UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY
BOWLING GREEN DIVISION

COMMONWEALTH BRANDS, INC.; CONWOOD COMPANY, LLC; DISCOUNT TOBACCO CITY & LOTTERY, INC.; LORILLARD TOBACCO COMPANY; NATIONAL TOBACCO COMPANY, L.P.; and R. J. REYNOLDS TOBACCO COMPANY,	*	
Plaintiffs,	*	CIVIL ACTION NO. 1:09CV-117-M
v.	*	(Electronically Filed)
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 IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION OF PLAINTIFFS COMMONWEALTH BRANDS, INC., CONWOOD COMPANY, LLC, DISCOUNT TOBACCO CITY & LOTTERY, INC., NATIONAL TOBACCO COMPANY, L.P., AND R. J. REYNOLDS TOBACCO COMPANY

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TABLE OF ABBREVIATIONS

Term	Description
Act	Family Smoking Prevention and Tobacco Control Act, Public Law No. 111-31 (2009)
APA	Administrative Procedures Act, 5 U.S.C. § 551 *et seq*.
FCLAA	Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331 *et seq*.
FDA	United States Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*.
MRTP	Modified Risk Tobacco Product
MSA	The November 1998 Master Settlement Agreement between certain tobacco companies and certain state Attorneys General

INTRODUCTION

"[S]o long as the sale and use of tobacco is lawful for adults, the tobacco industry has a protected interest in communicating information about its products and adult customers have an interest in receiving that information." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571 (2001). The Family Smoking Prevention and Tobacco Control Act, Public Law No. 111-31 (2009) (the "Act"), ignores this command and imposes unprecedented restrictions on Plaintiffs' First Amendment rights by cutting off virtually every meaningful avenue of speech about their products. It cripples Plaintiffs' ability to communicate through its many restrictions on advertising in magazines, on packaging, through direct mail, and at retail points-of-sale throughout the country. And it cuts off the remaining thoroughfares of speech, such as brand name sponsorship of artistic events in adult-only venues. Indeed, the Act goes so far as to impose sweeping restrictions on Plaintiffs' participation in core scientific and policy debates about tobacco products—a blatant challenge to core free speech that is subject to the highest level of protection and scrutiny.

The Government bears a great burden when, as here, it seeks to close off speech. At a minimum, it must show not only that these restrictions will directly and materially advance a substantial governmental interest, but also that they are precisely and narrowly drawn. The Government thus purports to adopt these radical, sweeping speech restrictions to reduce youth tobacco use. Plaintiffs fully support this objective and the restrictions (some imposed by law and many adopted voluntarily) that genuinely further that goal. But here, the Government gave *no* meaningful consideration to whether the Act would significantly and directly advance that objective and the Act's provisions broadly restrict *all* speech, regardless of whether it is aimed at or reaches youth. "'[T]he governmental interest in protecting children from harmful materials,'" however, "'does not justify an unnecessarily broad suppression of speech addressed to adults.'" *Lorillard*, 533 U.S. at 564 (citation omitted). Congress cast aside the repeated admonition that "'[t]he level of

discourse reaching a mailbox simply cannot be limited to that which would be suitable for a sandbox.'" *Reno v. ACLU*, 521 U.S. 844, 875 (1997) (citation omitted).

Certain Plaintiffs (hereinafter referred to as "Plaintiffs")[1] are presently being harmed by two of the challenged provisions of the Act that have already taken effect—the Modified Risk Tobacco Products requirement ("MRTP Requirement") (Count Three), *see infra* at Part I.B, and the ban on jointly marketing tobacco products with other FDA-regulated products ("Co-Marketing Ban") (Count Nine), *see infra* at Part I.C. Accordingly, Plaintiffs presently seek a preliminary injunction against these two provisions. Although this Court need only resolve the likelihood of success on these two provisions to grant the requested preliminary injunction, this brief explains the unconstitutional nature of all of the Act's provisions challenged in this suit because (1) a full understanding of the Act as a whole is necessary to understand the context in which the two immediately challenged provisions are applied; and (2) Plaintiffs are simultaneously seeking to have this case fully adjudicated on an expedited basis to avoid further irreparable harm from the imminency of the other provisions that will soon take effect. *See* Pls.' Mot. to Expedite the Scheduling of a R. 16(b) Conf. and the Filing of a R. 26(f) Rep. (filed simultaneously with this Motion and the Complaint). Absent such expedited treatment, Plaintiffs will need preliminary relief on these other provisions as well.

BACKGROUND

The Act prevents and/or significantly impairs Plaintiffs from publishing truthful information to adult consumers of tobacco products. Before passage of the Act, federal law barred Plaintiffs from any TV or radio advertising, the most effective way to reach large numbers of adult consumers. *See* 15 U.S.C. §§ 1335, 4402. The Act undermines the few remaining avenues.

First, subject to very limited exceptions, the Act prohibits Plaintiffs from using *any* color or

[1] *See* Certain Pls.' Mot. for Prelim. Inj.

imagery in *any* advertising—in magazines, in retail establishments at the point-of-sale, or even in direct marketing to existing adult tobacco consumers. It expressly 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)). Consequently, Plaintiffs' advertising is stripped of all imagery, graphics, and trade dress, including even a depiction of the product itself—all important communicative tools. Thus, under the Act, Plaintiffs cannot display their longstanding trademarked logos and trade dress in their advertisements or at retail stores. No other lawfully sold product in this country is subject to such draconian advertising restrictions.

Second, about the only remaining place where Plaintiffs can use their historic brand imagery and colors is on their packaging. But, the Act's new "warnings" appropriate the top fifty percent of both sides of all cigarette packaging for messages such as "Smoking can kill you," which must also be in 17-point font and include shocking "color graphics depicting the negative health consequences of smoking." Pub. L. No. 111-31, § 201(a) (amending 15 U.S.C. § 1333 to add subsections (a)(2) and (d)). The packaging must also include other mandated information.[2] In addition, the top twenty percent of advertisements must display the "warnings." *See id.* at § 201(a) (amending 15 U.S.C. § 1333 to add subsection (b)(2)). Similar "warnings" are required on smokeless tobacco packaging and advertisements.[3] This goes far beyond the Surgeon General's Warning that, for decades, has, as a matter of law and fact, effectively informed all Americans about the health effects of tobacco

[2] It must 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)).

[3] *See* Pub. L. No. 111-31, § 204(a) (amending 15 U.S.C. § 4402 to add subsection (a)(2) and require warnings on "at least 30 percent of" "the 2 principal display panels of the package"); *id.* at § 205(a) (amending 15 U.S.C. § 4402 to add subsection (d) and authorize the Secretary to "require color graphics to accompany the text"); *id.* at § 204(a) (amending 15 U.S.C. § 4402 to add subsection (b)(2)(B) and required new warning on twenty percent of advertisements).

consumption. Given the size and content of these new "warnings," they appear designed not to inform the public, but rather to drown out Plaintiffs' voices and to require Plaintiffs to stigmatize their own products through their packaging.

Consequently, Plaintiffs' brand names, trademarks, logos, color and imagery are relegated to the bottom of cigarette packaging and dominated by the "warnings" on all tobacco products. As a result of both the Act and state laws, however, retailers generally must keep tobacco products behind the counter and otherwise inaccessible to consumers,[4] and they are therefore commonly stored in cases at a distance, where the bottom portion of the package is not likely to be visible to adult consumers. It will therefore be difficult, and at times impossible, for those consumers to see the trade dress, including its color or imagery, that identifies and distinguishes one brand from another. Instead, the only message adult consumers will likely receive from Plaintiffs' packaging and advertisements is the government-drafted "warning." The Act thus effectively eliminates Plaintiffs' ability to use their packaging to communicate about their products and significantly impairs the value of their trademarked brand imagery, logos, and trade dress. This is particularly burdensome in the mature tobacco market, where Plaintiffs compete against entrenched market leaders, since the Act undermines Plaintiffs' ability to convince current adult consumers of a competitor's brand to switch.

Third, the Act's MRTP Requirement restricts Plaintiffs' ability to make indisputably true statements about their products in both commercial communications *and* non-commercial scientific, political, and public policy debates. In particular, it allows Plaintiffs to sell products that present reduced health risks relative to other products, but restricts their right to communicate truthful information about those products to the public absent prior approval from the FDA.

More specifically, the MRTP Requirement prohibits (1) "the label, labeling, or advertising"

[4] *See, e.g.*, Pub. L. No. 111-31, § 102(a)(2) (adopting 21 C.F.R. §§ 897.12-.16); N.Y. Pub. Health Law § 1399-cc(7) (requiring that tobacco products be stored behind a counter or in a locked container).

of a tobacco product from "explicitly or implicitly" 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. Pub. L. No. 111-31, § 101(b) (amending the FDCA to add § 911(b)(2)(A)) (emphases added). Requiring Government pre-approval of such speech is a classic form of unconstitutional prior restraint. And, the Act allows the FDA to *prohibit* altogether a truthful statement that a tobacco product will "significantly reduce harm and the risk of tobacco-related disease to *individual* tobacco users" if it determines, in its broad discretion, that such a truthful statement would not "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.* (adding § 911(g)(1)) (emphases added). Yet the law provides no standard by which such judgments shall be made, and thus relegates Plaintiffs' truthful, non-misleading speech to the vagaries of subjective assessments by Government officials.

Finally, having undermined every major avenue of speech, the Act systematically eliminates Plaintiffs' remaining means of communication with adult tobacco consumers. It thus:

- Bans 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." *Id.* at § 102(a)(2) (adopting 21 C.F.R. § 897.30(b)).[5]

- Prohibits Plaintiffs from brand-name sponsorship of any "athletic, musical, artistic, or other social or cultural event"—including adult-only events. *Id.* (adopting 21 C.F.R. § 897.34(c)).

- Bans Plaintiffs from distributing—even to age-verified, adult smokers—any non-tobacco good in exchange for purchase(s) of a tobacco product. *Id. (*adopting 21 C.F.R. § 897.34(b)).

[5] The Act permits Defendant Sebelius to modify this provision "in light of governing First Amendment case law." Public Law 111-31, Section 102(a)(2)(E). To date, Secretary Sebelius has proposed no such modification.

- Bars Plaintiffs from distributing any brand-name promotional items—including to adult consumers in adult-only venues. *Id.* (adopting 21 C.F.R. § 897.34(a)).

- Prohibits 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. *Id.* at § 103(b)(13) (amending 21 U.S.C. § 331 to add subsection (tt)).

- Bars Plaintiffs from distributing free samples of their cigarettes—including to adult consumers in adult-only venues—and prohibits the distribution of free smokeless tobacco samples except in very limited circumstances. *Id.* at § 102(a)(2)(G) (adopting and amending 21 C.F.R. § 897.16(d)).

- Bans Plaintiffs from jointly marketing tobacco with any other product regulated by the FDA. *Id.* at § 101(a) (amending 21 U.S.C. § 321 to add subsection (rr)(4)).

- Authorizes federal agencies, state and local governments, and Indian tribes to enact even more stringent regulations on 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)).

The Government's asserted justification for these restrictions—preventing or reducing youth tobacco use, *see, e.g.*, Pub. L. No. 111-31, § 2(1)—fails to withstand even minimal scrutiny. The bulk of these restrictions were proposed in 1996, when youth smoking rates were increasing, but never took effect 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).[6] Since then, youth tobacco use has continuously declined for the past ten years and stood at historic lows on the date this legislation was enacted. There is no demonstrable empirical proof that any of the new restrictions will reduce or prevent youth tobacco use. Nor is there any evidence that Congress performed its constitutionally mandated duty to determine whether there were less restrictive means of achieving the Government's stated interest in reducing or preventing youth tobacco use. The

[6] Rather than requiring the FDA to comply with the protections of the Administrative Procedures Act in promulgating these regulations, Congress "deemed" them to be in compliance with all rulemaking procedures. Pub. L. No. 111-31, § 102(a)(1)(B). Congress did not, with one exception, make any attempt to tailor the regulations to address intervening Supreme Court precedent.

restrictions are vastly overbroad in that they frequently apply to advertising that is carefully tailored to reach only adult consumers of tobacco products.[7]

In short, the Act unconstitutionally proscribes Plaintiffs from engaging in virtually all forms of ordinary communication with adult tobacco consumers and the broader public about lawful tobacco products. As explained below, individually and collectively, these provisions of the Act violate Plaintiffs' free speech rights under the First Amendment, Due Process rights under the Fifth Amendment, and effect an unconstitutional Taking under the Fifth Amendment.[8]

ARGUMENT

Plaintiffs request that the Court preliminarily enjoin two of the challenged provisions of the Act—the MRTP Requirement and the Co-Marketing Ban—so as to avoid the irreparable harm that will result from their enforcement prior to resolution of Plaintiffs' complaint. The factors to be considered in this determination weigh decisively in favor of a preliminary injunction: (1) Plaintiffs are substantially likely to succeed on the merits of their claims; (2) Plaintiffs will suffer significant and irreparable injury if enforcement of two of the challenged provisions presently in effect are not preliminarily enjoined; (3) the threatened injury to Plaintiffs outweighs any potential harm to Defendants and third parties; and (4) the public interest in the free dissemination of truthful information will be best served by enjoining the Act's speech restrictions. *Yolton v. El Paso Tenn. Pipeline Co.*, 435 F.3d 571, 578 (6th Cir. 2006). In addition, because a full understanding of the Act is necessary to understand the case as a whole and is relevant to the contemporaneously filed

[7] Congress, in fact, made *no* findings regarding smokeless tobacco, but nonetheless largely imposed the same excessive restrictions on speech related to smokeless tobacco as those imposed on cigarettes.

[8] In 1998, numerous tobacco manufacturers, including Plaintiffs Commonwealth, Lorillard, and Reynolds, entered into a Master Settlement Agreement ("MSA") with the states. The MSA imposes a variety of restrictions and limitations on the marketing and promotion of tobacco products that, but for the voluntary waiver by the signatories of their constitutional rights, would be unconstitutional. *See* MSA § XV. Not all Plaintiffs, however, are signatories to the MSA. More importantly, the Act, which goes far beyond the MSA, leaves Plaintiffs—whether they are signatories to the MSA or not—with few remaining avenues through which they may effectively communicate truthfully with adult tobacco consumers about Plaintiffs' lawful tobacco products.

Motion to Expedite the Scheduling of a Rule 16(b) Conference and the Rule 26(f) Conference, this brief sets forth a full discussion of the Act's unconstitutional provisions.

I. THE ACT'S CHALLENGED PROVISIONS ARE UNCONSTITUTIONAL AND PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS OF THEIR CHALLENGE TO THE MRTP REQUIREMENT AND CO-MARKETING BAN

The Act's marketing provisions broadly restrict Plaintiffs' right to engage in truthful commercial speech, and, in some instances—including the MRTP Requirement, upon which Plaintiffs seek a preliminary injunction—core First Amendment speech. These restrictions, at a minimum, are therefore governed by *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N. Y.*, 447 U. S. 557 (1980), and in some cases, strict scrutiny.[9]

Under *Central Hudson*, the Government first must demonstrate that it has a substantial governmental interest in regulating truthful commercial speech. *Id.* at 566. Next, the Government must prove that "'the speech restriction directly and materially advance[s] the asserted governmental interest.'" *Lorillard*, 533 U.S. at 555 (citation omitted). Under this prong, "a commercial speech regulation 'may not be sustained if it provides only ineffective or remote support for the government's purpose.'" *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 505 (1996) (plurality op.) (citations omitted). Thus, the Government "bears the burden of showing not merely that its regulation will advance its interest, but also that it will do so 'to a *material degree*,'" and "'speculation or conjecture' … is an unacceptable means of demonstrating that a restriction on commercial speech directly advances the [Government]'s asserted interests." *Id.* at 505, 507 (emphasis added) (citations omitted). Finally, the "last step of the *Central Hudson* analysis … 'ask[s] whether the speech restriction is not more extensive than necessary to serve the interests that support it.'" *Lorillard*, 533 U.S. at 556 (citation omitted). In conducting this analysis, the Court

[9] As a majority of the Supreme Court has argued, *Central Hudson* should be overruled and strict scrutiny should apply to commercial speech restrictions. *See, e.g.*, *Lorillard*, 533 U.S. at 554. Because the Act's speech restrictions are invalid even under *Central Hudson*, however, the Plaintiffs apply that standard and the Court need not determine whether strict scrutiny should be applied to all of Plaintiffs' First Amendment claims.

must determine whether other less burdensome restrictions are available because "regulating speech must be a last—not first—resort." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002). "[I]f the Government could achieve its interests in a manner that does not restrict speech or that restricts less speech, the Government must do so." *Id.* at 371.

The Court's decision in *44 Liquormart* demonstrates the rigorous judicial review required under this standard.[10] There, the Court invalidated a prohibition on referencing prices in alcohol advertising that assertedly furthered the Government's interest in "reducing alcohol consumption." 517 U.S. at 504 (plurality op.). The Court rejected the assertion that "the price advertising ban [would] *significantly* reduce alcohol consumption," explaining that a "commercial speech regulation 'may not be sustained if it provides only ineffective or remote support for the government's purpose.'" *Id.* at 505. It also found the restriction impermissible given the "obvious … alternative forms of regulation that would not involve any restriction on speech"—including "regulation or … increased taxation" and "educational campaigns focused on the problems of excessive, or even moderate, drinking." *Id.* at 507. In so holding, the Court rejected the existence of a "vice" exception to the First Amendment, concluding: "[A] 'vice' label that is unaccompanied by a corresponding prohibition against the commercial behavior at issue fails to provide a principled justification for the regulation of commercial speech about that activity." *Id.* at 514.

If, as in *44 Liquormart*, a provision narrowly aimed at referencing prices in advertising was unconstitutional, it follows, *a fortiori*, that the Act's sweeping restrictions on virtually *all* commercial speech, and on some core speech, cannot stand. While the Government's interest in protecting youth from harm is a substantial one, this interest is hardly served by the Act's broad

[10] Though none of the opinions analyzing the First Amendment issue in *44 Liquormart* garnered more than four votes, seven justices agreed that the speech restriction at issue was not constitutional under *Central Hudson*. *See 44 Liquormart*, 517 U.S. at 504-08 (plurality op. of Stevens, J.); *id.* at 529-31 (O'Connor, J., concurring). The two remaining Justices indicated they would apply an even higher standard of scrutiny. *See id.* at 517 (Scalia, J., concurring); *id.* at 518 (Thomas, J. concurring). Lower courts therefore regard Justice Stevens' opinion as "the narrowest majority holding." *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1233 n.5 (10th Cir. 1999).

speech restrictions, which ensnare speech regardless of whether it is seen by, aimed at, or appeals to youth. Rather, the true aim of these restrictions is to hijack all commercial depictions that diverge from the Government's message about Plaintiffs' lawful products, which assuredly is *not* a "*substantial* governmental interest." Indeed, the Government's "paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress it." *44 Liquormart*, 517 U.S. at 497 (plurality op.); *see also id*. at 518-19 (Thomas, J. concurring). In addition, the Act's commercial speech restrictions cannot satisfy *Central Hudson* because they do not "'directly and materially advanc[e] the asserted governmental interest'" in reducing youth tobacco use, *Lorillard,* 533 U.S. at 555 (citation omitted), and, beyond that, are not remotely tailored to that purpose. Rather, they broadly restrict *all* commercial speech, regardless of whether it is seen by, aimed at, or appeals to adults or youth.

Finally, several of the Act's restrictions—including the MRTP Requirement, upon which Plaintiffs are seeking a preliminary injunction—extend to Plaintiffs' core First Amendment speech, and thus are governed by strict scrutiny, a standard that the Government cannot possibly meet. Accordingly, the Act's challenged provisions are unconstitutional and, more specifically, Plaintiffs are likely to succeed on the merits of the two provisions on which they seek a preliminary injunction—the MRTP Requirement and the Co-Marketing Ban. The brief begins with a discussion of the black-and-white text requirements and mandated warnings, as these broad speech restrictions provide the context for considering the other challenged provisions. The brief then discusses the two provisions on which Plaintiffs are seeking a preliminary injunction before moving to the other ways in which the Act closes off all available avenues of speech.

A. The Black-and-White Text Provision And Mandated Warnings

The black-and-white text advertising provision and new mandatory "warnings," individually and collectively, effectively eliminate Plaintiffs' ability to use their advertising and packaging to

communicate with adult tobacco consumers. The black-and-white text requirement prohibits the use of *any* color or imagery—including Plaintiffs' trademarked logos and trade dress, such as Reynolds' "Camel Beast," Conwood's "Grizzly" bear and the picture of Levi Garrett's 18th century factory in Philadelphia, and Commonwealth's "Eagle"—in almost all advertisements, including point-of-sale advertisements in retail locations, direct-mail advertisements sent to existing adult tobacco users, and print advertisements in most magazines and newspapers. The use of color and imagery is limited to Plaintiffs' packaging, where it is neutralized by relegating it to a small portion of the packaging (and the bottom of cigarette packaging) and then prohibiting its display in most advertisements or at retail locations. The remainder of the packaging, in contrast, is overshadowed by a government-compelled anti-tobacco message. These "warnings" likewise dominate all advertising, since they stand in stark contrast to the black-and-white text, to which Plaintiffs' speech is limited. Consequently, the dominant message of Plaintiffs' advertisements and packaging is the government-drafted anti-tobacco "warning," in direct contravention of Plaintiffs' commercial interests.

These requirements violate Plaintiffs' free speech rights under the First Amendment and effect an unconstitutional Taking under the Fifth Amendment.

1. The Black-and-White Text Requirement Unconstitutionally Prohibits Commercial Speech

The Act's prohibition on the use of color or imagery in almost all tobacco advertisements is irreconcilable with the Supreme Court's decision in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985). There, applying *Central Hudson,* the Court invalidated a virtually identical restriction on commercial speech that prohibited attorneys from using "drawings, illustrations … [or] pictures" in attorney advertisements. *Id*. at 632-33 & n.4. "The use of illustrations or pictures in advertisements," the Court explained, "serves important communicative functions: it attracts the attention of the audience to the advertiser's message, and it may also serve to impart important

information directly." *Id.* at 647. If the constitutional protections "afforded commercial speech are to retain their force," the Court reasoned, the state could not implement "broad prophylactic rules" out of fear that a speaker will employ "subtle uses of illustrations to play on the emotions of his audience and convey false impressions." *Id*. at 648, 649. "[T]he free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful." *Id.* at 646.

As *Zauderer* makes clear, the Act's black-and-white text requirement cannot possibly survive *Central Hudson* review. *First*, it does not "directly" advance the Government's interest in reducing youth tobacco use. Here, the speech at issue is not harmful or offensive, as is the case with misleading or deceptive speech. Instead, the supposed harm arises only if a youth heeds the call to action assertedly urged by the color or imagery and (contrary to state law) purchases, possesses, or uses tobacco products. *See* Ky. Rev. Stat. Ann. §§ 438.310, 438.311, and 438.350. The Act therefore seeks to reduce youth tobacco use by shielding minors from expression that supposedly makes such use more appealing. Whatever the merits of this attenuated reasoning, this restriction on almost all color or imagery—including in speech aimed at adults—represents the very definition of "*in*direct" rejected by the Supreme Court and cannot possibly withstand First Amendment scrutiny. *See Zauderer*, 471 U.S. at 648-49; *Edenfield* v. *Fane*, 507 U.S. 761, 770-71 (1993).

Second, the Government cannot prove that this restriction would "*materially* advance" its interests, *Lorillard*, 533 U.S. at 555, by "*significantly* reduc[ing]" youth tobacco use, *44 Liquormart*, 517 U.S. at 505 (plurality op.). Although in some contexts, "it is no doubt fair to assume that more advertising would have some impact on overall demand for" a particular product, the Court has emphasized that "it is also reasonable to assume that much of that advertising would

merely channel [users] to one [brand] rather than another." *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 189 (1999). Indeed, the FDA itself has previously acknowledged that "[m]any behavioral and personal characteristics influence an adolescent's decision to use cigarettes or smokeless tobacco products, including: rebelliousness; risk-taking personality; use of other legal or illegal drugs; belief in the perceived utility of smoking (to cope with stress, control weight, or improve one's self-image); low self-esteem or depression; disbelief of or discounting health risks; and poor academic achievement." 60 Fed. Reg. at 41,330. The Government cites no evidence and cannot prove that proscribing Plaintiffs' use of color or imagery in advertisements will reduce youth tobacco use at all, much less that it will "significantly" do so, which is its burden under the First Amendment. *44 Liquormart*, 517 U.S. at 505 (plurality op.). Nor may it fill this evidentiary gap through "'speculation or conjecture … that [the Act's] restriction[s] on commercial speech directly advance[] [its] asserted interest." *Id.* at 507; *see also, e.g.*, *Linmark Assocs., Inc. v. Twp. of Willingboro*, 431 U.S. 85, 95 (1977) (invalidating ban on "for sale" signs because "the evidence [did] not establish that 'For Sale' signs … were a *major cause* of panic selling") (emphasis added).

Third, the Act's broad restrictions are not remotely tailored to reducing youth tobacco use, since they apply to almost all use of color or imagery. The black-and-white text restriction even prohibits Plaintiffs from using color or imagery in direct mail advertising that is carefully designed to reach *only* existing adult tobacco users who expressly state that they want to receive it.[11] Such a "broad prophylactic" regulation—based on the fear that "subtle uses of illustrations" will "play on the emotions of [the] audience"—is the very definition of a regulation that is *not* sufficiently tailored, as the Court held in *Zauderer*, 471 U.S. at 648-49. "If there is one fixed principle in the commercial speech arena, it is that 'a State's paternalistic assumption that the public will use

[11] Plaintiffs Lorillard and Reynolds, for example, currently require consumers seeking to join their direct marketing databases to certify they are legal age consumers of tobacco products and want to receive communications about those products. Both Lorillard and Reynolds then verify each registrant's age via independent means.

truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress it.'" *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 69-70 (D.D.C. 1998) (quoting *44 Liquormart*, 517 U.S. at 497), *vacated on other grounds by Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). The Supreme Court has thus repeatedly rejected governmental attempts to equate less information with better decision-making. *See, e.g.*, *44 Liquormart*, 517 U.S. at 503 ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.")

Indeed, the narrow *exception* for "an adult publication" confirms the black-and-white text requirement's breadth. It limits color and imagery to print publications that have (1) 15 percent or less readership under the age of 18, and (2) fewer than 2 million total readers under 18. Pub. L. No. 111-31, § 102(a)(2) (adopting 21 C.F.R. § 897.32(a)). Plaintiffs are thus *prohibited* from using color or imagery when advertising to five adult readers of a magazine because the sixth is under 18. The Government, however, "may claim no substantial interest in restricting truthful and nondeceptive [commercial] solicitations to those least likely to be read by the recipient." *Shapero v. Kentucky Bar Ass'n.*, 486 U.S. 466, 479 (1988) (plurality op.). This "exception" confirms that the black-and-white text restriction violates the fundamental principle that "the governmental interest in protecting children from harmful materials …. does not justify an unnecessarily broad suppression of speech addressed to adults." *Reno*, 521 U.S. at 875.

The black-and-white text requirement's other "exception" is equally narrow, allowing color or imagery in adult-only establishments, but only if "the advertising is not visible from outside the facility" *and* "is affixed to a wall or fixture in the facility." Pub. L. No. 111-31, § 102(a)(2) (adopting 21 C.F.R. § 897.32(a)). Thus, a windowless adult-only tavern cannot set a color advertisement on its bar, and an adult-only tavern with windows typically will be unable to display a color poster on its wall. This exception, moreover, is inapplicable to Plaintiff Discount Tobacco

City & Lottery, Inc. ("Discount Tobacco City") (and virtually all retailers) since to qualify as an "adult-only" location, it must "ensure[] that no person younger than 18 years of age is present or permitted to enter at any time." *Id.* (adopting 21 C.F.R. § 897.16(c)(2)(ii)); *id*. (adopting 21 C.F.R. § 897.32(a)(1)). Because Plaintiff Discount Tobacco City permits minors to enter its retail locations if accompanied by a parent, it would not qualify as "adult-only." The illusory nature of this "exception" is further narrowed by the Act's requirement that Plaintiff Discount Tobacco City and other specialty retailers "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." *Id*. at § 101(b) (amending the FDCA to add § 913). These specialty tobacco retailers are therefore also barred from using color or imagery in their stores, confirming that the Act's true purpose is not to decrease youth tobacco use, but bar Plaintiffs from attempting to persuade adult tobacco consumers of competitive tobacco brands to switch brands.

Finally, the black-and-white text requirement is far more extensive than necessary to serve the Government's asserted interest. Congress ignored numerous and obvious less burdensome alternatives, including, among others:

- increasing enforcement of existing state laws prohibiting the sale of tobacco products to minors;
- criminalizing possession of tobacco products by underage users;
- increasing funding for anti-smoking educational campaigns; and
- increasing funding for smoking cessation programs.

These are precisely the types of non-speech alternative regulations the Supreme Court has said must be enacted *before* the Government bans speech. *See, e.g.*, *Thompson*, 535 U.S. at 372; *44 Liquormart*, 517 U.S. at 507 (plurality op.); *id*. at 530 (O'Connor, J., concurring); *Rubin v. Coors Brewing Co*., 514 U.S. 476, 490-91 (1995). After all, "[i]f the First Amendment means anything, it means that regulating speech must be a last—not first—resort." *Thompson*, 535 U.S. at 373.

In short, the black-and-white text requirement ensures that Plaintiffs' advertisements will be dull and grim, visually uninteresting, and virtually indistinguishable from one another. As the Supreme Court has remarked on the impact of an analogous restriction, "an advertising diet limited to such spartan fare would provide scant nourishment." *Bates v. State Bar of Ariz.*, 433 U.S. 350, 367 (1977) (rejecting argument that attorneys could be limited to advertising their names and addresses in phone books). By leaving tobacco manufacturers unable to break through the visual clutter, catch consumers' attention, or distinguish one brand from another, the black-and-white text provision tramples Plaintiffs' rights in contravention of the First Amendment.

2. The "Warnings" Unconstitutionally Burden Commercial Speech

It is also well established that "unjustified or unduly burdensome disclosure requirements offend the First Amendment…." *Zauderer*, 471 U.S. at 651. Here, the Act's mandated "warnings," in combination with the black-and-white text requirement, drown out Plaintiffs' own commercial message on their packaging and advertisements, thus crippling their ability to market their tobacco brands to adult customers.

On cigarette packages, for example, the *top half* of both sides of the pack must be devoted to the government-drafted anti-tobacco message, including shocking color graphics disingenuously termed a "warning" under the Act because their true purpose is not to inform, but to stigmatize Plaintiffs' products. Even more of the package must be devoted to other government-mandated information. This leaves just a small portion of the *bottom* of the package for Plaintiffs' branding and product information, which is then generally placed behind a checkout counter, rendering it virtually invisible to adult customers. Similar "warnings" are required on smokeless tobacco products. Likewise, advertisements are dominated by "warnings" (forty percent of the advertisement will be a warning if smokeless tobacco and cigarettes are advertised together), whereas Plaintiffs' portion is limited to black-and-white-text-only "tombstones." Consequently, the

overwhelmingly dominant message adult consumers are likely to receive from tobacco product packaging and advertising is the government-drafted anti-tobacco message.

The Government cannot justify these sweeping limitations on Plaintiffs' commercial speech. "[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…." *Buckley v. Valeo*, 424 U.S. 1, 48-49 (1976). The proposition that constitutionally-protected speech can be stringently regulated in order to increase the impact of a *government* message makes the threat posed by the black-and-white text requirement and mandatory "warnings" even more self-evident. The Act's restrictions are particularly burdensome in the tobacco industry, where the focus of advertising is on convincing existing adult tobacco users to switch from a competitor's brand or trying a new brand. The black-and-white text requirement and "warnings" effectively ensure that this commercial message will never be heard by adult tobacco consumers.

Nor is this burden on Plaintiffs' commercial speech "reasonably related to the State's interest in preventing deception of consumers." *Zauderer*, 471 U.S. at 651. Existing federal and state laws proscribe commercial messages that are false and misleading. *See, e.g.*, 15 U.S.C. § 52 (prohibiting false advertising); Ky. Rev. Stat. Ann. § 367.170(1) (making unlawful any "[u]nfair, false, misleading, or deceptive acts or practices in … commerce"); *see also* 15 U.S.C. §§ 1336, 4404(c) (federal regulatory power over deceptive cigarette and smokeless tobacco advertisements). And the Act reaches all speech, even if it is truthful and non-misleading. The public has been inundated with information regarding the dangers of tobacco for decades under existing law. *See* 15 U.S.C. §§ 1333 (cigarette warnings) and 4402 (smokeless tobacco warnings). Indeed, there is universal awareness regarding the health risks related to tobacco. In fact, fully *fifteen years ago*, the Surgeon General reported that "virtually all U.S. adolescents—smokers and nonsmokers alike—are aware of the long-term health effects of smoking...." United States Dep't of Health & Human

Servs., *Report of the Surgeon General: Preventing Tobacco Use Among Young People* 135 (1994). The Surgeon General noted that this knowledge does not prevent the onset of tobacco use by young people because "many adolescents feel inherently invulnerable in their characteristically short-term view." *Id.* At most, then, the Act's additional "warnings" provide "'only ineffective or remote support for the government's purpose.'" *44 Liquormart,* 517 U.S. at 505 (plurality op.) (citation omitted). Even if the Government could demonstrate some marginal increase in youth awareness as a result of these new "warnings," it cannot demonstrate that any such marginal increase directly and materially reduces youth tobacco use or that comparable reductions could not be achieved by alternative measures not impairing Plaintiffs' speech rights at all (such as increased enforcement of underage access laws), or by less intrusive restrictions.

The Act's "warnings," alone and in conjunction with the black-and-white text requirement, are not narrowly tailored to further a legitimate governmental interest and sweep so broadly that they effectively drown out Plaintiffs' truthful commercial messages. Because "the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech," *Thompson*, 535 U.S. at 371, these restrictions are unconstitutional.

3. The "Warnings" Unconstitutionally Compel Plaintiffs to Disseminate Antagonistic Speech

The First Amendment guarantees "both the right to speak freely and the right to refrain from speaking at all." *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). "Mandating speech that a speaker would not otherwise make necessarily alters the content of the speech." *Riley v. Nat'l Fed'n of the Blind*, 487 U.S. 781, 795 (1988); *see also Nat'l Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157, 164 (7th Cir. 1977) (requiring the egg industry to "argue the other side of the controversy" over whether eggs increase the risk of heart disease would "interfer[e] unnecessarily with the effective presentation of the pro-egg position"). Accordingly, "[f]or corporations as for individuals, the choice to speak includes within it the choice of what not to say." *Pac. Gas & Elec. Co. v. Pub.*

Utils. Comm'n of Cal., 475 U.S. 1, 16 (1986). Here, the mandated "warnings" far exceed anything remotely necessary to inform consumers of the risks of tobacco use, particularly because the public is already universally aware of the hazards of tobacco under the pre-existing statutory regime. Thus, these "warnings" are not warnings at all, but are rather an unconstitutional attempt by the Government to compel Plaintiffs to stigmatize their own products by disseminating an anti-smoking message directly contrary to their interests.

In *Entertainment Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006), the Seventh Circuit invalidated a far less onerous mandated warning. There, a state law required video game retailers to display a four-inch-square label bearing "18" on any "sexually explicit" video game, which covered about one-tenth of the video game's packaging. *See id.* at 652 & n.13. This label, the court reasoned, did not set forth uncontroversial factual information, but rather, "ultimately communicate[d] a subjective and highly controversial message—that the game's content [was] sexually explicit." *Id.* at 652. The court struck down the law because it was overbroad, concluding that "the '18' sticker *literally* fails to be narrowly tailored—the sticker covers a substantial part of the box. The State has failed to even explain why a smaller sticker would not suffice." *Id.* The Court thus held: "Certainly we would not condone a health department's requirement that half of the space on a restaurant menu be consumed by the raw shellfish warning. Nor will we condone the State's unjustified requirement of the four square-inch '18' sticker." *Id.*

The labeling provisions in this case go far beyond the existing "surgeon general's warning of the carcinogenic properties of cigarettes," *id.*, particularly when Congress has determined that its prior warnings were adequate as a matter of law to inform the public of the risks of tobacco. Given the size and prominence of the newly mandated "warnings," including shocking color graphics on cigarettes, they plainly are intended to convey a "subjective" and "controversial" anti-

tobacco message. Moreover, given that Plaintiffs' own speech is limited either to small portions of their packaging (where it will not be seen) or black-and-white text in their advertisements (where it will not be noticed), the Act ensures that the *only* speech that will effectively reach consumers is the government-drafted anti-tobacco speech that Plaintiffs are compelled to convey. The Act, therefore, is far worse than *either* the "18" label in *Entertainment Software*, which covered one-tenth of the video game package, *or* the court's hypothetical and purely factual "raw shellfish warning," which would have covered "half of the space on a restaurant menu" and thus far exceeded anything the Constitution would allow. *Id*. Here, the Act compels Plaintiffs to disseminate graphic, duplicative government-drafted messages on the *top half* of their cigarette packaging, at least a *third* of their smokeless tobacco packaging, and a *fifth* of advertisements, while simultaneously crippling Plaintiffs' ability to convey their own commercial messages. Accordingly, the Act's "warnings" compel Plaintiffs to disseminate antagonistic speech in contravention of the First Amendment.

4. The Black-and-White Text Requirement And "Warnings" Constitute An Unconstitutional Taking Of Property

Plaintiffs have a vested property right in trade dress, trademarked images and logos, and packaging. *See, e.g., Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763 (1992); *Hamilton-Brown Shoe Co. v. Wolf Bros. & Co.*, 240 U.S. 251 (1916). The Act's black-and-white text and "warnings" requirements, however, invade Plaintiffs' packaging and destroy the value of their protected property interests. Thus, the Act violates the Fifth Amendment's Takings Clause in two ways.

First, the Act effects a *per se* taking by "direct[ly] appropriat[ing]" and "physical[ly] inva[ding]" Plaintiffs' packaging and advertisements. *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 537-38 (2005). In *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419 (1982), the Supreme Court invalidated a law that required a building owner to allow a small cable box to be affixed to the side of his building, explaining that "a physical invasion is a government intrusion of an unusually serious character," since "the owner may have no control over the timing, extent, or

nature of the invasion." *Id*. at 433, 436. Thus, "constitutional protection for the rights of private property cannot be made to depend on the size of the area permanently occupied." *Id*. at 436. Here, by contrast, the Act invades a far more substantial portion of Plaintiffs' property for a government-drafted anti-tobacco message. In this regard, the Act is no different than if the Government confiscated half of every billboard for a message on any other issue of public policy. This direct invasion of Plaintiffs' property therefore violates the Fifth Amendment *regardless* of whether it decreases the value of Plaintiffs' property.[12]

Second, a regulatory taking occurs when the Government "goes too far" by placing an overly burdensome restriction on property for which justice and fairness demand that compensation be given. *See, e.g., Pa. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922). In assessing whether a regulatory taking has occurred, courts consider (1) the economic impact of the regulation on the claimant; (2) the character of the government action; and (3) the extent to which the regulation has interfered with investment-backed expectations. *Connolly v. Pension Benefit Guar. Corp.*, 475 U.S. 211, 225 (1986). The Act runs afoul of all three factors:

- The Act will have a significant economic impact on Plaintiffs' trademarks, trade dress, and packaging.[13]
- The Government's action is a deliberate and targeted invasion of Plaintiffs' packaging and advertising designed to effectively destroy the value of Plaintiffs' property through a government-drafted anti-tobacco message.[14]
- For decades, Plaintiffs have invested countless millions of dollars and human resources in modifying and developing their trademarks and trade dress property; the

[12] *See, e.g.*, *Lingle*, 544 U.S. at 539 (2005) ("A permanent physical invasion, however minimal the economic cost it entails, eviscerates the owner's right to exclude others from entering and using her property—perhaps the most fundamental of all property interests."); *Loretto*, 458 U.S. at 430 (permanent physical occupations are takings "even if they occupy only relatively insubstantial amounts of space and do not seriously interfere" with the use of the property); *St. Louis v. W. Union Tel. Co*., 148 U.S. 92, 99 (1893) (the only relevant inquiry is whether the physical invasion "effectually and permanently dispossesses [the private party] as if it had destroyed that amount of ground").

[13] *See, e.g., Yancey v. United States*, 915 F.2d 1534, 1540 (Fed. Cir. 1990) (finding a compensable taking where a federal quarantine on breeder turkeys caused a loss of 77% of the flock's value).

[14] *See, e.g., Curtin v. Benson*, 222 U.S. 78, 86 (1911) (holding that the government cannot "destroy essential uses of private property" and invalidating federal rules that interfered with private grazing rights); *see also Hodel v. Irving*, 481 U.S. 704, 716 (1987) (the extreme character of the governmental action determined the takings issue).

Act destroys these reasonable investment-backed expectations.[15]

Accordingly, in addition to trampling Plaintiffs' free speech rights under the First Amendment, the Act also violates Plaintiffs' property rights under the Fifth Amendment.

B. The MRTP Requirement: Plaintiffs Are Likely to Succeed On The Merits And Therefore Are Entitled To A Preliminary Injunction

The MRTP Requirement permits Plaintiffs to sell tobacco products that pose fewer health risks than others, but prohibits Plaintiffs from disseminating this truthful information. Thus, absent prior approval from the FDA, Plaintiffs cannot, among other things, take "*any action* directed to consumers *through the media or otherwise* … that would be reasonably expected to result in consumers believing" that a particular tobacco product "may" be less harmful than other tobacco products. Pub. L. No. 111-31, § 101(b) (amending the FDCA to add § 911 (a)-(b)) (emphases added). And the FDA may deny approval altogether, and thereby absolutely prohibit truthful speech about the relative health risks of tobacco products, if it determines, in its broad discretion, that such truthful information would not "benefit the health of the population *as a whole*." *Id*. (adding § 911(g)) (emphases added). Violations are punishable by fines up to $10 million and three years in prison. *Id*. at § 103(c)(3) (amending 21 U.S.C. § 333 to add subsection (9)(B)); 21 U.S.C. § 333. The MRTP Requirement goes well beyond anything permitted by the First Amendment.

1. The MRTP Requirement Unconstitutionally Prohibits Core Speech

The MRTP Requirement is not limited to commercial speech, i.e., the "proposal of a commercial transaction." *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 423 (1993); *see also, e.g., Central Hudson*, 447 U.S. at 562. Instead, it applies to "*any* action directed to consumers through the media *or otherwise*." Pub. L. No. 111-31, § 101(b) (amending the FDCA to add § 911 (a)-(b) (emphases added)). For example, under the MRTP Requirement, if one of

[15] *See, e.g., Estate of Hage v. United States*, 82 Fed. Cl. 202, 212 (2008) ("It is unreasonable to expect that Plaintiffs would even purchase [their ranch] without the water rights which gave it its value.").

Plaintiffs' executives participated in a public debate about the relative risks of different tobacco products, Plaintiffs run the risk of committing a *crime* unless the FDA first reviewed and approved the speech. Likewise, the FDA could deny approval, and prohibit the speech altogether, if the FDA determined that this truthful information would not "benefit the health of the population *as a whole*," a subjective assessment for which the law provides no standards or guidance. *Id.* (adding § 911(g)) (emphasis added). The MRTP Requirement is a viewpoint-based restriction on core First Amendment speech and is therefore subject to strict scrutiny—it must be "narrowly tailored to promote a compelling Government interest." *United States v. Playboy Entm't Group, Inc.*, 529 U.S. 803, 813 (2000); *see also R.A.V. v. St. Paul*, 505 U.S. 377, 395-96 (1992). The Government cannot possibly meet this standard.

First, the Government cannot establish a compelling interest "of the highest order" in prohibiting Plaintiffs' truthful speech. *Florida Star v. B.J.F.*, 491 U.S. 524, 541 (1989). The Supreme Court has consistently rejected arguments that the Government has any interest in regulating which ideas may find their way into the public marketplace based on a justification that the public must be protected from information that it might misuse. When invalidating a Virginia statute that prohibited licensed pharmacists from advertising the prices of prescription drugs in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, the Court stated that "the State's protectiveness of its citizens rests in large measure on the advantages of their being kept in ignorance…. It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us." 425 U.S. 748, 769, 770 (1976). More recently, the Court invalidated the FDA's attempted restrictions on pharmacists soliciting prescriptions for, and advertising, "compounded" drugs, which the FDA considered a threat to public health and safety. The Court flatly rejected any reliance by the FDA on a paternalistic "fear that people would make bad decisions if given truthful information about

compounded drugs…. We have previously 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*, 535 U.S. at 374. Lower courts have applied those principles to reject other attempts by the FDA to restrict the free flow of information in the name of public health. For example, the D.C. district court recently upheld a challenge to the FDA's attempted restrictions on the dissemination of information regarding off-label uses of prescription drugs based on the FDA's fear that physicians will misunderstand or misuse information about such off-label use. *See Wash. Legal Found.*, 13 F. Supp. 2d at 61. The court explained that "[i]f there is one fixed principle in the commercial speech arena, it is that 'a State's paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress it.'" *Id.* at 69-70 (quoting *44 Liquormart*, 517 U.S. at 497). Just as in *Virginia Pharmacy*, *Thompson*, and *Washington Legal Foundation*, any attempt by the Government to justify the MRTP regulations based on the asserted abstract concern that some may "misuse" Plaintiffs' truthful communications must be rejected.

Second, under strict scrutiny's narrow tailoring requirement, "[i]f a less restrictive alternative would serve the Government's purpose, the legislature must use that alternative." *Playboy Entm't*, 529 U.S. at 813. The MRTP Requirement cannot meet this requirement either. This risk cannot be justified on the basis of the Government's interest in reducing youth tobacco use. And to the extent that the Government purports to harbor a concern over the dissemination of false or misleading information, such an interest can be met as it always has been met—through existing governmental actions against deceptive and unfair trade practices, *see, e.g.*, 15 U.S.C. § 1336; 15 U.S.C. § 4404(c), or an appropriately tailored disclosure, *see Central Hudson*, 447 U.S. at 565. But the Government vastly exceeded its power when it imposed a blanket restriction on

Plaintiffs' truthful speech about the relative health risks of different tobacco products.[16]

Accordingly, the MRTP Requirement's sweeping restrictions on Plaintiffs' core speech cannot possibly survive strict scrutiny review.

2. The MRTP Requirement Is An Unconstitutional Prior Restraint

The MRTP Requirement is also a classic prior restraint because "the exercise of [Plaintiffs'] 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). "[P]rior restraints on speech and publication are the most serious and the least tolerable infringement on First Amendment rights." *Neb. Press Ass'n v. Stuart*, 427 U.S. 539, 559 (1976). Accordingly, the MRTP Requirement bears "a heavy presumption against its constitutional validity." *Bantam Books, Inc. v. Sullivan*, 372 U.S. 58, 70 (1963). Yet the MRTP Requirement lacks any of the constitutionally-mandated procedural safeguards that the Supreme Court requires of prior restraints under any level of scrutiny.

First, a content-based prior restraint may not impose on the speaker the burden of proving that his or her speech should be permitted; instead, the Government must bear the burden of proving that the speech is impermissible. In *Southeastern Promotions, Ltd. v. Conrad*, for example, the Supreme Court invalidated an ordinance that permitted a city to prohibit a theatrical production upon a finding that it was not "in the best interest of the community," unless the producers proved otherwise. 420 U.S. 546, 548, 562 (1975). The Court reasoned that "the danger of suppressing constitutionally protected speech" requires the Government to prove that speech is not protected before it can overcome the presumption against prior restraints. *Id.* at 559. *See also Speiser v.*

[16] *See, e.g.*, *First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765, 786 (1978) (government "must employ means 'closely drawn to avoid unnecessary abridgment'" of free speech (citations omitted)); *Reno*, 521 U.S. at 871 (invalidating speech restriction where potential scope "undermines the likelihood that [it was] carefully tailored"); *Sable Commc'ns of Cal., Inc. v. FCC*, 492 U.S. 115, 131 (1989) (statute unconstitutional where speech restriction "far exceeds that which is necessary").

Randall, 357 U.S. 513, 526 (1958) ("The man who knows that he must bring forth proof and persuade another of the lawfulness of his conduct necessarily must steer far wider of the unlawful zone than if the State must bear these burdens."). Here, the Act violates this principle, allowing the Secretary to grant an application "only if … *the applicant has demonstrated*" that its statements will "benefit the health of the population as whole." Pub. L. No. 111-31, § 101(b) (amending the FDCA to add § 911(g)(1)) (emphasis added).

Second, there must be a "specified brief period" for the censor to decide whether to allow the speech. *Freedman v. Maryland*, 380 U.S. 51, 59 (1965). Thus, in *Riley v. National Federation of the Blind*, 487 U.S. 781, 802 (1988), the Supreme Court invalidated a licensing statute that "permit[ted] a delay without limit [and] on its face [did] not purport to require when a determination must be made…." Here too, the Act imposes no deadline for the FDA to conclude review of an MRTP application. Nor is this fatal defect cured because the Secretary must, within 2 years, issue regulations "establish[ing] a reasonable timetable for [her] to review an application under this section." Pub. L. No. 111-31, § 101(b) (adding § 911(l)(1)(F)). Those regulations have not been promulgated, and forcing Plaintiffs to wait two more years for the FDA to even issue such regulations is the antithesis of the "specified brief period" of review that the Constitution demands.

Finally, a permissible prior restraint must set objective standards to guide the Secretary's discretion and provide the basis for effective judicial review in order to provide a "guarantee against censorship." *Lakewood v. Plain Dealer Pub. Co*., 486 U.S. 750, 769-70 (1988). In *Lakewood*, for example, an ordinance allowed a town mayor to deny newspapers permits to display their racks on public property with nothing more than "the statement 'it is not in the public interest.'" *Id*. at 769. Because the "doctrine [forbidding unbridled discretion] requires that the limits [on discretion] be made explicit by textual incorporation," the Court invalidated the ordinance. *Id*. at 770. "To allow … illusory 'constraints' to constitute the standards necessary to bound a licensor's discretion

renders the guarantee against censorship little more than a high-sounding ideal." *Id*. at 769-70. *See also Southeastern Promotions*, 420 U.S. at 553. Here too, there is no "guarantee against censorship" because the Act permits the FDA to suppress truthful health information under the vague and subjective "benefits the health of the population as a whole" standard. Pub. L. No. 111-31, § 101(b) (adding § 911(g)(1)(B)).

In sum, because the MRTP Requirement lacks *all* of the constitutionally mandated procedural safeguards, it must be struck down as an unconstitutional prior restraint.

3. The MRTP Requirement Unconstitutionally Prohibits Commercial Speech

The MRTP Requirement fails to pass constitutional muster even as it applies to commercial speech. The Supreme Court has recognized that "the free flow of commercial information is 'indispensable to the proper allocation of resources in a free enterprise system' because it informs the numerous private decisions that drive the system." *Rubin*, 514 U.S. at 481 (citation omitted). Indeed, "a particular consumer's interest in the free flow of commercial information … may be as keen if not keener by far, than his interest in the day's most urgent political debate." *Va. State Bd. of Pharmacy*, 425 U.S. at 763.

Here, there are forty-five million adult smokers who might benefit from truthful information about the relative risks of various tobacco products but who, under the Act, will remain in the dark because Plaintiffs are barred from disseminating this information absent FDA approval. Individuals who fail to abide by the censorship provision face up to three years in prison. In the commercial context, however, the Supreme Court has 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." *Thompson*, 535 U.S. at 374; *see also, e.g.*, *44 Liquormart*, 517 U.S. at 497 (plurality op.) (criticizing the "paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely"); *id*. at 519 (Thomas, J., concurring).

Nor does this broadly-drawn provision directly advance any interest in preventing consumer deception in a narrowly tailored way. It is not limited to misleading speech. Instead, it restricts *all* speech about the relative health risks of different tobacco products. Likewise, it permits the FDA to bar altogether this truthful speech in a commercial context if, in the FDA's view, it would not "benefit the population as a whole." In other words, the FDA can ban the speech to serve what it deems to be the greater good.

In short, in one broad stroke, the Act gags all truthful, non-misleading commercial speech about MRTP. The Constitution does not tolerate such imprecision under *any* standard of review.

4. The MRTP Requirement Is Unconstitutionally Vague

Finally, the MRTP Requirement's various provisions are unconstitutionally vague in violation of the Due Process Clause of the Fifth Amendment. Particularly where, as here, criminal sanctions and free speech rights are at stake, due process requires "narrow specificity" and "precision of regulation." *NAACP v. Button*, 371 U.S. 415, 433, 438 (1963). "[T]he void-for-vagueness doctrine requires that a penal statute define the criminal offense with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement." *Kolender v. Lawson*, 461 U.S. 352, 357 (1983). The doctrine is particularly demanding where First Amendment rights are involved, because of the risk that such a statute will chill protected speech. *See Smith v. Goguen*, 415 U.S. 566, 573 (1974).

Here, the contours of the Act's restrictions are unknown. It prohibits "[a]ny action directed to consumers." *See* Pub. L. No. 111-31, § 101(b) (adding § 911(b)(2)(A)(iii)). That could include presentations at shareholders meetings, conversations with journalists, or even the publication of corporate subsidized research in peer-reviewed scientific journals. Similarly, the standard—"reasonably expected to result in consumers believing" a product "may present" a reduced risk—

could encompass the indisputable truism that smokeless tobacco does not produce second-hand smoke, and turns on a prediction of how consumers "may" interpret that speech. *Id*. Furthermore, the Secretary has the discretion to absolutely ban truthful speech under the subjective, standardless "benefit the health of the population as a whole" requirement. The severity of the civil and criminal sanctions behind the provision exacerbates its constitutional infirmity.

For example, Reynolds' website contains statements regarding the relative risks of smokeless tobacco products as compared to cigarettes. These statements are not in connection with a commercial transaction, not directed toward consumers, and not advertisements, but rather are part of Reynolds' contribution to the public health debate regarding tobacco products. *See* Decl. of Tommy J. Payne (Executive Vice President – Public Affairs, R. J. Reynolds Tobacco Company) ¶ 10-12, attached as Ex. 1 (hereinafter "Payne Decl."). These statements therefore are not covered by the Act. However, the MRTP Requirement is so broad and vague that Reynolds has no assurance of such and arguably risks criminal and severe civil penalties for exercising its core First Amendment rights. The threat of impermissible censorship cannot be justified, as here, where a vague statute will "unquestionably silence[] some speakers whose messages would be entitled to constitutional protection." *Reno*, 521 U.S. at 874.

It is, of course, conceivable (if doubtful) that the FDA could implement regulations clarifying the broad sweep of the MRTP Requirement in a constitutionally permissible manner. But it has not yet done so. And until it does, the Act chills Plaintiffs and others from engaging in constitutionally protected commercial *and* core speech. At a minimum, therefore, the enforcement of these unconstitutionally vague provisions should be enjoined unless and until the FDA issues regulations defining their terms with the constitutionally-mandated level of specificity. *See Ward v. Rock Against Racism*, 491 U.S. 781, 795 (1989) (noting the relevance of "[a]dministrative interpretation and implementation of a regulation … to [vagueness] analysis…." (citation omitted)).

C. The Co-Marketing Ban: Plaintiffs Are Likely to Succeed On The Merits And Therefore Are Entitled To A Preliminary Injunction

The Act also forbids marketing tobacco products "in combination with any other article or product" that the FDA regulates. Pub. L. No. 111-31, § 101(a) (amending Title 21 of the U.S. Code to add § 321(rr)(4)). As with other prohibitions in the Act, the Co-Marketing Ban is absolute, and precludes all joint marketing, no matter the circumstances. This unconstitutionally abridges commercial speech for the same reasons as the black-and-white text requirement. First, the Government has no substantial interest in banning tobacco companies from attempting to persuade adult consumers of competitive tobacco products to switch brands through such joint marketing efforts. *See supra* at Part I.A. Second, these restrictions do not "directly" advance any governmental interest in reducing youth tobacco use, since restricting speech in the name of curbing conduct is the very essence of "*in*direct." *See supra* at Part I.A.1. Third, they do not advance such interests "in a *material* way," since the Government cannot reliably demonstrate that this restriction would "significantly" reduce youth tobacco use or that comparable reductions could be achieved without burdening speech at all. *Id.* Fourth, this restriction is not tailored to combating youth tobacco use because it restricts marketing practices directed at adults. *Id.* Finally, there are numerous and obvious less speech-restrictive alternatives to this provision. *Id.*

Plaintiff R. J. Reynolds, for example, currently mails communications to independently verified adult consumers that contain not only marketing messages from Reynolds but also messages from more than 100 different retailers who have chosen to jointly market their products with Reynolds. *See* Decl. of Richard E. Cross (Vice President of Marketing Operations, R. J. Reynolds Tobacco Company) ¶ 4, attached as Ex. 2 (hereinafter "Cross Decl."). In particular, Reynolds' convenience store partners often will choose to market food or beverages in these communications. *See id.* ¶ 5. The Act, however, broadly bans this practice, even though the Government has no evidence at all that it increases youth tobacco use. In short, as with the Act's

many other restrictions, this one too can only be understood as part of a larger effort to prevent tobacco manufacturers from convincing adult tobacco consumers to choose their lawful products. The Constitution, however, does not permit the Government to restrict speech—even commercial speech—to further such paternalistic ends. The Co-Marketing Ban, like the many other restrictions, cannot withstand First Amendment scrutiny.

D. The Act's Myriad Other Marketing Restrictions

The Act's remaining marketing restrictions effectively block every other remaining thoroughfare of speech for Plaintiffs about tobacco products. *See supra* at pp. 5-6 (describing the Act's myriad speech restrictions). These many provisions unconstitutionally abridge commercial speech for the same reasons as the black-and-white text requirement and Co-Marketing Ban: the Government has no substantial interest in banning tobacco companies from attempting to persuade adult consumers of competitive tobacco products to switch brands, *see supra* at Parts I.A, I.C; the restrictions do not "directly" advance any governmental interest in reducing youth tobacco use, much less "in a *material* way," *see supra* at Parts I.A.1, I.C; they are not tailored to combating youth tobacco use, instead broadly restricting marketing practices directed at adults, *id.*; and there are numerous and obvious less burdensome alternatives, *id.* For these and other reasons explained below, these other restrictions violate the First Amendment.

1. Outdoor Advertising

The outdoor advertising ban requires the FDA to either (1) prohibit all outdoor advertising "within 1,000 feet of the perimeter of any public playground or playground area in a public park. . . elementary school, or secondary school," Pub. L. No. 111-31, § 102(a)(2) (adopting 21 C.F.R. § 897.30(b)), or (2) promulgate a modified version of this provision by approximately March 22, 2010, which, without regard to the requirements of the APA, shall become effective on June 22, 2010. Both options are unconstitutional. First, if left unmodified, the existing regulation is squarely

contrary to *Lorillard*, where the Supreme Court invalidated under the First Amendment a nearly identical Massachusetts regulation. *See Lorillard*, 533 U.S. at 535. Second, if the Secretary modifies the regulation, the Act fails to provide any meaningful procedural protection. Congress provided the Secretary, who is not politically accountable, unfettered discretion to issue a modified "final" regulation without any process and without any opportunity to be heard about the specifics of the regulation. Moreover, the lack of any prior notice of the specifics of the "final" regulation also severely prejudices Plaintiffs, who must plan advertising expenditures well in advance and will not have time to adjust their behavior to comply with the regulation. This lack of any procedural safeguards is unconstitutional. *See, e.g., Memphis Light, Gas & Water Division*, 436 U.S. 1, 20 (1978); *Armstrong v. Manzo*, 380 U.S. 545, 550 (1965).

2. Brand Name Sponsorship of Athletic, Cultural, And Other Events

The Act also impermissibly prohibits brand name sponsorships of "*any* athletic, musical, artistic, or *other social or cultural event*…." Pub. L. No. 111-31, § 102(a)(2) (adopting 21 C.F.R. § 897.34(c)) (emphasis added). This absolute prohibition extends to *any* "manufacturer, distributor or retailer" of tobacco products and the use of *any* "brand name, … logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to … any brand of cigarettes or smokeless tobacco." *Id.*

Among other things, this restriction prohibits the sponsorship of concerts in adult-only nightclubs that prohibit minors from attending. By contrast, the analogous restriction in the MSA expressly excludes adult-only facilities. *See* MSA § II(j); id. at § III(c). Although the MSA itself could not have been constitutionally imposed without the signatories' express waiver of their First Amendment rights, *see id.* at § XV, at the very least, it confirms that Congress had available to it obvious less onerous alternatives that it completely ignored. *See Rubin*, 514 U.S. at 491 (invalidating a restriction as "more extensive than necessary" when alternative restrictions "could

advance the government's asserted interest in a manner less intrusive to … First Amendment rights").

This provision, moreover, confirms that, although the world has changed dramatically since the FDA first promulgated these regulations in 1996, Congress failed to take these changes into account when passing the Act. In 1996, the FDA cited NASCAR's top racing series, the Winston Cup Series, as one of the primary examples of the type of brand-name tobacco sponsorship it was targeting. Yet in 2004, this series changed its name to the Nextel Cup Series, and is now the Sprint Cup Series. Nor have other prominent tobacco brand name sponsorships popped up in its place since the adoption of the MSA. Congress never explains why it believes that this restriction nevertheless remains necessary to further any substantial governmental interest.

3. Distribution Of Brand Name Promotional Items And All Promotional Giveaways

The Act also bans all promotional items bearing the "brand name …, logo, symbol, motto, selling message, recognizable color or pattern of colors" of any tobacco product brand and all promotional giveaways based on purchases of tobacco products or proofs of such purchases. Pub. L. No. 111-31, § 102(a)(2) (incorporating 21 C.F.R. § 897.34(a), .34(b)). The FDA's original justification for these provisions reveals that the FDA's primary motivation in passing them was not reducing youth tobacco use, but eviscerating the ability of tobacco manufacturers to speak about their lawful products. The FDA thus candidly acknowledged that these "advertising" bans were "necessary to eliminate the something-for-nothing appeal of these items, as well as to prevent wearers or users of these items from becoming image-laden walking advertisements." 61 Fed. Reg. at 44,521; *see also* 61 Fed. Reg. at 44,527. Nor can these prohibitions be justified by the possibility that some children might see an adult wearing the promotional item. Such an approach would be unconstitutional because it would impermissibly reduce the adult population to promotional items suitable for children. *See, e.g., Reno*, 521 U.S. at 875.

In any event, for the reasons explained above, these absolute prohibitions do not come close to the narrow tailoring that the Constitution demands. Like the sponsorship ban, they apply to all promotional items and giveaways, regardless of the type or design of the item, the age of the consumer, or the location of the distribution. The MSA's analogous provisions, by contrast, contain exceptions for the distribution of branded items to a "Participating Manufacturer's [adult] employees," for "coupons or other items used by Adults solely in connection with the purchase of Tobacco Products," for "apparel or other merchandise used within an Adult-Only Facility that is not distributed … to any member of the general public," and, in the case of items exchanged for the purchase of tobacco products, "any person with[] sufficient proof that such person is an Adult." MSA §§ III(f), (h). Again, while the MSA's requirements could not themselves be lawfully imposed absent the signatories' consent, at the very least, they demonstrate the obvious less burdensome alternatives that Congress ignored.

4. References To The FDA's Regulation Of Tobacco Products

The Act broadly prohibits "*any* express *or implied* statement or representation directed to consumers" "through the media or advertising" that "conveys" that a tobacco product is "less harmful by virtue of" either "regulation or inspection by the [FDA]" or "compliance with [the FDA's] regulatory requirements." Pub. L. No. 111-31, § 103(b)(13) (amending 21 U.S.C. § 331 to add subparagraph (tt)). This provision criminalizes even truthful statements if they "*implicitly*" convey the prohibited message. The Act thus authorizes the FDA "to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because … [it] is or may be harmful," *id.* at § 101(b) (amending the FDCA to add § 907(a)(3)(B)(ii)), but then absolves it of responsibility for the consequences of its decisions.

This provision chills any reference to FDA regulation of tobacco products, thus precluding not just Plaintiffs' commercial speech, but their core speech as well. Obviously, the very purpose of

government regulation of consumer products is to make those products "less harmful" than they would be absent such regulation. Consequently, any statement made by Plaintiffs that references FDA regulation could be construed as an "implied … representation" that tobacco products are "less harmful" as a result of FDA regulation. Indeed, this broad ban is not even limited to statements made by tobacco manufacturers and sellers: It applies to "*any* express or implied statement or representation," regardless of its source. Pub. L. No. 111-31, § 103(b) (amending 21 U.S.C. § 331 to add subparagraph (tt)) (emphasis added). Thus, published third-party scientific research indicating that health costs associated with tobacco-related diseases have dropped in the years after the Act went into effect would fall within the purview of this broad prohibition, as would a televised debate between political candidates over the FDA's regulatory competence.

"[T]he danger of censorship presented by [this] facially content-based statute requires that that weapon be employed only where it is *necessary* to serve the asserted [compelling] interest." *R.A.V.*, 505 U.S. at 395 (emphasis and second alteration in original) (internal quotation marks and citations omitted). This "content-based speech restriction … can stand only if it satisfies strict scrutiny." *Playboy Entm't*, 529 U.S. at 813; *see also R.A.V.,* 505 U.S. at 387. Nor does the ban pass the *Central Hudson* standard. The ban on references to FDA regulation does not even come close to satisfying this standard.

First, the Government has no substantial or compelling interest in prohibiting truthful statements about FDA regulation simply because such statements may "explicitly or implicitly" suggest that tobacco products are "less harmful" as a result of FDA regulation. If such a statement is true, then Plaintiffs have every right to make it, and the public has every right to receive it. After all, the First Amendment presumes "that the speaker and the audience, not the Government, should be left to assess the value of accurate and nonmisleading information about lawful conduct." *Greater New Orleans Broad. Ass'n*, 527 U.S. at 195.

Second, the Government has no evidence that this provision directly and materially advances any legitimate government interest. There is no evidence that consumers will mistakenly believe that FDA regulation will (or won't) result in tobacco products being "less harmful" than they would otherwise be absent regulation. Nor can the Government fill this evidentiary void through "speculation or conjecture," *44 Liquormart*, 517 U.S. at 507 (plurality op.); it "must present more than anecdote and supposition." *Playboy Entm't*, 529 U.S. at 822.

Third, this provision is not narrowly tailored to preventing consumer deception. It is not limited to false or misleading statements. Instead, it broadly prohibits *any* statement that merely "conveys" that tobacco products are "less harmful" because of FDA regulation. It is not even limited to tobacco manufacturers and sellers, but extends to true statements and good-faith opinions by *anyone* about the effects of FDA regulation on tobacco. Moreover, if the FDA truly believed that consumers are mistaken about the efficacy of FDA regulation, a more narrowly tailored approach would require a disclaimer—*e.g.,* "FDA regulation of tobacco products does not make them less harmful"—not an outright ban. *See Central Hudson*, 447 U.S. at 565.

As written, however, this provision "far exceeds" any restriction necessary to advance any legitimate governmental interest. *Sable Commc'ns*, 492 U.S. at 131.[17]

5. Free Product Samples

The Act also prohibits any "manufacturer, distributor, or retailer" of tobacco products from directly advertising or communicating with adult tobacco consumers by "distribut[ing] or caus[ing] to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products." Pub. L. No. 111-31, § 102(a)(2)(G) (adopting and amending 21 C.F.R. § 897.16(d)). This ban is

[17] *See also, e.g., Simon & Schuster, Inc. v. Members of the N.Y. State Crime Victims Bd.*, 502 U.S. 105, 121-23 (1991) (finding a speech restriction impermissibly overinclusive on the breadth of its potential scope); *Reno*, 521 U.S. at 874, 877-78 (noting that a statute's "burden on protected speech cannot be justified if it could be avoided by a more carefully drafted statute" and invalidating an open-ended speech prohibition that was "not limited to commercial speech or commercial entities"); *Edenfield*, 507 U.S. at 777 ("Broad prophylactic rules in the area of free expression are suspect. Precision of regulation must be the touchstone in an area so closely touching our most precious freedoms." (internal quotation marks and citation omitted)).

absolute for cigarettes, prohibiting the distribution of samples even to existing adult tobacco users in adult-only facilities. However, it contains a limited exception for smokeless tobacco products in "qualified adult-only facility[ies]"—a term that *excludes* entities that "sell, serve, or distribute alcohol." *Id*.

Again, it is difficult to understand how this blanket ban on direct advertising furthers any governmental interest other than banning tobacco manufacturers from attempting to persuade adult consumers of competitive tobacco products to switch brands. Indeed, the Act's exception for smokeless tobacco products undermines the purported governmental interest, articulated by the FDA in 1996, in "eliminating free samples because they are an inexpensive and easily accessible source of these products to young people and, when distributed at cultural or social events, may increase social pressure on young people to accept and use free samples." 61 Fed. Reg. at 44,460. If Congress truly believed that free samples posed such a danger, then its exception for smokeless tobacco products is inexplicable. As the Supreme Court has held, when the Government makes "decisions that select among speakers conveying virtually identical messages," such inconsistency "undermine[s] the asserted justifications for the restriction" and the means through which the Government is acting. *Greater New Orleans*, 527 U.S. at 192, 194 (invalidating ban on broadcast advertisements for privately operated commercial casino gambling but permitting such advertisements for Indian-run casinos); *Rubin*, 514 U.S. at 488-89 (invalidating a ban on statements of alcohol content on beer labels where the Government permitted such statements on wine and spirit labels).

Finally, there is no evidence that this prohibition directly and materially advances any governmental interest in reducing youth tobacco use. It is, for example, inconceivable that banning this direct communication with adult tobacco consumers will *significantly* reduce underage tobacco use, or indeed, reduce it at all. *See Edenfield*, 507 U.S. at 770; *Greater New Orleans*, 527 U.S. at

188. And such prophylactic rules cannot be justified to safeguard a "'few of the most enterprising and disobedient young people [who otherwise] would manage to secure access.'" *Sable Commc'ns*, 492 U.S. at 130 (citation omitted). Moreover, the MSA again demonstrates that the Act's blanket prohibition is not narrowly tailored, since, unlike the Act, the MSA permits signatories to distribute free samples in adult-only facilities or in conjunction with the sale of another tobacco product. *See* MSA § III(g). The Government cannot prove that this alternative—or the many others discussed above, *see supra* at Part I.A.1—would be less effective in reducing youth tobacco use than the Act's across-the-board ban.

6. Authorization of Further Restrictions

Finally, the Act authorizes federal agencies, state and local governments, and Indian tribes to enact even "more stringent" regulations. *See* Pub. L. No. 111-31, § 101(b) (amending the FDCA to add § 916(a)(1)); *id.* at § 203 (amending the FCLAA to insert 15 U.S.C. § 1334(c)). Since existing regulations are unconstitutional, it follows, *a fortiori*, that so too are "more stringent" ones. Moreover, the Act provides "literally no guidance" at all "for the exercise of discretion"—much less the required "intelligible principle." *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 474 (2001). Accordingly, the authorization of further restrictions violates the First Amendment and unconstitutionally delegates legislative power.

E. The Challenged Provisions Are Unconstitutional Because The Act Eliminates Alternative Avenues Of Speech

The Act collectively cuts off nearly every currently-available avenue of tobacco advertising and marketing. "[W]hen a State entirely prohibits the dissemination of truthful, nonmisleading commercial messages for reasons unrelated to the preservation of a fair bargaining process, there is far less reason to depart from the rigorous review that the First Amendment generally demands." *44 Liquormart*, 517 U.S. at 501 (plurality op); *see also, e.g., id.* at 518 (Thomas, J., concurring); *Central Hudson*, 447 U.S. at 566 n.9 ("We review with special care regulations that entirely

suppress commercial speech in order to pursue a nonspeech-related policy."). The Supreme Court has thus invalidated regimes that did not "leave[] open ample alternative channels for communication." *Linmark*, 431 U.S. at 93 (internal quotation marks and citation omitted). In *Linmark*, for example, the Court rejected the notion that the First Amendment was "less directly implicated" because alternative avenues remained "in theory," stating that "in practice" and "realistically," the alternatives "involve[d] more cost and less autonomy," were "less likely to reach persons not deliberately seeking sales information," "may be less effective media," and therefore, that the "alternatives ... [were] far from satisfactory." *Id*. (internal quotation marks and citations omitted). It follows *a fortiori* that the challenged provisions cannot stand where, as here, the Act eviscerates virtually *all* "alternative channels" of communication. *44 Liquormart*, 517 U.S. at 530-31 (O'Connor, J., concurring).[18]

II. IRREPARABLE HARM

As fully explained above, the Government has violated the First and Fifth Amendments in numerous ways. Two of these restrictions are already in effect and are currently chilling Plaintiffs' speech: The MRTP Requirement is preventing Plaintiffs' executives and scientists, who have in the past participated in scientific, public policy, and political debates regarding the use and regulation of tobacco products, from continuing to do so. *See* Payne Decl. ¶ 14. Likewise, the prohibition on jointly marketing tobacco products with other FDA-regulated products is currently restricting Plaintiffs' exercise of their First Amendment rights. *See* Cross Decl. ¶ 7-10. These present, ongoing violations of the First Amendment by definition inflict irreparable harm on Plaintiffs. As the Sixth Circuit has held, "when reviewing a motion for a preliminary injunction, if it is found that a constitutional right is being threatened or impaired, a finding of irreparable injury is mandated."

[18] *See also Lorillard*, 533 U.S. at 565 (restriction unconstitutional where it left no alternative channel for retailers); *Florida Bar v. Went For It, Inc*., 515 U.S. 618, 633-34 (1995) (upholding a commercial speech regulation where it allowed for "many [sufficient] alternative channels" to communicate the regulated information).

Am. Civil Liberties Union of Ky. v. McCreary County, Ky., 354 F.3d 438, 445 (6th Cir. 2003). "The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality op.); *see also* 11A Wright & Miller, Federal Practice and Procedure, Civil 2d § 2948.1 (1973) ("When an alleged deprivation of a constitutional right is involved, most courts hold that no further showing of irreparable injury is necessary.").

III. THE PUBLIC INTEREST AND ALLEGED HARM TO THE GOVERNMENT

Finally, a decision enjoining the FDA from violating Plaintiffs' speech and property rights serves the public interest. As the Sixth Circuit has held, "it is always in the public interest to prevent the violation of a party's constitutional rights." *G & V Lounge, Inc. v. Mich. Liquor Control Comm'n*, 23 F.3d 1071, 1079 (6th Cir. 1994). Thus, even though the Government has a legitimate interest in preventing underage tobacco use, the Government has no interest in achieving that goal in an unconstitutional manner.

Moreover, a panoply of federal and state governmental restrictions already exist and govern Plaintiffs' behavior. The Government has provided no evidence that these existing restrictions inadequately safeguard its asserted interests. As a result, there is no reason to run roughshod over Plaintiffs' constitutional rights and impose significant financial harm on Plaintiffs without considered judicial review. By granting a preliminary injunction to maintain the status quo, this Court will allow full resolution of these issues while protecting both Plaintiffs' constitutional rights and any legitimate governmental interests.

RELIEF REQUESTED

For the foregoing reasons, Plaintiffs request that this Court preliminarily enjoin the FDA from implementing and enforcing two of the challenged provisions of the Act that are currently in effect and establish an expedited schedule for resolving this case on the merits.

ENGLISH, LUCAS, PRIEST & OWSLEY, LLP
P.O. Box 770
1101 College Street
Bowling Green, KY 42102-0770
Telephone: (270) 781-6500
Facsimile: (270) 782-7782
E-mail: kames@elpolaw.com

ATTORNEYS FOR PLAINTIFFS

/s/ Charles E. English
Charles E. English
Charles E. English, Jr.
D. Gaines Penn
E. Kenly Ames

OF COUNSEL:

Philip J. Perry
Scott J. Ballenger
LATHAM & WATKINS LLP
555 11th Street, NW, Suite 1000
Washington DC 20004-1304
Telephone: (202) 637-2200

ATTORNEYS FOR PLAINTIFF
COMMONWEALTH BRANDS, INC.

Floyd Abrams
Joel Kurtzberg
CAHILL GORDON & REINDEL LLP
80 Pine Street
New York, NY 10005-1702
Telephone: (212) 701-3000

ATTORNEYS FOR PLAINTIFF
LORILLARD TOBACCO CO.

Robert F. McDermott, Jr.
Donald B. Ayer
Geoffrey K. Beach
Noel J. Francisco
JONES DAY
51 Louisiana Avenue, NW
Washington, D.C. 20001-2113
Telephone: (202) 879-3939

- and -

Leon F. DeJulius, Jr.
JONES DAY
500 Grant St., Suite 4500
Pittsburgh, PA 15219
Telephone: (412) 391-3939

ATTORNEYS FOR PLAINTIFFS
CONWOOD COMPANY, LLC AND R.J.
REYNOLDS TOBACCO COMPANY

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was this August 31, 2009, served by hand upon the following:

Ms. Candace G. Hill
Interim United States Attorney, W.D. Ky.
510 West Broadway, 10th Floor
Louisville, KY 40202

with additional copies sent by certified mail to the following:

Kathleen Sebelius, Secretary
United States Department of Health
and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dr. Margaret A. Hamburg, Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Eric H. Holder, Jr.
U.S. Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530-0001

/s/ E. Kenly Ames
E. KENLY AMES

853099