



July 19, 2010

Food and Drug Administration Division of Dockets Management (HFA-305) 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Re: Docket No. FDA-2010-N-0136. RIN No. 0910-AG33.

To Whom It May Concern:

The American Cancer Society, American Heart Association, American Legacy Foundation, American Lung Association and the Campaign for Tobacco-Free Kids hereby respond to FDA's Advance Notice of Proposed Rulemaking (ANPRM) seeking comment on implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). Specifically the agency has sought comment on the proper scope of restrictions on outdoor tobacco product advertising in light of the Family Smoking Prevention and Tobacco Control Act and governing First Amendment case law – specifically, the Supreme Court's decision in *Lorillard Tobacco Corp. v. Reilly*, 533 U.S. 525 (2001).

The FDA has done a good job over the last year in implementing many provisions of the Tobacco Control Act and deserves to be commended. However, we have concerns about its proposal concerning outdoor tobacco product advertising. Our comments make several major points:

- 1) Congress intended for the FDA to have in place a Final Rule that included the Outdoor Advertising provisions ready to go into effect on June 22, 2010 either in its original form or as modified by the FDA. Therefore, the FDA's decision to initiate a rulemaking proceeding governing outdoor advertising only after it has issued a Final Rule (Tobacco Control Act rule) governing the other portions of the 1996 Rule with no process for implementing the provisions on outdoor advertising by June 22, 2010 is contrary to the language and intent of the Tobacco Control Act. FDA's decision to unilaterally extend the time for comment to a date beyond June 22, 2010 compounds the problem. FDA was not free to ignore its statutory mandate.
- 2) Congress's mandate to FDA was specific: re-issue the 1996 Rule as it relates to outdoor advertising to "include such modifications ...if any, that the Secretary determines are appropriate in light of governing First Amendment law, including the decision of the Supreme Court of the United States in *Lorillard v. Reilly* (533 U.S. 525(2001)". The scope of FDA's ANPRM is inconsistent with that mandate and its proposed modifications go well beyond any changes arguably required by the Supreme Court's decision in *Lorillard*.

¹ 75 Federal Register 13241, March 19, 2010. The Tobacco Control Act is Public Law 111-31, 123 Stat. 1776, June 22, 2009.

- 3) The scientific evidence supporting the need for further restrictions on tobacco marketing is, if anything, stronger today than in 1996, as found by the U.S. Congress, the Institute of Medicine, the President's Cancer Panel, the National Cancer Institute, and the federal courts.
- 4) The proposed modifications by the FDA will neither protect, nor promote the public health because the proposed restrictions would do no more than what is already required of Participating Manufacturers by the terms of the Master Settlement Agreement. Therefore, such modifications would not produce any meaningful change to existing efforts to reduce tobacco use and its harms.
- I. FDA's Decision Not to Issue a Final Rule Implementing the Advertising Provisions of the 1996 Rule by June 22, 2010 Violates the Tobacco Control Act.

Section 102 of the Tobacco Control Act requires the FDA to reissue as a *final* rule the 1996 Rule 180 days after the date of enactment (i.e., on June 22, 2010), subject *only* to the qualification that such rule "shall . . . include such modifications to section 897.30(b), if any, that the Secretary determines are appropriate in light of governing First Amendment law, including the decision of the Supreme Court of the United States in *Lorillard Tobacco Co. v. Reilly* (533 U.S. 525 (2001))" 123 Stat. at 1831. Congress clearly intended the FDA to determine prior to June 22, 2010 what modifications, if any, were required by First Amendment law and to make effective a final rule on that date. Instead, the rule FDA issued on June 22, 2010 contained no provision restricting the outdoor advertising of tobacco products pending the receipt of public comments regarding such modifications. The result is that, contrary to the requirements of the law, and for an indeterminate period of time after June 22, 2010, *no* regulation restricting the outdoor advertising of tobacco products will be in place.

The provisions of the Tobacco Act give FDA a great deal of flexibility in many respects, however, the law is quite clear on this point – the FDA was to issue a final rule, including the outdoor advertising restrictions, by June 22, 2010.

- II. The Modifications to the 1996 Rule Proposed by the FDA Are Inconsistent with the Statutory Requirements and Fail to Protect the Legitimate Public Purpose of Reducing Youth Tobacco Use.
 - A. Congress Required that Any Modifications to the 1996 Rule Must be Limited to those Compelled by First Amendment Precedent. Given the Presumption in Favor of the Current Rule, Proponents of Any Changes Should Bear the Burden of Producing Information to Require the Change.

Section 897.30 of the 1996 Rule contained the following restrictions on outdoor advertising of tobacco products: "No outdoor advertising for cigarettes or smokeless tobacco, including billboards, posters, or placards, may be placed within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., a public park with equipment such as swings and seesaws, baseball diamonds, or basketball courts), elementary school, or secondary school." These regulations were based on an extensive administrative record.²

² Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, FDA Proposed Rule, 60 Federal Register 41314, 1995. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, FDA Final Rule, 61 Federal Register 44396, 1996.

In 1999 the Attorney General of Massachusetts promulgated a different set of regulations to limit the outdoor advertising of tobacco products in Massachusetts. These regulations were similar to but not identical to the 1996 FDA regulations and in significant respects were more restrictive than the 1996 FDA regulations. Moreover, they were not based on a separate administrative record that specifically addressed their effect in Massachusetts.³ Claims that the Massachusetts regulations were inconsistent with the requirements of the First Amendment were adjudicated by the Supreme Court in *Lorillard v. Reilly*.

In *Lorillard*, the Court applied the four-part test, first enunciated in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), for evaluating the validity of governmental restrictions on commercial speech to tobacco product advertising restrictions. The Court found that the Massachusetts regulations satisfied three of the four prongs of that test. The Court found that restricting outdoor tobacco product advertising was a legitimate means for the government to promote its substantial interest in reducing youth tobacco use. The Court also found that the Massachusetts' law would "directly and materially" advance the state's legitimate interest in reducing youth tobacco use. As the Court ruling stated, "limiting youth exposure to advertising will decrease underage use." As we note on page four, the evidence to support the Court's conclusions with regard to the second and third prong of the *Central Hudson* is even stronger today than it was when the FDA acted in 1996 or that was submitted to the Court. These findings inform any evaluation of what modifications, if any, are needed to section 897.30(b) to comply with current First Amendment precedent.

It was only the fourth prong of the *Central Hudson* test that led the Court to find that the Massachusetts ban violated the First Amendment. The Court found that under *Central Hudson*, the advertising restrictions in the Massachusetts law were more extensive than necessary to fulfill the government's legitimate interest in preventing and reducing youth tobacco use. The Court made it clear that it did not require regulations to be the minimum necessary to achieve the government's interest, but only that there be a "reasonable fit" between the scope of the regulations and their intended objective. Specifically, based on the record before it, the *Lorillard* Court decided 5-4 that the State's prohibition on outdoor advertising and outdoor facing ads near schools and playgrounds did not meet this criterion because the regulations failed to leave tobacco product manufacturers and retailers with adequate means to communicate truthful commercial information about the tobacco products to their legal adult customers because of evidence related to its impact in several densely populated areas.

The *Lorillard* Court noted that the Appellate Court had concluded that the advertising restrictions essentially "prohibited advertising in a substantial portion of the major metropolitan

³ See, e.g., *Lorillard*, 533 U.S. at 562-63. See, also, *Lorillard*, 533 U.S. at 601-603 [Dissent by Justice Stevens].

⁴ The tobacco product advertising restrictions at issue in *Lorillard* pertained to cigars and smokeless tobacco products, but the Court did not suggest that its First Amendment analysis of the restrictions would be any more or less valid in relation to cigarettes than to these other tobacco products.

⁵ *Lorillard*, 533 U.S. at 561.

⁶ Lorillard, 533 U.S. at 561-66.

areas of Massachusetts." The Court also noted that "[t]he substantial geographical reach [of the restrictions] is compounded by other factors. 'Outdoor' advertising includes not only advertising located outside an establishment, but also advertising inside a store that is visible from outside the store. . . and the term advertisement also includes oral statements." The Court concluded that these restrictions, taken together, violated the fourth prong of the *Central Hudson* test because "[i]n some geographical areas, these regulations would constitute nearly a complete ban on the communication of truthful information about [the tobacco products] to adult consumers."

When the Congress enacted the Tobacco Control Act in 2009 it re-examined section 897.30(b) of the 1996 Rule in the light of the Lorillard decision. Congress specifically found that the problems that section 897.30(b) was intended to solve in 1996 – specifically, underage use of cigarettes and smokeless tobacco, and tobacco advertising that impacts children and teenagers – still exist in 2009, and that the restrictions in the 1996 Rule were still necessary to address those problems and that these restrictions "directly and materially advance" the federal government's substantial interest in reducing youth tobacco use. 10 Congress further found in the Tobacco Act that the problem has in fact gotten worse, concluding that "[a]dvertising, marketing, and promotion of tobacco products . . . have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use." 11 Moreover, Congress has also found, again, that further restrictions on advertising are needed to solve the problem of underage tobacco use, concluding that "[c]omprehensive advertising restrictions will have a positive effect on the smoking rates of young people" and that "[r]estrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education about tobacco use."12

The evidence is stronger today than it was in 1996 to support a complete ban on any and all outdoor, or indoor, tobacco product advertising as the most effective way to stop such advertising from increasing youth and adult tobacco use and to support overall efforts to prevent initiation and reduce overall use and harms. ¹³ In particular, research since the FDA Final Rule was first implemented in 1996 has found that tobacco product advertising and marketing at retail outlets increased pre- and post-MSA, including increases in outdoor advertising, and a brandnew body of research has developed on the impact of tobacco product advertising and marketing

⁷ *Lorillard*, 533 U.S. at 562.

⁸ Lorillard, 533 U.S. at 562.

⁹ Lorillard, 533 U.S. at 562.

¹⁰ See, e.g., 123 Stat. at 1777-79, Findings 15-32 (noting the effect of tobacco advertising on young persons, the efforts made by the tobacco companies to attract young persons as customers through various forms of advertising, and the harms caused by tobacco use among young persons).

¹¹ Tobacco Control Act, Public Law 111-31, 123 Stat. at 1777-78, Finding 15, (emphasis added).

¹² Tobacco Control Act, Public Law 111-31, 123 Stat. at 1778, Findings 25, 26.

¹³ For more on the extensive new research and findings since 1996 and since the *Lorillard* case on the power of tobacco product advertising to increase youth initiation and use (as well as adult use), and the need to minimize youth exposure to tobacco product advertising to prevent and reduce youth initiation and use, see Appendix A.

specifically at retail outlets on increasing youth initiation and overall tobacco use. ¹⁴ On the basis of this evidence, Congress concluded that alternative approaches to preventing and reducing youth tobacco use have not and will not work quickly or effectively enough without new, more stringent restrictions on tobacco product advertising. ¹⁵

Accordingly, in section 102(a)(2)(E) Congress laid out a path for FDA's implementation of outdoor advertising provisions that the agency has not followed. First, Congress stated that section 897.30 is to be the starting point for consideration of outdoor advertising restrictions on tobacco products, to which "modifications" *might be* appropriate. Second, Congress provided that any deviation from the benchmark set by section 897.30 should be <u>limited</u> to changes that are "appropriate in light of" the prevailing First Amendment case law, and that would be justified on that basis. Third, Congress required that section 897.30 and any modifications there to be *included* in the final rule which under the Tobacco Control Act was required to be issued 180 days after the date of enactment.

FDA, however, did not follow Congress' mandate. Instead, it did not include any outdoor advertising provisions in the re-published Tobacco Act rule, initiated an entirely new rulemaking proceeding to determine a fresh "regulatory approach to outdoor advertising" in consideration of the *Lorillard* decision and other factors, and proposed a series of changes to the 1996 Rule that, as discussed further in Section III below, are neither required by the *Lorillard* decision nor contemplated by the Tobacco Act. ¹⁶ The amended proposed rule promulgated by FDA fails to recognize the differences between section 897.30 and the Massachusetts rules invalidated by *Lorillard*, fails to promote the government's legitimate interest in preventing underage tobacco use, and fails to adhere to the mandate of Congress to restrict outdoor advertising to the limit of its constitutional authority.

The issue for the FDA under the Tobacco Control Act is solely whether, in the light of the current record available to the FDA regarding the effects of advertising on youth tobacco use and Congress's findings in enacting the Tobacco Control Act, the restrictions in section 897.30 are "more extensive than necessary to protect the government's legitimate interest in preventing or reducing youth tobacco use" and, if so, what modifications need to be made to address those concerns.

The fact that the regulations at issue in Lorillard failed to meet the fourth prong of the *Central Hudson* test does not demonstrate that the less restrictive regulations contained in section 897.30 would fail to do so. The restrictions considered in *Lorillard* were more extensive than those contained in section 897.30 and the factual record supporting those restrictions was far more sparse. In light of these differences, FDA's presumption should be that the original rule should not be limited unless evidence is presented that its application would, as in *Lorillard*, result in a "nearly complete" ban on the communication of truthful information to consumers.

B. Lorillard Does Not Require Significant Changes in Section 897.30(b)

¹⁴ Appendix A provides citations to this new research as part of its broader referenced summary of all of the extensive new relevant research and findings since the 1996 Rule and the *Lorillard* case.

¹⁵ See, e.g., the previously referenced findings in the Tobacco Control Act.

¹⁶ 75 Federal Register at 13242.

The lesson of *Lorillard* is *not* that a 1,000-foot advertising restriction is inevitably unconstitutional, but rather that whether it is constitutional or not depends on evidence as to the geographic and demographic reach of the restrictions and, whether the tobacco manufacturers have alternate means available to them to communicate truthful non-deceptive information to adult consumers.

Although the Massachusetts law, the subsequent *Lorillard* decision, and the 1996 Rule all address the outdoor advertising of tobacco, there are several key differences between the advertising restrictions proposed by each that limit the applicability of the *Lorillard* decision to the 1996 Rule. First, two of the key Massachusetts provisions – the ban on indoor advertising directed outward of the retail establishment and the ban on oral statements – are not part of the 1996 Rule. Certain other restrictions contained in the Massachusetts rule are also not part of the 1996 Rule, such as a restriction on outdoor ads in enclosed stadiums.

Second, unlike Massachusetts, the FDA in promulgating the 1996 Rule also looked at the range of methods available to the tobacco industry to communicate truthful information to adult consumers and concluded that, taken as a whole, the Rule left adequate means available to the industry to do so.

Third, the *Lorillard* Court relied heavily on data showing that the 1,000-foot outdoor advertising restriction would substantially prohibit tobacco advertising in a large portion of Massachusetts' metropolitan areas, and concluded from the evidence that the effect of the restrictions were unconstitutionally broad. Implicit in the Court's analysis was that restrictions on tobacco advertising that analyzed and took into account the geographic breadth of the restrictions might not have presented the same problem. The Court took Massachusetts to task for adopting the 1,000-foot restriction from the 1996 Rule without considering the consequences of that rule in the specific geographical context of Massachusetts.

While the court in *Lorillard* expressed concern that the State ban on outdoor ads within 1,000 feet of schools and playgrounds – in combination with a ban on indoor advertising visible from outside and a ban on oral communication would effectively constitute a total ban on all outdoor advertising in some urban locations with many schools and playgrounds, the FDA has cited no evidence that such would be true if Section 897.30(b) was implemented.

New factual evidence shows that a 1,000-foot outdoor advertising restriction would not prevent all outdoor advertising of tobacco products. For example, a recent analysis of the situation in New York City has found that a ban on outdoor ads within 1,000 feet of schools or playgrounds would still leave more than half of the geographic area of the city available for outdoor advertising. Similarly, a study of the situation in both New York City and St. Louis by University of North Carolina researcher Kurt Ribisl, Washington University researcher Douglas Luke and others has found that a 1,000 foot ban in those urban areas would not reach all retailers but would leave many retailers unaffected in those two cities. Looking at all urban areas in

¹⁷ This data has been submitted to FDA in comments provided in response to the ANPRM by the New York City Department of Health and Mental Hygiene, dated June 3, 2010.

¹⁸ We have been informed that this data and related analysis will be submitted to FDA in comments provided by Mr. Ribisl and/or the other authors of this study. See, also, Luke, D, Ribisl, K, et al., "Impact upon retailers of banning outdoor tobacco advertising near schools and

New York State and in Missouri, the study found that more than a third and more than 60 percent of all retailers, respectively, would not be reached by section 897.30(b). This information shows that there is no need to reduce the 1,000 foot distance in section 897.30(b) to enable cigarette and smokeless tobacco product sellers to engage in significant amounts of outdoor advertising even in heavily or densely populated cities, and that if a decision were made to shorten the distance the change need not be substantial.

The FDA also failed to note that the 1,000-foot restriction would not pose similar problems in rural areas – where the distances between schools/playgrounds are greater than they are in cities, and therefore the amount of land freed from the restriction would be generally greater, percentage-wise and in absolute terms, than in cities.

The provision of the Massachusetts regulation banning indoor advertising visible from outside was an important consideration in the Court's decision. Citing the regulation's ban on indoor advertising visible from outside, the Court reasoned that "a retailer in Massachusetts may have no means of communicating to passersby on the street that it sells tobacco products because alternative forms of advertisement, like newspapers, do not allow that retailer to propose an instant transaction in the way that onsite advertising does." By contrast, Section 897.30(b) would enable retailers to reach these passersby through indoor ads that were visible from outside, such as ads on the inside of store windows facing out.

If FDA determines that, under First Amendment case law, the more limited regulations contained in section 897.30 still do not leave some retailers near schools and playgrounds with adequate means to reach passersby who are legal potential customers, section 897.30(b) could be amended to provide for some limited, narrow exceptions to enable retailers to inform consumers that cigarettes and smokeless tobacco products are sold at the outlet, providing the names of specific brands and, possibly, their prices, if FDA determined it necessary to comply with the First Amendment

C. The Changes Proposed by FDA in its ANPRM go Well Beyond the *Lorillard* Test Without Factual Justification.

In its ANPRM, FDA proposed a series of changes to the 1996 Rule. There is nothing in the current Agency record to support a determination that these specific changes or changes of this magnitude are required to comply with *Lorillard*. Even if some changes are ultimately determined to be appropriate, many of the current proposals go beyond what is necessary to comply with *Lorillard*.

The changes under consideration at FDA would amend the 1996 Rule as follows: Instead of banning all outdoor advertising within 1,000 feet of schools and playgrounds, FDA would:

1) limit the 1,000-foot rule to apply to billboards only;

playgrounds under the Family Smoking Prevention and Tobacco Control Act," unpublished paper; and Cohen, D & Ribisl, K, letter to FDA, Docket No. FDA-2010-N-0020, CTP 200910, February 18, 2010.

¹⁹ *Lorillard*, 533 U.S. at 565.

- 2) apply a new 350-foot restriction to "large signs or collections of advertisements greater than 14 square feet at retail establishments";
- 3) consider whether the restrictions should take the form of "limits" on, rather than outright prohibitions of, the advertising; and
- 4) apply the distance limits only to advertising near schools, not near playgrounds.

These regulations fail to provide adequate protection against advertising that contributes to youth tobacco use. First, the proposed amended rule would not result in any decrease in outdoor advertising for manufacturers who are parties to the Master Settlement Agreement because the Section III(d) of the MSA already prohibits billboards and outdoor signs of the size identified in the proposed rule. Parties to the MSA account for the vast majority of cigarette advertising and about 95 percent of cigarette sales in the United States. Banning billboard advertising for the remainder of the industry would have little positive impact. The futility of the proposal is legally significant because both Congress and the courts have found that the problem of marketing that impacts youth has not been solved by the Master Settlement Agreement. When Congress instructed FDA to re-enact the 1996 Rule, including section 897.30 (b), it did not intend its action to be a nullity.

Second, by eliminating the restriction on advertising near playgrounds without regard to the impact of that restriction on the ability of tobacco manufacturers to communicate to adult customers, FDA would allow tobacco product advertising signs of any size in areas close to where youth congregate.

Third, by reducing the distance restriction for non-billboard tobacco signage near schools – again, without regard to the specific impact of the original restriction – FDA would allow such signage to be placed along the path of young elementary and secondary schoolchildren, and the signage could possibly even be visible to those children as they sit in school. There is no basis in the administrative record for such a change.

Fourth, these modifications are unnecessary given that the 1996 Rule allowed retailers to display signs in their windows facing outward and did not ban oral advertising. As a result, under that rule, retailers and manufacturers could inform consumers that cigarettes and smokeless tobacco products are available for sale at that location, promote certain brands, and inform consumers of price and discount promotions.

If FDA is to consider modification to section 897.30(b), such modifications should:

²⁰ See, e.g., Tobacco Control Act, 123 Stat.. at 1781, Findings 47-48; *U.S. V. Philip Morris USA, Inc., et al.*, No. 99-CV-02496GK (U.S. Dist. Ct., D.C.), Final Opinion, August 17, 2006, http://www.tobaccofreekids.org/reports/doj/FinalOpinion.pdf, at pages 1607-1608. In addition, research shows that outdoor advertising at retail outlets has increased since the MSA went into effect. See, e.g., Celebucki CC & Diskin K., "A Longitudinal Study of Externally Visible Cigarette Advertising on Retail Storefronts in Massachusetts Before and After the Master Settlement Agreement," *Tobacco Control* 11 Suppl 2:ii47-53, June, 2002. Wakefield MA, et al., "Tobacco Industry Marketing at Point of Purchase After the 1998 MSA Billboard Advertising Ban," *American Journal of Public Health* 92:937–40, 2002.

- 1) Be limited to those changes necessary to comply with the fourth prong of the Central Hudson test;
- 2) Limit any exceptions to geographic locations where a tobacco manufacturer/retailer can demonstrate that the restrictions in section 897.30(b) would prevent it from effectively communicating the availability of tobacco products to potential adult customers; or alternatively, reduce the 1000 foot limitation nationally in heavily populated areas without exempting parks where youth play and without permitting outdoor signs at retail outlets near schools;
- 3) Limit outdoor advertising to what is necessary for a retailer to be able to communicate to those passing their retail outlet that they sell cigarettes, the brands that they sell and price or discount information, taking into account that under the 1996 Rule retailers may display ads on the inside of their windows facing outward; and
- 4) Adopt a procedure for putting the outdoor advertising restrictions in place within three months, rather than only after the drawn out process proposed by the FDA's ANPRM.

Accordingly, we urge FDA to move quickly to implement a final rule that follows the intent of Congress and the mandate of the Tobacco Control Act to establish the strongest possible restrictions on outdoor cigarette and smokeless tobacco product advertising near schools and playgrounds that are consistent with governing First Amendment law.

Sincerely,

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President

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Network

Nancy Brown

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APPENDIX A

<u>Tobacco Product Advertising Increases Youth Experimentation and Initiation, Impulse Purchases, and Overall Tobacco Use and All Its Attendant Harms and Costs</u>

There is compelling evidence that tobacco industry marketing and advertising increases tobacco use initiation among youths and young adults, increases overall consumption, is misleading and reduces cessation among youth and adult users. This evidence has grown significantly beyond that cited by the FDA in support of its 1996 Tobacco Rule. Numerous studies have demonstrated that exposure to tobacco marketing impacts potential new users, the majority of whom are young people, to try tobacco and become long-term addicted customers. While there are many important new sources, the conclusions of the National Cancer Institute (NCI) Monograph that summarized the evidence on tobacco use and tobacco marketing merit particular attention. The comprehensive report, released by NCI in 2008, found that "the evidence base indicates a causal relationship between tobacco advertising and increased levels of tobacco initiation and continued consumption" and that even brief exposure to tobacco advertising influences adolescents' attitudes and perceptions about smoking as well as their intentions to smoke.

This 2008 report adds to findings from an earlier NCI report from 2001 which concluded that "the conclusion that there is a causal relationship between tobacco marketing and smoking initiation seems unassailable." Additional findings regarding the relationship between tobacco marketing and smoking initiation include:

- A meta-analysis published in the December 2006 issue of *Archives of Pediatrics and Adolescent Medicine* found that exposure to tobacco product marketing more than doubles the odds that children under 18 will initiate tobacco use. The researchers also found that protobacco marketing and media depictions lead children who already smoke to smoke more heavily, increasing the odds of progression to heavier use by 42 percent.⁵
- A 2002 study in the *Archives of Pediatric and Adolescent Medicine* found that receptivity to tobacco advertising had a significant impact on each step of the progression from non-smoking to established regular smoking. The biggest impact was on influencing non-susceptible youth to becoming susceptible to smoking.⁶
- A longitudinal study of teenagers in the *Journal of the American Medical Association* showed that tobacco industry promotional activities influenced previously non-susceptible non-smokers to become susceptible to or experiment with smoking.⁷

While the tobacco industry claims that it does not market to children, many of the colors, images and themes used in tobacco advertisements and promotional materials appeal to youth. In 1994, the Institute of Medicine (IOM) concluded that images used in tobacco product advertising and promotion convey the message that tobacco use is desirable and create positive feelings towards smoking. Tobacco marketing often includes young, physically active, and attractive models which conveys the misleading idea that tobacco use is safe, healthful and a widely accepted and practiced behavior and falsely associates tobacco use with youth, energy, and sex appeal. These

themes and images resonate with youth and can satisfy adolescents' need to be popular, feel attractive, take risks and avoid or manage stress. As a result, according to the IOM, "tobacco advertising and promotion undoubtedly contribute to the multiple and convergent psychosocial influences that lead children and youths to begin using these products and to become addicted to them." ¹⁰

Recently, a study published in the *Journal of Preventive Medicine* – after summarizing some of the extensive research on a dose-response between cigarette advertising exposure and higher risk of smoking among youth – not only confirmed that dose-response impact but also found that "the association between tobacco advertising and youth smoking is specific to tobacco advertising content and not simply a marker of an adolescent who is generally receptive to marketing." This study not only supports the conclusion that youth exposure to tobacco product advertising must be minimized to protect youth and reduce their risk of becoming addicted smokers, but also shows that reducing the non-informational content (such as brand imagery) in those tobacco product ads that are still permitted would also help to protect youth against increased smoking risk.

In addition to increasing youth smoking initiation, research shows that the amount of advertising actually impacts tobacco consumption. While the tobacco industry has argued that the primary purpose of its advertising is to maintain brand loyalty and keep current consumers from switching to another tobacco product, data show that there is a positive correlation between the amount of advertising and overall tobacco consumption. Tobacco company internal documents also indicates that their advertising does more than just influence brand loyalty and brand switching. In addition, research shows that brand switching by itself justifies only a small percentage of a cigarette company's advertising and promotion expenditures.

Tobacco marketing also maintains and increases tobacco use among current tobacco users by providing smoking cues for current smokers. Studies show smokers of all ages have an increased desire to smoke when presented with smoking-related images, such as someone smoking or a cigarette pack, or other items associated with smoking. Studies have also found that tobacco advertisements may reduce current smokers' willingness to quit and provoke former smokers to resume their habit.

One way that tobacco product advertising increases overall use is by misleading consumers to believe that tobacco products are safer than they really are. For example, a study published in *Nicotine and Tobacco Research* found that smokers who viewed separate ads for "light" cigarettes and for regular cigarettes believed that the "light" cigarettes were less risky and that the "light" cigarette ads conveyed positive messages about health and safety – even though the ads did not make any explicit claims about health or safety or reduced risk and despite the fact that "light" cigarettes are no safer than regular cigarettes. Moreover, the smokers viewing the ads thought that the health claims they perceived in the "light" cigarette ads must have been approved by the government. While the new FDA tobacco law prohibits the use of misleading terms such as light, low or mild in cigarette and smokeless tobacco product packages and advertising, new research shows that other kinds of words, such as silver, can also mislead many smokers into thinking a particular brand is safer or less risky, as can brands sold with lighter colors or with pictures of filters. More broadly: "A dense environment of cigarette promotion

and imagery gives the impression that tobacco use is socially acceptable, desirable, and prevalent," which also increases initiation and overall use.²⁰

The evidence clearly demonstrates that exposure to the type of images that the tobacco industry's marketing continues to project is associated with a greater likelihood of smoking initiation and increased tobacco consumption. The limitations on advertising in publications with significant teen readership as well as outdoor and point-of-sale advertising, except in adult-only facilities, to black-text on white background is a reasonable and necessary approach that promotes the government's interest in reducing tobacco use based upon the available evidence. The IOM specifically endorsed the black-and-white, text only approach in its 2007 report.²¹

The Power of Tobacco Product Advertising and Imagery at Retail Outlets

Specific types of tobacco industry marketing, such as advertising and promotion in the retail environment, tobacco brand sponsorships, and tobacco promotional items, increase tobacco use initiation and overall tobacco consumption. It is clear that the tobacco industry recognizes the importance of influencing consumers at the moment of purchase by the amount spent on product packaging and marketing in the retail environment. In recent years, tobacco companies have significantly stepped up their marketing efforts in the retail environment, or point-of-purchase. Point-of-purchase tobacco advertising consists of cigarette and smokeless tobacco ads located inside, outside, and on the property of convenience stores, drug stores, gas stations, and other retail sales outlets. The tobacco companies significantly increased their point-of-sale advertising after the state tobacco settlements' ban on tobacco billboards went into effect in April 1999.²² In 2006 (the latest year for which data are available), the cigarette companies spent over \$242 million on point-of-sale advertising, a 33.1 percent increase from 2005. In 2006, smokeless tobacco companies spent over \$20.8 million on this type of advertising.²³

Several studies have documented the increasing pervasiveness of tobacco promotion in retail outlets. For example, in one survey, nearly eighty percent of retail outlets had interior tobacco product advertising, nearly 60 percent had exterior tobacco product advertising, and 70 percent had tobacco product functional items, such as display racks, counter mats, entrance and exit signs, and change cups; and forty percent of retailers that also sell gas had tobacco product advertising in the driveway and parking lot area. Another survey found that the average retail outlet had 25 pieces of in-store cigarette advertisements, alone; and another found more than 3,000 cigarette ads in just 184 stores, with nearly one-third of those stores being within 1,000 feet of a school. Section 1.25

Unfortunately, the massive amount of tobacco product advertising and marketing at retail outlets maintains tobacco use rates among adults and increases youth initiation. For example, a study published in the May 2007 *Archives of Pediatrics and Adolescent Medicine*, the first national study to examine how specific marketing strategies in convenience stores and other retail settings affect youth smoking, concluded that the more cigarette marketing teens are exposed to in retail stores, the more likely they are to smoke. Specifically, the study found that retail cigarette advertising increased the likelihood that youth would initiate smoking, and cigarette promotions increased the likelihood that youth will move from experimentation to regular smoking. ²⁷

An earlier study of middle-school youth concluded that those who visited convenience stores and similar retail outlets at least weekly and were, therefore, more exposed to retail tobacco marketing, had a 50 percent greater odds of ever smoking compared to kids who went to such retail stores less frequently. Similarly, a 2009 study found that more frequent visits to stores selling tobacco and greater awareness of cigarettes sold in stores increased the likelihood of teenagers being susceptible to initiating, experimenting, or becoming current smokers. These findings, corroborated by other studies, are especially troubling given past findings that three out of four teenagers shop at a convenience store at least once a week. Moreover, studies have found that tobacco product advertising is more prevalent in stores where adolescents shop frequently.

Research studies have also found that tobacco product selling retail outlets are disproportionately located in socially and economically disadvantaged neighborhoods, and that smoking rates are higher in areas with higher densities of tobacco product selling retail outlets than in areas with lower densities, even after controlling for other factors and influences.³² In particular, a higher density of such retailers near schools has been found to increase experimental smoking among high school students.³³

More generally, point-of-purchase tobacco product advertising and displays have been found to increase average retail tobacco product sales by as much as twelve to twenty-eight percent. A recent study found that cigarette pack displays at retail outlets stimulate impulse purchases among smokers and that those trying to avoid smoking commonly experience urges to purchase cigarettes when confronted with these displays, indicating that cigarette pack displays undermine intentions to quit among established smokers. That same study also found that 25 percent of the surveyed smokers had at least sometimes made an unplanned purchase of cigarettes in the last 12 months as a result of seeing point-of-purchase tobacco product displays. Similarly, a study based on interviews with persons having just bought cigarettes at retail outlets with point-of-purchase displays found that more than one out of five of the purchases were unplanned. 36

<u>Rigorous New Restrictions on Tobacco Product Advertising Are Necessary Because the Tobacco Industry Has a Long History of Irresponsible Advertising Practices Despite Prior Government Efforts to Prevent or Constrain Them</u>

The tobacco industry continues to advertise and market their products in ways that appeal to kids. In fact, in August 2006, U.S. District Court Judge Gladys Kessler released her final opinion in the U.S. Government's case against tobacco companies, describing how the tobacco companies continue to target youth with sophisticated marketing campaigns. According to Judge Kessler, "Defendants continue to engage in many practices which target youth, and deny that they do so." Judge Kessler also stated in finding 3296: "The evidence is clear and convincing - and beyond any reasonable doubt -- that Defendants have marketed to young people twenty-one and under while consistently, publicly, and falsely, denying they do so." 38

While the Master Settlement Agreement between the states and the major cigarette companies (MSA) and the parallel Smokeless Tobacco Master Settlement Agreement between the states and UST placed some restrictions on cigarette and smokeless tobacco product advertising and marketing, the MSA and STMSA have been limited in their effectiveness because they do not

address many important matters or do not address them adequately, and they do not apply to all cigarette and smokeless tobacco product manufacturers and importers – and do not directly reach or restrict retailers or wholesalers at all. Even in regard to the major cigarette companies that are subject to the MSA, Judge Kessler found that "Despite the provisions of the MSA, Defendants continue to track youth behavior and preferences and market to youth using imagery which appeals to the needs and desires of adolescents."³⁹

According to Federal Trade Commission (FTC) reports on tobacco industry marketing, industry spending on advertising and promotion has almost doubled since the 1998 Master Settlement Agreement. The major cigarette companies, alone, now spend about \$12.5 billion per year (or more than \$34.2 million every day) to promote their products; and many of their marketing efforts directly reach kids. ⁴⁰ In fact, cigarette company spending to market their deadly products increased by more than 85 percent from 1998 to 2006 (the most recent year for which complete data are available). ⁴¹ Much of the increase in spending is for strategies that reach and influence vulnerable underage populations. For example, the cigarette and spit-tobacco companies continue to advertise heavily at retail outlets, like convenience stores where teenagers are known to frequent; and studies have found that outdoor and outdoor visible ads at retail outlets increased pre- to post-MSA. ⁴² Cigarette companies increased their spending on point-of-sale marketing by more than \$60 million, or 30 percent, between 2005 and 2006, and spent the bulk of their marketing dollars (90 percent, or \$11.2 billion) on strategies that facilitated retail sales, such as price discounts and ensuring prime retail space. ⁴³

As numerous research studies have documented, the influence of the major tobacco companies on how tobacco products are displayed, advertised and otherwise marketed at retail outlets is enormous. 44 Moreover, an extensive analysis of tobacco company documents disclosed in court proceedings found that tobacco company marketing at retail is done to increase overall use, not just to promote existing users to switch brands. 45

In her August 2006 Opinion, Judge Gladys Kessler concluded, "As Defendants' senior executives took the witness stand at trial, one after another, it became exceedingly clear that these Defendants have not, as they claim, ceased their wrongdoing or, as they argued throughout the trial, undertaken fundamental or permanent institutional change." Given the tobacco industry's history of irresponsible marketing, there is little doubt that left unchecked the industry will continue these egregious marketing practices. As Judge Kessler concluded, "there is a reasonable likelihood that Defendants' RICO violations will continue..."

Here are two recent examples of tobacco industry marketing targeting to kids since that finding by Judge Kessler:

• In January 2007, R.J. Reynolds (RJR) launched a new version of its Camel cigarette, called Camel No. 9, packaged in shiny black boxes with hot pink and teal borders. The name evoked famous Chanel perfumes, and magazine ads that featured flowery imagery and vintage fashion ran in magazines popular with both young women and girls, including *Vogue*, *Glamour*, *Cosmopolitan*, *Marie Claire* and *InStyle*. Promotional giveaways included flavored lip balm, cell phone jewelry, tiny purses and wristbands, all in hot pink. 48

Also in 2007, RJR ran a multi-page ad in *Rolling Stone* magazine (1.5 million youth readers) that featured numerous cartoon drawings of animals, monsters and images from outer space. Shortly thereafter, eight state Attorneys General sued the company for violating the MSA. RJR then took down a website that featured images from the ad and announced that it would cease any advertising of its cigarettes in magazines.

Congress acted appropriately and included restrictions based upon a careful examination of the latest evidence regarding the amount of tobacco industry marketing and its impact on initiation and continued use of tobacco products. After reviewing the science, Congress accurately concluded that: (1) tobacco marketing has increased since the 1996 Tobacco Rule and the 1998 MSA; (2) tobacco marketing continues to be effective at getting kids to smoke and increase overall tobacco consumption; (3) the industry's egregious and irresponsible tobacco marketing practices will continue unless further restrictions are implemented; and (4) there is a serious and substantial need for reinstatement of the 1996 Rule.

To Reduce Tobacco Use and Its Harms Effectively, Strong New Tobacco Product Advertising Restrictions Are Needed to Curtail Tobacco Product Marketing that has the Greatest Impact on Youth Initiation and Use and that Misleads Consumers

As detailed above, exposure to tobacco product advertising, including such advertising at retail outlets, works directly to increase underage experimentation and initiation, mislead consumers, prompt impulse purchases, and increase overall tobacco use and harms. Reductions to tobacco product advertising exposure, including such advertising at retail outlets, will, accordingly, do the reverse. Indeed, research over the past decade and more shows that restrictions on the advertising and promotion of tobacco products lead to reductions in the number of children who use and eventually become addicted to these products, reaffirming the evidence cited by the FDA in support of the 1996 FDA Final Tobacco Rule. For example, the previously noted study in the *Archives of Pediatrics and Adolescent Medicine* found that retail cigarette advertising increased the likelihood that youth would initiate smoking and that reducing or eliminating these retail marketing practices would significantly reduce youth smoking. St

Moreover, based on a review of available research and data, the World Health Organization (WHO) has concluded that a comprehensive ban on tobacco advertising, promotion, and sponsorship is one of the most effective policy measures to reduce tobacco use, while also finding that partial bans work to reduce tobacco consumption, as well. 52

Similarly, the 2008 NCI Monograph on tobacco marketing, *The Role of the Media in Promoting and Reducing Tobacco Use*; the 2007 Report of the President's Cancer Panel, *Promoting Healthy Lifestyles: Policy, Program and Personal Recommendations for Reducing Cancer Risk*; and the 2007 Report of the Institute of Medicine on tobacco, *Ending the Tobacco Problem: A Blueprint for the Nation*, all found – based on available research and data – that more needs to be done to reduce the influence of tobacco industry advertising and marketing.⁵³ For example, the President's Cancer Panel recommended that "the influence of the tobacco industry – particularly on America's children – be weakened through strict Federal regulation of tobacco products sales and marketing."⁵⁴

Endnotes

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