1996) (plurality) (Whenever a law "requires the disclosure of beneficial consumer information, the purpose of its regulation is consistent with the reasons for according constitutional protection to commercial speech[.]").

The upshot: mandating accurate, factual, commercial information—as with these cigar warnings—"does not offend the core First Amendment values." *Sorrell*, 272 F.3d at 114. Instead, "[s]uch disclosure furthers . . . the First Amendment goal of the discovery of truth and contributes to the efficiency of the 'marketplace of ideas.'" *Id.* (citing Robert Post, *The Constitutional Status of Commercial Speech*, 48 U.C.L.A. L.Rev. 1, 28 (2000)). Thus, while the cigar industry tries to paint these cigar warnings as an affront to its First Amendment rights (at 20–38), the doctrine shows that it is really quite the opposite. These indisputably factual and accurate health warnings *further* the commercial-speech doctrine's foundation in consumers' interest in truthful information, and the industry has little constitutional interest in withholding information that could reasonably be considered beneficial to potential cigar purchasers.

That is why courts across the country routinely uphold mandated product warnings and disclosures, including those similar to the cigar warnings here. The Sixth Circuit, for example, upheld the requirement that 20% of the space on cigarette and smokeless tobacco advertisements be devoted to a health warning, and that 50% of cigarette packaging and 30% (as here) of smokeless tobacco packaging carry a health warning. *See Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 524, 530–31 (6th Cir. 2012). *See also, e.g.*, *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760

F.3d 18 (D.C. Cir. 2014); *Nat'l Restaurants Ass'n v. New York City Dep't of Health*, 49 N.Y.S. 3d 18 (N.Y. App. Div. Feb. 10. 2017).

And, despite the cigar industry's assertion (at 26 & n.7) that the law on health warnings recently changed in *NIFLA v. Beccera*, 138 S. Ct. 2361 (2018)—and that *NIFLA* invalidated all of these cases and modified *Zauderer* sub silencio—it has not. In *NIFLA*, the Court's direct response to the dissent's concern that the decision had heightened the scrutiny on health warnings was unequivocal: "we do not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products." *Id.* at 2376.

II. Scientific consensus demonstrates the efficacy of warning labels in communicating the health risks of dangerous products.

The scientific evidence demonstrates that the FDA's warnings on cigar packaging and advertisements satisfy the minimal First Amendment scrutiny applied to factual, accurate health warnings, as described above. But because these warnings are more than just "reasonably related" to the FDA's goal of advancing consumers understanding of the health risks associated with cigar use, *Zauderer*, 471 U.S. at 651, even if the Court were to apply more exacting scrutiny, the warnings should be still upheld. As a careful review of the scientific evidence demonstrates—and as confirmed by the FDA, the U.S. Surgeon General, and the National Academy of Sciences (formerly the Institute of Medicine)—warnings covering 20% of cigar advertisements and 30% of cigar packaging are an effective means of communicating

health risks to consumers. And they "directly advance" that important—and minimally-intrusive—goal of getting consumers to make informed choices. *Central Hudson*, 447 U.S. at 564.

A. In the context of tobacco products, it is well-established that health warnings improve consumer understanding of health risks.

Reviewing studies and data from researchers across the country, the scientific community has reached consensus that health warnings are an effective means of improving consumer understanding of the health consequences related to the use of tobacco products. After examining the breadth of empirical studies regarding health warnings, the U.S. Surgeon General concluded: ""health warnings on cigarette packages are a direct, cost-effective means of communicating information on health risks of smoking to consumers."[9] Likewise, the Institute of Medicine's seminal 2007 report on "Ending the Tobacco Problem" reported that "restrictions on package labeling are critical to reducing tobacco use and ensuring that smokers are adequately informed about the risks of smoking," and highlighted that "prominent health warnings on packages are among the most cost-effective forms of public health education available."[10] And, though the FDA cites to the U.S. Surgeon General and

[9] U.S. Surgeon General Report (2012), *supra* n. 8, at 715.

[10] Institute of Medicine, Ending the Tobacco Problem: A Blueprint for the Nation, National Academy of Sciences, C-9 (2007), *available at* https://perma.cc/N7ZM-7GH9.

Institute of Medicine in the Deeming Rule, it also conducted its own independent expert analysis of the studies of health warnings and came to the same conclusion: warnings "help consumers better understand and appreciate tobacco-related health risks" and "addictiveness risks." 79 Fed. Reg. at 23,164.[11] Specifically, exercising its expertise, the agency concluded that the mandated warnings "would help ensure that youth and young adults, who may be more susceptible to the addictiveness of nicotine, have a greater awareness of the dangers associated with these products before they might become addicted." *Id.*

That warnings are helpful in communicating health information follows common sense, particularly for package warnings. Warnings that are on the package of a box of cigarettes or on the wrapping of a $0.99 two-pack of berry-flavored cigarillos that a teen might buy are "delivered to tobacco users at the two most important times—when users are considering using or purchasing the tobacco product." 81 Fed. Reg. at 29064. Given the "frequency of exposure to users," the U.S. Surgeon General explained that "tobacco packages are an excellent medium for communicating health information."[12] Warnings on packages are "among the

[11] Proposed Rule, Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23141 et seq. (April 25, 2014).

[12] U.S. Surgeon General's Report (2012), *supra* n. 8, at 715.

most prominent sources of health information for smokers in many countries," as confirmed by the fact that smokers in Western countries report getting more information about the risks of smoking from packages than from any other source except television.[13] That makes sense; a smoker who goes through a pack a day is potentially exposed to the warnings more than 7,000 times per year.[14] And while people may smoke cigars at a lower rate (leading to less exposure to package warnings), recent trends in cigar use diverge sharply from the image of the occasional celebratory cigars that one may imagine. Rather, mini cigars are sold in packs of 20 just like cigarettes and used in a similar manner—and the rates of use are on the rise.[15] Though the cigar industry may not want cigar smokers to see so many warnings (at 7), placing warnings on cigar packages means that customers—including the increasing number of young people who are trending toward cigarillos and mini cigars—is an effective means for making sure cigar smokers understand the health consequences of their choices.

Lest there by any doubt, individual studies and meta-analyses that have researched the effects of health warnings in the tobacco context reinforce these conclusions. *See* 79 Fed. Reg. at 23164 ("Researchers have found that tobacco health

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[13] D. Hammond, et al., *Effectiveness of Cigarette Warning Labels In Informing Smokers About The Risks of Smoking: Findings from the International Tobacco Control (ITC) Four Country Survey*, Tobacco Control, 15 Suppl. III:iii19-iii25 (2006).

[14] U.S. Surgeon General's Report (2012), *supra* n. 8, at 715.

[15] *See* Brief of Amici Curiae Campaign for Tobacco Free Youth et al.

warnings on product packages and in advertisements can effectively provide this important health information to consumers."). These studies indicate that warning labels influence and increase awareness of the health risks associated with tobacco,[16] and discourage initiation in nonsmoking youth.[17]

Meta-analyses are an important scientific tool because they aggregate the results from a wide range of studies to paint a picture of the research conclusions overall. A prominent review of ninety-four separate studies on tobacco warnings concluded that "health warnings on packages are among the most direct and prominent means of communicating with smokers.[18] Specifically, the underlying studies demonstrated that "large text-based warnings are associated with increased perceptions of risk and health knowledge."[19] For example, "one-fifth of smokers in an EU-wide survey reported that health warnings have been effective in getting them to smoke less and in helping them try to quit."[20]

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[16] *See, e.g.*, S. Noar, et al., *The impact of strengthening cigarette pack warnings: Systematic review of longitudinal observational studies*, Social Science & Medicine, 118–129 (2016); D. Hammond, et al., *Text and Graphic Warnings on Cigarette Packages: Findings from the International Tobacco Control Four Country Study*, 32 Am. J. Preventive Medicine 202 (2007).

[17] C. Moodie, et al., *Adolescents' Response to Text-Only Tobacco Health Warnings: Results from the 2008 UK Youth Tobacco Policy Survey*, 20 European J. Pub. Health 463 (2010).

[18] D. Hammond, *Health Warning Messages on Tobacco Products: A Review*, 20 Tobacco Control 327 (2011).

[19] *Id.* at 329.

[20] *Id.*

Even though most of these studies focus on cigarettes and smokeless tobacco and not on cigars specifically, that is no basis for discarding these studies as important authority for the cigar warnings at issue. "[T]he fundamental similarities between cigarettes and smokeless tobacco and other tobacco products allow for the application of data regarding the effectiveness of cigarette and smokeless tobacco warnings to warnings for other tobacco products." 79 Fed. Reg. at 23,165. As the Supreme Court has explained, speech restrictions may be justified by reference to analogous circumstances, for example "'by reference to studies and anecdotes pertaining to different locales altogether.'" *Lorillard*, 533 U.S. at 555 (quoting *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 628 (1995)). The cigar industry fails to provide a basis for doubting that the studies regarding the efficacy of cigarette warnings are inapplicable to the efficacy of cigar warnings, especially given cigars carry many of the same characteristics and have been advertised and packaged in many ways similarly to cigarettes.

Besides, given the proliferation of cigar use, scientists are beginning to study the impact of warnings on cigars specifically. The results, consistent with the tobacco context generally, support the FDA's decision to require warnings on cigars. For instance, recent studies released after the Deeming Rule was finalized demonstrate that that 60% of adolescents found some of the exact same cigar warnings that are

mandated by the FDA to be believable[21] and 66.9% of adults said the those warning messages were very believable.[22] "Believability" is a critical measure of warning label impact, and warning believability is "associated with a decreased desire to smoke, increased feelings toward quitting, and heightened risk perceptions of [the product]." [23] Accordingly, this new evidence further demonstrates that cigar warnings—like tobacco warnings generally—are an important, albeit less restrictive, public health intervention.

B. The efficacy of a warning depends on the size and location of the label.

Of course, the efficacy of a health warning label depends on its size and location. For the communication of a health risk "to be effectively understood and appreciated, consumers must notice and pay attention to the warning." 79 Fed. Reg. at 23164. To achieve this goal, "the size, placement, and other design features of the warning" must be sufficient to bring the warning to consumers' attention. *Id.* That's a matter of common sense. A health warning that no consumer sees or notices, such as one that is too small or just blends in with the package or the advertisement, will not be read—and therefore cannot effectively convey the health risks of using the

[21] S. Kowitt et al., *Believability of Cigar Warning Labels Among Adolescents,* 60 J. Adolescent Health 299 (2017).

[22] K. Jarman et al., *Are Some of the Cigar Warnings Mandated in the U.S. More Believable Than Others?* 14 Int'l J. Environmental Research & Public Health 1370 (2017).

[23] *Id.*

product. As the cigar industry admits (at 22): "Of course, a larger disclosure would improve the communication of the Government's message."

This common sense conclusion is—again—confirmed by peer-reviewed, published, empirical research. "Numerous studies show that the likelihood that warnings are seen and noticed depends upon their size and position." 81 Fed. Reg. at 29063.[24] The meta-analysis described above concluded that, after consolidating the results of multiple scientific studies: "Youth and adults are more likely to recall larger warnings, rate larger warnings as having greater impact, and often equate the size of the warning with the magnitude of the risk."[25] For example, in studies in which Canadian youth were asked to rate the effectiveness of different health warnings, the largest warnings were most likely to be rated as effective.[26] These findings are consistent with research conducted among adults showing that smokers were more likely to recall larger warnings and often considered larger warnings to indicate graver risks.[27] Similarly, while the cigar industry finds these warnings

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[24] Citing, among others, Hammond (2011), *supra* n. 18; Hammond et al. (2007), *supra* n. 16; M. Bansal-Travers, et al., *The Impact of Cigarette Pack Design, Descriptors, and Warning Labels on Risk Perception in the U.S.*, 40 Am. J. Prev. Med. 674 (2011).

[25] Hammond (2011), *supra* n. 18 at 329.

[26] U.S. Surgeon General's Report (2012), *supra* n. 8 at 716.

[27] *Id.* (citing AGB Spectrum Research, *Testing the Positions of Health Warnings on Cigarette Packages*, Health Promotion Programme, Department of Health, New Zealand (1987); Cragg, Ross & Dawson Ltd., *Health Warnings on Cigarette and Tobacco Packs: Report on Research to Inform European Standardization* (1990); Centre for Behavioural Research in Cancer, *Health Warnings and Contents Labelling on Tobacco Products: Review, Research and Recommendations*, Carlton South, Australia (1992); Action

"glaring" (at 17), research demonstrates that using exactly this format is most effective. Using a box or perimeter around the outside of the message has been found to increase the salience and recall of warnings.[28] And contrasting colors, "such as black lettering on a white background, are the easiest to read and increase comprehension."[29]

Despite all this research, the cigar industry contends that there is insufficient evidence to support the FDA's expert determination that cigar warnings should cover 20% of advertisements and 30% of cigar packaging. Br. of Appellants at 26–37. Not only is its view of the evidentiary standard too exacting (and impracticable), but they also ignore how the existing evidence directly supports the FDA's warnings. Specifically, there is research supporting that the existing size of most tobacco warnings are too small, and that a warning covering 30% of the packaging—as with the cigar warnings here—would be effective in communicating the health risks of cigar use. Together those scientific conclusions provide the requisite evidence to sustain any plausible standard of review this Court could impose.

As an initial matter, studies to date demonstrate that the existing tobacco warnings in the United States are just too small. Based on these studies, in 2012 the

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on Smoking and Health, *Tobacco Product Warnings: A Survey of Effectiveness*, London (1998); E. Strahan, et al., *Enhancing the effectiveness of tobacco package warning labels: a social psychological perspective*, 11 Tobacco Control 183 (2002)).

[28] Hammond (2011), *supra* n.18 at 329.

[29] *Id.*

Surgeon General concluded that existing warnings were "given little attention or consideration by viewers."[30] And the Institute of Medicine's analysis showed that those warnings "fail to convey relevant information in an effective way."[31] For example, several studies focused on youth indicated that the existing text warnings in the United States are rarely noticed and suffer from low recall among youth. Several of these studies even used eye-tracking equipment to examine attention paid to U.S. tobacco ads and recall of these warnings.[32] One study of adolescents found that "more than 40 percent of subjects did not even view the warning. An additional 20 percent looked at the warning but failed to actually read it."[33] No wonder that the Institute of Medicine concluded that the warnings are "not prominent"; that "evidence regarding the ineffectiveness of the prescribed warnings has continued to accumulate"; and that "the basic problems with the U.S. warnings are that they are unnoticed and stale, and they fail to convey relevant information in an effective way."[34] The unavoidable conclusion is that small-text warnings just do not work.

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[30] U.S. Surgeon General's Report (2012), *supra* n. 8 at 168.

[31] Institute of Medicine (2007), *supra* n. 10 at 291.

[32] U.S. Surgeon General's Report (2012), *supra* n. 8 at 715 (citing Fischer, et al., *Recall and eye tracking study of adolescents viewing tobacco advertisements*, 26 JAMA 84 (1989) and Krugman et al., *Do adolescents attend to warnings in cigarette advertising: an eye-tracking approach*, 34 J. Advertising Research 39 (1994)).

[33] *Id.*

[34] Institute of Medicine (2007), *supra* n. 10 at 290–91.

So what does work to communicate the harms of tobacco use? Scientific analyses demonstrate that covering 30% of the primary panels of the package would be more effective. *See* 79 Fed. Reg. at 23,165 (studies demonstrate that similar format requirements "have been shown to increase the effectiveness of health warnings").[35] Some of the most powerful studies in this respect are analysis that compare the impact of warnings in European countries before and after the European Union increased the size of its warning on tobacco products. For example, in the United Kingdom, tobacco warning labels used to be small, as in the United States, but were enhanced in 2003 to 30% of the front and back of the packaging to meet the minimum standard of the World Health Organization's Framework Convention on Tobacco Control. One study of this change found that smokers in the United Kingdom indicated that their awareness of the warnings increased along with thoughts about the health risks of smoking once the size of the warning increased to 30%.[36] Another study found that, after the enhanced warnings were implemented, smokers were more likely to think about quitting, to think about the health risks of

[35] *See, e.g.*, F. Portillo and F. Antoñanzas, *Information Disclosure and Smoking Risk Perceptions: Potential Short-Term Impact on Spanish Students of the New European Union Directive on Tobacco Products*, 12 European J. Pub. Health 295 (2002); Hammond (2006), *supra* n. 13; Fischer (1989), *supra* n. 32; Krugman (1994), *supra* n. 32; R. Brubaker and S. Mitby, *Health Risk Warning Labels on Smokeless Tobacco Products: Are They Effective?*, 15 Addictive Behaviors 115 (1990); Les Etudes de Marché Créatec, *Health Warning Messages on Smokeless Tobacco, Cigars, and Pipe Products: A Qualitative Study With Consumers: Report Prepared for Health Canada*, H4097–02–5029 (2003).

[36] *See* Fischer (1989), *supra* n. 32.

smoking, and to be deterred from having a cigarette compared to smokers in Australia and the United States where smaller warnings did not conform to the international minimum standards.[37] The same was true of studies in other European countries that increased the size of their warnings to approximately the size of the FDA's cigar warnings here.[38]

In another study, the investigators compared the effectiveness of U.S. and Canadian health warnings in 1995 among a sample of young people. At the time, Canadian packages carried one of eight black-and-white text warnings on the front and back of packages, covering 25% of the display area on the package. Students were shown a package for one minute and then asked to recall everything they could about it. The most notable finding was that 83% of Canadian students mentioned the health warning on Canadian packs, a larger percentage than those who could recall the brand name. On the other hand, health warnings on U.S. packs were recalled by only 6% of the U.S. students.[39]

The sufficiency of this evidence for supporting tobacco warning labels of the exact same size has already withstood circuit court scrutiny. In *Discount Tobacco,* the

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[37] *See* Hammond (2007), *supra* n. 16.

[38] *See* Portillo (2002), *supra* n. 35; Hammond (2006), *supra* n. 13; U.S. Surgeon General's Report, *supra* n. 9 at 715 (citing Y. Teeboom, *Warning Texts on Cigarette Packs*, Dutch Institute for Public Opinion & Market Research (2002)).

[39] U.S. Surgeon General's Report (2012), *supra* n. 8 at 715 (citing studies).

Sixth Circuit considered and rejected the same First Amendment arguments against the size required for smokeless tobacco warnings. *Discount Tobacco,* 674 F.3d at 567. Based in part on many of the same studies detailed above, a decade ago Congress changed the warning labels on smokeless tobacco products to 20% of advertisements and 30% of the principal panels of the packaging—the *same* requirements the FDA has imposed on cigars. Upon challenge from the tobacco industry, the Sixth Circuit unanimously concluded that the size of the warnings for smokeless tobacco products was constitutional. If anything, the evidence has only mounted since then, and this Court should likewise hold that the cigar warnings are constitutional.

C. A single, out-of-context, experimental study does not rebut the scientific consensus.

In the face of all of these studies, and analysis by the FDA, the Institute of Medicine, and the U.S. Surgeon General, what evidence does the cigar industry offer to counter? A *single* amicus brief, based on a *single* article, which focuses largely on a *single* experimental study that has nothing to do with tobacco products. In his amicus brief (at 9), Professor J. Scott Armstrong contends that "compelled disclaimers are ineffective and frequently harmful." But it is his conclusions that are flawed and, by his own terms, inapplicable to the tobacco-related context here.

Professor Armstrong first argues that compelled disclaimers are unnecessary and even harmful because, according to "economic theory," sellers will already disclose any "useful information about their products and services to consumers,"

because they want their customers to be "satisfied" and to maintain their "reputation." Armstrong Br. at 10. According to Armstrong, because the government lacks these market-based "incentives" to make disclosures that are "effective and easy to understand," government disclaimers are "less useful," "poorly calibrated," and "can cause harm." *Id.* at 10–11.

Whatever the merits of this argument generally, they unravel in the context of the tobacco industry. Given the well-documented history of deception and widespread lying to the general public about the harms of tobacco use, can Armstrong really contend that tobacco warnings should left to those "voluntarily provided by sellers"? *Id.* at 11; *see generally United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006) (describing history of deception by tobacco industry). What incentive do tobacco executives have to tell customers that their product will kill them? As for cigars more specifically, despite their well-known carcinogenic effects, manufacturers did not place warnings on their products until 2000 to resolve a lawsuit by the Federal Trade Commission. *See* District Court Op. at 5. Nor does Armstrong's argument make sense in a context where consumer decision-making is influenced by the addictiveness of the product.

Professor Armstrong's analysis fares no better when he discusses the empirical research behind compelled disclaimers. As an initial matter, he overlooks all the above-cited studies and claims that that there is "no evidence" that this type of

compelled speech "generally provides benefits to consumers." Armstrong Br. at 9. That alone calls into question the scientific merit of his analysis.

Next, he bases his analysis primarily on an experimental study that has no bearing on the health warnings here. *Id.* at 11–12. In his brief, he describes at length an experiment he conducted at a mall based on Florida's requirement that a dentist advertising an advanced credential from the American Academy of Implant Dentistry must include a disclaimer that "implant dentistry" is not a recognized specialty and that the organization is not recognized as an accrediting organization in Florida. Meanwhile, other non-credentialed dentists could practice implant dentistry without such a disclaimer. One need not even conduct a study to recognize that such a scheme would be confusing; it is no surprise that consumers thought that those with credentials who must give a warning involving all sorts of generally unfamiliar organizations were less qualified that those who did not have to give a disclaimer before providing the same service.

But that cherry-picked example of a confusing government disclosure scheme has no bearing on the health warnings in the tobacco context here. A label stating "WARNING: Cigar smoking can cause lunch cancer and heart disease" has none of the hallmarks of Armstrong's dental experiment. Indeed, not even the cigar industry claims that the warnings are confusing; it brings no challenge at all to the label's content. *See* District Court Op. at 29. And Armstrong's article, as its title implies, is

about mandatory disclaimers, not health warning labels, like the ones at issue here.[40] The article itself even distinguishes between the two, noting, for example, that a health "warning was effective in changing perceptions in the intended direction, but the mandated disclaimer was not."[41] *See also* Appellee Br. at 46–47. In short, whatever merit Armstrong's argument may have, by its own terms it is inapplicable here.

III. An adverse decision would cast doubt on other important public health warnings.

Adopting the cigar industry's attack on warning labels in this case could have far reaching implications for the ability of public health officials to employ health and safety warnings in the tobacco context and beyond. For the industry (at 41), the evidence is not sufficient unless the Government can prove that the precise format of the warning is the "least restrictive means." That is an impossible standard, as there are simply not always existing studies that give such nuanced conclusions. For instance, cohort studies of the kind cited above in European countries can only be conducted on the warning labels adopted by different countries (or other jurisdictions). Yet the industry demands a study to evaluate every possible scenario

[40] Green & Armstrong, *Evidence of the Effects of Mandatory Disclaimers in Advertising*, 31 J. Pub. Pol'y & Marketing 293 (2012).

[41] *Id.* at 298.

to find the least restrictive means. Of course, that is not the law. *See* Appellees' Br. at 46.

If the empirical evidence garnered by the FDA in its rulemaking, and elaborated upon by amicus in this brief, is insufficient to withstand First Amendment scrutiny, it would cast doubt on other longstanding health warnings and disclosures. The effect would not only be that consumers would be less informed about the health consequences of various products, but also that regulators would be effectively precluded from employing this less-restrictive public health tool and may turn to other effective and justified (albeit more intrusive) means, like limiting a product's sale or requiring a change in the product's ingredients.

Consider the wide range of health warnings and other disclosures that could be implicated. In the tobacco context, Congress has required that cigarettes carry warning labels covering 50% of the principal panels of the packaging and 20% of advertisements. And the warnings for smokeless tobacco products must carry the exact same size warnings as cigars. If the evidentiary standard for withstanding First Amendment scrutiny is so high that the cigar warnings cannot survive, then what of these other important tobacco warnings that Congress mandated to fight all the disease and destruction caused by tobacco use? And that's just for tobacco.

The cigar industry's argument, if adopted, would require searching scrutiny and impracticable evidentiary burdens of all compelled commercial speech,

including warning labels aimed at protecting public health and safety and other "routine disclosure[s] of economically significant information designed to forward ordinary regulatory purposes." *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 316 (1st Cir. 2005). Prescription drug warnings on television advertisements can take twenty seconds or longer, *see* 21 C.F.R. § 202.1(e), and other warnings on alcoholic beverages, over-the-counter drugs, and hazardous chemicals would be subject to heightened evidentiary scrutiny. It would also call into doubt a host of other compelled disclosures meant to protect investors, workers, and consumers. As Judge Boudin commented: "There are literally thousands of similar regulations on the books—such as product labeling laws, environmental spill reporting, accident reports by common carriers, [and] SEC reporting as to corporate losses." *Rowe*, 429 R.3d at 316. And if the wealth of evidence supporting the cigar warnings is insufficient, then what of all these other warnings and disclosures? The cigar industry's argument has "wide-ranging implications" for these and other "long-established programs," *Sorrell*, 272 F.3d at 116.

The widespread implications of the cigar industry's argument demonstrate its folly. "The idea that these thousands of routine regulations" that compel speech "require an extensive First Amendment analysis is mistaken." *Rowe*, 429 F.3d at 316.

CONCLUSION

For these reasons, amicus curiae respectfully requests that the Court affirm the district court's decision.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that my word processing program, Microsoft Word, counted 6413 words in the foregoing brief, exclusive of the portions excluded by Rule 32(g)(1).

/s/ Rachel Bloomekatz
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CERTIFICATE OF SERVICE

I hereby certify that on May 6, 2019, I electronically filed the foregoing brief with the Clerk of the Court for the U.S. Court of Appeals for the District of Columbia Circuit by using the CM/ECF system. All participants are registered CM/ECF users and will be served by the appellate CM/ECF system.

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