No. 13-1053

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

NATIONAL ASSOCIATION OF TOBACCO OUTLETS, INC.; CIGAR ASSOCIATION OF AMERICA, INC.; LORILLARD TOBACCO COMPANY; R.J. REYNOLDS TOBACCO COMPANY; AMERICAN SNUFF COMPANY; PHILIP MORRIS USA INC.; U.S. SMOKELESS TOBACCO MANUFACTURING COMPANY LLC; U.S. SMOKELESS TOBACCO BRANDS INC.; and JOHN MIDDLETON COMPANY,

Plaintiffs-Appellants,

v.

CITY OF PROVIDENCE, RHODE ISLAND; PROVIDENCE BOARD OF LICENSES; PROVIDENCE POLICE DEPARTMENT; MICHAEL A. SOLOMON, Providence City Council President, in his official capacity; STEVEN M. PARÉ, Commissioner of Public Safety for the City of Providence, in his official capacity; and ANGEL TAVERAS, Mayor of Providence, in his official capacity,

Defendants-Appellees.

On Appeal From The United States District Court
For The District Of Rhode Island

BRIEF FOR APPELLANTS

Noel J. Francisco
Counsel of Record
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
Telephone: (202) 879-3939

Counsel for Appellants R.J. Reynolds Tobacco Company and American Snuff Company

Miguel A. Estrada
Counsel of Record
Michael J. Edney
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
Telephone: (202) 955-8500

Counsel for Appellants Philip Morris USA Inc.; U.S. Smokeless Tobacco Manufacturing Company LLC; U.S Smokeless Tobacco Brands Inc.; and John Middleton Company

Kenneth J. Parsigian
LATHAM & WATKINS LLP
John Hancock Tower, 20th Floor
200 Clarendon Street
Boston, MA 02116
Telephone: (617) 880-4510

Counsel for Appellants Philip Morris USA Inc.; U.S. Smokeless Tobacco Manufacturing Company, LLC; U.S. Smokeless Tobacco Brands, Inc.; and John Middleton Company

Floyd Abrams
Counsel of Record
Joel Kurtzberg
CAHILL GORDON & REINDEL LLP
80 Pine Street
New York, NY 10005
Telephone: (212) 701-3120

Counsel for Appellant Lorillard Tobacco Company

Gerald J. Petros
Counsel of Record
Adam M. Ramos
HINCKLEY ALLEN & SCHNYDER LLP
50 Kennedy Plaza, Ste. 1500
Providence, RI 02903
Telephone: (401) 457-5212

Counsel for Appellant Cigar Association of America, Inc.

James R. Oswald
Counsel of Record
Kyle Zambarano
ADLER POLLOCK & SHEEHAN P.C.
One Citizens Plaza, 8th Floor
Providence, RI 02903
Telephone: (401) 274-7200

Counsel of Record for Appellant National Association of Tobacco Outlets, Inc.; Counsel for Appellants Lorillard Tobacco Company; R.J. Reynolds Tobacco Company; American Snuff Company; Philip Morris USA Inc.; U.S. Smokeless Tobacco Manufacturing Company LLC; U.S. Smokeless Tobacco Brands Inc.; and John Middleton Company

CORPORATE DISCLOSURE STATEMENTS, RULE 26.1

The National Association of Tobacco Outlets, Inc. is a Minnesota non-profit corporation qualifying under Section 501(c)(6) of the Internal Revenue Code. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

Plaintiff Cigar Association of America, Inc. is an active New York corporation with headquarters in Washington, D.C., has no parent corporations, and no publicly held corporation owns 10% or more of its stock.

Lorillard Tobacco Company is a wholly-owned subsidiary of Lorillard, Inc. Shares of Lorillard, Inc. are publicly traded. No other publicly held corporation owns 10% or more of Lorillard Tobacco Company's stock.

R.J. Reynolds Tobacco Co. is a wholly-owned, indirect subsidiary of Reynolds American, Inc. ("RAI"), a publicly held corporation. Brown & Williamson Holdings, Inc. and Invesco Ltd. hold more than 10% of the stock of RAI. British American Tobacco p.l.c. indirectly holds more than 10% of the stock of RAI through Brown & Williamson Holdings, Inc.

Plaintiff American Snuff Company is a wholly-owned subsidiary of RAI, a publicly held corporation. Brown & Williamson Holdings, Inc. and Invesco Ltd. hold more than 10% of the stock of RAI. British American Tobacco p.l.c.

indirectly holds more than 10% of the stock of RAI through Brown & Williamson Holdings, Inc.

Philip Morris USA Inc. is a wholly-owned subsidiary of Altria Group, Inc. Altria Group, Inc. has no parent corporation. Shares of Altria Group, Inc. are publicly traded. No publicly held corporation owns 10% or more of Altria Group, Inc.'s stock.

U.S. Smokeless Tobacco Manufacturing Company LLC is a wholly-owned subsidiary of Altria Group, Inc. Altria Group, Inc. has no parent corporation. Shares of Altria Group, Inc. are publicly traded. No publicly held corporation owns 10% or more of Altria Group, Inc.'s stock.

U.S. Smokeless Tobacco Brands Inc. is a wholly-owned subsidiary of Altria Group, Inc. Altria Group, Inc. has no parent corporation. Shares of Altria Group, Inc. are publicly traded. No publicly held corporation owns 10% or more of Altria Group, Inc.'s stock.

John Middleton Company is a wholly-owned subsidiary of Altria Group, Inc. Altria Group, Inc. has no parent corporation. Shares of Altria Group, Inc. are publicly traded. No publicly held corporation owns 10% or more of Altria Group, Inc.'s stock.

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STATEMENT IN SUPPORT OF ORAL ARGUMENT

Pursuant to Fed. R. App. P. 34(a), Plaintiffs-Appellants respectfully request oral argument. Plaintiffs-Appellants seek to protect their First Amendment rights as guaranteed by the United States Constitution, to guard the federal Government's carefully crafted regulatory scheme governing tobacco product promotion and product standards, and to enforce the limits on municipal authority set down by the Rhode Island General Assembly. These are important legal questions, and oral argument will assist in their precise resolution.

JURISDICTIONAL STATEMENT

Plaintiffs-Appellants' claims that the Providence City Ordinances violate the First Amendment and the Supremacy Clause of the United States Constitution arise under the Constitution and the laws of the United States, over which the district court and this Court have federal question jurisdiction. 28 U.S.C. §§ 1331, 1343(a)(3). The district court and this Court have supplemental jurisdiction over Plaintiffs-Appellants' claims under Rhode Island law. *Id.* § 1367.

This Court has jurisdiction over this appeal from a final judgment of the district court, dated December 10, 2012. 28 U.S.C. § 1291. Plaintiffs-Appellants timely filed their Notice of Appeal and paid the requisite filing fee on January 8, 2013. Fed. R. App. P. 4(a)(1).

STATEMENT OF THE ISSUES

Whether a Providence City Ordinance banning the offer and redemption of tobacco product coupons and multi-product discounts is preempted by the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1331, *et seq.* (the "Labeling Act") (Addendum 53–59) ("Add."), violates the First Amendment of the United States Constitution, and exceeds the City's authority under Rhode Island law.

Whether a Providence City Ordinance banning the sale of flavored tobacco products is preempted by the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (June 22, 2009), codified at 21 U.S.C.

§ 387 ("FSPTCA") (Add. 67–80), and exceeds the City's authority under Rhode Island law.

STATEMENT OF THE CASE

I. Providence Passed Two Ordinances Regulating Tobacco Products And Promotion.

On January 5, 2012, the Providence City Council enacted two ordinances that contravene the careful federal regulatory scheme governing tobacco product promotion and product standards, violate the First Amendment, and ignore the limits on municipal authority established by Rhode Island law. The first, "An Ordinance Amending Section 14-300 and Section 14-303 of Article XV of Chapter 14 of the Code of Ordinances of the City of Providence, Entitled: 'Licenses – Tobacco Dealers'" (the "Promotion Ordinance") bans the offer and redemption of tobacco product coupons and multi-pack discounting. Providence Code of Ordinances §§ 14-300, 14-303 (Add. 47–49). The second, "An Ordinance Amending Article XV of Chapter 14 of the Code of Ordinances of the City of Providence, Entitled: 'Licenses' by Adding Thereto the Following Sections" (the "Flavor Ordinance"), bans "flavored tobacco products" in the City of Providence. *Id.* §§ 14-308–14-310 (Add. 50–52).

A. The Promotion Ordinance

The Promotion Ordinance forbids any licensed tobacco retailer to:

> accept or redeem, offer to accept or redeem, or cause or hire any person to accept or redeem or offer to accept or redeem any coupon

> that provides any tobacco products without charge or for less than the listed or non-discounted price.

Providence Code of Ordinances § 14-303 ¶ 3(1) (Add. 48). It further prohibits any tobacco retailers to

> sell tobacco products to consumers through any multi-pack discounts . . . or otherwise provide or distribute to consumers any tobacco products without charge or for less than the listed or non-discounted price in exchange for the purchase of any other tobacco product.

Id. § 14-303 ¶ 3(3) (Add. 49).

The Promotion Ordinance does not set a minimum price for tobacco products or directly regulate tobacco prices. For example, under the Ordinance, a retailer may unilaterally lower prices on a pack of cigarettes from $10 to $8, but may *not* offer or honor a coupon that describes the *same* $2 price discount as lower than the "listed or non-discounted" price of $10 per package. The Ordinance thus regulates what is said about prices and discount promotions, not the prices themselves.

The Promotion Ordinance has separate provisions covering both "cigarettes" and "tobacco products," although since cigarettes are included in the definition of "tobacco products," these provisions are redundant. Providence Code of Ordinances § 14-300 ¶ 6 (Add. 48).

B. The Flavor Ordinance

The Flavor Ordinance prohibits the sale of any non-cigarette "flavored tobacco product," except in a "smoking bar." Providence Code of Ordinances §§ 14-308 ¶ 6, 14-309 (Add. 51–52). A "flavored tobacco product" is one that "*contains a constituent* that imparts a characterizing flavor" other than tobacco, menthol, mint or wintergreen. *Id.* § 14-308 ¶¶ 3, 6 (emphasis added) (Add. 50–51). A "constituent" means "any ingredient, substance, chemical or compound, other than tobacco, water or reconstituted tobacco sheet, that is added by the manufacturer to a tobacco product during the processing, manufacture or packing of the tobacco product." *Id.* § 14-308 ¶ 5 (Add. 51). Thus, the Flavor Ordinance regulates tobacco product content by prohibiting the sale of any product to which a manufacturer has added any ingredient that produces a prohibited "characterizing flavor."

The exception for smoking bars, moreover, is extraordinarily narrow, requiring that the business be "devoted to the serving of tobacco products for consumption on the premises, in which the annual revenues generated by tobacco sales are greater than fifty percent (50%) of the total revenue for the establishment." *Id.* § 14-308 ¶ 9 (incorporating R.I. Gen. Laws § 23-20.10-2(15)) (Add. 51). The Rhode Island Division of Taxation identified twenty-one establishments as "smoking bars" in the City of Providence. *See* Declaration of

Kyle Zambarano (Mar. 30, 2012) ¶ 4 ("Zambarano Decl.") (JA 257). Of these, three are now out of business, seven appear not to sell any tobacco-related products, seven sell only hookah, and two do not sell any smokeless tobacco or cigars. *Id.* ¶¶ 9–11 (JA 258–59); Declaration of Robin Laquerre (Mar. 30, 2012) ¶¶ 2–16 ("Laquerre Decl.") (JA 296–300). Only two licensed "smoking bars" in Providence sell any smokeless tobacco or cigars. *See* Laquerre Decl. ¶¶ 15–16 (JA 299–300).

II. The Proceedings Below

On February 13, 2012, Plaintiffs filed a complaint alleging that the Ordinances violated federal and state law. (JA 12–66, Dkt. #1). Acknowledging the seriousness of the claims, the City agreed to stay enforcement of the Ordinances until July 30, 2012, (JA 7, Dkt. #23), later extended to fourteen days after the district court's ruling on the Ordinances' validity, (JA 8, 10, Dkt. #39, #56).

On March 30, 2012, Plaintiffs filed a joint motion for summary judgment, a permanent injunction, and a preliminary injunction. (JA 8, Dkt. #32). The City cross-moved for summary judgment on June 15, 2012. (JA 9, Dkt. #44). The district court held oral argument on the motions on August 22, 2012. On December 10, 2012, the district court issued its order and judgment denying Plaintiffs' motion, and granting Defendants' motion. (Add. 3–39, Dkt. #57).

The district court held that both Ordinances are "economic" regulations that do not limit commercial speech or expressive conduct, and therefore do not implicate Plaintiffs' First Amendment rights. (Add. 18, 19). In doing so, the court itself referred to the coupons and multi-pack discounts banned by the Promotion Ordinance as containing "pricing information" (Add. 17)—communications that constitute core protected commercial speech. *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc*., 425 U.S. 748, 762–64 (1976).

The court asserted that the Flavor Ordinance did not implicate the First Amendment, although it did strike down the Ordinance's ban on describing tobacco products by reference to "concepts such as spicy, arctic, ice, cool, warm, hot, mellow, fresh, and breeze,"—which Plaintiffs challenged on First Amendment grounds. *See* Providence Code of Ordinances § 14-308 ¶ 3 (Add. 50). That provision, the court explained, potentially reached thoughts and ideas, and "serve[d] to confuse rather than clarify the definition" of prohibited products. (Add. 19–20).[1] Because the district court invalidated the concepts term, Plaintiffs-Appellants are not pursuing a First Amendment claim against the Flavor Ordinance

[1] Plaintiffs argued below that the Flavor Ordinance violated the First Amendment, based largely on the Ordinance's ban on describing a tobacco product by reference to certain "concepts." Although the district court styled its order as a denial of summary judgment, it ordered that, "in order to keep the Section 14-309 ban against the sale of flavored tobacco products intact, the provision 'and concepts such as spicy, arctic, ice, cool, warm, hot, mellow, fresh, and breeze' shall be stricken from Section 14-308." (Add. 20).

on appeal. Nor did the City appeal from the district court's partial invalidation of the Ordinance. This issue, therefore, is not before the Court.

The district court held that federal law preempted neither Ordinance. Plaintiffs contended that the Labeling Act, which forbids states and localities from issuing certain regulations with respect to cigarette advertising and promotion, expressly preempts the Promotion Ordinance. The court did not contest that coupons and discounts are "promotion" as that term is used in Section 1334(b) of the Labeling Act. The court instead held that the Promotion Ordinance was a restriction on the "time, place, and manner," rather than the "content," of promotion under Section 1334(c) of the Labeling Act. (Add. 24–26). According to the court, even though the Ordinance prohibits retailers from "offering to redeem" coupons or providing consumers with multi-pack discounts, it "imposes no additional requirements" on the content of cigarette promotions. *Id.*

The district court also held that the FSPTCA did not preempt the Flavor Ordinance. According to the court, the City may ban the sale of any "flavored tobacco product" based on its "constituents," even if that product complies with the "tobacco product standards" established by Congress and FDA. The court so ruled notwithstanding Congress's express preemption of state and local tobacco product standards that are "different from, or in addition to" the federal requirements. 21 U.S.C. § 387p(a)(2)(A) (Add. 80).

Finally, the district court disregarded challenges to both Ordinances based on the limitations on municipal authority under Rhode Island law. The Ordinances amend and are fully integrated into the City's licensing scheme for tobacco retailers, even though Rhode Island law denies municipalities the authority to regulate businesses through licensing systems. The Ordinances' obligations are imposed only on City "licensees," and are enforced through penalties imposed by the City Board of Licenses. The court held that it need not reach that issue because "licensing is implicated only if a violation occurs." (Add. 34). Further, the court held that Rhode Island law did not preempt the Promotion Ordinance. According to the court, the General Assembly's regulation of tobacco sales to minors, the distribution of free tobacco products or coupons to minors and in the proximity of schools, and the use of price discounts by tobacco vendors did not occupy the field of tobacco promotion regulation. (Add. 35–37); (Add. 84–85, 87–88).

STATEMENT OF THE FACTS

I. The Federal Regulatory Scheme

Congress has established a comprehensive legislative framework for regulating tobacco products. Two federal enactments in that scheme are relevant here. The Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1331 *et seq.* (the "Labeling Act"), regulates cigarette advertising and promotion and restricts the authority of states and localities to legislate in this area. Additionally,

the Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 1776 (June 22, 2009), codified at 21 U.S.C. § 387 ("FSPTCA"), provides the Food and Drug Administration ("FDA") with primary regulatory authority over tobacco products and, among other things, sets specific standards for flavored tobacco products.

A. The Labeling Act

Congress enacted the Labeling Act to ensure that (1) the public is "adequately informed" about the health effects of cigarettes, 15 U.S.C. § 1331(1) (Add. 54), and (2) the national economy is "not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health," *id.* § 1331(2)(B) (Add. 54). With respect to enhancing consumer information, the Act forbids "any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes" that do not contain specified warning labels, and prohibits the advertising of cigarettes without these warnings. *Id.* § 1333(a), (b) (Add. 56).

To protect the economy from "diverse" and "nonuniform" regulations, the Labeling Act contains an express preemption provision:

> No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

Id. § 1334(b) (Add. 59). In 2009, Congress added a narrow exception to this provision for "specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes." *Id.* § 1334(c) (Add. 59).

B. The FSPTCA

The FSPTCA amends the Federal Food, Drug and Cosmetic Act to add a new Chapter IX, titled "Tobacco Products," that applies to "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." 21 U.S.C. § 387a(b) (Add. 68). The Act grants authority to FDA to issue and enforce many categories of regulations for tobacco products, *id.* § 387 note (1), (10) (Add. 67), while safeguarding "the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers," *id.* § 387 note (7) (Add. 67).

To this end, the FSPTCA empowers FDA to establish national "tobacco product standards" that it finds are "appropriate for the protection of public health." *Id.* §§ 387g(a)(3)(A), 387j(c)(2) (Add. 73, 78). FDA must consider scientific and other evidence concerning, *inter alia*, (1) "the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard," *id.* § 387g(a)(3)(B)(i) (Add. 74), and (2) "the countervailing effects of the tobacco product standard . . . such as the creation of a significant

demand for contraband." *Id.* § 387g(b)(2) (Add. 74). Tobacco products not in compliance with the standard are deemed "adulterated" and may not be sold in the United States. *Id.* §§ 387b(5), 331(a), (c), 381(e)(1) (Add. 71, 60, 65). Such products, however, may be manufactured in the United States and sold abroad. *Id.* § 381(e)(1) (Add. 65).

The FSPTCA contains a specific federal tobacco product standard that prohibits cigarettes that "contain, as a constituent . . . or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or its smoke." *Id.* § 387g(a)(l)(A) (Add. 73) (the "Federal Flavor Standard"). Congress elected to limit this prohibition to cigarettes and to allow flavored smokeless tobacco and other non-cigarette tobacco products. *Id.* Because of this standard, cigarettes with prohibited flavor characteristics may be manufactured here for sale abroad, but may not be sold in the United States. *Id.* §§ 387b(5), 331(a), (c), 381(e)(1) (Add. 71, 60, 65).

Congress expressly preempted any state or local regulation that establishes requirements "different from, or in addition to," the Federal Flavor Standard, as well as any other tobacco product standard established pursuant to the FSPTCA:

> No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is

> different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

21 U.S.C. § 387p(a)(2)(A) (Add. 80) (the "Preemption Clause"). It is followed by a Saving Clause that provides a limited exception for:

> requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products.

Id. § 387p(a)(2)(B) (Add. 80). The exception is narrow, preserving only the traditional right of state and local governments to impose restrictions relating to sales—those relating to where, when, and how a product may be sold, not *whether* it may be sold at all.

II. Rhode Island State Law Comprehensively Regulates Tobacco Product Coupons And Discounts.

The Rhode Island General Assembly has enacted a regulatory scheme for tobacco product coupons and discounts. State law criminally prohibits selling tobacco products to persons under eighteen-years-old at any price, R.I. Gen. Laws § 11-9-13.8 (Add. 84). It also proscribes "distribut[ing] . . . free tobacco products or coupons or vouchers redeemable for free tobacco products to any person under eighteen" and distributing such products, coupons, or vouchers to any person "regardless of the age of the person . . . within five hundred (500) feet of any school," *id.* § 11-9-13.10 (Add. 85). Further, Rhode Island's unfair sales practices

laws regulate how businesses can utilize price discounts and other promotions by, for example, making it "unlawful to use, communicate, or publish any advertisement that states that an item or product is being sold or offered for sale at below the regular price . . . without posting the regular price at the point of purchase." *Id.* § 6-13-11 (Add. 87). Tobacco retailers who violate the state's unfair sales practices laws are subject to punishment through the state tobacco licensing law. *See id.* § 44-20-8 (Add. 88). The General Assembly has chosen not to prohibit the use of tobacco coupons and discount offers with respect to adults, as long as those promotional materials are distributed outside a 500-foot radius of a school.

SUMMARY OF ARGUMENT

The Ordinances transgress well-established limitations on the authority of the City. *First*, the Ordinances are preempted by federal law because they subvert the exclusive power of the federal Government to regulate the content of cigarette advertising and promotion and to establish tobacco product standards.

The Promotion Ordinance forbids the acceptance, redemption of, or offer to redeem coupons and multi-pack discounts for tobacco products in Providence. But the Labeling Act reserves to the federal Government the authority to establish "requirement[s] or prohibition[s] . . . with respect to the advertising or promotion of any cigarettes." 15 U.S.C. § 1334(b) (Add. 59). Contrary to the district court's

one-paragraph holding, the Ordinance is not merely a restriction on "the time, place, and manner" of cigarette promotion. *Id.* § 1334(c) (Add. 59). Rather, it dramatically restricts promotions based on their *content*—banning certain promotions solely because they communicate that the offered price is less than the regular "listed" price. That is expressly forbidden by Section 1334(c).

The Flavor Ordinance attempts to expand the federal Government's flavored tobacco standard to cover smokeless tobacco and other non-cigarette tobacco products. The FSPTCA, however, sets forth the federal Government's exclusive authority to establish national tobacco product standards and preempts States and municipalities from attempting to change or expand them. 21 U.S.C. §§ 387g(a)(3)(A); 387p(a)(2)(A) (Add. 73, 80). The district court salvaged the Ordinance by claiming that it prohibited the sale of flavored tobacco products, not their manufacture or content. But the court's ruling ignores the plain language and practical effect of the Ordinance. The Flavor Ordinance prohibits the sale of any non-cigarette tobacco product that "contains a constituent that imparts a characterizing flavor," and defines a constituent as "any ingredient . . . that is added by the manufacturer . . . during the [product's] processing, manufacture or packaging." Providence Code of Ordinances § 14-308 ¶¶ 5, 6 (Add. 51–52). It functions the same as the Federal Flavor Standard by prohibiting the sale of

products based on their content, but it applies to non-cigarette products that the Federal Flavor Standard does not.

Second, the Promotion Ordinance unjustifiably restricts commercial speech in violation of the First Amendment. The district court erroneously held that the Ordinance does not even implicate the First Amendment. But the Ordinance does not regulate what a retailer may charge for a product: It sets no minimum price for tobacco products. Rather, the Ordinance regulates what is said about the price: It prohibits telling consumers that a product price is less than the regular, non-discounted price. Communicating pricing information to consumers is core commercial speech protected by the First Amendment. *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762–64 (1976). And under applicable First Amendment law—which the district court did not apply given its threshold error—the Promotion Ordinance is a plainly unconstitutional restriction on truthful speech to adults about a lawful product.

Third, the Ordinances ignore the division of authority between the State of Rhode Island and the City. The Rhode Island Supreme Court repeatedly has held that cities may not regulate businesses through municipal licensing schemes. *See, e.g., Amico's Inc. v. Mattos*, 789 A.2d 899, 903 (R.I. 2002). But that is precisely what the Ordinances do. They apply only to City tobacco licensees, and their penalties are imposed only through the City Board of Licenses.

At the same time, the Rhode Island General Assembly comprehensively has regulated coupons and discount offers for tobacco products, forbidding some and permitting others. The City seeks to revise lines drawn by the General Assembly by banning all tobacco product coupons and multi-pack offers. The General Assembly, by contrast, has repeatedly rejected almost identical amendments to the State tobacco coupon and discount laws. The General Assembly has "made provision for the regulation" of tobacco coupons and discount offers and "provided punishment" for violations. *Wood v. Peckham*, 80 R.I. 479, 483, 98 A.2d 669, 670 (1953). In Rhode Island, that means that additional City regulations of tobacco coupons and discount offers are preempted. *Id.*

ARGUMENT

This Court must "review a grant or denial of summary judgment by the district court *de novo*." *OneBeacon Am. Ins. Co. v. Commercial Union Assurance Co. of Can.*, 684 F.3d 237, 241 (1st Cir. 2012) (citation omitted). "The presence of cross-motions neither dilutes nor distorts [the *de novo*] standard of review." *Mass. Museum of Contemporary Art Found., Inc. v. Buchel*, 593 F.3d 38, 52 (1st Cir. 2010) (internal quotation marks omitted). Summary judgment is appropriate when, "construing the evidence in the light most favorable to the non-movant, there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

I. The Promotion Ordinance Is Preempted By The Labeling Act.

Under the Constitution's Supremacy Clause, a state or local law is void if it conflicts with federal law. U.S. Const. art. VI, cl. 2. Here, the Promotion Ordinance is expressly preempted by the Labeling Act.

A. The Promotion Ordinance Meets The Criteria For Express Preemption Under The Labeling Act.

The Labeling Act provides that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter." 15 U.S.C. § 1334(b) (Add. 59). The Promotion Ordinance satisfies all of the elements of Section 1334(b).

First, the Promotion Ordinance imposes "prohibition[s]" in Section 14-303 (Add. 48), entitled "*Prohibitions* applicable to license holders, their employees and agents" (emphasis added). Such individuals are forbidden from accepting or redeeming, or offering to accept or redeem, cigarette coupons and from selling cigarettes through "multi-pack discounts." Providence Code of Ordinances § 14-303 ¶3(2), (4) (Add. 49).

Second, the Promotion Ordinance is "based on smoking and health." The Labeling Act "prohibit[s] state cigarette advertising regulations *motivated* by concerns about smoking and health" and, as the Supreme Court explained, "concern about youth exposure to cigarette advertising is intertwined with the

concern about cigarette smoking and health." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 548 (2001) (emphasis added). In its Answer, the City admitted "that the Promotion Ordinance was designed, in part, to deal with the problem of underage tobacco consumption." Answer ¶ 57 (JA 71); *see also* Defs. Statement of Disputed Facts ¶ 3 (JA 481) (conceding that "[t]he Ordinances were motivated in part by concerns about smoking and health . . . ."). This is consistent with the legislative debate leading to the Ordinance's enactment. The Mayor's Director of Policy laid out the City's "motivations," describing the Promotion Ordinance as a "great step[] towards reducing the public health costs and the pain associated with nicotine addiction." Committee Tr. 16 (JA 517).

Third, the Promotion Ordinance is "with respect to the advertising or promotion" of cigarettes. The "with respect to" language of the Labeling Act has been interpreted by courts to have a broad meaning. *See Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 520–521 (1992) (plurality op.) (noting the 1969 amendments "broad[ened]" the Labeling Act); *Vango Media, Inc. v. City of New York*, 34 F.3d 68, 74 (2d Cir. 1994) (endorsing a "broad effect" of the language in accordance with its "plain meaning"). Here, there can be little doubt that the Promotion Ordinance is "with respect to" "advertising or promotion."

The Promotion Ordinance itself defines key terms in relation to the promotion and advertising of cigarettes. For example, "[c]oupon" is defined as

"any card, paper, note, form, statement, ticket or other issue distributed for commercial or *promotional* purposes." Providence Code of Ordinances § 14-300 ¶ 3 (Add. 47) (emphasis added). "Listed or non-discounted price" is defined as the price listed on a "package" or "any related shelving, posting, *advertising* or display," whichever is higher. *Id.* ¶ 4 (emphasis added). In a survey conducted in connection with this case, the City itself refers to a "buy-one-get-one-free" offer as a "promotion," *see* Price Survey Report 3 (JA 339), and the City's expert, Frank J. Chaloupka, describes both "buy-three-get-three free ('six pack') discounts" and "coupons" as "promotions," Chaloupka Aff. ¶ 48 (JA 553–54).

The Second and Eighth Circuits and the Federal Trade Commission ("FTC") have determined that cigarette advertising and promotion includes coupon and discount offers. In *23-34 94th St. Grocery Corp. v. New York City Board of Health*, 685 F.3d 174 (2d Cir. 2012), the Second Circuit said that the "[d]istribution of coupons and free samples . . . would *obviously* be classified as promotional activity as they further the sale of merchandise." *Id.* at 182 (emphasis added). Likewise, in *Jones v. Vilsack*, the Eighth Circuit held that the term "promotion" encompasses "[a]ll forms of communication other than advertising that call attention to products and services by adding extra values towards the purchase. [It i]ncludes *temporary discounts*, allowances, premium offers, *coupons*, contests, sweepstakes, etc." 272 F.3d 1030, 1036 (8th Cir. 2001) (citation omitted)

(emphases added); *see also Rockwood v. City of Burlington*, 21 F. Supp. 2d 411, 420 (D. Vt. 1998) (local law that "prohibits the distribution of free samples or coupons" preempted by the Labeling Act). And the FTC's annual report describes "coupons" and "[r]etail-value-added expenditures . . . such as 'buy one, get one free'" as types of "domestic cigarette advertising and promotional expenditures." *See* FTC, *Cigarette Report for 2007 and 2008* 6, tables 2A & 2B (2011), *available at* http://www.ftc.gov/os/ 2011/07/110729cigarettereport.pdf.

Accordingly, the Promotion Ordinance falls squarely within the Labeling Act's express preemption provision, 15 U.S.C. § 1334(b) (Add. 59).

B. The Promotion Ordinance Restricts The Content Of Cigarette Promotions, And Is Not Simply A Time, Place, And Manner Restriction.

The district court did not dispute that the Promotion Ordinance imposed prohibitions, based on smoking and health, with respect to cigarette promotion. Instead, it summarily concluded that the Promotion Ordinance was valid under a saving clause added to the Labeling Act in 2009, which allows states to "impos[e] specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes." 15 U.S.C. § 1334(c) (Add. 59).

The language of 15 U.S.C. § 1334(c) (Add. 60), allowing restrictions based on "time, place, and manner, but not content," is drawn from First Amendment jurisprudence, and long-standing case law informs its meaning. *Neder v. United*

States, 527 U.S. 1, 21 (1999) ("Where Congress uses terms that have accumulated settled meaning under the common law, a court must infer, unless the statute otherwise dictates, that Congress means to incorporate the established meaning of these terms." (internal quotation marks and alterations omitted)). This jurisprudence establishes a narrow *exception* to restrictions on *speech*. *See Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989) ("[T]he government may impose reasonable restrictions on the time, place, or manner of protected speech, provided the restrictions 'are justified without reference to the content of the regulated speech, that they are narrowly tailored to serve a significant governmental interest, and that they leave open ample alternative channels for communication of the information.'") (citation omitted). To qualify as a valid "time, place, and manner" restriction on *speech*, the restriction must be content-neutral. *See Linmark Assocs., Inc. v. Township of Willingboro*, 431 U.S. 85, 94 (1977). Here, for numerous reasons, Section 1334(c) is inapplicable.

First, "laws that by their terms distinguish favored speech from disfavored speech on the basis of the ideas or views expressed are content based." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 643 (1994); *see also*, *e.g.*, *Heffron v. Int'l Soc'y. for Krishna Consciousness, Inc.*, 452 U.S. 640, 649 (1981) (holding regulation not content-based because it "applies evenhandedly to all who wish to distribute and sell written materials or to solicit funds"); *Va. Pharmacy Bd.*, 425

U.S. at 771 (holding that law was not a time, place, or manner restriction because it "singles out [advertising] of a particular content"). Here, the Promotion Ordinance is content-based because it attacks only coupons and discounts that reference a specific subject matter—tobacco.

Second, the Promotion Ordinance is also content-based because it prohibits only certain promotions: Coupons and multi-pack discounts that tell consumers that prices offered are less than regular non-discounted prices of tobacco products. *See* Providence Code of Ordinances § 14-303 ¶ 3(2) (Add. 49) (forbidding the offer, acceptance, or redemption of coupons to purchase cigarettes "for less than the listed or non-discounted price"); *id.* at ¶ 3(4) (Add. 49) (forbidding the use of multi-pack discounts for cigarettes "for less than the listed or non-discounted price"). Significantly, it does not forbid price discounting generally; manufacturers and retailers are free to reduce their prices. Instead, it prohibits manufacturers and retailers from conveying the particular message, "you're getting a bargain." But when a "ban is predicated on the content" of the message, as this one is, "it is not a valid time, place, or manner restriction on protected speech." *City of Cincinnati v. Discovery Network*, 507 U.S. 410, 430 (1993).

Third, it is well-established that regulations targeting the "primary effects" of speech are content-based restrictions. *City of Los Angeles v. Alameda Books*, 535 U.S. 425, 433–35 (2002) (plurality op.). Conversely, regulations targeting the

"secondary effects" of speech—such as "crime rates, property values, and the quality of [a] city's neighborhoods"—are time, place, and manner restrictions. *Id.* at 434. Here, the Promotion Ordinance does not target the secondary effects of the banned promotions, like coupons littering the streets. Instead, it targets the "primary effect" of these practices—the alleged convincing of adult consumers to purchase tobacco products.

The district court did not address any of these issues. Instead, it held that the Promotion Ordinance does not "preclude the Plaintiffs from disseminating . . . coupons within the City, whether for promotional purposes or otherwise; instead, it only prohibits the redemption of coupons." (Add. 25). The district court thus held that the Promotion Ordinance was not a restriction on speech or promotion at all, and for that reason alone, was saved by Section 1334(c). *See id.* This is wrong for three reasons.

First, it is wrong because the Ordinance, by its express terms, forbids licensees to "accept or redeem, *offer* to accept or redeem, or cause or hire any person to accept or redeem or *offer* to accept or redeem any coupon." Providence Code of Ordinances § 14-303 ¶ 3(2) (Add. 49) (emphasis added). Moreover, a retailer offering a coupon or discount it cannot redeem arguably has engaged in an illegal deceptive trade practice. *See* 15 U.S.C. § 45; *see also*, *e.g.*, *FTC v. Magazine Solutions, LLC*, 432 F. App'x. 155, 157 (3d Cir. 2011) (affirming

judgment against a telemarketer who offered coupons to consumers who then "had difficulty redeeming them, or couldn't redeem them for their full value"). The Ordinance thus expressly restricts both speech and promotions.

Second, if the district court were correct that the Ordinance does not regulate speech or promotions at all, then Section 1334(c)'s saving clause would be entirely inapplicable. The Promotion Ordinance is preempted by Section 1334(b), which applies to speech and non-speech restrictions alike provided only that they are "with respect to" the "promotion" of cigarettes. (Add.59). The saving clause in Section 1334(c), in contrast, is narrower. It saves only (1) "bans or restrictions on . . . *the advertising or promotion* of any cigarettes," and then, (2) *only* if those bans and restrictions constitute "time, place, and manner" restrictions. 15 U.S.C. § 1334(c) (Add. 59) (emphasis added). The referenced "time, place, and manner" restrictions, moreover, encompass a category of permissible "restrictions on . . . protected *speech*." *Ward*, 491 U.S. at 791 (emphasis added). Consequently, if the Promotion Ordinance either (1) does not restrict "advertising and promotion" or (2) does not restrict speech (or both, as the district court held here), then the Section 1334(c) saving clause does not apply. Accordingly, even under the rationale adopted by the district court, the Promotion Ordinance is preempted.

Third, whether the Ordinance is "with respect to" cigarette promotion must be judged by its practical effect. As the Second Circuit recently explained in

striking down a New York City ordinance requiring retailers to append health warning signs to cigarette product displays, Section 1334 of the Labeling Act preempts a regulation that "is practically the same as" a direct regulation of a cigarette promotion's content. *23-34 94th St. Grocery Corp.*, 685 F.3d at 183. The district court's suggestion that Providence retailers might still distribute coupons that can only be redeemed elsewhere makes no practical or business sense. No rational retailer would do such a thing, for it would only drive business away from his store by encouraging consumers to make their purchases outside the City where they can use the coupon, defeating the purpose for offering the promotion in the first place. The district court ignores the practical effect of the Ordinance, which is to eliminate the distribution and redemption of coupons by Providence retailers based on their content.

C. The Entire Promotion Ordinance Is Preempted By The Labeling Act.

Finally, although the Labeling Act applies only to cigarettes, the Act requires invalidation of the entire Promotion Ordinance. Rhode Island courts will strike a portion of legislation and leave the remainder intact only if doing so will not destroy the intent of a legislative body. *See Landrigan v. McElroy*, 457 A.2d 1056, 1061 (R.I. 1983); *see also Bouchard v. Price*, 694 A.2d 670, 678 (R.I. 1997) (denying severance where the invalid portion is "indispensable to the rest of the act and [could not] be severed without destroying legislative intent").

Here, the City cannot carry that heavy burden, because the regulation of cigarette promotion is integrated throughout the text of the Promotion Ordinance. Two provisions of the Promotion Ordinance ban coupons and multi-pack discounts for cigarettes only. *See* Providence Code of Ordinances § 14-303 ¶ 3(2), (4) (Add. 49). But the parallel provisions for "tobacco products" also include cigarettes. *See id.* § 14-303 ¶ 3(1), (3) (Add. 48–49); *id.* § 14-300 ¶ 6 (Add. 48) (defining "[t]obacco products" as "any substance containing tobacco leaf, including, but not limited to *cigarettes*.") (emphasis added). Any attempt to sever cigarettes from the rest of the Promotion Ordinance would require this Court to leave "gaping loopholes" in the Ordinance text. *Randall v. Sorrell*, 548 U.S. 230, 262 (2006) (opinion of Breyer, J.).

It is doubtful that the City Council would have enacted the Promotion Ordinance without covering cigarettes. Cigarettes are by far the highest-volume tobacco product and the largest asserted public-health risk. Indeed, the legislative record reflects a City Council fixated on "smoking," not smokeless tobacco. *See*, *e.g.*, Committee Tr. 17 (JA 324) ("The most effective policy that communities have had to curb *smoking* rates and the pain and cost that they bring about in communities is taxation and the increase in overall pack price.") (emphasis added); *id.* (criticizing "pricing discounts to cushion the blow for new *smokers* and existing *smokers*") (emphases added). The Court therefore should find the entire

Promotion Ordinance preempted, and let the democratically elected City Council decide whether to reenact another version of the Ordinance without targeting cigarettes.

II. The Promotion Ordinance Violates The First Amendment.

The Promotion Ordinance also violates the First Amendment because it bans protected commercial speech and fails to survive scrutiny under the *Central Hudson* test. *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). [2] The district court held otherwise only because it believed that the Promotion Ordinance does not restrict speech at all. Having so concluded, it did not apply *Central Hudson*. The district court erred.

A. The Promotion Ordinance Restricts Commercial Speech.

The communication of pricing information, including through common marketing techniques such as coupons and other forms of discounts, is the essence

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[2] Plaintiffs believe that content-based commercial speech restrictions should be governed by strict scrutiny. In recent years, the Supreme Court has indicated an increasing willingness to apply strict scrutiny to commercial speech. *See*, *e.g.*, *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1342 (2010) ("I have never been persuaded that there is any basis in the First Amendment for the relaxed scrutiny this Court applies to laws that suppress nonmisleading commercial speech.") (Thomas, J., concurring in part and concurring in the judgment); *see also Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2664 (2011) ("The First Amendment requires heightened scrutiny whenever the government creates a regulation of speech because of disagreement with the message it conveys. . . . Commercial speech is no exception." (internal quotation marks omitted)). Although Plaintiffs expressly preserve this issue for later review, this brief applies controlling precedent.

of commercial speech. *See Va. Pharmacy Bd.*, 425 U.S. at 761–64. As the Supreme Court has explained, a consumer's interest in pricing information "may be as keen, if not keener by far, than his interest in the day's most urgent political debate." *Id.* at 763; *see also S. Ogden CVS Store, Inc. v. Ambach*, 493 F. Supp. 374, 379–80 (S.D.N.Y. 1980) (coupons and discount advertisements constitute protected commercial speech).

In *Bailey v. Morales*, for example, the Fifth Circuit held a ban on free "promotional gifts and items" was a restriction on "commercial speech" because the gifts and items were promoted with "an intent to convey a particularized message: hire me, try my service," and because "those who receive the money or anything of value are likely to understand the message because rebates, free samples and risk-free trials of products are common marketing tools." 190 F.3d 320, 321, 325 (5th Cir. 1999). Likewise, in *Discount Tobacco City & Lottery v. United States*, 674 F.3d 509 (6th Cir. 2012), *cert. denied*, No. 12-521, 2013 WL 1704718 (U.S. Apr. 22, 2013), the Sixth Circuit held that offers of free tobacco product samples and giving free gifts with tobacco product purchases "[we]re protected speech because they [we]re promotional methods that convey the twin messages of reinforcing brand loyalty and encouraging switching from competitors' brands." *Id.* at 538 (internal quotation marks omitted). Other courts have reached the same conclusion with regard to coupon bans, like the Promotion

Ordinance. *See*, *e.g.*, *Rockwood*, 21 F. Supp. 2d at 421–23 (restrictions on "coupons redeemable for tobacco products or promotional materials" restricted commercial speech).

Here, by its own terms, the Promotion Ordinance concerns classic commercial speech—promotion and advertising. A "[c]oupon" is defined as "any card, paper, note, form, statement, ticket or other issue distributed for commercial or *promotional* purposes." Providence Code of Ordinances § 14-300 ¶ 3 (Add. 47) (emphasis added). The district court likewise recognized that the Promotion Ordinance restricts common marketing techniques used to promote products, referring to "coupons, multi-pack *offers* or other *price discounting information*" as well as "coupons and multi-pack *pricing information.*" (Add. 16–17) (emphasis added). In short, like other laws banning coupons, discounts, and free gifts, the Promotion Ordinance restricts commercial speech.

The district court's contrary reasoning is erroneous. *First*, the district court held that the Promotion Ordinance does not affect speech because it "regulates" only "commercial activity" and not "communication regarding that activity." (Add. 14). But this squarely contradicts the case law above. As the Sixth Circuit explained in *Discount Tobacco*, where a governmental restriction "is an attempt to regulate the 'communicative impact' of the activity, not the activity itself," then it is restricting commercial speech. 674 F.3d at 539. That is the case here, where

"[t]he government has not articulated an interest in generally regulating" the redemption of coupons or multi-item discounts, "[n]or has it articulated an interest in regulating the act of providing" coupons or multi-item discounts "across consumer categories." *Id.* Instead, it is prohibiting this activity in order to blunt the communicative effect of these common marketing tools.[3]

Second, the district court held that the Promotion Ordinance does not "regulate 'what is said about prices.'" (Add. 14). But that is precisely what the Ordinance regulates. As explained in part I.B, *supra*, the Promotion Ordinance prevents manufacturers and retailers from communicating the message, "the price you're getting is less than the regular price" or "you're getting a bargain." Contrary to the district court's assertion, the Ordinance is not "a means to control the price of cigarettes and tobacco products in Providence." (Add. 14). It does not, for example, prevent manufacturers and retailers from cutting prices 20%. Instead, it prohibits them from using coupons or multi-product discounts to *communicate to consumers the message* that they can purchase tobacco products for 20% less than their regular price. This is clearly a restriction on speech.

[3] The communicative impact of these tools is plain. Because they communicate to consumers that they are getting a bargain, consumers *prefer* them over "everyday low prices"—even where those prices *are the same or lower* than discounts achieved through promotions. *See*, *e.g.*, Judith A. Garretson & Scot Burton, *Highly Coupon and Sale Prone Consumers: Benefits Beyond Price Savings*, 43 J. Advert. Res. 162, 162–63, 170 (2003).

Third, the court stated that "nothing in [the Promotion Ordinance] forbids the *dissemination* of coupons within the City, it prohibits only the *acceptance or redemption* of such coupons and the sale of tobacco products or cigarettes through multi-pack or bundled discounts." (Add. 14). This is incorrect. The Ordinance *does* prohibit the dissemination of certain coupons—specifically, those that say they can be redeemed at stores in Providence. *See* Providence Code of Ordinances, § 14-303 ¶ 3(1)–(2) (Add. 48–49) ("[n]o person . . . shall" either "accept or redeem . . . or *offer to accept or redeem* any coupon.") (emphasis added). Even if the court's claim were correct, the effect of such a ban is to burden *communicative* activity—that is, communicating to consumers that a deal is available that will enable them to buy a product for less than its regular price. A restriction on *redeeming* coupons thus burdens retailers' and manufacturers' ability to *communicate* a particular commercial message. Further, a retailer who distributes coupons that it is precluded from honoring arguably violates other laws, and, in all events, would be acting contrary to its own economic and competitive self-interest. Thus, the only likely effect of the Ordinance is to silence the targeted speech.

Accordingly, the Promotion Ordinance is clearly a speech restriction subject to *Central Hudson*.

B. The Promotion Ordinance Does Not Satisfy *Central Hudson*.

Under *Central Hudson*, when a regulation restricts non-misleading commercial speech about a lawful product, it is invalid unless the government affirmatively proves that the law (1) serves a substantial governmental interest, (2) directly and materially advances that interest, and (3) is no more extensive than necessary to serve that interest. 447 U.S. at 566. Here, the Ordinance restricts non-misleading speech about a lawful product, and cannot withstand scrutiny under *Central Hudson*.

First, the Promotion Ordinance does not further a substantial governmental interest. The City's stated purpose is to reduce underage tobacco use. *See* Answer ¶ 57 (JA 71); Committee Tr. 17–18, 24 (JA 324–25, 331). Although that interest is substantial, the Promotion Ordinance bears no relation to it. The legislative record does not show there is even a real problem with underage persons in Providence using coupons or multi-pack discounts to buy tobacco. *See* Declaration of Cecil R. Reynolds ¶ 62 ("Reynolds Decl.") (JA 123); *Turner Broad.*, 512 U.S. at 664 (The Government "must demonstrate that the recited harms are real, not merely conjectural, and that the regulation will in fact alleviate these harms in a direct and material way."). To the contrary: Rhode Island law already bans the distribution of coupons for free tobacco products to persons under eighteen, *see* R.I. Gen. Laws § 11-9-13.10 (Add. 85), and the sale of tobacco products to such persons *at any*

price, *see id.* §§ 11-9-13, 11-9-13.8 (Add. 83–84). The Promotion Ordinance's only addition to existing law is to restrict *lawful* communications to adults about pricing and promotional offers. *See Brown v. Entm't Merchs. Ass'n*, 131 S. Ct. 2729, 2740–41 (2011) (the incremental benefit provided over existing law must justify a restriction on speech).

The City has no legitimate interest in restricting non-misleading speech about lawful products *to adults*. As the Supreme Court recently held, the government "may not seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, nonmisleading" marketing of that product. *Sorrell*, 131 S. Ct. at 2671. "That the State finds expression too persuasive does not permit it to quiet speech or to burden its messengers." *Id.*; *see also 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 513 (1996) (plurality op.) (there is no "vice" exception under the First Amendment). Instead, if the City is "displeased" by the effectiveness of commercial speech, it "can express that view through its own speech. But [the City's] failure to persuade does not allow it to hamstring the opposition[,] . . . to tilt public debate in a preferred direction." *Sorrell*, 131 S. Ct. at 2671 (citation omitted); *see also*, *e.g.*, *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Worcester*, 851 F. Supp. 2d 311, 316 (D. Mass. 2012) ("[T]he City has no legitimate interest in prohibiting non-misleading advertising to adults to prevent them from making decisions of which the City disapproves.").

Second, "the State bears the burden of showing not merely that its regulation will advance its interest, but also that it will do so 'to a material degree.'" *44 Liquormart*, 517 U.S. at 505 (plurality op.) (citation omitted). Here, however, the City cannot demonstrate that the Promotion Ordinance directly and materially advances any interest in reducing underage tobacco use. The legislative record contains no evidence that underage persons in Providence are using coupons or multi-pack discounts to purchase tobacco products illegally from licensed retailers. Nor is there evidence that these promotions cause more underage persons to start using tobacco products. *See* Reynolds Decl. ¶¶ 61–70 (JA 122–28). Indeed, underage persons are particularly *unlikely* to use coupons to purchase tobacco products, since such use would draw attention to their *illegal* activity. *See id.* ¶¶ 62, 68–69 (JA 123, 127).

To be sure, there is evidence that, as the price of tobacco goes up, rates of tobacco use go down. *See* Chaloupka Aff. ¶¶ 12–25 (JA 530–40); Reynolds Decl. ¶¶ 68, 80, 82 (JA 127, 134–35). The Promotion Ordinance, however, does not establish a price floor; it simply bars manufacturers and retailers from *communicating* the fact that the prices being offered are lower than the regular price. Nor did the City introduce any evidence that eliminating these promotions would cause prices to rise. To the contrary, if manufacturers and retailers cannot conduct targeted promotions through coupons, the only alternative may be to

engage in across-the-board price reductions. *See* Reynolds Decl. ¶ 69 (JA 127). This would make tobacco products less expensive for everyone, including youth. The Promotion Ordinance therefore could well *increase* underage tobacco use.

To the extent that the Promotion Ordinance is an attempt to reduce tobacco use by lowering prices, it is an *indirect* way to do so. Rather than regulating prices directly—*e.g.*, by setting a minimum price—the Ordinance prohibits only certain promotions that are designed to convey to consumers that a discount is being offered. The Ordinance thus fails to satisfy *Central Hudson*'s requirement that it *directly* advance a governmental interest. *See Cent. Hudson*, 477 U.S. at 566.

The Ordinance's many loopholes also make it doubtful that it would directly and materially reduce underage tobacco use. The Ordinance, for example, prohibits "coupons" when "surrendered by the bearer," Providence Code of Ordinances § 14-300 ¶ 3, but *does not* prohibit *other* price-reducing promotions, such as "discount cards," which are scanned by retailers but retained by consumers. Laws with such loopholes cannot satisfy *Central Hudson*. *See*, *e.g.*, *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 488 (1995) (restrictions on beer alcohol content disclosure struck down when still permitted for other types of alcohol).

Finally, the Promotion Ordinance is more restrictive than necessary to serve any purported governmental interest. *Cent. Hudson*, 447 U.S. at 566. Under this

narrow tailoring requirement, if "the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government *must do so*." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002) (emphasis added).

Under narrow tailoring, the City may not broadly prohibit speech to everyone, including adults, because it wants to prohibit that speech from reaching the underaged. *See*, *e.g.*, *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 74 (1983) ("The level of discourse reaching a mailbox simply cannot be limited to that which would be suitable for a sandbox."); *Butler v. Michigan*, 352 U.S. 380, 383 (1957) (government may not "reduce the adult population . . . to reading only what is fit for children"). That, however, is precisely what the Ordinance does. In attempting to prevent youth from illegally purchasing tobacco products, it prevents manufacturers and retailers from using common marketing tools to reach adult customers. This restriction is all-the-more problematic because there is no evidence that coupons are being used by youth or otherwise persuading them to illegally purchase and use tobacco products.

In addition, there are numerous other non- and less-speech restrictive ways to reduce underage tobacco use, including: (1) engaging in a counter-marketing campaign; (2) working with the State of Rhode Island to increase enforcement of existing state laws prohibiting minors from purchasing and consuming such

products, *see* R.I. Gen. Laws §§ 11-9-13, 11-9-14 (Add. 83, 86); (3) enhancing the penalties for retailers who sell tobacco products to minors in violation of state law; and (4) increasing financial support for the numerous programs that have been demonstrated to reduce underage tobacco use. *See* Reynolds Decl. ¶¶ 78–80 (JA 131–35) (describing numerous alternatives). The City did not show "why these possibilities, alone or in combination, would be insufficient" to further any interest in reducing underage tobacco usage. *W. States Med. Ctr.*, 535 U.S. at 373. That, however, is the least Providence must do before trampling the free speech rights of private parties. As the Supreme Court has repeatedly held, "[i]f the First Amendment means anything, it means that regulating speech must be a last—not first—resort." *Id.*; *see also*, *e.g.*, *Rubin*, 514 U.S. at 490–91 (ban on beer alcohol content advertising not narrowly tailored given "several alternatives . . . all of which could advance the Government's asserted interest in a manner less intrusive to respondent's First Amendment rights"); *In re R.M.J.*, 455 U.S. 191, 206–07 (1982) (restriction on attorney advertising not narrowly tailored because "[t]here [was] no indication in the record" "that restrictions short of an absolute prohibition would not have sufficed to cure any possible deception").

C. The Promotion Ordinance Does Not Satisfy *United States v. O'Brien*.

Even if Plaintiffs' promotion of tobacco products could be considered "conduct" and not speech, that conduct would still be subject to *Central Hudson*.

Central Hudson applies to laws regulating conduct, provided that the laws are designed to regulate the communicative impact of advertisements or promotions. *See Lorillard*, 533 U.S. at 567 (applying *Central Hudson* to "height requirement" placed on indoor tobacco advertising because the height restriction was "an attempt to regulate directly the communicative impact of indoor advertising"). The Ordinance targets the message that the conduct conveys—namely, "buy this product because it is priced at a discount."

In any event, the test applicable to bans on expressive conduct established by *United States v. O'Brien*, 391 U.S. 367, 377 (1968), largely overlaps with the *Central Hudson* test. *See United States v. Edge Broad. Co.*, 509 U.S. 418, 429 (1993) ("[T]he validity of restrictions on commercial speech should not be judged by standards more stringent than those applied to expressive conduct entitled to full First Amendment protection or to relevant time, place, or manner restrictions."); *S.F. Arts & Athletics, Inc. v. U.S. Olympic Comm.*, 483 U.S. 522, 537 n.16 (1987) ("Both this [commercial speech] test and the test for a time, place, or manner restriction under *O'Brien* require a balance between the governmental interest and the magnitude of the speech restriction. Because their application to these facts is substantially similar, they will be discussed together."). Both tests require the government to advance a "substantial" "governmental interest," *Cent. Hudson*, 447 U.S. at 566; *O'Brien*, 391 U.S. at 377, and require the regulations to

be "no greater than is essential to the furtherance of [the governmental] interest," *O'Brien*, 391 U.S. at 377; *Cent. Hudson*, 447 U.S. at 566. In addition, to satisfy *O'Brien*, the regulation must be "within the constitutional power of the Government" and the governmental interest must be "unrelated to the suppression of free expression." 391 U.S. at 377.

The Promotion Ordinance fails the *O'Brien* standard. First, the City's asserted interest in passing the Promotion Ordinance is related to the suppression of free expression because the City is attempting to prevent consumers from hearing about certain promotions the City fears will persuade them to buy tobacco. Second, the Ordinance restricts First Amendment freedoms more than is "essential to the furtherance of [the government's stated] interest," *O'Brien*, 391 U.S. at 377, for the same reasons that it fails to satisfy prongs three and four of *Central Hudson*. Consequently, whether regulating expressive conduct or commercial speech, the Promotion Ordinance is unconstitutional.

III. The Flavor Ordinance Is Preempted By The FSPTCA.

The district court found the Flavor Ordinance flawed in part and invalidated its prohibition on describing any tobacco product by reference to "concepts such as spicy, arctic, ice, cool, warm, hot, mellow, fresh, and breeze." (Add. 20) (internal quotation marks omitted). The court should have invalidated the entire Flavor Ordinance because it is preempted by the FSPTCA. The district court's order to

the contrary violates several Supreme Court preemption precedents explaining that it is the *practical effect* of a state or local law that matters for preemption purposes, not how the law is labeled. The district court's ruling must be reversed.

Section 907 of the FSPTCA, titled "Tobacco Product Standards," establishes federal control over "the construction, components, ingredients, additives, constituents, . . . and properties" of tobacco products. 21 U.S.C. § 387g(a)(4)(B)(i) (Add. 74). A tobacco product that fails to conform to a federal tobacco product standard is an "adulterated" product, which may not be sold in the United States. *Id.* §§ 387b(5), 331(a), (c), 381(e)(1) (Add. 71, 60, 65). The FSPTCA establishes a tobacco product standard for flavored tobacco products, which provides that cigarettes "shall not contain" any "constituent" or "additive" (other than tobacco or menthol) that is a "characterizing flavor of the tobacco product." *Id.* § 387g(a)(1)(A) (Add. 73) (the "Federal Flavor Standard"). Notably, the Federal Flavor Standard does not prohibit flavored smokeless tobacco products or cigars, as the Ordinance does.

Three provisions in the FSPTCA inform the Court's preemption analysis: (i) the Preservation Clause, which, subject to the Preemption Clause, preserves certain state and local powers; (ii) the Preemption Clause, which preempts local requirements "different from or in addition to" a federal tobacco product standard; and (iii) the Saving Clause, which creates limited exceptions to the Preemption

Clause.

As an initial matter, there can be no serious doubt that the Flavor Ordinance falls within the scope of the FSPTCA's Preemption Clause. That clause expressly preempts any local law "establish[ing] . . . any requirement which is different from, or in addition to" federal law "relating to tobacco product standards." 21 U.S.C. § 387p(a)(2)(A) (Add. 80). Congress established a federal standard for flavored tobacco products that prohibits the sale of cigarettes with characterizing flavors but *permits* the sale of flavored smokeless tobacco products. 21 U.S.C. § 387g(a)(1)(A) (Add. 73). The Ordinance, however, effectively bans the sale of flavored smokeless tobacco products within city limits. If that is not a tobacco product standard that is "different from, or in addition to" a federal tobacco product standard, it is difficult to know what would be.

The Preservation Clause cannot save Providence's Flavor Ordinance. That clause only applies "[e]xcept as provided in paragraph (2)(A)," 21 U.S.C. § 387p(a)(1) (Add. 80)—*i.e.*, the Preemption Clause—and is thus subordinate to it. By its very terms, it does not preserve any state or local law that the Preemption Clause preempts.

The relevant question on this appeal, then, is whether Providence's Ordinance falls within the scope of the Saving Clause, which provides a limited safe haven from preemption for state or local "requirements relating to the sale,

distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age." 21 U.S.C. § 387p(a)(2)(B) (Add. 80). The district court concluded that the Ordinance is saved from preemption because it bans the *sale* of smokeless tobacco products based on their content, rather than banning the *manufacture* of smokeless tobacco products containing characterizing flavors, which it acknowledged would be preempted. (Add. 29). But that distinction between sales and manufacturing elevates form over substance, and directly violates two recent Supreme Court rulings that require courts to consider the practical effect of local laws in deciding preemption. This Court should reverse the district court and find the Ordinance preempted for four reasons.

First, under the district court's reasoning, manufacturing restrictions are the "exclusive domain of the federal government," and the regulation of sales on the basis of the content of tobacco products is for state and local governments. (Add. 29). Congress, however, enacted the FSPTCA because it was concerned about the content of tobacco products sold to consumers in the United States, not with abstract distinctions between manufacturing and sales regulations. That is why the FSPTCA *permits* the *manufacture* of tobacco products for export that do not comply with federal standards, 21 U.S.C. § 381(e)(1) (Add. 65), but prohibits the *sale* of tobacco products in the U.S. that do not meet federal requirements, even

if they are manufactured abroad, *see id.* § 331 (Add. 60). The district court's premise that sales regulations and tobacco product standards are somehow distinct is therefore belied by the FSPTCA itself, which enforces its tobacco product standards through a domestic *sales* ban.

Second, the district court erred by failing to consider the actual effects of the Flavor Ordinance. The Supreme Court has made clear that "[i]n a pre-emption case . . . a proper analysis requires consideration of *what the state law in fact does*, not how the litigant might choose to describe it." *Wos v. E.M.A.*, 133 S. Ct. 1391, 1398 (2013) (emphasis added). For that reason, the Supreme Court has squarely held that it would "make a mockery of . . . preemption" law if state and local governments could achieve the same effect as a prohibited manufacturing or operational regulation merely by "framing it as a ban on … sale[s]." *Nat'l Meat Ass'n v. Harris*, 132 S. Ct. 965, 973 (2012). The Ordinance does just that. Although framed as a sales restriction, it actually regulates the *content* of the tobacco products, and therefore achieves exactly the same effect as a content-based manufacturing regulation. Either way, smokeless tobacco products and cigars to which a manufacturer has added "constituents" that impart a prohibited characterizing flavor may not be sold under the Ordinance, although they may be sold under the Federal Flavor Standard. The Ordinance thus creates a preempted tobacco product standard that is "different from, or in addition to" the Federal

Flavor Standard. Styling the Ordinance as a sales restriction in a transparent attempt to bring it within the language of the Saving Clause is precisely the sort of semantic gamesmanship that the Supreme Court held *cannot* evade preemption. *See Wos*, 133 S. Ct. at 1398 ("Pre-emption is not a matter of semantics. A State may not evade the pre-emptive force of federal law by resorting to creative statutory interpretation or description at odds with the statute's intended operation and effect.").

Third, the district court's expansive reading of the Saving Clause violates settled principles of statutory interpretation. Courts are required to read saving clauses in harmony with preemption clauses—rather than employing the former to nullify the latter. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 870 (2000) (The Supreme Court has "repeatedly" held that saving clauses must not be construed so as to "upset the careful regulatory scheme established by federal law." (internal quotation marks omitted)).

The district court's reasoning cannot be reconciled with this principle. In fact, its reading of the Saving Clause would effectively nullify the Preemption Clause and Congress's desire to establish uniform national tobacco product standards by allowing state and local governments to establish any tobacco product standards they might choose, provided they frame them as "sales" bans. The district court forthrightly admitted as much, stating that the Preemption Clause

imposed absolutely "*no impediment* to the City's prohibition against the *sale* of flavored tobacco products." (Add. 30) (emphasis added).[4] But, as the Supreme Court has cautioned, "if one State or political subdivision may enact such rules, then so may any other; and the end result would undo Congress's carefully calibrated regulatory scheme." *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 255 (2004). That is precisely the specter raised by the district court's flawed interpretation here.

Read to work together, the Preemption Clause prohibits local laws that regulate the contents or ingredients of tobacco products, whether styled as a manufacturing or sales ban, while the Saving Clause permits state and local governments to regulate where, when, and how tobacco products are sold, not to ban sales altogether based on a tobacco product's contents. This reading not only gives meaning to both the Preemption Clause and the Saving Clause, but is true to Congress's express intent to establish uniform, national standards governing the contents of tobacco products. 21 U.S.C. § 387 note (3) (Add. 67).

This interpretation also is compelled by a careful reading of the Act's language. Section 387p(a) contains a Preservation Clause, followed immediately by the Preemption and Saving Clauses. The Preservation Clause preserves for the

[4] In this regard, the district court did not rest its conclusion on the Ordinance's exception for licensed smoking bars. Nor should it have, as only two such tobacco bars sell flavored smokeless tobacco products. Laquerre Decl. ¶¶ 15-16 (JA 299–300).

states—subject to the Preemption Clause—the right to promulgate laws "relating to or prohibiting the sale . . . . of tobacco products." (Add. 80) (emphasis added). The Preemption Clause comes next and prohibits state or local laws that establish tobacco product standards "different from, or in addition to" a federal standard, such as the Federal Flavor Standard. Finally, the Saving Clause exempts from preemption state or local requirements "relating to the sale . . . of[] tobacco products." Notably, while the Preservation Clause preserves state and local requirements "relating to or prohibiting" sales, the Saving Clause just three sentences later omits the "or prohibiting" language, referring only to requirements "relating to" sales. Under the district court's interpretation, "relating to" in the Saving Clause would mean the same thing as "relating to or prohibiting" in the Preservation Clause. That interpretation would run afoul of the Supreme Court's dictate that "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (international quotation omitted); *see also Corley v. United States*, 556 U.S. 303, 314 (2009) (statutes should be construed to give meaning to every word).

Fourth, the district court's reliance on the S.D.N.Y. decision in *U.S. Smokeless Tobacco Mfg. Co., LLC v. City of New York*, 703 F. Supp. 2d 329

(S.D.N.Y. 2010), *aff'd*, 708 F.3d 428 (2d Cir. 2013)—the only preemption case cited by the district court, (Add. 26–30)—is misplaced. That case also relied heavily on the mistaken premise that federal tobacco product standards relate only to the "manufacture of tobacco products," rather than sales. 703 F. Supp. 2d at 344. In addition, the district court in *U.S. Smokeless* was remarkably candid about the breadth of its reading of the Saving Clause, admitting it was creating "a hole in the statute big enough to drive a very large truck through." Joint Appendix at 73, *U.S. Smokeless*, 708 F.3d 428 (No. 11-5167). That is precisely what the Supreme Court has repeatedly held that a saving clause cannot do, including in *Harris*, where it specifically condemned using a sales ban to eviscerate exclusive federal manufacturing standards.

The Second Circuit, in affirming *U.S. Smokeless*, properly acknowledged that a local law that "in fact 'functions as a command' to tobacco manufacturers 'to structure their operations' in accordance with locally prescribed standards would not escape preemption simply because the City 'fram[ed] it as a ban on the sale of [tobacco] produced in whatever way [it] disapproved." 708 F.3d at 434 (quoting *Harris*, 132 S. Ct. at 972–73) (alterations in original). Thus, local laws that "require [tobacco] manufacturers to alter 'the construction, components, ingredients, additives, constituents . . . and properties'" of tobacco products would be expressly preempted by the FSPTCA. *Id.* (citation omitted) (alteration in

original). Under this part of the legal framework adopted by the Second Circuit's decision in *U.S. Smokeless*, the Providence Flavor Ordinance is clearly preempted. It bans the sale of tobacco products that contain "constituent[s] that impart[] a characterizing flavor," and it defines "constituent" as "any ingredient, substance, chemical, or compound, other than tobacco, water or reconstituted tobacco sheet, that is added by the manufacturer . . . during the processing, manufacture or packing of the tobacco product." Providence Code of Ordinances § 14-308 ¶¶ 5, 6 (Add. 51). The Ordinance thus recognizes that tobacco does not naturally taste like fruit and that, to achieve a fruit taste in a tobacco product, the manufacturer must add fruit flavoring or other ingredients. And, the Ordinance directly regulates the "ingredients" that manufacturers may and may not add "during . . . manufacture" as well as the "properties" of the finished product—*e.g.*, they may add water, tobacco and reconstituted tobacco sheet; but not "any [other] ingredient, chemical, substance or compound" that "imparts a characterizing flavor" to the finished product other than tobacco, menthol, mint, or wintergreen. *Id.* § 14-308 ¶¶ 3, 5 and 6 (Add. 50–51).

The Flavor Ordinance enforces its mandate in the same way as the Federal Flavor Standard after which it is patterned—banning the sale of those tobacco products whose flavor characteristics do not comply with its requirements. In this way, it functions as a command to manufacturers to make their products conform

to the City's requirements, or forego sales of those products. The Flavor Ordinance is Providence's own flavored tobacco product standard, and because it is "different from" and "in addition to" the Federal Flavor Standard, it is expressly preempted.

Although much of the legal framework adopted by the Second Circuit is correct—and requires a ruling that the Flavor Ordinance here is preempted—the Second Circuit ultimately misapplied the preemption provision to the New York Ordinance at issue in that case. Thus, the Second Circuit erred in stating that, while a local government could not "require manufacturers to alter 'the . . . ingredients, additives, constituents . . . and properties,'" it could nonetheless ban the sale of a product based "on its characteristics as an end product." 708 F.3d at 434–35 (citation omitted) (second alteration in original). That is precisely the sort of "description at odds with the statute's intended operation and effect" that the Supreme Court condemned in *Wos*, 133 S. Ct. at 1398—a decision released after the Second Circuit's decision and thus never addressed by it. The end-product characteristics at issue here—characterizing flavors—can be achieved only by adding flavorings to tobacco.[5] Therefore, banning the sale of a product based on

[5] The Second Circuit erroneously concluded that the NYC ordinance "does not concern itself . . . *with the ingredients that may be included in tobacco products*." *U.S. Smokeless*, 708 F.3d at 435 n.2 (emphasis added). In fact, however, the NYC Ordinance, like the Providence Ordinance here, does expressly concern itself with the "ingredients" that may be "added" to tobacco

flavor characteristics of the end product inescapably requires manufacturers to alter the ingredients of the product (which the Second Circuit agreed would be preempted). Thus, the Second Circuit's purported distinction between the N.Y.C. Ordinance and the Federal Flavor Standard—that the former, unlike the latter, supposedly "does not turn on 'the use of additives or flavorings,' but rather on whether the product itself imparts 'a distinguishable taste or aroma'"—does not withstand scrutiny. 708 F.3d at 435. Both the Federal Flavor Standard and the Providence Ordinance (like the N.Y.C. Ordinance) prohibit the sale of certain tobacco products based on whether ingredients are added to the tobacco that give the finished product a characterizing flavor. *Compare* N.Y.C. Admin. Code § 17-713 (d) & (e) (defining banned "constituents" as those "added by the manufacturer to a tobacco product" that "impart[] a characterizing flavor"), *with* 21 U.S.C. § 387g(a)(1)(A) (Add. 73) (banning cigarettes that contain a "constituent" or "additive" that imparts a characterizing flavor).

For all these reasons, this Court should reverse the district court and rule that the City's Flavor Ordinance is expressly preempted by the FSTPCA.

IV. The City Ignored State Law Limits On Municipal Authority.

The City attempted to exercise authority that Congress reserved to the federal Government and powers forbidden to any government subject to our

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products. A petition for rehearing and rehearing en banc is pending in *U.S. Smokeless* for just that reason.

federal Constitution and its First Amendment. But the City did not stop there. The City also overstepped the clear limits the Rhode Island Constitution and General Assembly have placed on municipalities.

A. The Promotion Ordinance And The Flavor Ordinance Violate The Rhode Island Constitution.

Both Ordinances plainly exceed the authority granted to municipalities by the Rhode Island Constitution and its Home Rule Amendment. R.I. Const. art. XIII, §§ 2, 4 (Add. 81–82). The Rhode Island Supreme Court has held, unambiguously, that municipalities lack authority to regulate businesses through licensing schemes. *See Amico's Inc. v. Mattos*, 789 A.2d 899, 903 (R.I. 2002); *Westerly Residents for Thoughtful Dev., Inc. v. Brancato*, 565 A.2d 1262, 1264 (R.I. 1989); *Bruckshaw v. Paolino*, 557 A.2d 1221, 1223 (R.I. 1989); *Nugent v. City of East Providence*, 103 R.I. 518, 526, 238 A.2d 758, 762–63 (1968) (explaining that the Rhode Island Constitution entrusts "the power in the legislature to regulate and control by licensing the conduct of business within the state"); *State v. Krzak*, 97 R.I. 156, 161, 196 A.2d 417, 420 (1964); *Newport Amusement Co. v. Maher*, 92 R.I. 51, 56, 166 A.2d 216, 218 (1960) ("The power to regulate occupations and businesses by licensing provisions . . . is not an incident of municipal administration and may not be exercised by municipalities except where it is lawfully delegated to them in particular instances expressly or by necessary implication."). These cases do not only prohibit cities from requiring

business licenses: Any municipal law that is enforced through a municipal licensing scheme is invalid. *Amico's*, 789 A.2d at 904 (where "licensing constitutes the sole enforcement mechanism of [an ordinance] . . . the authority to carry out that enforcement must flow from a delegation of power to do so from the General Assembly").

The Ordinances are enforced through a municipal business licensing scheme. They apply only to retailers who have obtained a license from the Providence Board of Licenses. *See* Providence Code of Ordinances § 14-300–302 (requiring tobacco vendors to obtain a license from the Providence Board of Licenses); *id.* § 14-303 (Add. 48) (applying the Promotion Ordinance to any "person who holds a license issued under this article" and "any employee or agent of the same"); *id.* § 14-308–310 (Add. 50–52) (amending the section of the Providence code entitled "Licenses"). And the Ordinances are enforced *exclusively* upon licensees through the City's licensing scheme. The Providence Board of Licenses, and no other body, has authority to impose punishment under both Ordinances. *Id.* §§ 14-300, -303, -308–310 (Add. 47–52); *id.* § 14-304. The Ordinances cannot be squared with unambiguous and binding Rhode Island Supreme Court decisions.

The district court never reached these substantive defects. Instead, it held that Plaintiffs failed to "challenge the City's licensing requirements directly" and

that the Ordinances' licensing foundation was not "implicated" because the Ordinances "ha[d] not yet been enforced and no suspension or revocation of a license ha[d] yet occurred in connection with an alleged violation of either Ordinance." (Add. 34). "[I]t would be improper," the court continued, "to determine the constitutionality of the City's licensing requirement and issue what amounts to an advisory opinion." *Id.*[6]

It was manifest error to disregard this Rhode Island constitutional defect in the Ordinances. Rhode Island law does not allow substantive restrictions with invalid penalties or enforcement mechanisms to remain in force. When a city imposes a penalty that falls outside delegated authority under Rhode Island law, the entire ordinance falls. *Krzak*, 97 R.I. at 160, 196 A.2d at 420 (declining to preserve portions of a licensing ordinance because it involved "a question of delegated authority" and the ordinance "constitute[d] an *ultra vires* exercise" of that delegated authority). Likewise, Providence has imposed a penalty outside of its delegated authority, because the penalty here is enforced through a licensing scheme established pursuant to an "authority" that the General Assembly has not

[6] To the extent that the court suggested that the issue was not properly before it because Plaintiff had failed to challenge the City's tobacco licensing scheme, that is simply incorrect. In both their Complaint, Dkt. #1 (JA 33–34 ¶¶ 73–74, JA 46–47 ¶¶ 127–28), and summary judgment papers, Dkt. #35 (Pls. Mem.) at 22–24, 40–41; Dkt. #49 (Pls. Reply Mem.) at 27–30, 45, Plaintiffs argued that the Ordinances were invalid because the City's licensing scheme was unauthorized by the Rhode Island General Assembly.

"lawfully delegated" to the City. *Newport Amusement Co.*, 92 R.I. at 56, 166 A.2d at 218. The district court should not have ignored how Rhode Island law addresses such defects in municipal ordinances.[7]

To the extent that the court was suggesting that this clear Rhode Island constitutional defect presented an unripe pre-enforcement challenge, that holding is contrary to federal law. *Abbott Labs. v. Gardner*, 387 U.S. 136, 153 (1967) (a case is ripe "where the legal issue presented is fit for judicial resolution, and where a regulation requires an immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance"). Whether the enforcement scheme violates the Rhode Island Constitution is a purely legal question, which requires no factual development or other data from any enforcement proceeding. The only entity authorized to enforce the Ordinances is the Providence Board of Licenses—there is no possibility that a constitutionally valid penalty will be imposed. A "purely legal question" involving no "statutory

[7] For this reason, the Court also erred in suggesting that it need not correct this Rhode Island constitutional defect because the Plaintiffs did not challenge the City's underlying tobacco licensing scheme. The Rhode Island case books are full of successful challenges to efforts to regulate businesses *substantively* through licensing, not merely to require a license. *See*, *e.g.*, *Nugent*, 103 R.I. 518, 238 A.2d 758; *Newport Amusement Co.*, 92 R.I. 51, 166 A.2d 216. In any event, it is not the law of federal courts that a plaintiff must challenge an unconstitutional law as soon as it is enacted; he may wait until the magnitude of harm justifies the expense of litigation. Any other rule would clog the courts with litigation seeking only to preserve rights in the event of future intolerable excesses.

ambiguity" that presents a "well-defined" controversy "amenable to complete and final resolution" is fit for review. *R.I. Ass'n of Realtors, Inc. v. Whitehouse*, 199 F.3d 26, 34 (1st Cir. 1999); *Chamber of Commerce of U.S. v. Reich*, 57 F.3d 1099, 1100 (D.C. Cir. 1995) (per curiam) ("Purely legal questions . . . are presumptively [fit] for judicial review." (internal quotation marks omitted) (second alteration in original)). Constitutional interpretation and issues of a municipality's authority under state law are generally purely legal questions. *See R.I. Ass'n of Realtors*, 199 F.3d at 34 (the constitutionality of a "Rhode Island[] prohibition on using public records for commercial solicitation" is a "purely legal question"); *Rhode Island v. Narragansett Indian Tribe*, 19 F.3d 685, 694 (1st Cir. 1994) (addressing the boundaries of state versus Indian tribe jurisdiction over certain lands in Rhode Island "project[ed] a purely legal issue . . . the resolution of which will not be changed by further factual development" (internal quotation marks omitted)); *Blue Sky Entm't, Inc. v. Town of Gardiner*, 711 F. Supp. 678, 687 (N.D.N.Y. 1989) ("To the extent that [a claim] present[ed] the court with an allegation that the Town acted outside its authority [granted by the state], it is a 'predominantly legal' question and fulfills the fitness prong of the ripeness test.").

Plaintiffs-Appellants need not subject themselves to enforcement proceedings before the Board of Licenses to ripen their claim. Where a law or regulation is final, a "[p]laintiff is not required to wait until the ax falls to seek

protective relief"—the "threat to enforce" the rule is enough. *Aetna Cas. & Sur. Co. v. Gailey*, 753 F. Supp. 46, 48–49 (D. Mass. 1990) (citing *Pac. Gas & Elec. Co. v. State Energy Res. Conserv. & Dev. Comm'n*, 461 U.S. 190, 201 (1983)). The Ordinances' integration with a constitutionally invalid licensing scheme, including their defective penalties, is ripe for review and requires invalidation of both Ordinances.

B. The Promotion Ordinance Is Preempted By Rhode Island Law.

A local ordinance is preempted by state law where "it conflicts with a state statute on the same subject" or "if the Legislature intended that its statutory scheme completely occupy the field of regulation on a particular subject." *Town of Warren v. Thornton-Whitehouse*, 740 A.2d 1255, 1261 (R.I. 1999). The Rhode Island General Assembly need not explicitly state an intention to occupy a regulatory field; "it may be implied in the legislative scheme." *See State ex rel. City of Providence v. Augur*, 44 A.3d 1218, 1230 n.9 (R.I. 2012) (internal quotation marks omitted). The State General Assembly may demonstrate its intent to occupy a field if the "state legislature has made provision for the regulation of conduct in a given situation and has provided punishment for the failure to comply therewith." *Wood v. Peckham*, 80 R.I. 479, 483, 98 A.2d 669, 670 (1953).

Here, Rhode Island law comprehensively regulates the offering and redemption of coupons and other discounts for tobacco products and so preempts the City's contrary regulatory scheme.

Rhode Island "regulate[s]" and "provides punishment for" the same conduct covered by the Promotion Ordinance—the offering and redemption of coupons and price discounts for tobacco products. State law prohibits: (i) selling tobacco products to persons under eighteen years of age, R.I. Gen. Laws § 11-9-13.8 (Add. 84); (ii) "distribut[ing] . . . free tobacco products or coupons or vouchers redeemable for free tobacco products to any person under eighteen (18) years of age"; and (iii) distributing such products, coupons, or vouchers to any person "regardless of the age of the person . . . within five hundred (500) feet of any school," *id.* § 11-9-13.10 (Add. 85). Rhode Island's unfair sales practices laws also regulate how businesses can utilize price discounts and other promotions by, for example, making it "unlawful to use, communicate, or publish any advertisement that states that an item or product is being sold or offered for sale at below the regular price . . . without posting the regular price at the point of purchase." *Id.* § 6-13-11 (Add. 87). Tobacco retailers who violate the state's unfair sales practices laws are subject to punishment through state tobacco licensing procedures. *See id.* § 44-20-8 (Add. 88). In short, the General Assembly chose the boundaries of its prohibitions on tobacco product coupons and price

offers, which permit the offering and redemption of coupons and discounts to those over 18 and outside 500 feet from any school, so long as the regular price is posted.

Through the Promotion Ordinance, the City seeks to revise these boundaries. The Ordinance attempts to close down the use of coupons by consumers of any age and for any amount of discount, and multi-pack discount offers. Indeed, the General Assembly has, at least six times in the last seven years, *rejected* bills with language virtually identical to the Promotion Ordinance. *See, e.g.*, H.R. 7700, 2010 Leg., Jan. Sess. (R.I. 2010); S. 2576, 2010 Leg., Jan. Sess. (R.I. 2010); H.R. 5551, 2009 Leg., Jan. Sess. (R.I. 2009); S. 742, 2009 Leg., Jan. Sess. (R.I. 2009); H.R. 7500, 2006 Leg., Jan. Sess. (R.I. 2006); S. 2621, 2006 Leg., Jan. Sess. (R.I. 2006).[8]

[8] For example, in 2009, both the House bill and the Senate bill proposed to restrict licensed tobacco retailers from: (i) "[s]ell[ing] or distribut[ing] a tobacco product for commercial purposes for free or . . . at a nominal or discounted price," H.R. 5551 § 1(a)(1), (c); (ii) "[d]istribut[ing] any coupon or other item redeemable by buyers in this state to obtain a tobacco product for free or . . . at a nominal or discounted price," *id.* § 1(a)(2), (c); (iii) [a]ccept[ing] or redeem[ing], offer[ing] to accept or redeem, or caus[ing] or hir[ing] any person to accept or redeem or offer to accept or redeem any coupon for providing members of the general public any tobacco product for free or . . . at a nominal or discounted price," *id.* § 1(a)(3), (c); (iv) "[c]aus[ing], requir[ing], or induc[ing] any person or persons to buy more than one pack or carton of cigarettes or one package of any other tobacco product at a time by reducing the price of the additional packs," *id.* § 1(a)(4); and (v) "[d]istribut[ing], sell[ing] or offer[ing] for distribution or sale any cigarettes or other tobacco product for free

Rhode Island law is plain—when the General Assembly has addressed a category of conduct, has distinguished improper from permitted activities, and has provided punishment for the improper activities, cities may not prohibit more. The Promotion Ordinance tries to ban more tobacco coupons and discounts than the General Assembly saw fit. It is preempted by state law.

CONCLUSION

For the foregoing reasons, this Court should reverse the district court's order and instruct the district court to enter judgment in favor of Plaintiffs-Appellants and permanently to enjoin enforcement of the Ordinances.

Respectfully submitted,

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or through a two-packs-for-the-price-of-one, buy-two-get-one-free, buy-two-cartons-get-one-free, or any similar arrangement." *Id.* § 1(a)(7).

JONES DAY

By: /s Noel. J. Francisco
Noel J. Francisco

51 Louisiana Avenue, N.W.
Washington, D.C. 20001
Telephone: (202) 879-3939
Facsimile: (202) 626-1700
njfrancisco@jonesday.com

Counsel for Appellants R.J. Reynolds Tobacco Co. and American Snuff Company

GIBSON, DUNN & CRUTCHER LLP

By: /s/ Michael J. Edney
Miguel A. Estrada
Michael J. Edney

1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
Telephone: (202) 955-8500
Facsimile: (202) 539-9547
mestrada@gibsondunn.com
medney@gibsondunn.com

Counsel for Appellants Philip Morris USA Inc.; U.S. Smokeless Tobacco Manufacturing Company, LLC; U.S. Smokeless Tobacco Brands, Inc.; and John Middleton Company

CAHILL GORDON & REINDEL LLP

By: /s/ Joel Kurtzberg
Floyd Abrams
Joel Kurtzberg

80 Pine Street
New York, NY 10005
Telephone: (212) 701-3120
Facsimile: (212) 378-2522
fabrams@cahill.com
jkurtzberg@cahill.com

Counsel for Appellant Lorillard Tobacco Company

LATHAM & WATKINS LLP

By: /s/ Kenneth J. Parsigian
Kenneth J. Parsigian

John Hancock Tower, 20th Floor
200 Clarendon Street
Boston, MA 02116
Telephone: (617) 880-4510
Facsimile: (617) 948-6001
kenneth.parsigian@lw.com

Counsel for Appellants Philip Morris USA Inc.; U.S. Smokeless Tobacco Manufacturing Company, LLC; U.S. Smokeless Tobacco Brands, Inc.; and John Middleton Company

ADLER, POLLOCK & SHEEHAN P.C.

By: /s/ James R. Oswald
James R. Oswald
Kyle Zambarano

One Citizens Plaza, 8th Floor
Providence, RI 02903
Telephone: (401) 274-7200
Facsimile: (401) 351-4607
joswald@apslaw.com
kzambarano@apslaw.com

Counsel for Appellant National Association of Tobacco Outlets, Inc.; Counsel for Appellants Lorillard Tobacco Company; R.J. Reynolds Tobacco Company; American Snuff Company; Philip Morris USA Inc.; U.S. Smokeless Tobacco Manufacturing Company LLC; U.S. Smokeless Tobacco Brands Inc.; and John Middleton Company

HINCKLEY, ALLEN & SNYDER LLP

By: /s/ Gerald J. Petros
Gerald J. Petros
Adam M. Ramos

50 Kennedy Plaza, Ste. 1500
Providence, RI 02903
Telephone: (401) 457-5212
Facsimile: (401) 277-9600
gpetros@haslaw.com
aramos@haslaw.com

Counsel for Appellant Cigar Association of America, Inc.

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/s/ Michael J. Edney

Michael J. Edney
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
Telephone: (202) 955-8500
Facsimile: (202) 539-9547
medney@gibsondunn.com

Counsel for Appellants Philip Morris USA Inc.; U.S. Smokeless Tobacco Manufacturing Company, LLC; U.S. Smokeless Tobacco Brands, Inc.; and John Middleton Company

CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2013, I caused a true and accurate copy of the Brief of Plaintiffs-Appellants to be filed with the Clerk of the Court and served in accordance with the Federal Rules of Appellate Procedure and the Local Rules of the United States Court of Appeals for the First Circuit, via the Court's CM/ECF system, on all counsel registered to receive electronic notices. I also certify that I caused paper copies of the Joint Appendix to be filed with the Court and served on all counsel listed below via United Postal Service overnight delivery, in accordance with Fed. R. App. P. 25(c).

Anthony F. Cottone
55 Dorrance Street, Suite 400
Providence, RI 02903
(401) 578-5696
Counsel for Appellees

Matthew T. Jerzyk
Deputy City Solicitor
City of Providence
444 Westminster Street, Suite 220
Providence, RI 02903
(401) 680-5333
Counsel for Appellees

/s/ Michael J. Edney
Michael J. Edney

ADDENDUM

ADDENDUM
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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

National Association of Tobacco Outlets, Inc.
Cigar Association of America, Inc.
Lorillard Tobacco Company
R.J. Reynolds Tobacco Company
American Snuff Company
Philip Morris USA, Inc.
U.S. Smokeless Tobacco Manufacturing Company, LLC
U.S. Smokeless Tobacco Brands Inc.
John Middleton Company

v. **CA 12-96ML**

City of Providence, RI
Providence Board of Licenses
Providence Police Department
Michael A. Solomon, Providence City Counsel President
Steven M. Pare, Commissioner of Public Safety for the City of Providence
and Angel Taveras, Mayor of Providence, in their official capacities

JUDGMENT

[X] Decision by the Court. This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

[ ] Jury Verdict. This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

IT IS ORDERED AND ADJUDGED:

Judgment shall enter in favor of defendants against plaintiffs pursuant to the Memorandum and Order dated 12/10/2012 granting defendant's motion for summary judgment and denying the plaintiff's motion for summary judgment.

Enter:

/s/ Kerrie Jackson
Deputy Clerk

DATED: **December 10, 2012**

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FOR THE DISTRICT OF RHODE ISLAND

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

NATIONAL ASSOCIATION OF TOBACCO OUTLETS, INC.; CIGAR ASSOCIATION OF AMERICA, INC.; LORILLARD TOBACCO COMPANY; R.J. REYNOLDS TOBACCO COMPANY; AMERICAN SNUFF COMPANY; PHILIP MORRIS USA INC.; U.S. SMOKELESS TOBACCO MANUFACTURING COMPANY LLC; U.S. SMOKELESS TOBACCO BRANDS INC.; JOHN MIDDLETON COMPANY,

Plaintiffs,

v. C.A. No. 12-96-ML

CITY OF PROVIDENCE, Rhode Island; PROVIDENCE BOARD OF LICENSES; PROVIDENCE POLICE DEPARTMENT; MICHAEL A. SOLOMON, Providence City Council President, in his official capacity; STEVEN M. PARE, Commissioner of Public Safety for the City of Providence, in his official capacity; ANGEL TAVERAS, Mayor of Providence, in his official capacity,

Defendants.

MEMORANDUM AND ORDER

Mary M. Lisi, Chief United States District Judge.

The plaintiffs in this case (the "Plaintiffs") are (1) the National Association of Tobacco Outlets, Inc. ("NATO"), a nationwide association of tobacco retailers, manufacturers and distributors; (2) the Cigar Association of America, Inc. ("CAA"), a nationwide association of cigar manufacturers, distributors and importers; and (3) seven tobacco manufacturers and distributors, including Lorillard Tobacco Company ("Lorillard"), R.J. Reynolds Tobacco Company ("RJRT"), American Snuff Company ("ASC"), Philip

Morris USA Inc. ("PM USA"), U.S. Smokeless Tobacco Manufacturing Company LLC ("USSTMC"), U.S. Smokeless Tobacco Brands, Inc. ("USSTB") and the John Middleton Company ("JMC").

The Plaintiffs seek a declaration that two new provisions[1] added to Providence municipal ordinances are unconstitutional and they seek a permanent injunction against the City's enforcement of those provisions. Complaint 51-52 (Docket # 1). The case is before the Court on the Plaintiffs' joint motions for summary judgment, a permanent injunction, and a preliminary injunction (Docket # 32) and the City's cross motion for summary judgment. (Docket # 44). Although the Plaintiffs have styled their request for relief in the form of a motion for summary judgment, the Court understands that the parties are seeking a decision on the merits. The City has agreed to stay enforcement of the provisions at issue until after the Court has ruled on the parties' motions.

I. Factual Background and Procedural History

On January 5, 2012,[2] the Providence City Council, motivated by concerns about smoking and health in the City of Providence, amended existing Sections 14-300 and 14-303 (the "Price Ordinance") and enacted Sections 14-308, 14-309, and 14-310 (the "Flavor" Ordinance, together with the Price Ordinance, the "Ordinances").

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[1] The provisions are set forth in their entirety in Appendices I and II of this Memorandum and Order.

[2] The Ordinances were subsequently re-enacted on February 17, 2012, in order to cure any violation of the Rhode Island Open Meetings Act ("OMA").

The Ordinances were designed, in part, to reduce tobacco consumption by persons under the age of eighteen.[3] PSUF ¶¶ 2, 3.

According to the Complaint, the Plaintiffs (with the exception of Lorillard, which does not sell "flavored tobacco products") sell products and "advertise them and promote them in ways that would be prohibited by both ordinances." Complaint 2. Lorillard takes exception only to Section 14-303. Both Ordinances were to take effect on March 1, 2012; however, in light of the pending litigation, neither has been enforced thus far.

On February 13, 2012, the Plaintiffs filed a 56-page complaint (the "Complaint") against the City. (Docket # 1). The Plaintiffs asserted claims of violation of Plaintiffs' First Amendment rights (Counts I and VII)[4], Federal Law Preemption (Counts II and IX), Deprivation of Civil Rights pursuant to 42 U.S.C. § 1983 (Counts III and X), Violation of the Rhode Island Constitution (Counts IV and XI), Preemption by Rhode Island Law (Count V), Violation of the Rhode Island Open Meetings Act (Counts VI and XII), and Violation of Plaintiffs' Due Process Rights pursuant to the Fourteenth Amendment (Count VIII). Docket # 1. The Plaintiffs sought a declaration from the Court that the Ordinances were unconstitutional and preempted by Federal and state law and,

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[3] The Ordinances make no specific reference to underage consumers.

[4] Counts I, II, III, IV, V, and VI pertain to the Price Ordinance, Counts VII, VIII, IX, X, XI, and XII pertain to the Flavor Ordinance.

therefore, of no force. Complaint 51. They also sought a temporary restraining order and preliminary injunction to enjoin the City from enforcing the Ordinances pending final resolution of this litigation, id. at 52, as well as attorney fees pursuant to 42 U.S.C. § 1988 and R.I. Gen. Laws § 42-46-8(d).

On February 17, 2012, the parties filed a stipulation staying enforcement of the Ordinances until July 30, 2012. (Docket # 23). On the same day, the Providence City Council reenacted the Ordinances at a hearing for which forty-eight hours' notice had been given as required by the OMA. Pltfs.' Mem. 9. On February 21, 2012, the Court entered the parties' stipulation, Text Order 02/21/2012 (Docket # 23).

On March 15, 2012, the City filed an answer to the Complaint in which it generally denied that the Ordinances were unconstitutional or preempted, but acknowledged that the City Council "inadvertently committed a technical violation of the Open Meetings Act," when the Ordinances were passed. Answer at 3 ¶ 10. (Docket # 30). However, the City denied that the Ordinances were, as the Plaintiffs alleged, "null and void" as a result, because any such violation had been subsequently cured when the City Council passed the Ordinances, as amended, on or about February 17, 2012, and when they were signed by the Mayor on February 20, 2012. Id. at 3, ¶10.

On March 30, 2012, the Plaintiffs filed a joint motion for summary judgment and for a permanent injunction. (Docket # 32), together with the Declaration of Cecil R. Reynolds, Ph.D.

("Reynolds"), (Docket # 33), a Statement of Undisputed Facts ("PSUF"), (Docket # 34), and a Memorandum in support of their motion, (Docket # 35). On April 16, 2012, the Rhode Island Department of Behavioral Healthcare, Developmental Disabilities and Hospitals, the Rhode Island Department of Health, the Tobacco Control Legal Consortium and various health care and/or health research organizations (together, the "amici") filed a joint motion for leave to file amicus briefs, (Docket # 37), which was granted by the Court. Text Order 06/14/2012. The parties also agreed by amended stipulation that enforcement of the Ordinances would be stayed until October 15, 2012, (Docket # 39).

On June 15, 2012, the City filed its response in Opposition to the Plaintiffs' motion, (Docket # 42), together with a cross motion for summary judgment, (Docket # 44), a Statement of Disputed Facts ("DSDF"), (Docket # 43), and a Statement of Undisputed Facts ("DSUF"), (Docket # 45).

The Plaintiffs filed a reply to the City's response on July 16, 2012, (Docket # 49), together with a response in opposition to the City's motion, (Docket # 50), a Statement of Disputed Facts ("PSDF"), (Docket # 51), and a further declaration by Reynolds, (Docket # 52). In reply, the City filed a memorandum on July 30, 2012, (Docket # 55).

On August 22, 2012, the Court held a hearing at which the parties and one of the amici were given an opportunity to argue their respective positions and address questions posed to them by the Court. The Court then took the motions under advisement. Minute

Entry 08/22/2012. Following the hearing, the Court entered a further stipulation by the parties that stayed enforcement of the Ordinances until the later of October 15, 2012 or fourteen days following the Court's ruling on the pending motions. Text Order 09/13/2012 (Docket # 56).

II. Standard of Review

Summary judgment is appropriate only "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)(2). "A dispute is genuine if the evidence about the fact is such that a reasonable jury could resolve the point in the favor of the non-moving party." Prescott v. Higgins, 538 F.3d 32, 40 (1st Cir. 2008) (citations omitted). "A fact is material if it has the potential of determining the outcome of the litigation." Id. (quoting Maymi v. Puerto Rico Ports Auth., 515 F.3d 20, 25 (1st Cir. 2008)).

The party seeking summary judgment bears the burden of establishing the lack of a genuine issue of material fact. Merchants Ins. Co. of New Hampshire, Inc. v. U.S. Fidelity and Guar. Co., 143 F.3d 5, 7 (1st Cir. 1998). Once such requisite showing has been made, "the opposing party can then defeat the motion by showing that there is a genuine issue of material fact." Rivera-Colon v. Mills, 635 F.3d 9, 12 (1st Cir. 2011). "Summary judgment is not appropriate where 'the evidence on the record is sufficiently open-ended to permit a rational fact finder to resolve

the issue in favor of either side.'" Perez-Cordero v. Wal-Mart Puerto Rico, Inc., 656 F.3d 19, 25 (1st Cir. 2011)(internal citation omitted). The Court, in considering a motion for summary judgment, "read[s] the record in the light most favorable to the non-moving party, drawing all reasonable inferences in its favor." Merchants Ins. Co. of New Hampshire, Inc. v. U.S. Fidelity and Guar. Co., 143 F.3d at 7 (citing Reich v. John Alden Life Ins. Co., 126 F.3d 1, 6 (1st Cir. 1997)).

The fact that cross motions for summary judgment have been filed "'neither dilutes nor distorts this standard of review.'" Scottsdale Ins. Co. v. Torres, 561 F.3d 74, 77 (1st Cir. 2009)(quoting Specialty Nat'l Ins. Co. v. OneBeacon Ins. Co., 486 F.3d 727, 732 (1st Cir. 2007)). Instead, "'[c]ross motions simply require [the court] to determine whether either of the parties deserves judgment as a matter of law on facts that are not disputed.'" Scottsdale Ins. Co. v. Torres, 561 F.3d at 77 (quoting Littlefield v. Acadia Ins. Co., 392 F.3d 1, 6 (1st Cir. 2004)); Reich v. John Alden Life Ins. Co., 126 F.3d 1, 6 (1st Cir. 1997) ("When deciding cross-motions for summary judgment, the court must consider each motion separately, drawing inferences against each movant in turn.").

III. Discussion

The parties' respective positions with regard to the two Ordinances at issue in this litigation are reflected in the labels they have attached to them. The Plaintiffs, who take the position that Section 14-303 limits "their ability to communicate pricing

information," refer to it as the "Promotion Ordinance." Complaint 3. The City, countering that Section 14-303 "regulates the sale and/or distribution of price-discounted tobacco products," refers to it as the "Price Ordinance." Def.'s Mem. 1 (Docket # 44-1). With respect to Sections 14-308 and 14-309, the Plaintiffs allege that, under the "Flavor Description Ordinance," manufacturers and retailers "are prohibited from describing the taste or aroma of certain tobacco products to consumers;" whereas the City argues that the "Flavored Tobacco Ordinance" only "regulates the sale of certain flavored and smokeless tobacco products." Def.'s Mem. 1-2. For ease of reading, the Court will refer to the Ordinances as the "Price" and the "Flavor" Ordinance.

(A) Violation of Plaintiffs' First Amendment Rights

(Counts I and VII)

With respect to the Price Ordinance, the Plaintiffs asserted in their Complaint that the "ban on the use of coupons and certain promotion discounts for cigarettes and other tobacco products restricts communication with adult tobacco consumers about the price of tobacco products" and, therefore, is protected as "commercial speech." Complaint 38. The Plaintiffs further suggest that, by prohibiting retailers from accepting or redeeming coupons or providing multi-pack discounts, the Price Ordinance "regulates *what is said* about prices." Pltfs.' Mem. 11 (emphasis in original).

Regarding Section 14-308 of the Flavor Ordinance, the

Plaintiffs alleged that the "ban on many public statements referencing an open-ended series of 'tastes', 'aromas,' or 'concepts' in describing non-cigarette tobacco products violates" the First and Fourteenth Amendments. Complaint 44. In their memorandum, the Plaintiffs argue that (1) the prohibition of the Flavor Ordinance is "triggered" by speech because it provides that a "public statement or claim . . . shall constitute presumptive evidence that the tobacco product is a flavored tobacco product," essentially banning a product because of what is said about it; and (2) Section 14-308 of the Flavor Ordinance prohibits reference to a non-exclusive list of concepts even if such concepts apply to an underlying product that is "seemingly exempt." Pltfs.' Mem. 26-27.

In their supporting memorandum and at the August 22, 2012 hearing, the Plaintiffs suggested that the four-prong test of Central Hudson[5] provides the applicable standard for determining whether Section 14-303 and/or Sections 14-308 - 309 are violative of the First Amendment. Pltfs's Mem. 11-17, 26-30.

In response, the City took the position that neither Ordinance at issue concerns speech or expressive conduct protected by the First Amendment. City Mem. 30. The City pointed out that the plain language of Section 14-303 regulates the commercial activity of a tobacco retailer in Providence and does not preclude the Plaintiffs from disseminating coupons or multi-pack offers; instead, it merely

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[5] Cent. Hudson Gas & Elect. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980).

prohibits the redemption of such price reduction means in the City. City Mem. 31. With respect to the Flavor Ordinance, the City noted that the Plaintiffs' argument is primarily based on the definitions in Section 14-308, whereas the actual prohibition in Section 14-309 only makes the sale of flavored tobacco products unlawful (unless the sale occurs in a smoking bar). City Mem. 31. The City also stated that, notwithstanding the statement in Section 14-308 that a claim by the manufacturer of a tobacco product that such a product "has or produces a characterizing flavor shall constitute presumptive evidence" that such product is a flavored tobacco product, this provision does not preclude the Plaintiffs' communications regarding their flavored tobacco products. City Mem. 33. Because both Ordinances limit only specific commercial activities - the local sale and distribution of certain tobacco products - neither speech nor expressive conduct is implicated. Id. 3. The City also suggested that, even if the Court were to apply the O'Brien[6] test applicable to expressive conduct protected by the First Amendment, the Ordinances advance a compelling state interest.

The Plaintiffs' contention that the Ordinances take aim at "commercial speech" and, therefore, such speech should be afforded protection under the First Amendment, is undermined by the plain language of the Ordinances. It is well-established law that

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[6] United States v. O'Brien, 391 U.S. 367, 88 S.Ct. 1673, 20 L.Ed.2d 672 (1968).

commercial speech, including truthful advertising "is entitled to a measure of protection under the First Amendment." Wine and Spirits Retailers, Inc. v. Rhode Island, 418 F.3d 36, 48-49 (1st Cir. 2005)(listing cases). As the Plaintiffs correctly point out, truthful, nonmisleading, commercial information including accurate price information is protected by the First Amendment as commercial speech. 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 496, 116 S.Ct. 1495, 1505, 134 L.Ed.2d 711 (1996) (noting that "[a]dvertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what product, for what reason, and at what price.") The Plaintiffs fail, however, to establish that the practice of reducing the price of cigarettes and tobacco products through coupons and multi-pack discounts is subject to constitutional protection. See Wine and Spirits Retailers, Inc. v. Rhode Island, 418 F.3d at 49 (noting that "it is the duty of the party seeking to engage in allegedly expressive conduct to demonstrate that the First Amendment applies to that conduct")(citing Clark v. Cmty. for Creative Non-Violence, 468 U.S. 288, 293 n. 5, 104 S.Ct. 3065, 82 L.Ed. 2d 221 (1984). Neither of the Ordinances at issue precludes the Plaintiffs from engaging in activities that can be considered "commercial speech."

Section 14-303 prohibits the use of coupons or multi-pack discounts which would make cigarettes or tobacco products available to purchasers at a reduced price. It does not, however, preclude licensed tobacco dealers from communicating pricing information to

their customers, nor does it regulate "what is said about prices." Pltfs.' Mem 11. As such, Section 14-303 regulates the commercial activity itself; it does not prohibit any communication regarding that activity. Moreover, nothing in Section 14-303 forbids the dissemination of coupons within the City, it only prohibits the acceptance or redemption of such coupons and the sale of tobacco products or cigarettes through multi-pack or bundled discounts. In other words, Section 14-303 is a means to control the price of cigarettes and tobacco products in Providence. Because it does so without implicating "commercial speech," First Amendment protection under the Central Hudson doctrine is not warranted under these circumstances.

Nor is the prohibition against coupon redemption or discount pricing "so inherently expressive" as to fall under the O'Brien analysis. Wine and Spirits Retailers, Inc. v. Rhode Island, 481 F.3d 1, 7 (1st Cir. 2007)(acknowledging applicability of O'Brien test to "expressive conduct"). The protection of the First Amendment is extended "only to conduct that is inherently expressive." Rumsfeld v. Forum for Acad. and Inst. Rights, Inc., 547 U.S. 47, 66, 126 S.Ct. 1297, 1311, 164 L.Ed.2d 156 (2006). While a prohibition of the dissemination of pricing information for cigarettes and tobacco products, e.g. via coupons, may fall within the expressive conduct category, a prohibition against the redemption of coupons or the sale of such products in multi-packs does not. Section 14-303, rather than limiting speech, only directly regulates the conduct with which the City is concerned.

See Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 586, 121 S.Ct. 2404, 2438, 150 L.Ed.2d 532 (2001)(suggesting alternative means for State to advance its interest in preventing access to tobacco products by minors). Moreover, the Plaintiffs, by insisting that Section 14-303 regulates commercial speech, appear to concede that "it is not a regulation of 'expressive conduct' under United States v. O'Brien." Pltfs. Reply 9 (Docket # 49).

The Plaintiffs' reliance on a "long line of cases that have applied Central Hudson to challenges to similar promotional offers" as those at issue in the instant case is misplaced. In Rockwood v. City of Burlington, Vt, 21 F.Supp.2d 411 (D.Vt. 1998), the Ordinance at issue - which primarily concerned tobacco advertising - prohibited "the distribution of free samples or coupons for the purposes of promoting tobacco products." Id. at 420. In Knapp v. Miller, 843 F.Supp. 633 (D. Nev. 1993)(related to a legal brothel business), the court determined that the "[p]laintiff's flyers providing three-for-one coupons and newspaper advertisements constitute commercial speech." Id. at 641. Wild West Gambling Hall & Brewery, Inc. v. City of Cripple Creek, 853 F.Supp. 371 (D. Colo. 1994) likewise dealt with the distribution of promotional materials, including coupons or, in this case, a free $1 token to promote casino gambling. In Discount Tobacco City & Lottery v. United States, 674 F.3d 509 (6th Cir. 2012), the Sixth Circuit undertook a Central Hudson analysis after determining that the challenged ordinance - which prohibited the distribution of free samples of tobacco products and other gifts or promotional

materials - attempted "to regulate the 'communicative impact' of the activity, not the activity itself." Id. at 539. The Court then proceeded to uphold the restrictions, with the exception of the distribution of free gifts with a tobacco purchase.

In the cases cited by the Plaintiffs, the ordinances in question all prohibited the distribution of promotional materials. Section 14-303, however, does not prohibit the distribution of coupons or the dissemination of pricing information - it prohibits the redemption of such coupons and the sale of cigarettes or tobacco products through multi-pack discounts. Therefore, the prohibited activity constitutes neither commercial speech nor expressive conduct and is not subject to First Amendment protection under either the Central Hudson or the O'Brien standard. See 44 Liquormart, Inc. v. Rhode Island, 517 U.S. at 499, 116 S.Ct. at 1506 (noting the distinction between "'the right to speak and hear expression about goods and services and the right of government to regulate the sales of such goods and services.'") (internal citation omitted).

Although the term "offer" in Section 14-303 appears to indicate that the prohibition extends to some manner of communication, a closer reading reveals that the provision only precludes licensed tobacco retailers from offering what the Ordinance explicitly forbids them to do: to accept or redeem coupons in Providence. As the City acknowledges, Section 14-303 does not preclude the Plaintiffs from distributing coupons, multi-pack offers or other price discounting information in Providence,

see City Mem. 31 (Section 14-303 "in no way affects the ability of the Plaintiffs. . . to continue to disseminate price reduction instruments and multi-pack offers in Providence.") Instead, the provision prohibits the redemption of coupons and the sale of cigarettes and tobacco products in multi-pack form in Providence only.

Moreover, it is well established that commercial speech which concerns unlawful activity or is misleading, is not subject to First Amendment protection and may be freely regulated by the government. Florida Bar v. Went For It, Inc., 515 U.S. 618, 623-624, 115 S.Ct. 2371, 132 L.Ed.2d 541 (1995)(citing Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York, 447 U.S. at 563-564, 100 S.Ct. at 2350). Therefore, although the dissemination of coupons and multi-pack pricing information for use elsewhere is allowed under the Price Ordinance, the redemption of coupons and sale of multi-packs in Providence is prohibited and no constitutional protection is applicable to the offer of redeeming such coupons or selling multi-packs in Providence.

In sum, because Section 14-303 does not involve commercial speech or expressive conduct, its prohibition against certain coupon discount and other price reduction practices does not conflict with the Plaintiffs' exercise of their First Amendment rights.

With respect to the prohibition against the sale of flavored tobacco products (except in a smoking bar), the operative provision of the Flavor Ordinance, Section 14-309, is also directed at

economic conduct that qualifies neither as "commercial speech" nor "expressive conduct." The Plaintiffs' argument is focused on Section 14-308, which defines "characterizing flavor" and "flavored tobacco product." Specifically, the Plaintiffs assert that (1) the Flavor Ordinance "presumptively bans products based on what Plaintiffs *say* about them," Pltfs.'s Mem. 26 (emphasis in original); (2) the Flavor Ordinance "prohibits any reference to an open-ended, non-exclusive list of 'concepts' or 'tastes or aromas' to describe tobacco products," id. at 26; and (3) such references render the Flavor Ordinance "unconstitutionally vague." Id. at 29-30.

With respect to the first contention, the case offered by the Plaintiffs in support is distinguishable. In Virgina v. Black, 538 U.S. 343, 123 S.Ct. 1536, 155 L.Ed.2d 535 (2003), the Supreme Court upheld a Virginia statute which banned cross burning with intent to intimidate. However, the Court deemed unconstitutional a provision of the statute which provided that "[a]ny such burning of a cross shall be prima facie evidence of an intent to intimidate a person or group of persons." Id. 538 U.S. at 364. The holding of the Court was based the Commonwealth's adoption of a model jury instruction which stated that "[t]he burning of a cross, by itself, is sufficient evidence from which you may infer the required intent." Id. ("The prima facie evidence provision, as interpreted by the jury instruction, renders the statute unconstitutional.") Because the provision permitted the Commonwealth to "arrest, prosecute, and convict a person based solely on the fact of cross burning itself,"

it allowed for the possibility that a person could be convicted for engaging in core political speech, without any intent of intimidation. Id. at 365.

Section 14-309, which prohibits the sale of flavored tobacco products, except in a smoking bar, offers no possibility for creating "an unacceptable risk of the suppression of ideas." Virginia v. Black, 538 U.S. at 365. It is an economic regulation of the sale of a particular product and, as such, it involves neither commercial speech nor expressive conduct. The inclusion of a "public claim or statement made by the manufacturer" to determine whether the described product falls under the definition of a "flavored tobacco product" in Section 14-308 does not amount to a prohibition against speech. The sale of flavored tobacco products in Providence (outside a smoking bar) constitutes a violation of Section 14-309, regardless of whether it is specifically described as a flavored tobacco product or not. In other words, the Plaintiffs are free to describe their products as having or producing a characterizing flavor; they are, however, precluded from selling flavored tobacco products in Providence (with the exception of tobacco bars).

The definition of "characterizing flavor" also contains no explicit or implied prohibition against statements regarding the Plaintiffs' tobacco products; it merely serves to explain which tobacco products fall under the prohibition of Section 14-309. It also expressly exempts tobacco products with the distinguishable "taste or aroma of tobacco, menthol, mint or wintergreen," the sale

of which is permissible under Section 14-309.

However, with respect to "concepts such as spicy, arctic, ice, cool, warm, hot mellow, fresh and breeze," the Court is of the opinion that the inclusion of this phrase serves to confuse rather than clarify the definition. Not only is it unexplained how a concept[7] can relate to a tobacco product but, as the Plaintiffs correctly point out, it is at least conceivable that terms such as "arctic, ice, cool, and fresh" could be interpreted to include tobacco products flavored with menthol, mint or wintergreen, which are specifically excepted from the sales prohibition of Section 14-309. Therefore, in order to keep the Section 14-309 ban against the sale of flavored tobacco products intact, the provision "and concepts such as spicy, arctic, ice, cool, warm, hot, mellow, fresh, and breeze" shall be stricken from Section 14-308. See Section 14-307.

Because neither the Price Ordinance nor the Flavor Ordinance conflicts with the Plaintiffs' First Amendment Rights, the Ordinances are subject to a rational basis standard of review, which examines only whether "the means chosen by the legislature are rationally related to some legitimate government purpose." Wine and Spirits Retailers, Inc. v. Rhode Island, 418 F.3d 36, 53 (1st Cir. 2005). To meet that standard, the City must "articulate some 'conceivable set of facts' that could establish a rational

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[7] One dictionary definition of "concept" is "something conceived in the mind: THOUGHT, IDEA, NOTION." Webster's Third New International Dictionary 469 (2002).

relationship between the challenged laws and the government's legitimate ends," Kittery Motorcycle, Inc. v. Rowe, 320 F.3d 42, 47 (1st Cir. 2003), which requires no evidentiary record. See e.g., F.C.C. v. Beach Commc'ns, 508 U.S. 307, 315, 113 S.Ct. 2096, 2102, 124 L.Ed.2d 211 (1993) (noting that "a legislative choice . . . may be based on rational speculation unsupported by evidence or empirical data.")

The City has submitted several affidavits in support of its motion for summary judgment. Professor Frank J. Chaloupka, Ph.D., a specialist in the field of health economics, asserts that Section 14-303 will reduce the use of tobacco, particularly among young people, by banning the redemption of coupons and the use of multi-packs, which have "a larger impact on use among young people, given their greater price sensitivity." Chaloupka Aff. 38 (Docket # 44-3). Professor Gregory N. Connolly, D.M.D., M.P.H., who has published more than 100 scientific articles on tobacco use and health, states that Section 14-309, which restricts the sale of flavored tobacco products to smoking bars, would "substantially reduce the sale of flavored tobacco products to underage consumers[8] and would reduce the attractiveness of these products to underage consumers by removing them from sales counters frequented by adolescents." Connolly Aff. 18 (Docket # 44-4). Once the City has articulated the connection between its stated goal to reduce the

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[8] The Court notes that sale of tobacco products to any individual under eighteen(18) years of age is prohibited by Rhode Island law. R.I. Gen. Laws § 11-9-13.8 (1).

use of tobacco by underage consumers and young adults and the provisions contained in the Ordinances, the burden is on the Plaintiffs to show that "there exists no fairly conceivable set of facts that could ground a rational relationship" between the Ordinance provisions and the City's objective. Medeiros v. Vincent, 431 F.3d 25, 29 (1st Cir. 2005)(internal citation omitted). Although the Plaintiffs offer several declarations to support their allegation that the Ordinances interfere with their communications with adult customers, their submissions fail to demonstrate the absence of a rational basis. See Gonzalez-Droz v. Gonzalez-Colon, 660 F.3d 1, 10 (1st Cir. 2011) (noting that rational basis review requires only that the legislating entity "could rationally have concluded" that the challenged regulation "*might* advance its legitimate interests")(emphasis in original).

(B) Federal Preemption

(1) Count II - Price Ordinance

Under the Supremacy Clause, constitutionally enacted federal law is supreme to state law. U.S. Const. Art.VI. Cl.2. State law may be preempted by federal law either expressly or by implication. New Hampshire Motor Transport Ass'n v. Rowe, 448 F.3d 66, 74 (1st Cir. 2006). To make a determination whether a particular state or local law is preempted, congressional intent is "the ultimate touchstone." Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). Although "the primary indicator of that intent is the text of the congressional act claimed to have preemptive effect . . . [t]he text of the

preemption provision must be viewed in context, with proper attention paid to the history, structure, and purpose of the legislative scheme in which it appears." Good v. Altria Grp., Inc., 501 F.3d 29, 34 (1st Cir. 2007).

Even in the presence of an express preemption clause, a court may consider the statute as a whole to determine whether "the scope of the statute indicates that Congress intended federal law to occupy the legislative field." Altria Grp., Inc. v. Good, 555 U.S. 70, 76-77, 129 S.Ct. 538, 543, 172 L.Ed.2d 398 (2008). Preemption is not indicated unless there is evidence of "a clear and manifest congressional purpose." Massachusetts v. Ass'n of Health Maintenance, 194 F.3d 176, 179 (1st Cir. 1999).

The Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1331 *et seq.* (the "Labeling Act"), was enacted by Congress in 1965 in order to "establish a comprehensive Federal program to deal with cigarette labeling and advertising." 15 U.S.C. § 1331. The aim of the legislation was to inform the public about adverse health effects of cigarette smoking while, at the same time, ensuring that commerce and the national economy were "not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health." 15 U.S.C. § 1331; 23-34 94th Grocery Corp. V. New York City Bd. of Health, 685 F.3d 174, 177 (2d Cir. 2012).

Subsection 1334(b), which addresses preemption of state regulations regarding the labeling, advertising, and promotion of cigarettes, provides:

> No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter. 15 U.S.C. § 1334(b).

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act ("FSPTCA"), Pub. L. No. 111-31, 123 Stat. 1776 (2009), which added an exclusionary provision applicable to subsection 1334(b). The newly added subsection 1334(c) provides:

> Notwithstanding subsection (b), a State or locality may enact statutes and promulgate regulations, based on smoking and health, that take effect after the effective date of the Family Smoking Prevention and Tobacco Control Act, imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes. 15 U.S.C. § 1334(c).

The Plaintiffs argue that Section 14-303 is expressly preempted under the Labeling Act because the Labeling Act forbids states and localities from establishing a "requirement or prohibition" that is "based on smoking and health" and "with respect to the advertising or promotion of any cigarettes.[9]" Pltfs.' Mem 1-2, 17-22. Specifically, the Plaintiffs argue that Section 1334(b) of the Labeling Act precludes the City from enacting and enforcing Section 14-303, which the Plaintiffs characterize as a "wholesale attack on cigarette promotion." Pltfs.' Mem. 18. The Plaintiffs also suggest that, since coupons are defined in terms of "promotional purposes" in Section 14-300,

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[9] The Labeling Act applies to cigarettes only; it does not apply to cigars or other tobacco products.

the prohibition in Section 14-303 is preempted. Id. at 19. The Plaintiffs maintain that the Price Ordinance is directed at the content of pricing information communicated to adult consumers and that it bans discounts in forms of coupons and multi-packs because such discount offers have "the content of offering a reduced unit price." Id. at 20. In response, the City asserts that Section 14-303 is not preempted by the Labeling Act because it "does not concern itself with the content of advertisements or of promotional materials." City Mem. 51.

Section 14-303 imposes no additional requirements on labeling or advertising of cigarettes or the content of other promotional materials, including coupons or special pricing offers. Even accepting the Plaintiffs' argument that coupons are a form of promotion, Section 14-303 does not regulate the content of such coupons, nor does it preclude the Plaintiffs from disseminating the coupons within the City, whether for promotional purposes or otherwise; instead, it only prohibits the redemption of coupons. Likewise, Section 14-303 does not regulate the information provided on cigarette packaging, it only prohibits the sale of cigarettes through multi-pack discounts or the distribution of cigarettes for less than the listed price in exchange for the purchase of other cigarettes.

Although the Plaintiffs assert that "[e]very federal court to consider the question has . . . recognized" that "the offering acceptance, and redemption of coupons are core promotional activities under the Labeling Act," the cases to which they cite

precede the exclusionary provision of Section 1334(c). Pltfs.' Mem. 19 (citing Jones v. Vilsack, 272 F.3d 1030 (8th Cir. 2001) and Rockwood v. City of Burlington, 21 F.Supp.2d 411 (D.Vt.1998). Section 1334(c), however, explicitly permits states and localities to impose "specific bans or restrictions on the time, place, and manner but not content, of the advertising or promotion of any cigarettes." Nothing in the prohibition against coupon redemption or multi-pack sales set forth in Section 14-303 imposes "diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health." Rather than controlling the content of promotional or advertising materials, Section 14-303 regulates the "time, place, and manner" of how cigarettes may be purchased in the City of Providence. As such, the Ordinance falls into the category of conduct specifically excluded from preemption by Subsection 1334(c) and provides no conflict with the intended purpose of the Labeling Act regarding uniform cigarette labeling and advertising.

(2) Count IX - Flavor Ordinance

With respect to the Flavor Ordinance, the Plaintiffs argue that it is preempted by the FSPTCA because the Ordinance attempts to establish local requirements that are "different from" and "in addition to" federal requirements related to tobacco product standards and tobacco product labeling. While the FSPTCA only prohibits cigarettes that contain artificial or natural flavors (other than menthol), it does not apply to smokeless tobacco or other non-cigarette tobacco products. The Plaintiffs suggest that

Section 14-309 impermissibly extends the scope of the federal flavor standards to such non-cigarette products. Pltfs.' Mem. 31-32. Further, the Plaintiffs point out that the FSPTCA only applies to cigarettes that "contain, as a constituent . . . or additive" an ingredient that imparts a "characterizing flavor," whereas Section 14-309 "presumptively applies to any tobacco product publicly described as containing a "characterizing flavor." Id. at 32-33.

On its part, the City argues that the Plaintiffs' reliance on the FSPTCA's preemption clause fails to take into consideration that the FSPTCA also includes a savings clause and a preservation clause, which, together "create the balance of power between the state and federal governments." City's Mem. 56-57.

The stated purpose of the FSPTCA is "to provide authority to the FDA to regulate tobacco products, in order to 'address issues of particular concern to public health officials, including the use of tobacco by young people and dependence on tobacco." Pub.L. No. 111-31, § 3(2). Discount Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 520 (6th Cir. 2012). The FSPTCA authorizes the FDA to "regulate the sale, distribution, advertising, promotion and use of tobacco products," although it prohibits a complete ban on a class of nicotine products. Id.; U.S. Smokeless Tobacco Mfg. Co., LLC v. City of New York, 703 F. Supp.2d 329, 336-337 (S.D.N.Y. 2010)(noting that the FSPTCA "responds, at least in part" to the holding in Lorillard Tobacco v. Reilly, 533 U.S. 525, 121 S.Ct. 2404, 150 L.Ed.2d 532 (2001), in which the Court held, *inter alia*, that the Labeling Act preempted a state law regulating outdoor

cigarette advertising aimed at reducing tobacco consumption by minors).

With respect to cigarettes only, the FSPTCA prohibits the use of "characterizing flavors" other than tobacco or menthol. 21 U.S.C. § 387g.[10]

Section 387p(a)(1) of the FSPTCA provides:

> Except as provided in paragraph (2)(A), nothing in this subchapter, or rules promulgated under this subchapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this subchapter shall limit or otherwise affect any State, tribal, or local taxation of tobacco products. 21 U.S.C. §387p(a)(1)(emphasis added).

In a recent decision by the United States District Court of the Southern District of New York analyzing a local statute nearly identical to the challenged definition of the Flavor Ordinance in

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[10] Subsection 387g(a) provides, *inter alia*, that "a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke." 21 U.S.C. § 387g (a).

this case, the court concluded that the FSPTCA allows a state or locality to impose its own, more restrictive, regulations on the sale of tobacco products. U.S. Smokeless Tobacco Mfg. Co., LLC v. City of New York, 703 F.Supp.2d at 340.

Although the FSPTCA contains a preemption provision prohibiting state and local governments to adopt its own "tobacco product standards," that provision is followed, and limited by, a further exclusionary provision.

Section 387p(a)(2)(A) provides:

> No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

As such, the FSPTCA preemption provision relates to tobacco product standards, not the sale and/or distribution of tobacco products prohibited by Section 14-309 of the Flavor Ordinance. Moreover, while the setting of tobacco product standards remains in the exclusive domain of the federal government, the additional exclusionary provision of subsection 387p(a)(2)(B) reaffirms that state or local regulations related to the sale and/or distribution of tobacco products are not preempted by the FSPTCA:

> Section 387p(a)(2)(B) provides, in pertinent part:
>
> Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety

standards for tobacco products.

When considered together, along with the FSPTCA's explicit ban of flavored cigarettes but not of other flavored tobacco products, the three provisions of the FSPTCA constitute no impediment to the City's prohibition against the sale of flavored tobacco products. Furthermore, there is no conflict between the FSPTCA's ban on flavored cigarettes and Section 14-309, which bans the sale of tobacco products (with the exception of tobacco bars), not cigarettes.

(C) Due Process Violations under the 14th Amendment and Civil Rights Deprivation under Section 1983 (Counts III, VIII and X)

In their Complaint, the Plaintiffs asserted that by "enacting and threatening to enforce" the Ordinances, the City has "unlawfully and substantially deprived" them of rights secured by the First and Fourteenth Amendments to the United States Constitution and 42 U.S.C. § 1983. Complaint 39 - 40, 48-49. However, those claims remained without evidentiary support or argument and they were not further addressed in the Plaintiffs' memoranda or at the August 22, 2012 hearing.

The Plaintiffs also claimed that Section 14-309 violated their due process rights because it contained "unconstitutionally vague prohibitions" and undefined terms, Complaint 44-45. Specifically, the Plaintiffs took exception to the "non-exhaustive list of 'tastes' and 'aromas' - i.e. a list 'including, but not limited to,' the enumerated flavors." Pltfs.' Mem. 29. As this Court previously determined herein, Section 14-309 constitutes a

prohibition against the sale of flavored tobacco products (outside of a smoking bar), which does not infringe on "commercial speech" or "expressive conduct." See *supra*. Therefore, the heightened scrutiny employed by the Supreme Court in Reno v. American Civil Liberties Union, 521 U.S. 844, 117 S.Ct. 2329, 138 L.Ed.2d 874 (1997) (holding that vagueness of content-based regulation of speech in criminal statute raised special First Amendment concerns because of its obvious chilling effect on free speech) is not applicable here. Instead, the question is whether the language of the statute is "'sufficiently specific to provide fair notice of what [it] proscribe[s].'" Kittery Motorcycle, Inc. v. Rowe, 320 F.3d at 50 (quoting Brasslett v. Cota, 761 F.2d 827, 838 (1st Cir. 1985)). The offense must be defined "'with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement.'" United States v. Lachman, 387 F.3d 42, 57 (1st Cir. 2004) (quoting Kolender v. Lawson, 461 U.S. 352, 357, 103 S.Ct. 1855, 75 L.Ed.2d 903 (1983)). As stated by the First Circuit in Lachman, "[t]he mere fact that a statute or regulation requires interpretation does not render it unconstitutionally vague," particularly where "the statute deals with economic regulation and is addressed to sophisticated businessmen and corporations." United States v. Lachman, 387 F.3d at 57.

The definition of "characterizing flavor" in Section 14-308 states that it includes, but is not limited to, "tastes and aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa,

dessert, alcoholic beverage, herb or spice."[11] As such, it is closely modeled after the FSPTCA provision prohibiting the sale of flavored cigarettes. Subsection 387g(a) of the FSPTCA lists a number of possible flavors that are prohibited, but explicitly preserves the FDA's authority to take action with respect to "any artificial or natural flavor, herb, or spice not specified in this subparagraph." 21 U.S.C. § 387g (a)(1)(A). The fact that a statute includes a "non-exhaustive list" of examples does not render the statute vague. Rather, "[t]he existence of clear examples of conduct covered by law may, in certain circumstances, help to insulate the law against an accusation of vagueness." URI Student Senate v. Town of Narragansett, 631 F.3d 1, 14 (1st Cir. 2011)(upholding statute furnishing "a non-exhaustive list of predicate offenses" that will allow a police officer to enforce the ordinance at issue).

Moreover, the Plaintiffs' suggestion that, pursuant to Section 14-309, the ban of flavored tobacco product sales could arguably apply to "tobacco, menthol, or mint flavored" products is expressly foreclosed by the exclusion of those flavors in the Section 14-308 definition of "characterizing flavor."

In sum, the Court is of the opinion that Section 14-309 of the Flavor Ordinance prohibiting the sale (outside of a tobacco bar) of

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[11] Because the Court concluded that the inclusion of "concepts" in Section 14-308 confused, rather than clarified, the definition of "characterizing flavor," that portion of Section 14-308 was ordered stricken. See *supra*.

flavored tobacco products as defined by Section 14-308 is not unconstitutionally vague.

(D) Violation of the Rhode Island Constitution

(Counts IV and XI)

This particular challenge of the Price and the Flavor Ordinances is based on the Plaintiffs' contention that the two Ordinances are "predicated on the City of Providence's unauthorized tobacco retailer licensing scheme." Pltfs.' Mem. 23, 40-41. In the event of any violation under either provision, Section 14-310 provides that a "tobacco dealer's license holder" will be subject to a range of civil fines based on the number of offenses. In addition, the City's Licensing Board "may suspend or revoke the license." Section 14-310.

The Plaintiffs, although they have not brought a direct challenge against the City's requirement of a tobacco dealer's license for selling tobacco products within the City, generally allege that Rhode Island has a "comprehensive, statewide tobacco retailer licensing law" and that the General Assembly "has not delegated authority to Providence or any other municipality to enact laws requiring local tobacco licenses." Pltfs.' Mem. 23.

In response, the City argues that (1) the Ordinances do not depend on the validity of the license requirement in Section 14-301, City's Mem. 66; (2) there is no exclusive constitutional delegation of power to the Rhode Island General Assembly with respect to all licensing, id. at 67; and (3) the provisions in the Ordinances referencing local licensing can be severed while

upholding the remaining substantive provisions. Id. at 70. The City also points out that two other Rhode Island municipalities have enacted ordinances requiring licenses for sellers or distributors of tobacco products. Id. 69 n. 59.

At the August 22, 2012 hearing, the Plaintiffs candidly acknowledged that they had not challenged the City's licensing requirements directly. Nevertheless, the Plaintiffs suggested that the City's licensing ordinance was "clearly unconstitutional," and that Rhode Island not only prohibits the requirement of licenses by municipalities but also the regulation of businesses through a licensing scheme.

The Plaintiffs' challenge of the two Ordinances with respect to the Rhode Island Constitution is based solely on their contention that the Ordinances are part of, and depend on, a licensing scheme which, while not challenged in this case, the Plaintiffs ask this Court to deem unconstitutional. In other words, the question of whether the licensing requirement set forth in Section 14-301 of the Tobacco Dealers Ordinance is an unauthorized overreaching by the City is not before the Court. With respect to the Price and the Flavor Ordinance, licensing is implicated only if a violation occurs. The Ordinances have not yet been enforced and no suspension or revocation of a license has yet occurred in connection with an alleged violation of either Ordinance. Under those circumstances, it would be improper for this Court to determine the constitutionality of the City's licensing requirement and issue what amounts to an advisory opinion. For that reason,

Counts IV and XI are dismissed.

(E) Preemption under Rhode Island Law (Count V)

Next, the Plaintiffs suggest that Section 14-303 is preempted by Rhode Island law because of the State's extensive regulation of tobacco coupons and discount offers. Pltfs.' Mem. 24. The City, on its part, asserts that none of the referenced provisions in Rhode Island statutes conflict with Section 14-303 in any way, nor do the state law provisions indicate an intent to preempt the field. City Mem. 62-63.

For their argument, the Plaintiffs primarily rely on three provisions of Rhode Island law, two of which are criminal statutes related to the sale or distribution of tobacco products to minors, and a third provision which generally relates to product pricing. Sections 11-9-13.8 and 11-913.10[12] prohibit selling tobacco to underage persons; distributing free tobacco products or coupons or

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[12] Section 11-9-13.8 prohibits the sale of tobacco products (1) to any individual under 18; (2) in any form other than an original factory-wrapped package; or (3) the sale of single cigarettes, or "loosies." R.I. Gen. Laws § 11-9-13.8.

Section 11-9-13.10, in pertinent part, provides:

> The distribution of free tobacco products or coupons or vouchers redeemable for free tobacco products to any person under eighteen (18) years of age shall be prohibited. Further, the distribution of free tobacco products or coupons or vouchers redeemable for free tobacco products shall be prohibited, regardless of the age of the person to whom the products, coupons, or vouchers are distributed, within five hundred (500) feet of any school. R.I. Gen. Laws § 11-9-13.10.

vouchers redeemable for free tobacco products to underage persons; and distributing such products or coupons/vouchers to any person within 500 feet of any school. Section 6-13-11[13], Rhode Island's Unfair Sales Practices Act, regulates how businesses can utilize price discounts and other promotions. Id. at 25. Tobacco dealers in violation of the unfair sales practices act are subject to suspension or revocation of their license to sell tobacco products. R.I. Gen. Laws § 44-20-8.

In addition, the Plaintiffs point out that the General Assembly has repeatedly considered - and declined - to further regulate the use of discounts and coupons for the sale of tobacco products. Id. at 25-26. The Plaintiffs allege that Section 14-303 "conflicts with the General Assembly's repeated determination not to further regulate the use of discounts and coupons for the sale of tobacco products." Pltfs.' Mem. 25, referencing proposed legislation restricting the sale of tobacco products in Note 12.

A municipal ordinance is preempted by state law when it is

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[13] (3) Section 6-13-11 provides:
It shall be unlawful to use, communicate, or publish any advertisement that states that an item or product is being sold or offered for sale at below the regular price or at a percentage off the regular price without posting the regular price at the point of purchase. Whenever an item or product is advertised for sale at below the regular price or at a percentage off the regular price, the advertisement shall clearly state whether there is an additional charge for equipment or services which are reasonably necessary for the proper use of the product. Any person, firm, or corporation who shall violate the provisions of this section shall be punished by a fine of not more than five hundred dollars ($500).

determined that "'the General Assembly intended that its statutory scheme completely occupy the field of regulation on a particular subject.'" State ex rel. City of Providence v. Auger, 44 A.3d 1218, 1230 (R.I. 2012)(quoting Grasso Serv. Ctr., Inc. v. Sepe, 962 A.2d 1283, 1289 (R.I. 2009)). In considering field preemption, the Court must determine whether "it was the *expressed intent* of the General Assembly that 'the state control is to be exclusive or whether the control is to be exercised concurrently by the state and by the municipality.'" Auger, 44 A.3d at 1230 (quoting Wood v. Peckham, 80 R.I. 479, 483, 98 A.2d 669, 671 (1953)(emphasis in Auger)).

Sections 11-9-13.8 and 11-9-13-10, to which the Plaintiffs refer, are provisions in Rhode Island's criminal statutes which address offenses against children. As such, the provisions primarily concern conduct deemed to endanger the safety, health, or well-being of minors under the age of 18. Neither of the two state law sections prohibiting the sale or free distribution of tobacco products to minors contains an express reservation of power over the regulation of the distribution of tobacco products. Moreover, as noted in Amico's, "there is no indication that the General Assembly even impliedly intended to occupy the field of regulating smoking." Amico's, 789 A.2d at 907 (listing state statutes that demonstrate the Legislature's recognition of municipalities' authority to regulate smoking in certain areas). Finally, the Plaintiffs' reference to the General Assembly's apparent disinclination to enact measures similar to the provision in Section 14-303 is simply insufficient to support an inference that

the Legislature intended to preempt completely the regulation of tobacco product sales.

(F) Violation of the Open Meetings Act (Counts VI and XII)

In their Complaint, the Plaintiffs allege that the Providence City Council's enactment of the Ordinances on January 5, 2012 was in violation of the Rhode Island Open Meetings Act, R.I. Gen. Laws § 42-46-6(b)[14] because the Council failed to provide supplemental written notice at least forty-eight hours prior to the meeting. Complaint 43, 50. According to the Plaintiffs, the Council first read and voted on the Ordinance on January 3, 2012. Pltfs.' Mem. 8. Although Rhode Island's Open Meetings Act requires forty-eight hours' notice, the Council only gave notice one day before the January 5, 2012 meeting, in the course of which the final vote and enactment of the Ordinances occurred. Id. 9. In response, the City asserts that any violations of the Open Meetings Act were cured when the Council approved the Ordinances a second time. Defs.' Mem. 6.

Upon questioning by the Court at the August 22, 2012 hearing on the parties' motions, Plaintiffs' counsel agreed that the Ordinances had been repassed but suggested that, by reenacting the Ordinance, the City had conceded that the Plaintiffs had stated a

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[14] R.I. Gen. Laws § 42-46-6(b) provides, in pertinent part, that "[p]ublic bodies shall give supplemental written public notice of any meeting within a minimum of forty-eight (48) hours before the date."

valid claim and that the City had acted to correct the error. Nevertheless, no further argument based on an alleged violation of the Open Meetings Act was made with respect to the reenacted Ordinances. Because the Ordinances were properly reenacted with the requisite notice under R.I. Gen. Laws § 42-46-6(b), Counts VI and XII are moot and will be dismissed.

Conclusion

The Plaintiffs' motion for summary judgment is DENIED. The City's motion for summary judgment is GRANTED. The provisions of Section 14-303 shall be modified consistent with this Memorandum and Order. The Plaintiffs' request for a preliminary injunction is DENIED. The Plaintiffs' request for a permanent injunction is DENIED and the Clerk is directed to enter judgment in favor of the Defendants.

SO ORDERED.

/s/ Mary M. Lisi

Mary M. Lisi
Chief United States District Judge

December 10, 2012

Appendix I

Sec. 14-300
Sec. 14-303

Appendix II

Sec. 14-308
Sec. 14-309
Sec. 14-310

Appendix I

City of Providence

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

CHAPTER 2012-14

No. 133

AN ORDINANCE AMENDING SECTION 14-300 AND SECTION 14-303 OF ARTICLE XV OF CHAPTER 14 OF THE CODE OF ORDINANCES OF THE CITY OF PROVIDENCE, ENTITLED: "LICENSES - TOBACCO DEALERS."

Approved February 20, 2012

Be it ordained by the City of Providence:

SECTION 1. Section 14-300 of Article XV of Chapter 14 of the Code of Ordinances of the City of Providence is hereby amended as follows:

Sec. 14-300. Definitions.

"Board of Licenses" shall mean the Providence Board of Licenses as established by Sec. 1102 of the Providence Home Rule Charter of 1980.

"Compliance check violation" shall mean any sale of tobacco products to a person who is less than eighteen (18) years of age.

"*Coupon*" shall mean any card, paper, note, form, statement, ticket or other issue distributed for commercial or promotional purposes to be later surrendered by the bearer so as to receive an article, service or accommodation without charge or at a discount price.

"*Listed or non-discounted price*" shall mean the higher of the price listed for a tobacco product on its package or the price listed on any related shelving, posting, advertising or display at the place where the tobacco product is sold or offered for sale plus all applicable taxes if such taxes are not included in the stated price, and before the application of any discounts or coupons.

"*Cigarette*" means any product that contains nicotine, is intended to be burned or heated under ordinary conditions of use, and consists of or contains: (1) any roll of tobacco wrapped in paper or in any substance not containing tobacco; (2) tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette; or (3) any roll of tobacco wrapped in any substance containing

tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to or purchased by, consumers as a cigarette described in clause (1) of this definition.

"Tobacco products" shall mean any substance containing tobacco leaf, including, but not limited to cigarettes, cigars, pipe tobacco, snuff, chewing tobacco, dipping tobacco, orbs, sticks, ~~and~~ dissolvable tobacco products, and electronic cigarette cartridges; provided, however, that "tobacco products" shall not include any product that has been approved by the United States Food and Drug Administration for use as a medical treatment to reduce and eliminate nicotine or tobacco dependence.

"Vending machines" shall mean any mechanical, electric or electronic self service device which, upon insertion of money, tokens, or any other form of payment, dispenses tobacco products.

SECTION 2. Section 14-303 of Article XV of Chapter 14 of the Code of Ordinances of the City of Providence is hereby amended as follows:

Sec. 14-303. Prohibitions applicable to license holders, their employees and agents.

A person who holds a license issued under this article, or any employee or agent of same, is prohibited from selling, distributing, delivering, offering for sale, or giving away, or possessing with the intention of selling, distributing, delivering, offering for sale, or giving away tobacco products within the city to any individual that is under eighteen (18) years of age, whether said tobacco is sold, distributed or delivered in person or via vending machine.

A person who holds a license issued under this article, or any employee or agent of same, is prohibited from selling as a single cigarette sale, or as a sale of cigarettes by the individual piece, known as "loosies."

No person who holds a license issued under this article, nor any employee or agent of same, shall:

(1) accept or redeem, offer to accept or redeem, or cause or hire any person to accept or redeem or offer to accept or redeem any coupon that provides any tobacco products without charge or for less than the listed or non-discounted price; or

(2) accept or redeem, offer to accept or redeem, or cause or hire any person to accept or redeem or offer to accept or redeem any coupon that provides any cigarettes without charge or for less than the listed or non-discounted price; or

Page 3

(3) sell tobacco products to consumers through any multi-pack discounts (e.g., "buy-two-get-one-free") or otherwise provide or distribute to consumers any tobacco products without charge or for less than the listed or non-discounted price in exchange for the purchase of any other tobacco product; or

(4) sell cigarettes to consumers through any multi-pack discounts (e.g., "buy-two-get-one-free") or otherwise provide or distribute to consumers any cigarette without charge or for less than the listed or non-discounted price in exchange for the purchase of any other cigarette.

SECTION 3. This Ordinance shall take effect March 1, 2012.

IN CITY COUNCIL
JAN 03 2012
FIRST READING
READ AND PASSED
CLERK

IN CITY COUNCIL
FEB 17 2012
FINAL READING
READ AND PASSED
PRESIDENT
ACTING CLERK

I HEREBY APPROVE.
Mayor
Date: 2/20/12

City of Providence

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

CHAPTER 2012-13

No. 132 AN ORDINANCE AMENDING ARTICLE XV OF CHAPTER 14 OF THE CODE OF ORDINANCES OF THE CITY OF PROVIDENCE, ENTITLED: "LICENSES" BY ADDING THERETO THE FOLLOWING SECTIONS.

Approved February 20, 2012

Be it ordained by the City of Providence:

SECTION 1. Article XV of Chapter 14 of the Code of Ordinances of the City of Providence is hereby amended by adding thereto the following:

Sec. 14-308. Definitions.

Whenever used in this ordinance, the following terms shall be defined as follows:

"Cigarette" means any product that contains nicotine, is intended to be burned or heated under ordinary conditions of use, and consists of or contains: (1) any roll of tobacco wrapped in paper or in any substance not containing tobacco; (2) tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette; or (3) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to or purchased by, consumers as a cigarette described in clause (1) of this definition.

"Characterizing flavor" means a distinguishable taste or aroma, other than the taste or aroma of tobacco, menthol, mint or wintergreen, imparted either prior to or during consumption of a tobacco product or component part thereof, including, but not limited to, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, herb or spice and concepts such as spicy, arctic, ice, cool, warm, hot, mellow, fresh, and breeze; provided, however, that no tobacco product shall be determined to have a characterizing flavor solely because of the use of additives or flavorings or the provision of ingredient information.

"Component part" means any element of a tobacco product, including, but not limited to, the tobacco, filter and paper, but not including any constituent.

"Constituent" means any ingredient, substance, chemical or compound, other than tobacco, water or reconstituted tobacco sheet, that is added by the manufacturer to a tobacco product during the processing, manufacture or packing of the tobacco product. Such term shall include a smoke constituent.

"Flavored tobacco product" means any tobacco product or any component part thereof that contains a constituent that imparts a characterizing flavor. A public statement or claim made or disseminated by the manufacturer of a tobacco product, or by any person authorized or permitted by the manufacturer to make or disseminate public statements concerning such tobacco product, that such tobacco product has or produces a characterizing flavor shall constitute presumptive evidence that the tobacco product is a flavored tobacco product.

"Person" means any natural person, partnership, firm, joint stock company, corporation, or employee thereof, or other legal entity.

"Smoke constituent" means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the tobacco product to the smoke or that is formed by the combustion or heating of tobacco, additives or other component of the tobacco product.

"Smoking bar" has the meaning as such term is defined in Sec. 23-20.10-2(15) of the Rhode Island general laws.

"Tobacco product" means any product containing tobacco or nicotine, including but not limited to cigars, pipe tobacco, snuff, chewing tobacco, dipping tobacco, bidis, snus, dissolvable tobacco products, and electronic cigarette cartridges; provided, however, that such term shall not include: (1) cigarettes, including those cigarettes subject to the Special Rule for Cigarettes relating to characterizing flavors of the federal Family Smoking and Tobacco Prevention Act; and (2) any product that has been approved by the U.S. Food and Drug Administration, pursuant to its authority over drugs.

Sec. 14-309. Sale of flavored tobacco products prohibited.

It shall be unlawful for any person to sell or offer for sale any flavored tobacco product to a consumer, except in a smoking bar.

Sec. 14-310. Enforcement and penalties.

The Providence police department shall enforce the provisions of this ordinance. If an alleged violation occurs, the Providence police department shall issue a citation that will require the tobacco dealer's license holder to appear for a show cause hearing before the Board of Licenses. If, after a hearing, the Board finds that a violation has occurred, the Board shall impose a civil fine of two hundred fifty dollars ($250.00) for the first offense, three hundred fifty dollars ($350.00) for the second offense, and five hundred dollars ($500.00) for any subsequent offense. Additionally, the Board may suspend or revoke the license. If a holder of a tobacco dealer's license maintains said license for thirty-six (36) consecutive months without a violation, any new violation will be treated as a first offense.

It is the intent of this legislation that all fines collected by the City hereunder shall be used by the Board of Licenses and the Police Department for the purpose of conducting tobacco compliance checks.

SECTION 2. This Ordinance shall take effect March 1, 2012.

IN CITY COUNCIL
JAN 03 2012
FIRST READING
READ AND PASSED
CLERK

IN CITY COUNCIL
FEB 17 2012
FINAL READING
READ AND PASSED
PRESIDENT
ACTING CLERK

I HEREBY APPROVE.
Mayor
Date: 2/20/12

Council President Solomon
Councilman Yurdin

City of Providence

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

CHAPTER

No. **AN ORDINANCE AMENDING SECTION 14-300 AND SECTION 14-303 OF ARTICLE XV OF CHAPTER 14 OF THE CODE OF ORDINANCES OF THE CITY OF PROVIDENCE, ENTITLED: "LICENSES - TOBACCO DEALERS."**

Approved

Be it ordained by the City of Providence:

SECTION 1. Section 14-300 of Article XV of Chapter 14 of the Code of Ordinances of the City of Providence is hereby amended as follows:

Sec. 14-300. Definitions.

"Board of Licenses" shall mean the Providence Board of Licenses as established by Sec. 1102 of the Providence Home Rule Charter of 1980.

"Compliance check violation" shall mean any sale of tobacco products to a person who is less than eighteen (18) years of age.

"*Coupon*" shall mean any card, paper, note, form, statement, ticket or other issue distributed for commercial or promotional purposes to be later surrendered by the bearer so as to receive an article, service or accommodation without charge or at a discount price.

"*Listed or non-discounted price*" shall mean the higher of the price listed for a tobacco product on its package or the price listed on any related shelving, posting, advertising or display at the place where the tobacco product is sold or offered for sale plus all applicable taxes if such taxes are not included in the stated price, and before the application of any discounts or coupons.

"*Cigarette*" means any product that contains nicotine, is intended to be burned or heated under ordinary conditions of use, and consists of or contains: (1) any roll of tobacco wrapped in paper or in any substance not containing tobacco; (2) tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette; or (3) any roll of tobacco wrapped in any substance containing

tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to or purchased by, consumers as a cigarette described in clause (1) of this definition.

"Tobacco products" shall mean any substance containing tobacco leaf, including, but not limited to cigarettes, cigars, pipe tobacco, snuff, chewing tobacco, dipping tobacco, orbs, sticks, ~~and~~ dissolvable tobacco products, and electronic cigarette cartridges; provided, however, that "tobacco products" shall not include any product that has been approved by the United States Food and Drug Administration for use as a medical treatment to reduce and eliminate nicotine or tobacco dependence.

"Vending machines" shall mean any mechanical, electric or electronic self service device which, upon insertion of money, tokens, or any other form of payment, dispenses tobacco products.

SECTION 2. Section 14-303 of Article XV of Chapter 14 of the Code of Ordinances of the City of Providence is hereby amended as follows:

Sec. 14-303. Prohibitions applicable to license holders, their employees and agents.

A person who holds a license issued under this article, or any employee or agent of same, is prohibited from selling, distributing, delivering, offering for sale, or giving away, or possessing with the intention of selling, distributing, delivering, offering for sale, or giving away tobacco products within the city to any individual that is under eighteen (18) years of age, whether said tobacco is sold, distributed or delivered in person or via vending machine.

A person who holds a license issued under this article, or any employee or agent of same, is prohibited from selling as a single cigarette sale, or as a sale of cigarettes by the individual piece, known as "loosies."

No person who holds a license issued under this article, nor any employee or agent of same, shall:

(1) accept or redeem, offer to accept or redeem, or cause or hire any person to accept or redeem or offer to accept or redeem any coupon that provides any tobacco products without charge or for less than the listed or non-discounted price; or

(2) accept or redeem, offer to accept or redeem, or cause or hire any person to accept or redeem or offer to accept or redeem any coupon that provides any cigarettes without charge or for less than the listed or non-discounted price; or

(3) sell tobacco products to consumers through any multi-pack discounts (e.g., "buy-two-get-one-free") or otherwise provide or distribute to consumers any tobacco products without charge or for less than the listed or non-discounted price in exchange for the purchase of any other tobacco product; or

(4) sell cigarettes to consumers through any multi-pack discounts (e.g., "buy-two-get-one-free") or otherwise provide or distribute to consumers any cigarette without charge or for less than the listed or non-discounted price in exchange for the purchase of any other cigarette.

SECTION 3. This Ordinance shall take effect March 1, 2012.

IN CITY COUNCIL
JAN 03 2012
FIRST READING
READ AND PASSED

CLERK

Council President Solomon
Councilman Yurdin

6

City of Providence

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

CHAPTER

No. AN ORDINANCE AMENDING ARTICLE XV OF CHAPTER 14 OF THE CODE OF ORDINANCES OF THE CITY OF PROVIDENCE, ENTITLED: "LICENSES" BY ADDING THERETO THE FOLLOWING SECTIONS.

Approved

Be it ordained by the City of Providence:

SECTION 1. Article XV of Chapter 14 of the Code of Ordinances of the City of Providence is hereby amended by adding thereto the following:

Sec. 14-308. Definitions.

Whenever used in this ordinance, the following terms shall be defined as follows:

"Cigarette" means any product that contains nicotine, is intended to be burned or heated under ordinary conditions of use, and consists of or contains: (1) any roll of tobacco wrapped in paper or in any substance not containing tobacco; (2) tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette; or (3) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to or purchased by, consumers as a cigarette described in clause (1) of this definition.

"Characterizing flavor" means a distinguishable taste or aroma, other than the taste or aroma of tobacco, menthol, mint or wintergreen, imparted either prior to or during consumption of a tobacco product or component part thereof, including, but not limited to, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, herb or spice and concepts such as spicy, arctic, ice, cool, warm, hot, mellow, fresh, and breeze; provided, however, that no tobacco product shall be determined to have a characterizing flavor solely because of the use of additives or flavorings or the provision of ingredient information.

"Component part" means any element of a tobacco product, including, but not limited to, the tobacco, filter and paper, but not including any constituent.

"Constituent" means any ingredient, substance, chemical or compound, other than tobacco, water or reconstituted tobacco sheet, that is added by the manufacturer to a tobacco product during the processing, manufacture or packing of the tobacco product. Such term shall include a smoke constituent.

"Flavored tobacco product" means any tobacco product or any component part thereof that contains a constituent that imparts a characterizing flavor. A public statement or claim made or disseminated by the manufacturer of a tobacco product, or by any person authorized or permitted by the manufacturer to make or disseminate public statements concerning such tobacco product, that such tobacco product has or produces a characterizing flavor shall constitute presumptive evidence that the tobacco product is a flavored tobacco product.

"Person" means any natural person, partnership, firm, joint stock company, corporation, or employee thereof, or other legal entity.

"Smoke constituent" means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the tobacco product to the smoke or that is formed by the combustion or heating of tobacco, additives or other component of the tobacco product.

"Smoking bar" has the meaning as such term is defined in Sec. 23-20.10-2(15) of the Rhode Island general laws.

"Tobacco product" means any product containing tobacco or nicotine, including but not limited to cigars, pipe tobacco, snuff, chewing tobacco, dipping tobacco, bidis, snus, dissolvable tobacco products, and electronic cigarette cartridges; provided, however, that such term shall not include: (1) cigarettes, including those cigarettes subject to the Special Rule for Cigarettes relating to characterizing flavors of the federal Family Smoking and Tobacco Prevention Act; and (2) any product that has been approved by the U.S. Food and Drug Administration, pursuant to its authority over drugs.

DRAFT

Sec. 14-309. Sale of flavored tobacco products prohibited.

It shall be unlawful for any person to sell or offer for sale any flavored tobacco product to a consumer, except in a smoking bar.

Sec. 14-310. Enforcement and penalties.

The Providence police department shall enforce the provisions of this ordinance. If an alleged violation occurs, the Providence police department shall issue a citation that will require the tobacco dealer's license holder to appear for a show cause hearing before the Board of Licenses. If, after a hearing, the Board finds that a violation has occurred, the Board shall impose a civil fine of two hundred fifty dollars ($250.00) for the first offense, three hundred fifty dollars ($350.00) for the second offense, and five hundred dollars ($500.00) for any subsequent offense. Additionally, the Board may suspend or revoke the license. If a holder of a tobacco dealer's license maintains said license for thirty-six (36) consecutive months without a violation, any new violation will be treated as a first offense.

It is the intent of this legislation that all fines collected by the City hereunder shall be used by the Board of Licenses and the Police Department for the purpose of conducting tobacco compliance checks.

SECTION 2. This Ordinance shall take effect March 1, 2012.

IN CITY COUNCIL
JAN 03 2012
FIRST READING
READ AND PASSED
CLERK

(c) Petition for order modifying or setting aside demand for production of product of discovery; grounds for relief; stay of compliance with demand and of running of time allowed for compliance with demand

Whenever any such demand is an express demand for any product of discovery, the person from whom such discovery was obtained may file, at any time prior to compliance with such express demand, in the district court of the United States for the judicial district in which the proceeding in which such discovery was obtained is or was last pending, and serve upon any antitrust investigator named in the demand and upon the recipient of the demand, a petition for an order of such court modifying or setting aside those portions of the demand requiring production of any such product of discovery. Such petition shall specify each ground upon which the petitioner relies in seeking such relief and may be based upon any failure of such portions of the demand to comply with the provisions of this chapter, or upon any constitutional or other legal right or privilege of the petitioner. During the pendency of such petition, the court may stay, as it deems proper, compliance with the demand and the running of the time allowed for compliance with the demand.

(d) Petition for order requiring performance by custodian of duties; venue

At any time during which any custodian is in custody or control of any documentary material or answers to interrogatories delivered, or transcripts of oral testimony given by any person in compliance with any such demand, such person, and, in the case of an express demand for any product of discovery, the person from whom such discovery was obtained, may file, in the district court of the United States for the judicial district within which the office of such custodian is situated, and serve upon such custodian a petition for an order of such court requiring the performance by such custodian of any duty imposed upon him by this chapter.

(e) Jurisdiction; appeal; contempts

Whenever any petition is filed in any district court of the United States under this section, such court shall have jurisdiction to hear and determine the matter so presented, and to enter such order or orders as may be required to carry into effect the provisions of this chapter. Any final order so entered shall be subject to appeal pursuant to section 1291 of title 28. Any disobedience of any final order entered under this section by any court shall be punished as a contempt thereof.

(f) Applicability of Federal Rules of Civil Procedure

To the extent that such rules may have application and are not inconsistent with the provisions of this chapter, the Federal Rules of Civil Procedure shall apply to any petition under this chapter.

(g) Disclosure exemption

Any documentary material, answers to written interrogatories, or transcripts of oral testimony provided pursuant to any demand issued under this chapter shall be exempt from disclosure under section 552 of title 5.

(Pub. L. 87–664, §5, Sept. 19, 1962, 76 Stat. 551; Pub. L. 94–435, title I, §104, Sept. 30, 1976, 90 Stat. 1389; Pub. L. 96–349, §2(b)(5), Sept. 12, 1980, 94 Stat. 1155.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original ''this Act'', meaning Pub. L. 87–664, which is classified generally to this chapter. For complete classification of this Act to the Code, see Short Title note set out under section 1311 of this title and Tables.

The Federal Rules of Civil Procedure, referred to in subsec. (f), are set out in the Appendix to Title 28, Judiciary and Judicial Procedure.

AMENDMENTS

1980—Subsec. (b). Pub. L. 96–349, §2(b)(5)(A), designated existing provisions as par. (1), provided for filing and serving a petition for an order modifying or setting aside a demand in the case of an express demand for any product of discovery upon the person from whom the discovery was obtained, incorporated existing provision in cl. (A), added cl. (B), and designated existing provisions as par. (2).

Subsecs. (c), (d). Pub. L. 96–349, §2(b)(5)(B) to (D), added subsec. (c), redesignated former subsec. (c) as (d) and authorized petition, in the case of an express demand for any product of discovery, by the person from whom the discovery was obtained, for an order requiring performance by the custodian of his duties. Former subsec. (d) redesignated (e).

Subsecs. (e) to (g). Pub. L. 96–349, §2(b)(5)(B), redesignated former subsecs. (d) to (f) as (e) to (g), respectively.

1976—Subsec. (a). Pub. L. 94–435, §104(a), struck out provision which permitted a petition for an enforcement order to be filed in the judicial district where a person who had failed to comply with a demand and who transacted business in one or more districts, maintained his principal place of business, or in such other district, in which such person transacted business, as was agreed upon by the parties to the petition.

Subsec. (b). Pub. L. 94–435, §104(b), (c), inserted ''or within such period exceeding twenty days after service or in excess of such return date as may be prescribed in writing, subsequent to service, by any antitrust investigator named in the demand,'' after ''whichever period is shorter'', substituted ''antitrust investigator'' for ''custodian'' before ''a petition for an order'', and inserted proviso that petitioner should comply with portions of a contested demand which are not being challenged.

Subsec. (c). Pub. L. 94–435, §104(d), substituted ''or answers to interrogatories delivered, or transcripts of oral testimony given'' for ''delivered''.

Subsec. (f). Pub. L. 94–435, §104(e), added subsec. (f).

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–435 effective Sept. 30, 1976, see section 106 of Pub. L. 94–435, set out as a note under section 1311 of this title.

CHAPTER 35—SEAT BELT REGULATION

§§ 1321 to 1323. Repealed. Pub. L. 89–563, title I, §117(a), Sept. 9, 1966, 80 Stat. 727

Sections, Pub. L. 88–201, §§1–3, Dec. 13, 1963, 77 Stat. 361, provided for the promulgation of standards for seat belts in motor vehicles and set the penalty for the unlawful sale, importation, or introduction into commerce of seat belts not meeting the published standards. For savings provision, see section 117(b) to (e) of Pub. L. 89–563, formerly set out as a note under section 1301 of this title.

CHAPTER 36—CIGARETTE LABELING AND ADVERTISING

Sec.
1331. Congressional declaration of policy and purpose.

§ 1331. Congressional declaration of policy and purpose

It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal Program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—

(1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and

(2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

(Pub. L. 89–92, § 2, July 27, 1965, 79 Stat. 282; Pub. L. 91–222, § 2, Apr. 1, 1970, 84 Stat. 87; Pub. L. 98–474, § 6(a), Oct. 12, 1984, 98 Stat. 2204.)

AMENDMENTS

1984—Par. (1). Pub. L. 98–474 substituted ''about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement;'' for ''that cigarette smoking may be hazardous to health by inclusion of a warning to that effect on each package of cigarettes;''.

1970—Pub. L. 91–222 reenacted section without change.

EFFECTIVE DATE OF 1970 AMENDMENT

Section 3 of Pub. L. 91–222 provided in part that: ''All other provisions of the amendment made by this Act [enacting section 1340 of this title, amending this section and sections 1332 and 1335 to 1339 of this title, and enacting provisions set out as notes under this section] except where otherwise specified shall take effect on January 1, 1970.''

EFFECTIVE DATE

Section 12, formerly § 11, of Pub. L. 89–92 as renumbered by Pub. L. 98–474, § 5(a), Oct. 12, 1984, 98 Stat. 2203, provided that: ''This Act [this chapter] shall take effect on January 1, 1966.''

SHORT TITLE OF 1984 AMENDMENT

Section 1 of Pub. L. 98–474 provided that: ''This Act [enacting sections 1335a and 1341 of this title, amending this section and sections 1332, 1333, 1336, and 1337 of this title, and enacting provisions set out as notes under this section and sections 1333 and 1335a of this title] may be cited as the 'Comprehensive Smoking Education Act'.''

SHORT TITLE OF 1973 AMENDMENT

Section 1 of Pub. L. 93–109 provided: ''That this Act [amending sections 1332 and 1335 of this title] may be cited as the 'Little Cigar Act of 1973'.''

SHORT TITLE OF 1970 AMENDMENT

Section 1 of Pub. L. 91–222 provided: ''That this Act [enacting section 1340 of this title, amending this section and sections 1332 to 1339 of this title, and enacting provisions set out as notes under this section and sections 1333 and 1334 of this title] may be cited as the 'Public Health Cigarette Smoking Act of 1969'.''

SHORT TITLE

Section 1 of Pub. L. 89–92 provided: ''This Act [enacting this chapter] may be cited as the 'Federal Cigarette Labeling and Advertising Act'.''

SEPARABILITY

Section 13, formerly § 12, of Pub. L. 89–92 as added by section 2 of Pub. L. 91–222, and renumbered Pub. L. 98–474, § 5(a), Oct. 12, 1984, 98 Stat. 2203, provided that: ''If any provision of this Act [this chapter] or the application thereof to any person or circumstances is held invalid, the other provisions of this Act [this chapter] and the application of such provisions to other persons or circumstances shall not be affected thereby.''

CONGRESSIONAL STATEMENT OF PURPOSE

Section 2 of Pub. L. 98–474 provided that: ''It is the purpose of this Act [see Short Title of 1984 Amendment note above] to provide a new strategy for making Americans more aware of any adverse health effects of smoking, to assure the timely and widespread dissemination of research findings and to enable individuals to make informed decisions about smoking.''

§ 1332. Definitions

As used in this chapter—

(1) The term ''cigarette'' means—

(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and

(B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).

(2) The term ''commerce'' means (A) commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof; (B) commerce between points in any state, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or (C) commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island.

(3) The term ''United States'', when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island. The term ''State'' includes any political division of any State.

(4) The term ''package'' means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

(5) The term ''person'' means an individual, partnership, corporation, or any other business or legal entity.

(6) The term ''sale or distribution'' includes sampling or any other distribution not for sale.

(7) The term ''little cigar'' means any roll of tobacco wrapped in leaf tobacco or any substance containing tobacco (other than any roll of tobacco which is a cigarette within the meaning of subsection (1)) and as to which one thousand units weigh not more than three pounds.

(8) The term ''brand style'' means a variety of cigarettes distinguished by the tobacco used, tar and nicotine content, flavoring used, size of the cigarette, filtration on the cigarette, or packaging.

(9) The term ''Secretary'' means the Secretary of Health and Human Services.

(Pub. L. 89–92, § 3, July 27, 1965, 79 Stat. 282; Pub. L. 91–222, § 2, Apr. 1, 1970, 84 Stat. 88; Pub. L. 93–109, § 2, Sept. 21, 1973, 87 Stat. 352; Pub. L. 98–474, § 6(b), Oct. 12, 1984, 98 Stat. 2204; Pub. L. 99–92, § 11(b), Aug. 16, 1985, 99 Stat. 403.)

AMENDMENTS

1985—Pars. (8), (9). Pub. L. 99–92 added par. (8) and redesignated former par. (8) as (9).

1984—Par. (8). Pub. L. 98–474 added par. (8).

1973—Subsec. (7). Pub. L. 93–109 added subsec. (7).

1970—Subsec. (3). Pub. L. 91–222 inserted provisions defining ''State''.

EFFECTIVE DATE OF 1973 AMENDMENT

Section 4 of Pub. L. 93–109 provided that: ''The amendment made by this Act [amending this section and section 1335 of this title] shall become effective thirty days after the date of enactment [Sept. 21, 1973].''

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–222 effective Jan. 1, 1970, except where otherwise specified, see section 3 of Pub. L. 91–222, set out in part as a note under section 1331 of this title.

§ 1333. Labeling; requirements; conspicuous statement

(a) Required warnings; packages; advertisements; billboards

(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

(2) It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised (other than through the use of outdoor billboards) within the United States any cigarette unless the advertising bears, in accordance with the requirements of this section, one of the following labels:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

(3) It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised within the United States through the use of outdoor billboards any cigarette unless the advertising bears, in accordance with the requirements of this section, one of the following labels:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, And Emphysema.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Health Risks.

SURGEON GENERAL'S WARNING: Pregnant Women Who Smoke Risk Fetal Injury And Premature Birth.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

(b) Conspicuous statement; label statement format; outdoor billboard statement format

(1) Each label statement required by paragraph (1) of subsection (a) of this section shall be located in the place label statements were placed on cigarette packages as of October 12, 1984. The phrase ''Surgeon General's Warning'' shall appear in capital letters and the size of all other letters in the label shall be the same as the size of such letters as of October 12, 1984. All the letters in the label shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package.

(2) The format of each label statement required by paragraph (2) of subsection (a) of this section shall be the format required for label statements in cigarette advertising as of October 12, 1984, except that the phrase ''Surgeon General's Warning'' shall appear in capital letters, the area of the rectangle enclosing the label shall be 50 per centum larger in size with a corresponding increase in the size of the type in the label, the width of the rule forming the border around the label shall be twice that in effect on October 12, 1984, and the label may be placed at a distance from the outer edge of the advertisement which is one-half the distance permitted on October 12, 1984. Each label statement shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material in the advertisement.

(3) The format and type style of each label statement required by paragraph (3) of sub-

section (a) of this section shall be the format and type style required in outdoor billboard advertising as of October 12, 1984. Each such label statement shall be printed in capital letters of the height of the tallest letter in a label statement on outdoor advertising of the same dimension on October 12, 1984. Each such label statement shall be enclosed by a black border which is located within the perimeter of the format required in outdoor billboard advertising of the same dimension on October 12, 1984, and the width of which is twice the width of the vertical element of any letter in the label statement within the border.

(c) Rotation of label statement; plan; submission to Federal Trade Commission

(1) Except as provided in paragraph (2), the label statements specified in paragraphs (1), (2), and (3) of subsection (a) of this section shall be rotated by each manufacturer or importer of cigarettes quarterly in alternating sequence on packages of each brand of cigarettes manufactured by the manufacturer or importer and in the advertisements for each such brand of cigarettes in accordance with a plan submitted by the manufacturer or importer and approved by the Federal Trade Commission. The Federal Trade Commission shall approve a plan submitted by a manufacturer or importer of cigarettes which will provide the rotation required by this subsection and which assures that all of the labels required by paragraphs (1), (2), and (3) will be displayed by the manufacturer or importer at the same time.

(2)(A) A manufacturer or importer of cigarettes may apply to the Federal Trade Commission to have the label rotation described in subparagraph (C) apply with respect to a brand style of cigarettes manufactured or imported by such manufacturer or importer if—

(i) the number of cigarettes of such brand style sold in the fiscal year of the manufacturer or importer preceding the submission of the application is less than one-fourth of 1 percent of all the cigarettes sold in the United States in such year, and

(ii) more than one-half of the cigarettes manufactured or imported by such manufacturer or importer for sale in the United States are packaged into brand styles which meet the requirements of clause (i).

If an application is approved by the Commission, the label rotation described in subparagraph (C) shall apply with respect to the applicant during the one-year period beginning on the date of the application approval.

(B) An applicant under subparagraph (A) shall include in its application a plan under which the label statements specified in paragraph (1) of subsection (a) of this section will be rotated by the applicant manufacturer or importer in accordance with the label rotation described in subparagraph (C).

(C) Under the label rotation which a manufacturer or importer with an approved application may put into effect each of the labels specified in paragraph (1) of subsection (a) of this section shall appear on the packages of each brand style of cigarettes with respect to which the application was approved an equal number of times within the twelve-month period beginning on the date of the approval by the Commission of the application.

(d) Application; distributors; retailers

Subsection (a) of this section does not apply to a distributor or a retailer of cigarettes who does not manufacture, package, or import cigarettes for sale or distribution within the United States.

(Pub. L. 89–92, § 4, July 27, 1965, 79 Stat. 283; Pub. L. 91–222, § 2, Apr. 1, 1970, 84 Stat. 88; Pub. L. 98–474, § 4(a), Oct. 12, 1984, 98 Stat. 2201; Pub. L. 99–92, § 11[(a)], Aug. 16, 1985, 99 Stat. 402; Pub. L. 99–117, § 11(d), Oct. 7, 1985, 99 Stat. 495; Pub. L. 111–31, div. A, title II, §§ 201(a), 202(b), 206, June 22, 2009, 123 Stat. 1842, 1845, 1849.)

AMENDMENT OF SECTION

Pub. L. 111–31, div. A, title II, § 201, June 22, 2009, 123 Stat. 1842, provided that, effective 15 months after the issuance of the regulations required by section 201(a) of Pub. L. 111–31, this section is amended to read as follows:

§ 1333. Labeling

(a) Label requirements

(1) In general

It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

WARNING: Cigarettes are addictive.

WARNING: Tobacco smoke can harm your children.

WARNING: Cigarettes cause fatal lung disease.

WARNING: Cigarettes cause cancer.

WARNING: Cigarettes cause strokes and heart disease.

WARNING: Smoking during pregnancy can harm your baby.

WARNING: Smoking can kill you.

WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

WARNING: Quitting smoking now greatly reduces serious risks to your health.

(2) Placement; typography; etc.

Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise the top 50 percent of the front and rear panels of the package. The word ''WARNING'' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (c).

(3) Does not apply to foreign distribution

The provisions of this subsection do not apply to a tobacco product manufacturer or distributor

of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

(4) Applicability to retailers

A retailer of cigarettes shall not be in violation of this subsection for packaging that—

(A) contains a warning label;

(B) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and

(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

(b) Advertising requirements

(1) In general

It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

(2) Typography, etc.

Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area. The Secretary may revise the required type sizes in such area in such manner as the Secretary determines appropriate. The word ''WARNING'' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under subsection (c). The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital ''W'' of the word ''WARNING'' in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that—

(A) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

(3) Matchbooks

Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

(4) Adjustment by Secretary

The Secretary may, through a rulemaking under section 553 of title 5, adjust the format and type sizes for the label statements required by this section; the text, format, and type sizes of any required tar, nicotine yield, or other constituent (including smoke constituent) disclosures; or the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act. The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of cigarette advertisements provided by paragraph (2). The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

(c) Marketing requirements

(1) Random display

The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

(2) Rotation

The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

(3) Review

The Secretary shall review each plan submitted under paragraph (2) and approve it if the plan—

(A) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

(B) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

(4) Applicability to retailers

This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b).

(d) Graphic label statements

Not later than 24 months after June 22, 2009, the Secretary shall issue regulations that require color

graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1). The Secretary may adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2) as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area.

Pub. L. 111–31, div. A, title II, § 202(b), June 22, 2009, 123 Stat. 1845, provided that this section, as amended by section 201 of Pub. L. 111–31, is further amended by adding at the end the following:

(d) Change in required statements

The Secretary through a rulemaking conducted under section 553 of title 5 may adjust the format, type size, color graphics, and text of any of the label requirements, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.

Pub. L. 111–31, div. A, title II, § 206, June 22, 2009, 123 Stat. 1849, provided that this section, as amended by sections 201 and 202 of Pub. L. 111–31, is further amended by adding at the end the following:

(e) Tar, nicotine, and other smoke constituent disclosure

(1) In general

The Secretary shall, by a rulemaking conducted under section 553 of title 5, determine (in the Secretary's sole discretion) whether cigarette and other tobacco product manufacturers shall be required to include in the area of each cigarette advertisement specified by subsection (b) of this section, or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand. Any such disclosure shall be in accordance with the methodology established under such regulations, shall conform to the type size requirements of subsection (b) of this section, and shall appear within the area specified in subsection (b) of this section.

(2) Resolution of differences

Any differences between the requirements established by the Secretary under paragraph (1) and tar and nicotine yield reporting requirements established by the Federal Trade Commission shall be resolved by a memorandum of understanding between the Secretary and the Federal Trade Commission.

(3) Cigarette and other tobacco product constituents

In addition to the disclosures required by paragraph (1), the Secretary may, under a rulemaking conducted under section 553 of title 5, prescribe disclosure requirements regarding the level of any cigarette or other tobacco product constituent including any smoke constituent. Any such disclosure may be required if the Secretary determines that disclosure would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products, except that no such prescribed disclosure shall be required on the face of any cigarette package or advertisement. Nothing in this section shall prohibit the Secretary from requiring such prescribed disclosure through a cigarette or other tobacco product package or advertisement insert, or by any other means under the Federal Food, Drug, and Cosmetic Act.

(4) Retailers

This subsection applies to a retailer only if that retailer is responsible for or directs the label statements required under this section.

AMENDMENTS

1985—Subsec. (c). Pub. L. 99–92 designated existing provisions as par. (1), substituted ''Except as provided in paragraph (2), the'' for ''The label'', and added par. (2).

Subsec. (c)(2)(A). Pub. L. 99–117 substituted ''brand style'' for ''brand'' in provisions preceding cl. (i).

1984—Pub. L. 98–474 amended section generally, designating existing provisions as subsec. (a), expanding choice of warnings to be placed on cigarette packaging and further expanding scope of places that must contain warnings to include advertisements and outdoor billboards, and adding subsecs. (b) to (d).

1970—Pub. L. 91–222 substituted ''Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health'' for ''Caution: Cigarette Smoking May Be Hazardous to Your Health.''

EFFECTIVE DATE OF 2009 AMENDMENT

Pub. L. 111–31, div. A, title II, § 201(b), June 22, 2009, 123 Stat. 1845, provided that: ''The amendment made by subsection (a) [amending this section] shall take effect 15 months after the issuance of the regulations required by subsection (a) [amending this section]. Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by subsection (a).''

EFFECTIVE DATE OF 1985 AMENDMENT

Section 11(c) of Pub. L. 99–92 provided that:

''(1) The amendments made by subsection (a) [probably refers to undesignated par. preceding subsec. (b), amending this section] shall take effect October 12, 1985, except that—

''(A) on and after the date of the enactment of this Act [Aug. 16, 1985] a manufacturer or importer of cigarettes may apply to the Federal Trade Commission to have the label rotation specified in section 4(c)(2) of the Federal Cigarette Labeling and Advertising Act [subsec. (c)(2) of this section], as amended by subsection (a), apply to its brand styles of cigarettes and the Commission may take action on such an application, and

''(B) a manufacturer or importer of cigarettes may elect to have the amendments apply at an earlier date or dates selected by the manufacturer or importer.

''(2) The Federal Trade Commission may, upon application of a manufacturer or importer of cigarettes with an approved application under section 4(c)(2) of the Federal Cigarette Labeling and Advertising Act [subsec. (c)(2) of this section], as amended by subsection (a), extend the effective date specified in paragraph (1) to January 11, 1986. The Commission may approve an application for such an extension only if the Commission determines that the effective date specified in such paragraph (1) would cause unreasonable economic hardship to the applicant. Section 4 of the Federal Cigarette Labeling and Advertising Act [this section], as in effect before October 12, 1985, shall apply with respect to a manufacturer or importer with an application approved under this paragraph.''

EFFECTIVE DATE OF 1984 AMENDMENT

Section 4(b) of Pub. L. 98–474 provided that: ''The amendment made by subsection (a) [amending this section] shall take effect upon the expiration of a one-year period beginning on the date of the enactment of this Act [Oct. 12, 1984].''

EFFECTIVE DATE OF 1970 AMENDMENT

Section 3 of Pub. L. 91–222 provided in part that: ''Section 4 of the amendment made by this Act [amending this section] shall take effect on the first day of the seventh calendar month which begins after the date of the enactment of this Act [Apr. 1, 1970].''

§ 1334. Preemption

(a) Additional statements

Except to the extent the Secretary requires additional or different statements on any cigarette package by a regulation, by an order, by a standard, by an authorization to market a product, or by a condition of marketing a product, pursuant to the Family Smoking Prevention and Tobacco Control Act (and the amendments made by that Act), or as required under section 387c(a)(2) of title 21 or section 387t(a) of title 21, no statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package.

(b) State regulations

No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

(c) Exception

Notwithstanding subsection (b), a State or locality may enact statutes and promulgate regulations, based on smoking and health, that take effect after the effective date of the Family Smoking Prevention and Tobacco Control Act, imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes.

(Pub. L. 89–92, § 5, July 27, 1965, 79 Stat. 283; Pub. L. 91–222, § 2, Apr. 1, 1970, 84 Stat. 88; Pub. L. 111–31, div. A, title II, §§ 202(a), 203, June 22, 2009, 123 Stat. 1845, 1846.)

REFERENCES IN TEXT

The Family Smoking Prevention and Tobacco Control Act, referred to in subsec. (a), is div. A of Pub. L. 111–31, June 22, 2009, 123 Stat. 1776. For complete classification of this Act to the Code, see Short Title of 2009 Amendment note set out under section 301 of Title 21, Food and Drugs, and Tables.

The effective date of the Family Smoking Prevention and Tobacco Control Act, referred to in subsec. (c), probably means the date of enactment of Pub. L. 111–31, which was approved June 22, 2009.

AMENDMENTS

2009—Subsec. (a). Pub. L. 111–31, § 202(a), substituted ''Except to the extent the Secretary requires additional or different statements on any cigarette package by a regulation, by an order, by a standard, by an authorization to market a product, or by a condition of marketing a product, pursuant to the Family Smoking Prevention and Tobacco Control Act (and the amendments made by that Act), or as required under section 387c(a)(2) of title 21 or section 387t(a) of title 21, no'' for ''No''.

Subsec. (c). Pub. L. 111–31, § 203, added subsec. (c).

1970—Subsec. (b). Pub. L. 91–222 substituted provision that no requirement or prohibition based on smoking and health should be imposed under State law with respect to the advertising or promotion of any cigarettes which packages are labeled in conformity with the provisions of this chapter for provision that no statement relating to smoking and health should be required in the advertising of any cigarettes which packages are labeled in conformity with the provisions of this chapter.

Subsecs. (c), (d). Pub. L. 91–222 struck out subsecs. (c) and (d) relating to the authority of the Federal Trade Commission with respect to unfair or deceptive advertising acts or practices, and reports to Congress by the Secretary of Health, Education, and Welfare and the Federal Trade Commission. See sections 1336 and 1337 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Section 3 of Pub. L. 91–222 provided in part that: ''Section 5 of the amendment made by this Act [amending this section] shall take effect as of July 1, 1969.''

§ 1335. Unlawful advertisements on medium of electronic communication

After January 1, 1971, it shall be unlawful to advertise cigarettes and little cigars on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission.

(Pub. L. 89–92, § 6, July 27, 1965, 79 Stat. 283; Pub. L. 91–222, § 2, Apr. 1, 1970, 84 Stat. 89; Pub. L. 93–109, § 3, Sept. 21, 1973, 87 Stat. 352.)

AMENDMENTS

1973—Pub. L. 93–109 extended prohibition against advertisements to little cigars.

1970—Pub. L. 91–222 substituted provision that after January 1, 1971, it shall be unlawful to advertise cigarettes on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission, for provision that a violation of this chapter should constitute misdemeanor and be punishable by fine. See, now, section 1338 of this title.

EFFECTIVE DATE OF 1973 AMENDMENT

Amendment by Pub. L. 93–109 effective thirty days after Sept. 21, 1973, see section 4 of Pub. L. 93–109, set out as a note under section 1332 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–222 effective Jan. 1, 1970, except where otherwise specified, see section 3 of Pub. L. 91–222, set out in part as a note under section 1331 of this title.

§ 1335a. List of cigarette ingredients; annual submission to Secretary; transmittal to Congress; confidentiality

(a) Each person who manufactures, packages, or imports cigarettes shall annually provide the Secretary with a list of the ingredients added to tobacco in the manufacture of cigarettes which does not identify the company which uses the ingredients or the brand of cigarettes which contain the ingredients. A person or group of persons required to provide a list by this subsection may designate an individual or entity to provide the list required by this subsection.

(b)(1) At such times as the Secretary considers appropriate, the Secretary shall transmit to the

tum by weight of moisture. The fat content is not over 1½ per centum by weight unless otherwise indicated.

The term ''milk'', when used herein, means sweet milk of cows.

(Mar. 2, 1944, ch. 77, 58 Stat. 108; July 2, 1956, ch. 495, 70 Stat. 486.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act of June 26, 1938 (ch. 675, sec. 1, 52 Stat. 1040), referred to in text, probably means act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to this chapter (§ 301 et seq.). For complete classification of this Act to the Code, see section 301 of this title and Tables.

CODIFICATION

Section was not enacted as a part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter, but was made applicable thereto.

AMENDMENTS

1956—Act July 2, 1956, substituted ''nonfat dry milk'' for ''nonfat dry milk solids or defatted milk solids''.

§ 321d. Market names for catfish and ginseng

(a) Catfish labeling

(1) In general

Notwithstanding any other provision of law, for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)—

(A) the term ''catfish'' may only be considered to be a common or usual name (or part thereof) for fish classified within the family Ictaluridae; and

(B) only labeling or advertising for fish classified within that family may include the term ''catfish''.

(2) Omitted

(b) Ginseng labeling

(1) In general

Notwithstanding any other provision of law, for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)—

(A) the term ''ginseng'' may only be considered to be a common or usual name (or part thereof) for any herb or herbal ingredient derived from a plant classified within the genus Panax; and

(B) only labeling or advertising for herbs or herbal ingredients classified within that genus may include the term ''ginseng''.

(2) Omitted

(Pub. L. 107–171, title X, § 10806, May 13, 2002, 116 Stat. 526.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a)(1), (b)(1), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to this chapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

CODIFICATION

Section is comprised of section 10806 of Pub. L. 107–171. Subsecs. (a)(2) and (b)(2) of section 10806 of Pub. L. 107–171 amended section 343 of this title.

Section was enacted as part of the Farm Security and Rural Investment Act of 2002, and not as part of Federal Food, Drug, and Cosmetic Act which comprises this chapter.

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

§ 331. Prohibited acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 350d, 355, or 360bbb–3 of this title.

(e) The refusal to permit access to or copying of any record as required by section 350a, 350c, 350f(j), 350e, 354, 360bbb–3, 373, 374(a), 379aa, or 379aa–1 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 350c(b), 350f, 350e, 354, 355(i) or (k), 360b(a)(4)(C), 360b(j), (*l*) or (m), 360ccc–1(i), 360e(f), 360i, 360bbb–3, 379aa, 379aa–1, 387i, or 387t of this title or the refusal to permit access to or verification or copying of any such required record; or the violation of any record-keeping requirement under section 2223[1] of this title (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 333(c)(2) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333(c)(3) of this title, which guaranty or undertaking is false.

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 344 or 379e of this title.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing,

[1] See References in Text note below.

or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of section 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360ccc, 360ccc–1, 360ccc–2, 374, 379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b) of this title concerning any method or process which as a trade secret is entitled to protection; or the violating of section 346a(i)(2) of this title or any regulation issued under that section..[2] This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(*l*) Repealed. Pub. L. 105–115, title IV, § 421, Nov. 21, 1997, 111 Stat. 2380.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of subsections (b) or (c) of section 347 of this title.

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 374 of this title.

(*o*) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

(p) The failure to register in accordance with section 360 or 387e of this title, the failure to provide any information required by section 360(j), 360(k), 387e(i), or 387e(j) of this title, or the failure to provide a notice required by section 360(j)(2) or 387e(i)(3) of this title.

(q)(1) The failure or refusal—

(A) to comply with any requirement prescribed under section 360h, 360j(g), 387c(b), 387g, 387h, or 387*o* of this title;

(B) to furnish any notification or other material or information required by or under section 360i, 360j(g), 387d, 387i, or 387t of this title; or

(C) to comply with a requirement under section 360*l* or 387m of this title.

(2) With respect to any device or tobacco product, the submission of any report that is required by or under this chapter that is false or misleading in any material respect.

(r) The movement of a device or tobacco product in violation of an order under section 334(g) of this title or the removal or alteration of any mark or label required by the order to identify the device or tobacco product as detained.

(s) The failure to provide the notice required by section 350a(c) or 350a(e) of this title, the failure to make the reports required by section 350a(f)(1)(B) of this title, the failure to retain the records required by section 350a(b)(4) of this title, or the failure to meet the requirements prescribed under section 350a(f)(3) of this title.

(t) The importation of a drug in violation of section 381(d)(1) of this title, the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title, the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 353(c)(2) of this title, the distribution of a drug sample in violation of section 353(d) of this title or the failure to otherwise comply with the requirements of section 353(d) of this title, or the distribution of drugs in violation of section 353(e) of this title or the failure to otherwise comply with the requirements of section 353(e) of this title.

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 360b(a)(4)(A), 360b(a)(4)(D), or 360b(a)(5) of this title.

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 350b of this title.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 381(d)(3) of this title; the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 381(e) or 382 of this title, or with section 262(h) of title 42; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 360d(c) of this title or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food—

(1) the submission of a report or recommendation by a person accredited under section 360m of this title that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 360m of this title of confidential

[2] So in original.

commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 360m of this title of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this chapter.

(z) Omitted.

(aa) The importation of a prescription drug in violation of section 384 of this title, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

(bb) The transfer of an article of food in violation of an order under section 334(h) of this title, or the removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person debarred under section 335a(b)(3) of this title.

(dd) The failure to register in accordance with section 350d of this title.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 381(m) of this title.

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 381(*o*) of this title.

(gg) The knowing failure to comply with paragraph (7)(E) of section 374(g) of this title; the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under section 350e of this title.

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 379aa or 379aa–1 of this title) or the falsification of a serious adverse event report (as defined under section 379aa or 379aa–1 of this title) submitted to the Secretary.

(jj)(1) The failure to submit the certification required by section 282(j)(5)(B) of title 42, or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 282 of title 42.

(3) The submission of clinical trial information under subsection (j) of section 282 of title 42 that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) The dissemination of a television advertisement without complying with section 353b of this title.

(*ll*) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 355 of this title, a biological product licensed under section 262 of title 42, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless—

(1) such drug or such biological product was marketed in food before any approval of the drug under section 355 of this title, before licensure of the biological product under such section 262 of title 42, and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

(A) a regulation issued under section 348 of this title prescribing conditions of safe use in food;

(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

(D) a food contact substance notification that is effective under section 348(h) of this title; or

(E) such drug or biological product had been marketed for smoking cessation prior to September 27, 2007; or

(4) the drug is a new animal drug whose use is not unsafe under section 360b of this title.

(mm) The failure to submit a report or provide a notification required under section 350f(d) of this title.

(nn) The falsification of a report or notification required under section 350f(d) of this title.

(*oo*) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 333(f) of this title.

(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 387k of this title.

(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing

any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(rr) The charitable distribution of tobacco products.

(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that—

(1) the product is approved by the Food and Drug Administration;

(2) the Food and Drug Administration deems the product to be safe for use by consumers;

(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

(4) the product is safe or less harmful by virtue of—

(A) its regulation or inspection by the Food and Drug Administration; or

(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 387c of this title.

(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 350g of this title.

(vv) The failure to comply with the requirements under section 350h of this title.

(ww) The failure to comply with section 350i of this title.

(xx) The refusal or failure to follow an order under section 350*l* of this title.

(yy) The knowing and willful failure to comply with the notification requirement under section 350f(h) of this title.

(zz) The importation or offering for importation of a food if the importer (as defined in section 384a of this title) does not have in place a foreign supplier verification program in compliance with such section 384a of this title.

(June 25, 1938, ch. 675, § 301, 52 Stat. 1042; Dec. 22, 1941, ch. 613, § 1, 55 Stat. 851; July 6, 1945, ch. 281, § 1, 59 Stat. 463; Mar. 10, 1947, ch. 16, § 1, 61 Stat. 11; June 24, 1948, ch. 613, § 1, 62 Stat. 582; Mar. 16, 1950, ch. 61, § 3(b), 64 Stat. 20; Aug. 7, 1953, ch. 350, § 2, 67 Stat. 477; Pub. L. 85–929, § 5, Sept. 6, 1958, 72 Stat. 1788; Pub. L. 86–618, title I, §§ 104, 105(a), July 12, 1960, 74 Stat. 403; Pub. L. 87–781, title I, §§ 103(c), 104(e)(1), 106(c), 114(a), title III, § 304, Oct. 10, 1962, 76 Stat. 784, 785, 788, 791, 795; Pub. L. 89–74, §§ 5, 9(c), July 15, 1965, 79 Stat. 232, 235; Pub. L. 90–399, § 103, July 13, 1968, 82 Stat. 352; Pub. L. 90–639, § 2(b), Oct. 24, 1968, 82 Stat. 1361; Pub. L. 91–513, title II, § 701(a), Oct. 27, 1970, 84 Stat. 1281; Pub. L. 92–387, § 4(e), Aug. 16, 1972, 86 Stat. 562; Pub. L. 94–295, §§ 3(b), 4(b)(1), 7(b), May 28, 1976, 90 Stat. 576, 580, 582; Pub. L. 96–359, § 5, Sept. 26, 1980, 94 Stat. 1193; Pub. L. 99–570, title IV, § 4014(b)(2), Oct. 27, 1986, 100 Stat. 3207–120; Pub. L. 100–293, § 7(a), Apr. 22, 1988, 102 Stat. 99; Pub. L. 101–502, § 5(j), Nov. 3, 1990, 104 Stat. 1289; Pub. L. 101–508, title IV, § 4755(c)(2), Nov. 5, 1990, 104 Stat. 1388–210; Pub. L. 102–300, § 3(a)(1), June 16, 1992, 106 Stat. 238; Pub. L. 102–571, title I, § 107(2), (3), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(c), Aug. 13, 1993, 107 Stat. 775; Pub. L. 103–396, § 2(b)(1), Oct. 22, 1994, 108 Stat. 4154; Pub. L. 103–417, § 10(b), Oct. 25, 1994, 108 Stat. 4332; Pub. L. 104–134, title II, § 2103, Apr. 26, 1996, 110 Stat. 1321–319; Pub. L. 104–170, title IV, § 403, Aug. 3, 1996, 110 Stat. 1514; Pub. L. 104–250, § 5(d), Oct. 9, 1996, 110 Stat. 3156; Pub. L. 105–115, title I, § 125(a)(2)(A), (C), (b)(2)(B), title II, §§ 204(b), 210(c), title IV, §§ 401(b), 421, Nov. 21, 1997, 111 Stat. 2325, 2336, 2345, 2364, 2380; Pub. L. 106–387, § 1(a) [title VII, § 745(d)(1)], Oct. 28, 2000, 114 Stat. 1549, 1549A–39; Pub. L. 107–188, title III, §§ 303(b), 304(d), 305(b), 306(c), 307(b), 321(b)(2), 322(b), June 12, 2002, 116 Stat. 664, 666, 668, 670, 672, 676, 677; Pub. L. 107–250, title II, § 201(d), Oct. 26, 2002, 116 Stat. 1609; Pub. L. 108–136, div. A, title XVI, § 1603(c), Nov. 24, 2003, 117 Stat. 1690; Pub. L. 108–173, title XI, § 1121(b)(1), Dec. 8, 2003, 117 Stat. 2469; Pub. L. 108–214, § 2(b)(2)(A), Apr. 1, 2004, 118 Stat. 575; Pub. L. 108–282, title I, § 102(b)(5)(C), (D), Aug. 2, 2004, 118 Stat. 902; Pub. L. 109–59, title VII, § 7202(d), (e), Aug. 10, 2005, 119 Stat. 1913; Pub. L. 109–462, §§ 2(c), 3(b), 4(a), Dec. 22, 2006, 120 Stat. 3472, 3475; Pub. L. 110–85, title VIII, § 801(b)(1), title IX, §§ 901(d)(1), 912(a), title X, § 1005(d), Sept. 27, 2007, 121 Stat. 920, 939, 951, 968; Pub. L. 111–31, div. A, title I, § 103(b), June 22, 2009, 123 Stat. 1833; Pub. L. 111–353, title I, §§ 102(d)(1), 103(e), 105(c), 106(d), title II, §§ 204(j)(1), 206(d), 211(b), (c), title III, § 301(b), Jan. 4, 2011, 124 Stat. 3889, 3898, 3904, 3906, 3937, 3943, 3953, 3954.)

REFERENCES IN TEXT

Section 2223 of this title, referred to in par. (e), was in the original ''section 204 of the FDA Food Safety Modernization Act'', meaning section 204 of Pub. L. 111–353, which enacted section 2223 of this title and amended this section and section 381 of this title.

AMENDMENTS

2011—Par. (d). Pub. L. 111–353, § 102(d)(1), inserted ''350d,'' after ''344,''.

Par. (e). Pub. L. 111–353, §§ 204(j)(1), 211(c), substituted ''350f(j)'' for ''350f(g)'' and inserted before period at end ''; or the violation of any recordkeeping requirement under section 2223 of this title (except when such violation is committed by a farm)''.

Par. (uu). Pub. L. 111–353, § 103(e), added par. (uu).

Par. (vv). Pub. L. 111–353, § 105(c), added par. (vv).

Par. (ww). Pub. L. 111–353, § 106(d), added par. (ww).

Par. (xx). Pub. L. 111–353, § 206(d), added par. (xx).

Par. (yy). Pub. L. 111–353, § 211(b), added par. (yy).

Par. (zz). Pub. L. 111–353, § 301(b), added par. (zz).

2009—Pars. (a) to (c). Pub. L. 111–31, § 103(b)(1)–(3), inserted ''tobacco product,'' after ''device,''.

Par. (e). Pub. L. 111–31, § 103(b)(4)(B), which directed substitution of ''379aa–1, 387i, or 387t of this title or the refusal to permit access to'' for ''or 379aa–1 of this title or the refusal to permit access to'', was executed by

making the substitution for ''or 379aa–1 of this title, or the refusal to permit access to'', to reflect the probable intent of Congress.

Pub. L. 111–31, §103(b)(4)(A), struck out period after ''360ccc–1(i)''.

Pars. (g), (h). Pub. L. 111–31, §103(b)(5), (6), inserted ''tobacco product,'' after ''device,''.

Par. (j). Pub. L. 111–31, §103(b)(7), struck out period after ''360ccc–2'' and substituted ''379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b)'' for ''379, or 379e''.

Par. (k). Pub. L. 111–31, §103(b)(8), inserted ''tobacco product,'' after ''device,''.

Par. (p). Pub. L. 111–31, §103(b)(9), added par. (p) and struck out former par. (p) which read as follows: ''The failure to register in accordance with section 360 of this title, the failure to provide any information required by section 360(j) or 360(k) of this title, or the failure to provide a notice required by section 360(j)(2) of this title.''

Par. (q)(1). Pub. L. 111–31, §103(b)(10), added subpar. (1) and struck out former subpar. (1) which read as follows: ''The failure or refusal to (A) comply with any requirement prescribed under section 360h or 360j(g) of this title, (B) furnish any notification or other material or information required by or under section 360i or 360j(g) of this title, or (C) comply with a requirement under section 360*l* of this title.''

Par. (q)(2). Pub. L. 111–31, §103(b)(11), substituted ''device or tobacco product,'' for ''device,''.

Par. (r). Pub. L. 111–31, §103(b)(12), inserted ''or tobacco product'' after ''device'' in two places.

Pars. (*oo*) to (tt). Pub. L. 111–31, §103(b)(13), added pars. (*oo*) to (tt).

2007—Par. (e). Pub. L. 110–85, §1005(d)(1), substituted ''350c, 350f(g),'' for ''350c,'' and ''350c(b), 350f'' for ''350c(b)''.

Par. (jj). Pub. L. 110–85, §801(b)(1), added par. (jj).

Par. (kk). Pub. L. 110–85, §901(d)(1), added par. (kk).

Par. (*ll*). Pub. L. 110–85, §912(a), added par. (*ll*).

Pars. (mm), (nn). Pub. L. 110–85, §1005(d)(2), added pars. (mm) and (nn).

2006—Par. (e). Pub. L. 109–462, §3(b), substituted ''374(a), 379aa, or 379aa–1'' for ''374(a), or 379aa'' and ''360bbb–3, 379aa, or 379aa–1'' for ''360bbb–3, or 379aa''.

Pub. L. 109–462, §2(c), substituted '', 374(a), or 379aa'' for '', or 374(a)'' and '', 360bbb–3, or 379aa'' for '', or 360bbb–3''.

Par. (ii). Pub. L. 109–462, §4(a), added par. (ii).

2005—Par. (e). Pub. L. 109–59, §7202(d), inserted ''350e,'' before ''354,'' in two places.

Par. (hh). Pub. L. 109–59, §7202(e), added par. (hh).

2004—Par. (e). Pub. L. 108–282, §102(b)(5)(C), which directed the substitution of ''360b(a)(4)(C), 360b (j), (*l*) or (m), 360ccc–1(i).'' for ''360b(a)(4)(C), 360b(j), (*l*) or (m)'' was executed by making the substitution for ''360b(a)(4)(C), 360b(j), (*l*), or (m)'', to reflect the probable intent of Congress.

Par. (j). Pub. L. 108–282, §102(b)(5)(D), substituted ''360j, 360ccc, 360ccc–1, 360ccc–2.'' for ''360j''.

Par. (gg). Pub. L. 108–214 amended par. (gg) generally. Prior to amendment, text read as follows: ''The knowing failure of a person accredited under paragraph (2) of section 374(g) of this title to comply with paragraph (7)(E) of such section; the knowing inclusion by such a person of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.''

2003—Par. (d). Pub. L. 108–136 substituted ''section 344, 355, or 360bbb–3'' for ''section 344 or 355''.

Par. (e). Pub. L. 108–136 inserted ''360bbb–3,'' after ''350c, 354,'' and substituted ''360i, or 360bbb–3'' for ''or 360i''.

Par. (aa). Pub. L. 108–173 substituted ''prescription drug in violation of section 384'' for ''covered product in violation of section 384''.

2002—Par. (e). Pub. L. 107–188, §306(c)(1), substituted ''by section 350a, 350c, 354, 373, or 374(a) of this title'' for ''by section 350a, 354, or 373 of this title'' and ''under section 350a, 350c(b)'' for ''under section 350a''.

Par. (j). Pub. L. 107–188, §306(c)(2), inserted ''350c,'' after ''350a,''.

Par. (w). Pub. L. 107–188, §322(b), amended par. (w) generally. Prior to amendment, par. (w) read as follows: ''The making of a knowingly false statement in any record or report required or requested under subparagraph (A) or (B) of section 381(d)(3) of this title, the failure to submit or maintain records as required by sections 381(d)(3)(A) and 381(d)(3)(B) of this title, the release into interstate commerce of any article imported into the United States under section 381(d)(3) of this title or any finished product made from such article (except for export in accordance with section 381(e) or 382 of this title or section 262(h) of title 42), or the failure to export or destroy any component, part or accessory not incorporated into a drug, biological product or device that will be exported in accordance with section 381(e) or 382 of this title or section 262(h) of title 42.''

Par. (bb). Pub. L. 107–188, §303(b), added par. (bb).

Par. (cc). Pub. L. 107–188, §304(d), added par. (cc).

Par. (dd). Pub. L. 107–188, §305(b), added par. (dd).

Par. (ee). Pub. L. 107–188, §307(b), added par. (ee).

Par. (ff). Pub. L. 107–188, §321(b)(2), added par. (ff).

Par. (gg). Pub. L. 107–250 added par. (gg).

2000—Par. (aa). Pub. L. 106–387 added par. (aa).

1997—Par. (e). Pub. L. 105–115, §125(b)(2)(B), struck out ''357(d) or (g),'' after ''355(i) or (k),''.

Par. (i)(1). Pub. L. 105–115, §125(a)(2)(C), struck out '', 356, 357,'' before ''or 379e of this title''.

Par. (j). Pub. L. 105–115, §125(a)(2)(A), struck out ''356, 357,'' before ''360,''.

Par. (*l*). Pub. L. 105–115, §421, struck out par. (*l*) which read as follows: ''The using, on the labeling of any drug or device or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under section 355, 360e, or 360j(g) of this title, as the case may be, or that such drug or device complies with the provisions of such section.''

Par. (x). Pub. L. 105–115, §204(b), added par. (x).

Par. (y). Pub. L. 105–115, §210(c), added par. (y).

Par. (z). Pub. L. 105–115, §401(b), temporarily added par. (z) which related to dissemination of information in violation of section 360aaa of this title. See Effective and Termination Dates of 1997 Amendment note below.

1996—Par. (e). Pub. L. 104–250 inserted '', 354,'' before ''or 373 of this title'' and ''354,'' before ''355(i) or (k)''.

Par. (j). Pub. L. 104–170 inserted before period at end of first sentence ''; or the violating of section 346a(i)(2) of this title or any regulation issued under that section.''

Pars. (u) to (w). Pub. L. 104–134 redesignated par. (u) relating to introduction into interstate commerce of unsafe dietary supplement as (v) and added par. (w).

1994—Par. (e). Pub. L. 103–396, §2(b)(1)(A), substituted ''357(d) or (g), 360b(a)(4)(C),'' for ''357(d) or (g),''.

Par. (u). Pub. L. 103–417 added par. (u) relating to introduction into interstate commerce of unsafe dietary supplement.

Pub. L. 103–396, §2(b)(1)(B), added par. (u) relating to failure to comply with regulations or orders of Secretary.

1993—Par. (j). Pub. L. 103–80, §3(c)(1), substituted ''379, or 379e'' for ''379e, or 379''.

Par. (s). Pub. L. 103–80, §3(c)(2), substituted ''350a(e)'' for ''350a(d)''.

1992—Pars. (i)(1), (j). Pub. L. 102–571 substituted ''379e'' for ''376''.

Par. (q)(1)(C). Pub. L. 102–300 added cl. (C).

1990—Par. (e). Pub. L. 101–502 substituted ''or (k)'' for ''or (j)''.

Par. (j). Pub. L. 101–508 inserted at end ''This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.''

1988—Par. (t). Pub. L. 100–293 added par. (t).

1986—Par. (s). Pub. L. 99–570 amended par. (s) generally. Prior to amendment, par. (s) read as follows: ''The

by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) of this section or section 382 of this title, or with section 262(h) of title 42.

(II) The statement identifies the manufacturer of such article and each processor, packer, distributor, or other entity that had possession of the article in the chain of possession of the article from the manufacturer to such importer of the article.

(III) The statement is accompanied by such certificates of analysis as are necessary to identify such article, unless the article is a device or is an article described in paragraph (4).

(ii) At the time of initial importation and before the delivery of such article to the importer or the initial owner or consignee, such owner or consignee executes a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury.

(iii) Such article is used and exported by the initial owner or consignee in accordance with the intent described under clause (i)(I), except for any portions of the article that are destroyed.

(iv) The initial owner or consignee maintains records on the use or destruction of such article or portions thereof, as the case may be, and submits to the Secretary any such records requested by the Secretary.

(v) Upon request of the Secretary, the initial owner or consignee submits a report that provides an accounting of the exportation or destruction of such article or portions thereof, and the manner in which such owner or consignee complied with the requirements of this subparagraph.

(B) Notwithstanding subparagraph (A), the Secretary may refuse admission to an article that otherwise would be imported into the United States under such subparagraph if the Secretary determines that there is credible evidence or information indicating that such article is not intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) of this section or section 382 of this title, or with section 262(h) of title 42.

(C) This section may not be construed as affecting the responsibility of the Secretary to ensure that articles imported into the United States under authority of subparagraph (A) meet each of the conditions established in such subparagraph for importation.

(4) The importation into the United States of blood, blood components, source plasma, or source leukocytes or of a component, accessory, or part thereof is not permitted pursuant to paragraph (3) unless the importation complies with section 262(a) of title 42 or the Secretary permits the importation under appropriate circumstances and conditions, as determined by the Secretary. The importation of tissue or a component or part of tissue is not permitted pursuant to paragraph (3) unless the importation complies with section 264 of title 42.

(e) Exports

(1) A food, drug, device, tobacco product or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this chapter, and a tobacco product intended for export shall not be deemed to be in violation of section 387f(e), 387g, 387k, or 387t(a) of this title, if it—

(A) accords to the specifications of the foreign purchaser,

(B) is not in conflict with the laws of the country to which it is intended for export,

(C) is labeled on the outside of the shipping package that it is intended for export, and

(D) is not sold or offered for sale in domestic commerce.

(2) Paragraph (1) does not apply to any device—

(A) which does not comply with an applicable requirement of section 360d or 360e of this title,

(B) which under section 360j(g) of this title is exempt from either such section, or

(C) which is a banned device under section 360f of this title,

unless, in addition to the requirements of paragraph (1), either (i) the Secretary has determined that the exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export or (ii) the device is eligible for export under section 382 of this title.

(3) A new animal drug that requires approval under section 360b of this title shall not be exported pursuant to paragraph (1) if such drug has been banned in the United States.

(4)(A) Any person who exports a food, drug, animal drug, or device may request that the Secretary—

(i) certify in writing that the exported food, drug, animal drug, or device meets the requirements of paragraph (1) or section 382 of this title; or

(ii) certify in writing that the food, drug, animal drug, or device being exported meets the applicable requirements of this chapter upon a showing that the food, drug or device meets the applicable requirements of this chapter.

The Secretary shall issue such a certification within 20 days of the receipt of a request for such certification.

(B) If the Secretary issues a written export certification within the 20 days prescribed by subparagraph (A), a fee for such certification may be charged but shall not exceed $175 for each certification. Fees collected for a fiscal year pursuant to this subparagraph shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriations Acts until expended without

fiscal year limitation. Such fees shall be collected in each fiscal year in an amount equal to the amount specified in appropriations Acts for such fiscal year and shall only be collected and available for the costs of the Food and Drug Administration.

(C) For purposes of this paragraph, a certification by the Secretary shall be made on such basis, and in such form (including a publicly available listing) as the Secretary determines appropriate.

(D) With regard to fees pursuant to subparagraph (B) in connection with written export certifications for food:

(i) Such fees shall be collected and available solely for the costs of the Food and Drug Administration associated with issuing such certifications.

(ii) Such fees may not be retained in an amount that exceeds such costs for the respective fiscal year.

(f) Labeling of exported drugs

(1) If a drug (other than insulin, an antibiotic drug, an animal drug, or a drug exported under section 382 of this title) being exported in accordance with subsection (e) of this section is being exported to a country that has different or additional labeling requirements or conditions for use and such country requires the drug to be labeled in accordance with those requirements or uses, such drug may be labeled in accordance with such requirements and conditions for use in the country to which such drug is being exported if it also is labeled in accordance with the requirements of this chapter.

(2) If, pursuant to paragraph (1), the labeling of an exported drug includes conditions for use that have not been approved under this chapter, the labeling must state that such conditions for use have not been approved under this chapter. A drug exported under section 382 of this title is exempt from this section.

(g) Warning notice of importation in violation of chapter

(1) With respect to a prescription drug being imported or offered for import into the United States, the Secretary, in the case of an individual who is not in the business of such importations, may not send a warning notice to the individual unless the following conditions are met:

(A) The notice specifies, as applicable to the importation of the drug, that the Secretary has made a determination that—

(i) importation is in violation of subsection (a) of this section because the drug is or appears to be adulterated, misbranded, or in violation of section 355 of this title;

(ii) importation is in violation of subsection (a) of this section because the drug is or appears to be forbidden or restricted in sale in the country in which it was produced or from which it was exported;

(iii) importation is or appears to be in violation of subsection (d)(1) of this section; or

(iv) importation otherwise is or appears to be in violation of Federal law.

(B) The notice does not specify any provision described in subparagraph (A) that is not applicable to the importation of the drug.

(C) The notice states the reasons underlying such determination by the Secretary, including a brief application to the principal facts involved of the provision of law described in subparagraph (A) that is the basis of the determination by the Secretary.

(2) For purposes of this section, the term ''warning notice'', with respect to the importation of a drug, means a communication from the Secretary (written or otherwise) notifying a person, or clearly suggesting to the person, that importing the drug for personal use is, or appears to be, a violation of this chapter.

(h) Protection against adulteration of food

(1) The Secretary shall give high priority to increasing the number of inspections under this section for the purpose of enabling the Secretary to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food.

(2) The Secretary shall give high priority to making necessary improvements to the information management systems of the Food and Drug Administration that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of the Secretary to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is in compliance with this chapter.

(3) The Secretary shall improve linkages with other regulatory agencies of the Federal Government that share responsibility for food safety, and shall with respect to such safety improve linkages with the States and Indian tribes (as defined in section 450b(e) of title 25).

(i) Testing for rapid detection of adulteration of food

(1) For use in inspections of food under this section, the Secretary shall provide for research on the development of tests and sampling methodologies—

(A) whose purpose is to test food in order to rapidly detect the adulteration of the food, with the greatest priority given to detect the intentional adulteration of food; and

(B) whose results offer significant improvements over the available technology in terms of accuracy, timing, or costs.

(2) In providing for research under paragraph (1), the Secretary shall give priority to conducting research on the development of tests that are suitable for inspections of food at ports of entry into the United States.

(3) In providing for research under paragraph (1), the Secretary shall as appropriate coordinate with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Administrator of the Environmental Protection Agency, and the Secretary of Agriculture.

(4) The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the progress made in research under paragraph (1), including progress regarding paragraph (2).

of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system.

''(38) As the National Cancer Institute has found, many smokers mistakenly believe that 'low tar' and 'light' cigarettes cause fewer health problems than other cigarettes. As the National Cancer Institute has also found, mistaken beliefs about the health consequences of smoking 'low tar' and 'light' cigarettes can reduce the motivation to quit smoking entirely and thereby lead to disease and death.

''(39) Recent studies have demonstrated that there has been no reduction in risk on a population-wide basis from 'low tar' and 'light' cigarettes, and such products may actually increase the risk of tobacco use.

''(40) The dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product.

''(41) As the Federal Trade Commission has found, consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification.

''(42) Permitting manufacturers to make unsubstantiated statements concerning modified risk tobacco products, whether express or implied, even if accompanied by disclaimers would be detrimental to the public health.

''(43) The only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers sold or distributed for risk reduction be reviewed in advance of marketing, and to require that the evidence relied on to support claims be fully verified.

''(44) The Food and Drug Administration is a regulatory agency with the scientific expertise to identify harmful substances in products to which consumers are exposed, to design standards to limit exposure to those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health. In connection with its mandate to promote health and reduce the risk of harm, the Food and Drug Administration routinely makes decisions about whether and how products may be marketed in the United States.

''(45) The Federal Trade Commission was created to protect consumers from unfair or deceptive acts or practices, and to regulate unfair methods of competition. Its focus is on those marketplace practices that deceive or mislead consumers, and those that give some competitors an unfair advantage. Its mission is to regulate activities in the marketplace. Neither the Federal Trade Commission nor any other Federal agency except the Food and Drug Administration possesses the scientific expertise needed to implement effectively all provisions of the Family Smoking Prevention and Tobacco Control Act [div. A of Pub. L. 111–31, see Short Title of 2009 Amendment note set out under section 301 of this title].

''(46) If manufacturers state or imply in communications directed to consumers through the media or through a label, labeling, or advertising, that a tobacco product is approved or inspected by the Food and Drug Administration or complies with Food and Drug Administration standards, consumers are likely to be confused and misled. Depending upon the particular language used and its context, such a statement could result in consumers being misled into believing that the product is endorsed by the Food and Drug Administration for use or in consumers being misled about the harmfulness of the product because of such regulation, inspection, approval, or compliance.

''(47) In August 2006 a United States district court judge found that the major United States cigarette companies continue to target and market to youth. USA v. Philip Morris, USA, Inc., et al. (Civil Action No. 99–2496 (GK), August 17, 2006).

''(48) In August 2006 a United States district court judge found that the major United States cigarette companies dramatically increased their advertising and promotional spending in ways that encourage youth to start smoking subsequent to the signing of the Master Settlement Agreement in 1998. USA v. Philip Morris, USA, Inc., et al. (Civil Action No. 99–2496 (GK), August 17, 2006).

''(49) In August 2006 a United States district court judge found that the major United States cigarette companies have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction while also concealing much of their nicotine-related research. USA v. Philip Morris, USA, Inc., et al. (Civil Action No. 99–2496 (GK), August 17, 2006).''

PURPOSE

Pub. L. 111–31, div. A, §3, June 22, 2009, 123 Stat. 1781, provided that: ''The purposes of this division [see Short Title of 2009 Amendment note set out under section 301 of this title] are—

''(1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products as provided for in this division;

''(2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;

''(3) to authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;

''(4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;

''(5) to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

''(6) in order to ensure that consumers are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products;

''(7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;

''(8) to impose appropriate regulatory controls on the tobacco industry;

''(9) to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases; and

''(10) to strengthen legislation against illicit trade in tobacco products.''

MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION

Pub. L. 111–31, div. A, §6, June 22, 2009, 123 Stat. 1783, provided that:

''(a) DELAYED COMMENCEMENT OF DATES FOR SECRETARIAL ACTION.—

''(1) IN GENERAL.—Except as provided in subsection (c), with respect to any time periods specified in this division [see Short Title of 2009 Amendment note set out under section 301 of this title] (or in an amendment made by this division) that begin on the date of enactment of this Act [June 22, 2009], within which the Secretary of Health and Human Services is required to carry out and complete specified activities, the calculation of such time periods shall commence on the date described in subsection (b).

''(2) LIMITATION.—Subsection (a) shall only apply with respect to obligations of the Secretary of Health and Human Services that must be completed within a specified time period and shall not apply to the obligations of any other person or to any other provision of this division (including the amendments made by this division) that do not create such obligations of the Secretary and are not contingent on actions by the Secretary.

''(b) DATE DESCRIBED.—The date described in this subsection is the first day of the first fiscal quarter following the initial 2 consecutive fiscal quarters of fiscal year 2010 for which the Secretary of Health and Human Services has collected fees under section 919 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387s] (as added by section 101).

''(c) EXCEPTION.—Subsection (a) shall not apply to any time period (or date) contained—

''(1) in section 102 [21 U.S.C. 387a–1], except that the reference to '180 days' in subsection (a)(1) of such section shall be deemed to be '270 days'; and

''(2) in sections 201 through 204 [amending sections 1333, 1334, and 4402 of Title 15, Commerce and Trade, and enacting provisions set out as notes under sections 1333 and 4402 of Title 15] (or the amendments made by any such sections).

''(d) ADJUSTMENT.—The Secretary of Health and Human Services may extend or reduce the duration of one or more time periods to which subsection (a) applies if the Secretary determines appropriate [sic], except that no such period shall be extended for more than 90 days.''

§ 387a. FDA authority over tobacco products

(a) In general

Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 387k of this title, shall be regulated by the Secretary under this subchapter and shall not be subject to the provisions of subchapter V.

(b) Applicability

This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter.

(c) Scope

(1) In general

Nothing in this subchapter, or any policy issued or regulation promulgated thereunder, or in sections 101(a), 102, or 103 of title I, title II, or title III of the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect, expand, or limit the Secretary's authority over (including the authority to determine whether products may be regulated), or the regulation of, products under this chapter that are not tobacco products under subchapter V or any other subchapter.

(2) Limitation of authority

(A) In general

The provisions of this subchapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

(B) Exception

Notwithstanding subparagraph (A), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this subchapter in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

(C) Rule of construction

Nothing in this subchapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

(d) Rulemaking procedures

Each rulemaking under this subchapter shall be in accordance with chapter 5 of title 5. This subsection shall not be construed to affect the rulemaking provisions of section 102(a) of the Family Smoking Prevention and Tobacco Control Act [21 U.S.C. 387a–1(a)].

(e) Center for tobacco products

Not later than 90 days after June 22, 2009, the Secretary shall establish within the Food and Drug Administration the Center for Tobacco Products, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this subchapter and related matters assigned by the Commissioner.

(f) Office to assist small tobacco product manufacturers

The Secretary shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this chapter.

(g) Consultation prior to rulemaking

Prior to promulgating rules under this subchapter, the Secretary shall endeavor to consult with other Federal agencies as appropriate.

(June 25, 1938, ch. 675, § 901, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1786.)

REFERENCES IN TEXT

The Family Smoking Prevention and Tobacco Control Act, referred to in subsec. (c)(1), is div. A of Pub. L. 111–31, June 22, 2009, 123 Stat. 1776. Section 101(a) of

title I of the Act amended section 321 of this title. Section 102 of title I of the Act enacted section 387a–1 of this title. Section 103 of title I of the Act amended sections 331, 333, 334, 355, 360m, 372 to 374, 375, 379a, 381, 393, 399, and 679 of this title and enacted provisions set out as notes under sections 331, 333, and 387c of this title. Title II of the Act amended sections 1333, 1334, 4402, and 4406 of Title 15, Commerce and Trade, and enacted provisions set out as notes under sections 1333 and 4402 of Title 15. Title III of the Act enacted section 387t of this title. For complete classification of this Act to the Code, see Short Title of 2009 Amendment note set out under section 301 of this title and Tables.

PRIOR PROVISIONS

A prior section 901 of act June 25, 1938, was renumbered section 1001 and is classified to section 391 of this title.

§ 387a–1. Final rule

(a) Cigarettes and smokeless tobacco

(1) In general

On the first day of publication of the Federal Register that is 180 days or more after June 22, 2009, the Secretary of Health and Human Services shall publish in the Federal Register a final rule regarding cigarettes and smokeless tobacco, which—

(A) is deemed to be issued under chapter 9[1] of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387 et seq.], as added by section 101 of this division; and

(B) shall be deemed to be in compliance with all applicable provisions of chapter 5 of title 5 and all other provisions of law relating to rulemaking procedures.

(2) Contents of rule

Except as provided in this subsection, the final rule published under paragraph (1),[2] shall be identical in its provisions to part 897 of the regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615–44618). Such rule shall—

(A) provide for the designation of jurisdictional authority that is in accordance with this subsection in accordance with this division and the amendments made by this division;

(B) strike Subpart C—Labels and section 897.32(c);

(C) strike paragraphs (a), (b), and (i) of section 897.3 and insert definitions of the terms ''cigarette'', ''cigarette tobacco'', and ''smokeless tobacco'' as defined in section 900 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387];

(D) insert ''or roll-your-own paper'' in section 897.34(a) after ''other than cigarettes or smokeless tobacco'';

(E) 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 of the United States in Lorillard Tobacco Co. v. Reilly (533 U.S. 525 (2001));

(F) become effective on the date that is 1 year after June 22, 2009; and

(G) amend paragraph (d) of section 897.16 to read as follows:

''(d)(1) Except as provided in subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

''(2)(A) Subparagraph (1) does not prohibit a manufacturer, distributor, or retailer from distributing or causing to be distributed free samples of smokeless tobacco in a qualified adult-only facility.

''(B) This subparagraph does not affect the authority of a State or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

''(C) For purposes of this paragraph, the term 'qualified adult-only facility' means a facility or restricted area that—

''(i) requires each person present to provide to a law enforcement officer (whether on or off duty) or to a security guard licensed by a governmental entity government-issued identification showing a photograph and at least the minimum age established by applicable law for the purchase of smokeless tobacco;

''(ii) does not sell, serve, or distribute alcohol;

''(iii) is not located adjacent to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities;

''(iv) is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose of distributing free samples of smokeless tobacco in accordance with this subparagraph;

''(v) is enclosed by a barrier that—

''(I) is constructed of, or covered with, an opaque material (except for entrances and exits);

''(II) extends from no more than 12 inches above the ground or floor (which area at the bottom of the barrier must be covered with material that restricts visibility but may allow airflow) to at least 8 feet above the ground or floor (or to the ceiling); and

''(III) prevents persons outside the qualified adult-only facility from seeing into the qualified adult-only facility, unless they make unreasonable efforts to do so; and

''(vi) does not display on its exterior—

''(I) any tobacco product advertising;

''(II) a brand name other than in conjunction with words for an area or enclosure to identify an adult-only facility; or

''(III) any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship that would violate section 897.34(c).

''(D) Distribution of samples of smokeless tobacco under this subparagraph permitted to be taken out of the qualified adult-only facility shall be limited to 1 package per adult consumer containing no more than 0.53 ounces (15 grams) of smokeless tobacco. If such package of smokeless tobacco contains individual portions of

[1] So in original. Probably should be ''chapter IX''.

[2] So in original. The comma probably should not appear.

smokeless tobacco, the individual portions of smokeless tobacco shall not exceed 8 individual portions and the collective weight of such individual portions shall not exceed 0.53 ounces (15 grams). Any manufacturer, distributor, or retailer who distributes or causes to be distributed free samples also shall take reasonable steps to ensure that the above amounts are limited to one such package per adult consumer per day.

''(3) Notwithstanding subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of smokeless tobacco—

''(A) to a sports team or entertainment group; or

''(B) at any football, basketball, baseball, soccer, or hockey event or any other sporting or entertainment event determined by the Secretary to be covered by this subparagraph.

''(4) The Secretary shall implement a program to ensure compliance with this paragraph and submit a report to the Congress on such compliance not later than 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

''(5) Nothing in this paragraph shall be construed to authorize any person to distribute or cause to be distributed any sample of a tobacco product to any individual who has not attained the minimum age established by applicable law for the purchase of such product.''.

(3) Amendments to rule

Prior to making amendments to the rule published under paragraph (1), the Secretary shall promulgate a proposed rule in accordance with chapter 5 of title 5.

(4) Rule of construction

Except as provided in paragraph (3), nothing in this section shall be construed to limit the authority of the Secretary to amend, in accordance with chapter 5 of title 5, the regulation promulgated pursuant to this section, including the provisions of such regulation relating to distribution of free samples.

(5) Enforcement of retail sale provisions

The Secretary of Health and Human Services shall ensure that the provisions of this division, the amendments made by this division, and the implementing regulations (including such provisions, amendments, and regulations relating to the retail sale of tobacco products) are enforced with respect to the United States and Indian tribes.

(6) Qualified adult-only facility

A qualified adult-only facility (as such term is defined in section 897.16(d) of the final rule published under paragraph (1)) that is also a retailer and that commits a violation as a retailer shall not be subject to the limitations in section 103(q)[3] and shall be subject to penalties applicable to a qualified adult-only facility.

(7) Congressional review provisions

Section 801 of title 5 shall not apply to the final rule published under paragraph (1).

[3] So in original. See References in Text note below.

(b) Limitation on advisory opinions

As of June 22, 2009, the following documents issued by the Food and Drug Administration shall not constitute advisory opinions under section 10.85(d)(1) of title 21, Code of Federal Regulations, except as they apply to tobacco products, and shall not be cited by the Secretary of Health and Human Services or the Food and Drug Administration as binding precedent:

(1) The preamble to the proposed rule in the document titled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents'' (60 Fed. Reg. 41314–41372 (August 11, 1995)).

(2) The document titled ''Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act'' (60 Fed. Reg. 41453–41787 (August 11, 1995)).

(3) The preamble to the final rule in the document titled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents'' (61 Fed. Reg. 44396–44615 (August 28, 1996)).

(4) The document titled ''Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act; Jurisdictional Determination'' (61 Fed. Reg. 44619–45318 (August 28, 1996)).

(Pub. L. 111–31, div. A, title I, § 102, June 22, 2009, 123 Stat. 1830.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a)(1)(A), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§ 301 et seq.) of this title. Chapter 9 [IX] of the Act is classified generally to this subchapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

This division, referred to in subsec. (a)(2)(A), (5), is div. A of Pub. L. 111–31, June 22, 2009, 123 Stat. 1776, known as the Family Smoking Prevention and Tobacco Control Act. For complete classification of division A to the Code, see Short Title of 2009 Amendment note set out under section 301 of this title and Tables.

The date of enactment of the Family Smoking Prevention and Tobacco Control Act, referred to in subsec. (a)(2)(G), is the date of enactment of Pub. L. 111–31, which was approved June 22, 2009.

Section 103(q), referred to in subsec. (a)(6), is section 103(q) of Pub. L. 111–31, which enacted provisions set out as notes under sections 333 and 387c of this title.

CODIFICATION

Section was enacted as part of the Family Smoking Prevention and Tobacco Control Act and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION

For provision deeming reference to ''180 days'' in subsec. (a)(1) to be ''270 days'', see section 6 of Pub. L. 111–31, set out as a note under section 387 of this title.

§ 387b. Adulterated tobacco products

A tobacco product shall be deemed to be adulterated if—

(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is

otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;

(2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

(3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(4) the manufacturer or importer of the tobacco product fails to pay a user fee assessed to such manufacturer or importer pursuant to section 387s of this title by the date specified in section 387s of this title or by the 30th day after final agency action on a resolution of any dispute as to the amount of such fee;

(5) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 387g of this title unless such tobacco product is in all respects in conformity with such standard;

(6)(A) it is required by section 387j(a) of this title to have premarket review and does not have an order in effect under section 387j(c)(1)(A)(i) of this title; or

(B) it is in violation of an order under section 387j(c)(1)(A) of this title;

(7) the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 387f(e)(1) of this title or an applicable condition prescribed by an order under section 387f(e)(2) of this title; or

(8) it is in violation of section 387k of this title.

(June 25, 1938, ch. 675, §902, as added Pub. L. 111–31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1787.)

PRIOR PROVISIONS

A prior section 902 of act June 25, 1938, was renumbered section 1002. Subsec. (a) of section 1002 is set out as a note under section 301 of this title. Subsecs. (b) and (c) of section 1002 are classified to section 392 of this title. Subsec. (d) of section 1002 is set out as a note under section 392 of this title.

§ 387c. Misbranded tobacco products

(a) In general

A tobacco product shall be deemed to be misbranded—

(1) if its labeling is false or misleading in any particular;

(2) if in package form unless it bears a label containing—

(A) the name and place of business of the tobacco product manufacturer, packer, or distributor;

(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

(C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and

(D) the statement required under section 387t(a) of this title,

except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary;

(3) if any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;

(5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations;

(6) if it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 387e(b), 387e(c), 387e(d), or 387e(h) of this title, if it was not included in a list required by section 387e(i) of this title, if a notice or other information respecting it was not provided as required by such section or section 387e(j) of this title, or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 387e(e) of this title as the Secretary by regulation requires;

(7) if, in the case of any tobacco product distributed or offered for sale in any State—

(A) its advertising is false or misleading in any particular; or

(B) it is sold or distributed in violation of regulations prescribed under section 387f(d) of this title;

(8) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product—

(A) a true statement of the tobacco product's established name as described in paragraph (4), printed prominently; and

(B) a brief statement of—

(i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and

(ii) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that such action is appropriate to protect the public health, a full description of the components of such tobacco product or the formula showing quantitatively each ingredient of such tobacco product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing;

(9) if it is a tobacco product subject to a tobacco product standard established under section 387g of this title, unless it bears such labeling as may be prescribed in such tobacco product standard; or

(10) if there was a failure or refusal—

(A) to comply with any requirement prescribed under section 387d or 387h of this title; or

(B) to furnish any material or information required under section 387i of this title.

(b) Prior approval of label statements

The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product to ensure that such statements do not violate the misbranding provisions of subsection (a) and that such statements comply with other provisions of the Family Smoking Prevention and Tobacco Control Act (including the amendments made by such Act). No regulation issued under this subsection may require prior approval by the Secretary of the content of any advertisement, except for modified risk tobacco products as provided in section 387k of this title. No advertisement of a tobacco product published after June 22, 2009, shall, with respect to the language of label statements as prescribed under section 1333 of title 15 and section 4402 of title 15 or the regulations issued under such sections, be subject to the provisions of sections 52 through 55 of title 15.

(June 25, 1938, ch. 675, § 903, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1788.)

REFERENCES IN TEXT

The Family Smoking Prevention and Tobacco Control Act, referred to in subsec. (b), is div. A of Pub. L. 111–31, June 22, 2009, 123 Stat. 1776. For complete classification of this Act to the Code, see Short Title of 2009 Amendment note set out under section 301 of this title and Tables.

PRIOR PROVISIONS

A prior section 903 of act June 25, 1938, was renumbered section 1003 and is classified to section 393 of this title.

Another prior section 903 of act June 25, 1938, was renumbered section 1004 and is classified to section 394 of this title.

EFFECTIVE DATE

Pub. L. 111–31, div. A, title I, § 103(q)(5), (6), June 22, 2009, 123 Stat. 1840, provided that:

''(5) PACKAGE LABEL REQUIREMENTS.—The package label requirements of paragraphs (3) and (4) of section 903(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387c(a)] (as amended by this division) shall take effect on the date that is 12 months after the date of enactment of this Act [June 22, 2009]. The package label requirements of paragraph (2) of such section 903(a) for cigarettes shall take effect on the date that is 15 months after the issuance of the regulations required by section 4(d) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333[(d)]), as amended by section 201 of this division. The package label requirements of paragraph (2) of such section 903(a) for tobacco products other than cigarettes shall take effect on the date that is 12 months after the date of enactment of this Act. The effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 903(a)(2), (3), and (4) and section 920(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387t(a)].

''(6) ADVERTISING REQUIREMENTS.—The advertising requirements of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387c(a)(8)] (as amended by this division) shall take effect on the date that is 12 months after the date of enactment of this Act [June 22, 2009].''

§ 387d. Submission of health information to the Secretary

(a) Requirement

Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Secretary the following information:

(1) Not later than 6 months after June 22, 2009, a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.

(2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Secretary in accordance with section 1333(e) of title 15.

(3) Beginning 3 years after June 22, 2009, a listing of all constituents, including smoke constituents as applicable, identified by the Secretary as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand. Effective beginning 3 years after June 22, 2009, the manufacturer, importer, or agent shall comply with regulations promulgated under section 387*o* of this title in reporting information under this paragraph, where applicable.

(4) Beginning 6 months after June 22, 2009, all documents developed after June 22, 2009 that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.

(b) Data submission

At the request of the Secretary, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit the following:

(1) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, behavioral, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

(2) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) that relate to the issue of whether a reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer.

(June 25, 1938, ch. 675, § 906, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1795.)

PRIOR PROVISIONS

A prior section 906 of act June 25, 1938, was renumbered section 1006 and is classified to section 396 of this title.

MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION

With respect to any time periods specified in an amendment by div. A of Pub. L. 111–31 that begin on June 22, 2009, within which the Secretary of Health and Human Services is required to carry out and complete specified activities, with certain limitations, the calculation of such time periods shall commence on the first day of the first fiscal quarter following the initial 2 consecutive fiscal quarters of fiscal year 2010 for which the Secretary has collected fees under section 387s of this title, and the Secretary may extend or reduce the duration of one or more such time periods, except that no such period shall be extended for more than 90 days, see section 6 of Pub. L. 111–31, set out as a note under section 387 of this title.

§ 387f–1. Enforcement action plan for advertising and promotion restrictions

(a) Action plan

(1) Development

Not later than 6 months after June 22, 2009, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall develop and publish an action plan to enforce restrictions adopted pursuant to section 387f of this title, as added by section 101(b) of this division, or pursuant to section 387a–1(a) of this title, on promotion and advertising of menthol and other cigarettes to youth.

(2) Consultation

The action plan required by paragraph (1) shall be developed in consultation with public health organizations and other stakeholders with demonstrated expertise and experience in serving minority communities.

(3) Priority

The action plan required by paragraph (1) shall include provisions designed to ensure enforcement of the restrictions described in paragraph (1) in minority communities.

(b) State and local activities

(1) Information on authority

Not later than 3 months after June 22, 2009, the Secretary shall inform State, local, and tribal governments of the authority provided to such entities under section 1334(c) of title 15, as added by section 203 of this division, or preserved by such entities under section 387p of this title, as added by section 101(b) of this division.

(2) Community assistance

At the request of communities seeking assistance to prevent underage tobacco use, the Secretary shall provide such assistance, including assistance with strategies to address the prevention of underage tobacco use in communities with a disproportionate use of menthol cigarettes by minors.

(Pub. L. 111–31, div. A, title I, § 105, June 22, 2009, 123 Stat. 1841.)

CODIFICATION

Section was enacted as part of the Family Smoking Prevention and Tobacco Control Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION

With respect to any time periods specified in div. A of Pub. L. 111–31 that begin on June 22, 2009, within which the Secretary of Health and Human Services is required to carry out and complete specified activities, with certain limitations, the calculation of such time periods shall commence on the first day of the first fiscal quarter following the initial 2 consecutive fiscal quarters of fiscal year 2010 for which the Secretary has collected fees under section 387s of this title, and the Secretary may extend or reduce the duration of one or more such time periods, except that no such period shall be extended for more than 90 days, see section 6 of Pub. L. 111–31, set out as a note under section 387 of this title.

§ 387g. Tobacco product standards

(a) In general

(1) Special rules

(A) Special rule for cigarettes

Beginning 3 months after June 22, 2009, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this chapter applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

(B) Additional special rule

Beginning 2 years after June 22, 2009, a tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.

(2) Revision of tobacco product standards

The Secretary may revise the tobacco product standards in paragraph (1) in accordance with subsection (c).

(3) Tobacco product standards

(A) In general

The Secretary may adopt tobacco product standards in addition to those in paragraph (1) if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health.

(B) Determinations

(i) Considerations

In making a finding described in subparagraph (A), the Secretary shall consider scientific evidence concerning—

(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

(II) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(III) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(ii) Additional considerations

In the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because the Secretary has found that the additive, constituent, or other component is or may be harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Secretary's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

(4) Content of tobacco product standards

A tobacco product standard established under this section for a tobacco product—

(A) shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

(i) for nicotine yields of the product;

(ii) for the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product; or

(iii) relating to any other requirement under subparagraph (B);

(B) shall, where appropriate for the protection of the public health, include—

(i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

(iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;

(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title;

(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product; and

(D) shall require tobacco products containing foreign-grown tobacco to meet the same standards applicable to tobacco products containing domestically grown tobacco.

(5) Periodic reevaluation of tobacco product standards

The Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary may provide for testing under paragraph (4)(B) by any person.

(6) Involvement of other agencies; informed persons

In carrying out duties under this section, the Secretary shall endeavor to—

(A) use personnel, facilities, and other technical support available in other Federal agencies;

(B) consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Secretary's judgment can make a significant contribution.

(b) Considerations by Secretary

(1) Technical achievability

The Secretary shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard.

(2) Other considerations

The Secretary shall consider all other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this subchapter and the significance of such demand.

(c) Proposed standards

(1) In general

The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

(2) Requirements of notice

A notice of proposed rulemaking for the establishment or amendment of a tobacco product standard for a tobacco product shall—

(A) set forth a finding with supporting justification that the tobacco product standard is appropriate for the protection of the public health;

(B) invite interested persons to submit a draft or proposed tobacco product standard for consideration by the Secretary;

(C) invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco; and

(D) invite the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed tobacco product standard.

(3) Finding

A notice of proposed rulemaking for the revocation of a tobacco product standard shall set forth a finding with supporting justification that the tobacco product standard is no longer appropriate for the protection of the public health.

(4) Comment

The Secretary shall provide for a comment period of not less than 60 days.

(d) Promulgation

(1) In general

After the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a tobacco product standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall—

(A) if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product standard and publish in the Federal Register findings on the matters referred to in subsection (c); or

(B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

(2) Effective date

A regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade. In establishing such effective date or dates, the Secretary shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard. If the Secretary determines, based on the Secretary's evaluation of submitted comments, that a product standard can be met only by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer, the effective date of that product standard shall be not less than 2 years after the date of publication of the final regulation establishing the standard.

(3) Limitation on power granted to the Food and Drug Administration

Because of the importance of a decision of the Secretary to issue a regulation—

(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or

(B) requiring the reduction of nicotine yields of a tobacco product to zero,

the Secretary is prohibited from taking such actions under this chapter.

(4) Amendment; revocation

(A) Authority

The Secretary, upon the Secretary's own initiative or upon petition of an interested person, may by a regulation, promulgated in accordance with the requirements of subsection (c) and paragraph (2), amend or revoke a tobacco product standard.

(B) Effective date

The Secretary may declare a proposed amendment of a tobacco product standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Secretary determines that making it so effective is in the public interest.

(5) Referral to Advisory Committee

(A) In general

The Secretary may refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product standard to the Tobacco Products Scientific Advisory Committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment.

(B) Initiation of referral

The Secretary may make a referral under this paragraph—

(i) on the Secretary's own initiative; or

(ii) upon the request of an interested person that—

(I) demonstrates good cause for the referral; and

(II) is made before the expiration of the period for submission of comments on the proposed regulation.

(C) Provision of data

If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Secretary shall provide the Advisory Committee with the data and information on which such proposed regulation is based.

(D) Report and recommendation

The Tobacco Products Scientific Advisory Committee shall, within 60 days after the re-

ferral of a proposed regulation under this paragraph and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

(E) Public availability

The Secretary shall make a copy of each report and recommendation under subparagraph (D) publicly available.

(e) Menthol cigarettes

(1) Referral; considerations

Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee under section 387q(a) of this title, the Secretary shall refer to the Committee for report and recommendation, under section 387q(c)(4) of this title, the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsections (a)(3)(B)(i) and (b).

(2) Report and recommendation

Not later than 1 year after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

(3) Rule of construction

Nothing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this chapter applicable to menthol.

(f) Dissolvable tobacco products

(1) Referral; considerations

The Secretary shall refer to the Tobacco Products Scientific Advisory Committee for report and recommendation, under section 387q(c)(4) of this title, the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsection (a)(3)(B)(i).

(2) Report and recommendation

Not later than 2 years after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

(3) Rule of construction

Nothing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this chapter at any time applicable to any dissolvable tobacco product.

(June 25, 1938, ch. 675, § 907, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1799.)

PRIOR PROVISIONS

A prior section 907 of act June 25, 1938, was renumbered section 1007 and is classified to section 397 of this title.

§ 387h. Notification and other remedies

(a) Notification

If the Secretary determines that—

(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health; and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this subchapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to eliminate such risk. The Secretary may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

(b) No exemption from other liability

Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided under such order shall be taken into account.

(c) Recall authority

(1) In general

If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(2) Amendment of order to require recall

(A) In general

If, after providing an opportunity for an informal hearing under paragraph (1), the

§ 387j. Application for review of certain tobacco products

(a) In general

(1) New tobacco product defined

For purposes of this section the term ''new tobacco product'' means—

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(2) Premarket review required

(A) New products

An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

(i) the manufacturer has submitted a report under section 387e(j) of this title; and the Secretary has issued an order that the tobacco product—

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this chapter; or

(ii) the tobacco product is exempt from the requirements of section 387e(j) of this title pursuant to a regulation issued under section 387e(j)(3) of this title.

(B) Application to certain post-February 15, 2007, products

Subparagraph (A) shall not apply to a tobacco product—

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009; and

(ii) for which a report was submitted under section 387e(j) of this title within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

(3) Substantially equivalent defined

(A) In general

In this section and section 387e(j) of this title, the term ''substantially equivalent'' or ''substantial equivalence'' means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

(i) has the same characteristics as the predicate tobacco product; or

(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

(B) Characteristics

In subparagraph (A), the term ''characteristics'' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

(C) Limitation

A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

(4) Health information

(A) Summary

As part of a submission under section 387e(j) of this title respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

(B) Required information

Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

(b) Application

(1) Contents

An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

(D) an identifying reference to any tobacco product standard under section 387g of this title which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

(F) specimens of the labeling proposed to be used for such tobacco product; and

(G) such other information relevant to the subject matter of the application as the Secretary may require.

(2) Referral to Tobacco Products Scientific Advisory Committee

Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may, on the Secretary's own initiative; or

(B) may, upon the request of an applicant,

refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(c) Action on application

(1) Deadline

(A) In general

As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under subsection (b)(2), shall—

(i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(B) Restrictions on sale and distribution

An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title.

(2) Denial of application

The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of this title;

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of this title, and there is a lack of adequate information to justify the deviation from such standard.

(3) Denial information

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

(4) Basis for finding

For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(5) Basis for action

(A) Investigations

For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

(B) Other evidence

If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

(d) Withdrawal and temporary suspension

(1) In general

The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a tobacco product for which an order was issued under subsection (c)(1)(A)(i), issue an order withdrawing the order if the Secretary finds—

(A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

(B) that the application contained or was accompanied by an untrue statement of a material fact;

(C) that the applicant—

(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 387i of this title;

(ii) has refused to permit access to, or copying or verification of, such records as required by section 374 of this title; or

(iii) has not complied with the requirements of section 387e of this title;

(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 387f(e) of this title and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 387g of this title, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

(2) Appeal

The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A)(i) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 387*l* of this title.

(3) Temporary suspension

If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the authority of the manufacturer to market the product. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

(e) Service of order

An order issued by the Secretary under this section shall be served—

(1) in person by any officer or employee of the department designated by the Secretary; or

(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

(f) Records

(1) Additional information

In the case of any tobacco product for which an order issued pursuant to subsection (c)(1)(A)(i) for an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

(2) Access to records

Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(g) Investigational tobacco product exemption for investigational use

The Secretary may exempt tobacco products intended for investigational use from the provisions of this subchapter under such conditions as the Secretary may by regulation prescribe.

(June 25, 1938, ch. 675, § 910, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1807.)

PRIOR PROVISIONS

A prior section 910 of act June 25, 1938, was renumbered section 1010 and is classified to section 399a of this title.

§ 387k. Modified risk tobacco products

(a) In general

No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product.

(b) Definitions

In this section:

(1) Modified risk tobacco product

The term ''modified risk tobacco product'' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

(4) Additional extension

In addition to the time that may be provided under paragraph (3), the Secretary may provide further extensions of time, in increments of no more than 1 year, for required testing and reporting to occur if the Secretary determines, based on evidence properly and timely submitted by a small tobacco product manufacturer in accordance with paragraph (2), that a lack of available laboratory capacity prevents the manufacturer from completing the required testing during the period described in paragraph (3).

(f) Rule of construction

Nothing in subsection (d) or (e) shall be construed to authorize the extension of any deadline, or to otherwise affect any timeframe, under any provision of this chapter or the Family Smoking Prevention and Tobacco Control Act other than this section.

(June 25, 1938, ch. 675, § 915, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1820.)

REFERENCES IN TEXT

The Family Smoking Prevention and Tobacco Control Act, referred to in subsec. (f), is div. A of Pub. L. 111–31, June 22, 2009, 123 Stat. 1776. For complete classification of this Act to the Code, see Short Title of 2009 Amendment note set out under section 301 of this title and Tables.

MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION

With respect to any time periods specified in an amendment by div. A of Pub. L. 111–31 that begin on June 22, 2009, within which the Secretary of Health and Human Services is required to carry out and complete specified activities, with certain limitations, the calculation of such time periods shall commence on the first day of the first fiscal quarter following the initial 2 consecutive fiscal quarters of fiscal year 2010 for which the Secretary has collected fees under section 387s of this title, and the Secretary may extend or reduce the duration of one or more such time periods, except that no such period shall be extended for more than 90 days, see section 6 of Pub. L. 111–31, set out as a note under section 387 of this title.

§ 387p. Preservation of State and local authority

(a) In general

(1) Preservation

Except as provided in paragraph (2)(A), nothing in this subchapter, or rules promulgated under this subchapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this subchapter shall limit or otherwise affect any State, tribal, or local taxation of tobacco products.

(2) Preemption of certain State and local requirements

(A) In general

No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

(B) Exception

Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of title 5 shall be treated as a trade secret and confidential information by the State.

(b) Rule of construction regarding product liability

No provision of this subchapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

(June 25, 1938, ch. 675, § 916, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1823.)

§ 387q. Tobacco Products Scientific Advisory Committee

(a) Establishment

Not later than 6 months after June 22, 2009, the Secretary shall establish a 12-member advisory committee, to be known as the Tobacco Products Scientific Advisory Committee (in this section referred to as the ''Advisory Committee'').

(b) Membership

(1) In general

(A) Members

The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee individuals who are technically qualified by training and experience in medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified professional backgrounds. The committee shall be composed of—

(i) 7 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;

(ii) 1 individual who is an officer or employee of a State or local government or of the Federal Government;

West's General Laws of Rhode Island Annotated Currentness
Constitution of the State of Rhode Island and Providence Plantations
Article XIII. Home Rule for Cities and Towns

§ 2. Local legislative powers

Every city and town shall have the power at any time to adopt a charter, amend its charter, enact and amend local laws relating to its property, affairs and government not inconsistent with this Constitution and laws enacted by the general assembly in conformity with the powers reserved to the general assembly.

Const. Art. 13, § 2, RI **CONST Art. 13,** § 2

Current through chapter 491 of the January 2012 session

END OF DOCUMENT

C

West's General Laws of Rhode Island Annotated Currentness
Constitution of the State of Rhode Island and Providence Plantations
Article XIII. Home Rule for Cities and Towns

§ 4. Powers of general assembly over cities and towns

The general assembly shall have the power to act in relation to the property, affairs and government of any city or town by general laws which shall apply alike to all cities and towns, but which shall not affect the form of government of any city or town. The general assembly shall also have the power to act in relation to the property, affairs and government of a particular city or town provided that such legislative action shall become effective only upon approval by a majority of the qualified electors of the said city or town voting at a general or special election, except that in the case of acts involving the imposition of a tax or the expenditure of money by a town the same shall provide for the submission thereof to those electors in said town qualified to vote upon a proposition to impose a tax or for the expenditure of money.

Const. Art. 13, § 4, RI CONST Art. 13, § 4

Current through chapter 491 of the January 2012 session

END OF DOCUMENT

West's General Laws of Rhode Island Annotated Currentness
Title 11. Criminal Offenses
Chapter 9. Children

§ 11-9-13. Purchase, sale or delivery of tobacco products to persons under eighteen--Posting notice of law

No person under eighteen (18) years of age shall purchase, nor shall any person sell, give or deliver to any person under eighteen (18) years of age, any tobacco in the form of cigarettes, bidi cigarettes, cigars, little cigars, flavored cigars known as “blunts”, unflavored “blunts”, flavored and unflavored blunt wraps, cigarette rolling papers of any size or composition, cigarillos, and tiparillos, pipe tobacco, chewing tobacco, or snuff. Any person, firm, or corporation that owns, manages, or operates a place of business in which tobacco products are sold, including sales through cigarette vending machines, shall post notice of this law conspicuously in the place of business in letters at least three-eighths of an inch (3/8 ”) high.

CREDIT(S)

P.L. 1987, ch. 84, § 1; P.L. 1988, ch. 159, § 1; P.L. 1996, ch. 321, § 2; P.L. 2001, ch. 124, § 1; P.L. 2001, ch. 149, § 1; P.L. 2011, ch. 88, § 1, eff. June 21, 2011; P.L. 2011, ch. 98, § 1, eff. June 21, 2011.

Codifications: G.L. 1896, ch. 281, § 28; G.L. 1909, ch. 347, § 29; G.L. 1923, ch. 399, § 28; G.L. 1938, ch. 610, § 28.

Current through chapter 491 of the January 2012 session

END OF DOCUMENT

West's General Laws of Rhode Island Annotated Currentness
Title 11. Criminal Offenses
Chapter 9. Children
§ 11-9-13. 8. Prohibitions applicable to license holders and their employees and agents

A person that holds a license issued under chapter 20 of title 44, or an employee or agent of that person, is prohibited from selling, distributing, or delivering a tobacco product:

(1) To any individual that is under eighteen (18) years of age; or

(2) In any form other than an original factory-wrapped package; or

(3) As a single cigarette sale (§ 44-20-31), or as a sale of cigarettes by the individual piece, known as "loosies."

CREDIT(S)

P.L. 1996, ch. 321, § 1.

LIBRARY REFERENCES

Infants 13.
Westlaw Key Number Search: 211k13.
C.J.S. Infants §§ 110 to 114, 118 to 121.

Gen. Laws, 1956, § **11-9-13. 8**, RI ST § **11-9-13. 8**

Current through chapter 491 of the January 2012 session

END OF DOCUMENT

West's General Laws of Rhode Island Annotated Currentness
Title 11. Criminal Offenses
Chapter 9. Children
§ 11-9-13. 10. Prohibition on the distribution of free tobacco products

The distribution of free tobacco products or coupons or vouchers redeemable for free tobacco products to any person under eighteen (18) years of age shall be prohibited. Further, the distribution of free tobacco products or coupons or vouchers redeemable for free tobacco products shall be prohibited, regardless of the age of the person to whom the products, coupons, or vouchers are distributed, within five hundred (500) feet of any school. The attorney general shall bring an action for any violation of this section. Every separate free tobacco product or coupon or voucher redeemable for a free tobacco product in violation of this section shall constitute a separate offense subject to a fine of five hundred dollars ($500). The penalty shall be assessed against the business or individual responsible for initiating the Rhode Island distribution of the free tobacco products or coupons or vouchers redeemable for free tobacco products.

CREDIT(S)

P.L. 1996, ch. 321, § 1.

LIBRARY REFERENCES

Infants 13.
Westlaw Key Number Search: 211k13.
C.J.S. Infants §§ 110 to 114, 118 to 121.

Gen. Laws, 1956, § **11-9-13. 10**, RI ST § **11-9-13. 10**

Current through chapter 491 of the January 2012 session

END OF DOCUMENT

West's General Laws of Rhode Island Annotated Currentness
Title 11. Criminal Offenses
Chapter 9. Children
§ 11-9-14. Use of tobacco by minors

No person under eighteen (18) years of age shall smoke or chew or possess when such possession is clearly visible tobacco in any public street, place or resort, any tobacco in any form whatsoever. Any person under eighteen (18) years of age violating the provisions of this section shall be required to perform up to thirty (30) hours of community service or shall be required to enter into a tobacco treatment program approved by any local substance abuse prevention task force, at the option of a minor charged with a violation of this section.

CREDIT(S)

P.L. 2001, ch. 124, § 1;P.L. 2001, ch. 148, § 1;P.L. 2001, ch. 149, § 1;P.L. 2005, ch. 251, § 1; P.L. 2007, ch. 426, § 1, eff. July 7, 2007.

Codifications: G.L. 1896, ch. 281, § 29; G.L. 1909, ch. 347, § 30; G.L. 1923, ch. 399, § 29; G.L. 1938, ch. 610, § 29.

Current through chapter 491 of the January 2012 session

END OF DOCUMENT

West's General Laws of Rhode Island Annotated Currentness
Title 6. Commercial Law--General Regulatory Provisions
Chapter 13. Unfair Sales Practices
§ 6-13-11. Discount price advertisement

It shall be unlawful to use, communicate, or publish any advertisement that states that an item or product is being sold or offered for sale at below the regular price or at a percentage off the regular price without posting the regular price at the point of purchase. Whenever an item or product is advertised for sale at below the regular price or at a percentage off the regular price, the advertisement shall clearly state whether there is an additional charge for equipment or services which are reasonably necessary for the proper use of the product. Any person, firm, or corporation who shall violate the provisions of this section shall be punished by a fine of not more than five hundred dollars ($500).

CREDIT(S)

P.L. 1977, ch. 87, § 1; P.L. 1986, ch. 212, § 1.

LIBRARY REFERENCES

Antitrust and Trade Regulation 459, 475.
Westlaw Key Number Searches: 29Tk459; 29Tk475.

Gen. Laws, 1956, § **6-13-11**, RI ST § **6-13-11**

Current through chapter 491 of the January 2012 session

END OF DOCUMENT

West's General Laws of Rhode Island Annotated Currentness
Title 44. Taxation
Chapter 20. Cigarette Tax
§ 44-20-8. Suspension or revocation of license

The tax administrator may suspend or revoke any license under this chapter for failure of the licensee to comply with any provision of this chapter or with any provision of any other law or ordinance relative to the sale of cigarettes; and the tax administrator may also suspend or revoke any license for failure of the licensee to comply with any provision of chapter 13 of title 6, and, for the purpose of determining whether the licensee is complying with any provision of chapter 13 of title 6, the tax administrator and his or her authorized agents are empowered, in addition to authority conferred by § 44-20-40, to examine the books, papers, and records of any licensee. The administrator shall revoke the license of any person who would be ineligible to obtain a new or renew a license by reason of any of the conditions for licensure provided in § 44-20-4.1. Any person aggrieved by the suspension or revocation may apply to the administrator for a hearing as provided in § 44-20-47, and may further appeal to the district court as provided in § 44-20-48.

CREDIT(S)

P.L. 1939, ch. 663, § 4; P.L. 1941, ch. 1039, § 1; P.L. 1968, ch. 263, art. 8, § 2; P.L. 1978, ch. 167, § 3; P.L. 1988, ch. 84, § 97; P.L. 2007, ch. 246, § 3, eff. Oct. 1, 2007; P.L. 2007, ch. 250, § 3, eff. Oct. 1, 2007.

LIBRARY REFERENCES

Licenses 38.
Westlaw Key Number Search: 238k38.

Gen. Laws, 1956, § **44-20-8**, RI ST § **44-20-8**

Current through chapter 491 of the January 2012 session

END OF DOCUMENT

Federal Trade Commission

Cigarette Report

for 2007 and 2008

ISSUED: 2011

facility and that display the name or logo of a company's cigarettes or otherwise refer to cigarettes.[8]

All reporting companies indicated that no money had been spent on endorsements and testimonials, or on audio-visual advertising, in 2007 or in 2008.

The companies reported spending $81.9 million for direct mail advertising in 2007, down from $102.4 million in 2006.[9] Direct mail spending then rose in 2008 to $89.9 million.

The industry reported spending $366.8 million on coupons in 2007 (a decrease from the $625.8 million reported in 2006), and $359.8 million in 2008.[10]

Retail-value-added expenditures are the costs associated with offers such as "buy one, get one free" and "buy three, get a free T-shirt," where the bonus item is distributed at retail when the cigarettes are purchased.[11] The companies spent $981.6 million in 2007 on retail-value-added involving free cigarettes. They also spent $17.7 million on retail-value-added involving free non-cigarette items. Total retail-value-added expenditures were $999.3 million in 2007, an increase from the $832.4 million spent in 2006. In 2008, the companies spent $732.8 million on retail-value-added: $721.8 million involving free cigarettes and $11.0 million involving free non-cigarette items.

In 2007, the companies reported spending $2.4 million on advertising on company websites;

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[8] As explained in footnote 4, above, the Commission is not reporting the amount spent on general audience public entertainment or on sponsorships.

[9] This category does not include direct mail containing coupons, which are reported separately.

[10] In 2002, the Commission clarified that when coupons are distributed for free cigarettes and no purchase is required to redeem them, such activities should be reported only as "sampling," not as "coupons."

[11] The cigarettes and the bonus items are often packaged together as a single unit.

TABLE 2A

DOMESTIC CIGARETTE ADVERTISING AND PROMOTIONAL EXPENDITURES FOR YEARS 1986 1995 (DOLLARS IN THOUSANDS)*

	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995
Newspapers	$119,629	$95,810	$105,783	$76,993	$71,174	$48,212	$35,467	$36,220	$24,143	$19,122
	5.0%	3.7%	3.2%	2.1%	1.8%	1.0%	0.7%	0.6%	0.5%	0.4%
Magazines	$340,160	$317,748	$355,055	$380,393	$328,143	$278,110	$237,061	$235,253	$251,644	$248,848
	14.3%	12.3%	10.8%	10.5%	8.2%	6.0%	4.5%	3.9%	5.2%	5.1%
Outdoor	$301,822	$269,778	$319,293	$358,583	$375,627	$386,165	$295,657	$231,481	$240,024	$273,664
	12.7%	10.5%	9.7%	9.9%	9.4%	8.3%	5.7%	3.8%	5.0%	5.6%
Transit	$34,725	$35,822	$44,379	$52,294	$60,249	$60,163	$53,293	$39,117	$29,323	$22,543
	1.5%	1.4%	1.4%	1.4%	1.5%	1.3%	1.0%	0.6%	0.6%	0.5%
Point of Sale	$135,541	$153,494	$222,289	$241,809	$303,855	$344,580	$366,036	$400,943	$342,650	$259,035
	5.7%	5.9%	6.8%	6.7%	7.6%	7.4%	7.0%	6.6%	7.1%	5.3%
Promotional Allowances	$630,036	$702,430	$879,703	$999,843	$1,021,427	$1,156,280	$1,514,026	$1,557,635	$1,678,917	$1,865,657
	26.4%	27.2%	26.9%	27.6%	25.6%	24.9%	28.9%	25.8%	34.7%	38.1%
Sampling Distribution	$98,866	$55,020	$74,511	$57,771	$100,893	$56,970	$49,315	$40,202	$6,974	$13,836
	4.1%	2.1%	2.3%	1.6%	2.5%	1.2%	0.9%	0.7%	0.1%	0.3%
Specialty Item Distribution	$210,128	$391,351	$190,003	$262,432	$307,037	$184,348	$339,997	$755,780	$850,810	$665,173
	8.8%	15.2%	5.8%	7.3%	7.7%	4.0%	6.5%	12.5%	17.6%	13.6%
Public Entertainment	$71,439	$71,389	$88,072	$92,120	$125,094	$118,622	$89,739	$84,276	$81,292	$110,669
	3.0%	2.8%	2.7%	2.5%	3.1%	2.6%	1.7%	1.4%	1.7%	2.3%
Direct Mail	$187,057	$187,931	$42,545	$45,498	$51,875	$65,002	$34,345	$31,463	$31,187	$34,618
	7.9%	7.3%	1.3%	1.3%	1.3%	1.4%	0.7%	0.5%	0.7%	0.7%
Endorsements & Testimonials	$384	$376	$781	$0	$0	$0	$0	$0	$0	$0
	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Coupons & Retail Value Added	**	**	$874,127	$959,965	$1,183,798	$1,882,905	$2,175,373	$2,559,387	$1,248,896	$1,348,378
			26.7%	26.5%	29.6%	40.4%	41.6%	42.4%	25.8%	27.5%
Other***	$252,570	$299,355	$78,366	$89,290	$62,917	$68,758	$41,608	$63,680	$47,672	$33,680
	10.0%	11.6%	2.4%	2.5%	1.6%	1.5%	0.8%	1.2%	1.0%	0.7%
Total	$2,382,357	$2,580,504	$3,274,853	$3,616,993	$3,992,008	$4,650,114	$5,231,917	$6,035,437	$4,833,532	$4,895,223
	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

* Because of rounding, sums of percentages may not equal 100 percent.

** Prior to 1987, the Commission did not specifically collect information on Coupons & Retail Value Added.

*** Expenditures for audio visual are included in the "All Others" category to avoid potential disclosure of individual company data.

TABLE 2B

DOMESTIC CIGARETTE ADVERTISING AND PROMOTIONAL EXPENDITURES FOR YEARS 1996 2001 (DOLLARS IN THOUSANDS)*

	1996	1997	1998	1999	2000	2001
Newspapers	$14,067 0.3%	$16,980 0.3%	$29,444 0.4%	$50,952 0.6%	$51,652 0.5%	$31,676 0.3%
Magazines	$243,046 4.8%	$236,950 4.2%	$281,296 4.2%	$377,364 4.6%	$294,916 3.1%	$172,853 1.5%
Outdoor	$292,261 5.7%	$295,334 5.2%	$294,721 4.4%	$53,787 0.7%	$9,262 0.1%	$8,241 0.1%
Transit	$28,865 0.6%	$26,407 0.5%	$40,158 0.6%	$5,573 0.1%	$4 0.0%	$0 0.0%
Point of Sale	$252,619 4.9%	$305,360 5.4%	$290,739 4.3%	$329,429 4.0%	$347,038 3.6%	$284,319 2.5%
Promotional Allowances	$2,150,838 42.1%	$2,438,468 43.1%	$2,878,919 42.8%	$3,542,950 43.0%	$3,913,997 40.8%	$4,452,709 39.7%
Sampling Distribution	$15,945 0.3%	$22,065 0.4%	$14,436 0.2%	$33,711 0.4%	$22,330 0.2%	$17,175 0.2%
Specialty Item Distribution	$544,345 10.7%	$512,602 9.6%	$355,835 5.3%	$335,680 4.1%	$327,826 3.4%	$333,394 3.0%
Public Entertainment	$171,177 3.4%	$195,203 3.4%	$248,536 3.7%	$267,379 3.3%	$309,610 3.2%	$312,366 2.8%
Direct Mail	$38,703 0.8%	$37,310 0.7%	$57,772 0.9%	$94,610 1.2%	$92,902 1.0%	$133,947 1.2%
Endorsements & Testimonials	$0 0.0%	$0 0.0%	$0 0.0%	$0 0.0%	$0 0.0%	$0 0.0%
Coupons	$1,308,708** 25.6%	$552,550 9.8%	$624,199 9.3%	$531,004 6.5%	$705,299 7.4%	$602,110 5.4%
Retail Value Added		$970,363 17.1%	$1,555,391 23.1%	$2,559,883 31.1%	$3,453,446 36.0%	$4,761,792 42.5%
Internet	$432 0.0%	$215 0.0%	$125 0.0%	$651 0.0%	$949 0.0%	$841 0.0%
Other***	$46,696 0.9%	$50,207 1.0%	$61,584 0.9%	$54,658 0.7%	$63,395 0.7%	$104,797 0.9%
Total	$5,107,700 100%	$5,660,014 100%	$6,733,157 100%	$8,237,631 100%	$9,592,627 100%	$11,216,220 100%

* Because of rounding, sums of percentages may not equal 100 percent.
** Prior to 1997, Coupons and Retail Value Added were reported as a single category.
*** Expenditures for audio visual are included in the "All Others" category to avoid potential disclosure of individual company data.