UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
BOWLING GREEN DIVISION

CIVIL ACTION NO. 1:09-CV-117-M

COMMONWEALTH BRANDS, INC.; CONWOOD COMPANY, LLC; DISCOUNT TOBACCO CITY AND LOTTERY, INC.; LORILLARD TOBACCO COMPANY; NATIONAL TOBACCO COMPANY, L.P.; and R. J. REYNOLDS TOBACCO COMPANY **PLAINTIFFS**

V.

UNITED STATES OF AMERICA; UNITED STATES FOOD AND DRUG ADMINISTRATION; MARGARET HAMBURG, Commissioner of the United States Food and Drug Administration; and KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services **DEFENDANTS**

MEMORANDUM OPINION AND ORDER

This matter is before the Court on cross-motions for summary judgment on Plaintiffs' claim that various provisions of the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 (2009) individually and collectively violate their free speech rights under the First Amendment; their Due Process rights under the Fifth Amendment; and effect an unconstitutional Taking under the Fifth Amendment. Fully briefed, the matter is ripe for decision. For the reasons that follow, Plaintiffs' motion is **GRANTED IN PART** and **DENIED IN PART** and Defendants' motion is

GRANTED IN PART and **DENIED IN PART**.

I. BACKGROUND

On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 (2009) into law. The Act aims "to curb tobacco use by adolescents," §§ 2(6), 3(2), while "continu[ing] to permit the sale of tobacco products to adults." Id. § 3(7). To that end, it significantly curtails the ability of tobacco manufacturers to market their products. The Act provides that "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." See Pub. L. No. 111-31, § 102(a)(2) (adopting 21 C.F.R. § 897.32(a)). It requires tobacco companies to print new government "warnings" on the top fifty percent of both sides of all cigarette packaging for messages like "Cigarettes cause cancer," which must be in 17-point font and include "color graphics depicting the negative health consequences of smoking."[1] Pub. L. No. 111-31, § 201(a) (amending 15 U.S.C. § 1333 to add subsections (a)(2) and (d)).

The Act's Modified Risk Tobacco Products ("MRTP") provision prohibits (1) "the label, labeling, or advertising" of a tobacco product from "explicitly or implicitly"

[1] Packaging must also include the statement "Sale only allowed in the United States"; the name and address of the manufacturer, packer, or distributor; a net quantity statement; and the percentage of foreign versus domestic tobacco. Id. at §§ 101(b), 301 (amending the Federal Food, Drug, and Cosmetic Act ("FDCA") to add §§ 903(a)(2)) and 920(a)(1)).

suggesting that the product is less harmful than other tobacco products, and (2) a "tobacco product manufacturer" from taking "any action directed to consumers through the media or otherwise . . . respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may" be less harmful than other tobacco products, without prior FDA approval of the product as "modified risk." Pub. L. No. 111-31, § 101(b) (amending the FDCA to add § 911(b)(2)(A)). The Act also bans, subject to the Secretary's modification of the provision "in light of governing First Amendment case law," i.e., the Supreme Court's decision in Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001), all "outdoor advertising for cigarettes or smokeless tobacco, including billboards, posters, or placards, . . . within 1,000 feet of the perimeter of any public playground or playground area in a public park . . ., elementary school, or secondary school." Public Law 111-31, §§ 102(a)(2)(E), 102(a)(2) (adopting 21 C.F.R. § 897.30(b)).

Additionally, the Act bars tobacco manufacturers from promoting their brands through sponsorship of "athletic, musical, artistic, or other social or cultural event[s]"; from distributing any nontobacco good in exchange for purchase of a tobacco product; from distributing any brand-name promotional items; from making any "express or implied" statement "through the media or advertising" that "conveys" that the product is "less harmful" because it is regulated by the FDA or complies with the FDA's prescribed standards; from distributing free samples of their cigarettes; from distributing free smokeless tobacco samples except in very limited circumstances; and from jointly

marketing tobacco with any other product regulated by the FDA. Id. at §§ 101(a), 102(a)(2)(G), 103(b)(13). Finally, the Act authorizes federal agencies, state and local governments, and Indian tribes to enact more stringent regulations pertaining to the marketing and sale of tobacco products. Id. at §§ 101(b) (amending the FDCA to add 21 U.S.C. § 916), and 203 (amending the Federal Cigarette Labeling and Advertising Act ("FCLAA") to add 15 U.S.C. § 1334(c)).[2]

II. STANDARD OF REVIEW

Except for the Modified Risk Tobacco Product provision and the ban on statements implying that FDA regulation of tobacco products makes those products less harmful, the parties agree that where the statute regulates speech it regulates commercial speech and must therefore satisfy the requirements set forth in Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York, 447 U.S. 557 (1980). Under Central Hudson, the first question is whether the speech concerns lawful activity and is not misleading; if the answer is no, the speech is not protected and may be regulated without violating the First Amendment. Id. at 565 (explaining that "there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity"). If the answer is yes, however, the speech can be constitutionally regulated only if the government has a substantial interest in regulating

[2] The majority of these restrictions are identical to those proposed by the FDA in 1996. The restrictions did not take effect at that time, however, because the Supreme Court held that the FDA lacked regulatory authority to promulgate them. See FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

the speech; the regulation directly advances the government's interest; and the regulation is not more extensive than is necessary to serve that interest. Id. at 565; Board of Trustees v. Fox, 492 U.S. 469, 480 (1989); Pagan v. Fruchey, 492 F.3d 766, 771 (6th Cir. 2007) (en banc).

To grant a motion for summary judgment, the Court must find that the pleadings, together with the depositions, interrogatories and affidavits, establish that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. The moving party bears the initial burden of specifying the basis for its motion and of identifying that portion of the record which demonstrates the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). Once the moving party satisfies this burden, the non-moving party thereafter must produce specific facts demonstrating a genuine issue of fact for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). "The mere existence of a scintilla of evidence in support of the [non-moving party's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [non-moving party]." Anderson, 477 U.S. at 252.

III. DISCUSSION

Plaintiffs argue that various provisions of the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 (2009), violate their free speech rights under the First Amendment; their rights to Due Process under the Fifth Amendment; and effect an unconstitutional Taking under the Fifth Amendment. The

government counters that the restrictions on the use of color and imagery, brand-name event sponsorship, and branded merchandise "directly advance the paramount public interest in addressing the crisis caused by the use and marketing of tobacco products, and they do so with minimal infringement on speech"; that the ban on outdoor advertising is not ripe because the Secretary has not yet taken any final action; that the warning requirement, Modified Risk Tobacco Products provision, and the ban against claims implying FDA approval satisfy the First Amendment by making sure that a decision to use tobacco is based on information that is accurate and not misleading; that the restrictions on free samples, gifts, and combination marketing regulate conduct without a "significant expressive element" and therefore do not implicate the First Amendment; and that adjudication of the Takings claim is jurisdictionally barred and without merit. (Government's Brief, pp. 2-3, 5, 45, 55) (quoting Arcara v. Cloud Books, Inc., 478 U.S. 697, 706-07 (1986)). The Court considers these arguments in turn.

A. First Amendment

1. Ban on Color and Graphics

The Act directs the FDA to reissue regulations requiring that labels and advertisements for tobacco products include only black text on a white background with no graphics: "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." See Pub. L. No. 111-31, § 102(a)(2) (adopting 21 C.F.R. § 897.32(a)). There are two

exceptions. First, the ban will not apply to magazine advertising if the publication has an under-18 readership that "constitutes 15 percent or less of the total readership as measured by competent and reliable survey evidence," and which is "read by fewer than 2 million persons younger than 18 years of age." Act § 102(a); 21 C.F.R. § 897.32(a) (1997). Second, the Act exempts advertising in adult-only facilities, excluding tobacco-specialty shops, where (1) the retailer "ensures" that no person under 18 "is present, or permitted to enter, at any time," (2) the advertisement is "affixed to a wall or fixture in the facility," and (3) the advertisement is not "visible from outside the facility." § 102(a)(2).

The government argues that this regulation satisfies Central Hudson because Congress has a substantial interest in reducing tobacco use by minors and the provision is "carefully tailored to address the 'particular advertising and promotion practices that appeal to youth,'" (Government's Brief, p. 39) (quoting Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 563 (2001)), since it "restricts the noninformational aspects of tobacco advertising that lure adolescents into beginning tobacco use, without restricting the communication of information about tobacco products."[3] (Government's Brief, p. 34). Plaintiffs argue that the provision does not advance the Government's asserted interest, and that, if it does, the provision is more extensive than necessary to achieve Congress's

[3] The government also suggests that the provision is constitutional because the speech it regulates is "relate[d] to [an] unlawful activity," i.e., the sale of tobacco to minors, such that it would fail the first step of the Central Hudson analysis. (Government Brief, p. 34). However, the government does not develop this argument, and the Court in any event fails to see how the use of color and graphics in labels and advertisements relates to unlawful activity whenever the associated product is only for lawful use by adults.

goal. As they put it, "[t]here is no evidence that [these] speech restrictions will significantly reduce youth tobacco use [and] . . . [t]here are literally dozens of widely accepted non-speech-restrictive alternatives that would reduce youth tobacco use." (Plaintiffs' Brief, p. 1).

Before addressing these arguments, the government's use of the word "noninformational" must be explained. What the government means by "noninformational" is not that color and graphics do not communicate information, for surely they do. The Supreme Court has recognized that "[t]he use of illustrations or pictures in advertisements serves important communicative functions: it attracts the attention of the audience to the advertiser's message, and it may also serve to impart information directly." Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 647 (1985). The same is undoubtedly true of the use of color. In fact, it is partly the communicative nature of color that the government is concerned with: they cite recent studies that show U.S. manufacturers are "substituting color and imagery for their 'light' and 'low tar' descriptors in anticipation of restrictions that will take effect in June 2010'" and conclude that "many smokers [will] perceive [cigarettes with such colors] to be healthier and easier to kick." (Government's Response, p. 44) (quoting "Taste the Rainbow: Cigarette Makers' Colorful Answer to FDA Packaging Regs," FastCompany.com (Oct. 22, 2009)). What the government means, instead, is that the information invariably communicated by color and graphics *in tobacco advertising and labels* is not the sort of commercial information the First Amendment protects because it

does nothing to "assur[e] informed and reliable decisionmaking," Bates v. State Bar of Arizona, 433 U.S. 350, 364 (1977), and, to the contrary, often purposefully creates meaningless associations between tobacco products and attractive lifestyles. (Government's Brief, pp. 35-37, Addendum B).

The central idea behind the ban on color and graphics is Congress's conclusion that "[c]hildren are more influenced by tobacco marketing than adults." Legislative Findings 15. The reason children are "more influenced" is twofold. First, they are "more susceptible to influence from peripheral cues such as color and imagery" because they have less "motivation and ability to 'elaborate' upon the arguments (pay attention to and think about the factual information)." 61 Fed. Reg. 44468. Second, as the Institute of Medicine ("IOM") has explained, "smoking experimentation commonly occurs at transition points in adolescence when there is a threat to a teen's emerging self-concept . . . [and] [t]hey are more subject to social pressure and more attuned to advertising than most groups in the population." 1994 IOM Report, at 119 (internal quotation marks omitted). As a result, "adolescents may be motivated to use tobacco, even when they view smoking as negative . . . . [i]n order to acquire selected attributes of model smokers." Id.

Tobacco companies know this well. In enacting the law, Congress explained that "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products." Legislative Findings 23. Similarly, the district court in Philip Morris concluded that there was "overwhelming"

evidence that the industry "exploit[ed] adolescents' vulnerability to imagery" through advertisements placed in magazines, on billboards, at retail points of sale, and "in other venues that historically and currently reach millions of teens." U.S. v. Philip Morris USA, Inc., 449 F.Supp.2d 1, 571 (D.D.C. 2006) (Finding 2674). Indeed, the court opined that "[t]he central purpose of the tobacco companies' image advertising is motivating adolescents to smoke." Id. at 572 (Finding 2680); see also (Krugman Affidavit, pp. 9-13, 17-21) (providing recent examples of tobacco companies' image-based advertising in youth magazines); (Government's Brief, Addendum B, pp. 9-36).

The government argues that the prohibition on color and graphics in tobacco labels and advertising is tailored to address this problem because "[f]rom the standpoint of the initiation of smoking by youth, the most important feature of tobacco advertising is its noninformational characteristics." 2007 IOM Report, at 322 (explaining that "[t]he images used in tobacco marketing associate smoking with lifestyles and experiences that appeal to young people, and these positive associations tend to displace or override risk information in adolescent decision making."); see also 2008 NCI Report, at 280 (reviewing recent scientific literature and finding that exposure to advertising causes adolescents to begin smoking or move to smoking on a regular basis and that even brief exposure to cigarette advertising influences adolescents' intentions to smoke).

Plaintiffs' argue that the ban is overbroad because it makes no exceptions—or at least makes only illusory exceptions—for color and graphic communications that have no special appeal to youth or that are virtually inaccessable by youth. They say, for example,

that the ban on color text and graphics "unnecessarily sweeps in" direct mail restricted to age-verified existing adult consumers; tobacco-specialty shops that restrict or prohibit youth access; publications such as The Arkansas Trooper whose subject matter "has no conceivable interest to youth"; and prohibits them from "depicting their own packaging in their advertising" and using "simple brand symbols such as National's Beech-Nut chewing tobacco insignia." (Plaintiffs' Response, p. 16); see also (Plaintiffs' Brief, pp. 4-6, 28-30).

Some of these objections are readily dismissed. Plaintiffs' argument that "direct mail" should be exempt from the restriction on color and imagery because that mail is sent only to adults ignores the fact that such mail is nevertheless easily accessible by minors. Moreover, as the government observes, despite the industry's reassurance about its use of direct mailings to age-verified adults, "the FDA found that 1.6 million adolescents aged 12 to 17 received tobacco industry mail addressed personally to them in a single year." (Government's Response, p. 31) (citing 61 Fed. Reg. 44510). A survey of Massachusetts youth in 2001-2002 similarly showed that that 33,000 youth aged 12-17 received mail directly from a tobacco company. Id. (citing Bogen, K., et al., "Consequences of marketing exceptions in the Master Settlement Agreement: Exposure of youth to adult-only tobacco promotions," 8 Nicotine & Tobacco Research 467, 469 (2006). Accordingly, the Court concludes that the lack of an exemption for direct mail to adults does not make the ban more extensive than necessary.

Plaintiffs' argument that "the Act bans the use of color or graphics in

tobacco-specialty shops even if youth are excluded from such shops and cannot possibly see the advertisements inside" is also uncompelling because Plaintiffs do not contend that such shops actually exist. (Plaintiffs' Brief, p. 30). Rather, they say that "'virtually all retailers of . . . tobacco products permit underage persons to enter their stores,'" (Plaintiffs' Brief, p. 5), and they note that "the only locations that readily come to mind that sell cigarettes and restrict access to persons 18+ are some bars and nightclubs, and such locations account for a very small percentage of cigarette sales (much less than 1%)." (Dunham Decl. ¶ 23); see also (Lindsley Decl. ¶ 50; Jones Decl. ¶ 25; Jennette Decl. ¶ 14; Terry Decl. ¶ 22; Hinton Decl. ¶ 8-9). The Court, accordingly, concludes that Plaintiffs lack standing to challenge this provision. Even if standing were satisfied, however, the Court would conclude that Congress reasonably tailored the ban to its interest because there is substantial evidence that minors are regularly exposed to tobacco advertising at ostensible adult-only facilities. (Government's Response, pp. 31-32) (citing Bogen et al., at 469) (referring to survey evidence that showed nearly half of Massachusetts youth aged 12-17, over 214,000 teens, were exposed to tobacco advertising inside "adult-only" stores).

Plaintiffs' claim that the cost of providing "competent and reliable" readership evidence before advertising in magazines "effectively prohibits color or graphic advertising in 99% of all publications" is also readily rejected. (Plaintiffs' Brief, p. 4-5) (citing Williard Decl. ¶¶16-23). For one thing, the total number of consumer magazines that have existing survey evidence concerning youth readership is irrelevant because

Plaintiffs have only identified two unsurveyed magazines—Playboy and The Arkansas Trooper—in which they wish to advertise. In addition, while they have said that it "could" cost "approximately $50,000-$100,000" to fund a readership survey "for a single large national magazine," (Plaintiffs' Brief, p. 5) (quoting Dunham Decl. ¶ 23), it is unclear whether Playboy is such a magazine, and certainly a small regional publication like The Arkansas Trooper is not, and would accordingly cost much less. Whatever the case may be, the Court finds that the requirement of "competent and reliable" evidence of magazine readership is crucial to ensure that the exception does not swallow the rule, and that the aforementioned costs are trivial for an industry that spent $13 billion to promote its products in 2005. See Legislative Finding 16.

Plaintiffs' expert alternatively suggests classifying magazines based on "their editorial content" or "the targeted audience to whom they were marketing" as a way of avoiding the imposition of such costs on the industry. (Williard Decl. ¶ 5). However, as the FDA explained in its rulemaking, the "concern is not with the 'intended' audience of the publication because there is no magic curtain between the interests of young adults and adolescents." 61 Fed. Reg. 44514. Because similar publications may have different levels of youth readership, the "only way of judging the likelihood that an advertisement that appears in a publication will be seen by those under the age of 18 is by considering the readership profile of that publication." Id. at 44518. The same reasoning applies to Plaintiffs' alternative suggestion that the exception be defined by reference to a subscriber list: minors may well read publications to which they do not subscribe. 61 Fed. Reg.

44517.13; see also (Dunham Decl. ¶ 23); (Williard Decl. ¶27) (acknowledging that People Magazine has more than 3.5 million readers aged 12 to 17).

Plaintiffs' last argument fares better. They are clearly right when they say that images of packages of their products, simple brand symbols, and some uses of color communicate important commercial information about their products, i.e., what the product is and who makes it. Bates, 433 U.S. at 364. The government's contrary suggestion—that all use of images in tobacco labels and advertising create noninformative associations of the sort likely to encourage minors to use a tobacco product—is plainly wrong. There is no suggestion in any of the literature cited by the government that symbols such as National's Beech-Nut chewing tobacco insignia, Conwood's sketch of its original Levi Garrett tobacco factory, the color of Lorillard's Newport menthol cigarette packaging, or illustrations such as Reynolds' depiction of how its new Camel Crush menthol product works, are a part of what Congress found to be problematic associative advertising techniques aimed at minors. Nor is it enough to say, as the government does, that these sorts of symbols and images can be replaced by text at no informational cost, for, at the very least, a symbol is often able to communicate the same information in a smaller amount of space and thereby leave more room for commercial speech.

The Court therefore concludes that the ban on color and graphics fails review. As the Supreme Court explained in Central Hudson, "[t]he regulatory technique may extend only as far as the interest it serves. The State cannot regulate speech that poses no danger

to the asserted state interest . . . nor can it completely suppress information when narrower restrictions on expression would serve its interest as well." Central Hudson, 447 U.S. at 565; cf. Zauderer, 471 U.S. at 648 (finding law unconstitutional where there was no "evidence or authority of any kind for [the government's] contention that the potential abuses associated with the use of illustrations in attorneys' advertising [could] not be combated by any means short of a blanket ban."). Because Congress could have exempted large categories of innocuous images and colors—e.g., images that teach adult consumers how to use novel tobacco products, images that merely identify products and producers, and colors that communicate information about the nature of a product, at least where such colors and images have no special appeal to youth—the Act's "blanket ban" on all uses of color and images in tobacco labels and advertising has a "uniformly broad sweep . . . [that] demonstrates a lack of tailoring." Lorillard, 533 U.S. at 563.

2. Brand-Name Event Sponsorship and Merchandise

a. Sponsorship

Congress also directed the FDA to reissue regulations that prohibit the sponsorship of athletic, social, and cultural events "in the brand name" of a tobacco product. Act § 102(a)(2); 21 C.F.R. § 897.34(c) (1997). The purpose of the regulation is to prevent the tobacco industry from using event sponsorships as a means of "associat[ing] tobacco use with exciting, glamorous, or fun events such as car racing and rodeos," 61 Fed. Reg. 44527, which is an associative technique that "is particularly effective with young people." Id. at 44521. As the Institute of Medicine put it, "The very purpose of

noninformational tobacco advertising is to associate smoking . . . with lifestyles and experiences that appeal to young people . . . . [and such] positive associations tend to displace or override risk information in adolescent decision making." 2007 IOM Report, at 322; see also Attorney General of Canada v. JTI-Macdonald Corp., 2007 SCC 30, ¶120 (explaining that "sponsorship promotion is essentially lifestyle advertising in disguise.").

Congress also found that "the exposure (which includes television broadcasts) of young people to sponsored events is substantial." 61 Fed. Reg. 44529. Indeed, at the time of the 1996 FDA rulemaking, it was estimated that more than 64 million children each year were exposed to tobacco-related advertising on television through auto-racing sponsorship. Id. at 44528; see also Philip Morris, 449 F. Supp. 2d at 664 ("millions of youth watching [televised racing] events are exposed to . . . cigarette marketing imagery"); 61 Fed. Reg. 44528 (explaining that NASCAR "'is a great kids' business'") (quotation omitted); see also 2008 NCI Report, at 158 ("[s]ports sponsorship in communities and on television has permitted Winston, Marlboro, Copenhagen, and Skoal to reach large numbers of youth and young adults in settings that facilitate sampling and promotions and to associate the brands with the allure of racing and rodeo heroes").

Plaintiffs argue that the ban on brand-name sponsorship is "unduly broad" because Congress did "not even attempt to differentiate between marketing practices directed at adults and those directed at youth." (Plaintiffs' Brief, p. 32). They say that while the Master Settlement Agreement permits "specified types of brand name sponsorships, including those in adult-only facilities like bars and nightclubs," the Act's ban on brand-

name event sponsorship would prohibit Lorillard's Newport Pleasure Draw blackjack tournament, which, they argue, will not advance Congress's goal since that tournament is "restricted to adult smokers" and held in an "adult-only facility" into which "minors are not allowed to enter." (Lindsley Aff. ¶¶ 60-63). Plaintiffs therefore conclude that because Congress could have achieved its goal by restricting less speech, e.g., by mimicking the MSA, the Act's ban is not narrowly tailored under Central Hudson. The Court disagrees.

The problem with Plaintiffs' argument is that the Act's ban is, in part, a reflection of Congress's view that the MSA is inadequate. See Legislative Finding 48. Because the MSA does not apply to non-signatories like Plaintiff Conwood, and because it permits signatories to have one "brand name sponsorship" each year, which is defined as "a single or multi-state series or tour," id. § II(j), "cigarette manufacturers have used auto racing sponsorships to successfully circumvent both the ban on televised cigarette advertising and the intent of the [MSA] not to target youth." Morrison, M.A., et al., "Inhaling and Accelerating: Tobacco Motor Sports Sponsorship In Televised Auto Races, 2000-2002," 15 Sports Marketing Quarterly 7, 12 (2006); see also Siegel, M., "Counteracting Tobacco Motor Sports Sponsorship as a Promotional Tool: Is the Tobacco Settlement Enough?," 91 Am. J. Pub. Health 1100, 1102-03 (2001) (predicting that "the tobacco settlement is unlikely to have any major [reductive] effect on the marketing of cigarettes through motor sports sponsorship."); Philip Morris, 449 F. Supp. 2d at 664 (finding that tobacco companies "increased their sponsorship budgets [after] signing the MSA."). In light of

this evidence, the Court believes that there is a reasonable fit between the ends and means of the sponsorship ban.[4]

b. Merchandise

Congress also directed the FDA to reissue regulations that preclude a tobacco manufacturer from distributing items such as caps, t-shirts, and sporting goods that bear the name or logo of a tobacco brand. § 102(a); 21 C.F.R. § 897.34(a) (1997). This is because obtaining branded merchandise "precedes, and reliably predicts, smoking initiation, even when controlling for other factors that have been shown to influence smoking uptake." National Cancer Institute, "Changing Adolescent Smoking Prevalence," at 206 (2001); see also Biener, L. & Siegel, M., "Tobacco Marketing and Adolescent Smoking: More Support for a Causal Inference," 90 Am. J. Pub. Health 407, 409 (2000) (intensive longitudinal study showing that brand-name merchandise influences smoking receptivity). Plaintiffs contend that the ban is more extensive than necessary to achieve Congress's goal because it "prohibits Plaintiffs from marketing their products by placing their brand-name on any promotional items—including items given solely to adult consumers in adult-only venues or to Plaintiffs' adult employees." (Plaintiffs' Brief, p. 12); see also § 102(a)(2) (adopting 21 C.F.R. § 897.34(a)). They say, for example, that "Conwood will be barred from using the Grizzly name or logo on

[4] To the extent Plaintiffs are arguing that the ban is unconstitutional as-applied to the Newport Pleasure Draw blackjack tournament, the Court disagrees for the same reason: brand-name sponsorship of that event reaches minors directly through media coverage of the event, regardless of the fact that minors themselves are not permitted to enter the casino.

'poker chips' even though such merchandise is given solely to adult tobacco consumers in connection with a legal purchase." (Jennette Decl. ¶ 51); see also (Dunham Decl. ¶ 37). The Court finds the provision sufficiently tailored.

Notwithstanding the fact that merchandise such as Conwood's poker chips are given solely to adult tobacco consumers, Congress found that "[t]here is no way to limit the distribution of these items to adults only." 61 Fed. Reg. 44526. Indeed, during the 1996 FDA rulemaking, the industry claimed that "it [was] already taking sufficient action to ensure that only adults get these items"; however, the evidence showed that "a substantial number of young people" had them. Id. at 44525-26 (citing a 1992 Gallup poll finding that nearly half of adolescent smokers – and more than a quarter of adolescent non-smokers – owned at least one tobacco-related promotional item). Moreover, even if such items were "distributed to adults only, [and retained by adults only,] this would not prevent the wearers from becoming walking advertisements that would continue to display the attractive imagery." 61 Fed. Reg. 44526. "Because [such items] penetrate the young persons' world, they are very effective in creating the sense that tobacco use is widely accepted, which . . . is extremely important to children and adolescents." Id. As the Institute of Medicine explained, the "ubiquity of such specialty items . . . conveys the impression that tobacco use is the norm," 1994 IOM Report, at 110, which in turn "fosters experimentation with tobacco and smokeless products by young people." 61 Fed. Reg. 44525 (citing 1994 IOM Report, at 110). Accordingly, the Court concludes that the Act's ban on brand-name tobacco product merchandise is not more extensive than necessary to

serve Congress's substantial interest in reducing youth tobacco use by reducing youth possession of and exposure to branded merchandise.[5]

3. Authorization of "Further Restrictions"

Plaintiffs next argue that the Act "further authorizes federal agencies, state and local governments, and Indian tribes to enact even 'more stringent' regulations. § 101(b)(3) (adding 21 U.S.C. § 387p(a)(1)); § 203 (adding 15 U.S.C. § 1334(c)). In their view, this "authorization" is an unconstitutional delegation of legislative power because the Act provides "'literally no guidance . . . for the exercise of discretion'—much less the constitutionally required 'intelligible principle.'" (Plaintiffs' Brief, p. 55) (quoting Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 474 (2001)). The Court disagrees. This provision does not *authorize* further restrictions, it simply states that it does not limit such restrictions: "nothing in this subchapter, or rules promulgated under this subchapter, shall be construed to limit the authority" of federal, state, local, and tribal governments to "adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter." 21 U.S.C. § 387p. As this language does not constitute a delegation of Legislative power, unconstitutional or otherwise, Plaintiffs' argument must

[5] The regulation also permits Plaintiffs to distribute items marked with their corporate names, 61 Fed. Reg. 44524 ("RJR may continue to sell or distribute hats and tee shirts with the name 'R.J. Reynolds' on them, but not the name 'Camel.'"), which surely satisfies any interest they may have in providing employees with "a simple way to bond and communicate pride in their team and work" and in "identifying the agent as a representative of the company." (Dunham Decl. ¶ 37).

be rejected.

4. Tobacco Product Warnings

Plaintiffs contend that the Act's warning requirement is unconstitutional because it "unjustifiably and unduly burden[s] Plaintiffs' commercial speech . . . [and] unconstitutionally compel[s] Plaintiffs to disseminate the Government's anti-tobacco message."[6] (Plaintiffs' Brief, p. 44). The provision mandates the use of updated "warnings" for cigarette packages that occupy the top 50% of the front and rear panels of packaging and include "color graphics depicting the negative health consequences of smoking to accompany the label statements." 21 U.S.C. § 201(a), (d). Similar warnings, occupying 30% of each of the two principal display panels, are required for smokeless tobacco products. Id. § 204(a); see also id. § 205(a) (authorizing the Secretary to require color images for smokeless tobacco products). For all categories of tobacco products, the new "warnings" must occupy 20% of any advertisments. Id. §§ 201(a), 204(a).

In support of their argument that the updated warning requirement is unconstitutional, Plaintiffs direct the Court to Ibanez v. Florida Dept. of Business and Professional Regulation, Bd. of Accountancy, 512 U.S. 136 (1994) and Entertainment Software Ass'n v. Blagojevich, 469 F.3d 641 (7th Cir. 2006). In Ibanez, a state regulatory board sought to require accountants who wished to use any type of privately-accredited "specialist" designation to include a disclaimer explaining that the

[6] They also argue that the expanded warning requirement "constitute[s] a per se taking." (Plaintiffs' Brief, p. 44). That argument is addressed separately below.

accrediting organization was not governmentally affiliated and setting forth the organization's accreditation requirements. Id. at 146. The Supreme Court held that "[g]iven the . . . the failure of the Board to point to any harm that is potentially real, not purely hypothetical[,] . . . the Board's action is unjustified." Id. The Court also found that the proposed disclaimer was unduly burdensome because the detail it 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.

In Entertainment Software Ass'n, the Seventh Circuit invalidated a state law requiring video game retailers to display a four square-inch "18" sticker on video games that fell within the state law's definition of "sexually explicit." Id. at 652. Because the the "18" sticker "force[d] the game-seller to include . . . a subjective and highly controversial message-that the game's content is sexually explicit," rather than just publish uncontroversial factual information, the court concluded that the law had to satisfy strict scrutiny—and it did not. The Seventh Circuit reasoned that the sticker "literally fail[ed] to be narrowly tailored" since "[t]he State ha[d] failed to even explain why a smaller sticker would not suffice." Id. at 652. Moreover, since 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," the court explained that it would not "condone the State's unjustified requirement of the four square-inch . . . sticker." Id.

Plaintiffs say that the Act's warnings are unjustified here "because, as in Ibanez,

the Government cannot 'point to any harm that is potentially real' . . . that these 'warnings' are needed to remedy." (Plaintiffs' Brief, p. 45). The reason is that the "only conceivable harm is consumer ignorance about the health risks of smoking . . . . [and] the record demonstrates that the public—both adults and youth—is not only fully aware of those risks, but, in fact, substantially overestimates them." Id. at 45-46; (Viscusi Decl. ¶¶ 28, 36-37, 41-43) (explaining that "[n]umerous national surveys demonstrate that over the last half century, the awareness of smoking-related risks is widespread" and noting that "surveys demonstrate that Americans perceive a significantly higher lost life expectancy due to smoking" than is warranted based on the Surgeon General's reports, and "young people overestimate the dangers of smoking to an even greater degree" than adults.).

Plaintiffs also argue that the warning requirement is "far more burdensome than the disclosure invalidated in Ibanez, id. at 146-47; the '18' label invalidated in Entertainment Software that covered just one-twentieth of the video game package, 469 F.3d at 652 & n.13; or the hypothetical and purely factual 'raw shellfish warning' in Entertainment Software that would have covered 'half of the space on a restaurant menu' and thus '[c]ertainly' exceeded anything the Constitution would allow, id. at 652." (Plaintiffs' Brief, p. 49). Because "the only place where color or imagery may be used, the 'warnings,' confiscate the top 50% of both sides of cigarette packaging (including shocking color graphics), and 30% of both sides of smokeless packaging," Plaintiffs contend that their speech will be "completely drown[ed] out" by the government's

message and the use of many of their existing packages will also be "effectively ruled out." Id. (quoting Ibanez, 512 U.S at 146-47).

Finally, Plaintiffs argue that the warning requirement must satisfy strict scrutiny (and that it does not) because this is not a case mandating publication of "purely factual and uncontroversial information," Zauderer, 471 U.S. at 651, but rather a case of "forcing Plaintiffs to become the mouthpieces for a Government marketing campaign designed . . . to promote the Government's subjective desire that consumers stop using tobacco products altogether." (Plaintiffs' Brief, p. 50); (Viscusi Decl. ¶ 68) (explaining that "[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.'"); cf. Entertainment Software Ass'n, 469 F.3d at 652. Even the Surgeon General's 1994 report, Plaintiffs' observe, acknowledged that 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" was mistaken. Id. ¶ 34.

The Court does not agree. Plaintiffs' entire argument rests on the idea that, since the public already appreciates the health risks associated with using tobacco products, the government's goal must be to browbeat potential tobacco consumers, including youths, over the head with its anti-tobacco message at the manufacturers' expense. But the government's goal is not to stigmatize the use of tobacco products on the industry's dime; it is to ensure that the health risk message is actually *seen* by consumers in the first

instance. In 1994, the Surgeon General reported that the few empirical studies dealing "with the visibility of cigarette warnings in advertising . . . consistently indicate that the Surgeon General's warnings are given little attention or consideration by viewers." 1994 Surgeon General's Report, at 168; see also id. at 19 (concluding that "although the shape of the warnings in smokeless tobacco advertisements may have been novel initially, the size and color of these warnings may now have a reduced effect" and finding that warnings on billboard advertisements were so small that passing motorists could read them only with "great difficulty.").

In 2007, the Institute of Medicine likewise declared that the "basic problems with the U.S. warnings are that they are unnoticed and stale, and they fail to convey relevant information in an effective way." IOM Report, at 291. In testimony to Congress, the Chair of the IOM's Committee on Reducing Tobacco Use described the warning on cigarette packs as "invisible." H.R. 1108, Family Smoking Prevention And Tobacco Control Act: Hearing Before the House Subcommittee on Health of the Committee on Energy and Commerce, 110th Cong. 42 (2007) (testimony of Richard Bonnie). Indeed, a study of warnings in magazine ads found that "more than 40 percent of subjects did not even view the warning," and that "an additional 20 percent looked at the warning but failed to actually read it." Id. The IOM Report also cited several studies showing that "that the U.S. text warnings on the side of packages demonstrate low levels of salience among smokers." 2007 IOM Report, at C-3. And, on top of this, it emphasized that graphical warnings "may be particularly important for communicating" with consumers

with low levels of education, given evidence that such smokers "are less likely to recall health information in text-based messages than people with more education." 2007 IOM Report, at 295, C-3 (finding that one study showed that the current warnings "require a college reading level" and thus "may be inappropriate for youth and Americans with poor reading abilities."). Based on this evidence, the Court finds Congress's decision to revise the content and format of the tobacco warnings justified.

Plaintiffs' argument that the new warnings are too large and too prominent is unpersuasive. Unlike Entertainment Software, where the state failed to give any reason for why a smaller warning would be inappropriate, Congress has provided reasons for the particular features of the warning requirement here. Most obviously, it relied on the international consensus reflected in the World Health Organization's Framework Convention on Tobacco Control, which calls for warnings that "shall be rotating," "shall be large, clear, visible and legible," "should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas," and "may be in the form of or include pictures or pictograms." WHO Framework Convention on Tobacco Control, art. 11.1(b). Its requirements track this recommendation: warnings on cigarette packs must include images and "comprise the top 50 percent of the front and rear panels," § 1333(a)(2); warnings on smokeless tobacco packs may include images and must be "located on the 2 principal display panels of the package," and "comprise 30 percent of such display," § 4402(a)(2); and warnings in "press and poster advertisements" must comprise 20% of the area of the advertisement. Id. §§ 1333(b)(2), 4402(b)(2)(B). This is

not, as Plaintiffs contend, too burdensome, for half of cigarette packs, 70% of smokeless tobacco packages, and 80% of advertisements remain available for their speech.

Congress also informed its warning requirement by looking at the use of a nearly identical warning requirement in Canada. See 2007 IOM Report, at 291-92 (example of a Canadian package warning) (reproduced at Addendum B1); H.R. 1108, Family Smoking Prevention And Tobacco Control Act: Hearing Before the House Subcommittee on Health of the Committee on Energy and Commerce, 110th Cong. 36 (2007) (testimony of Richard Bonnie). Studies of Canadian smokers have shown that more than half "reported that the pictorial warnings have made them more likely to think about the health risks of smoking" and that "approximately 95 percent of youth smokers and 75 percent of adult smokers report that the pictorial warnings have been effective in providing them with important health information." 2007 IOM Report, at 294. One study comparing Canadian and U.S. warnings found that while "83 percent of Canadian students mentioned health warnings in a recall test of cigarette packages," only "7 percent of U.S. students" did the same. 2007 IOM Report, at C-3 to C-4.

Finally, this is not a case, like Entertainment Software, where strict scrutiny is required. The government message in that case was "subjective" and "controversial"; in this case, the government's message is objective and has not been controversial for many decades: e.g., 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. 15 U.S.C. § 1333.[7] The Court does not believe that the addition of a graphic image will alter the substance of such messages, at least as a general rule. Accordingly, and for all of the above reasons, the Court finds that the warning requirement is sufficiently tailored to advance the government's substantial interest under Central Hudson.

5. Modified Risk Tobacco Products

Plaintiffs argue that the Modified Risk Tobacco Product ("MRTP") provision is an unconstitutional prior restraint; an unconstitutional restriction on Plaintiffs' commercial speech; an unconstitutional restriction on Plaintiffs' core speech; and unconstitutionally vague. (Plaintiffs' Brief, pp. 22-29); (Plaintiffs' Preliminary Injunction Reply, pp. 1-14). The Court largely rejected these arguments in its Memorandum Opinion and Order denying Plaintiffs' motion for a preliminary injunction on November 5, 2009. It first noted the "difficulty" of deciding whether the MRTP provision implicated the First Amendment in its regulation of modified risk tobacco products by using speech as evidence of intent to market such a product. (Order, p. 5). Because of this, the Court concluded that it was "best to assume for purposes of this preliminary injunction motion

[7] Indeed, the Seventh Circuit itself rejected such a conclusion when it explained that the "18" sticker in Entertainment Software was "unlike a surgeon general's warning of the carcinogenic properties of cigarettes," precisely because the former "communicate[d] a subjective and highly controversial message" and the latter did not. Id. at 652.

that the MRTP provision regulates speech and must satisfy the First Amendment," id., and it went on to determine that the provision regulated commercial speech and facially satisfied the standard set out in Central Hudson. Id. at 6, 9. Plaintiffs now emphasize in their response that they are also challenging the provision "as applied," (Plaintiffs' Response, p. 38), and they present new arguments regarding the constitutionality of the MRTP provision as a prior restraint. The Court considers these arguments in turn.

a. As Applied

Plaintiffs emphasize in their summary judgment response that they are challenging the constitutionality of the MRTP provision as applied to "the 60 Minutes interview . . ., their statements on their websites about the public debate over tobacco harm reduction, and the various other statements identified in Plaintiffs' declarations, testimony, and briefs." (Plaintiffs' Response, p. 38); (Amended Complaint, ¶ 170). However, the exact number of statements, and in some cases their content, is not entirely clear. But even if it were, the exercise has convinced the Court that the approach adopted by the United States Court of Appeals for the District of Columbia Circuit in Whitaker v. Thompson, 353 F.3d 947 (D.C. Cir. 2004) is correct. Because what the MRTP provision bans is the "introduc[tion] or deliver[y] for introduction into interstate commerce" of a modified risk tobacco product without prior FDA approval, and because a manufacturer's speech is only used to determine whether a product is sold "for [such] use," the Court concludes that provision does not implicate the First Amendment outside of the context of the

proposed advertising and labels submitted as part of an MRTP application. 21 U.S.C. § 387k(b)(1), (b)(2)(A); see generally (Order, p. 4-5).

b. Prior Restraint

The Court, as mentioned, still agrees with Plaintiffs' argument that the MRTP provision operates as a prior restraint on speech to the extent that it "requir[es] applicants to submit 'proposed advertising and labeling' and 'sample product labels and labeling' with their applications to market modified risk tobacco products" and holds that speech captive until the FDA completes its review. (Order, pp. 19, 23) (quotations omitted). At the time of the Court's November 5, 2009 Order, Plaintiffs had not filed an application to market a modified-risk tobacco product. Because of this, and because a 540-day review period in a similar circumstance was found constitutionally permissible, see Nutritional Health Alliance v. Shalala, 144 F.3d 220 (2d Cir. 1998), the Court concluded that Plaintiffs were not entitled to a preliminary injunction.

Since that time, the FDA has proposed a 360-day time period for review of an MRTP application. See Draft Guidance for Industry and FDA Staff: Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products under the [FDCA] (Nov. 25, 2009). Plaintiffs argue that the constitutional deficiency, i.e., the lack of a reasonable time limit, is not fixed by the FDA's proposed timeline since that timeline is not binding: "This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public." Id. The

Court agrees. Ruling on the reasonableness of the FDA's proposed 360-day period for review of modified risk tobacco products would, at this point, be tantamount to issuing an advisory opinion, which this Court may not do. But the government now also directs the Court to a provision in the Administrative Procedure Act that "imposes a general but nondiscretionary duty upon an administrative agency to pass upon a matter presented to it 'within a reasonable time,' 5 U.S.C. § 555(b), and authorizes a reviewing court to 'compel agency action unlawfully withheld or unreasonably delayed,' id. § 706(1)." Mashpee Wampanoag Tribal Council, Inc. v. Norton, 336 F.3d 1094, 1099 (D.C. Cir. 2003). The Court finds this provision sufficient to satisfy the reasonable time limit requirement, until such time as the FDA formally adopts one pursuant to § 387k(l)(1)(F).

Plaintiffs also object to the Court's earlier order denying a preliminary injunction of the MRTP provision on the grounds that the Court ignored their viewpoint discrimination argument; mistakenly relied on FW/PBS, Inc. v. City of Dallas, 493 U.S. 215 (1990) for the proposition that the FDA is not required to bear the usual burden-of-proof procedural safeguard outside of the context of content-neutral regulations; and overlooked their challenge to the portions of the prior restraint scheme that cover "any action directed to consumers" and statements that reasonably might cause consumers to believe that a tobacco product "may present a lower risk of disease." § 101(b)(3). (Plaintiffs' Brief, p. 53). A brief response is warranted. First, the Court's citation to FW/PBS, Inc. was not for its precise holding, but for the Supreme Court's conclusion that the First Amendment does not require the same procedural safeguards in all

circumstances—i.e., that the necessity of a safeguard in a particular context depends on whether the reasons for that particular safeguard make sense in the context. (Order, p. 10). Here, the Court does not believe the First Amendment requires the burden to be on the government when that burden is not related directly to speech but to showing that a regulated product should be approved for sale.

For this same reason, the Court does not believe that the MRTP provision is a viewpoint-based restriction on speech. The hallmark of unconstitutional viewpoint discrimination is the government's prohibition of speech or expressive conduct because of its disapproval of the idea expressed. R.A.V. v. City of St. Paul, Minn., 505 U.S. 377, 387-88 (1992). As Justice Stevens explained in Consolidated Edison Co. v. Public Service Comm'n, of N.Y., 447 U.S. 530, 546, (1980), "A regulation of speech that is motivated by nothing more than a desire to curtail expression of a particular point of view on controversial issues of general interest is the purest example of a 'law . . . abridging the freedom of speech, or of the press.'" Id. This is not such a regulation. Here, the government is not proscribing a viewpoint, e.g., that smokeless tobacco products pose less health risks than other tobacco products; it is requiring tobacco manufacturers to go through a process of having their regulated product approved for sale as "modified risk" before making untested claims about the relative health benefits of that product. Non-manufacturers are free to express the ostensibly-suppressed viewpoint, and even

manufacturers may do so after their product is approved for the purposes for which it is intended to be marketed.[8]

Plaintiffs' third argument is no more persuasive. While the Court did not specifically address Plaintiffs' reference to the portions of the prior restraint scheme that cover "any action directed to consumers" and statements that reasonably might cause consumers to believe that a tobacco product "may present a lower risk of disease," § 101(b)(3), the Court's determination that the MRTP provision "provides an objective standard by which Plaintiffs may judge their conduct," applies broadly to the whole provision. Plaintiffs' citation to United Food & Commercial Workers Union v. Sw. Ohio Reg'l Transit Auth., 163 F.3d 341 (6th Cir. 1998) does not convince the Court otherwise. In that case, the Sixth Circuit found that a statute was unconstitutionally vague, in part, because the statute's use of the word "may" failed to limit governmental discretion by making the statute's use of the word "controversy" any less subjective, id. at 360; here, contrary to Plaintiffs' suggestion, any subjectivity in the MRTP provision's use of the words "may" and "any action" are rendered objective by the inclusion of "directed to consumers" and "reasonably be expected"—not the other way around. Accordingly, the Court finds, for the reasons outlined here and in its November 5, 2009 Order, that summary judgment for the government is proper on Plaintiffs' constitutional challenge to the MRTP provision.

[8] The impact of 21 U.S.C. § 331(tt)(4) is a separate issue, which the Court addresses in the following subsection.

6. Claims Implying FDA Approval

Next is Plaintiffs' claim that the ban on mentioning the FDA's regulation of tobacco products is unconstitutional. The provision prohibits "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 [FDA]; (2) the [FDA] deems the product to be safe for use by consumers; (3) the product is endorsed by the [FDA] for use by consumers; or (4) the product is safe or less harmful by virtue of – (A) its regulation or inspection by the [FDA]; or (B) its compliance with regulatory requirements set by" the FDA. 21 U.S.C. § 331(tt). Plaintiffs' challenge is to part (4). They argue that "almost any public comment on these 'product standards,' other than perhaps a comment denigrating them, could be construed as an 'implied' statement that they made Plaintiffs' products 'less harmful,' since that is, after all, their express purpose." (Plaintiffs' Brief, p. 34). And they say that the provision's "uniform breadth . . . reveals a lack of narrow tailoring and is overinclusive." Id. The Court agrees.

The government's contention that the ban would not extend to "news organizations" and "politicians," (Government's Response, p. 23), rests not on any clear distinction in the statute, but on the assumption that those categories of speakers would have no need to make statements through the media "directed to consumers with respect to a tobacco product." 21 U.S.C. § 331(tt). That is simply untenable. Surely journalists, doctors, scientists, politicians, and numerous other groups and individuals with access to

the media have an interest in and are capable of making statements about the effect of the FDA regulation that are "directed to consumers with respect to a tobacco product." Id. It is therefore without question that the ban applies to more than just commercial speech and must satisfy strict scrutiny. United States v. Playboy Entm't Group, Inc., 529 U.S. 803, 813 (2000); see also Bd. of Trs. of SUNY v. Fox, 492 U.S. 469, 481-82 (1989) (explaining that the overbreadth doctrine allows commercial speakers to facially challenge a speech restriction based on its application to the non-commercial speech of others). Because the government has not even attempted to justify the ban under the strict scrutiny standard, and because it seems clear that it cannot be so justified,[9] the Court finds 21 U.S.C. § 331(tt)(4) facially unconstitutional.[10]

7. The Ban on Outdoor Advertising

Plaintiffs also argue that the Act's nationwide ban on outdoor advertising within 1,000 feet of a school or playground is unconstitutional. Because that ban is indistinguishable from the Massachusetts' ban the Supreme Court struck down in

[9] For one thing, it is not clear why provisions (1)-(3) are insufficient to meet the government's asserted interest in preventing misleading information being given to consumers. For another thing, provision (4) does not seem to advance that interest, not least because it makes no exception for statements about products the FDA has already approved as modified risk.

[10] In its response, the government also argues, without citation to any law, that "plaintiffs identify no statement about the FDA's role that gives rise to a live controversy over this provision" and concludes that "[s]uch conjecture does not provide a basis for a constitutional challenge." (Government's Response, pp. 23-24). The Court disagrees. The Plaintiffs are not challenging any currently nonexistent substantive regulation, but a currently existing restriction on speech. Nor, as the government suggests, is that speech restriction clearly limited to narrow statements about the actual effect of compliance with FDA tobacco "standards [that have yet to be developed] through future rulemaking." Id. It also apparently applies to any general suggestion that future compliance with FDA regulation will make a tobacco product safer.

Lorillard, Plaintiffs are undoubtedly right. Compare § 102(a)(2) (adopting 21 C.F.R. § 897.30(b)), with 533 U.S. at 556. However, before the provision takes effect, Congress has instructed the Secretary to "include such modifications [to the outdoor advertising ban], if any, that the Secretary determines are appropriate in light of governing First Amendment case law." § 102(a)(2)(E). The Secretary must issue as a "final" regulation on March 22, 2010, §§ 6(c)(1), 102(a)(1), which will be conclusively "deemed to be in compliance" with the APA, and will go into effect on June 22, 2010, § 102(a)(2)(F). The Court therefore concludes that Plaintiffs' First Amendment challenge to the ban on outdoor advertising is unripe. Renne v. Geary, 501 U.S. 312, 320 (1991) (plaintiff alleging First Amendment violation must "demonstrate a live dispute involving the actual or threatened application of [a statute or policy] to bar particular speech").

Plaintiffs argue that their challenge is ripe because, since it will take them more than three months to comply with any modified regulation, they are presently put to a Hobson's choice: "either surrender their constitutional rights and cease all outdoor advertising within 1,000 feet of a school or public playground area or guess at what the FDA will ultimately do and risk violating the regulation if, as is eminently likely, they guess wrong." (Plaintiffs' Brief, p. 31; Plaintiffs' Response, p. 24). They contend that this choice is analogous for First Amendment purposes to the compelled oath in Speiser v. Randall, 357 U.S. 513 (1958), because it coerces them into relinquishing their free speech rights. The Court rejects the comparison. All other distinctions aside, the basic problem with Plaintiffs' characterization is that any coercion in this case is the result of their

decision to plan their advertising many months in advance, not Congress's direct or intentional attempt to get them to waive their rights under the First Amendment.

Nor does the Court find Plaintiffs' argument that the outdoor advertising ban violates their Due Process rights compelling. Surely Congress, which created the APA's notice and comment requirement, can "deem" a regulation to comply with that requirement, or get rid of the requirement altogether, when and if it so chooses without violating the Fifth Amendment. See, e.g., 5 U.S.C. § 553(b). Statutory process rights, after all, may satisfy Due Process – but they do not define it. The gist of Plaintiffs' argument, therefore, is that Due Process requires them to have *some* opportunity to be heard by the FDA after it makes modifications to the ban. (Plaintiffs' Brief, p. 32); see generally Bd. of Regents v. Roth, 408 U.S. 564, 570 (1971). However, because Plaintiffs have already been heard on this issue at various times throughout the lengthy history of this regulation-now-turned-legislation, and because the only task before the Secretary is to conform the earlier ban to existing case law, the Court does not believe that Due Process requires such a hearing here.

8. Non-Speech-Restrictive Alternatives

Plaintiffs also contend that the speech-restrictive provisions of the Act individually and collectively violate the First Amendment because "there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech." (Plaintiffs' Brief, p. 16) (quoting Discovery Network, 507 U.S. at 417 n.13); see also BellSouth Telecommunications, Inc. v. Farris, 542 F.3d 499, 509 (6th Cir. 2008) (same). Congress,

they say, was "well aware of many such alternatives that, according to the public health community—including the very government agencies tasked with regulating in this area and the very amici devoted to the same—would dramatically advance the Act's interest in reducing tobacco use; yet Congress bypassed these alternatives and, instead, went straight to Plaintiffs' speech." Id. They argue that Congress should have considered numerous alternatives: preventing the unlawful retail sale of tobacco products to youth by, e.g., "increas[ing] the compliance rate" required by the Synar Amendment, Pub. L. No. 102-321, § 1926[11]; requiring states to use CDC-recommended levels of tobacco revenues for tobacco control programs; raising the legal age to purchase, possess, or consume tobacco products to 19 years; increasing the price of tobacco products; increasing support for interventions that address the personal and social factors that influence tobacco use; improving penalties for underage tobacco use; enforcing strict policies regarding tobacco possession or use by anyone at schools; increasing penalties for adults who unlawfully provide tobacco products to minors; and prohibiting smoking in all workplaces with employees below the legal smoking age. (Plaintiffs' Brief, pp. 19-23).

The government counters that Plaintiffs' proposals are "variations on strategies already adopted . . . notable for the extent to which they would impose substantial new costs on state and local governments and private persons . . . . to counter the impact that

[11] The idea being that "states would lose federal block grants if they failed to achieve a violation rate of less than, say, 5%, and to require that non-compliant states lose block grants rather than leaving that determination to [the Substance Abuse and Mental Health Services Administration]'s discretion" Id.

[Plaintiffs'] billions of dollars of advertising has on youth." (Government's Response, p. 36). The Act, the government explains, already bars tobacco sales to persons under age 18; requires age verification through age 26; prohibits sales through vending machines except in adult-only facilities, § 102; 21 C.F.R. §§ 897.14, 897.16 (1997); provides civil penalties for retailer violations, 21 U.S.C. §§ 331(oo), 333(f)(5); directs the Secretary to "implement a program to ensure compliance," id. §§ 387a-1(a)(2)(G), (a)(5); and requires the FDA to convene an expert panel to study the implications of raising the minimum age to purchase tobacco products. § 104. Beyond this, the government says that strengthening the Synar Amendment would hardly be less burdensome; and it would also have dubious impact since there is "little evidence that increased retailer compliance has had a meaningful impact on the availability of tobacco to minors or that retailer compliance has had any independent effect in reducing the rates of youth smoking initiation or levels of cigarette consumption," (Government's Response, p. 37) (quoting 2007 IOM Report, at 204), because "[m]inors tend to 'shift to social sources' of cigarettes, such as older friends and siblings, 'when commercial sources become problematic.'" Id.; cf. (Reynolds Decl. ¶ 40).

The government also observes that Congress already discourages youth demand by increasing the price of tobacco products. In February 2009, for example, the President signed into law a 62-cent increase in the federal excise tax on cigarettes, along with similar increases on smokeless tobacco products. Children's Health Insurance Program Reauthorization Act of 2009, Title VII, § 701, Pub. L. No. 111-3, 123 Stat. 8, 106-107

(2009). This raised the federal cigarette tax from 39 cents to $1.01 per pack, bringing the combined federal and average state excise tax for cigarettes to $2.21 per pack. Centers for Disease Control, "Federal and State Cigarette Excise Taxes – United States, 1995-2009," 58 Morbidity & Mortality Weekly Rep. 524 (2009). And, in any event, the government explains that increasing tobacco prices has its costs—e.g., it unfairly burdens low-income users and promotes purchases through lower-tax venues such as Native American reservations and the Internet[12]—and limitations—e.g., tobacco companies use targeted discounts to "population subgroups that are more price-sensitive (e.g. young smokers not yet addicted), countering the depressing effect of general price increases on smoking." (Government's Response, p. 39) (quoting Pierce, J. et al., "Tobacco Industry Price-Subsidizing Promotions May Overcome the Downward Pressure of Higher Prices on Initiation of Regular Smoking," 14 Health Economics 1061, 1066-67 (2005)). Finally, the government argues that it would not be "less burdensome" to increase penalties on minors falling victim to the "industry's advertising techniques" rather than directly curtailing those techniques. Id. The Court generally agrees with the government.

Plaintiffs' argument is premised on the idea that "[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

[12] See also "Stop Tobacco Increases", http://www.NoCigTax.com (Reynolds website) (last visited December 12, 2009); Campaign for Tobacco-Free Kids, Press Release (May 8, 2003) (noting that "Lorillard's ads, which are running in Delaware, New Jersey and Pennsylvania, argue that cigarette tax increases lead to increased crime and cigarette smuggling").

trick." (Plaintiffs' Brief, p. 26) (quoting BellSouth, 542 F.3d at 508); see also Western States, 535 U.S. at 373. However, that is precisely what Congress has done here. Contrary to Plaintiffs' contention, this is not a case where Congress went "straight to [their] speech." (Plaintiffs' Brief, p. 19). This is a case where Congress, after decades of implementing various measures that did not affect Plaintiffs' speech, decided to add label and advertising restrictions to its comprehensive regulation of the tobacco industry. That decision seems eminently reasonable, too, since every other tool in the government's arsenal is made less effective and more costly by Plaintiffs' use of advertising "to stimulate underage demand." (Government's Response, p. 40). Accordingly, the Court rejects Plaintiffs' contention that the existence of "numerous obvious non-speech-restrictive alternatives" renders the Act's speech restrictions unconstitutional for lack of tailoring.

B. Samples, Gifts with Purchase, and Combination Marketing

Plaintiffs also advance a First Amendment challenge to the Act's restrictions on their ability to offer free samples of tobacco products; provide gifts with the purchase of tobacco products; and market their products with non-tobacco products. (Amended Complaint ¶¶ 95, 158). The Court does not believe any of these provisions implicate, let alone violate, Plaintiffs' free speech rights. First, notwithstanding Plaintiffs' contention that free samples are "'one of the most effective means of communicating' a product's superior qualities to a consumer of a competitor's product," (Plaintiffs' Brief, p. 33) (quoting Dunham Decl. ¶ 48), the Act's ban on free samples clearly regulates the

distribution of a product, not speech—and, even if thought of as a speech restriction, it would seem fully permissible as a restriction on price, i.e., tobacco products cannot be free. 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 507 (1996) (describing price regulation as an "alternative form[] of regulation that would not involve any restriction on speech"). Second, the Court does not believe Plaintiffs have any First Amendment interest in rewarding purchasers of tobacco products with "prizes, such as MP3 players, digital cameras, and prepaid gift cards from the Discover Network." (Amended Complaint ¶¶ 95, 158).

Third, as the government explains, the co-marketing ban does not implicate the First Amendment because it "prohibits the marketing of a tobacco product 'in combination with any other article or product regulated under [the FDCA] (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement)," 21 U.S.C. § 321(rr)(4)," which means that it "prohibits the physical combination of a tobacco product with an FDA-regulated non-tobacco product (such as a soda that contains nicotine derived from tobacco); the physical packaging of a tobacco product together with a regulated non-tobacco product (such as soda and cigarettes packaged together in a shrink-wrapped container); or a 'package deal' in which discounts for regulated non-tobacco products are conditioned on the purchase of tobacco products." (Government's Brief, p. 50) (citing Draft Guidance for Industry and FDA Staff: The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act, Section II.A (Sept. 30, 2009)). As

such, any impact these regulations have on Plaintiffs' speech is incidental and outside the scope of the First Amendment. See Philip Morris USA Inc. v. City & County of San Francisco, No. 08-17649, 2009 WL 2873765, at *1 (9th Cir. Sept. 9, 2009) (explaining that "[s]elling cigarettes isn't [protected activity] because it doesn't involve conduct with a 'significant expressive element.'") (quoting Arcara v. Cloud Books, Inc., 478 U.S. 697, 701-02, 706 (1986)).

C. Takings

Finally, Plaintiffs contend that the Act's mandated warning requirement "deprives [them] of their trademarks, trade dress, packaging, and advertising without just compensation," and is "no different than if the Government confiscated half of every billboard for a message on any other issue of public policy." (Amended Complaint ¶¶ 66, 119); (Plaintiffs' Brief, p. 52) (citing Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency, 535 U.S. 302, 324 (2002)). The government counters that, in addition to being meritless, Plaintiffs' takings claim must be brought "in the Court of Federal Claims under the Tucker Act" and is therefore outside this Court's jurisdiction. Plaintiffs, in turn, argue that jurisdiction is properly in this Court because they do not seek monetary compensation but injunctive and declaratory relief; they also contend that jurisdiction is proper because "'Congress could not have contemplated that the Treasury would compensate' Plaintiffs for the taking because the challenged law 'requires a direct transfer of funds'" (Plaintiffs' Response, p. 34) (quoting E. Enters. v. Apfel, 524 U.S. 498, 521

(1998) (plurality opinion). The Court agrees with the government on the question of jurisdiction.

It is true, as Plaintiffs note, that some courts have "accepted the view that the Tucker Act does not apply to suits seeking only equitable relief." E. Enters., 524 U.S. 498 (citing In re Chateaugay Corp., 53 F.3d 478, 493 (2d Cir. 1995) and Southeast Kansas Community Action Program, Inc. v. Secretary of Agriculture, 967 F.2d 1452, 1455-1456 (10th Cir. 1992)). However, the Supreme Court has acknowledged that "other[] [courts] have concluded that a claim for equitable relief under the Takings Clause is hypothetical, and therefore not within the district court's jurisdiction, until compensation has been sought and refused in the Court of Federal Claims." Id. (citing Bay View, Inc. v. Ahtna, Inc., 105 F.3d 1281, 1286 (9th Cir. 1997) and Rose Acre Farms, Inc. v. Madigan, 956 F.2d 670, 673-674 (7th Cir. 1997)). And it went on to say that "this Court's precedent can be read to support the latter conclusion that regardless of the nature of the relief sought, the availability of a Tucker Act remedy renders premature any takings claim in federal district court." Id. (citing Preseault v. ICC, 494 U.S. 1, 11 (1990) and Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1016 (1984)). Because the Sixth Circuit appears to have adopted this latter view, see Coalition for Government Procurement v. Federal Prison Indus., Inc., 365 F.3d 435, 479 (6th Cir. 2004), Plaintiffs' first argument in favor of jurisdiction must be rejected.

Plaintiffs' second argument in favor of jurisdiction is based on the Supreme Court's determination in E. Enters. that holding a district court action premature until

after adjudication in the Court of Federal Claims under the Tucker Act would be "utterly pointless" where "it [could not] be said that monetary relief against the Government is an available remedy" since the challenged statute "'rather than burdening real or physical property, requires a direct transfer of funds' mandated by the Government." Id. at 521 (quoting In re Chateaugay Corp., 53 F.3d at 493). The logic behind this rule is that where Congress has set up an alleged taking in the form of a cash transfer, it has implicitly "withdrawn the Tucker Act grant of jurisdiction . . . to hear [the claim for compensation]." Preseault, 494 U.S. at 12; accord Student Loan Marketing Ass'n v. Riley, 104 F.3d 397, 402 (D.C. 1997) (reading the applicable Supreme Court precedent to say that "in cases involving straightforward mandates of cash payment to the government, courts may reasonably infer either that Tucker Act jurisdiction has been withdrawn or at least that any continued availability does not wipe out equitable jurisdiction.").

Contrary to Plaintiffs' contention, this is not such a case. Although, as they emphasize, the Act includes a transfer of funds to the Government in the form of "user fees," § 101(b)(3) (adding 21 U.S.C. § 387s), that transfer is not the alleged "taking." The purported taking is the "physical" invasion of Plaintiffs' "trademarks, trade dress, packaging, and advertising." (Amended Complaint ¶¶66, 119). While Congress *may* not have contemplated that the Treasury would compensate Plaintiffs for the taking allegedly perpetrated by the Act (when that would, in Plaintiffs' view, simply off-set the Act's fees), it surely *could* have. This is because unlike in E. Enters and similar decisions, this case does not involve a situation where "[e]very dollar paid pursuant to a statute would be

presumed to generate a dollar of Tucker Act compensation," since the value of the alleged "physical" taking and the amount paid as statutory "user fees" are separate and distinct. Id. at 521 (quoting In re Chateaugay Corp., 53 F.3d at 493); see also Student Loan Marketing Ass'n, 104 F.3d at 402. The upshot is that resort to the Tucker Act would not be "utterly pointless" in this case, such that the Court could reasonably infer that Congress withdrew its "presumption" in favor of initial jurisdiction in the Court of Federal Claims. Coalition for Government Procurement, 365 F.3d at 479. Accordingly, the Court concludes that it lacks jurisdiction to address the merits of Plaintiffs' takings claim.

* * *

To the extent Plaintiffs have alleged that the Modified Risk Tobacco Product provision violates their Due Process rights (Amended Complaint, p. 44); that, other than what is addressed above, provisions of the Act are unconstitutional under the First Amendment as-applied to Plaintiffs' speech or as prior restraints on speech, (Amended Complaint, ¶ 170); and that provisions other than the warning requirement constitute unconstitutional takings in violation of the Fifth Amendment, (Amended Complaint, ¶ 168), they have not pursued these arguments in their memoranda, and the Court concludes that summary judgment in favor of the government on these claims warranted.

IV. CONCLUSION

For the foregoing reasons, **IT IS HEREBY ORDERED** that Plaintiffs' motion for summary judgment is **GRANTED IN PART** and **DENIED IN PART.** It is **GRANTED** as to the ban on color and graphics in labels and advertising, Pub. L. No. 111-31, § 102(a)(2), and the ban on claims implying that a tobacco product is safer because of FDA regulation, 21 U.S.C. § 331(tt)(4). It is **DENIED** in all other respects. The Defendants' motion for summary judgment is, respectively, **GRANTED IN PART** and **DENIED IN PART**. It is **DENIED** as to Pub. L. No. 111-31, § 102(a)(2) and 21 U.S.C. § 331(tt)(4). It is **GRANTED** in all other respects.

IT IS FURTHER ORDERED that the Defendants United States of America; United States Food and Drug Administration; Margaret Hamburg, Commissioner of the United States Food and Drug Administration; and Kathleen Sebelius, Secretary of the United States Department of Health and Human Services, are permanently enjoined from enforcing Pub. L. No. 111-31, § 102(a)(2) and 21 U.S.C. § 331(tt)(4). A judgment will be entered consistent with this Opinion.

Joseph H. McKinley, Jr., Judge
United States District Court
January 4, 2010

cc. Counsel of Record