



July 19, 2010

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

Re: Request for Comment on Implementation of the
Family Smoking Prevention and Tobacco Control Act
Docket No. FDA-2010-N-0136
RIN Number 0910-AG33

Dear Sir or Madam:

The National Association of Convenience Stores (“NACS”) presents the following comments with respect to the Food and Drug Administration’s (“FDA’s”) “Request for Comment on Implementation of the Family Smoking Prevention and Tobacco Control Act,” Docket No. FDA-2010-N-0136, 75 Fed. Reg. 13,241 (March 19, 2010) (the “Request”).

Background

NACS is an international trade association representing the convenience store industry. The industry as a whole includes approximately 145,000 stores in the United States, sells nearly 80 percent of the gasoline in the nation, and employs about 1.7 million workers. It is truly an industry for small businesses, and more than 60 percent of convenience stores are owned by one-store operators. On average, approximately 35-40% of a convenience store’s merchandise sales are tobacco products.

NACS members rely on in-store and outdoor advertising to inform their customers about the availability of products in their stores, prices, limited-time offers and specials, and a variety of other purposes. Accordingly, NACS is vitally interested in any restrictions on tobacco advertising that the FDA may consider.

The Family Smoking Prevention and Tobacco Control Act

In the Family Smoking Prevention and Tobacco Control Act (the “Tobacco Control Act” or the “Act”),¹ Congress presented the FDA with a seemingly impossible task: devising a regulatory regime for tobacco advertising that will pass U.S. Constitutional muster. The pertinent language appears in section 102 of the Act, which requires FDA to reissue its 1996 final rule² on tobacco and “include such modifications to section 897.30(b), if any, that the Secretary determines are appropriate in light of governing First Amendment case law, including the decision of the Supreme Court in *Lorillard Tobacco Co. v. Reilly* (533 U.S. 525 (2001)).” (Emphasis omitted in original).³

Of course, Congress could have adopted its own advertising rules if it chose to do so. It did not, instead delegating an extremely complex and constitutionally delicate decision to the FDA.

The FDA plays a vital role in implementing statutes governing the safety and efficacy of food, drugs, cosmetics, and myriad other matters (now including cigarettes and smokeless tobacco). It is at best, however, a suspect selection for the agency to regulate the commercial advertising of an everyday, legal product. It is simply irrational to require an agency to determine the safety of a new pharmaceutical for pregnant women in the morning, and then in the afternoon make a constitutional determination of how many feet from a public swingset a

¹ Tobacco Control Act, Pub. Law No. 111-31 (2009).

² Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396 (Aug. 28, 1996) (the “Final Rule”).

³ Tobacco Control Act, sec. 102(a)(2)(E).

sign of a certain amount of square feet can be placed. Congress has done the FDA no favors with this assignment.

The FDA Should Decline Congress's Invitation to Regulate

The Tobacco Control Act does not require the FDA to promulgate a rule governing tobacco advertising. For the reasons set forth below, the agency should simply terminate the proceeding it has begun. In doing so, the FDA will avoid what will inevitably be a long, drawn-out regulatory and judicial war that the agency will lose. The FDA's very limited resources are far better spent elsewhere.

No requirement to act. The statutory authority under which the FDA is now acting (quoted above, and in the Request) seemingly *permits* the agency to act on advertising matters, but it does not *require* it to do so. FDA admits as much by deferring any decision on reissuing section 897.130(b) of the Final Rule, in contrast to all other aspects of that rule, on March 19, 2010,⁴ as directed by the Tobacco Control Act. Thus, at present, there is no FDA regulation of advertising that *has* passed constitutional muster under Lorillard. "Modifications" to section 897.130(b), "*if any,*" that "are appropriate" under Lorillard may clearly encompass a decision not to regulate outdoor advertising at all. That is precisely what the FDA should do.

Any rule under Section 102 will be struck down. It is impossible to believe that any regulation of tobacco advertising promulgated by the FDA will not be judicially challenged on any number of grounds.⁵ NACS does not seek to litigate these matters in the context of the

⁴ Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents, 75 Fed. Reg. 13,225 (March 19, 2010) (the "2010 Rule").

⁵ Indeed, a different, but not completely unrelated, provision of the Tobacco Control Act has already been challenged successfully in Federal District Court. Commonwealth Brands, Inc. v. United States, No. 1:09-CV-117-M (W.D. Ky. Jan. 4, 2010). In part, Commonwealth

Request, but the administrative record should be clear that the FDA was forewarned about the fatal infirmities of its proceedings at this stage.

First, the Tobacco Control Act's delegation of authority in section 102 is constitutionally impermissible. As a result, it seems clear that any advertising rule promulgated by the FDA will be successfully challenged under the non-delegation doctrine.

In permitting the FDA to regulate in the advertising area, Congress merely requested that a final rule "be appropriate in light of governing First Amendment case law."⁶ The U.S. Supreme Court, however, has repeatedly "said that when Congress confers decisionmaking authority upon agencies *Congress* must 'lay down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform.'"⁷ Here, *of course* any rule promulgated by FDA must comport with the U.S. Constitution. But under the non-delegation doctrine, compliance with the First Amendment does not come close to providing a "guiding principle" for regulation.

In the Tobacco Control Act, Congress has abdicated its legislative authority and told the FDA: "We give up. If you are going to regulate, do whatever you think you can get away with

Brands struck down the provisions of the Final Rule banning color graphics in labeling and advertising.

⁶ Tobacco Control Act, sec. 102(a)(2)(E). FDA suggests in the Request that it will consider "*Lorillard*, other provisions in the Tobacco Control Act, and other developments and information . . . that have occurred since the original publication of the 1996 final rule" in proposing a new rule. 75 Fed. Reg. at 13,242. That is not what Congress put in its statute, however. Section 102(a)(2)(E) requires that any modifications to the invalid Final Rule be made "in light of First Amendment case law" (citing Lorillard), not Lorillard and a host of other criteria.

⁷ Whitman v. American Trucking Assn., 531 U.S. 457, 472 (2001) (emphasis in original), quoting J. W. Hampton, Jr., & Co. v. United States, 276 U. S. 394, 409 (1928). See generally Mistretta v. United States, 488 U.S. 361 (1989) and cases cited therein.

under the constitution.” A requirement not to violate the U.S. Constitution does not come close to providing the agency with a “guiding principle” upon which it can regulate. The First Amendment is so broad, complex, and controversial that it provides no guidance that a court could possibly recognize.⁸ Any rule that the FDA promulgates will therefore be constitutionally invalid under the non-delegation doctrine.

Second, Lorillard itself poses an insuperable barrier to FDA’s stated mission of ultimately promulgating a rule on outdoor advertising “necessary to protect children and adolescents from the harms caused by tobacco use.”⁹ In the advertising context, following Central Hudson Gas & Electric Corporation v. Pub. Serv. Comm.,¹⁰ Lorillard made clear that regulations cannot be “more extensive than is necessary” to address the perceived harm at issue.

The sweeping precedent set by Lorillard makes it abundantly clear that any Sisyphean attempt at regulating outdoor advertising will meet the same outcome as the Massachusetts regulations at issue in that case. If the FDA’s goal is to shield children and adolescents from any exposure to the marketing and advertising of cigarettes and smokeless tobacco, it cannot propose doing anything less than propose the kinds of prohibitions that Massachusetts did. Those prohibitions are unconstitutional under the First Amendment and Lorillard, and will be struck down in the courts.

There is one enormous, dispositive development since the Final Rule with respect to underage use of tobacco: the enactment of the Tobacco Control Act itself. Unlike 1996, there is now a federal statute that comprehensively addresses the manufacture, distribution, and sale of

⁸ “Whether the statute delegates legislative power is a question for the courts . . .”. Whitman, 531 U.S. at 473.

⁹ 75 Fed. Reg. at 13,242.

¹⁰ 447 U.S. 557 (1980).

cigarettes and smokeless tobacco. Among other things, there is now a federal requirement that all purchasers of cigarettes and smokeless tobacco have their age verified prior to sale.¹¹

Through age-verification and a panoply of other provisions, Congress itself has provided the FDA with more than ample reason not to attempt to address whatever ills it perceives that are associated with tobacco advertising.

Imprudent use of resources. Litigating two fatally flawed premises – that Congress can delegate lawmaking authority to the FDA, which then can craft a regulation in a manner that “is not more extensive than is necessary” – will be time-consuming and expensive. It is far from a secret that the FDA is an agency in crisis, horribly overburdened by the myriad missions that Congress continues to foist on it. The U.S. House of Representatives Energy and Commerce Committee, for one, has held over a dozen hearings over the last several years that amply demonstrate that the FDA lacks the resources to accomplish its current missions.¹²

The mission the FDA has begun in the Request is optional, it is doomed, and it diverts resources from other critical activities of the agency. Rather than pursuing the Request, the FDA should dedicate its limited personnel to matters that would far better serve all of its constituencies, including those directly affected by other provisions of the Tobacco Control Act.

¹¹ *See generally* the 2010 Rule.

¹² *E.g.*, “The Role and Performance of FDA in Ensuring Food Safety,” Hearing before the Subcommittee on Oversight and Investigation (May 6, 2010); “Drug Safety: An Update from the FDA,” Hearing before the Subcommittee on Health (March 10, 2010) (“FDA clearly needs more authorities and more resources to do a better job policing the safety of imported products.” Prepared Statement of Committee Chairman Henry Waxman); “Medical Devices: Are Current Regulations Doing Enough for Patients?” Hearing before the Subcommittee on Health (June 18, 2009); “How Do We Fix Our Ailing Food Safety System?” Hearing before the Subcommittee on Health (March 11, 2009);

Any Restrictions on Outdoor Advertising Must Be Extremely Limited

Should the FDA choose to continue the mission it has set forth for itself in the Request, it obviously needs to tread with the utmost care. Without being able to scrutinize any specific restrictions or prohibitions, neither NACS nor any other interested party can confidently opine on whether future requirements may be “justified, lawful, and appropriate.”¹³

Suffice it to say, however, that the concepts that the FDA discusses in its Request are no more acceptable to NACS than the actual regulatory language involved in Lorillard. Indeed, NACS firmly believes that its members have the right, under the First Amendment and Lorillard, to advertise, at a bare minimum, the availability and pricing of the products they sell. Congress has made the decision that the sale of cigarettes and smokeless tobacco shall remain legal.¹⁴ As a result, it is incumbent upon the FDA not to restrict a retailers’ ability to inform customers about where they can purchase a legal product and the price of that product.

Below, NACS provides responses to some of the larger questions the FDA raises in the Request.

Would restrictions advance the public health goal of protecting children and adolescents from the harms caused by tobacco use? (Emphasis added.)

No. The only way to protect children and adolescents from harms associated with tobacco use is to prevent them from using tobacco products. The Tobacco Control Act, which was *not* on the books in 1996, provides a comprehensive, federal regime to prohibit cigarette and smokeless tobacco sales to those under the age of eighteen, with severe penalties for violations. The Act’s

¹³ 75 Fed. Reg. at 13,242. NACS cannot determine the origin of this nebulous standard; it certainly does not appear in the Tobacco Control Act.

¹⁴ *See* Tobacco Control Act, sec. 101(b)(3), adding new section 907(d)(3)(B) to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 *et seq.*

new regulatory regime will prevent underage use, which has been in sharp decline in recent years even before its enactment.¹⁵

If so, could this public health goal be achieved with narrower restrictions?

See above. The enactment of the Tobacco Control Act obviates any perceived need for restrictions or prohibitions on cigarette and smokeless tobacco advertising. This is so regardless of the size of billboards, the geographical locations of advertisements, or any other criteria that the FDA may propose.

Or would a broader prohibition be necessary to achieve the public health goal?

No.

Should FDA consider requiring stores that sell tobacco products to post graphic anti-tobacco messages in order to counter the effects of advertisements on children?

NACS adamantly opposes this suggestion. It would be outrageously burdensome and completely nonsensical to require retailers to post messages in their stores concerning products that federal law dictates may not be sold to underage individuals – for the assumed benefit of those very individuals. All convenience stores, by their very nature, have extremely limited space available for advertising and required federal, state, and local governmental notifications, permits, and so forth. Requiring yet another “message” will simply confuse customers without any real benefit. Under the Tobacco Act, no underage individual may purchase cigarettes or smokeless tobacco. Posting any kind of message for those individuals is simply not necessary

¹⁵ FDA’s sister agency, the Substance Abuse and Mental Health Services Administration (“SAMHSA”), is responsible for monitoring the prevalence of youth smoking. Its efforts have not been in vain. See “12 Year Nationwide Drop in Tobacco Sales to Minors Continues Under State/Federal Partnership Program,” Press Release from SAMHSA, (Aug. 11, 2009) *available at* <http://www.samhsa.gov/newsroom/advisories/0908112615.aspx>.

because it will not make any difference. If the FDA desires to spread anti-tobacco use messages, under the FDA's own logic, it would be far more efficacious to require them in locations where the FDA would ban or restrict tobacco advertising (near schools, recreational facilities, and other gathering places), rather than at establishments where *federal law* prohibits the purchase of tobacco products.

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NACS appreciates this opportunity to comment on the Request. Please do not hesitate to contact me if I may provide any further information or otherwise be of assistance.

Sincerely yours,

A handwritten signature in black ink that reads "Lyle Beckwith". The signature is written in a cursive style with a large, looped initial "L".

Lyle Beckwith
Senior Vice President, Government Relations