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**Re: Request for Comment on Implementation of the Family Smoking Prevention and Tobacco Control Act: Advance Notice Of Proposed Rulemaking On Outdoor Advertising Restrictions, Docket No. FDA-2010-N-0136; RIN 0910-AG33**

These comments are respectfully submitted by Lorillard Tobacco Company (Lorillard) in response to FDA's Advance Notice of Proposed Rulemaking (ANPRM) regarding potential limitations on outdoor advertising for tobacco products. 75 Fed. Reg. at 13241.

In a final rule published on March 19, 2010, the FDA repromulgated the agency's Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (referred to hereafter as the "Final Rule"), which were originally promulgated in 1996. Following Congress's directive in the Family Smoking Prevention and Tobacco Control Act (FSPTCA), FDA reserved the section of the Final Rule that relates to outdoor advertising. Instead, in a separate ANPRM, the agency stated that it was considering a regulation that would (1) prohibit or otherwise limit billboards located within 1,000 feet of any elementary or secondary school (k-12) and (2) prohibit or otherwise limit large signs or collections of advertisements greater than 14 square feet at retail establishments located in close proximity to any elementary or secondary school (e.g., within 350 feet or approximately

one city block). 75 Fed. Reg. at 13241. The ANPRM requested comments on a wide array of issues, including whether the restrictions under consideration, “or close variations,” would be “justified, lawful, and appropriate.” The ANPRM also asks whether FDA should consider requiring stores that sell tobacco products to post graphic anti-tobacco messages in order to counter the effects of advertisements on children. 75 Fed. Reg. 13242.

### **INTRODUCTION**

Lorillard strongly supports the goal of reducing the rate of youth smoking and tobacco use. Towards that goal, Lorillard has supported initiatives to prevent tobacco use among minors and to reduce their ability to obtain such products. These programs have contributed to the positive trend in the declining rates of youth and adult smoking and tobacco use. Use of tobacco by minors is currently at an all-time low according to numerous studies.

At the same time, cigarettes and smokeless tobacco products remain legal products used by adult consumers. These adult consumers have a constitutionally protected right to receive truthful and accurate information about tobacco products. Companies that manufacture tobacco products have a corresponding right to communicate truthful information to adult consumers. Therefore, any restrictions on the speech rights of tobacco companies imposed by FDA must comply with the constitutional protections accorded to commercial speech. *See Lorillard v. Reilly*, 533 U.S. 525 (2001).

Under the commercial speech doctrine, FDA bears the burden of demonstrating that any restriction on speech will directly advance an important government interest and that the restraint is carefully calculated to restrict no more speech than is necessary to advance the government’s interest. Critically, FDA must make these showings against the reality of the marketplace today -- not historical practices that existed when FDA initially promulgated its

regulation in 1996. The reality is that the world of tobacco advertising is dramatically different from the world of 1995 and 1996. Billboards advertising cigarettes have all but disappeared, and for the companies that control over 90 percent of the market share for cigarettes, billboards have disappeared completely. Cartoons and similar imagery are gone. Spending on outdoor advertising is a fraction of what it once was. Simply put, the justifications advanced by FDA in 1995 and 1996 cannot serve as the basis for restrictions on outdoor advertising today. Whereas FDA once characterized tobacco advertising as pervasive and inescapable, the same cannot be reasonably said of today's world.

Lorillard and the other major tobacco companies are all signatories to the 1998 Master Settlement Agreement (MSA), which includes significant limitations on outdoor advertising for cigarettes. FDA's proposal is consistent with the MSA. However, this does not mean that the restrictions the MSA signatories have voluntarily agreed to would be constitutionally defensible if promulgated by FDA. Moreover, if FDA sought to go beyond the MSA to promulgate even greater restrictions on speech (*e.g.*, restrictions on smaller signs or restrictions on point of sale (POS) materials), the rights of adult consumers, tobacco manufacturers, and retailers would certainly be infringed.

## DISCUSSION

### **I. The Changed Landscape for Outdoor Advertising of Tobacco Products**

Since the FDA rulemaking in 1996, the scope and nature of tobacco product advertising have changed dramatically. Tobacco companies' use of traditional advertising tools, including the use of billboards and other outdoor advertising, has declined precipitously and is no longer pervasive. During this same time, efforts to promote existing youth smoking

prevention programs and access limitations have achieved dramatic success, resulting in a significant decline in youth smoking rates, which have reached record low levels.

**A. The Historical Background Cited in FDA's 1996 Final Rule**

FDA's 1996 Final Rule proposed significant limitations on "outdoor advertising."<sup>1</sup> When FDA issued its Notice of Proposed Rulemaking in 1995, FDA reported at the time that tobacco products were "among the most heavily advertised [products] . . . in the United States," with the industry spending \$6.2 billion on advertising, promotion, and marketing in 1993, including \$1.9 billion on advertising and promotional activities alone. 60 Fed. Reg. at 41315. In 1995, the tobacco industry invested \$740 million or 12 percent of its marketing dollars in advertising in print and billboards.<sup>2</sup> FDA reported that "[t]obacco brand names, logos, and advertising messages [were] pervasive, appearing on billboards, on buses and trains, in magazines and newspapers, and on clothing and other goods." 60 Fed. Reg. at 41315.

FDA asserted a connection between industry advertising and youth awareness of tobacco products. FDA cited a 1994 report issued by the Surgeon General that concluded the industry relied on advertising, including outdoor advertising billboards, to increase brand

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<sup>1</sup> While the rule addressed "outdoor advertising" generally, it is evident that the agency's focus was on billboards specifically. For example, a subheading in the 1996 rule described the section covering outdoor advertising prohibitions as simply "Billboards." 61 Fed. Reg. at 44397.

<sup>2</sup> National Cancer Institute, *The Role of Media in Preventing and Reducing Tobacco Use*, Tobacco Control Monograph 19 at 119 (NIH Pub. 07-6242. June 2008) (hereinafter "Monograph 19"). Although this figure is for "measured media," which Monograph 19 defines to include print and billboards, as well as radio and television advertisements, tobacco companies have not advertised using radio or television since 1971, when Congress passed a statute prohibiting cigarette advertising through those mediums. See 15 U.S.C. § 1335.

familiarity among youth.<sup>3</sup> According to the report, the messages in tobacco advertising were image-driven and frequently used “human models or human-life cartoon characters to display images of youthful activities, independence, healthfulness, and adventure-seeking.” *Id.* One report concluded that billboards advertising tobacco products at the time were “highly visible, difficult to ignore, and a leading source of tobacco advertising exposure among youth.”

Monograph 19, at 158. As support for its final rule, FDA cited an *Advertising Age* study that found 46 percent of children aged 8 to 13 years old most often saw cigarette advertising on billboards and 34 percent of children 14 to 18 years old considered billboards the “predominant” advertising medium for tobacco products. 61 Fed Reg. at 44505 (citing Levin, G., *Poll Shows Camel Ads are Effective with Kids; Preteens Best Recognize Brand* at 12, *Advertising Age* (April 27, 1992)). FDA further relied on billboard industry marketing materials to emphasize their effectiveness as a marketing device. *Id.*

**B. The Master Settlement Agreement and Changes to Advertising and Promotion**

The advertising landscape in which FDA proposed its 1996 Final Rule changed dramatically over the next fifteen years. The types of advertising that the 1996 Final Rule sought to restrict -- such as large billboards visible from highways or placed in stadiums, and cigarette advertisements on buses and trains -- are virtually nonexistent. Today, for nearly all cigarette manufacturers, outdoor advertising for tobacco products is limited to signs no greater than 14 square feet in and around retail outlets. Even this limited outdoor advertising is not widespread, as less than half of all retail outlets display outdoor advertising. This dramatic reduction is due

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<sup>3</sup> U.S. Department of Health and Human Services, *Preventing Tobacco Use Among Young People, A Report of the Surgeon General* (July 1994).

largely to the 1998 MSA among the four largest tobacco companies, including Lorillard, and 46 states.<sup>4</sup> The agreement includes several mandates governing advertising and promotional activities:

- The MSA wholly eliminates cigarette transit and billboard advertising. MSA, Ch. III, § D.<sup>5</sup>
- The MSA limits advertising placed outdoors or on the inside surfaces of windows facing outward to only retail establishments provided signs or placards are no larger than 14 square feet. MSA, Ch. III, § D; Ch. II, § (ii).
- The MSA bans cigarette advertising, promotions, or marketing targeted at young people. *Id.* at § A.
- The MSA forbids cartoons in advertising, promotions, packaging, and labeling of cigarettes. *Id.* at § B.
- The MSA places additional prohibitions or limitations on sponsorships, product placement, samples, and certain forms of brand marketing for cigarettes. *Id.* at §§ C, E-G.

Since the MSA went into effect, Lorillard has responsibly worked with the States' Attorneys General to honor both the letter and spirit of the agreement. As part of the agreement, Lorillard developed corporate principles that emphasize its commitment to the MSA and to the reduction of youth smoking. *See Lorillard Corporate Principles.*<sup>6</sup> Based in part on implementation of the MSA but also on a host of other factors, the reality of tobacco advertising and promotional activities in today's world differs dramatically from the world in which FDA proposed the 1996 rule. For the MSA participating manufacturers:

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<sup>4</sup> While a small number of other tobacco companies are not similarly bound by the provisions of the MSA, participating manufacturers to the MSA account for more than 90 percent of the market share for cigarettes.

<sup>5</sup> The MSA is available at <<http://www.naag.org/backpages/naag/tobacco/msa/msa-pdf>> (last viewed July 14, 2010).

<sup>6</sup> Available at <<http://www.lorillard.com/index.php?id=29>> (last viewed July 14, 2010).

- Outdoor advertising is limited to signs no greater than 14 square feet at retail.
- Billboards and transit advertisements have disappeared from the advertising landscape.
- There are no television, radio, or newspaper advertisements for tobacco products.<sup>7</sup>
- There are no cartoon characters or similar images.
- There is no branded clothing or other branded continuity advertising.
- Event sponsorship is limited to one sponsorship in a twelve-month period, if any.

In fact, outdoor advertising has declined to the point of representing a statistically insignificant portion of marketing and promotional efforts for tobacco products. Monograph 19 references the over \$13 billion spent by the industry on advertising and promotional expenditures in 2005. Monograph 19, at 119. This figure is not relevant to the issue of outdoor advertising. Price discounts and promotional allowances to cigarette retailers or wholesalers accounted for \$9.78 billion or 74.6 percent of the reported \$13 billion spent on advertising and promotional expenditures in 2005. *See* Federal Trade Commission, Cigarette Report for 2006 (2009). In contrast, advertising in measured media categories represented only 1.7 percent of the total reported budget in 2005. *Id.* For the types of advertising that children could potentially see -- outdoor and point of sale advertising -- the industry spent only \$192 million in 2005. Only \$9.8 million of that total was spent on outdoor advertising (defined as billboards; signs and placards in arenas, stadiums, and shopping malls; and any other advertisement placed outdoors, including those on cigarette retailer property), which is close to 0 percent of those \$13 billion marketing dollars. *Id.* This total of \$9.8 million spent on outdoor advertising in 2005 for the *entire*

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<sup>7</sup> As noted above, *see* note 3 *supra*, tobacco companies have not advertised using radio or television since 1971. *See* 15 U.S.C. § 1335.

*industry* is down from a high of \$386.1 million in 1991, which is a pronounced reduction even excluding the 2005 inflation adjusted value of the 1991 figure. *Id.* This reality is far removed from the history of 1995, when billboards, and signs in arenas, stadiums, and shopping malls were widely used.

**C. Restrictions on Youth Access to Cigarettes**

In addition to these changes in advertising practices, restrictions on youth access to cigarettes since 1996 have been significantly strengthened. The industry has worked with Congress and retail establishments to enforce common-sense solutions to preventing tobacco use among youths. In 1992, Congress enacted the Synar Amendment as part of the Substance Abuse and Mental Health Services Administration, which required states to (1) enact and enforce laws prohibiting tobacco sales to youth and achieve a retail violation rate of less than 20 percent by 2003 or (2) risk losing 40 percent of federal block grant funding. Pub. L. No. 102-321 § 1926. Before the Synar Amendment, retailer violations in many states ranged from 60 to 90 percent. *See* U.S. Dep't of Health and Human Services, FFY 2006 Annual Synar Reports, Youth Tobacco Sales. In 2009, the national average for retailer violations was 10.9 percent; and every state in the nation was in compliance with the Synar requirements. *See* U.S. Dep't of Health and Human Services, FFY 2009 Annual Synar Reports, Youth Tobacco Sales. As a result of the Synar Amendment and other initiatives, the rates of tobacco use among both youth and adults have drastically declined since 1996, and the smoking rate among 12th grade students is the lowest on record, in fact showing a decline of 49.5 percent from 1996 to 2009.<sup>8</sup>

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<sup>8</sup> *See, e.g.*, University of Michigan, Institute for Social Research, "Monitoring the Future" (finding that cigarette smoking rates among American teens in 2008 are at the lowest levels since (continued...))

Monograph 19 observed that high school students' cigarette brand preferences "correlated with the brands most heavily advertised in the convenience stores within a one-mile radius of their schools." *See* 75 Fed. Reg. 13242 (citing Monograph 19). But Monograph 19 fails to properly consider two important points. First, retailers are prohibited by law from selling cigarettes to youth. Since 1995, when youth smoking rates were at unacceptable levels, initiatives by manufacturers, retailers, and state and federal government to eliminate youth tobacco sales through retailer training have been enormously successful. *See* U.S. Dep't of Health and Human Services, FFY 2006 Annual Synar Reports, Youth Tobacco Sales (all 50 states reporting compliance in not selling cigarettes to youth).

Second, the most heavily advertised brands are also the brands that are most often purchased by adult smokers. Therefore, youth access to cigarettes is not primarily through retail sales; rather, youth access to cigarettes comes from other sources, such as family and friends. Monograph 19 cannot therefore reliably demonstrate a causal connection between advertising and youth smoking.

**D. Family Smoking Prevention and Tobacco Control Act**

In addition to the changes brought on by the MSA, the recently enacted Family Smoking Prevention and Tobacco Control Act (FSPTCA) has and will require additional changes to the advertising and promotion of tobacco products.<sup>9</sup> Most importantly, the FSPTCA will require advertisements to contain the same warning statements as required for packaging (at

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at least as far back as the early 1990s and the smoking rate among 12th grade students today is the lowest it has been since the study started measuring youth tobacco use 33 years ago).

<sup>9</sup> Family Smoking Prevention and Tobacco Control Act, Pub. Law No. 111-31 (2009).

least 20 percent of total ad space) and new, explicit warnings in colored graphics and rotating statements in bold type on packaging depicting the negative health consequences of smoking. *Id.*

## **II. Constitutional Protections for Commercial Speech**

Advertising for tobacco products is commercial speech entitled to protection under the First Amendment, and requiring retailers to post graphic anti-tobacco messages is content-based compelled speech subject to strict scrutiny. Therefore, any steps that FDA takes to discourage or prohibit such advertising must be scrutinized for consistency with constitutional principles.

### **A. The *Central Hudson* Balancing Test As Applied in *Reilly***

Restrictions on commercial speech are evaluated under the four-part test announced in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). First, the government may prohibit commercial speech if it demonstrates that the speech is inherently false or misleading or proposes an unlawful transaction. *Id.* at 566; *see also Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 142 (1994). If commercial speech does not fall within the first prong of *Central Hudson*, then a government restriction of that speech must satisfy the second, third, and fourth prongs to pass constitutional muster.

The second prong requires the government to establish that it has a “substantial” interest in restricting the speech. *Cent. Hudson*, 447 U.S. at 566. Third, the government must establish that its restriction “advances the Government’s interest ‘in a direct and material way.’” *Fla. Bar v. Went for It, Inc.*, 515 U.S. 618, 626 (1995) (quoting *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995)). The government may not satisfy this burden with “mere speculation and conjecture.” *Coors Brewing Co.*, 415 U.S. at 487 (quoting *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993)). Instead, it “must demonstrate that the harms it recites are real and that its

[regulation] will in fact alleviate them to a material degree.” *Ibanez*, 512 U.S. at 143 (citing *Edenfield*, 507 U.S. at 770). Fourth, the government must demonstrate that the governmental restriction is no more extensive than necessary to achieve the governmental interest. *Cent. Hudson*, 447 U.S. at 566.

In *Reilly*, the Court applied its commercial speech doctrine specifically to outdoor advertising for tobacco products. In that case, the Court struck down a Massachusetts law that prohibited, among other things, “outdoor advertising . . . in any location that is within a 1,000 foot radius of any public playground, playground area in a public park, elementary school, or secondary school.” *Id.* at 535. Specifically, the Court held that the “broad sweep” of the regulation “did not ‘carefully calculat[e]’ the costs and benefits associated with the burden on speech imposed” by the regulations. 533 U.S. at 561 (quoting *Cincinnati Discovery Network, Inc.*, 507 U.S. 410, 417 (1993)). The Court noted that when combined with other generally applicable zoning laws, the advertising ban’s 1,000 foot restriction prohibited advertising in 87 to 91 percent of Boston, Worcester, and Springfield, Massachusetts. *Id.* at 561-62. The Court concluded that “[i]n some geographical areas, these regulations would constitute nearly a complete ban on the communication of truthful information . . . to adult consumers.” *Id.* at 562. Specifically, the Court noted that the Attorney General did not consider the impact of the 1,000 foot restriction on commercial speech in major metropolitan areas. *Id.* at 562. The Court reasoned that “[t]he impact of a restriction on speech will undoubtedly vary from place to place,” and that a uniformly broad speech restriction “demonstrates a lack of tailoring.” *Id.* The Court also noted that “a ban on all signs of any size seems ill suited to target the problem of highly visible billboards, as opposed to smaller signs.” *Id.*

The Court emphasized that “tobacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products.” *Id.* at 564. The Court concluded that “a speech regulation cannot unduly impinge on the speaker’s ability to propose a commercial transaction and the adult listener’s opportunity to obtain information about products.” *Id.* at 565. The calculations regarding the outdoor advertising regulations were insufficient for purposes of the First Amendment. *Id.* at 565-66.

**B. FDA’s Burden**

FDA bears the burden of justifying any outdoor tobacco advertising restrictions. In doing so, FDA must take into account both First Amendment principles and the reality of tobacco advertising today. Lorillard has voluntarily agreed to not advertise using billboards and to limit all outdoor advertisements to no more than 14 square feet, and FDA’s proposal to ban billboards within 1,000 feet of schools, and to ban signs larger than 14 square feet within 350 feet of schools would therefore be consistent with the MSA. Even so, were FDA to promulgate regulations imposing such restrictions, it would have to justify them as constitutional restrictions on speech. Moreover, if FDA sought to impose even more draconian limitations, such as restrictions on outdoor signs or collections smaller than 14 square feet or restrictions on point of sale material, such restrictions would raise significant constitutional concerns and almost certainly not survive a legal challenge.

**1. FDA Must Demonstrate That Limiting Outdoor Advertising Would Directly Advance The Government’s Interest In Reducing Youth Smoking and Tobacco Use.**

Under the third prong of *Central Hudson*, FDA bears the burden of demonstrating that outdoor advertising restrictions advance the public health goal of protecting minors from the

harms caused by tobacco use “in a direct and material way.” *Edenfield*, 507 U.S. at 767; *Central Hudson*, 447 U.S. at 564. “[M]ere speculation and conjecture” will not suffice. *Edenfield*, 507 U.S. at 770. Nor will a justification that “provides only the most limited incremental support for the interest asserted.” *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 73 (1983). To meet this burden, FDA must demonstrate by reliable scientific evidence that outdoor advertising actually does impact tobacco use among youth and that limiting outdoor advertising would reduce the rate of youth tobacco use.

The ANPRM cites Monograph 19 for its conclusion that there is “a causal relationship between tobacco advertising and promotion and increased tobacco use.” 75 Fed. Reg. 13242. However, Monograph 19 engages in a historical review of tobacco advertising, and after evaluating tobacco marketing in all forms over the course of decades, it claims simply that “the evidence base indicates a causal relationship between tobacco advertising and increased levels of tobacco initiation and continued consumption.” Monograph 19, at 211. This generalized assessment could not satisfy FDA’s burden of proving specifically that the proposed restrictions *on outdoor advertising* would directly advance the government’s interest *in reducing tobacco use by minors* in a direct and material way. Additionally, Monograph 19 acknowledges that outdoor advertising as it exists today is vastly different than it was when FDA promulgated the 1996 rule, noting that tobacco companies currently spend “almost no[]” money on advertising through television, radio, newspapers, magazines, and billboards. Monograph 19, at 14. The conclusions in the monograph therefore do not even purport to show that imposing restrictions on outdoor advertising would have any material impact on underage tobacco use.

FDA must also consider and assess the scientific data indicating that outdoor advertising has limited or even no impact on youth tobacco use. At least two meta-studies of the

effects of tobacco advertising have demonstrated that advertising does not have a significant effect on cigarette consumption. One meta-study concludes that “[m]ost US studies of cigarette demand report small and insignificant advertising elasticities, which refutes the view that advertising has an important spillover effect on aggregate demand and smoking behaviors.” Jon P. Nelson, *Cigarette Advertising Regulation: A Meta-Analysis*, *Int’l Rev. of L. & Econ.* 195, 217 (2006).

Another meta-study that analyzed all previous research on the correlation between advertising bans and demand for cigarettes concludes that “cigarette advertising bans do not have a significant effect on cigarette consumption” and that “advertising restrictions do not . . . appear to be salient in a consumer’s decision to smoke cigarettes.” Michael L. Capella et al., *The Effect of Cigarette Advertising Bans on Consumption: A Meta-Analysis* 37 *J. of Advertising* 7, 13 (2008). This study observed that its results were consistent with product life cycle (PLC) predictions regarding the general effectiveness of advertising. *Id.* Early in the PLC, particularly when a product is being introduced into the market, the focus of advertising is to build demand for a product. *Id.* at 8. As the product moves through the PLC and competitors enter the market, the emphasis shifts to building selective demand for individual brands. *Id.* The study notes “[i]t is clear that cigarettes have reached the mature stage, and possibly even the decline stage of the PLC,” and that advertising in mature markets “ha[s] a relatively minor impact on product category sales.” *Id.* In other words, advertising for a product that has reached the mature stage of the PLC, like cigarettes, does very little to increase the number of people who use tobacco products; instead, it simply causes people to choose one brand of cigarettes over another.

FDA must assess all of this data against the reality of today’s outdoor advertising, which is significantly reduced in scope and primarily announces the availability of products,

rather than “image” advertising that is highlighted throughout Monograph 19. FDA must also consider the need for outdoor advertising restrictions in light of the other legal requirements that are in place (or will soon be in place) as a result of the FSPTCA, such as: (1) the requirement that advertisements contain the same warning statements as required for packaging (at least 20% of total advertising space); (2) the restriction on advertising to black text on white background only; and (3) the mandate of new, explicit warnings in colored graphics on packaging depicting the negative health consequences of smoking. Pub. L. No. 111-31 § 201. To withstand a constitutional challenge, FDA must be able to demonstrate that these requirements have a substantial effect on the rate of youth tobacco use, otherwise they are a meaningless infringement upon manufacturers’ advertising space.<sup>10</sup> Assuming these requirements have some effect on the rate of youth tobacco use, any outdoor advertising restrictions must take this into account. *See Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 372 (2002) (concluding that to achieve government’s goal of preventing large-scale drug compounding, “it might . . . be sufficient to rely on the non-speech-related provisions of the [federal statute],” and government had burden to show that non-speech provisions would be insufficient to accomplish government’s goal).

Even if “the record suggests that [an] advertising ban may have some impact,” that is legally insufficient in the absence of “evidence to suggest that [the] speech prohibition will *significantly* reduce [the relevant target group’s] marketwide consumption.” *44 Liquormart*, 517 U.S. at 506 (striking down Rhode Island law prohibiting the advertising of alcohol prices,

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<sup>10</sup> FDA is defending challenges to many of these restrictions in a case pending the Western District of Kentucky. *See Commonwealth Brands, Inc. v. United States*, No. 1:09-cv-0117-M (W.D. Ky.) FDA should therefore assess the necessity of an outdoor advertising ban under the assumption that it will prevail in the *Commonwealth* litigation.

noting that “the abusive drinker will probably not be deterred by a marginal price increase, and . . . the true alcoholic may simply reduce his purchases of other necessities”); *Rubin*, 514 U.S. at 487 (striking down federal statute prohibiting display of alcohol content on beer labels because speech restriction did not significantly advance the government’s interest in health, safety, and welfare of its citizens).

**2. FDA Must Demonstrate That The Chosen Limitations On Outdoor Advertising Are No More Extensive Than Necessary To Advance The Government’s Interests.**

*Central Hudson* also places the burden on the government to establish that any restrictions it places on outdoor advertising are no more extensive than necessary to advance the government’s interest in preventing youth tobacco use. 447 U.S. at 418.

Given the Supreme Court’s observations in *Reilly* that “[t]he impact of a restriction on speech will undoubtedly vary from place to place” and that FDA’s 1996 final rule “would have had widely disparate effects nationwide,” *id.* at 562, a blanket nationwide ban on advertising based on distance from schools that does not reflect the disparate effects the ban would have in urban, suburban, and rural areas would not be narrowly tailored. The Court in *Reilly* said as much, noting that a uniformly broad speech restriction “demonstrates lack of tailoring” and “do[es] not demonstrate a careful calculation of the speech interests involved.” *Id.* Thus, before publishing any proposed rule, FDA must demonstrate by rigorous evidence that the restriction does not unduly burden speech in metropolitan areas.<sup>11</sup>

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<sup>11</sup> During the *Reilly* litigation, the industry commissioned studies regarding the impact of the Massachusetts limitations, which demonstrated that the state’s restrictions would have significantly impacted the ability of adult consumers to obtain information about tobacco products in major metropolitan areas. *Reilly*, Nos. 00-596 & 00-597, J.A. 165-167; *see Reilly*, 533 U.S. at 561. Similarly, in 1995, the industry commissioned studies on the impact of FDA’s (continued...)

The Supreme Court also recognized in *Reilly* that “a speech restriction cannot unduly impinge on the speaker’s ability to propose a commercial transaction and the adult listener’s opportunity to obtain information about products.” 533 U.S. 565. The Court has repeatedly emphasized this essential right to freedom of speech that underlies the Court’s commercial speech doctrine. See *Reno v. Am. Civil Liberties Union*, 521 U.S. 844, 875 (1997) (“[T]he governmental interest in protecting children from harmful materials . . . does not justify an unnecessarily broad suppression of speech addressed to adults.”); *Bolger*, 463 U.S. at 74 (invalidating federal statute prohibiting unsolicited mailed advertisements for contraceptives, noting that “[t]he level of discourse reaching a mailbox simply cannot be limited to that which would be suitable for a sandbox.”); *Butler v. Michigan*, 352 U.S. 380, 383 (1957) (“The incidence of this enactment is to reduce the adult population . . . to reading only what is fit for children.”). Tobacco product manufacturers, distributors, and retailers have a right to advertise their lawful products to adult consumers in a truthful and non-misleading manner. *Reilly*, 533 U.S. at 564. FDA cannot impose outdoor advertising restrictions that significantly restrict the ability of industry to communicate with adult consumers.

**C. FDA’s Proposal To Require Stores To Display Graphic Anti-Tobacco Messages Would Not Survive Strict Scrutiny.**

The notice of proposed rulemaking also asks whether FDA should consider requiring stores that sell tobacco products to post graphic anti-tobacco messages in order to counter the effects of advertisements on children. 75 Fed. Reg. 13242. This requirement would

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proposal on major metropolitan areas. That analysis -- even if limited to only 1,000 foot buffers around schools (and not including parks/playgrounds) -- demonstrated that FDA’s proposed rule created a near-blackout in major metropolitan areas, similar to the impact of the Massachusetts rule that was found to be unconstitutional.

also be subject to First Amendment scrutiny, because the First Amendment protects the right not to speak just as it protects the right to speak. *See Wooley v. Maynard*, 430 U.S. 705, 714 (1977). By forcing retailers to post graphic anti-tobacco messages, FDA would be regulating the content of the retailers' speech. *See Riley v. Nat'l Federation of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988). Content-based speech regulations are subject to strict scrutiny and are presumptively invalid, unless they come within a narrowly crafted exception for certain compelled disclosures. *See Zauderer*, 471 U.S. at 651.<sup>12</sup>

The Court has carved from strict scrutiny the compelled disclosure of "purely factual and uncontroversial information" so long as it is "reasonably related to the State's interest in preventing deception of consumers" and is not "unjustified or unduly burdensome." *Id.* at 561 (upholding compelled disclosure in attorney advertisements of "purely factual and uncontroversial information about the terms under which his services will be available"); *see also Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S.Ct. 1324, 1340 (2010) (upholding compelled disclosure that a law firm functioned as a debt relief agency because disclosure was "intended to combat the problem of inherently misleading commercial advertisements" and "entail[ed] only an accurate statement identifying the advertiser's legal status and the character of the assistance provided"). However, the Court has consistently rejected government attempts to force private speakers to carry government advocacy on the government's terms. *See Wooley*, 430 U.S. at 714 (holding that New Hampshire could not require residents to display state motto "Live Free or Let Die" on license plates); *Pac. Gas & Elec. Co. v. Pub. Util. Comm'n of Cal.*,

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<sup>12</sup> These graphic anti-tobacco messages would not be commercial speech, because they do not "propose a commercial transaction." *Bd. of Trs. of SUNY v. Fox*, 492 U.S. 469, 473-74 (1989).

475 U.S. 1, 15 (1986) (holding that California could not require utility company to include newsletter in monthly billing statements that contained message with which company disagreed); *see also Entertainment Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006) (striking down Illinois law that required retailers to post signs near video games warning customers that games contained sexually explicit content).

The ANPRM refers to “graphic anti-tobacco messages,” 75 Fed. Reg. 13242, which are not the type of “purely factual and uncontroversial information” that the Supreme Court has exempted from strict scrutiny. Moreover, unlike in *Zauderer* and *Milavetz*, there is nothing misleading about the sale of cigarettes. Cigarette advertising and packages display factual, uncontroversial federal warnings that the Supreme Court has held are “sufficient to achieve [Congress’s] purpose of informing the public of the health consequences of smoking.” *Altria Group, Inc. v. Good*, 129 S.Ct. 538, 544 (2008).

Under strict scrutiny, FDA’s proposed graphic anti-tobacco messages “must be narrowly tailored to serve a compelling government interest.” *Pleasant Grove City v. Summum*, 129 S.Ct. 1125, 1132 (2009). If FDA could achieve its goal through a non-speech alternative, then it must do so. *See Playboy Entertainment Group*, 529 U.S. at 813. Regardless of FDA’s asserted interest here, requiring retailers to display graphic anti-tobacco messages would not survive strict scrutiny because, numerous alternatives are available to the government that do not compel speech, including improving enforcement of laws restricting sales to minors, and the creation or funding of smoking prevention and cessation campaigns.

### CONCLUSION

In justifying any restriction on truthful and accurate commercial speech, FDA will bear a heavy burden. Manufacturers of tobacco products have a right to communicate with adult

consumers, and adult consumers have a right to obtain information about tobacco products. FDA's initial proposal as described in the ANPRM is consistent with the restrictions to which Lorillard voluntarily agreed in the MSA. However, to impose these or further restrictions as government-mandated limitations on speech, FDA would have to justify any restrictions as consistent with the First Amendment. Accordingly, FDA must be prepared to demonstrate that any proposed limitation on outdoor advertising is carefully calculated to restrict no more speech than is necessary, directly advances the government's interest in reducing youth smoking, and preserves the ability of adult consumers to receive information about tobacco products.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Michael Shannon', is written over the word 'Sincerely,'. The signature is stylized and somewhat illegible due to the cursive style.

Michael Shannon