



FDA Final Rule Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco

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Summary

On March 19, 2010, the Food and Drug Administration (FDA) reissued a 1996 final rule aimed at reducing underage smoking and use of smokeless tobacco products (e.g., snuff, chewing tobacco). The agency's rulemaking was mandated by the Family Smoking Prevention and Tobacco Control Act, which was enacted last year in response to a 2000 decision by the Supreme Court holding that FDA lacked the statutory authority to regulate tobacco products. The Family Smoking Prevention and Tobacco Control Act (P.L. 111-31) expressly gives FDA broad statutory authority under the Federal Food, Drug, and Cosmetic Act (FFDCA) to regulate the manufacture, distribution, advertising, sale, and use of cigarettes and other tobacco products.

The new FDA tobacco rule builds on the youth access, marketing, and advertising restrictions that the tobacco companies agreed to as part of the 1998 Master Settlement Agreement, which settled lawsuits filed by the states to recover the public health costs of tobacco-related illness. Among its provisions, the rule prohibits the sale of tobacco products to any person under age 18; requires retailers to verify a purchaser's age by photo ID; restricts the sale of tobacco products through vending machines and self-service displays to adult-only facilities; limits tobacco advertising in publications to which children and adolescents are exposed to a black-on-white, text-only format; prohibits the sale of tobacco brand-identified promotional items such as caps and T-shirts; and prohibits brand-name sponsorship of sporting and other cultural events. The rule became effective on June 22, 2010.

The original 1996 rule included a ban on outdoor cigarette and smokeless tobacco advertising (e.g., billboards, posters) within 1,000 feet of schools and playgrounds. The reissued rule does not incorporate such a ban. In *Lorillard Tobacco Co. v. Reilly* (2001), the U.S. Supreme Court struck down a similar outdoor advertising ban in Massachusetts, arguing that it violated the First Amendment protection of commercial speech. FDA has reserved a section in the reissued rule for future rulemaking on outdoor advertising restrictions. In a separate advanced notice of proposed rulemaking, the agency has requested public comment on this issue and offered several options for more narrowly tailored outdoor advertising restrictions that the agency believes would not violate the First Amendment.

In August 2009, several tobacco companies filed a federal lawsuit against FDA claiming that the Family Smoking Prevention and Tobacco Control Act violates their constitutional right to commercial free speech. On January 5, 2010, a federal district court judge struck down the tobacco rule's provision that limits advertising in publications with significant youth readership to a black-on-white, text-only format. FDA is expected to appeal the court's ruling.

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Introduction

On March 19, 2010, the Food and Drug Administration (FDA) reissued a 1996 final rule aimed at reducing underage smoking and use of smokeless tobacco products (e.g., snuff, chewing tobacco).¹ The agency's rulemaking was mandated by the Family Smoking Prevention and Tobacco Control Act (FSPTCA), which was enacted in 2009 after the Supreme Court, in a 2000 case entitled *FDA v. Brown & Williamson Tobacco Corp.*, determined that FDA lacked statutory authority to regulate tobacco products.² The new law expressly amends the Federal Food, Drug, and Cosmetic Act (FFDCA)³ to give FDA broad statutory authority to regulate the manufacture, distribution, advertising, sale, and use of cigarettes and other tobacco products.

The FDA tobacco rule limits underage access to cigarettes and smokeless tobacco, and places new restrictions on the advertising and marketing of tobacco products. Among its provisions, the rule prohibits the sale of tobacco products to any person under age 18; requires retailers to verify a purchaser's age by photo ID; restricts the sale of tobacco products through vending machines and self-service displays; limits tobacco advertising in publications to which children and adolescents are exposed to a black-on-white, text-only format; prohibits the sale of tobacco brand-identified promotional items such as caps and T-shirts; and prohibits brand-name sponsorship of sporting and other cultural events. The rule took effect on June 22, 2010.

This report discusses FDA's initial failed attempt at regulating tobacco products under the then existing provisions of the FFDCA, summarizes FDA's current tobacco rule—reissued pursuant to statutory authority granted under the FSPTCA, and compares the reissued rule's provisions to the youth access, advertising, and marketing restrictions that went into effect pursuant to the 1998 Master Settlement Agreement between the states and the tobacco companies. The report then discusses the First Amendment implications of the rule's advertising restrictions and includes an analysis of the U.S. Supreme Court's decision in *Lorillard Tobacco Co. v. Reilly*, which struck down a Massachusetts law restricting outdoor tobacco advertising, and a recent federal district court ruling against FDA. The report will be updated to reflect further regulatory actions taken by FDA and any future court decisions.

FDA's Initial Attempt to Regulate Tobacco Products

Recognizing the health hazards of smoking, FDA first attempted to regulate tobacco products in the 1990s as a “drug or device” under the then existing provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA). Accordingly, FDA published a final rule on August 28, 1996, aimed at reducing underage smoking and use of smokeless tobacco products.⁴ The FDA rule included three sets of provisions: restrictions on the sale and distribution of tobacco products to minors, limits on tobacco-product marketing and advertising, and new labeling requirements for packaging and advertising. The agency said that the purpose of the rule was to reduce the easy access to tobacco

¹ Department of Health and Human Services, Food and Drug Administration, “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents,” 75 *Federal Register* 13225-13232, March 19, 2010.

² P.L. 111-31; 123 Stat. 1776; 529 U.S. 120 (2000).

³ 21 U.S.C. §§ 301 et seq.

⁴ 61 *Federal Register* 44396-45318; 21 C.F.R. Parts 801, 803, 804, 807, 820, and 897.

products by minors. It also hoped to reduce the amount of positive advertising imagery used by manufacturers to make their products appealing to minors. While the rule did not directly address adult tobacco use, FDA argued that over time it would help reduce adult tobacco consumption. Data from the National Survey on Drug Use and Health indicate that the vast majority of smokers take up the habit as teenagers. Thus, reducing the number of new teenage smokers, who were needed to replace adult smokers who quit or die, was expected to lower overall tobacco consumption in the future.

Agency Assertion of Jurisdiction over Tobacco Products

The FDA initially asserted regulatory jurisdiction over cigarettes and smokeless tobacco under the FFDCAs by concluding that nicotine was a “drug” and that cigarettes and smokeless tobacco were a drug-delivery “device” as defined by the act. The statute defines a drug, in relevant part, as “articles (other than food) *intended* to affect the structure or any function of the body.”⁵ In its rulemaking, the FDA drew on the extensive scientific literature documenting nicotine’s pharmacologic effects on the body, including satisfaction of addiction, stimulation, and sedation. The agency also concluded that cigarettes and smokeless tobacco are devices that deliver nicotine into the body. As with drugs, the FFDCAs’ definition of medical devices includes articles that are intended by the manufacturer to affect the structure and function of the body.⁶ Unlike a drug, however, a device is defined, in part, as an article “which does not achieve its primary intended purpose through chemical action.”⁷

Having made the determination that tobacco products fell under the statutory definitions of drugs and devices, the FDA further concluded that these products were combination products because they have both a drug and a device components. Under the FFDCAs, the FDA is authorized to regulate products that “constitute a combination of a drug, device, or biologic product.”⁸ The agency interpreted this provision as giving it the discretion to regulate combination products as drugs, as devices, or as biologic products.⁹ In its final rule, the FDA chose to regulate tobacco products under the device provisions of the FFDCAs because they offered the agency greater regulatory flexibility than did the drug provisions of the act.¹⁰

Under the FFDCAs, drug and device manufacturers must demonstrate that their products are both safe and effective in order to gain FDA marketing approval.¹¹ The safety and effectiveness standard poses a difficult challenge for regulating tobacco products, which are manifestly unsafe when used as intended. Critics of FDA’s 1996 rule argued that in asserting regulatory authority over tobacco products, the agency would have no choice but to ban them because of their harmful and addictive effects. In commenting on the rule, the FDA conceded that tobacco products are “unsafe” as that term is generally understood, but concluded that banning tobacco products was

⁵ 21 U.S.C. § 321(g)(1)(C); FFDCAs § 201(g)(1)(C) (emphasis added).

⁶ 21 U.S.C. § 321(h)(3); FFDCAs § 201(h)(3).

⁷ 21 U.S.C. § 321(h); FFDCAs § 201(h).

⁸ 21 U.S.C. § 353(g); FFDCAs § 503(g).

⁹ 61 *Federal Register* 44396, 44400 (1996).

¹⁰ *Id.* at 44403. In 2005, FDA published a final rule setting forth definitions and an algorithm the agency uses to assign combination products to an agency component for regulatory oversight. 69 *Federal Register* 49848 (2005).

¹¹ See CRS Report RL32826, *The Medical Device Approval Process and Related Legislative Issues*, by Erin D. Williams.

not a realistic option because the health care system would be overwhelmed by more than 40 million nicotine addicts seeking assistance for withdrawal symptoms. Moreover, the agency argued, banning cigarettes would create an enormous black market, which might lead to the use of unregulated and potentially even more harmful products.

The FFDCA’s device authorities present a range of mandatory controls that apply to devices and their manufacturers including labeling and recordkeeping requirements, registration and inspection, and good manufacturing practices. In addition to mandatory controls, the FFDCA contains various discretionary provisions that apply to devices under certain circumstances. The FDA predicated its authority to regulate tobacco products on one such provision regarding restricted devices. The act’s restricted device provision states, in relevant part, that “[t]he Secretary may by regulation require that a device be restricted to sale, distribution, or use ... upon such other conditions as the Secretary may prescribe in such regulation, if, *because of its potentiality for harmful effect or the collateral measures necessary for its use*, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.”¹²

In the final tobacco rule, the FDA relied on the FFDCA’s restricted device provision when it concluded that, because of the harmful effects of cigarette and smokeless tobacco and in the absence of a reasonable assurance of the safety and effectiveness of such products, it needed to implement additional restrictions on tobacco access and advertising in order to prevent new users from becoming addicted.¹³

Legal Challenge to the 1996 Rule

Following the release of the 1996 tobacco rule, tobacco companies filed a lawsuit against the FDA and sought summary judgment on the grounds that the agency lacked the authority to regulate tobacco products when such products are marketed and sold without explicit claims of therapeutic benefit. The lawsuit further charged that the FDA exceeded its statutory authority because the FFDCA did not authorize the FDA to regulate tobacco products as drugs or devices.¹⁴ Finally, the companies argued that the rule’s advertising restrictions, which limited most advertisements to a black-on-white text-only format, violated the First Amendment protection of commercial speech.

In a 2000 case entitled *FDA v. Brown & Williamson Tobacco Corp.*, the U.S. Supreme Court, in a 5-4 decision written by Justice Sandra Day O’Connor, affirmed that the FDA did not have the authority to regulate tobacco products as drug-delivery devices.¹⁵ Although the majority opinion acknowledged the public health threat posed by tobacco use, the Court concluded that “Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products. Such authority is inconsistent with the intent that Congress has expressed in the [FFDCA’s] overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the [FFDCA].”¹⁶

¹² 21 U.S.C. § 360j(e); FFDCA § 520(e) (emphasis added).

¹³ 61 *Federal Register* 44396, 44405.

¹⁴ *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374 (M.D.N.C. 1997).

¹⁵ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

¹⁶ *Id.* at 126.

In reaching its decision, the Court examined the FDA tobacco rule in light of the precedents that govern cases involving an agency's construction of a statute that it administers. As part of such a review, the Court must determine whether an agency's interpretation of its statute is entitled to deference and presents a reasonable or permissible construction of the law. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.* is the leading case on judicial review of agency interpretations of statutes.¹⁷ This case involved the Environmental Protection Agency's rules regulating emissions under the Clean Air Act. In *Chevron*, the Court enunciated a two-step test for judicial review of an agency's interpretation of its statute: (1) has Congress spoken directly to the precise question at issue? and (2) if Congress has not done so and the statute is silent or ambiguous with respect to the specific issue, is the agency's answer based on a permissible construction of the statute?¹⁸

Under *Chevron* step one, if Congress has spoken directly to the question at issue, then *Chevron* deference is not due and the court "must give effect to the unambiguously expressed intent of Congress."¹⁹ In this case, the Court examined both the FFDCA and other tobacco-related statutes, ultimately concluding that Congress had clearly intended to preclude the FDA from regulating tobacco. As a result, the Court did not need to reach step two of *Chevron*. In reaching its decision, the court relied on a number of factors. First, the Court found that, because tobacco is a dangerous product and because the FFDCA prohibits the marketing of products that have not been found to be safe and effective, the statute would require the FDA to ban tobacco products if the agency did indeed have jurisdiction over such products. Such a ban, argued the Court, would plainly contradict the congressional intent reflected in the enactment of several pieces of legislation that clearly contemplate the continued marketing of tobacco products.²⁰ Thus, the Court held that Congress had clearly "intended to exclude tobacco products from the FDA's jurisdiction."²¹

In addition, the Court found that the FDA had repeatedly denied that it had jurisdiction over tobacco and that Congress had repeatedly rejected bills that would have granted the agency such authority.²² Instead, Congress had demonstrated its intent to create a distinct regulatory scheme for tobacco by enacting other tobacco-related regulatory statutes, such as the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act.²³ The Court cited these tobacco-related statutes as additional evidence in support of its conclusion that Congress had intended to preclude the FDA from regulating tobacco.²⁴

¹⁷ 467 U.S. 837 (1984).

¹⁸ *Id.* at 842-43.

¹⁹ *Id.* at 843.

²⁰ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134-43 (2000). Examples of such tobacco-related legislation include the Federal Cigarette Labeling and Advertising Act (P.L. 89-92, 15 U.S.C. §§ 1331 et seq.); the Public Health Cigarette Smoking Act of 1969 (P.L. 91-222, 15 U.S.C. §§ 1331 et seq.); the Comprehensive Smoking Education Act (P.L. 98-474, 15 U.S.C. §§ 1331 et seq.); the Comprehensive Smokeless Tobacco Health Education Act of 1986 (P.L. 99-252, 15 U.S.C. §§ 4401 et seq.); and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (P.L. 102-321, § 202, 42 U.S.C. § 300x-26).

²¹ *Brown & Williamson*, 529 U.S. at 143.

²² According to the tobacco companies, beginning in 1906 and as recently as 1993, Congress rejected any legislation designed to give the FDA jurisdiction over tobacco. *See*, First Amended Complaint for Declaratory and Injunctive Relief at 6-11, *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374 (M.D.N.C. 1997) (No. 2:95CV00591).

²³ These statutes, both of which are administered by the FTC, require health warnings on cigarette and smokeless tobacco packages and advertising, respectively.

²⁴ *Brown & Williamson*, 529 U.S. at 143-156.

Writing in dissent, Justice Stephen Breyer argued that cigarettes and other tobacco products clearly fall within the plain meaning of the statutory definition of drugs and devices because such products are intended to affect the structure and function of the body. In addition, the dissent argued that the purpose of the FFDCA—to protect the public health—also supported the conclusion that the FDA was authorized to regulate tobacco products. For these reasons, the dissent would have upheld the FDA’s jurisdiction over such products.²⁵

Family Smoking Prevention and Tobacco Control Act

Following *Brown & Williamson*, it was evident that the FDA could not regulate tobacco products unless Congress provided the agency with the express statutory authority to do so. To that end, the Family Smoking Prevention and Tobacco Control Act (H.R. 4433, S. 2461) was first introduced in the 108th Congress by Representatives Tom Davis and Henry Waxman and Senators Mike DeWine and Ted Kennedy to grant FDA statutory authority over tobacco products. The legislation was the product of months of negotiations in which lawmakers sought to balance the competing interests of public health groups and the tobacco industry. The Senate added S. 2461 as an amendment to a corporate tax package,²⁶ but the language was subsequently removed in conference by House conferees.

The Family Smoking Prevention and Tobacco Control Act was reintroduced in the 109th Congress (H.R. 1376, S. 666) and again in the 110th Congress (H.R. 1108, S. 625), during which it was approved by committees in both the House and Senate. The House passed H.R. 1108 in July 2008, but no further legislative action was taken during the 110th Congress. Reintroduced in the 111th Congress, the Family Smoking Prevention and Tobacco Control Act (H.R. 1256) passed the House on April 2, 2009. The Senate passed a slightly different version of the legislation (S. 982) on June 11, 2009, which the House agreed to the following day. The Family Smoking Prevention and Tobacco Control Act (FSPTCA) was signed into law on June 22, 2009 (P.L. 111-31).

The FSPTCA amended the FFDCA by granting FDA authority over the regulation of tobacco products based on a public health standard rather than the safety and effectiveness standard by which the FDA regulates pharmaceutical drugs and medical devices. The new law gives FDA the authority to develop regulations restricting the sale, distribution, advertising, and promotion of tobacco products. Any proposed regulation must meet the new public health standard. That standard requires FDA to demonstrate that the proposal is appropriate for the protection of the public health, taking into account the risks and benefits to the population as a whole, including users and nonusers of tobacco products. In addition, FDA has the authority to require changes in the design and characteristics of current and future tobacco products, such as the reduction or elimination of harmful ingredients and additives. Again, the agency must show that any such proposal is appropriate for protecting public health, based on a consideration of the risks and benefits to the population as a whole.

Under the FSPTCA, manufacturers must obtain FDA approval in order to market a new tobacco product. The same public health standard applies to such applications. However, the law provides

²⁵ *Id.* at 161-64.

²⁶ American Jobs Creation Act of 2004, P.L. 108-357; 118 Stat. 1418.

two exceptions to the requirement that manufacturers obtain premarket approval for new products: (1) the manufacturer makes a claim and FDA, upon review, agrees that the new product is substantially equivalent to a product already on the market, or (2) the new product is determined to be a “minor modification” of an existing product.²⁷ For the first 21 months after enactment (i.e., until March 22, 2011), manufacturers are permitted to introduce and market a new product for which a substantial equivalence claim has been submitted, provided FDA has not reviewed and rejected the claim.²⁸

The FSPTCA prohibits the use of descriptors such as “light” and “mild.”²⁹ Manufacturers seeking to market a tobacco product for which they wish to make a reduced-risk claim, explicitly or implicitly, must provide evidence substantiating that claim and meet additional requirements in order to obtain FDA approval to market the product.³⁰ The law requires a number of other important changes in the labeling, advertising, and marketing of cigarettes and smokeless tobacco products. Beginning on June 22, 2010, more explicit and conspicuous health warnings will start to appear on smokeless tobacco product labels and advertising.³¹ New health warnings on cigarette labeling and advertising will appear at a later date. FDA also has the authority to revise the size and content of the warnings, if it determines that such changes would promote a greater public understanding of the health risks of tobacco use.³²

FDA Rule on Cigarettes and Smokeless Tobacco

The FSPTCA also required FDA to reissue a modified version of the 1996 tobacco rule that the Supreme Court struck down in *Brown & Williamson*.

Summary of Provisions

The reissued tobacco rule’s provisions restricting the sale, advertising, and marketing of cigarettes and smokeless tobacco are summarized in the box below.³³ Generally, each manufacturer, distributor, and retailer is responsible for ensuring that the tobacco products it manufactures, labels, advertises, distributes, or sells comply with these provisions.³⁴ Retailers, for example, must ensure that all self-service displays and advertising located within their establishments that do not comply with the rule’s provisions are removed or brought into compliance.³⁵

²⁷ 21 U.S.C. § 387j.

²⁸ 21 U.S.C. § 387j

²⁹ 21 U.S.C. § 387k.

³⁰ 21 U.S.C. § 387k.

³¹ As of 30 days after June 22, 2010 manufacturers may not introduce into interstate commerce any smokeless tobacco product, regardless of its date of manufacture, that does not bear the new health warnings.

³² 15 U.S.C. § 1333; 15 U.S.C. § 4402.

³³ The FDA tobacco rule is codified in a new Part 1140 in Title 21 of the Code of Federal Regulations.

³⁴ 21 C.F.R. § 1140.10.

³⁵ 21 C.F.R. § 1140.14(e).

Summary of FDA Final Rule Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco (21 C.F.R. Part 1140)

Youth Access Restrictions

- Prohibits the sale of cigarettes or smokeless tobacco to persons under age 18.
- Requires retailers to check photo ID to verify age of purchasers under age 27.
- Requires that retail sales be conducted in a direct, face-to-face exchange, with the exception of vending machine sales and self-service displays as described below.
- Permits tobacco-product vending machines and self-service displays but only in facilities where individuals under age 18 are not permitted to enter at any time.
- Prohibits the sale or distribution of individual cigarettes or packages containing fewer than 20 cigarettes, except in vending machines located in facilities where individuals under age 18 are not permitted to enter at any time.
- Prohibits free samples of cigarettes; permits free samples of smokeless tobacco in qualified adult-only facilities, as defined.

Marketing and Advertising Restrictions

- Limits advertising in publications with significant youth readership to a black-on-white, text-only format.^a
- Limits advertising in audio format to words with no music or sound effects; limits advertising in video format to static, black-on-white text.
- Prohibits the marketing, licensing, distribution, or sale of all non-tobacco items and services identified with a cigarette or smokeless tobacco brand name (e.g., promotional T-shirts and caps).
- Prohibits gifts, credits, and coupons linked to the purchase of tobacco products.
- Prohibits brand-name sponsorship of sporting and other cultural events, but permits corporate-name sponsorship of such events.
- Prohibits the use of a non-tobacco trade or brand name as a tobacco product trade or brand name, unless that tobacco product trade or brand name was on both a tobacco product and a non-tobacco product sold in the United States on Jan. 1, 1995.

- a. Due to the ruling by the U.S. District Court for the Western District of Kentucky in *Commonwealth Brands v. U.S.*, discussed *infra*, FDA has stated it does not intend to commence enforcement actions under this provision while litigation is pending.

The FSPTCA instructed FDA to reissue the 1996 rule as a final rule with the following specified exceptions. First, the agency was instructed to drop the original rule's labeling provisions that would have required cigarette and smokeless tobacco packaging and advertising to include the statement "Nicotine Delivery Device for Persons 18 and Older."³⁶ The FSPTCA gives FDA new authority to regulate tobacco product labeling and advertising. Second, FDA was required to replace the definitions of "cigarettes," "cigarette tobacco," and "smokeless tobacco" as they appeared in the original rule with the definitions of those terms included in the FSPTCA.³⁷ Third, the agency was directed to modify the provision in the original rule that would have prohibited the distribution of free samples of cigarettes or smokeless tobacco with language in the FSPTCA

³⁶ FSPTCA § 102, P.L. 111-31.

³⁷ FSPTCA § 102, P.L. 111-31.

that permits the distribution of free smokeless tobacco samples in “qualified adult-only facilities,” as defined.³⁸

Finally, the FSPTCA instructed FDA to consider modifications to the original rule’s ban on outdoor cigarette and smokeless tobacco advertising (e.g., billboards, posters) within 1,000 feet of schools and playgrounds so as to address First Amendment case law, including the 2001 U.S. Supreme Court decision in *Lorillard Tobacco Co. v. Reilly*.³⁹ In *Lorillard*, discussed in more detail *infra*, the Court struck down a Massachusetts state ban on outdoor tobacco advertising within 1,000 feet of any school or playground, holding that it violated the First Amendment protection of commercial speech. The reissued final rule does not include the outdoor advertising ban. FDA has instead reserved a section in the rule for future rulemaking on outdoor advertising restrictions. In a separate advanced notice of proposed rulemaking, the agency has requested public comment on this issue and offered several options for more narrowly tailored outdoor advertising restrictions that it believes would not violate the First Amendment.⁴⁰

Retail establishments are responsible for providing training to their employees on the new regulations. FDA is planning to publish guidance to assist retailers in complying with the new regulations. The agency intends to enforce retailer compliance with the rule through inspections. The FSPTCA requires the agency to contract with states to inspect retail establishments.⁴¹ FDA has indicated that it will enter into these contracts on a rolling basis, but that in the interim it intends to conduct its own inspections and take enforcement action when appropriate. FDA has a variety of enforcement tools to address retailer noncompliance, including civil monetary penalties, warning letters, injunctions, and/or criminal prosecution. Retailers who violate the regulations may also be in violation of state law and subject to a variety of state remedies.⁴²

In August 2009, several tobacco companies filed a federal lawsuit against FDA claiming that the FSPTCA violated their constitutional right to commercial free speech. On January 5, 2010, a federal district court judge struck down the tobacco rule’s provision that limits advertising in publications with significant youth readership to a black-on-white text-only format. That ruling, which FDA is expected to appeal, is discussed in more detail below.

Comparison of FDA Rule with the Master Settlement Agreement

The FDA rule builds on the youth access, marketing, and advertising restrictions that the tobacco companies agreed to as part of the 1998 Master Settlement Agreement (MSA). Attorneys general from 46 states, the District of Columbia (DC), and the five U.S. territories signed the MSA with the major cigarette companies to settle lawsuits filed by the states to recover the public health costs of treating smokers. The remaining four states (Florida, Minnesota, Mississippi, and Texas) reached comparable individual settlements with the companies. The MSA committed the tobacco companies to pay the states approximately \$200 billion over the first 25 years, subject to inflation

³⁸ FSPTCA § 102, P.L. 111-31.

³⁹ 533 U.S. 525 (2001); FSPTCA § 102, P.L. 111-31.

⁴⁰ Department of Health and Human Services, Food and Drug Administration, “Request for Comment on Implementation of the Family Smoking Prevention and Tobacco Control Act,” 75 *Federal Register* 13241-13243, March 19, 2010.

⁴¹ FSPTCA § 103(g), P.L. 111-31.

⁴² FDA has more information about retailer compliance, inspection, and enforcement, at <http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/RegsRestrictingSale/default.htm>.

and other adjustments, with payments to continue in perpetuity.⁴³ In addition, the MSA included the following restrictions on youth access, marketing, and advertising, all of which remain in effect (unless noted otherwise).

Summary of the Tobacco Master Settlement Agreement (MSA) Restrictions on Youth Access, Marketing and Advertising

Youth Access Restrictions

- Limits free samples to adult-only facilities.
- Prohibits packages containing fewer than 20 cigarettes. (Note: This provision expired at the end of 2001.)

Marketing and Advertising Restrictions

- Prohibits the use of cartoon images in advertising.
- Prohibits industry payments to promote tobacco products in movies, TV shows, live performances, commercial films and videos, or video games, unless the audience or viewers are in an adult-only facility.
- Prohibits non-tobacco merchandise (e.g., caps, T-shirts) with tobacco brand-name logos, except at brand-name sponsored events.
- Prohibits gifts of non-tobacco items to youth in exchange for the purchase of tobacco products.
- Permits corporate-name sponsorship of sporting and cultural events and limits each company to brand-name sponsorship of one event per year (which may not include concerts, team sports, events with a significant youth audience, or events with underage contestants).
- Prohibits public transit advertising, and prohibits outdoor billboard advertising in arenas, stadiums, shopping malls, and arcades. Permits such advertising at brand-name sponsored events.
- Permits poster-sized advertising (up to 14 sq. ft.) on or outside retail establishments.

The FDA rule expands the MSA youth access restrictions by restoring the 20-cigarette minimum pack size and banning free samples of cigarettes entirely. In addition, the rule places new restrictions on retailers—requiring photo identification of persons under age 28 and face-to-face retail exchanges—and limits vending machine sales to adult-only locations. Comparable provisions were not included in the MSA.

Regarding tobacco product marketing and advertising, the FDA rule goes beyond the MSA in banning all brand-name sponsorship of sporting and other cultural events. And, unlike the MSA, the rule places new restrictions on tobacco labeling and advertising in publications with a significant youth readership and in audio and video advertisements. However, FDA has decided not to include a ban on all outdoor tobacco advertising within 1,000 feet of a school or playground. As discussed in more detail in the next section of this report, the agency is seeking public comment on more narrowly tailored outdoor advertising restrictions.

⁴³ A detailed analysis of the MSA is beyond the scope of this report. For more information on the MSA payment formula and adjustments, and the states' allocations of those funds, see U.S. Government Accountability Office, *Tobacco Settlement: States' Allocations of Payments from Tobacco Companies for Fiscal Years 2000 through 2005*, GAO-07-534T, February 27, 2007, <http://www.gao.gov/new.items/d07534t.pdf>.

First Amendment Challenges to the Tobacco Rule

The FDA's reissued tobacco rule includes marketing and advertising restrictions that raise constitutional questions as to the resulting burden placed on commercial speech.⁴⁴ As authorized by the FSPTCA, FDA is also considering modifications to a ban on outdoor advertising within 1,000 feet of a school or playground in light of First Amendment case law.⁴⁵ The U.S. Supreme Court has issued a series of decisions striking down government restrictions on certain types of commercial speech, including tobacco product advertising.⁴⁶ These cases are instructive and form the basis for a federal court's analysis of the early legal challenges to the reissued tobacco rule.

Legal Overview of Restrictions on Tobacco Advertising and Marketing

In *Central Hudson Gas & Electric Corp. v. Public Service Commission*, the U.S. Supreme Court established a four-part test for deciding the constitutionality of commercial speech regulation.⁴⁷ First, in order to be protected by the First Amendment, the commercial speech must concern lawful activity and not be false or misleading. Second, the government must demonstrate that by restricting such speech, it is seeking to further a substantial government interest. Third, the restrictions must directly advance that interest. Fourth, there has to be a reasonable fit between the type of restrictions imposed and the government's objectives; in other words, the regulation cannot be "more extensive than is necessary to service that interest."⁴⁸

As discussed previously, the FSPTCA required FDA to reissue most of the agency's 1996 tobacco rule as a final rule, with some additional language. In developing the 1996 tobacco rule, FDA created a set of advertising restrictions aimed at reducing underage smoking and smokeless tobacco use that it hoped would withstand a constitutional challenge. However, whether the

⁴⁴ The tobacco rule implements a number of marketing and advertising restrictions, including (1) limiting tobacco labeling and advertising to black text on a white background in publications with a significant youth readership that does not meet the rule's definition of an adult population; and (2) prohibiting brand-name event sponsorship and brand-name merchandising. See, 21 C.F.R. § 1140.32(a) ("...any labeling or advertising for cigarettes or smokeless tobacco shall use only black text on a white background."). Except in facilities "where vending machines and self-service displays are permitted ... provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility" or in an "adult publication." An adult publication is defined under 21 C.F.R. § 1140.32(a)(2) as:

a newspaper, magazine, periodical, or other publication: (i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and (ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

See also, 21 C.F.R. § 1140.34(a) ("No manufacturer or distributor ... may market, license, distribute, sell ... any item (other than cigarettes or smokeless tobacco or roll-your-own paper) or service which bears the brand name ... logo, symbol ... or any other indicia of product identification identical or similar to ... those used for any brand of cigarettes or smokeless tobacco."). See also, 21 C.F.R. § 1140.34(c) ("No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event....").

⁴⁵ 21 U.S.C. § 387a-1.

⁴⁶ Ronald Beyer et al., "Tobacco Advertising in the United States: A Proposal for a Constitutionally Acceptable Form of Regulation," *Journal of the American Medical Association*, vol. 287, no. 22 (June 2002), pp. 2990-95.

⁴⁷ *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980).

⁴⁸ 447 U.S. at 566.

FDA's 1996 rule—which included the restrictions on outdoor advertising, color graphics, and sponsorships—would have passed the *Central Hudson* test was a question never reached by the Supreme Court. In *FDA v. Brown & Williamson*, the Court instead confined itself to the more fundamental issue of agency authority to regulate tobacco at all. The Court did not address the constitutionality of the rule's marketing restrictions.

Although the Supreme Court did not reach the merits of the 1996 FDA rule's advertising restrictions in *Brown & Williamson*, the Court has considered similar state restrictions on tobacco product advertising. In the 2001 case, *Lorillard Tobacco Co. v. Reilly*, the Court found a number of Massachusetts state regulations restricting outdoor and point-of-sale advertising for cigars and smokeless tobacco products to be unconstitutional.⁴⁹ The Court determined that the regulations restricted speech more than was reasonable to advance the state's interest in reducing underage (i.e., illegal) use of tobacco products and, thus, failed to meet the fourth part of the *Central Hudson* test.⁵⁰

One of the invalidated restrictions was an outdoor advertising provision with nearly identical language to the 1996 FDA tobacco rule's prohibition on outdoor tobacco advertisements within 1,000 feet of a school or playground.⁵¹ Such a restriction, in conjunction with other zoning restrictions, reasoned the Court, “would constitute a nearly complete ban on the communication of truthful information about smokeless tobacco and cigars to adult consumers.”⁵² The Court found that the restrictions on outdoor advertising of cigars and smokeless tobacco were too broad in that they prohibited advertising “in a substantial portion of the major metropolitan areas of Massachusetts,” included oral communications, and imposed burdens on retailers with limited advertising budgets.⁵³ The Court also upheld challenges by smokeless tobacco and cigar companies to the outdoor advertising restrictions on the grounds that adults have a right to information and the tobacco industry has a right to communicate truthful speech on legal products.⁵⁴

The Court's reasoning in *Lorillard* is likely to be instructive for any future consideration of the FDA's outdoor advertising provisions. In defending the state regulation, the Massachusetts Attorney General relied to a substantial degree on studies and evidence associated with the advertising restrictions in the FDA's 1996 rule.⁵⁵ Although the Court determined that Massachusetts had presented sufficient evidence to satisfy the first three prongs of the *Central Hudson* test, the outdoor advertising regulations were found to be too broad to meet the fourth requirement—that is, that the regulation not be “more extensive than is necessary.”⁵⁶

The Court's key finding in the *Lorillard* case was that Massachusetts had not engaged in a “careful calculation” of the costs of the advertising regulation, nor did the state “seem to consider

⁴⁹ 533 U.S. 525 (2001).

⁵⁰ *Id.* at 561-66.

⁵¹ The Massachusetts regulation prohibited 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.” 940 Code of Mass. Regs. § 21.04(5)(a).

⁵² *Lorillard*, 533 U.S. at 562.

⁵³ *Id.* at 562, 564-65.

⁵⁴ *Id.* at 564.

⁵⁵ *Id.* at 557 (“The Attorney General relies in part on evidence gathered by the FDA...”).

⁵⁶ *Id.* at 561 (“[W]e conclude that the regulations do not satisfy the fourth step of the *Central Hudson* analysis.”).

the impact of the 1,000-foot restriction on commercial speech in major metropolitan areas.”⁵⁷ Rather, the Attorney General simply imposed a 1,000 foot restriction that was identical to the FDA’s restriction in the 1996 rule. The Court accepted the lower court’s finding that the broad restriction would prohibit advertising in 87%-91% of the greater Boston metropolitan area.⁵⁸ Such an extensive ban, reasoned the Court, “would constitute nearly a complete ban on the communication of truthful information about smokeless tobacco and cigars to adult consumers” and therefore did not “demonstrate a careful calculation of the speech interests involved.”⁵⁹ The Court also criticized the fact that the regulation constituted a ban on signs of any size, prevented retailers from communicating legitimate commercial messages to passersby, and applied to indoor communications that could be seen from the outside.⁶⁰ In short, Massachusetts had failed to demonstrate that the regulation was sufficiently tailored to achieving the state’s substantial interest in preventing minors’ access to tobacco.⁶¹

Because Massachusetts relied greatly on studies and evidence supporting the FDA’s proposed 1996 outdoor advertising regulation, the Court did, in dicta, reference the FDA rule. In discussing the geographical implications of Massachusetts’ 1,000-foot ban, the Court simply noted that “the FDA’s regulations would have had widely disparate effects nationwide.”⁶² The Court also suggested that a “uniform . . . geographical limitation,” without taking account of the differences between rural, suburban, and urban communities, “demonstrates a lack of tailoring.”⁶³ FDA received comments in response to the 1996 rule that identified this very issue. In the FDA’s 1996 final rule, the agency took note of comments that focused on the impact of the rule in major metropolitan areas, including a survey that “showed that outdoor tobacco advertising would be prohibited in 94 percent and 78 percent of the respective land mass of Manhattan and Boston under the [1,000-foot] proposal.”⁶⁴ However, the FDA attributed “the possibility that its restrictions effectively outlaw outdoor advertising in most urban areas” to population density in cities.⁶⁵ The agency then stated that its intent in establishing the 1,000-foot restriction was “to restrict the accessible and intrusive communications of information about cigarettes and smokeless tobacco to children and adolescents at school and at play.”⁶⁶ The rule explained that the FDA “considered the cost of its [1,000-foot] restriction but conclude[d] that a narrower restriction would not adequately advance its purpose of protecting young people from unavoidable advertising.”⁶⁷

Early Legal Challenges to the Reissued Tobacco Rule

Several tobacco companies were quick to challenge the advertising and marketing provisions of the reissued tobacco rule, citing *Lorillard* and arguing that the restrictions violated the free speech

⁵⁷ *Id.* at 562.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.* at 563-66.

⁶¹ *Id.* at 563 (“The uniformly broad sweep of the geographical limitation demonstrates a lack of tailoring.”).

⁶² *Id.*

⁶³ *Id.*

⁶⁴ 61 *Federal Register* 44506.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

protections of the First Amendment. The Federal District Court for the Western District of Kentucky, the first court to consider the validity of the new rule, released a “mixed ruling” on January 5, 2010, striking down some provisions of the regulation while upholding others.⁶⁸ The district court specifically upheld the sponsorship and merchandise limitations of the rule as “not more extensive than necessary to serve Congress’s substantial interest in reducing youth tobacco use by reducing youth possession of and exposure to branded merchandise.”⁶⁹ However, the court struck down the rule’s ban on color graphics in tobacco advertising as well as a provision in the FSPTCA that prohibits “any express or implied statement or representation directed to consumers” that would suggest that a tobacco product is less harmful by virtue of the fact that it is either regulated by the FDA or in compliance with FDA regulations.⁷⁰ Finally, because the FDA had not yet released its final language, the district court determined that the challenge to the rule’s outdoor advertising provision was unripe.⁷¹ The case, discussed in more detail below, will likely be appealed to the U.S. Court of Appeals for the Sixth Circuit.

In *Commonwealth Brands v. U.S.*, the district court held that the FSPTCA’s prohibition on color and graphical advertising violated the tobacco company’s First Amendment free speech rights.⁷² Identifying the rule’s provision as a government restriction on “commercial speech,” the court applied the *Central Hudson* test in striking down the “blanket ban” as not sufficiently tailored to Congress’s asserted interest of protecting minors.⁷³ The court characterized the graphics limitation as too broad, noting that Congress could have exempted “large categories of innocuous images and colors, e.g., images that teach adult consumers how to use novel tobacco products.”⁷⁴ Plaintiffs had effectively argued that color images are often used to “communicate important commercial information” rather than simply to “encourage minors to use a tobacco product.”⁷⁵ The court concluded that the “broad sweep” of the provision failed to satisfy the requirement that a restriction on commercial speech “directly advance the government’s interest” while not being “more extensive than is necessary.”⁷⁶

The district court, however, did not reach the merits of the tobacco rule’s outdoor advertising restrictions. While the court implied that a ban on outdoor advertising within 1,000 feet of a school or playground, such as the prohibition found in the original 1996 rule, was “undoubtedly” unconstitutional under *Lorillard*, the court held that an immediate challenge to the outdoor advertising ban was not yet ripe for review.⁷⁷ Under the FSPTCA, Congress mandated that the FDA “include such modifications” to the outdoor advertising restriction as deemed appropriate

⁶⁸ *Commonwealth Brands, Inc. v. U.S.*, 678 F. Supp. 2d 512 (W.D. Ky. 2010); Duff Wilson, *Judge Lifts Some Limits on Tobacco Advertising*, N.Y. Times, Jan. 6, 2009 at B3.

⁶⁹ The district court also upheld the Tobacco Control Act’s authorization of further tobacco related restrictions, increased tobacco health and safety warning requirements, and modified risk tobacco product restrictions. *Commonwealth Brands*, 678 F. Supp. 2d 512 (W.D. Ky. 2010).

⁷⁰ *Id.* at 521-26, 535.

⁷¹ *Id.* at 536.

⁷² *Id.* at 525-26.

⁷³ *Id.* Whereas most speech restrictions must survive “strict scrutiny” analysis, commercial speech is afforded a lesser level of protection as discussed *supra*. See, *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980).

⁷⁴ *Commonwealth Brands*, at 525.

⁷⁵ *Id.*

⁷⁶ *Id.* at 521.

⁷⁷ *Id.* at 536.

“in light of governing First Amendment case law.”⁷⁸ The FDA has yet to issue any such modifications. Accordingly, a challenge to the restriction is not yet ripe for judicial consideration.

The validity of the reissued tobacco rule’s outdoor advertising restrictions will likely hinge on the nature of the modifications issued by the FDA. Analyzing the restriction on outdoor advertising in the context of *Central Hudson*, *Lorillard*, and *Commonwealth Brands*, it does not appear that an unconditional or unaltered restriction on advertisements within 1,000 feet of a school or playground would survive the fourth step of the *Central Hudson* test (i.e., that the regulation cannot be “more extensive than is necessary” to serve the substantial government interest).⁷⁹ In *Lorillard*, for example, the Court explained that a “careful calculation of the costs of a speech regulation does not mean that a State must demonstrate that there is no incursion on legitimate speech interests, but 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.”⁸⁰ Thus, any modification to the rule’s outdoor advertising provision will need to carefully balance the FDA’s substantial interest in protecting children from tobacco products with the tobacco companies’ legitimate right to convey commercial information to adults.

Although the FSPTCA does not require the FDA to modify the outdoor advertising restrictions included in the 1996 rule,⁸¹ the FDA appears to have determined that a more narrowly tailored restriction is advisable. The reissued final rule does not include the outdoor advertising ban. FDA has instead reserved a section in the rule for future rulemaking on outdoor advertising restrictions. In a separate advanced notice of proposed rulemaking that FDA published on the same day as the final rule, the agency has requested comments, data, and research “pertaining to potential outdoor advertising restrictions for tobacco products that may have developed since ... 1996.”⁸² In addition, FDA announced that it was considering “several options” for altering the 1996 outdoor advertising provision, including limiting the outdoor advertising prohibition to only apply to billboards within 1,000 feet of elementary or secondary schools, or prohibiting “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).”⁸³ FDA also noted that it was considering creating a sliding scale regulatory scheme that prohibits advertisements of varying size in relation to the sign’s proximity to a elementary or secondary school.

Given the legal restraints, some public health law experts believe that the U.S. Supreme Court in its decisions on the regulation of commercial speech has left public health authorities with limited room to craft tobacco advertising restrictions that meet both the third (effectiveness) and fourth (extensiveness) parts of the *Central Hudson* test.⁸⁴ On the one hand, tobacco advertising restrictions that are narrowly tailored may not provide clear evidence of effectiveness, thus failing

⁷⁸ 21 U.S.C. § 387a-1.

⁷⁹ 447 U.S. at 566.

⁸⁰ 533 U.S. at 565-66.

⁸¹ The language of the Tobacco Control Act provides only that the FDA “include such modifications, if any, that the Secretary determines are appropriate.” 21 U.S.C. § 387a-1.

⁸² Department of Health and Human Services, Food and Drug Administration, “Request for Comment on Implementation of the Family Smoking Prevention and Tobacco Control Act,” 75 *Federal Register* 13241-13243, March 19, 2010.

⁸³ *Id.* at 13242.

⁸⁴ Beyer et al., *supra* n. 42.

the third part of *Central Hudson* test. On the other hand, more sweeping (and potentially effective) restrictions may be viewed as too extensive and not reasonably related to the government's asserted interest, thus failing the fourth part of the *Central Hudson* test.

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