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 (Electronically Filed)
v.	*	
UNITED STATES OF AMERICA; UNITED STATES FOOD AND DRUG ADMINISTRATION; MARGARET HAMBURG, Commissioner of the United States Food and Drug Administration; and KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,	*	
Defendants.	*	

MEMORANDUM IN REPLY TO DEFENDANTS' OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

There is an ongoing public debate about whether migration to smokeless tobacco products should be part of a public health strategy addressed to tobacco use (or to reduce the risk to health faced by the millions of adult smokers who will not quit). As set forth in Plaintiffs' Response to the Amici Brief, numerous individuals and organizations on both sides of this debate are making their viewpoints known. It is now clear, however, that under the Government's interpretation of the Modified Risk Tobacco Products Requirement ("MRTPR"), the Act would reach virtually any statement Plaintiffs make in this public health debate—including in "press releases, reports, booklets, newsletters, television and radio appearances, and scientific symposia and publications." Opp. Br. at 6. Indeed, while the Government's brief clearly asserts that Plaintiffs' co-marketing conduct is not covered by the Act's Co-Marketing Ban,[1] it pointedly does *not* make the same representation regarding the statements on Reynolds' website about smokeless tobacco.

Plaintiffs, as manufacturers of tobacco products, but, more importantly, as corporate citizens, have a right to participate in this public debate. They would like to continue to make policy statements on their websites, present at scientific conferences, and publish scientific papers, among other activities. However, the MRTPR, as written and defended by the Government, would bar them from doing so unless the FDA first reviewed and approved their speech under a vague standard with no deadline for approval or denial. Consequently, this case is not about whether the FDA has authority to regulate tobacco products or the FDA's regulatory regime in general. Plaintiffs challenge neither. Rather, the issue is whether, under the First Amendment, the FDA may impose a one-sided moratorium on truthful speech about important matters of public policy.

[1] As explained in part II, *infra*, Plaintiffs hereby withdraw their request for a preliminary injunction on this issue at this time.

I. THE MODIFIED RISK TOBACCO PRODUCTS REQUIREMENT

1. MRTPR Regulates Speech, Not Conduct. As noted, the Government clearly is of the view that the MRTPR broadly bars Plaintiffs, on pain of criminal punishment, from engaging in the public debate about smokeless tobacco absent prior FDA approval of their speech. The Government nevertheless makes the shocking assertion that this criminal prohibition does not implicate the First Amendment *at all*. Opp. Br. at 18.

The Government has peddled this argument before, and it has been decisively rejected. That is because the principle it relies upon, exemplified by *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004), is entirely inapposite. The only issue in cases such as *Whitaker* is whether the FDA can consider a manufacturer's commercial statements about its product to determine whether the product's "intended use" makes it a "drug" subject to pre-sale approval. *Id.* at 948-50, 952-53. And courts have held that it can because such statements are merely "evidence whether the product is or is not a drug" under the "intended use" standard. *Id.* at 953. Here, however, Plaintiffs' statements are not being used as *mere evidence* of whether smokeless tobacco falls within a substantive regulatory standard. Under the MRTPR, the *only* regulatory standard for whether the products require FDA pre-approval is whether Plaintiffs *speak* about the properties of those products. In short, the MRTPR is a naked speech restriction.

In *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002), the Supreme Court squarely held that the First Amendment applies in such circumstances. There, the question was whether a "compounded drug" was a "new drug" that required FDA pre-approval. *See id.* at 360-65. Under the Food and Drug Administration Modernization Act of 1997, pharmacists were permitted to *sell* compounded drugs without pre-approval, but they were prohibited from *advertising* that they sold such drugs. *Id.* If they engaged in prohibited advertising, then the compounded drugs became "new drugs" which could then not be sold at all until approved by the FDA. *Id.* As the Supreme Court

explained, under this regime, "advertising [was] the trigger for requiring FDA approval." *Id.* at 370. Notwithstanding the Government's claim that advertising was merely a "fair proxy" for inferring that Congress wanted to treat the compounded drug as a "new drug," *id.* at 370-71, the Supreme Court squarely held that this was a *speech* restriction subject to First Amendment scrutiny—indeed, it *invalidated* the statute. *Id.* at 368-77. As commentators have observed, "[a]fter *Western States*, FDA can no longer assert that its use of speech as a proxy for conduct is exempt from First Amendment scrutiny."[2] And so the courts have uniformly rejected both the Government's purported "analogy to *Whitaker*" and "the notion that promotion of an approved drug [for unapproved uses] is conduct, as opposed to speech within the ambit of the First Amendment." *United States v. Caronia*, 576 F. Supp. 2d 385, 394-95 (E.D.N.Y. 2008).[3]

W. States Med. Ctr. controls this case. Here, as there, the *only* factor that triggers the MRTPR is whether plaintiffs *speak* about smokeless tobacco products—speech, in other words, is "the trigger for requiring FDA approval." 535 U.S. at 370. The only question, therefore, is whether this speech restriction survives First Amendment scrutiny. It does not.

2. The MRTPR Is An Unconstitutional Prior Restraint. The MRTPR is a classic prior restraint: If Plaintiffs speak about the relative health risks of smokeless tobacco without first getting prior FDA approval, then, for that reason and that reason alone, they have committed a crime. *See, e.g.*, *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*., 487 U.S. 781, 802 (1988) (striking down statute "requiring fundraisers to obtain a license before soliciting"). Indeed, the Act expressly provides that speech about such products is the *only* speech subject to a prior restraint. *See* 21

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[2] A. Elizabeth Blackwell & James M. Beck, *Drug Manufacturers' First Amendment Right to Advertise and Promote Their Products for Off-Label Use: Avoiding a Pyrrhic Victory*, 58 Food & Drug L.J. 439, 445-46 (2003).

[3] *See also, e.g.*, *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 59 (D.D.C. 1998) ("This court is hard pressed to believe that the [FDA] is seriously contending that 'promotion' of an [unapproved] activity is conduct and not speech, or that 'promotion' is entitled to no First Amendment protection."), *vacated in part as moot sub nom. Washington Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000); *Pearson v. Shalala*, 164 F.3d 650, 655-60 (D.C. Cir. 1999) (invalidating under First Amendment FDA's prohibition of health claims concerning dietary supplements).

U.S.C. § 387c(b) ("No regulation issued under this subsection may require prior approval by the Secretary of the content of any advertisement, *except for modified risk tobacco products* as provided in section 387k of this title" (emphasis added).). But as the Supreme Court has held, "[a]ny system of prior restraints of expression comes to this Court bearing a heavy presumption against its constitutional validity." *N.Y. Times Co. v. U.S.*, 403 U.S. 713, 714 (1971) (internal quotation marks and citations omitted). They must therefore satisfy rigorous substantive and procedural requirements. The MRTPR has neither.

First, a prior restraint is valid only if there are "*neutral criteria* to insure that the licensing decision is *not* based on the *content or viewpoint* of the speech being considered." *City of Lakewood v. Plain Dealer Publ'g Co.*, 486 U.S. 750, 760 (1988) (emphases added). But the MRTPR is a viewpoint-based restriction—it prohibits Plaintiffs from publicly describing the benefits of smokeless tobacco products to public health, but leaves their opponents free to articulate their contrary views anywhere, anytime. The MRTPR therefore fails at the gate. *See Forsyth County v. Nationalist Movement*, 505 U.S. 123, 133-34 (1992) (holding facially invalid a licensing scheme that allowed the state to "encourag[e] some views and discourag[e] others" and determine fees "based on the content of the speech"); *Burk v. Augusta-Richmond County*, 365 F.3d 1247, 1255 (11th Cir. 2004) (applying strict scrutiny to content-based licensing requirement).

Second, even content-neutral prior restraints are unconstitutional absent numerous "procedural safeguards designed to obviate the dangers of a censorship system." *Se. Promotions, Ltd. v. Conrad*, 420 U.S. 546, 559 (1975). The MRTPR, however, lacks *virtually every one* of these procedural safeguards, *each* of which the Constitution demands:

- It does not require "that the licensor 'will, within a *specified brief period*," "issue a license." *Riley*, 487 U.S. at 802 (emphasis added) (citation omitted). Indeed, it does not specify *any* period of time for final FDA action. *See, e.g.*, *Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 222, 228 (2d Cir. 1998) ("the absence of a final

deadline constituted a prior restraint of unlimited duration, and . . . without such a deadline, the preauthorization scheme would not pass constitutional muster.").

- It does not establish "narrow, objective, and definite standards to guide the licensing authority," *Se. Promotions*, 420 U.S. at 553, instead allowing the FDA to suppress truthful speech that it deems would not "benefit the health of the population as a whole," 21 U.S.C. § 387k(g)(1)(B). *See, e.g.*, *Desert Outdoor Advertising, Inc. v. City of Moreno Valley*, 103 F.3d 814, 818 (9th Cir. 1996) (invalidating a prior restraint on commercial speech because the "harmful effect upon the health or welfare of the general public" standard gave government officials "discretion to deny a permit on the basis of ambiguous and subjective reasons").

- It places the burden of proof on Plaintiffs to show that their speech is permissible, requiring "the *applicant* … [to] demonstrat[e]" that a product will reduce risk to individuals *and* "benefit the health of the population as a whole," 21 U.S.C. § 387k(g)(1), even though when "the constitutional right to speak" is at stake, it is "*the State*" that must "come[] forward with sufficient proof to justify its inhibition." *Speiser v. Randall*, 357 U.S. 513, 528-29 (1958) (emphasis added).

The Government offers no response to how the MRTPR can pass constitutional muster notwithstanding these fatal defects, *regardless* of whether the substance of the restriction is treated (correctly) as viewpoint-based regulation of core political speech or (incorrectly) as regulation of commercial speech. Indeed, it does not address this issue *at all.*

3. The MRTPR Cannot Survive Any Standard Of Scrutiny. Even setting aside the specific rules governing prior restraints, the MRTPR is unconstitutional. The Government does not even attempt to defend the proposition that viewpoint-based regulation of political speech is constitutionally permissible. Instead, it argues that the MRTPR is a permissible regulation of commercial speech. Opp. Br. at 22-33. It is wrong on both counts.

a. The MRTPR bans core political speech. "[T]he test for identifying commercial speech" is whether the speech at issue "'propose[s] a commercial transaction.'" *Bd. of Trs. of SUNY v. Fox*, 492 U.S. 469, 473-74 (1989); *see also id.* at 482 (making "clear" that "the difference between commercial and noncommercial speech" is that the former is "define[d]" as "speech that *proposes* a commercial transaction" (emphasis in original)). The MRTPR, however, covers "any

action directed to consumers through the media or otherwise," which, *by definition*, includes *only* speech that is *not* in "label, labeling, or advertising." 21 U.S.C. § 387k(b)(2)(A)(iii). Although some corporate speech other than in "label, labeling, or advertising" could be commercial speech, just as surely, most of it is not. And the Government concedes as much, because in its view, this broad prohibition reaches "press releases" and "television appearances" that *do not* "constitute the proposal of a commercial transaction." Opp. Br. at 28 (internal quotation marks omitted); *see also id.* at 6 (criticizing Plaintiffs' "press releases, reports, booklets, newsletters, television and radio appearances, and scientific symposia and publications" (citation omitted)).[4] If such speech is deemed commercial, then there is literally *no* speech that Plaintiffs could utter that is not. But as the Supreme Court has repeatedly held, "[s]ome of our most valued forms of fully protected speech are uttered for a profit." *Fox*, 492 U.S. at 482.

Nor do the cases the Government cites warrant such a stunning and counter-intuitive result. *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60 (1983), simply held that businesses cannot obtain heightened constitutional protection for speech that proposes a commercial transaction by artificially linking that speech to a current public debate and then claiming that, combined, the speech does *more than* propose a commercial transaction. *See id.* at 66-68; *see also Fox*, 492 U.S. at 474-75; *U.S. v. Philip Morris USA Inc.*, 566 F.3d 1095, 1144 (D.C. Cir. 2009). Likewise, while the Sixth Circuit has held that "[s]peech need not closely resemble a typical advertisement to be commercial," *Semco, Inc. v. Amcast, Inc.*, 52 F.3d 108, 112 (6th Cir. 1995), that in no way eliminates the requirement that such atypical advertisements *at least* "propose a commercial

[4] The Government's position means that Reynolds would have to pre-clear a press release, like the one it issued in July 2008, *opposing* the enactment of laws restricting reduced-risk products or urging their repeal. *See, e.g.,* Ex. 1. Indeed, even the ban on "advertising" in 21 U.S.C. § 387k(b)(2)(A)(i) can reach core political speech that does not propose a commercial transaction, *see, e.g.*, *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 265-66 (1964), and that is especially true with respect to Plaintiffs' "advertising," since their ability to engage in traditional *commercial* "advertising" is heavily restricted under federal law, 15 U.S.C. §§ 1335, 4402, and (for some Plaintiffs) the Master Settlement Agreement.

transaction"—a requirement plainly satisfied in *Semco*, where the magazine article at issue was "peppered with advertising" of the author-manufacturer's products and he "used the article as a promotional brochure at trade shows." *Id.* at 111, 113.[5]

At a minimum, Plaintiffs' so-called "commercial speech" is "inextricably intertwined with otherwise fully protected speech" and thus still governed by the "test for fully protected expression." *Riley*, 487 U.S. at 796. After all, Plaintiffs are not just choosing to "link[]" smokeless tobacco products to a public debate. *Fox*, 492 U.S. at 474-75; *see also Semco*, 52 F.3d at 113. Rather, it is difficult, if not impossible, to "delink" the two because the debate is *about* whether migration to certain categories of products could reduce tobacco-related disease. It would be difficult for Plaintiffs to engage in this debate *without* referencing such products. Thus, deeming Plaintiffs' speech to be "commercial" while holding their opponents' speech to be "political" would be tantamount to a judicial "license [for] one side of [the] debate to fight freestyle, while requiring the other to follow Marquis of Queensberry rules." *R.A.V. v. City of St. Paul*, 505 U.S. 377, 392 (1992). This "[v]iewpoint discrimination is censorship in its purest form." *Id.* at 430 (Stevens, J., concurring).

b. Even if treated as commercial speech, the MRTPR cannot survive review. Since this is, at the very least, *viewpoint-based* commercial speech, it is still subject to strict scrutiny, which the MRTPR cannot possibly survive. *R.A.V.*, 505 U.S. at 391-96 (holding that viewpoint-based distinction in *unprotected speech*—"fighting words"—was subject to strict scrutiny). And for the same reasons, it cannot survive *Central Hudson* review. The asserted substantial interest here is "protecting consumers from misleading claims about the relative health risks of tobacco products."

[5] For these reasons, amici's reliance on *Washington Legal Foundation* is equally unavailing. There, the district court explicitly found that speech by drug manufacturers to prescribing physicians did "propose a commercial transaction" by "suggest[ing] that a physician should prescribe – and a consumer therefore [would] purchase – the subject drug." 13 F. Supp. 2d at 64 (citation omitted).

Opp. Br. at 22. The MRTPR, however, does not "directly advance[]," nor is it "narrowly tailored" to, this purported interest. *Fox*, 492 U.S. at 475, 480.

First, "evaluated in the context of the entire regulatory scheme," it is self-evident from the face of the Act that the MRTPR is not intended to, and does not, "directly and materially advance[]" the Government's purported interest in preventing misleading speech. *Greater New Orleans Broad. Ass'n, Inc. v. U.S.*, 527 U.S. 173, 192-93 (1999). "[T]he directly advance prong seeks to ferret out whether a law ostensibly premised on legitimate public policy objectives in truth serves those objectives." *BellSouth Telecommunications, Inc. v. Farris*, 542 F.3d 499, 507 (6th Cir. 2008). The Supreme Court has thus admonished that courts must not "turn away if it appears that the stated interests are not the actual interests served by the restriction," lest the Government "with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression." *Edenfield v. Fane*, 507 U.S. 761, 768, 771 (1993).

Here, the Government has failed to sustain its burden. The Government's purported interest in preventing "misleading" speech is belied by the fact that virtually every clause in the challenged provisions facially proscribes indisputably truthful speech:

- 21 U.S.C. § 387k(g)(1) absolutely bans the indisputably truthful statement to consumers that a product will "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users," if the FDA determines that the product will not *also* "benefit the health of the population as a whole" because its availability causes too many consumers not to quit.

- 21 U.S.C. §§ 387k(b)(2)(A)(i)(II)-(III) absolutely ban the indisputably truthful statement to consumers that a product contains reduced amounts or is free of "a substance" *for reasons completely unrelated to health*, because such products will *never* satisfy the requirements of § 387k(g)(1).

- 21 U.S.C. § 387k(b)(2)(A)(i)(I) bans reduced-risk claims for smokeless tobacco even though the scientific record overwhelmingly and indisputably establishes (and for purposes of argument the Government concedes) that such products substantially reduce individual health risks relative to smoking cigarettes. *See* Reply to Amici Brief at 3-7 (summarizing scientific evidence).

The MRTPR, therefore, is precisely the type of law for which the "ostensibly … legitimate public policy objectives," *Bellsouth,* 542 F.3d at 507, are, in truth, "in the service of other objectives that could not themselves justify a burden on commercial expression," *Edenfield*, 507 U.S. at 771—*i.e.,* suppressing truthful information about smokeless products out of "concern" that smokeless tobacco "marketing might 'reduce cessation or delay cessation attempts' by current cigarette smokers," Opp. Br. at 11. But "[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.'" *Wash. Legal Found.*, 13 F. Supp. 2d at 69-70 (quoting *44 Liquormart, Inc. v. R.I.*, 517 U.S. 484, 497 (1996) (plurality op.)).

Consequently, while the Government and its amici spend page after page discussing the vigorously disputed and not yet final judicial findings concerning the veracity of Plaintiffs' marketing of "low tar" and "light" cigarettes, *see* Opp. Br. at 5-14; Amici Br. at 3-4, those findings are simply beside the point. Plaintiffs are not challenging the Act's ban on descriptors for "low tar" cigarettes. Rather, they are challenging the MRTPR's *other* restrictions, which are patently overbroad. *These* restrictions on their face suppress indisputably truthful speech.[6]

Second, the Government fails to prove that the MRTPR is narrowly tailored, because the Act's "broad sweep" also "indicates that [Congress] did not 'carefully calculate the costs and benefits associated with the burden on speech imposed.'" *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 561 (2001) (citation omitted); *see also BellSouth*, 542 F.3d at 508 ("[T]he reasonable-fit requirement generally guards against over-inclusive laws (those that do too much)."). In *Lorillard*,

[6] The Government concedes for purpose of this argument that Plaintiffs' speech is truthful. Opp. Br. at 35. And, it must. The Government proffers no evidence that Plaintiffs' speech is misleading or false. The few random statements in the congressional record—none of which are specific to Plaintiffs' statements in any event—are hearsay and inadmissible. *See, e.g.*, *Pearce v. E.F. Hutton Group, Inc.*, 653 F. Supp. 810, 813-15 (D.D.C. 1987) ("[T]estimony before a congressional committee is manifestly hearsay. . . . It is one of the most fundamental rules of evidence that such testimony is inadmissible. Under no stretch of the imagination could such evidence fit within one of the exceptions to the hearsay rule.").

for example, the Supreme Court facially invalidated Massachusetts' outdoor advertising regulations in part because they applied across the board without regard to whether different types of speech truly implicated the state's interest. *See* 533 U.S. at 561-66. Likewise, in *W. States Med. Ctr.*, the Court facially invalidated a Congressional ban on compound drug advertising because of the sizeable "amount of beneficial speech" covered by the ban that did "not appear to directly further any asserted governmental objective." 535 U.S. at 376-77. Here, too, the Act's consistent coverage of *indisputably truthful speech*, as demonstrated above, proves beyond doubt that Congress did not "carefully calculate the costs and benefits associated with the burden on speech imposed."

Finally, and equally fatal under *Central Hudson*'s narrow-tailoring prong, the Act eschews "a full arsenal of options short of restricting speech." *BellSouth*, 542 F.3d at 508. Most obviously, the asserted government interest could be met through enforcement actions against advertising that is false or misleading, *see Nutritional Health Alliance*, 144 F.3d at 223 n.4 (noting that this is the enforcement mechanism for non-label advertisements about nutritional supplements), strengthened fraud laws, or appropriate disclaimers. *See BellSouth*, 542 F.3d at 508-09.[7] At a minimum, the Government could have limited the MRTPR to manufacturers' claims about specific products on their labeling or commercial advertising rather than potentially criminalizing all of their truthful speech in an ongoing public health debate. "The Government has not offered any reason why these possibilities, alone or in combination, would be insufficient to" protect consumers from misleading claims about smokeless products, even though it is established that "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, *the Government must do so*." *W. States Med. Ctr.*, 535 U.S. at 371, 373 (emphasis added). In short, to

[7] Although the Government observes that Congress included a legislative finding that the FTC had concluded that disclaimers would not be effective, *see* Opp. Br. at 14, 24-25, neither the Act nor the Government provide the FTC's reasoning for that alleged conclusion or even the context in which it was made. But as the D.C. Circuit has held, the Government's "conclusory assertion" that it needs to "choos[e] suppression over disclosure as a response to the problem of consumer confusion … falls far short" under *Central Hudson*. *Pearson*, 164 F.3d at 659. The Constitution does not permit regulation-by-*ipse dixit* when our First Amendment rights are at stake.

the extent that the MRTPR was even intended to directly advance a governmental interest in preventing misleading speech, an unduly onerous speech restriction once again "seems to have been the first strategy the Government thought to try," rather than its "last … resort." *Id*. at 373.

4. The FDA Drug Regime Is Inapposite. Lacking any doctrinal justification for the MRTPR, the Government diverts this Court's attention by arguing that it "mirrors" the FDA's regulation of prescription drug marketing. Opp. Br. at 15. But the Supreme Court has struck down a similar prescription drug regime as unconstitutional and, in any event, the FDA's drug regulation is *less* restrictive of speech.

First, as explained *supra*, the Supreme Court struck down the FDA's attempt to prohibit pharmacists from advertising that they provided prescription compounded drugs, primarily because there were multiple non-speech options available to the FDA. *W. States Med. Ctr.*, 535 U.S. at 368-77. Indeed, where there are non-speech alternatives available to Congress or the FDA, the courts have not hesitated to invalidate the regimes governing prescription drugs and nutritional supplements.[8] In fact, the cases upholding the FDA regime involved off-label drug use by drug manufacturers, where the Government has demonstrated there are *no* "non-speech restrictions that would likely constrain in any effective way manufacturers from circumventing th[e] [new drug] approval process." *Caronia*, 576 F. Supp. 2d at 401. Here, the Government contends the MRTPR is intended to prohibit "misleading claims about the relative health risks of tobacco products." Opp. Br. at 22. But *that* purpose can be served in myriad ways that do *not* prohibit Plaintiffs from engaging in truthful speech. S*ee supra*, at I.3.b.

[8] *See, e.g., Washington Legal Fdn*., 13 F. Supp. 2d at 73-74 (sustaining facial challenge to FDA guidance prohibiting drug manufacturers from marketing off-label uses by disseminating medical articles promoting such off-label use because the guidance ignored "the most obvious alternative" to the speech ban—"full, complete, and unambiguous disclosure by the manufacturer"); *Pearson*, 164 F.3d at 658 (finding unconstitutional the FDA's refusal to approve health claims for dietary supplements because "when government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a 'far less restrictive' means.").

Second, the prescription drug regime and similar regime governing nutritional supplement labels in fact provide numerous examples of *less* speech-restrictive alternatives than the MRTPR. For example:

- The FDA drug regime applies only to labels and advertisements, whereas the MRTPR applies broadly to all statements "directed to consumers through the media or otherwise," including press releases and scientific debates. When the FDA has sought to apply its regulations broadly to encompass drug manufacturers' speech to physicians, for example, the courts have struck them down as unconstitutional. *Washington Legal Fdn.*, 13 F. Supp. 2d at 73-74.

- The FDA generally regulates false and misleading advertisements through after-the-fact enforcement. 21 U.S.C. § 352(n) ("except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement."). Instead of a prior restraint in advertising, the prescription drug regime requires only that advertising be submitted to the FDA at the time of initial publication, thereby facilitating FDA enforcement against non-compliant advertising. 21 C.F.R. § 314.81(b)(3)(i).

- The FDA expressly permits drug manufacturers to say that "a drug is safer or more effective than another drug in some particular" if that representation is supported by "substantial evidence" or "substantial clinical experience." 21 C.F.R. § 202.1(e)(6)(ii). *See also id.* § 202.1(e)(6)(i). These are the same types of statements for which the MRTPR requires prior FDA approval. 21 U.S.C. § 387k(b)(2)(A).

- The prescription drug regime does not permit censorship based on an open-ended "health of the population as a whole" standard. Instead, it spells out specific grounds on which the FDA must refuse the application of new drug applications. *See, e.g.*, 21 U.S.C. § 355(d).

- Where the prescription drug regime does impose a prior restraint (*i.e.*, on "labeling" for a new drug), it sets forth specific timetables for the FDA to complete its review. *See* 21 U.S.C. § 355(c). The MRTPR has no such timetables.

Thus, unlike the MRTPR, these regimes generally reflect the First Amendment's strong preference "to punish the few who abuse rights of speech after they break the law than to throttle them and all others beforehand." *Se. Promotions*, 420 U.S. at 559. Accordingly, far from undermining Plaintiffs' arguments, the prescription drug and nutritional supplement regimes confirm the MRTPR's patent unconstitutionality.

5. The MRTPR Is Unconstitutionally Vague. The Government barely addresses the inherent ambiguity that permeates the MRTPR. Its main arguments appear to be that the provision regarding "any action directed to consumers" is clear, Opp. Br. at 28-29, presumably because (in the Government's view) it clearly covers *everything* that Plaintiffs might say about smokeless tobacco. If that is not the Government's position, then it fails to explain what, if anything, is *not* covered. And the Government completely ignores the MRTPR's regulation of any statement "reasonably expected to result in consumers believing" a product "may present" a reduced risk, *see* Pls. Br. at 28-29, even though the Sixth Circuit has specifically condemned such open-ended and discretionary standards. *See United Food & Commercial Workers Union, Local 1099 v. Sw. Ohio Reg'l Transit Auth.*, 163 F.3d 341, 359-60 (6th Cir. 1998); *see also City of Chicago v. Morales*, 527 U.S. 41, 56-57 (1999) (plurality op.) (ordinance prohibiting loitering "with no apparent purpose"); *Kolender v. Lawson*, 461 U.S. 352, 358-61 (1983) (statute requiring an individual to provide "credible and reliable" identification when requested by a police officer).[9]

The Government also defends the open-ended "benefit[s] the health of the population as a whole" standard, because the statute requires the Secretary to "take into account" factors such as whether, if given truthful information, "existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application." *See* Opp. Br. at 32 (quoting 21 U.S.C. § 387k(g)(4). It is difficult to understand why the Government believes that this *restrains* the FDA's discretion, rather than confirming, beyond doubt, that the FDA has virtually *carte blanche* to restrict indisputably truthful information in order to save "the public [from] us[ing] truthful, nonmisleading commercial information unwisely." *44 Liquormart*, 517 U.S. at 497 (plurality op.). Like the First Amendment, the Due Process Clause

[9] The Government notes that the MRTPR permits Plaintiffs to call their smoke-free products "smoke-free." Opp. Br. 29 (quoting 21 U.S.C. § 387k(b)(2)(C)). But what the Government omits is that the MRTPR prohibits Plaintiffs from stating that smoke-free products "do not pose the health risks caused by second-hand smoke."

does not permit such unrestrained governmental power. *See Interstate Circuit, Inc. v. City of Dallas*, 390 U.S. 676, 681-83 (1968) (noting that courts "start with the premise that 'precision of regulation must be the touchstone'" where regulated activity is "protected by the First Amendment" and emphasizing that "[t]he vice of vagueness is particularly pronounced where expression is sought to be subjected to licensing") (citation omitted).

6. Plaintiffs' Challenge Is Ripe And They Will Suffer Irreparable Harm. The Government argues that Plaintiffs' claim is not ripe because they have not yet subjected themselves to the MRTPR's unconstitutional licensing scheme. Opp. Br. 30-31. But as the Sixth Circuit has held, a First Amendment challenge to a permitting scheme is ripe even though the plaintiffs "have not yet sought a permit." *Deja Vu of Nashville, Inc. v. Nashville and Davidson County*, 274 F.3d 377, 399 (6th Cir. 2001).[10] Plaintiffs' claim is also ripe because the MRTPR's patent overbreadth and lack of tailoring render it facially unconstitutional whether treated as core or commercial speech. *See Lorillard*, 533 U.S. at 561-66. Finally, Plaintiffs easily demonstrate irreparable harm: they are currently subject to the MRTPR, and therefore are presently refraining from engaging in truthful speech that they would otherwise make, as Plaintiffs' witnesses will attest at the upcoming hearing. Such a concrete "chilling effect" plainly establishes the requisite harm. *See e.g.*, *Deja Vu*, 274 F.3d at 399-400; *United Food*, 163 F.3d at 363.

7. The Public Interest Favors A Preliminary Injunction. Finally, the Government claims that a preliminary injunction should be denied because it "is crucial to the public health that

[10] *See also, e.g., Freedman v. Md.,* 380 U.S. 51, 56 (1965) ("In the area of freedom of expression it is well established that one has standing to challenge a statute on the ground that it delegates overly broad licensing discretion to an administrative office, whether or not his conduct could be proscribed by a properly drawn statute, and whether or not he applied for a license."); *Plain Dealer Publ'g Co.*, 486 U.S. at 755-56 ("[O]ur cases have long held that when a licensing statute allegedly vests unbridled discretion in a government official over whether to permit or deny expressive activity, one who is subject to the law may challenge it facially without the necessity of first applying for, and being denied, a license."); *Int'l Outdoor, Inc. v. City of Romulus*, No. 07-15125, 2008 WL 4792645, at *6 (E.D. Mich. Oct. 29, 2008) (same); *New Mexicans for Bill Richardson v. Gonzales*, 64 F.3d 1495, 1503-04 (10th Cir. 1995) (holding vagueness challenge ripe and recognizing that "the arguable vagueness of a statute greatly militates in favor of finding an otherwise premature controversy to be ripe"); *Am. Broad. Co. v. Blackwell*, 479 F. Supp. 2d 719, 731 (S.D. Ohio 2006) (holding vagueness challenge ripe).

tobacco products not be marketed as reduced risk products unless they will, in fact, reduce risks." Opp. Br. at 33. But "it is *always* in the public interest to prevent violation of a party's constitutional rights," *Deja Vu*, 274 F.3d at 400 (quoting *G & V Lounge, Inc. v. Mich. Liquor Control Comm'n*, 23 F.3d 1071, 1079 (6th Cir. 1994)) (emphasis added), and "if the plaintiff shows a substantial likelihood that the challenged law is unconstitutional, *no* substantial harm to others can be said to inhere in its enjoinment," *Deja Vu*, 274 F.3d at 400 (emphasis added). Nowhere is that more true than where the Government has curtailed discussion on a matter of public importance. *See United Food*, 163 F.3d at 363. Moreover, here, the Government *concedes* "for purposes of argument, that [Plaintiffs] would be able to demonstrate to the FDA that [their] smokeless products pose reduced risks of tobacco-related disease," Opp. Br. at 35—a concession born out by the overwhelming scientific evidence. This concession not only forecloses the Government's asserted public interest; it irrefutably establishes that if a preliminary injunction does not issue, the *suppression* of this truthful information will deny existing individual smokers information that could reduce their health risks by orders of magnitude. The public interest therefore clearly favors an injunction.

II. THE CO-MARKETING BAN

In view of the Department of Justice and FDA's representation in their jointly-filed and jointly-signed brief that "[t]he marketing practices cited in plaintiffs' declaration … are not covered by the combination marketing provision," Opp. Br. at 40, Plaintiffs hereby withdraw their request for a preliminary injunction on this issue at this time. Plaintiffs continue to believe that this provision, which on its face applies to *marketing*, is unconstitutional and reserve their right to challenge it at an appropriate time.

* * *

For the foregoing reasons, as well as those explained in Plaintiffs' opening brief, this Court should preliminarily enjoin the challenged provisions of the MRTPR.

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CERTIFICATE OF SERVICE

I hereby certify that on October 5, 2009, I electronically filed the foregoing document with the clerk of the court by using the CM/ECF system, which will send a notice of electronic filing to the following:

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