No. 10-5234

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

DISCOUNT TOBACCO CITY & LOTTERY, INC.; LORILLARD TOBACCO COMPANY; NATIONAL TOBACCO COMPANY, L.P.; R.J. REYNOLDS TOBACCO COMPANY; COMMONWEALTH BRANDS, INC.; AMERICAN SNUFF COMPANY, LLC, FKA CONWOOD COMPANY, LLC,
Plaintiffs-Appellants/Cross-Appellees,

v.

UNITED STATES OF AMERICA; UNITED STATES FOOD AND DRUG ADMINISTRATION; MARGARET HAMBURG, COMMISSIONER OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION; KATHLEEN SEBELIUS, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendants-Appellees/Cross-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF KENTUCKY, CASE NO. 1:09-CV-117-M
(HONORABLE JOSEPH H. MCKINLEY, JR., DISTRICT JUDGE)

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CORPORATE DISCLOSURE FORM

Plaintiff Discount Tobacco City & Lottery, Inc. ("Discount Tobacco") is not a subsidiary or affiliate of a publicly owned corporation.

Plaintiff Lorillard Tobacco Company ("Lorillard") is a wholly-owned subsidiary of Lorillard, Inc. Shares of Lorillard, Inc. are public traded.

Plaintiff National Tobacco Company, L.P. ("National Tobacco") is not a subsidiary or affiliate of a publicly owned corporation.

Plaintiff R.J. Reynolds Tobacco Company ("Reynolds") is a wholly-owned, indirect subsidiary of Reynolds American Inc., a publicly held corporation. Brown & Williamson Holdings, Inc. owns more than 10 percent of the stock of Reynolds American Inc. Brown & Williamson Holdings, Inc. is a wholly-owned, indirect subsidiary of British American Tobacco p.l.c. Shares of British American Tobacco p.l.c. are publicly traded.

Plaintiff Commonwealth Brands, Inc. ("Commonwealth") is a wholly-owned subsidiary of CBHC, Inc., which is a wholly-owned subsidiary of Imperial Tobacco Group p.l.c. Shares of Imperial Tobacco Group p.l.c. are publicly traded.

Plaintiff American Snuff Company, LLC, fka Conwood Company, LLC ("American Snuff") is a wholly-owned, indirect subsidiary of Reynolds American Inc., the ownership of which is set forth above.

No other publicly-owned corporation has a financial interest in this appeal.

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STATEMENT IN SUPPORT OF ORAL ARGUMENT

Pursuant to 6th Cir. R. 34(a), Plaintiffs-Appellants/Cross-Appellees ("Plaintiffs") contend that oral argument should be heard in this case because it will significantly aid this Court's decision process. In particular, given the numerous issues of federal constitutional law raised in Plaintiffs' appeal and the Government's cross-appeal, oral argument will assist this Court in identifying and answering the key questions necessary to resolve this case.

STATEMENT OF JURISDICTION

Plaintiffs challenged certain provisions of the Family Smoking Prevention and Tobacco Control Act, Pub. Law No. 111-31, 123 Stat. 1776 (2009) ("Act"), under the First Amendment. R.33 (Amended Complaint) at 35-45. Subject-matter jurisdiction exists under 28 U.S.C. § 1331. On January 14, 2010, the court entered final judgment on all of Plaintiffs' claims, resolving some favorably and others adversely. R.104. Plaintiffs' notice of appeal was timely filed on March 5, 2010. R.106. Appellate jurisdiction exists under 28 U.S.C. § 1291.

STATEMENT OF ISSUES

Whether the district court erroneously granted summary judgment to the Government, and denied it to Plaintiffs, on Plaintiffs' claims that the following provisions of the Act violate the First Amendment:

1) the new mandated warnings on tobacco-product packaging and advertising;

2) the restriction on speech concerning modified risk tobacco products (the "MRTPR");

3) the marketing bans on brand-name sponsorships and merchandise, sample tobacco products, and continuity programs.

STATEMENT OF CASE

The Act is the most sweeping regulation of the speech of a lawful industry in American history and consequently violates the First Amendment in myriad ways. On September 21, 2009, Plaintiffs filed an amended complaint seeking declaratory

and injunctive relief against the marketing restrictions specified above as well as against the Act's bans on color or graphics in tobacco advertising and references to the efficacy of FDA regulation. R.33 at 35-37, 38-41, 42-45.

The district court mostly rejected Plaintiffs' claims. On November 5, 2009, the court, after briefing and a limited evidentiary hearing, denied Plaintiffs' motion for a preliminary injunction on the MRTPR. R.65 at 1. Then, on January 5, 2010, after Plaintiffs' submission of lay and expert testimony by affidavit, R.71-72 (Notices of Filing), and the Government's submission of limited expert testimony by affidavit and public-record materials by exhibit, R.70 (Notice of Filing), the court granted summary judgment for Plaintiffs on the bans on color or graphics in advertising and references to the efficacy of FDA regulation, R.100 (SJ Op.) at 6-15, 34-35, but for the Government on Plaintiffs' other challenges raised here, *id.* at 15-33, 41-42.[1]

The district court fundamentally erred in upholding the provisions of the Act challenged in this appeal. Although the Government defended these provisions based on its interests in ensuring the accuracy of tobacco marketing and reducing youth tobacco use, the record unequivocally demonstrates that neither interest can justify these sweeping speech restrictions. At a minimum, Plaintiffs' evidence on these issues foreclosed the entry of summary judgment for the Government.

[1] On January 14, 2010, the district court granted the Government's unopposed motion to clarify the scope of relief. R.102-04.

STATEMENT OF FACTS

Adults consume more than 98% of all tobacco products sold in this country. R.71-1 (Reynolds Decl.) ¶ 5. Plaintiffs, moreover, must engage in vigorous inter-brand competition to maintain and increase their relative market share among those consumers. *See, e.g.*, R.71-5 (Faber Decl.) ¶¶ 6, 12-14, 26, 30; *see also infra* at 15-16. Even prior to the Act, however, Plaintiffs' ability to engage in such competition through marketing was subject to extensive restrictions. For example, federal law bans all tobacco advertising on radio and television. 15 U.S.C. §§ 1335, 4402(f). Likewise, for decades, all tobacco products and advertisements have carried the ubiquitous Surgeon General's Warning. *Id.* §§ 1333(a), 4402(a). Some (though not all) Plaintiffs are also subject to the Master Settlement Agreement ("MSA") with the states, which imposes numerous other marketing restrictions, including, for example, bans on billboards and marketing that "target[s]" youth. *See* R.71-11 § III. Consequently, even before passage of the Act, Plaintiffs had limited avenues to advertise their products. *See, e.g.*, R.71-10 (Lindsley Aff.) ¶¶ 12-20. The Act effectively closes down Plaintiffs' few remaining avenues for communicating with and competing for existing adult tobacco consumers.

A. New Mandated Warnings

One of the few places the Act permits Plaintiffs to use color or graphics to

communicate with adult tobacco consumers is on tobacco packaging.[2] But under the Act, such packaging is dominated by burdensome new warnings that, in an obtrusive and argumentative manner, reiterate information of which consumers are already well aware.

1. For cigarette packages, the new warnings must occupy the top 50% of the front and back of packaging and include "color graphics depicting the negative health consequences of smoking." Pub. L. No. 111-31, § 201(a) (amending 15 U.S.C. § 1333(a), (d)). For smokeless packages, the new warnings must similarly occupy 30% of the two principal display areas of the package (some of which have only three display areas) and the Secretary may mandate the inclusion of the anti-tobacco graphics. *Id.* §§ 204(a), 205(a) (amending 15 U.S.C. § 4402(a), (d)). The portion of packaging not devoted to the new warnings, moreover, must also include the name and address of the manufacturer, packer, or distributor; a net quantity statement; the percentage of tobacco that is foreign versus domestic; and

[2] The Act elsewhere restricts the use of color or graphics by mandating the re-promulgation of a 1996 FDA regulation requiring that Plaintiffs generally "shall use only black text on a white background" in "any labeling or advertising for cigarettes or smokeless tobacco." 21 U.S.C. § 387a-1(a)(2); 21 C.F.R. § 1140.32(a). Because the district court invalidated this restriction, R.100 (SJ Op.) at 6-15, Plaintiffs will discuss it in greater detail in their response to the Government's cross-appeal. For now, it suffices to note that the district court was correct because the ban, notwithstanding its illusory exceptions, effectively encompasses 100% of direct mail, 99% of magazines, and 99% of retail point-of-sale locations, R.71-8 (Dunham Decl.) ¶¶ 11, 23; R.71-7 (Williard Decl.) ¶ 24, and eviscerates Plaintiffs' ability to effectively communicate with adult tobacco consumers using advertising that captures their attention, *see, e.g.*, R.71-5 (Faber Decl.) ¶¶ 12-17, 30-37; R.71-8 (Dunham Decl.) ¶ 19; R.71-10 (Lindsley Aff.) ¶ 6.

the statement "sale only allowed in the United States." 21 U.S.C. §§ 387c(a)(2), 387t(a)(1). Finally, the new warnings must occupy 20% of all cigarette and smokeless tobacco advertising. Pub. L. No. 111-31 §§ 201(a), 204(a) (amending 15 U.S.C. §§ 1333(b), 4402(b)); *see also id.* § 206 (amending 15 U.S.C. § 1333(e)); 21 U.S.C. § 387c(a)(8)(b)(ii) (authorizing Secretary to require that advertising include tar and nicotine yields and a full description of the product's ingredients).

2. These new warnings are not necessary to address any information deficit on the part of the American public. To the contrary, there is no dispute in the record that "the risks of tobacco ha[ve] been disseminated to and absorbed by an overwhelmingly high percentage of the population." R.71-3 (Viscusi Decl.) ¶¶ 28-29; *see also id.* ¶¶ 59-68. For example, "in a 1998 Gallup poll of youth aged 13-17, 99% of surveyed youth agreed that smoking can cause lung cancer." *Id.* ¶ 29. That is more than "are aware that George Washington was the first U.S. President, [or] that the Earth revolves around the Sun." *Id.* ¶ 20. Likewise, a recent survey "demonstrates overwhelming belief that smokeless tobacco use causes: gum disease (98% agree), tooth loss (97% agree), [and] oral cancer (98% agree)." *Id.* ¶ 67. Indeed, the undisputed record establishes that the public actually *over-estimates* the risks of tobacco use: "[T]he average perceived risk that a smoker will develop lung cancer is over 40%," whereas the "actual risk" is "about

10% of smokers." *Id.* ¶¶ 36-37. Similarly, the public's perception of the overall mortality risk from smoking "can be as much as three times higher" than the actual mortality risk, and, significantly, "young people overestimate the dangers of smoking to an even greater degree" than adults. *Id.* ¶¶ 41-43.

Accordingly, it is no surprise that "[i]ndependent studies have demonstrated that more information about the risks of smoking does not influence smoking rates or consumer behavior." *See id.* ¶¶ 31-34. Even the Surgeon General's 1994 report acknowledges the *inaccuracy* of the "'assumption … [that] young people had a deficit of information that could be addressed by presenting them with health messages in a manner that caught their attention and provided them with sufficient justification not to smoke.'" *Id.* ¶ 34. It specifically notes that "'comprehensive reviews [have] concluded that smoking-prevention programs based on the information deficit approach were not effective.'" *Id.* As Plaintiffs' expert, Dr. Viscusi, further explained, "warnings can only change behavior through the effect on risk beliefs by providing relevant information of which an individual was previously *unaware*." *Id.* ¶ 71. "Warnings that instead attempt to simply browbeat individuals into changing their behavior will not be successful." *Id.* There is, in short, "no evidence that the warnings mandated by the Act will result in a statistically significant reduction in smoking initiation among youth or overall use of tobacco." *Id.* ¶ 5.

3. Although there is little, if any, justification for the new warnings, they substantially burden Plaintiffs' ability to market their products. On cigarette packaging, Plaintiffs' marketing message is relegated to the *bottom half* of the pack, while the new warning, including its color-graphic anti-tobacco images, dominates the top half. Likewise, the warning occupies almost one-third of smokeless packaging. Tobacco products, however, are "typically [kept] several feet behind a sales counter," R.71-8 (Dunham Decl.) ¶ 29, because federal and state laws generally prohibit self-service displays, *see, e.g.*, 21 C.F.R. § 1140.16(c). Consequently, the Act's "relegation of [Plaintiffs'] trademarks and other information to the bottom half" of packaging renders Plaintiffs' speech "illegible, and hence, invisible." R.71-8 (Dunham Decl.) ¶ 29; *see also* R.71-13 (Jones Decl.) ¶ 31.

In addition, "[g]iven the dramatically reduced amount of physical space available" to Plaintiffs on their packaging, "the amount of information [Plaintiffs] are able to include on the[ir] packaging is adversely affected." R.71-8 (Dunham Decl.) ¶ 28; *see also* R.71-14 (Jennette Decl.) ¶ 28. Indeed, the new warnings effectively ban many of Plaintiffs' existing marketing messages. For example, Reynolds' packages for Camel cigarettes can no longer describe how "[a] master-crafted blend of only the finest hand-picked Samsun & Izmir Turkish tobaccos with a robust domestic tobacco blend creates Camel's distinctive flavor and world-

class smoothness." R.71-8 (Dunham Decl.) ¶ 28; *see also* R.71-15 (Terry Decl.) ¶ 29 (describing the displacement of National Tobacco's Stoker family tradition).

Finally, the Act undermines Plaintiffs' ability to market their products through advertising. While the Act limits Plaintiffs' marketing message in their advertising to black-and-white-only text, *see supra* at 4 n.2, the warnings in contrast occupy 20% of all advertisements and for cigarettes must include "shocking color graphics," R.71-10 (Lindsley Aff.) ¶ 70. Consequently, Plaintiffs' "advertisements effectively will be dominated by the mandated warnings," which are "plainly intended to deliver a visually striking, attention-grabbing anti-smoking message [that] drown[s] out any message from the manufacturer of the product." *Id.* ¶¶ 65, 70.

4. In sum, rather than curing an information deficit on the part of consumers, the new warnings are instead designed as a sophisticated Government marketing campaign to stigmatize and embarrass fully informed consumers who disagree with Congress as to whether "the use of tobacco [is] socially acceptable," 21 U.S.C. § 387 note, Findings (17). In other words, the so-called warnings, in substance and effect, convey "no more than [the] generalized anti-tobacco message: 'don't buy this product.'" R.71-3 (Viscusi Decl.) ¶ 68.

B. The MRTPR

The Act, moreover, goes beyond Plaintiffs' packaging and advertising, and

even inhibits Plaintiffs from participating in public-policy debates about their own products. In particular, the MRTPR stifles Plaintiffs' participation in the ongoing debate over the role that reduced-risk tobacco products—*i.e.*, those that pose less health risks than conventional cigarettes—should play in the larger public-health strategy to mitigate the health effects of tobacco use.

1. The public-health community is currently debating whether and to what extent reduced-risk tobacco products should be part of a tobacco harm-reduction strategy. Some participants in this debate, like Plaintiffs, believe that, "while no tobacco product has been shown to be safe[,] some present more risks than others," and so "[p]olicies should encourage [users] of higher-risk products, like cigarettes, who can't or won't quit tobacco use altogether to switch to nicotine products or to [smokeless] tobacco products that present lower risk." *E.g.*, R.71-17, Ex.A (Payne Testimony) at 32:7-34:14 (discussing R.71-17, Ex.D-2 (Reynolds American July 31, 2008, Press Release) at 1). In contrast, others, like the Government, fear that "marketing" products with reduced-risk attributes "might reduce cessation or delay cessation attempts by current cigarette smokers" or cause non-tobacco-users to try a lower-risk product, thus "increasing rather than decreasing the fraction of the population using tobacco products." *E.g.*, R.43-1 (Gov't PI Opp.) at 11-12 (internal quotation marks omitted).

Plaintiffs wish to participate in this debate in different ways. For example,

on November 3, 2009, a producer for the *60 Minutes* CBS news-program contacted Reynolds to inquire whether "a senior executive [could be made] available for an on-air interview on (i) smokeless tobacco and the debate over harm reduction in tobacco control, and (ii) certain Reynolds business activities." R.71-9 (Howard Decl.) ¶ 3. As a direct result of the capacious scope of the MRTPR and the expansive interpretation advanced by the Government in this litigation, discussed further below, Reynolds was forced to decline the offer to participate in the news-program. *Id.* ¶¶ 3-8; *see also* R.71-17, Ex.A (Payne Testimony) at 37:13-21. Plaintiffs also wish to participate in the debate through press releases on regulatory issues, print and electronic media interviews, presentations to scientists and public health groups, and meetings with elected officials. R.71-17, Ex.A (Payne Testimony) at 31:15-35:4, 37:13-21; R.71-17, Ex.B (Swauger Testimony) at 71:11-72:22.

Such publications, and such types of statements about reduced-risk tobacco products, are neither advertisements nor proposals to engage in commercial transactions. Instead, they are part of a public-policy debate in which Plaintiffs, as tobacco manufacturers and retailers, but also as well-informed corporate citizens, wish to be heard. Notably, Plaintiffs' emphasis on the *relative* health risks of smoke-free tobacco and nicotine products for *individual* users is essentially undisputed in the scientific community, R.72-1 (Rodu Decl.) ¶¶ 3-5, 18-37, 53-61;

R.71-17, Ex.B (Swauger Testimony) at 64:10-70:24, 72:23-73:18, and was uncontested by the Government below.

2. The MRTPR prohibits tobacco-product manufacturers from participating in this policy debate. Under the MRTPR, manufacturers are generally free to sell tobacco products that pose reduced health risks relative to cigarettes. But, as demonstrated below, the MRTPR imposes criminal liability upon manufacturers if, and only if, they publicly describe these reduced-risk characteristics without FDA pre-approval, *regardless of whether* their speech is false or misleading.

The Act defines the term "modified risk tobacco product" solely by reference to the manufacturer's speech describing the product. *First*, it includes a tobacco product the "label, labeling, or advertising of which represents explicitly or implicitly that" the product (a) "presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products," (b) "contains a reduced level of a substance or presents a reduced exposure to a substance," or (c) "does not contain or is free of a substance." 21 U.S.C. § 387k(b)(2)(A)(i). *Second*, the definition also includes a tobacco product for which a "manufacturer … has taken *any action* directed to consumers *through the media or otherwise*" that "respect[s] the product" and "would be reasonably expected to result in consumers believing" that any of the three characteristics

above is (or, as to the first characteristic, "may" be) present. *Id.* § 387k(b)(2)(A)(iii) (emphasis added).[3]

The MRTPR thus leaves a manufacturer perfectly free to *sell* a product that has any of the above-listed characteristics. But if the manufacturer truthfully *describes* those characteristics to consumers, the product instantly transforms into a "modified risk tobacco product" and the manufacturer must immediately pull it from the market pending FDA approval. *Id.* § 387k(a), (g). Otherwise, the manufacturer will have committed a crime. *Id.* § 331(a), 333(a), 387b(8).

Finally, the FDA may grant approval "*only* if the Secretary determines that *the applicant has demonstrated* that" a product "will—(A) significantly reduce harm and the risk of tobacco-related disease to *individual* tobacco users; *and* (B) *benefit the health of the population as a whole* taking into account both users of tobacco products and persons who do not currently use tobacco products." *Id.* § 387k(g)(1) (emphases added). Consequently, even if a manufacturer establishes beyond doubt the accuracy of its claim that a product will reduce risk to "individual tobacco users," the FDA is required to deny approval unless the manufacturer *also* proves that the product will "benefit the health of the population as a whole." And in making the latter determination, the FDA is *required* to

[3] The final category of the definition covers a product "the label, labeling, or advertising of which uses the descriptors 'light,' 'mild,' or 'low' or similar descriptors." 21 U.S.C. § 387k(b)(2)(A)(ii). Plaintiffs have not challenged this provision.

consider, not whether the manufacturer's speech is misleading in this respect, but instead whether the product will cause "existing users of tobacco products who would otherwise stop using such products [to] switch to the tobacco product that is the subject of the application" or cause "persons who do not use tobacco products [to] start using the tobacco product" at issue. *Id.* § 387k(g)(4).

3. The MRTPR has already chilled Plaintiffs' speech. Although Plaintiffs do not believe that their participation in this public-health debate is either "directed to consumers" or "respecting [a] product," *id.* § 387k(b)(2)(A)(iii), the Government has steadfastly refused to agree. To the contrary, in this very litigation, the Government has maintained that the MRTPR applies to statements made by Plaintiffs, not just on product "labels" or "advertising," but also in "press releases, reports, booklets, newsletters, television and radio appearances, and scientific symposia and publications," even where the statement does not mention a specific brand but only a generic category of products, such as smokeless tobacco. *See* R.43-1 (Gov't PI Opp.) at 6, 28. Consequently, Reynolds, for example, was forced to decline a request to participate in the *60 Minutes* news-program on tobacco harm reduction. *See supra* at 9-10. The public is thus being deprived of an important viewpoint in this policy debate.

C. The Act's Marketing Bans

In 1996, the FDA promulgated a series of marketing restrictions to reduce

youth tobacco use, which the Supreme Court subsequently invalidated as beyond the FDA's regulatory authority. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125-26 (2000). At the time the regulations were promulgated, the FDA hoped they would cut youth tobacco use by half within seven years. 61 Fed. Reg. 44396, 44423, 44541-42 (1996). Since then, the states, the federal government, and the public-health community have employed a variety of non-speech- and less-speech-restrictive strategies to reduce youth tobacco use and, as a result, such use has dropped by the FDA's target amount and more, notwithstanding the *absence* of the 1996 marketing bans. *See, e.g.*, R.71-1 (Reynolds Decl.) ¶¶ 20, 23, 50-66. Moreover, in a 2007 report, the Institute for Medicine stated that "even if tobacco control activities remain at present levels," smoking "is likely to decline" even further, "from about 21 percent in 2005 to a little less than 16 percent in 2025." *Id.* ¶ 8.

Notwithstanding this powerful evidence that youth tobacco use can be and has been addressed *without* the speech restrictions in the 1996 regulations, the Act mandates that those regulations be re-promulgated virtually verbatim. 21 U.S.C. § 387a-1(a)(2). Thus, the Act imposes the following marketing bans:

- Brand-Name Sponsorships. Plaintiffs are prohibited from brand-name sponsoring any "athletic, musical, artistic, or other social or cultural event"—including events restricted to age-verified adults in adult-only venues. 21 C.F.R. § 1140.34(c). For example, the Act prohibits Lorillard's Newport Pleasure Draw blackjack tournament, which is "restricted to adult smokers" and held in an "adult-only facility"—

within a casino—into which "minors are not allowed to enter." R.71-10 (Lindsley Aff.) ¶¶ 60-63.

- Brand-Name Merchandise. Plaintiffs are prohibited from placing their brand-name on any promotional merchandise—including items given solely to adult consumers in adult-only venues or to Plaintiffs' adult employees. 21 C.F.R. § 1140.34(a). For example, American Snuff is barred from using the Grizzly name or logo on poker chips even though such merchandise is given *solely* to adult tobacco consumers "in connection with a legal purchase." R.71-14 (Jennette Decl.) ¶ 51. Likewise, Reynolds is barred from distributing branded shirts identifying their "employees" "who work in adult only facilities and who engage with adult consumers." R.71-8 (Dunham Decl.) ¶ 37.

- Sampling. Plaintiffs are prohibited from marketing cigarettes through the distribution of free samples, 21 C.F.R. § 1140.16(d)(1), even when done in person to existing age-verified adults customers, *e.g.*, R.71-15 (Terry Decl.) ¶¶ 33-34. Such marketing is also effectively barred for smokeless products, as it is permitted *only* in a "qualified adult-only facility," which is defined so narrowly as to *exclude* facilities that, among other things, sell alcohol or are permanent structures. 21 C.F.R. § 1140.16(d)(2); *see also* R.71-8 (Dunham Decl.) ¶¶ 46-50; R.71-14 (Jennette Decl.) ¶¶ 43-46.

- Continuity Programs. Plaintiffs are prohibited from marketing using continuity programs, 21 C.F.R. § 1140.34(b), pursuant to which existing age-verified adult customers are rewarded for their purchases with non-branded, non-tobacco merchandise, *e.g.*, R.71-10 (Lindsley Aff.) ¶¶ 53-57.

It is undisputed that each of these means of communicating with adult tobacco consumers is of vital importance to Plaintiffs when seeking to convince them to use their brands rather than those of their competitors, particularly given the myriad restrictions on tobacco advertising that already existed before the Act was passed. *See, e.g.*, R.71-14 (Jennette Decl.) ¶¶ 6-10, 33-55; *see also* R.71-5 (Faber Decl.) ¶¶ 6, 12-14, 26, 30, 43-49; R.71-8 (Dunham Decl.) ¶¶ 8-10, 32-50;

R.71-10 (Linsley Aff.) ¶¶ 6-7, 12-20, 53-63, 83-87; R.71-13 (Jones Decl.) ¶¶ 9-12, 33-41; R.71-15 (Terry Decl.) ¶¶ 6-11, 31-48.

SUMMARY OF ARGUMENT

The Act's sweeping speech restrictions block or impede virtually every avenue of communication that Plaintiffs have with their adult customers. In so doing, the Act violates the First Amendment in several ways.

First, even if the new warnings are erroneously treated as purely factual and noncontroversial, they constitute "unjustified [and] unduly burdensome" disclosures under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). Moreover, by forcing Plaintiffs to carry an anti-tobacco message tantamount to "Don't Buy This Product," they are compelled speech subject to strict scrutiny, which they cannot possibly survive. *See Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006).

Second, the MRTPR suffers from numerous constitutional defects, both on its face and as applied to Plaintiffs' speech. As a viewpoint-based restriction on one class of speakers in a political debate, the MRTPR is invalid under strict scrutiny. *See Bd. of Trs. of SUNY v. Fox*, 492 U.S. 469, 473-74 (1989); *R.A.V. v. City of St. Paul*, 505 U.S. 377, 391-96 (1992). Even if (erroneously) treated as a commercial-speech restriction, it violates the strictures of *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). It also is a classic

prior restraint that lacks every one of the procedural and substantive safeguards demanded by the First Amendment. *See Se. Promotions, Ltd. v. Conrad*, 420 U.S. 546, 553, 559-60 (1975).

Finally, the Act's marketing bans—on brand-name sponsorships and merchandise, sampling, and continuity programs—also fail *Central Hudson*. The Government has adduced no meaningful evidence that: (1) these restrictions will "*significantly* reduce" youth tobacco use, *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 506 (1996) (plurality opinion); (2) Congress' goal of reducing such use could not be met by the myriad non-speech- and less-speech-restrictive alternatives championed by the public-health community, *BellSouth Telecomms., Inc. v. Farris*, 542 F.3d 499, 508-09 (6th Cir. 2008); or (3) these across-the-board bans on speech directed *to adults* are reasonably needed to reduce *youth* tobacco use, *Lorillard Tobacco Co. v. Reilly*, 553 U.S. 525, 561-65 (2001).

In sum, Plaintiffs are entitled to summary judgment because the Act tramples their "protected interest in communicating information about [their] products and [their] adult customers['] … interest in receiving that information." *Id.* at 571. At a bare minimum, it was error to grant summary judgment to the Government on this factual record. Even if the Government *could* possibly satisfy its onerous burden of justifying these speech restrictions—which it cannot—the numerous issues addressed below demonstrate at the very least that the

Government has not yet done so.

ARGUMENT

I. STANDARD OF REVIEW

This Court "review[s] the district court's grant of summary judgment de novo." *Westfield Ins. Co. v. Tech Dry, Inc.*, 336 F.3d 503, 506 (6th Cir. 2003). It likewise "review[s] de novo a district court's order denying summary judgment, if the denial is based on purely legal grounds," such as "the ground that [the court] is granting summary judgment to another party." *Id.* "When reviewing cross-motions for summary judgment, [this Court] must evaluate each motion on its own merits and view all facts and inferences in the light most favorable to the nonmoving party." *Id.* "Summary judgment is appropriate if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact." *Id.* (internal quotation marks omitted). Thus, because "the party seeking to uphold a restriction on commercial speech carries the burden of justifying it," *Edenfield v. Fane*, 507 U.S. 761, 770 (1993), the Government must identify a disputed issue of fact on *each* element of the relevant First Amendment tests to avoid summary judgment, and, further, prove the absence of *any* disputed facts to obtain summary judgment.

II. THE NEW WARNINGS VIOLATE THE FIRST AMENDMENT

The Supreme Court's "leading First Amendment precedents have

established the principle that freedom of speech prohibits the government from telling people what they must say." *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 61 (2006); *see also Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 16 (1986) (plurality opinion) ("For corporations as for individuals, the choice to speak includes within it the choice of what not to say."). Although, under current law, there is a limited exception permitting the Government to require factually straightforward commercial disclosures that are "reasonably related to [its] interest in preventing deception of consumers," *Zauderer*, 471 U.S. at 651, the Government must survive strict scrutiny if it instead attempts to convert commercial speakers into its mouthpiece for "a subjective and highly controversial" marketing campaign expressing its disapproval of their lawful products, *Blagojevich*, 469 F.3d at 652.[4]

The new warnings transgress these constitutional limitations. The record unequivocally demonstrates that the scale and intrusiveness of the new warnings far outweighs any legitimate interest in conveying factual information to prevent consumer confusion, particularly since consumers *already overestimate* these health risks. Indeed, the obtrusive new warnings serve only to market Congress'

[4] Indeed, Plaintiffs believe strict scrutiny should govern *all* commercial-speech restrictions, including mandated commercial disclosures. *See Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1342-43 (2010) (Thomas, J., concurring in part and concurring in the judgment). Although Plaintiffs expressly preserve these issues for later review, this brief applies controlling precedent, under which the Act's speech restrictions are also unconstitutional.

subjective belief that tobacco products are socially unacceptable, in essence impermissibly forcing Plaintiffs to disseminate the stigmatizing anti-tobacco campaign slogan: "Don't Buy This Product." Accordingly, Plaintiffs are entitled to summary judgment on this issue and, at a minimum, the factual record forecloses summary judgment for the Government.

A. The New Warnings Unjustifiably And Unduly Burden Plaintiffs' Speech

The Government may mandate commercial disclosures that are "purely factual and uncontroversial," but not if they impose an "unjustified or unduly burdensome" restriction on the speaker. *Zauderer*, 471 U.S. at 651. For example, in *Ibanez v. Fl. Dep't of Bus. & Prof'l Reg.*, 512 U.S. 136 (1994), the Supreme Court invalidated a requirement that accountants who wished to use any type of privately-accredited "specialist" designation also include a disclaimer explaining that the accrediting organization was not governmentally affiliated and setting forth the organization's accreditation requirements. *Id.* at 146. The Court held that the requirement was "unjustified" because the state regulatory board "fail[ed] … to point to any harm that [was] potentially real, not purely hypothetical." *Id.* The Court also held that it was "unduly burdensome" because the detail required "effectively rule[d] out notation of the 'specialist' designation on a business card or letterhead, or in a yellow pages listing." *Id.* at 146-47.

The Seventh Circuit reached a similar result in *Blagojevich*, where it

invalidated a state law requiring video-game retailers to display a four-square-inch sticker stating "18" on video games that fell within the law's definition of "sexually explicit." 469 F.3d at 652. Although the sticker took up only approximately 5% of the front-and-back panels of the game packaging, the court deemed that "a substantial portion of the box." *See id.* at 652 & n.13. It thus held that the sticker "*literally* fail[ed] to be narrowly tailored," because "[t]he State ha[d] failed to even explain why a smaller sticker would not suffice." *Id.* at 652. Indeed, in an analogy of direct relevance here, the court held that it "[c]ertainly … would not condone a health department's requirement that half of the space on a restaurant menu be consumed by the raw shellfish warning," and so it likewise would not "condone the State's unjustified requirement of the four square-inch … sticker." *Id.*

Here, even if treated as "purely factual and uncontroversial" disclosures, the new warnings are unconstitutional under *Zauderer*, *Ibanez*, and *Blagojevich*.

1. Unjustified. The only legitimate justification for radically expanding the warnings on tobacco packaging and advertising would be to redress consumer ignorance about the factual health risks of tobacco use that persists despite the old warnings. *See Zauderer*, 471 U.S. at 651. But the undisputed record below establishes not only that consumers *know* these risks—more people know the risks of tobacco use than "are aware that … the Earth revolves around the Sun"—but

that they *overestimate* them by as much as 400%. *See supra* at 5-6. Given the absence of any information deficit on the topics addressed by the new warnings, the massive expansion of the warnings cannot be justified on informational grounds.

Indeed, Plaintiffs' expert, Dr. Viscusi, attested that the new warnings will not reduce tobacco use. *See supra* at 6. And notably, his conclusion was in part "based on [his] analysis of the impact … of similar warnings on cigarettes in other countries." R.71-3 ¶ 72. He explained how Australia, Canada, and the United Kingdom have utilized similar large-text and/or color-graphic warnings for many years. *Id.* ¶¶ 72-75. Yet, "[d]espite the presence of these large text warnings and/or large text and graphic warnings … in Australia, Canada, and the U.K., there is no evidence that … [they] produced a reduction in smoking among adults or youth in those countries based on analysis of smoking prevalence in each country." *See id.* ¶¶ 76-78. Indeed, in Canada, which uses "nearly identical" warnings to the Act's, R.100 (SJ Op.) at 27, smoking rates sharply *increased* after the warnings went into effect, R.71-3 (Viscusi Decl.) ¶¶ 73, 76-77. Significantly, the Government introduced no evidence that contradicts Dr. Viscusi's analysis of consumer awareness or of the non-effect of other countries' expanded warnings, and the Act contains no congressional findings on these issues.

The district court nevertheless granted summary judgment to the

Government, reasoning that the new warnings were needed "to ensure that the health risk message is actually *seen* by consumers in the first instance," based upon studies and congressional testimony that the old warnings were "given little attention or consideration by viewers." *See* R.100 at 24-28. But as any frequent airline passenger knows, *fully informed* consumers often "give little attention or consideration" to *repetitive* safety warnings. Accordingly, the uncontradicted record below—including the Surgeon General's own 1994 report—establishes that the "'assumption … [that] young people ha[ve] a deficit of information that c[an] be addressed by presenting them with health messages *in a manner that ca[tches] their attention*'" is belied by numerous "'comprehensive reviews [that have] concluded that smoking-prevention programs based on the information deficit approach [are] not effective.'" R.71-3 (Viscusi Decl.) ¶ 34 (emphasis added). Indeed, this is vividly illustrated by the Canadian experience: although the "nearly identical warning requirement in Canada" might have "made [consumers] more likely to think about the health risks of smoking," R.100 (SJ Op.) at 27, adult and youth smoking rates nonetheless sharply *increased* in the wake of the expanded warnings, R.71-3 (Viscusi Decl.) ¶¶ 76-77.

In short, the new warnings are more "unjustified" than the disclosure invalidated in *Ibanez*, as they address an informational deficit that is not even "potentially real" or "purely hypothetical," but non-existent. 512 U.S. at 146.

2. Unduly Burdensome. The new warnings also drown out Plaintiffs' commercial speech by occupying (1) the top 50% of both sides of cigarette packaging, including with color graphics, (2) 30% of the two principal displays of smokeless tobacco packaging, and (3) 20% of all advertisements, including with color graphics for cigarettes, while the Act simultaneously limits Plaintiffs' commercial speech to black-and-white text in virtually all tobacco advertisements. *See supra* at 3-5, 7-8. Collectively, these restrictions ensure that Plaintiffs' speech "will be dominated by the mandated warnings." R.71-10 (Lindsley Aff.) ¶ 70. Indeed, the new warnings are "plainly intended to deliver a visually striking, attention-grabbing anti-smoking message [that] drown[s] out any message from the manufacturer of the product." *Id.* ¶ 65. In addition, the new warnings "effectively rule[] out" many of Plaintiffs' existing packaging conveying substantive information about their products. *Ibanez*, 512 U.S at 146-47; *see supra* at 7-8 (discussing displacement on Camel- and Stoker-brand packaging).

The new warnings are thus far more burdensome than the disclosure invalidated in *Ibanez*, 512 U.S. at 146-47, the "18" label invalidated in *Blagojevich*, which covered just one-twentieth of the video-game package, *see* 469 F.3d at 652 & n.13, or the purely factual "raw shellfish warning" referenced in *Blagojevich*, which would have covered "half of the space on a restaurant menu" and so "[c]ertainly" exceeded anything the Constitution would allow, *see id.* at

652. This burden is, moreover, magnified by the fact that on the other side of the balance is information that, at best, reiterates health risks that consumers not only already know, but in fact overestimate. *See supra* at 5-6. If the new warnings are not an "unduly burdensome" restriction on Plaintiffs' speech, then it is difficult to imagine what types of tobacco-product warnings would be.

The district court's reasoning in upholding the new warnings does not begin to address these deficiencies. The court primarily relied upon the so-called "international consensus reflected in the World Health Organization's Framework Convention on Tobacco Control," and the warnings adopted in Canada. R.100 (SJ Op.) at 26-27. But neither the WHO nor Canada is bound by the First Amendment. As a result, there is no record evidence that the WHO or Canada considered the burden imposed by their warnings, the efficacy of a smaller warning, or "the tobacco industry['s] … protected interest in communicating information about its products [to] adult consumers," *Lorillard*, 533 U.S. at 571. Indeed, it is entirely possible that the WHO simply selected the largest warning that it believed the signatories would accept. And, in Canada, tobacco use sharply *increased* after the expanded warnings went into effect. *See supra* at 22. Consequently, the views of international bodies and foreign governments do not support—and indeed undermine—the district court's conclusion.

Thus, the new warnings cannot be upheld even if treated as "purely factual

and uncontroversial" disclosures under *Zauderer*.

B. The New Warnings Compel Plaintiffs To Disseminate The Government's Anti-Tobacco Message

In any event, the new warnings do not merely disseminate factual information about the risks of tobacco use, but, in reality, force Plaintiffs to market to consumers Congress' belief that tobacco use is socially unacceptable. After all, the factual health information in the so-called warnings has been (more than) successfully disseminated to the public for decades through the familiar Surgeon General's Warnings, other health warnings, and other means. *See supra* at 5-6. Thus, Congress' obtrusive, shocking, and gratuitous defacement of Plaintiffs' packaging and advertising—such as confiscating the *top 50% of both sides of cigarette packages*, including with *color-graphic images* depicting negative consequences of tobacco use—serves no purpose other than "to deliver a visually striking, attention-grabbing anti-smoking message." R.71-10 (Lindsley Aff.) ¶ 65. As Dr. Viscusi attested below, without contradiction, "[g]iven that the new mandated warnings are conveying information that is already well known, it would appear that they are really no more than a generalized anti-tobacco message: 'don't buy this product.'" R.71-3 ¶ 68. The new warnings are, in short, a sophisticated government marketing campaign designed to stigmatize the product and convey Congress' belief that "the use of tobacco" is *not* "socially acceptable," 21 U.S.C. § 387 note, Findings (17).

Even *Zauderer*, however, acknowledged that strict scrutiny applies when the speech compelled is so subjective and controversial. 471 U.S. at 650-51. Accordingly, in *Blagojevich*, the Seventh Circuit applied strict scrutiny when invalidating the requirement that video games display the "18"-sticker, because the sticker required retailers to implicitly "communicate[] [the] subjective and highly controversial message[] that the game's content is sexually explicit." 469 F.3d at 652. Even more so than in *Blagojevich*, the Act's new warnings deliver a "subjective and highly controversial message"—one that is wholly "unlike [the old] surgeon general's warning of the carcinogenic properties of cigarettes." *Id.*

Accordingly, this compelled speech is subject to strict-scrutiny review, under which the new warnings are plainly unconstitutional. The Government is free to wage its own marketing campaign to get citizens to make lifestyle choices the Government prefers, but it has given no reason why it is necessary to force Plaintiffs to do so for it and none exists. *See, e.g.*, *id.* At a minimum, the Government cannot compel Plaintiffs to carry the Government's anti-tobacco message in a manner that unnecessarily compromises Plaintiffs' *own* speech. After all, "[t]he concept that government may restrict the speech of some elements of our society in order to enhance the relative voice of others is wholly foreign to the First Amendment." *Citizens United v. FEC*, 130 S. Ct. 876, 904 (2010).

III. THE MRTPR VIOLATES THE FIRST AMENDMENT

Under the MRTPR, Plaintiffs are free to sell products that pose less health risks than conventional cigarettes, but it is a crime for them to truthfully describe that characteristic to consumers without obtaining FDA pre-approval. *See supra* at 11-13. As a result, Plaintiffs are shut out of the public-policy debate over the role of reduced-risk products in a tobacco harm-reduction strategy. Thus, on its face and as applied to Plaintiffs' speech, the MRTPR is an unconstitutional restriction on political and commercial speech and, in addition, an unconstitutional prior restraint. Accordingly, Plaintiffs are entitled to summary judgment on this issue. At a minimum, summary judgment for the Government was improper.

A. The MRTPR Fails Strict-Scrutiny Review

The MRTPR is subject to, and invalid under, strict scrutiny, regardless of whether it is (correctly) understood to restrict core speech or (erroneously) understood as limited to commercial speech.

1. It is black-letter law that a content-based restriction on a corporation's core political speech is subject to strict scrutiny. *See, e.g.*, *Consol. Edison Co. of NY, Inc. v. Pub. Serv. Comm'n of NY*, 447 U.S. 530, 536, 540 (1980). The MRTPR is such a restriction.

"[T]he difference between commercial and noncommercial speech" is that the former is "define[d]" as "speech that *proposes* a commercial transaction." *Fox*,

492 U.S. at 482; *see also id.* at 473-74. This distinction is crucial because, as the Supreme Court has held, the First Amendment demands that "[a] company ha[ve] the full panoply of protections available to its direct comments on public issues"—*i.e.*, statements *not* "made in the context of commercial transactions." *Zauderer*, 471 U.S. at 637 n.7. "Corporations and other associations, like individuals, contribute to the discussion, debate, and the dissemination of information and ideas that the First Amendment seeks to foster." *Citizens United*, 130 S. Ct. at 900 (internal quotation marks omitted). Indeed, "[o]n certain topics[,] corporations may possess valuable expertise, leaving them the best equipped to point out errors or fallacies in speech of all sorts." *Id.* at 912.

The MRTPR restricts precisely this type of core public-policy speech. On its face, it is not limited to Plaintiffs' speech in their "label[s], labeling, or advertising." In addition, it extends to "*any action* directed to consumers *through the media or otherwise*" that "respect[s] the product" and causes consumers to perceive a prohibited message. 21 U.S.C. § 387k(b)(2)(A)(i), (iii) (emphasis added). Particularly where, as here, the Government has maintained that the MRTPR applies to speech in "press releases, reports, booklets, newsletters, television and radio appearances, and scientific symposia and publications," R.43-1 (Gov't PI Opp.) at 6, 28, the MRTPR inhibits Plaintiffs' participation in the public-health debate concerning tobacco harm reduction, even when that debate

plays out in scientific symposia, regulatory press releases, or news programming such as *60 Minutes*, and even when Plaintiffs limit their speech to discussions of generic product categories like smoke-free tobacco products, *see supra* at 13.

The cases cited by the district court in defense of its conclusion that all such speech is commercial, *see* R.65 (PI Op.) at 11-12, do not remotely support that breathtaking proposition. In *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60 (1983), the Supreme Court held that businesses cannot obtain heightened constitutional protection for speech that *does* propose a commercial transaction by artificially linking the speech to a public debate and then claiming that, combined, it does *more* than propose a commercial transaction. *See id.* at 66-68; *see also Fox*, 492 U.S. at 474-75. Likewise, *Semco, Inc. v. Amcast, Inc.*, 52 F.3d 108 (6th Cir. 1995), involved a magazine article that was "peppered with advertising" of the author-manufacturer's products, which he then "used … as a promotional brochure at trade shows." *See id.* at 111-13. Neither of these cases contradicts the established rule that "commercial speech" must, at a minimum, propose a commercial transaction. In contrast, under the Government's interpretation, the MRTPR regulates speech that indisputably does *not* propose such a transaction.

At a minimum, Plaintiffs' supposedly "commercial speech" is "inextricably intertwined with otherwise fully protected speech" and thus still governed by the "test for fully protected expression." *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*,

487 U.S. 781, 796 (1988); *see also BellSouth*, 542 F.3d at 505. After all, since the public debate is *about* Plaintiffs' products, it would be impossible for them to participate *without* referencing them.

The district court nonetheless held that Plaintiffs' speech, including the chilled *60 Minutes* interview and similar statements made in regulatory press releases or scientific debates, is "commercial" simply because it is made "by economically-motivated tobacco-product manufacturers, … 'directed to consumers' and 'respecting a product." R.65 (PI Op.) at 12. It further claimed that "the fact that it is 'difficult to "delink"' a product from an alleged 'debate' about smokeless tobacco products [does not] seem especially significant." *Id.* But this is not the law. Otherwise, corporations could never engage in public debate about their products, because all such speech would be "directed at consumers" and (unless the corporation was violating its fiduciary duties) "economically-motivated." The Supreme Court, however, has repeatedly admonished that "[s]ome of our most valued forms of fully protected speech are uttered for a profit." *E.g.*, *Fox*, 492 U.S. at 482.

2. Even if (erroneously) treated as a commercial-speech restriction, the MRTPR is still subject to strict scrutiny. Under the MRTPR, government agencies, ideological anti-tobacco organizations, and commercial manufacturers of tobacco-cessation products are all free to publicly denigrate the relative health risks

of Plaintiffs' products. Plaintiffs, however, cannot respond without first receiving FDA pre-approval. 21 U.S.C. § 387k(a), (b), (g). This "license [for] one side of [the] debate to fight freestyle, while requiring the other to follow Marquis of Queensberry rules" is "viewpoint discrimination," *R.A.V.*, 505 U.S. at 391-92, which constitutes "censorship in its purest form," *id.* at 430 (Stevens, J., concurring in the judgment). The MRTPR is thus unconstitutional even if treated as a commercial-speech restriction. *See id.* at 391-96 (majority opinion) (applying strict scrutiny to invalidate viewpoint-based restriction on "fighting words" even though such speech is otherwise categorically *unprotected* under the First Amendment); *Citizens United*, 130 S. Ct. at 898-99 ("Speech restrictions based on the identity of the speaker are all too often simply a means to control content," which is why "the First Amendment stands against … restrictions distinguishing among different speakers, allowing speech by some but not others.").

3. Accordingly, the MRTPR is subject to strict scrutiny. It therefore "may be sustained only if the government can show that the regulation is a precisely drawn means of serving a compelling state interest." *Consol. Edison*, 447 U.S. at 540. The Government cannot possibly meet this standard and, in the court below, it did not even try.

B. The MRTPR Fails *Central Hudson*

In any event, the MRTPR is also unconstitutional under *Central Hudson*'s

"four-part test" governing "the validity of commercial-speech regulations":

> (1) … does the proposed speech concern lawful activity and is it non-misleading? (2) is the governmental interest substantial? (3) does the regulation directly advance the governmental interest? and (4) is the regulation more extensive than necessary to serve that interest?

BellSouth, 542 F.3d at 505.

1. Non-Misleading Speech. The Supreme Court has held that, "where … truthful and nonmisleading expression will be snared along with fraudulent or deceptive commercial speech, the State must satisfy the remainder of the *Central Hudson* test." *Fane*, 507 U.S. at 768-69. The MRTPR plainly ensnares truthful, non-misleading speech, both on its face and as applied to Plaintiffs.

First, and most significantly, even where a manufacturer proves the accuracy of its claim that its product will "significantly reduce harm and the risk of tobacco-related disease to *individual* tobacco users," the FDA is *required* to deny approval unless the manufacturer also proves that the product will "benefit the health of *the population as a whole*." 21 U.S.C. § 387k(g)(1)(A)-(B) (emphases added). The population-wide requirement, moreover, applies even if Plaintiffs' accurate statements about individual health benefits are not potentially misleading with respect to population-wide benefits, and, indeed, even if Plaintiffs' speech *unambiguously disavows* any population-wide health benefit. Thus, on its face, the MRTPR prohibits truthful and non-misleading speech.

Second, the Government appears to take the position that the MRTPR

absolutely bars a manufacturer from truthfully and non-misleadingly claiming that a tobacco product "presents a reduced exposure to," or "is free of," "a substance" for reasons that are *entirely unrelated to health*. *Id.* § 387k(b)(2)(A)(i)(II)-(III), (iii). For example, it argued below that, if a tobacco product is grown without using chemical fertilizers, a manufacturer must seek FDA approval before truthfully informing consumers of that fact—even if such a claim only appeals to consumers who prefer organic products for environmental or other reasons and is *not* perceived by any consumer to convey a health benefit and even if the claim is accompanied by an *FTC-approved disclaimer* of health benefits. *See* R.80-1 (Gov't Memo. in Support of SJ) at 30-31; *see also* R.71-17, Ex.A-1 (Payne Testimony) at 52:21-53:25. Plaintiffs disagree with this position precisely because, if accepted, the FDA could *never* grant approval, since the product was never intended to satisfy the threshold criterion that it "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users." 21 U.S.C. § 387k(g)(1)(A).

Finally, the MRTPR restricts fact-based health claims that are indisputably true (and, for purposes of this litigation, uncontested). One obvious example is the fact that *smokeless* tobacco products do not pose whatever health risks are caused by combustion or secondhand smoke. Although an exception to the MRTPR allows manufacturers to use terms such as "smokeless tobacco" or "smoke-free"

without elaboration, *id.* § 387k(b)(2)(C), that exception does *not* permit manufacturers to explain the relative health significance of that characteristic even when, as here, it is entirely indisputable and non-misleading. *See supra* at 10-11.

2. Directly and Materially Advance. "[T]he directly advance prong seeks to ferret out whether a law ostensibly premised on legitimate public policy objectives in truth serves those objectives." *BellSouth*, 542 F.3d at 507. Courts may not "turn away if it appears that the stated interests are not the actual interests served by the restriction," lest the Government "with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression." *Fane*, 507 U.S. at 768, 771. Here, although the Act invokes an interest in preventing Plaintiffs from making misleading statements about relative health risks, *see* 21 U.S.C. § 387 note, Findings (40), "evaluated in the context of the entire regulatory scheme," it is clear that the MRTPR does not "advance[] th[at] interest[] in a direct and material way," *Fane*, 507 U.S. at 767.

The MRTPR does not even attempt to limit its scope to speech that is "potentially misleading." *Ibanez*, 512 U.S. at 146. Instead, on its face, the MRTPR is intended to prevent consumers from receiving truthful and non-misleading information about the relative health risks that different types of tobacco products pose to individual users, because the Government fears that, if given such information, consumers will use that information to make "bad"

decisions. Indeed, Congress enshrined this purpose in the MRTPR's operative text. As described above, even where it is undisputed that a manufacturer is accurately claiming that its product "significantly reduce[s] harm … to *individual* tobacco users," the FDA is *prohibited* from approving the product if it does not *also* "benefit the health of *the population as a whole*." 21 U.S.C. § 387k(g)(1)(A)-(B) (emphases added). And in making this latter determination, the MRTPR *requires* the FDA to consider, not whether the speech is misleading, but whether, if given truthful and non-misleading information about relative risks to individual users, (1) "existing users of tobacco products" will decide "to switch to the" lower-risk product rather than "stop using [tobacco] products" altogether, and (2) non-tobacco users "will start using the [lower-risk] tobacco product." *Id.* § 387k(g)(4).

Consequently, the statute, on its face, makes clear that the purpose of the MRTPR is to "protect" consumers from truthful and non-misleading information out of fear that they will "misuse" it. The Supreme Court, however, has repeatedly "rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002). Indeed, the wisdom of the First Amendment's ban on such paternalistic laws is especially apparent where, as here, the Government's suppression of information keeps in the dark the "approximately

24 million adult smokers" who have "been unable or unwilling to quit" but who could potentially migrate to a relatively less harmful product. *See* R.72-1 (Rodu Decl.) ¶¶ 39-41. Accordingly, the MRTPR fails *Central Hudson*'s "directly and materially advance" prong.

3. Narrow Tailoring. Unsurprisingly, the MRTPR also is not narrowly tailored to achieve any interest in preventing misleading speech. There are two components to *Central Hudson*'s narrow-tailoring requirement, both of which the MRTPR fails.

First, narrow tailoring requires Congress to "distinguish[] the truthful from the false, the helpful from the misleading, and the harmless from the harmful." *Zauderer*, 471 U.S. at 646. Thus, to "guard[] against over-inclusive laws," *BellSouth*, 542 F.3d at 508, Congress must "carefully calculate the costs and benefits associated with the burden on speech imposed," *Lorillard*, 533 U.S. at 561. In *Lorillard*, the Supreme Court facially invalidated Massachusetts' outdoor-advertising regulations because they "ma[de] no distinction among practices on th[e] basis" of the state's interest in reducing youth smoking and thus were "unduly broad." *Id.* at 563. Likewise, in *Thompson*, the Court facially invalidated a federal law that restricted a sizeable "amount of beneficial speech" that did "not appear to directly further any asserted governmental objective." 535 U.S. at 376-77. Here too, the MRTPR is dramatically overinclusive, proscribing vast amounts of

indisputably truthful and non-misleading speech for no valid reason. *See supra* at 33-35.

Second, this Court also must consider whether "there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech." *BellSouth*, 542 F.3d at 509. The Supreme Court's "cases … have made clear" that "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*, 535 U.S. at 371. Thus, in *Thompson*, the Court invalidated a federal law restricting speech because "[s]everal non-speech-related means of drawing [the] line [Congress intended] might [have] be[en] possible," yet the Government had failed to explain "why these possibilities, alone or in combination, would be insufficient." *Id.* at 372-73.

Likewise, in *BellSouth*, this Court invalidated a state-law speech restriction designed to prevent consumer confusion because the state ignored a "full arsenal of options short of restricting speech," including "enforc[ing] existing state law" prohibitions on false and misleading trade practices, "rely[ing] on enforcement of federal regulations already on the books," "requir[ing] a disclaimer," and "add[ing] an award of costs and fees to litigants who successfully challeng[ed] a misleading" statement. 542 F.3d at 508-09. As this Court explained, "[b]efore a government may resort to suppressing speech to address a policy problem, it must show that

regulating conduct has not done the trick or that as a matter of common sense it could not do the trick." *Id.* at 508.

Here too, Congress eschewed a "full arsenal of options short of restricting speech," *id.*, including:

Consumer Disclaimers: The Supreme Court has "repeatedly point[ed] to disclaimers as constitutionally preferable to outright suppression." *Pearson v. Shalala*, 164 F.3d 650, 657 (D.C. Cir. 1999); *see also BellSouth*, 542 F.3d at 508-09. Although the Act contains unadorned findings that in some unspecified context the FTC determined that disclaimers were inadequate, 21 U.S.C. § 387 note, Findings (41)-(43), such a "conclusory assertion" by Congress that it needs to "choos[e] suppression over disclosure as a response to the problem of consumer confusion … falls far short" of what the Constitution demands, *Pearson*, 164 F.3d at 659. In any event, the Act's findings are belied by the fact that the FTC *approved* a disclaimer for a "no-additive" tobacco product stating that "No additives in our tobacco does **NOT** mean safer." FTC Consent Order, No. C-3952 (June 12, 2000), *available at* http://www.ftc.gov/os/2000/06/santafe.do.htm (last visited May 27, 2010); R.71-17, Ex.A (Payne Testimony) at 53:22-25.

FDA Disclosures: Instead of imposing a prior restraint on "advertising" and other forms of *non-label* speech—including the vague coverage of "any action directed to consumers through the media or otherwise … respecting the product,"

21 U.S.C. § 387k(b)(2)(A)(iii)—Congress could have limited its non-label speech restrictions to *commercial advertisements* and, for those advertisements, *only* "require[d] [manufacturers] to file … with [the FDA]" any such advertisements post-dissemination, along with any relevant scientific information in their possession, thus "giving the [FDA] ample opportunity to supervise [the advertisements] and penalize actual abuses." *Shapero v. Ky. Bar Ass'n*, 486 U.S. 466, 476 (1988). Notably, that is the regulatory regime governing prescription-drug advertising. 21 U.S.C. § 352(n) (generally banning "prior approval by the Secretary of the content of any advertisement"); 21 C.F.R. § 314.81(b)(3)(i) (requiring submission to the FDA of advertisement "at the time of initial publication"). The Government embraced that regime as the general model on which the MRTPR was based, yet provided no explanation for departing from this specific less-speech-restrictive aspect. *See* R.43-1 (Gov't PI Opp.) at 15.

Improved Enforcement of Fraud Laws: The FTC could more vigorously enforce laws against false or misleading statements. And Congress could have increased the penalties for laws proscribing false or misleading speech. *BellSouth*, 542 F.3d at 508-09. Although the district court pointed to the alleged past failure of the fraud laws to deter the tobacco industry, *see* R.65 (PI Op.) at 18, those allegations are not responsive to whether more vigorous enforcement and/or strengthened fraud laws would be effective.

Public Advertising Campaign: Congress could have sponsored public advertising campaigns about smokeless tobacco products, emphasizing that, regardless of whether such products are safer than cigarettes, consumers are still better off not using tobacco products at all.

Some Combination Of The Above: Congress bears the burden of proving "why these possibilities, alone or in combination, would be insufficient." *Thompson*, 545 U.S. at 373. But the Government put forth no evidence why any of these alternatives alone would not suffice, and therefore cannot possibly demonstrate that they would be ineffective when combined.

In sum, the MRTPR is "precisely the kind of blunderbuss legislation that cannot satisfy the First Amendment's preference for resolving policy problems by regulating conduct rather than speech." *BellSouth*, 542 F.3d at 509.

C. The MRTPR Is An Unconstitutional Prior Restraint

A "prior restraint" exists "whe[re] the exercise of First Amendment rights depends on the prior approval of public officials." *Deja Vu of Nashville, Inc. v. Metro. Gov't of Nashville & Davidson County*, 274 F.3d 377, 400 (6th Cir. 2001). As the district court recognized, the MRTPR is a prior restraint because it "holds [Plaintiffs'] speech captive until the FDA completes its review." R.100 (SJ Op.) at 30 (internal quotation marks omitted). Indeed, the Act itself explicitly acknowledges that "[n]o 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." 21 U.S.C. § 387c(b) (emphasis added).

A prior restraint, however, is "the most serious and the least tolerable infringement on First Amendment rights," *Neb. Press Ass'n v. Stuart*, 427 U.S. 539, 559 (1976), because "a free society prefers to punish the few who abuse rights of speech after they break the law than to throttle them and all others beforehand," *Se. Promotions*, 420 U.S. at 559. Accordingly, a prior restraint bears "a heavy presumption against its constitutional validity," *Bantam Books, Inc. v. Sullivan*, 372 U.S. 58, 70 (1963), and is constitutional only if it contains rigorous procedural and substantive protections specifically designed to prevent government abuse, *see Se. Promotions*, 420 U.S. at 553, 559-60. Here, the MRTPR lacks every one of these constitutionally-mandated safeguards.

1. The MRTPR Lacks the Necessary Procedural Safeguards

"The settled rule is that a system of prior restraint avoids constitutional infirmity only if it takes place under procedural safeguards designed to obviate the dangers of a censorship system." *Id.* at 559 (internal quotation marks omitted). The MRTPR, however, lacks *all three* of the constitutionally-mandated procedural safeguards.

a. Burden of Proof. For any valid prior restraint, "the burden of …

proving that the material is unprotected[] must rest on the censor." *Id.* at 560. The MRTPR, however, improperly flips that burden, requiring "the applicant … [to] demonstrat[e]" that approval should be granted. 21 U.S.C. § 387k(g)(1).

The district court held that it could discard the burden-of-proof requirement under *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215 (1990). R.100 (SJ Op.) at 31-32. But that is plainly wrong. In *FW/PBS*, a plurality of the Supreme Court held that the burden-of-proof requirement does not apply to certain prior restraints involving the licensing of adult-entertainment businesses. *See* 493 U.S. at 228-30. That holding, however, was expressly predicated on the fact that the licensing scheme at issue did not require the city to "exercise discretion by passing judgment on the content of any protected speech," but rather, involved "a ministerial" "review[] [of] the general qualifications of each license applicant." *See id.* at 229; *see also City of Littleton v. Z.J. Gifts D-4, L.L.C.*, 541 U.S. 774, 783-84 (2004). Here, far from being "ministerial," the FDA's approval process is highly subjective and content-based, requiring the FDA to determine, among other things, whether the product, if truthfully described, will "benefit the health of the population as a whole." 21 U.S.C. § 387k(g)(1), (4).

b. Prompt Administrative Decision. "[A]ny restraint prior to judicial review can be imposed only for a specified brief period." *Se. Promotions*, 420 U.S. at 560. The MRTPR, however, contains no "specified brief period" at all.

Rather, it grants the Secretary "2 years" before she must even "issue regulations or guidance" that will *then* "establish a reasonable timetable for [her] to review an application." 21 U.S.C. § 387k(*l*)(1), (*l*)(1)(F). This is patently unconstitutional. *See, e.g.*, *Riley*, 487 U.S. at 802.

Although the district court agreed at the preliminary-injunction stage that it was "likely that this two-year delay is unconstitutional," R.65 at 23, 26-27, it reversed course on summary judgment and held that "the reasonable time limit" requirement was satisfied by "a provision in the Administrative Procedure Act" that "impose[d] a general but nondiscretionary duty upon an administrative agency to pass upon a matter presented to it 'within a reasonable time,'" R.100 at 31 (quoting 5 U.S.C. § 555(b)). The Supreme Court's jurisprudence, however, demands a "*specified* brief period," *Se. Promotions*, 420 U.S. at 560 (emphasis added), and a general requirement that an agency act "within a reasonable time" cannot possibly suffice. Indeed, the district court's unprecedented holding is irreconcilable with *Nutritional Health Alliance v. Shalala*, 144 F.3d 220 (2d Cir. 1998), which found that "the absence of a final deadline [for a restraint on dietary-supplement labeling]… would not pass constitutional muster," notwithstanding the fact that the APA applied to the FDA in that case no less so than here. *Id.* at 228.[5]

[5] Although the FDA has issued "Draft Guidance" proposing a 360-day review period for MRTPR applications, the district court correctly held that does not satisfy the "specified brief period" requirement because it is neither final nor binding. R. 100 (SJ Op.) at 30-31. In any event, even a binding 360-day review

c. Prompt Judicial Decision. Regardless of the length of time required for *agency* decisionmaking, "a prompt final judicial determination must be assured." *Se. Promotions*, 420 U.S. at 560. And, once again, while that requirement may be relaxed for "objective" schemes that "do[] not seek to censor content," the type of "subjective standards" at issue in the MRTPR "necessitate … that strict time limits be placed on judicial review." *729, Inc. v. Kenton County Fiscal Ct.*, 515 F.3d 485, 495 (6th Cir. 2008). The Act's judicial review provision, however, conspicuously neglects to reference the MRTPR *at all*. 21 U.S.C. § 387*l*.

2. The MRTPR Lacks the Requisite Substantive Safeguards

"[A] law subjecting the exercise of First Amendment freedoms to the prior restraint of a license, without narrow, objective, and definite standards to guide the licensing authority, is unconstitutional." *Se. Promotions*, 420 U.S. at 553. Such "neutral criteria … insure that the licensing decision is not based on the content or viewpoint of the speech being considered." *City of Lakewood v. Plain Dealer Publ'g Co.*, 486 U.S. 750, 760 (1988).

Here, the MRTPR is facially viewpoint-discriminatory, *see supra* at 31-32, and thus invalid. *See Forsyth County v. Nationalist Movement*, 505 U.S. 123, 133-34 (1992) (invalidating a licensing scheme that allowed the state to "encourag[e]

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period would be far too protracted to satisfy the requirement that the "specified … period" be "brief." *See, e.g., Teitel Film Corp. v. Cusack*, 390 U.S. 139, 141-42 (1968) (*per curiam*) (invalidating a *57-day* period for reviewing films).

some views and discourag[e] others" and determine fees "based on the content of the speech"). Moreover, even were the MRTPR (improperly) deemed viewpoint-neutral on its face, its standards are unconstitutionally subjective for at least three independent reasons.

First, the FDA must deny an MRTPR application unless Plaintiffs convince it that their products will "benefit the health of the population as a whole." 21 U.S.C. § 387k(g)(1). This amorphous standard plainly gives the FDA cover to make licensing decisions based on the content and viewpoint of Plaintiffs' speech and is materially indistinguishable from "public health" standards that have been held unconstitutionally subjective for that reason. *E.g.*, *Desert Outdoor Adver., Inc. v. City of Moreno Valley*, 103 F.3d 814, 818 (9th Cir. 1996) ("harmful effect upon the health or welfare of the general public" standard impermissibly gave licensors "discretion to deny a permit on the basis of ambiguous and subjective reasons"); *see also Plain Dealer Publ'g*, 486 U.S. at 669 ("not in the public interest").

Although the district court acknowledged that "Plaintiffs might well be right," "[i]f the 'benefit to the population as a whole' standard was undefined," it believed that the factors set out in 21 U.S.C. § 387k(g)(4) cured the defect. R.65 (PI Op.) at 21-22. But, if anything, those factors exacerbate the problem because, rather than focusing on whether Plaintiffs' speech is misleading, they *require* the

Secretary to consider the unconstitutionally paternalistic question whether consumers will use truthful information to make "bad" decisions. *See supra* at 35-37. In any event, these factors are just as subjective as the "health of the population as a whole" standard; they do not tell the Secretary how to balance the factors when they point in different directions; and they do not even purport to be exhaustive. Thus, they cannot possibly constitutionally cabin the overly broad discretion the statute affords the Secretary.

Second, the MRTPR is triggered, not just by Plaintiffs' speech on a "tobacco product's label, labeling, or advertising," but when Plaintiffs take "any action directed to consumers through the media or otherwise." 21 U.S.C. § 387k(b)(2)(A)(iii). To the extent the Government maintains its position that this provision encompasses Plaintiffs' speech in news programming, scientific presentations, and legislative lobbying, it is an unconstitutional restriction on core political speech. *See supra* at 28-31. And to the extent the Secretary belatedly tries to narrow the scope of the provision, she possesses an unconstitutional amount of subjective discretion in decreeing when Plaintiffs' speech is *not* "directed to consumers" and thus safe from the FDA's censorship. Either way, the provision is unconstitutional.

Third, the MRTPR restricts consumer-directed speech that the FDA deems to be "reasonably expected to result in consumers believing that the tobacco

product … *may* present a lower risk of disease." 21 U.S.C. § 387k(b)(2)(A)(iii) (emphasis added). Thus, the FDA need not conclude that speech will cause a third-party to believe a lower risk definitely exists, or even that it is more likely than not to cause a third-party to so believe, but only that the speech is reasonably likely to cause a third-party to believe a product *might* present a reduced risk. In *Union Food & Commercial Workers Union v. Sw. Ohio Reg'l Transit Auth.*, 163 F.3d 341 (6th Cir. 1998) ("*SORTA*"), this Court invalidated a materially indistinguishable law that permitted a municipal transit authority to "reject[] … controversial ads" if such ads "merely '*may*' affect [its] ridership." *Id.* at 360 (emphasis added).

D. The MRTPR Is Not a Restriction on Conduct Exempt From The First Amendment

The district court also cryptically concluded, contrary to its preliminary-injunction opinion, *see* R.65 at 10-11, that the MRTPR, at least in part, does not implicate the First Amendment. *See* R.100 (SJ Op.) at 29-30. The court's holding was predicated on the Government's argument that the MRTPR regulates conduct—the unapproved sale of "modified risk tobacco products"—and that, under *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004), Plaintiffs' speech is simply used as evidence of "intent" to sell that prohibited product, no different than using speech to prove illicit motive in hate-crimes cases. *See* R.43-1 (Gov't PI Opp.) at 18-21. The court's limited adoption of the Government's "conduct"

argument is erroneous.

Here, speech is not used as "evidence" of Plaintiffs' "intent" to sell a "modified risk tobacco product." Instead, Plaintiffs' speech is what *defines* whether their tobacco products are "modified risk tobacco products" subject to the MRTPR, *regardless of Plaintiffs' intent*. In particular, a tobacco product *is* a "modified risk tobacco product" *if, and only if*, Plaintiffs convey certain prohibited messages (a) in the product's "label, labeling, or advertising," or (b) through "any action directed to consumers through the media or otherwise." 21 U.S.C. § 387k(b)(2)(A)(i), (iii). Lest there be any doubt, the MRTPR unambiguously declares that "[n]o tobacco product shall be considered" covered "except as described in [§ 387k(b)(2)(A)]," *id.* § 387k(b)(2)(B), which, as just discussed, makes Plaintiffs' speech the *sole basis* for triggering MRTPR review.

Thus, "intent" is irrelevant under the MRTPR. On the one hand, Plaintiffs could send a confidential letter to the FDA *admitting* that they were selling smokeless tobacco products *with the intent* that consumers with independent knowledge would migrate to those products to reduce the risk of tobacco-related harm, and those products *still* would not be "modified risk tobacco products" *unless* Plaintiffs publicly uttered one of the proscribed messages. On the other hand, the MRTPR applies to speech that "represents … implicitly," or "would be reasonably expected to result in consumers believing," that a product "may" have

relative health benefits, *id.* § 387k(b)(2)(A)(i), (iii), *even if* Plaintiffs did *not* intend their products to be used for a health-related purpose.

This case is therefore squarely controlled by the Supreme Court's decision in *Thompson*. There, the question was whether a "compounded drug"—*i.e.*, a "medication tailored to the needs of an individual patient" by "combin[ing], mix[ing], or alter[ing] ingredients"—was a "new drug" that required FDA pre-sale-approval. *See* 535 U.S. at 360-65. Under the statute at issue, pharmacists were permitted to *sell* compounded drugs without pre-approval as a new drug. *Id.* at 364-65. If, however, they *advertised* that they sold any particular compounded drug, that otherwise-authorized "compounded drug" then became a "new drug" that was subject to the "new drug" pre-sale-approval requirement. *Id.* In short, "advertising [was] the trigger for requiring FDA approval." *Id.* at 370. Consequently, notwithstanding the Government's claim that advertising was merely a "fair proxy" for inferring that Congress wanted to treat the compounded drug as a "new drug," *id.* at 370-71, the Supreme Court held that the law was a *speech* restriction and then promptly invalidated it under the First Amendment, *id.* at 368-77. Since *Thompson*, courts and commentators have uniformly "rejected" the Government's reliance on "*Whitaker* and similar cases" as well as "the notion that promotion of an approved drug [for unapproved uses] is conduct, as opposed to speech within the ambit of the First Amendment." *See* R.65 (PI Op.) at 9-10

(citing authorities). Yet the district court did not even attempt to distinguish *Thompson*. R.100 (SJ Op.) at 28-30.

Even apart from *Thompson*, the analogy to *Whitaker* and the pre-approval requirement for "new drugs" is inapposite. The pre-approval requirement at issue in *Whitaker* turned on the "intended … use" of a product. *See* 353 U.S. at 949 (quoting 21 U.S.C. § 321(g)(1)(B)). The statute banned the *conduct* of selling a product that a manufacturer "intended" to be used for certain disease-related purposes, and the FDA used the manufacturer's speech as one factor among many to divine that "intended use." *See id.* at 952-53. Indeed, the FDA's regulations in that context make clear that "intent is determined," not just "by [the manufacturer's] expressions," but by *all* "the circumstances surrounding the distribution of the article." 21 C.F.R. § 201.128. In *Whitaker*, then, the court held that the FDA could consider the manufacturer's statements "as evidence of the sellers' intent that consumers will purchase and use the product for a particular purpose." 353 U.S. at 953.

Here, in contrast, Plaintiffs' speech is not "evidence" of Plaintiffs' "intent." Rather, it is the *sole* determinant of whether a tobacco product is subject to MRTPR review. To repeat, Plaintiffs are free to sell a product that poses less health risk than conventional cigarettes, *even if they indisputably intend consumers to use it to reduce tobacco-related health risks.* But if, and only if, they also

describe that health characteristic publicly, they will have committed a crime, even if their speech is non-misleading. If that is not a restriction on speech, nothing is.

IV. THE ACT'S MARKETING BANS VIOLATE THE FIRST AMENDMENT

Finally, Plaintiffs are entitled to summary judgment on the bans on brand-name sponsorships and merchandise, sampling, and continuity programs, because they are unconstitutional restrictions on commercial speech under *Central Hudson*. At a minimum, Plaintiffs' evidentiary showing forecloses summary judgment for the Government.

A. The Marketing Bans Fail *Central Hudson*

The *Central Hudson* standard is described at length above. *See supra* at 33, 35, 37-39. Here, the Act's marketing bans each violate *Central Hudson*'s third and fourth prongs.

1. Directly and Materially Advance. The Government did not prove that the marketing bans will "advance[]" the Government's interest in reducing youth tobacco use "in a direct and material way." *Fane*, 507 U.S. at 767. In *44 Liquormart*, the Supreme Court invalidated a ban on referencing prices in liquor advertising that was purportedly designed to reduce alcohol consumption. 517 U.S. at 492-93, 516. The plurality acknowledged that "the record suggests that the price advertising ban may have some impact on the purchasing patterns of temperate drinkers of modest means," but emphasized that "the State has presented

no evidence to suggest that its speech prohibition will *significantly* reduce marketwide consumption." *Id.* at 506. Therefore, "any conclusion that elimination of the ban would significantly increase alcohol consumption would require … the sort of 'speculation or conjecture' that is an unacceptable means of demonstrating that a restriction on commercial speech directly advances the State's asserted interest." *Id*. at 507.

Here, there is no evidence that the marketing bans will "directly" advance the Government's interest in decreasing youth tobacco use, since even the Surgeon General's 1994 Report concludes that advertising is only a "distal or *indirect*" factor among dozens of risk factors for youth tobacco use. R.71-1 (Reynolds Decl.) ¶ 31 (emphasis added). In any event, the Government did not even come close to showing the bans will "materially" reduce youth tobacco use. Actions undertaken since 1996 have already resulted in the same reductions in youth tobacco use that the FDA hoped would have resulted had the 1996 regulations taken effect. *See supra* at 13-14. And the Government put forth *no* evidence that the Act's marketing bans will cause a *further* "*significant*[]" reduction in youth tobacco use. *44 Liquormart*, 517 U.S. at 506 (plurality opinion). Indeed, the district court's opinion contains no discussion at all of the magnitude by which it believed youth tobacco use would be further reduced as a result of these marketing bans. In contrast, Plaintiffs' experts explained that, because these bans do not

address the root causes of youth tobacco use (*e.g.*, peer pressure, youthful rebellion, risk-seeking personalities), the Act's speech restrictions likely will *not* "reduce underage tobacco use in a meaningful way." R.71-1 (Reynolds Decl.) ¶50; *see also id.* ¶¶ 5-8, 19-49; R.71-5 (Faber Decl.) ¶ 5, 57-64.

2. Narrow Tailoring. The Government also failed to prove that the marketing bans satisfy either component of *Central Hudson*'s narrow-tailoring requirement.

First, the Act's marketing bans are drastically "over-inclusive," *BellSouth*, 542 F.3d at 508, casting an "unduly broad" net that sweeps in vital speech to Plaintiffs' adult tobacco customers, *Lorillard*, 533 U.S. at 563-65. Without any regard for the critical role played by such marketing in inter-brand competition for adult consumers, the Act bans: *all* brand-name sponsorships and merchandise, including at private events held in adult-only venues; *virtually all* marketing through the distribution of product samples, including in bars and nightclubs that prohibit entry by youth; and *all* continuity programs, including those limited to age-verified adult tobacco users. *See supra* at 14-16. In short, these bans fail to "distinguish[] the truthful from the false, the helpful from the misleading, and the harmless from the harmful." *Zauderer*, 471 U.S. at 646.

Despite the breadth of these bans, the district court held they were a reasonable means of ensuring that youth were never exposed to the prohibited

advertising. *See* R.100 (SJ Op.) at 16-18, 19-20, 41-43. But that is no justification at all. Plaintiffs use such marketing to legitimately compete for the *adults* who consume over *98%* of all tobacco products, R.71-1 (Reynolds Decl.) ¶ 5, and the Supreme Court has repeatedly admonished that "[t]he level of discourse reaching a mailbox simply cannot be limited to that which would be suitable for a sandbox," as that would "reduce the adult population … to reading only what is fit for children," *Lorillard*, 533 U.S. at 564. At a minimum, more tailored solutions were available to address the court's youth-spill-over concerns, such as restricting media coverage of brand-name-sponsored events or limiting the brand-name merchandise ban to the types of items that can become "walking advertisements" (*e.g.*, caps and t-shirts, but not matchbooks or key chains), R.100 (SJ Op.) at 18-19. For example, the across-the-board bans encompass even Lorillard's Newport Pleasure Draw blackjack tournament in a youth-restricted casino, for which there is *no evidence whatsoever* of *any* media coverage, *see* R.71-10 (Lindsley Aff.) ¶¶ 60-63, thereby demonstrating both the bans' facial lack of tailoring as well as their unconstitutionality as applied to Lorillard's event. The district court's *unfounded speculation* that there is media coverage of Lorillard's blackjack tournament, *see* R.100 (SJ Op.) at 18 n.4, is plainly insufficient to satisfy *the Government's burden* of proving that the sponsorship ban is narrowly tailored in this respect, *Fane*, 507 U.S. at 770.

Second, the Government put forth no evidence why its interest in reducing youth tobacco use could not be served by myriad non-speech-restrictive alternatives (alone or in combination), *Thompson*, 535 U.S. at 371-73, including the dozens that were described in detail by Plaintiffs' expert, such as:

Reducing Illegal Retail Sales: Preventing unlawful sales of tobacco products to youth has, unsurprisingly, proven to be an effective means of reducing youth tobacco use, and the federal Synar Amendment, which requires states to enact and enforce laws prohibiting such sales and to achieve a retail violation rate of less than 20%, has proved extraordinarily effective. R.71-1 (Reynolds Decl.) ¶¶ 52, 61. Congress was specifically urged to "'strengthen[] the Synar Amendment" rather than "impos[e] clearly unconstitutional restrictions of First Amendment rights.'" H.R. Rep. No. 111-58 at 130 (Mar. 26, 2009) (dissenting views).

Improving The States' Use of MSA Funds: The MSA provides billions of dollars to the states annually, which are intended for tobacco-related programs or costs but are instead spent by the states on unrelated issues. The Government's own agencies and *amici* below believe that requiring the states to increase the allocation of MSA funds earmarked to youth tobacco prevention—from the meager 3.5% recently employed to the still-modest CDC-recommended 15%—would be effective in reducing youth tobacco use. R.71-1 (Reynolds Decl.) ¶¶ 54-

60. Once again, members of Congress implored that such an approach would "protect[] our children … while protecting our Constitution." 155 Cong. Rec. H4310, H4312 (Apr. 1, 2009).

Comprehensive Programs Targeting Youth Risk Factors: There are dozens of non-speech-restrictive strategies that the Government's own agencies and the public-health community believe would reduce youth tobacco use, because they address the social factors that directly influence such use: *e.g.*, raising the legal age of purchase to 19 years-old, which would remove legal-age tobacco users from high schools; penalizing youth use by suspending offenders' drivers' licenses; public advertising campaigns; and social-influence-focused interventions. *See* R.71-1 (Reynolds Decl.) ¶¶ 28-30, 50-66.

As Plaintiffs' expert attested without contradiction, the existing (and thus far limited) deployment of these strategies has already proven as effective at reducing youth tobacco use as the FDA hoped its untested marketing restrictions would be in 1996. *See id.* ¶¶ 6-8, 20, 23. That undisputed fact proves that, the district court's *ipse dixit* notwithstanding, this is "a case where Congress went 'straight to [Plaintiffs'] speech.'" R.100 (SJ Op.) at 41.

Although the court noted that some of these alternatives "would impose substantial new costs on state and local governments and private persons," *id.* at 38, the Act's speech restrictions likewise will "impose substantial new costs" on

Plaintiffs and their *adult* customers, who, it bears emphasizing, consume more than 98% of all tobacco products sold in this country, R.71-1 (Reynolds Decl.) ¶ 5. As a constitutional matter, the relative priority of these costs has already been decided by the First Amendment's mandate "that regulating speech must be a last—not first—resort." *BellSouth*, 542 F.3d at 508.

B. Sampling And Continuity Programs Are Protected Speech

The district court did not reject Plaintiffs' challenge to the bans on sampling and continuity programs under *Central Hudson*. Instead, it held that these restrictions regulate conduct, not speech, and therefore do not implicate the First Amendment at all. R.100 (SJ Op.) at 41-43. This is wrong.

As Plaintiffs' witnesses attested, sampling and continuity programs are promotional methods that convey the twin messages of reinforcing brand loyalty and encouraging switching from competitors' brands. *See* R.71-8 (Dunham Decl.) ¶¶ 10, 41, 44, 48; R.71-5 (Faber Decl.) ¶¶ 30, 47-48; R.71-10 (Lindsley Aff.) ¶¶ 53, 83. Sampling, for example, is one of the "most effective ways to reach adult tobacco consumers of a different brand and to convince them" to switch, because "[m]ere advertising alone ordinarily is not sufficient to induce brand switching by an adult consumer who is otherwise satisfied with the competitor's brand and, thus, does not want to spend money to experiment." R.71-14 (Jennette Decl.) ¶¶ 35-46; *see also* R.71-5 (Faber Decl.) ¶¶ 47-48; R.71-15 (Terry Decl.) ¶¶ 33-42. Likewise,

continuity programs, like frequent flyer programs, "are designed to maintain the loyalty of existing customers, not to attract new ones, . . . [by] offer[ing] an added benefit for existing customers that may help prevent brand-switching." R.71-10 (Lindsey Aff.) ¶ 54. Thus, even the FDA originally characterized the continuity-programs ban as a speech restriction governed by *Central Hudson*. *See* 61 Fed. Reg. at 44469-70, 44521-27; *see also* James J. White & Robert S. Summers, *Uniform Commercial Code* § 9-6, 356 (5th ed. 2000) (product samples can constitute "symbolic statements" giving rise to "express warranties"). In short, these marketing techniques communicate a distinct marketing message—"please use or keep using this product." Consequently, these bans are commercial-speech restrictions governed by *Central Hudson*.

At a minimum, these marketing restrictions are subject to *Central Hudson* review because they regulate conduct that is *expressive*. A two-part test defines such "expressive conduct": *first*, "an intent to convey a particularized message [must be] present"; and *second*, "the likelihood [must be] great that the message would be understood by those who [heard] it." *Texas v. Johnson*, 491 U.S. 397, 403-04 (1989). If a message is intended by the speaker and likely to be understood by the recipient, the activity is at least protected by intermediate First Amendment scrutiny. *See id.*

The Fifth Circuit's decision in *Bailey v. Morales*, 190 F.3d 320 (5th Cir.

1999), is directly on point. There, a marketing restriction criminalized "innocent marketing techniques," such as the distribution of free "promotional gifts and items." *Id.* at 321, 325. The Fifth Circuit squarely held that, under *Johnson*, such distributions were expressive conduct protected by the First Amendment. It reasoned that chiropractors "engage in such conduct with an intent to convey a particularized message: hire me, try my service." *Id.* at 325. And "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." *Id.* With each prong of *Johnson* satisfied, the court concluded that the law "regulates speech" and then invalidated it under *Central Hudson*. *Id.*

Here, just like the free gifts in *Bailey*, the ban on sampling and continuity programs is (at least) expressive conduct, since these "common marketing tools" "convey a particularized message: … try[, or keep using,] my [product]." *Id.* Indeed, that each represents one of the most effective facets of Plaintiffs' advertising, *see supra* at 58-59, speaks volumes about Plaintiffs' intended message and consumers' ability to understand it. Consumers fully recognize that companies give away product samples and rewards for continued product use, not out of generosity, but as marketing tools. Although Plaintiffs fully briefed this issue, the district court did not address this argument or even attempt to distinguish the directly on-point decision in *Bailey*. R. 100 (SJ Op.) at 41-43.

CONCLUSION

This Court should reverse the district court's grant of summary judgment to the Government on the Act's provisions challenged herein—(1) the new warnings for tobacco-product packaging and advertising; (2) the MRTPR; and (3) the marketing bans on brand-name sponsorships and merchandise, sampling, and continuity programs—and remand for entry of summary judgment for Plaintiffs. At a minimum, it should vacate and remand for a full trial on the merits.

May 28, 2010

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to 6th Cir. R. 32(a), I certify that this brief meets the type-volume limitations of Fed. R. App. P. 28.1(e)(2)(A) because it contains 13,995 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), as calculated using the word-count function on Microsoft Word software.

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CERTIFICATE OF SERVICE

I hereby certify that on May 28, 2010, I electronically filed the foregoing document with the clerk of the court by using the CM/ECF system, which will send a notice of docket activity by electronic mail to the following counsel for Defendants-Appellees/Cross-Appellants:

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ADDENDUM

DESIGNATION OF DISTRICT COURT RECORD

Document No.	Description of Document
	Docket Sheet
R.1	Complaint
R.3	Motion for Preliminary Injunction on MRTPR
R.33	Amended Complaint
R.43-1	Gov't Preliminary Injunction Opposition
R.61	Answer to Amended Complaint
R.65	Preliminary Injunction Memo. Opinion and Order
R.70	Gov't Notice of Filing
R.71	Pltfs. Notice of Filing
R.71-1	Reynolds Declaration
R.71-3	Viscusi Declaration
R.71-5	Faber Declaration
R.71-7	Williard Declaration
R.71-8	Dunham Declaration
R.71-9	Howard Declaration
R.71-10	Lindsley Affidavit
R.71-11	Master Settlement Agreement
R.71-13	Jones Declaration
R.71-14	Jennette Declaration
R.71-15	Terry Declaration
R.71-16	Hinton Declaration

R.71-17	Ames Declaration
R.71-17, Ex.A	Payne Testimony
R.71-17, Ex.B	Swauger Testimony
R.71-17, Ex.D-2	Reynolds American Press Release
R.72	Pltfs. Notice of Filing
R.72-1	Rodu Declaration
R.76	Clarification Order Amending Preliminary Injunction Memo. Opinion and Order
R.80	Gov't Motion for Summary Judgment
R.80-1	Gov't Memo. in Support of Summary Judgment
R.81	Pltfs. Motion for Summary Judgment
R.100	Summary Judgment Memo. Opinion and Order
R.102	Gov't Motion to Alter or Amend Judgment
R.103	Order Granting Gov't Motion to Alter or Amend Judgment
R.104	Final Judgment
R.106	Pltfs. Notice of Appeal
R.108	Gov't Notice of Appeal

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PUB. L. NO. 111-31, § 201(a):

SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.

(a) AMENDMENT.—Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

''SEC. 4. 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 permitholding 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, United States Code, 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 the date of enactment of the Family Smoking Prevention and Tobacco Control Act, 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. NO. 111-31, § 204(a):

SEC. 204. SMOKELESS TOBACCO LABELS AND ADVERTISING WARNINGS.

(a) AMENDMENT.—Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) is amended to read as follows:

''SEC. 3. SMOKELESS TOBACCO WARNING.

''(a) GENERAL RULE.—

''(1) 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 smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, one of the following labels:

''WARNING: This product can cause mouth cancer.

''WARNING: This product can cause gum disease and tooth loss.

''WARNING: This product is not a safe alternative to cigarettes.

''WARNING: Smokeless tobacco is addictive.

''(2) Each label statement required by paragraph (1) shall be—

''(A) located on the 2 principal display panels of the package, and each label statement shall comprise at least 30 percent of each such display panel; and

''(B) in 17-point conspicuous and legible type and in black text on a white background, or white text 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 (b)(3), except that if the text of a label statement would occupy more than 70 percent of the area specified by subparagraph (A), such text may appear in a smaller type size, so long as at least 60 percent of such warning area is occupied by the label statement.

''(3) The label statements required by paragraph (1) shall be introduced by each tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

''(4) The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

''(5) A retailer of smokeless tobacco products 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 permitholding 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) REQUIRED LABELS.—

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

''(2)(A) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph.

''(B) For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall comprise at least 20 percent of the area of the advertisement.

''(C) The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type.

''(D) The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

''(E) 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.

''(F) 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 wholepage magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 0 centimeter by 2 column advertisement.

''(G) The label statements shall be in English, except that—

''(i) 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

''(ii) 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)(A) 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.

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

''(C) The Secretary shall review each plan submitted under subparagraphs (A) and (B) and approve it if the plan—

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

''(ii) 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.

''(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements under this section, unless 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.

''(4) The Secretary may, through a rulemaking under section 553 of title 5, United States Code, 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 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 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) TELEVISION AND RADIO ADVERTISING.—It is unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.''.

PUB. L. NO. 111-31, § 205(a):

SEC. 205. AUTHORITY TO REVISE SMOKELESS TOBACCO PRODUCT WARNING LABEL STATEMENTS.

(a) IN GENERAL.—Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by section 204, is further amended by adding at the end the following:

''(d) AUTHORITY TO REVISE WARNING LABEL STATEMENTS.—

The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, 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 smokeless tobacco products.''.

PUB. L. NO. 111-31, § 206:

SEC. 206. TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE TO THE PUBLIC.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by sections 201 and 202, 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, United States Code, 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, United States Code, 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.''.

5 U.S.C. § 555:

§ 555. Ancillary matters

(a) This section applies, according to the provisions thereof, except as otherwise provided by this subchapter.

(b) A person compelled to appear in person before an agency or representative thereof is entitled to be accompanied, represented, and advised by counsel or, if permitted by the agency, by other qualified representative. A party is entitled to appear in person or by or with counsel or other duly qualified representative in an agency proceeding. So far as the orderly conduct of public business permits, an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding, whether interlocutory, summary, or otherwise, or in connection with an agency function. With due regard for the convenience and necessity of the parties or their representatives and within a reasonable time, each agency shall proceed to conclude a matter presented to it. This subsection does not grant or deny a person who is not a lawyer the right to appear for or represent others before an agency or in an agency proceeding.

(c) Process, requirement of a report, inspection, or other investigative act or demand may not be issued, made, or enforced except as authorized by law. A person compelled to submit data or evidence is entitled to retain or, on payment of lawfully prescribed costs, procure a copy or transcript thereof, except that in a nonpublic investigatory proceeding the witness may for good cause be limited to inspection of the official transcript of his testimony.

(d) Agency subpenas authorized by law shall be issued to a party on request and, when required by rules of procedure, on a statement or showing of general relevance and reasonable scope of the evidence sought. On contest, the court shall sustain the subpena or similar process or demand to the extent that it is found to be in accordance with law. In a proceeding for enforcement, the court shall issue an order requiring the appearance of the witness or the production of the evidence or data within a reasonable time under penalty of punishment for contempt in case of contumacious failure to comply.

(e) Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person made in connection with any agency proceeding. Except in affirming a prior denial or when the denial is self-explanatory, the notice shall be accompanied by a brief statement of the grounds for denial.

15 U.S.C. § 1333:

§ 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 subsection (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.

15 U.S.C. § 1335:

§ 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.

15 U.S.C. § 4402:

§ 4402. Smokeless tobacco warning

(a) General rule

(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this chapter, one of the following labels:

"WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER

"WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS

"WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES".

(2) It shall be unlawful for any manufacturer, packager, or importer of smokeless tobacco products to advertise or cause to be advertised (other than through the use of outdoor billboard advertising) within the United States any smokeless tobacco product unless the advertising bears, in accordance with the requirements of this chapter, one of the labels required by paragraph (1).

(b) Label format

The Federal Trade Commission shall issue regulations requiring the label statement required by subsection (a) of this section to appear--

(1) in the case of the smokeless tobacco product package--

(A) in a conspicuous and prominent place on the package, and

(B) in a conspicuous format and in conspicuous and legible type in contrast with all other printed material on the package, and

(2) in the case of advertising subject to subsection (a)(2) of this section--

(A) in a conspicuous and prominent location in the advertisement and in conspicuous and legible type in contrast with all other printed material in the advertisement,

(B) in the following format:

[TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE.]

(C) the label statement shall appear in capital letters and the area of the circle and arrow shall be determined by the Federal Trade Commission.

(c) Label display

The Federal Trade Commission shall issue regulations requiring each label statement required by subsection (a) of this section to--

(1) in the case of a smokeless tobacco product package, be randomly displayed by each manufacturer, packager, or importer of a smokeless tobacco product 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 parts of the United States in which such product is marketed, and

(2) in the case of any advertisement of a smokeless tobacco product, be rotated every 4 months by each manufacturer, packager, or importer of a smokeless tobacco product in an alternating sequence in the advertisement for each brand of the product.

(d) Plan

(1) Each manufacturer, packager, or importer of a smokeless tobacco product shall submit a plan to the Federal Trade Commission which specifies the method such manufacturer, packager, or importer will use to rotate, display, and distribute the statements required by subsection (a) of this section in accordance with the requirements of subsections (b) and (c) of this section.

(2) The Federal Trade Commission shall approve a plan submitted by a manufacturer, packager, or importer of a smokeless tobacco product under paragraph (1) if such plan provides for the rotation, display, and distribution on smokeless tobacco product packages and advertisements of the statements required by subsection (a) of this section in a manner which complies with this section and the regulations promulgated pursuant to this section.

(e) Application

This section does not apply to a distributor or a retailer of any smokeless tobacco product which does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

(f) Television and radio advertising

Effective 6 months after February 27, 1986, it shall be unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.

21 U.S.C. § 321(g):

§ 321. Definitions; generally

For the purposes of this chapter--

…

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

…

21 U.S.C. § 331(a):

§ 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.

…

21 U.S.C. § 331(tt):

§ 331. Prohibited acts

The following acts and the causing thereof are prohibited:

…

(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.

21 U.S.C. § 333(a):

§ 333. Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section[1], if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

…

[1] So in original. Words "of this section" probably should not appear.

21 U.S.C. § 352(n):

§ 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded--

…

(n) Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling; construction of the Convention on Psychotropic Substances

In the case of any prescription drug distributed or offered for sale in any State, unless 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 drug a true statement of (1) the established name as defined in paragraph (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under paragraph (e) of this section, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with section 371(a) of this title, and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: 'You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.', except that (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 52 to 57 of Title 15. This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title. Nothing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers. In the case of an advertisement for a drug subject to section 353(b)(1) of this title presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.

…

21 U.S.C. § 387 note, Findings:

§ 387. Definitions

…

Findings

Pub.L. 111-31, Div. A, § 2, June 22, 2009, 123 Stat. 1776, provided that:

"The Congress finds the following:

"(1) The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults.

"(2) A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.

"(3) Nicotine is an addictive drug.

"(4) Virtually all new users of tobacco products are under the minimum legal age to purchase such products.

"(5) Tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents.

"(6) Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed.

"(7) Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products.

"(8) Federal and State public health officials, the public health community, and the public at large recognize that the tobacco industry should be subject to ongoing oversight.

"(9) Under article I, section 8 of the Constitution, the Congress is vested with the responsibility for regulating interstate commerce and commerce with Indian tribes.

"(10) The sale, distribution, marketing, advertising, and use of tobacco products are activities in and substantially affecting interstate commerce because they are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the Nation's economy.

"(11) The sale, distribution, marketing, advertising, and use of such products substantially affect interstate commerce through the health care and other costs attributable to the use of

tobacco products.

"(12) It is in the public interest for Congress to enact legislation that provides the Food and Drug Administration with the authority to regulate tobacco products and the advertising and promotion of such products. The benefits to the American people from enacting such legislation would be significant in human and economic terms.

"(13) Tobacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking.

"(14) Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease. Such a reduction in youth smoking would also result in approximately $75,000,000,000 in savings attributable to reduced health care costs.

"(15) Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use.

"(16) In 2005, the cigarette manufacturers spent more than $13,000,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.

"(17) Tobacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors.

"(18) Tobacco product advertising is regularly seen by persons under the age of 18, and persons under the age of 18 are regularly exposed to tobacco product promotional efforts.

"(19) Through advertisements during and sponsorship of sporting events, tobacco has become strongly associated with sports and has become portrayed as an integral part of sports and the healthy lifestyle associated with rigorous sporting activity.

"(20) Children are exposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who begin to use tobacco.

"(21) The use of tobacco products in motion pictures and other mass media glamorizes its use for young people and encourages them to use tobacco products.

"(22) Tobacco advertising expands the size of the tobacco market by increasing consumption of tobacco products including tobacco use by young people.

"(23) Children are more influenced by tobacco marketing than adults: more than 80 percent of youth smoke three heavily marketed brands, while only 54 percent of adults, 26 and older, smoke these same brands.

"(24) Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market. Children, who tend to be more price sensitive than adults, are influenced by advertising and promotion practices that result in drastically reduced cigarette prices.

"(25) Comprehensive advertising restrictions will have a positive effect on the smoking rates of young people.

"(26) Restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education about tobacco use.

"(27) International experience shows that advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones.

"(28) Text only requirements, although not as stringent as a ban, will help reduce underage use of tobacco products while preserving the informational function of advertising.

"(29) It is in the public interest for Congress to adopt legislation to address the public health crisis created by actions of the tobacco industry.

"(30) The final 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) for inclusion as part 897 of title 21, Code of Federal Regulations, are consistent with the first amendment to the United States Constitution and with the standards set forth in the amendments made by this subtitle [sic …] for the regulation of tobacco products by the Food and Drug Administration, and the restriction on the sale and distribution of, including access to and the advertising and promotion of, tobacco products contained in such regulations are substantially related to accomplishing the public health goals of this division […].

"(31) The regulations described in paragraph (30) will directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use. An overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18. Tobacco advertising and promotion play a crucial role in the decision of these minors to begin using tobacco products. Less restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations. The reasonable restrictions on the advertising and promotion of tobacco products contained in such regulations will lead to a significant decrease

in the number of minors using and becoming addicted to those products.

"(32) The regulations described in paragraph (30) impose no more extensive restrictions on communication by tobacco manufacturers and sellers than are necessary to reduce the number of children and adolescents who use cigarettes and smokeless tobacco and to prevent the life-threatening health consequences associated with tobacco use. Such regulations are narrowly tailored to restrict those advertising and promotional practices which are most likely to be seen or heard by youth and most likely to entice them into tobacco use, while affording tobacco manufacturers and sellers ample opportunity to convey information about their products to adult consumers.

"(33) Tobacco dependence is a chronic disease, one that typically requires repeated interventions to achieve long-term or permanent abstinence.

"(34) Because the only known safe alternative to smoking is cessation, interventions should target all smokers to help them quit completely.

"(35) Tobacco products have been used to facilitate and finance criminal activities both domestically and internationally. Illicit trade of tobacco products has been linked to organized crime and terrorist groups.

"(36) It is essential that the Food and Drug Administration review products sold or distributed for use to reduce risks or exposures associated with tobacco products and that it be empowered to review any advertising and labeling for such products. It is also essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.

"(37) Unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk. Those who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death. The costs to society 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 […].

"(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)."

21 U.S.C. § 387a-1:

§ 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 this subchapter; 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), 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 387 of this title;

(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 [21 U.S.C.A. § 321]).

"(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 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 [June 22, 2009].

"(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) 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).

(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)).

21 U.S.C. § 387b:

§ 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.

21 U.S.C. § 387c:

§ 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.

21 U.S.C. § 387k:

§ 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.

(2) Sold or distributed

(A) In general

With respect to a tobacco product, the term "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" means a tobacco product--

(i) the label, labeling, or advertising of which represents explicitly or implicitly that--

(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

(III) the tobacco product or its smoke does not contain or is free of a substance;

(ii) the label, labeling, or advertising of which uses the descriptors "light", "mild", or "low" or similar descriptors; or

(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after June 22, 2009, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially

marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

(B) Limitation

No tobacco product shall be considered to be "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products", except as described in subparagraph (A).

(C) Smokeless tobacco product

No smokeless tobacco product shall be considered to be "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" solely because its label, labeling, or advertising uses the following phrases to describe such product and its use: "smokeless tobacco", "smokeless tobacco product", "not consumed by smoking", "does not produce smoke", "smokefree", "smoke-free", "without smoke", "no smoke", or "not smoke".

(3) Effective date

The provisions of paragraph (2)(A)(ii) shall take effect 12 months after June 22, 2009 for those products whose label, labeling, or advertising contains the terms described in such paragraph on June 22, 2009. 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 paragraph (2)(A)(ii).

(c) Tobacco dependence products

A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a modified risk tobacco product under this section if it has been approved as a drug or device by the Food and Drug Administration and is subject to the requirements of subchapter V of this chapter.

(d) Filing

Any person may file with the Secretary an application for a modified risk tobacco product. Such application shall include--

(1) a description of the proposed product and any proposed advertising and labeling;

(2) the conditions for using the product;

(3) the formulation of the product;

(4) sample product labels and labeling;

(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;

(6) data and information on how consumers actually use the tobacco product; and

(7) such other information as the Secretary may require.

(e) Public availability

The Secretary shall make the application described in subsection (d) publicly available (except matters in the application which are trade secrets or otherwise confidential, commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying such application.

(f) Advisory Committee

(1) In general

The Secretary shall refer to the Tobacco Products Scientific Advisory Committee any application submitted under this section.

(2) Recommendations

Not later than 60 days after the date an application is referred to the Tobacco Products Scientific Advisory Committee under paragraph (1), the Advisory Committee shall report its recommendations on the application to the Secretary.

(g) Marketing

(1) Modified risk products

Except as provided in paragraph (2), the Secretary shall, with respect to an application submitted under this section, issue an order that a modified risk product may be commercially marketed only if the Secretary determines that the applicant has demonstrated that such product, as it is actually used by consumers, will--

(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

(B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

(2) Special rule for certain products

(A) In general

The Secretary may issue an order that a tobacco product may be introduced or delivered for introduction into interstate commerce, pursuant to an application under this section, with respect to a tobacco product that may not be commercially marketed under paragraph (1) if the Secretary makes the findings required under this paragraph and determines that the applicant has demonstrated that--

(i) such order would be appropriate to promote the public health;

(ii) any aspect of the label, labeling, and advertising for such product that would cause the tobacco product to be a modified risk tobacco product under subsection (b) is limited to an explicit or implicit representation that such tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;

(iii) scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1); and

(iv) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies.

(B) Additional findings required

To issue an order under subparagraph (A) the Secretary must also find that the applicant has demonstrated that--

(i) the magnitude of the overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;

(ii) the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;

(iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product--

(I) is or has been demonstrated to be less harmful; or

(II) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products; and

(iv) issuance of an order with respect to the application is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

(C) Conditions of marketing

(i) In general

Applications subject to an order under this paragraph shall be limited to a term of not more than 5 years, but may be renewed upon a finding by the Secretary that the requirements of this paragraph continue to be satisfied based on the filing of a new application.

(ii) Agreements by applicant

An order under this paragraph shall be conditioned on the applicant's agreement to conduct postmarket surveillance and studies and to submit to the Secretary the results of such surveillance and studies to determine the impact of the order on consumer perception, behavior, and health and to enable the Secretary to review the accuracy of the determinations upon which the order was based in accordance with a protocol approved by the Secretary.

(iii) Annual submission

The results of such postmarket surveillance and studies described in clause (ii) shall be submitted annually.

(3) Basis

The determinations under paragraphs (1) and (2) shall be based on--

(A) the scientific evidence submitted by the applicant; and

(B) scientific evidence and other information that is made available to the Secretary.

(4) Benefit to health of individuals and of population as a whole

In making the determinations under paragraphs (1) and (2), the Secretary shall take into account--

(A) the relative health risks to individuals of the tobacco product that is the subject of the application;

(B) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;

(C) the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;

(D) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under subchapter V of this chapter to treat nicotine dependence; and

(E) comments, data, and information submitted by interested persons.

(h) Additional conditions for marketing

(1) Modified risk products

The Secretary shall require for the marketing of a product under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.

(2) Comparative claims

(A) In general

The Secretary may require for the marketing of a product under this subsection that a claim comparing a tobacco product to 1 or more other commercially marketed tobacco products shall compare the tobacco product to a commercially marketed tobacco product that is representative of that type of tobacco product on the market (for example the average value of the top 3 brands of an established regular tobacco product).

(B) Quantitative comparisons

The Secretary may also require, for purposes of subparagraph (A), that the percent (or fraction) of change and identity of the reference tobacco product and a quantitative comparison of the amount of the substance claimed to be reduced shall be stated in immediate proximity to the most prominent claim.

(3) Label disclosure

(A) In general

The Secretary may require the disclosure on the label of other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that

may affect a disease or health-related condition or may increase the risk of other diseases or health-related conditions associated with the use of tobacco products.

(B) Conditions of use

If the conditions of use of the tobacco product may affect the risk of the product to human health, the Secretary may require the labeling of conditions of use.

(4) Time

An order issued under subsection (g)(1) shall be effective for a specified period of time.

(5) Advertising

The Secretary may require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the product comply with requirements relating to advertising and promotion of the tobacco product.

(i) Postmarket surveillance and studies

(1) In general

The Secretary shall require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the applicant conduct postmarket surveillance and studies for such a tobacco product to determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the order was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product. The results of postmarket surveillance and studies shall be submitted to the Secretary on an annual basis.

(2) Surveillance protocol

Each applicant required to conduct a surveillance of a tobacco product under paragraph (1) shall, within 30 days after receiving notice that the applicant is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of the data or other information designated by the Secretary as necessary to protect the public health.

(j) Withdrawal of authorization

The Secretary, after an opportunity for an informal hearing, shall withdraw an order under subsection (g) if the Secretary determines that--

(1) the applicant, based on new information, can no longer make the demonstrations required

under subsection (g), or the Secretary can no longer make the determinations required under subsection (g);

(2) the application failed to include material information or included any untrue statement of material fact;

(3) any explicit or implicit representation that the product reduces risk or exposure is no longer valid, including if--

(A) a tobacco product standard is established pursuant to section 387g of this title;

(B) an action is taken that affects the risks presented by other commercially marketed tobacco products that were compared to the product that is the subject of the application; or

(C) any postmarket surveillance or studies reveal that the order is no longer consistent with the protection of the public health;

(4) the applicant failed to conduct or submit the postmarket surveillance and studies required under subsection (g)(2)(C)(ii) or subsection (i); or

(5) the applicant failed to meet a condition imposed under subsection (h).

(k) Subchapter IV or V of this chapter

A product for which the Secretary has issued an order pursuant to subsection (g) shall not be subject to subchapter IV or V of this chapter.

(l) Implementing regulations or guidance

(1) Scientific evidence

Not later than 2 years after June 22, 2009, the Secretary shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Such regulations or guidance shall--

(A) to the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under subsection (g) to show that a substantial reduction in morbidity or mortality among individual tobacco users occurs for products described in subsection (g)(1) or is reasonably likely for products described in subsection (g)(2);

(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;

(C) establish minimum standards for postmarket studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints,

consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate;

(D) establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception;

(E) require that data from the required studies and surveillance be made available to the Secretary prior to the decision on renewal of a modified risk tobacco product; and

(F) establish a reasonable timetable for the Secretary to review an application under this section.

(2) Consultation

The regulations or guidance issued under paragraph (1) shall be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance.

(3) Revision

The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.

(4) New tobacco products

Not later than 2 years after June 22, 2009, the Secretary shall issue a regulation or guidance that permits the filing of a single application for any tobacco product that is a new tobacco product under section 387j of this title and which the applicant seeks to commercially market under this section.

(m) Distributors

Except as provided in this section, no distributor may take any action, after June 22, 2009, with respect to a tobacco product that would reasonably be expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

21 U.S.C. § 387*l*:

§ 387*l*. Judicial review

(a) Right to review

(1) In general

Not later than 30 days after--

(A) the promulgation of a regulation under section 387g of this title establishing, amending, or revoking a tobacco product standard; or

(B) a denial of an application under section 387j(c) of this title,

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

(2) Requirements

(A) Copy of petition

A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Secretary.

(B) Record of proceedings

On receipt of a petition under subparagraph (A), the Secretary shall file in the court in which such petition was filed--

(i) the record of the proceedings on which the regulation or order was based; and

(ii) a statement of the reasons for the issuance of such a regulation or order.

(C) Definition of record

In this section, the term “record” means--

(i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed;

(ii) all information submitted to the Secretary with respect to such regulation or order;

(iii) proceedings of any panel or advisory committee with respect to such regulation or

order;

(iv) any hearing held with respect to such regulation or order; and

(v) any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

(b) Standard of review

Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of Title 5, and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of Title 5.

(c) Finality of judgment

The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of Title 28.

(d) Other remedies

The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

(e) Regulations and orders must recite basis in record

To facilitate judicial review, a regulation or order issued under section 387f, 387g, 387h, 387i, 387j, or 387p of this title shall contain a statement of the reasons for the issuance of such regulation or order in the record of the proceedings held in connection with its issuance.

21 U.S.C. § 387m:

§ 387m. Equal Treatment of retail outlets

The Secretary shall issue regulations to require that retail establishments for which the predominant business is the sale of tobacco products comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

21 U.S.C. § 387t:

§ 387t. Labeling, recordkeeping, records inspection

(a) Origin labeling

(1) Requirement

Beginning 1 year after June 22, 2009, the label, packaging, and shipping containers of tobacco products other than cigarettes for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement "sale only allowed in the United States". Beginning 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), as amended by section 201 of Family Smoking Prevention and Tobacco Control Act, the label, packaging, and shipping containers of cigarettes for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement "Sale only allowed in the United States".

(2) Effective date

The effective date specified in paragraph (1) 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 such paragraph.

(b) Regulations concerning recordkeeping for tracking and tracing

(1) In general

The Secretary shall promulgate regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products.

(2) Inspection

In promulgating the regulations described in paragraph (1), the Secretary shall consider which records are needed for inspection to monitor the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products.

(3) Codes

The Secretary may require codes on the labels of tobacco products or other designs or devices for the purpose of tracking or tracing the tobacco product through the distribution system.

(4) Size of business

The Secretary shall take into account the size of a business in promulgating regulations under this section.

(5) Recordkeeping by retailers

The Secretary shall not require any retailer to maintain records relating to individual purchasers of tobacco products for personal consumption.

(c) Records inspection

If the Secretary has a reasonable belief that a tobacco product is part of an illicit trade or smuggling or is a counterfeit product, each person who manufactures, processes, transports, distributes, receives, holds, packages, exports, or imports tobacco products shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times and within reasonable limits and in a reasonable manner, upon the presentation of appropriate credentials and a written notice to such person, to have access to and copy all records (including financial records) relating to such article that are needed to assist the Secretary in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products. The Secretary shall not authorize an officer or employee of the government of any of the several States to exercise authority under the preceding sentence on Indian country without the express written consent of the Indian tribe involved.

(d) Knowledge of illegal transaction

(1) Notification

If the manufacturer or distributor of a tobacco product has knowledge which reasonably supports the conclusion that a tobacco product manufactured or distributed by such manufacturer or distributor that has left the control of such person may be or has been--

(A) imported, exported, distributed, or offered for sale in interstate commerce by a person without paying duties or taxes required by law; or

(B) imported, exported, distributed, or diverted for possible illicit marketing,

the manufacturer or distributor shall promptly notify the Attorney General and the Secretary of the Treasury of such knowledge.

(2) Knowledge defined

For purposes of this subsection, the term “knowledge” as applied to a manufacturer or distributor means--

(A) the actual knowledge that the manufacturer or distributor had; or

(B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

(e) Consultation

In carrying out this section, the Secretary shall consult with the Attorney General of the United States and the Secretary of the Treasury, as appropriate.

21 C.F.R. § 201.128:

§ 201.128 Meaning of "intended uses".

The words intended uses or words of similar import in §§ 201.5, 201.115, 201.117, 201.119, 201.120, and 201.122 refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

21 C.F.R. § 314.81(b):

§ 314.81 Other postmarketing reports.

…

(b) Reporting requirements. The applicant shall submit to the Food and Drug Administration at the specified times two copies of the following reports:

(1) NDA--Field alert report. The applicant shall submit information of the following kinds about distributed drug products and articles to the FDA district office that is responsible for the facility involved within 3 working days of receipt by the applicant. The information may be provided by telephone or other rapid communication means, with prompt written followup. The report and its mailing cover should be plainly marked: "NDA--Field Alert Report."

(i) Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article.

(ii) Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specification established for it in the application.

(2) Annual report. The applicant shall submit each year within 60 days of the anniversary date of U.S. approval of the application, two copies of the report to the FDA division responsible for reviewing the application. Each annual report is required to be accompanied by a completed transmittal Form FDA 2252 (Transmittal of Periodic Reports for Drugs for Human Use), and must include all the information required under this section that the applicant received or otherwise obtained during the annual reporting interval that ends on the U.S. anniversary date. The report is required to contain in the order listed:

(i) Summary. A brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study. The summary shall briefly state whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Where possible, an estimate of patient exposure to the drug product, with special reference to the pediatric population (neonates, infants, children, and adolescents) shall be provided, including dosage form.

(ii)(a) Distribution data. Information about the quantity of the drug product distributed under the approved application, including that distributed to distributors. The information is required to include the National Drug Code (NDC) number, the total number of dosage

units of each strength or potency distributed (e.g., 100,000/5 milligram tablets, 50,000/10 milliliter vials), and the quantities distributed for domestic use and the quantities distributed for foreign use. Disclosure of financial or pricing data is not required.

(b) Authorized generic drugs. If applicable, the date each authorized generic drug (as defined in § 314.3) entered the market, the date each authorized generic drug ceased being distributed, and the corresponding trade or brand name. Each dosage form and/or strength is a different authorized generic drug and should be listed separately. The first annual report submitted on or after January 25, 2010 must include the information listed in this paragraph for any authorized generic drug that was marketed during the time period covered by an annual report submitted after January 1, 1999. If information is included in the annual report with respect to any authorized generic drug, a copy of that portion of the annual report must be sent to the Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drug Quality Assessment, Bldg. 21, rm. 2562, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, and marked "Authorized Generic Submission" or, by e-mail, to the Authorized Generics electronic mailbox at AuthorizedGenerics@fda.hhs.gov with "Authorized Generic Submission" indicated in the subject line. However, at such time that FDA has required that annual reports be submitted in an electronic format, the information required by this paragraph must be submitted as part of the annual report, in the electronic format specified for submission of annual reports at that time, and not as a separate submission under the preceding sentence in this paragraph.

(iii) Labeling.

(a) Currently used professional labeling, patient brochures or package inserts (if any), and a representative sample of the package labels.

(b) The content of labeling required under § 201.100(d)(3) of this chapter (i.e., the package insert or professional labeling), including all text, tables, and figures, must be submitted in electronic format. Electronic format submissions must be in a form that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files). Submissions under this paragraph must be made in accordance with part 11 of this chapter, except for the requirements of § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30.

(c) A summary of any changes in labeling that have been made since the last report listed by date in the order in which they were implemented, or if no changes, a statement of that fact.

(iv) Chemistry, manufacturing, and controls changes.

(a) Reports of experiences, investigations, studies, or tests involving chemical or physical properties, or any other properties of the drug (such as the drug's behavior or properties in relation to microorganisms, including both the effects of the drug on

microorganisms and the effects of microorganisms on the drug). These reports are only required for new information that may affect FDA's previous conclusions about the safety or effectiveness of the drug product.

(b) A full description of the manufacturing and controls changes not requiring a supplemental application under § 314.70 (b) and (c), listed by date in the order in which they were implemented.

(v) Nonclinical laboratory studies. Copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the applicant concerning the ingredients in the drug product. The applicant shall submit a copy of a published report if requested by FDA.

(vi) Clinical data.

(a) Published clinical trials of the drug (or abstracts of them), including clinical trials on safety and effectiveness; clinical trials on new uses; biopharmaceutic, pharmacokinetic, and clinical pharmacology studies; and reports of clinical experience pertinent to safety (for example, epidemiologic studies or analyses of experience in a monitored series of patients) conducted by or otherwise obtained by the applicant. Review articles, papers describing the use of the drug product in medical practice, papers and abstracts in which the drug is used as a research tool, promotional articles, press clippings, and papers that do not contain tabulations or summaries of original data should not be reported.

(b) Summaries of completed unpublished clinical trials, or prepublication manuscripts if available, conducted by, or otherwise obtained by, the applicant. Supporting information should not be reported. (A study is considered completed 1 year after it is concluded.)

(c) Analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. An assessment of data needed to ensure appropriate labeling for the pediatric population shall be included.

(vii) Status reports of postmarketing study commitments. A status report of each postmarketing study of the drug product concerning clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology that is required by FDA (e.g., accelerated approval clinical benefit studies, pediatric studies) or that the applicant has committed, in writing, to conduct either at the time of approval of an application for the drug product or a supplement to an application, or after approval of the application or a supplement. For pediatric studies, the status report shall include a statement indicating whether postmarketing clinical studies in pediatric populations were required by FDA under § 201.23 of this chapter. The status of these postmarketing studies shall be reported annually until FDA notifies the applicant, in writing, that the agency concurs with the applicant's determination that the study commitment has been fulfilled or that the study is

either no longer feasible or would no longer provide useful information.

(a) Content of status report. The following information must be provided for each postmarketing study reported under this paragraph:

(1) Applicant's name.

(2) Product name. Include the approved drug product's established name and proprietary name, if any.

(3) NDA, ANDA, and supplement number.

(4) Date of U.S. approval of NDA or ANDA.

(5) Date of postmarketing study commitment.

(6) Description of postmarketing study commitment. The description must include sufficient information to uniquely describe the study. This information may include the purpose of the study, the type of study, the patient population addressed by the study and the indication(s) and dosage(s) that are to be studied.

(7) Schedule for completion and reporting of the postmarketing study commitment. The schedule should include the actual or projected dates for submission of the study protocol to FDA, completion of patient accrual or initiation of an animal study, completion of the study, submission of the final study report to FDA, and any additional milestones or submissions for which projected dates were specified as part of the commitment. In addition, it should include a revised schedule, as appropriate. If the schedule has been previously revised, provide both the original schedule and the most recent, previously submitted revision.

(8) Current status of the postmarketing study commitment. The status of each postmarketing study should be categorized using one of the following terms that describes the study's status on the anniversary date of U.S. approval of the application or other agreed upon date:

(i) Pending. The study has not been initiated, but does not meet the criterion for delayed.

(ii) Ongoing. The study is proceeding according to or ahead of the original schedule described under paragraph (b)(2)(vii)(a)(7) of this section.

(iii) Delayed. The study is behind the original schedule described under paragraph (b)(2)(vii)(a)(7) of this section.

(iv) Terminated. The study was ended before completion but a final study report has not been submitted to FDA.

(v) Submitted. The study has been completed or terminated and a final study report has been submitted to FDA.

(9) Explanation of the study's status. Provide a brief description of the status of the study, including the patient accrual rate (expressed by providing the number of patients or subjects enrolled to date, and the total planned enrollment), and an explanation of the study's status identified under paragraph (b)(2)(vii)(a)(8) of this section. If the study has been completed, include the date the study was completed and the date the final study report was submitted to FDA, as applicable. Provide a revised schedule, as well as the reason(s) for the revision, if the schedule under paragraph (b)(2)(vii)(a)(7) of this section has changed since the last report.

(b) Public disclosure of information. Except for the information described in this paragraph, FDA may publicly disclose any information described in paragraph (b)(2)(vii) of this section, concerning a postmarketing study, if the agency determines that the information is necessary to identify the applicant or to establish the status of the study, including the reasons, if any, for failure to conduct, complete, and report the study. Under this section, FDA will not publicly disclose trade secrets, as defined in § 20.61 of this chapter, or information, described in § 20.63 of this chapter, the disclosure of which would constitute an unwarranted invasion of personal privacy.

(viii) Status of other postmarketing studies. A status report of any postmarketing study not included under paragraph (b)(2)(vii) of this section that is being performed by, or on behalf of, the applicant. A status report is to be included for any chemistry, manufacturing, and controls studies that the applicant has agreed to perform and for all product stability studies.

(ix) Log of outstanding regulatory business. To facilitate communications between FDA and the applicant, the report may, at the applicant's discretion, also contain a list of any open regulatory business with FDA concerning the drug product subject to the application (e.g., a list of the applicant's unanswered correspondence with the agency, a list of the agency's unanswered correspondence with the applicant).

(3) Other reporting--

(i) Advertisements and promotional labeling. The applicant shall submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Mailing pieces and labeling that are designed to contain samples of a drug product are required to be complete, except the sample of the drug product may be omitted. Each submission is required to be accompanied by a completed transmittal Form FDA-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) and is required to include a copy of the product's current professional labeling. Form FDA-2253 is available on the Internet at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html.

(ii) Special reports. Upon written request the agency may require that the applicant submit the reports under this section at different times than those stated.

(iii) Notification of discontinuance.

(a) An applicant who is the sole manufacturer of an approved drug product must notify FDA in writing at least 6 months prior to discontinuing manufacture of the drug product if:

(1) The drug product is life supporting, life sustaining, or intended for use in the prevention of a serious disease or condition; and

(2) The drug product was not originally derived from human tissue and replaced by a recombinant product.

(b) For drugs regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER), one copy of the notification required by paragraph (b)(3)(iii)(a) of this section must be sent to the CDER Drug Shortage Coordinator, at the address of the Director of CDER; one copy to the CDER Drug Registration and Listing Team, Division of Compliance Risk Management and Surveillance; and one copy to either the director of the review division in CDER that is responsible for reviewing the application, or the director of the office in CBER that is responsible for reviewing the application.

(c) FDA will publicly disclose a list of all drug products to be discontinued under paragraph (b)(3)(iii)(a) of this section. If the notification period is reduced under § 314.91, the list will state the reason(s) for such reduction and the anticipated date that manufacturing will cease.

(iv) Withdrawal of approved drug product from sale.

(a) The applicant shall submit on Form FDA 2657 (Drug Product Listing), within 15 working days of the withdrawal from sale of a drug product, the following information:

(1) The National Drug Code (NDC) number.

(2) The identity of the drug product by established name and by proprietary name.

(3) The new drug application or abbreviated application number.

(4) The date of withdrawal from sale. It is requested but not required that the reason for withdrawal of the drug product from sale be included with the information.

(b) The applicant shall submit each Form FDA-2657 to the Records Repository Team (HFD-143), Center for Drug Evaluation and Research, Food and Drug Administration,

5600 Fishers Lane, Rockville, MD 20857.

(c) Reporting under paragraph (b)(3)(iv) of this section constitutes compliance with the requirements under § 207.30(a) of this chapter to report "at the discretion of the registrant when the change occurs."

…

21 C.F.R. § 1140.16:

§ 1140.16 Conditions of manufacture, sale, and distribution.

(a) Restriction on product names. A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.

(b) Minimum cigarette package size. Except as otherwise provided under this section, no manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

(c) Vending machines, self-service displays, mail-order sales, and other "impersonal" modes of sale.

(1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include vending machines and self-service displays.

(2) Exceptions. The following methods of sale are permitted:

(i) Mail-order sales, excluding mail-order redemption of coupons and distribution of free samples through the mail; and

(ii) Vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

(d)(1) Except as provided in paragraph (d)(2) of this section, 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)(i) Paragraph (d)(1) of this section 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.

(ii) Paragraph (d)(2) of this section does not affect the authority of a State or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

(iii) For purposes of paragraph (d) of this section, the term "qualified adult-only facility" means a facility or restricted area that:

(A) 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;

(B) Does not sell, serve, or distribute alcohol;

(C) 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;

(D) 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 paragraph (d)(2) of this section;

(E) Is enclosed by a barrier that:

(1) Is constructed of, or covered with, an opaque material (except for entrances and exits);

(2) 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

(3) 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

(F) Does not display on its exterior:

(1) Any tobacco product advertising;

(2) A brand name other than in conjunction with words for an area or enclosure to identify an adult-only facility; or

(3) Any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship that would violate § 1140.34(c).

(iv) Distribution of samples of smokeless tobacco under paragraph (d)(2) of this section permitted to be taken out of the qualified adult-only facility shall be limited to one 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 smokeless tobacco, the individual portions of smokeless tobacco shall not exceed eight 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 amounts in this paragraph (d)(2)(iv) are limited to one such package per adult consumer per day.

(3) Notwithstanding paragraph (d)(2) of this section, no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of smokeless tobacco:

(i) To a sports team or entertainment group; or

(ii) At any football, basketball, baseball, soccer, or hockey event or any other sporting or entertainment event determined by the Secretary to be covered by paragraph (d)(3) of this section.

(4) The Secretary shall implement a program to ensure compliance with paragraph (d) of this section 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 paragraph (d) of this section 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.

(e) Restrictions on labels, labeling, and advertising. No manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with subpart D of this part, and other applicable requirements.

21 C.F.R. § 1140.32:

§ 1140.32 Format and content requirements for labeling and advertising.

(a) Except as provided in paragraph (b) of this section, each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any labeling or advertising for cigarettes or smokeless tobacco shall use only black text on a white background. This section does not apply to advertising:

(1) In any facility where vending machines and self- service displays are permitted under this part, provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility; or

(2) Appearing in any publication (whether periodic or limited distribution) that the manufacturer, distributor, or retailer demonstrates is an adult publication. For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication:

(i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

(b) Labeling and advertising in an audio or video format shall be limited as follows:

(1) Audio format shall be limited to words only with no music or sound effects.

(2) Video formats shall be limited to static black text only on a white background. Any audio with the video shall be limited to words only with no music or sound effects.

21 C.F.R. § 1140.34:

§ 1140.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

(a) No manufacturer and no distributor of imported cigarettes or smokeless tobacco may market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold any item (other than cigarettes or smokeless tobacco or roll-your-own paper) or service, which bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

(b) No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other than cigarettes or smokeless tobacco) to any person purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

(c) No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995, and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.