UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
BOWLING GREEN DIVISION

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

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

V.

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

MEMORANDUM OPINION AND ORDER

This matter is before the Court on Plaintiffs' motion for a preliminary injunction against enforcement of the Modified Risk Tobacco Products provision of the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 (2009). See 21 U.S.C. § 387k. The Court held a hearing on the motion on October 8, 2009. Fully briefed, the matter is ripe for decision. For the reasons that follow, Plaintiffs' motion is **DENIED**.

I. BACKGROUND

On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 (2009) into law. The Act was prompted, in part, by Congress's determination that "consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification" and its conclusion that "[t]he only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers [sell] or distribute[] for risk reduction be reviewed in advance of marketing, and to require that the evidence relied on to support claims be fully verified." 21 U.S.C. § 387 (Findings 41 and 43).

These findings resulted in the Modified Risk Tobacco Products ("MRTP") provision, which prohibits the introduction into interstate commerce of any "modified risk tobacco product" without prior FDA approval. 21 U.S.C. § 387k(a). The MRTP provision defines a "modified risk tobacco product" as any tobacco product that is "sold or distributed for use to reduce harm or the risk of tobacco-related disease." Id. § 387k(b)(1). The term "sold or distributed for use to reduce harm or the risk of tobacco-related disease" means a product—

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

> (I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;
>
> (II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or
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> (III) the tobacco product or its smoke does not contain or is free of a substance;
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> (ii) the label, labeling, or advertising of which uses the descriptors "light", "mild", or "low" or similar descriptors; or
>
> (iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after June 22, 2009, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

Id. § 387k(b)(2)(A).

To market a modified risk tobacco product, Plaintiffs must first file an application with the Secretary of the United States Department of Health and Human Services. Id. § 387k(d). That application will be made available for public comment and referred to the Tobacco Products Scientific Advisory Committee, which will provide a recommendation to the Secretary within sixty days. Id. § 387k(e), (f)(2). The Secretary will grant the application to market a modified risk tobacco product only if she determines that the applicant has demonstrated that "the product, as it is actually used by consumers, will (1)

significantly reduce harm and risk of tobacco-related disease to individual tobacco users; and (2) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." Id. § 387k(g)(1).

II. DISCUSSION

The question before the Court is whether Plaintiffs have met their burden of showing the need for the "extraordinary remedy" of a preliminary injunction against enforcement of the MRTP provision. Tennessee Scrap Recyclers Ass'n v. Bredesen, 556 F.3d 442, 447 (6th Cir. 2009). In determining whether to issue a preliminary injunction, courts consider four factors: (a) whether the movant has a strong likelihood of success on the merits; (b) whether the movant would suffer irreparable injury without the injunction; (c) whether issuance of the injunction would cause substantial harm to others; and (d) whether the public interest would be served by the issuance of the injunction. Certified Restoration Dry Cleaning Network, L.L.C. v. Tenke Corp., 511 F.3d 535, 542 (6th Cir. 2007). Generally, the "district court [is] to make specific findings concerning each of these four factors, unless fewer are dispositive of the issue." In re DeLorean Motor Co., 755 F.2d 1223, 1228 (6th Cir. 1985) (citing United States v. Sch. Dist. of Ferndale, 577 F.2d 1339, 1352 (6th Cir. 1978)).

A.

The first factor asks whether a plaintiff has "demonstrated a strong likelihood of success on the merits." Tenke, 511 F.3d at 543. To satisfy this burden, a plaintiff must

show "more than a mere possibility of success" on the merits; he must raise "questions . . . so serious, substantial, difficult, and doubtful as to make them a fair ground for litigation and thus for more deliberate investigation." Id. (quotations omitted). In this case, Plaintiffs contend that the MRTP provision "is a viewpoint-based restriction on core First Amendment speech . . . subject to strict scrutiny" which fails to pass review because "it is not necessary to serve the asserted interest." (Plaintiffs' Brief, p. 23, 35) (quotation omitted). In the alternative, they say that the MRTP provision fails under the test for commercial speech because "it restricts *all* speech about the relative health risks of different tobacco products." Id. at 28 (emphasis theirs).

Plaintiffs also argue that the MRTP provision is an unconstitutional prior restraint because it "lacks any of the constitutionally-mandated procedural safeguards that the Supreme Court requires of prior restraints under any level of scrutiny." (Plaintiffs' Brief, p. 25). Finally, they contend that the MRTP provision is unconstitutionally vague because a tobacco company has no assurance that, e.g., posting the "indisputable truism that smokeless tobacco does not produce second-hand smoke" on its website will not subject its management to criminal penalties because the act prohibits "[a]ny action directed to consumers" which according to the FDA may "reasonably [be] expected to result in consumers believing" a product "may present" a reduced health risk. Id. at 29. It is also unconstitutionally vague, Plaintiffs argue, because the "benefit[s] the health of the population as a whole" standard in 21 U.S.C. § 387k(g)(1)(B) gives the FDA virtually unlimited discretion to ban truthful, nonmisleading speech. Id. at 28-29.

The government counters that "the purpose of the modified risk provisions, like that of the provisions governing drugs and devices, is to evaluate a manufacturer's evidence that the product will, in fact, achieve its claimed purpose." (Government's Response, p. 21). In other words, the government's primary contention is that "the statutory provisions regulating modified risk tobacco products do not restrict speech; they restrict the distribution of certain products without FDA review." Id. The government also asserts that strict scrutiny is inapplicable; and it contends that, if the commercial speech test applies, "[t]he dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product" and the statute is narrowly tailored to advance that important interest. Id. at 23-24 (quoting Finding 40). The Court considers these arguments in turn.

1.

One of the initial questions presented is whether the MRTP provision regulates speech, and if it does, whether that speech is protected by the First Amendment. The government argues that the MRTP provision does not implicate the First Amendment and directs the Court to Whitaker v. Thompson, 353 F.3d 947 (D.C. Cir. 2004), which involved a First Amendment challenge to the FDA's refusal to allow a manufacturer's promotional claims about his product—saw palmetto. In that case, the FDA found that the manufacturer's proposed label contained a claim about the product which constituted

a "drug claim" as opposed to a "health claim." This meant that the product had to go through the FDA's rigorous drug approval process before it could be marketed with Whitaker's desired label. Whitaker brought suit challenging the "drug claim" versus "health claim" determination, and also argued that the FDA's refusal to allow the marketing of saw palmetto under his proposed label violated the First Amendment because the Federal Food, Drug, and Cosmetic Act's ("FFDCA") pre-market approval process barred a "true and non-misleading statement about [his product's] salutary effects." Id. at 952.

The district court analyzed Whitaker's challenge under the Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York, 447 U.S. 557 (1980) test for commercial speech. That test first asks whether the speech concerns lawful activity and is not misleading; if the answer is no, the speech is not protected. Id. at 565 (explaining that "there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity"). If the answer is yes, however, the speech can only be regulated if the government has a substantial interest in regulating the speech; the regulation directly advances the government's interest; and the regulation is not more extensive than is necessary to serve that interest. Id. at 565. In Whitaker, the district court rejected the plaintiff's challenge under the first prong because the FDA had determined the claim was a "drug claim" and therefore, "because [the] sale pursuant to the claim was 'unlawful' under the statute, the speech related to an unlawful transaction and enjoyed no First Amendment protection." Id. at 953.

The Court of Appeals affirmed. It acknowledged that the district court's analysis was circular; however, it thought it could "recharacterize the analysis in a way that avoid[ed] the circularity." Id. at 953. Starting with the unchallenged premise that the FDA may prohibit the sale of certain products prior to an approval process, the court focused on the fact that the classification of a particular substance as a regulated product turned on the nature of the claims made about it. In other words, it viewed the regulation as addressed to products and found that any regulated speech merely "serve[d] as evidence of the sellers' intent that consumers will purchase and use the product for a particular purpose – and, therefore, as evidence whether the product is or is not a drug." Id. That was "constitutionally permissible," the court concluded, "[because] the First Amendment allows 'the evidentiary use of speech to establish the elements of a crime or to prove motive or intent.'" Id. at 953 (quoting Wisconsin v. Mitchell, 508 U.S. 476, 489 (1993)).

That same reasoning would seem to apply here. In this case, the MRTP provision bans the "introduc[tion] or deliver[y] for introduction into interstate commerce" of a modified risk tobacco product without prior FDA approval. It defines a modified risk product as one that "is sold or distributed *for use* to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." 21 U.S.C. § 387k(b)(1) (emphasis added). And, like the FFDCA language at issue in Whitaker, the MRTP provision defines whether a product is sold "for [such] use" based on the manufacturer's promotional statements about the product, including "labels,"

"advertising," and "any action directed to consumers." Id. § 387k(b)(2)(A). In the Court's view, then, the MRTP provision seems indistinguishable from the regulation presented in Whitaker: it criminalizes the sale or distribution of a product and merely uses speech as evidence of the manufacturer's intent to market a product as a "modified risk tobacco product."

At the same time, however, Plaintiffs' contention that Thompson v. Western States Medical Center, 535 U.S. 357 (2002) controls this case is not easily rejected. There, the Supreme Court invalidated on First Amendment grounds a provision in the Food and Drug Administration Modernization Act of 1997 that allowed pharmacists to sell compounded drugs without pre-approval so long as the pharmacists did not advertise that they sold such drugs. Plaintiffs argue that Western States "controls" this case because the high court "squarely held that [the FDA regulation of compounded drug advertising] was a speech restriction subject to First Amendment scrutiny" and there, as here, "advertising [was] the trigger for requiring FDA approval." (Plaintiffs' Reply, p. 2) (quoting in part Western States at 370; citing 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)). Thus, at the very least, Western States suggests that product regulations that are triggered solely by speech are in fact regulations of speech.

This point is illustrated by the United States District Court for the Eastern District of New York's decision in United States v. Caronia, 576 F. Supp. 2d 385 (E.D.N.Y.

2008). In that case, a pharmaceutical sales representative was charged with "misbranding" violations of the FDCA for promoting a prescription sleep medication for off-label uses. On a motion to dismiss, the government argued, as it does here, that the misbranding regulation applied to conduct not speech. The court disagreed. It found that the government's argument "overlooks case law which has generally rejected the notion that promotion of an approved drug is conduct, as opposed to speech within the ambit of the First Amendment." Id. at 394-95 (citing 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")). It also concluded that, post-Western States, "Whitaker and similar cases may be confined to the particular context of restrictions on the marketing of drugs and devices that are *not approved for any use*, rather than the marketing of off-label uses of drugs and devices that have been FDA-approved . . ." Id. (emphasis added).

The Court finds this reasoning somewhat persuasive, particularly when one considers that the goal of the MRTP provision is not to prevent tobacco manufacturers from selling products that are, e.g., low tar, but to prevent manufacturers from saying their tobacco products are "low tar" insofar as such a statement might imply that a product poses a reduced health risk when, according to the FDA, it does not. In this sense, it is solely the manufacturer's promotional claims about the product that "triggers" FDA review. See, e.g., § 387k(b)(2)(A)(iii). Given the difficulty of this initial question,

the Court thinks it best to assume for purposes of this preliminary injunction motion that the MRTP provision regulates speech and must satisfy the First Amendment.

2.

Assuming that the MRTP provision implicates the First Amendment, it seems likely that its restrictions on speech are constitutionally permissible. The government argues that the MRTP provision need only satisfy the test for commercial speech outlined in Central Hudson because it applies to speech that "proposes a commercial transaction." Bd. of Trs. of SUNY v. Fox, 492 U.S. 469, 473-74 (1989). Plaintiffs argue that the MRTP provision must satisfy strict scrutiny because it covers "any action directed to consumers through the media or otherwise," which they say clearly applies to "press releases, booklets, and television appearances" that are in whole or in part "'fully protected speech' and thus . . . governed by the 'test for fully protected expression.'" 21 U.S.C. § 387k(b)(2)(A)(iii); (Plaintiffs' Reply, pp. 6-7) (quoting Riley v. Nat'l Fed'n of the Blind of N.C., Inc., 487 U.S. 781, 796 (1988)). Plaintiffs also contend that, unlike cases where the Supreme Court has found that commercial speech remained commercial speech notwithstanding the inclusion of a political statement, "it is difficult, if not impossible, to 'delink' [smokeless tobacco products from the public debate] because the debate is about whether migration to certain categories of products could reduce tobacco-related disease." Id. (citing Bolger v. Youngs Drug Products Corp., 463 U.S. 60, 66 (1983)).

At this time, the Court is not persuaded by Plaintiffs' arguments. Simply because

the MRTP provision is not limited to forms of communication traditionally recognized as proposing a commercial transaction, e.g., labels and advertising, does not necessarily mean that the provision applies to noncommercial speech. That contention appears to have no basis in either fact or law. See generally U.S. v. Philip Morris USA Inc., 566 F.3d 1095, 1121 (D.C. Cir. 2009) (discussing tobacco-product manufacturers' history of advancing their bottom line by misleading consumers about the health risks associated with their products through a variety of media including scientific research papers); Semco, Inc. v. Amcast, Inc., 52 F.3d 108, 112 (6th Cir. 1995) (explaining that "[s]peech need not closely resemble a typical advertisement to be commercial."). Nor does the fact that it is "difficult to 'delink'" a product from an alleged "debate" about smokeless tobacco products seem especially significant. It appears enough, in the Court's view, that the MRTP provision only addresses speech by economically-motivated tobacco-product manufacturers that is "directed to consumers" and "respecting a product" to conclude that Central Hudson exclusively applies. Cf. Bolger, 463 U.S. at 66 (finding "strong support" for the conclusion that speech was commercial where it was directed to consumers in the form of an advertisement, referenced a specific product, and was motivated by the speaker's economic interest).

3.

Under Central Hudson, the Court reviews "a government scheme to regulate

potentially misleading commercial speech by applying a three-part test."[1] Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999) (citing Central Hudson, 447 U.S. at 566). The first part of that test asks whether the asserted governmental interest is substantial. Id. Here, the government argues that given the significant health risks associated with the use of tobacco products and the history of marketing "low tar" and "light" cigarettes, it has a substantial interest in protecting consumers from misleading tobacco industry claims about allegedly reduced risk tobacco products.[2] The Court agrees. See id.; see also Edenfield v. Fane, 507 U.S. 761, 769 (1993) (finding that "there is no question that [the

[1] This skips the usual first step of Central Hudson, which requires a court to determine whether the speech is unlawful or misleading, presumably because of the enormous difficulty of judicially deciding that question prior to an agency record. In fact, courts presented with the question have generally balked, finding reasons to treat the pre-enforcement facial challenge as nonjusticiable. See, e.g., Nutritional Health Alliance v. Shalala, 144 F.3d 220, 225 (2d Cir. 1998) (finding facial challenge to FDA "health claim" regulations "preferably deemed not to be ready for judicial review" because "in the abstract without a full record . . . . it is extremely difficult for the court to conduct a Central Hudson analysis."); see also National Council for Improved Health v. Shalala, 122 F.3d 878, 883 n.7 (10th Cir. 1997) (concluding similarly and explaining that "[w]ithout knowing what claims plaintiffs seek to disseminate, this court cannot assess whether such claims are truthful and not misleading. Therefore an analysis of this issue would rest on mere speculation."). Here, there are similar grounds for saying that Plaintiffs' facial challenge is not ripe for judicial review. After all, Plaintiffs have not filed and the FDA has not ruled on any application for a modified risk tobacco product. (Government's Response, p. 31). However, because the D.C. Circuit's approach in Pearson makes the Central Hudson question purely a legal one, because that question is not merely speculative since Plaintiffs also challenge the MRTP provision on grounds that are eminently ripe for judicial review (vagueness and as an unconstitutional licensing system), and because the MRTP provision appears to cover at least some truthful, nonmisleading speech, the Court believes the challenge is ripe. See Warshak v. United States, 532 F.3d 521, 528 (6th Cir. 2008); Deja Vu of Nashville, Inc. v. Nashville and Davidson County, 274 F.3d 377, 399 (6th Cir. 2001); cf. National Council, 144 F.3d at 226.

[2] As Congress put it: "The dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product." (Finding 40).

government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial"); Rubin v. Coors Brewing Co., 514 U.S. 476, 485 (1995) (observing that the government has a substantial interest in "promoting the health, safety, and welfare of its citizens"). Because the Court has concluded that the government's asserted interest is valid, Plaintiffs' argument that the government has no "interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions" is better understood as a challenge to the MRTP provision under the next two steps of the commercial speech analysis. (Plaintiffs' Brief, p. 27).

The second step of the Central Hudson test asks whether the challenged provision "directly and materially advanc[es] the asserted governmental interest." Id. at 566. This step "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 government argues that the MRTP provision advances Congress's goal of ensuring that tobacco products that "purport to reduce risk . . . actually reduce such risks" by requiring tobacco manufacturers to obtain FDA approval before making statements about a product that suggest that the product poses a reduced health risk vis-a-vis other tobacco products. (Government's Response, p. 23); 21 U.S.C. § 387 (Finding 37). Plaintiffs contend, on the other hand, that 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." (Plaintiffs'

Reply, p. 8). They note, for example, that 21 U.S.C. §§ 387k(b)(2)(A)(i)(II) and (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)," i.e., the "benefit the population as a whole" standard. Id.

The Court again tends to agree with the government at this time. The basic flaw in Plaintiffs' argument is that a claim may be absolutely true and still be misleading. In fact, this is particularly likely in the context of regulated drugs and other such products where the determination of whether a particular claim is misleading inherently depends on many things, including scientific evidence about the product, the intended consumers' use of the product, and the ability of would-be consumers to recognize that narrowly true health or risk claims may only be narrowly true. Indeed, it is in just this broad sense that the MRTP provision seeks to prevent misleading claims about so-called modified risk tobacco products: it authorizes the FDA to "review the scientific evidence that the product will, in fact, 'reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.'" Id. § 387k(b)(1). Based on the Congressional record, and in light of the detailed requirements for testing and approval of modified risk tobacco products in the statute, the Court finds that the government has "demonstrate[d] that the harms it recites are real" and that the MRTP provision will "alleviate [the harms] to a material degree.'" Greater New Orleans Broadcasting Ass'n, Inc. v. U.S., 527 U.S. 173, 188 (1999).

The next question is whether the MRTP provision is "more extensive than necessary" or, put differently, whether there is "a reasonable fit between the means and ends of the regulatory scheme."[3] Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 561 (2001); Board of Trustees of State University of New York v. Fox, 492 U.S. 469, 480 (1989); Central Hudson, 447 U.S. at 569. The Supreme Court has explained that there is a "reasonable fit" where regulations are "in proportion to the interest served." Edenfield, 507 U.S. at 767; In re R.M.J., 455 U.S. 191, 203 (1982). Here, the MRTP provision requires that "products that tobacco manufacturers s[ell] or distribute[] for risk reduction be reviewed in advance of marketing, and . . . the evidence relied on to support claims be fully verified." (Finding 43). Plaintiffs argue that the MRTP provision is not reasonably fitted to the regulation's legitimate ends because it covers "indisputably truthful" speech and the government has no "interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions." (Plaintiffs' Brief, p. 27) (quoting Western States, 535 U.S. at 374).

The Court has, however, already noted the flawed premise of this argument, i.e., that indisputably truthful information in the form of a modified risk claim is necessarily

[3] Plaintiffs suggest that the Supreme Court has shifted away from the "reasonable fit" interpretation and closer to a plain reading of Central Hudson's "more extensive than necessary" requirement by saying 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." Western States, 535 U.S. at 371, 373 (emphasis added); cf. IMS Health Inc. v. Ayotte, 550 F.3d 42, 58 (1st Cir. 2008). But the Sixth Circuit has implicitly rejected that view, see Pagan v. Fruchey, 492 F.3d 766, 771 (6th Cir. 2007) (en banc), and in any event, the Court's analysis and conclusion remain the same under either construction.

nonmisleading. Contrary to Plaintiff's contention, this is not a case like Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976), 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484 (1996), or Thompson v. Western States Medical Center, 535 U.S. 357 (2002), where the regulated speech was patently truthful *and nonmisleading* because the respective statutes addressed advertising related only to a product's price or sale. Rather, the MRTP provision targets *misleading* commercial speech by requiring the FDA to test whether a tobacco product promoted as modified risk actually reduces health risks associated with tobacco use. The Supreme Court's skepticism of statutes founded on the "paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely" is therefore inapplicable here. 44 Liquormart, 517 U.S. at 497.

Plaintiffs also argue that the MRTP provision is more extensive than necessary because it "eschews 'a full arsenal of options short of restricting speech'" and because "an unduly onerous speech restriction once again 'seems to have been the first strategy the Government thought to try,' rather than its 'last . . . resort.'" (Plaintiffs' Reply, pp. 10-11) (quoting BellSouth Telecommunications, Inc. v. Farris, 542 F.3d 499, 508 (6th Cir. 2008) and Western States, 535 U.S. at 373). They contend that the asserted governmental interest could be met through less-restrictive means such as enforcement actions against advertising that is false or misleading, strengthened fraud laws, or appropriate disclaimers. And they further argue that the MRTP provision could have restricted less speech by only regulating manufacturers' claims in commercial advertisements and on

product labels rather than applying to "any action" by a manufacturer directed to consumers "respecting a product." (Plaintiffs' Reply, p. 11); 21 U.S.C. § 387k(b)(2)(A)(iii). The Court is currently unconvinced.

Here, the government has offered reasons why Plaintiffs' proposed alternatives would be insufficient to protect consumers from misleading claims about modified risk tobacco products. First, Congress found that pre-market FDA review is the "*only way* to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products[.]" (Finding 43) (emphasis added). It noted that other less restrictive means had been tried and found wanting, primarily because of the industry's success in evading regulation: "No one can forget the parade of tobacco executives who testified under oath before Congress that smoking cigarettes is not addictive. Overwhelming evidence in industry documents . . . proves that the companies not only knew of this addictiveness for decades, but actually relied on it as the basis for their marketing strategy." (Government's Response, p. 25). In this sense, then, the MRTP provision's system of prior approval—rather than, e.g., relying on stonger enforcement mechanisms ex post—is no more extensive than necessary to achieve Congress's goal.

Second, Congress expressly rejected the idea that requiring disclaimers for modified risk tobacco products would be effective, citing the Federal Trade Commission's determination that "consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification." (Findings 41-

42). Third, limiting the MRTP provision to advertising and labels on specific products would fail to achieve Congress's goal because it ignores the reality of today's consumer marketing techniques, see, e.g., Nike v. Kasky, 539 U.S. 654 (2003), cert. dismissed, (involving the corporate use of press releases, letters to editors of newspapers, university presidents, and athletic directors, and a commissioned report, as part of a campaign to boost sales), and overlooks the tobacco industry's participation in "[t]he largest disinformation campaign in the history of the corporate world." 155 Cong. Rec. S6408 (June 10, 2009) (Sen. Kennedy); see generally Philip Morris, 566 F.3d at 1121. Accordingly, the Court concludes that there is at least a reasonable fit between the means and ends of the MRTP regulatory scheme.

4.

Next, the Plaintiffs argue that the MRTP provision is an unconstitutional prior restraint. To a limited extent, the Court agrees. By requiring applicants to submit "proposed advertising and labeling" and "sample product labels and labelling" with their applications to market modified risk tobacco products, 21 U.S.C. § 387k(d)(1), (5), the MRTP provision operates as a prior restraint by holding that speech captive and effectively "compel[ling] [Plaintiffs'] silence" until the FDA completes its review. Riley v. Nat'l Fed'n of the Blind of N.C., Inc., 487 U.S. 781, 802 (1988); cf. Nutritional Health Alliance v. Shalala, 144 F.3d 220, 225 (2d Cir. 1998) (finding a prior restraint on speech while FDA assessed whether there was "significant scientific agreement" for purposes of approving a proposed "health claim" about a nutritional supplement).

The Supreme Court has indicated that the "traditional prior restraint doctrine may not apply" in the commercial speech context. Central Hudson, 447 U.S. at 571 n. 13 (citing Virginia Pharmacy Board v. Virginia Citizens Consumer Council, 425 U.S. 748, 762 (1976). This is because commercial speech "relates to a particular product or service . . . [and is therefore] more objective, hence more verifiable, than other varieties of speech . . . . [and it] is also less likely than other forms of speech to be inhibited by proper regulation." Friedman v. Rogers, 440 U.S. 1, 10 (1979). However, the Supreme Court has suggested, and lower courts have consistently found, that prior restraints on commercial speech must at least include procedural safeguards to avoid the danger of unfettered discretion inherent in governmental censorship systems. Central Hudson, 447 U.S. at 571 n. 13 (citing Freedman v. Maryland, 380 U.S. 51 (1965)); New York Magazine v. MTA, 136 F.3d 123, 131-32 (2d Cir. 1998); Desert Outdoor Adver. v. City of Moreno Valley, 103 F.3d 814, 818 (9th Cir. 1996); In re Search of Kitty's East, 905 F.2d 1367, 1371-72 & n. 4 (10th Cir. 1990).

Plaintiffs argue that the MRTP provision fails to guard against such unfettered FDA discretion because (1) it does not establish "narrow, objective, and definite standards to guide the licensing authority"; (2) "[i]t 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); and (3) it does not place any time limit on the FDA's administrative decision. (Plaintiffs' Reply, p. 5) (quoting in part

Southeastern Promotions, Ltd. v. Conrad, 420 U.S. 546, 553 (1975)). Plaintiffs' first argument is based on the idea that the "benefit the health of the population as a whole" standard in 21 U.S.C. § 387k(g)(1), like the "harmful effect upon the health or welfare of the general public" standard struck down in Desert Outdoor Advertising, Inc. v. City of Moreno Valley, 103 F.3d 814 (9th Cir. 1996), gives the FDA "discretion to deny a permit on the basis of ambiguous and subjective reasons." Id. at 818.

If the "benefit to the population as a whole" standard was undefined, Plaintiffs might well be right. However, the MRTP provision provides a standard by which the FDA must determine whether a modified risk tobacco product will benefit the population as a whole. It states that "the Secretary shall take into account"—

> (A) the relative health risks to individuals of the tobacco product that is the subject of the application;
>
> (B) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;
>
> (C) the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;
>
> (D) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under subchapter V of this chapter to treat nicotine dependence; and
>
> (E) comments, data, and information submitted by interested persons.

21 U.S.C. § 387k(g)(4).

The Court finds these criteria "narrow, objective, and definite." See Se.

Promotions, 420 U.S. at 553. They show that the FDA does not, as Plaintiffs contend, have "virtually carte blanche" to deny an application to market a modified risk tobacco product based on the "benefit the population as a whole" language; on the contrary, the FDA must base its determination on certain "increased or decreased likelihood[s]" and "risks and benefits" which presumably can and will be established by evidence that Plaintiffs and other interested parties are expressly invited to provide.[4]

Plaintiffs' second argument that the MRTP provision unconstitutionally "places the burden of proof on Plaintiffs to show that their speech is permissible" is also unpersuasive. (Plaintiffs' Reply, p. 5). The burden-on-the-government procedural safeguard originated in the context of a film censorship system involving the "transcendent value of speech" and the "presumptively invalid . . . . direct censorship of particular expressive material." Freedman v. Maryland, 380 U.S. 51, 58 (1965); FW/PBS, Inc. v. City of Dallas, 493 U.S. 215, 229 (1990) (describing Freedman). The MRTP provision, of course, involves neither. It regulates modified risk tobacco products and requires applicants to show that such products are modified risk—it does not require applicants to prove that the proposed commercial speech is itself permissible. The Court therefore concludes that the MRTP provision need not place the burden of proof on the government in order to satisfy the First Amendment. See generally FW/PBS, Inc., 493 U.S. at 229 (explaining that not all procedural safeguards are required in every case).

[4] Plaintiffs also make this argument in the context of their vagueness challenge. The Court rejects it there for the same reason.

Plaintiffs' third argument is more compelling. Under the MRTP provision, tobacco manufacturers must submit not only the would-be modified risk product but any "proposed advertising and labeling" and "sample product labels and labelling" to the FDA for review. 21 U.S.C. § 387k(d)(1), (5). Thus, any such proposed speech about a modified risk tobacco product is effectively silenced until the FDA issues a decision. Because this is so, the reasonable time limit safeguard is necessary to satisfy the "principle that the freedoms of expression must be ringed about with adequate bulwarks." Bantam Books, Inc. v. Sullivan, 372 U.S. 58, 66 (1963). At this point, such a time limit is missing. While Congress has charged the FDA with "establish[ing] a reasonable timetable for the Secretary to review an application under this section," it has given the FDA two years to come up with one. 21 U.S.C. § 387k(k)(F). The Court thinks it likely that this two-year delay is unconstitutional given that certain portions of the MRTP provision have been in effect since June 22, 2009. Id. §§ 387k(b)(2)(A)(iii), (b)(3); cf. 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.").

5.

Finally, Plaintiffs argue that the MRTP provision is void for vagueness. A statute is not unconstitutionally vague unless it "fails to provide a person of ordinary intelligence fair notice of what is prohibited." United States v. Williams, 128 S. Ct. 1830, 1845

(2008); U.S. v. Paull, 551 F.3d 516, 525 (6th Cir. 2009). "[T]he Constitution does not require impossible standards; all that is required is that the language conveys sufficiently definite warning as to the proscribed conduct when measured by common understanding and practices." Hamling v. United States, 418 U.S. 87, 111 (1974). (quotation omitted); see also Ward v. Rock Against Racism, 491 U.S. 781, 794 (1989) (explaining that "perfect clarity and precise guidance have never been required even of regulations that restrict expressive activity."). In this case, Plaintiffs contend that the statute must be struck down on vagueness grounds because they cannot be sure what "any action directed to consumers" covers, or what statements can "reasonably be expected to result in consumers believing" a product "may present" a reduced risk.[5] (Plaintiffs' Brief, p. 28).

The Court disagrees. Unlike statutes that "tie[] criminal culpability to whether the defendant's conduct was 'annoying' or 'indecent'-wholly subjective judgments without statutory definitions, narrowing context, or settled legal meanings[,]" which the Supreme

[5] Plaintiffs' main concern seems to be that the MRTP provision covers anything they would want to say about smokeless tobacco products, including the "indisputable truism that smokeless tobacco does not produce second-hand smoke." (Plaintiffs' Brief, p. 29); 21 U.S.C. § 387k(b)(2)(A)(iii). However, this sort of statement seems pretty clearly to be excluded from the MRTP provision. Section 387k(b)(2)(C) states that "[n]o smokeless tobacco product shall be considered to be 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products' solely because its label, labeling, or advertising uses the following phrases to describe such product and its use: 'smokeless tobacco', 'smokeless tobacco product', 'not consumed by smoking', 'does not produce smoke', 'smokefree', 'smoke-free', 'without smoke', 'no smoke', or 'not smoke.'" See 21 U.S.C. § 387k(b)(2)(C). Even if the FDA were to conclude otherwise, however, the lack of certainty regarding a single hypothetical is not dispositive for purposes of a facial vagueness challenge. See Hill v. Colorado, 530 U.S. 703, 733 (2000) (explaining that "speculation about possible vagueness in hypothetical situations not before the Court will not support a facial attack on a statute when it is surely valid 'in the vast majority of its intended applications.'") (quotation omitted).

Court has struck down as unconstitutionally vague, the MRTP provision provides an objective standard by which Plaintiffs may judge their conduct: whether the tobacco manufacturer's action can "*reasonably be expected* to result in consumers believing" that a product may present a reduced risk. Id. § 387k(b)(2)(A)(iii) (emphasis added). U.S. v. Williams, 128 S.Ct. 1830 (2008) (citing Coates v. Cincinnati, 402 U.S. 611, 614 (1971); Reno v. American Civil Liberties Union, 521 U.S. 844, 870-71 (1997)). To be sure, the objective standard is relatively broad in the sense that tobacco companies may have to account for even unreasonable consumers in deciding what a particular action may "reasonably be expected" to do. But on its face the statute gives fair notice of what it prohibits.

* * *

In sum, the Court concludes that Plaintiffs have little likelihood of success on the merits of their facial First Amendment challenge to the MRTP provision except on the theory that it operates as a prior restraint on speech and lacks a reasonable time limit for FDA review. Because this first factor is not determinative unless there is absolutely "*no* likelihood of success on the merits," the Court next proceeds to address the other three factors of the preliminary injunction analysis. Gonzales v. National Bd. of Medical Examiners, 225 F.3d 620, 625 (6th Cir. 2000) (emphasis added).

B.

Plaintiffs argue that they "easily demonstrate irreparable harm" because "they are currently subject to the MRTP [provision] and therefore are presently refraining from engaging in truthful speech that they would otherwise make." (Plaintiffs' Reply, p. 13). While the testimony at the hearing on the motion for a preliminary injunction showed that Plaintiffs are refraining from speech about the relative health risks associated with the use of smokeless tobacco products, Plaintiffs' conclusion that their self-censorship establishes irreparable harm is erroneous. It is only where a plaintiff has a strong likelihood of success on the merits that self-censorship is necessarily irreparable harm. See Elrod v. Burns, 427 U.S. 347, 373 (1976); United Food & Commercial Workers Union, Local 1099 v. Southwest United Food & Commercial Workers Union, Local 1099 v. Southwest Ohio Regional Transit Authority, 163 F.3d 341, 363 (6th Cir. 1998).

Here, Plaintiffs only have a strong likelihood of success on the merits of their claim that the MRTP provision is an unconstitutional prior restraint because it lacks a time limit for FDA review. Because Plaintiffs have not filed an application for review of a modified risk tobacco product with the FDA, however, the lack of a time limit is not harming them now at all. Indeed, even if Plaintiffs had filed an application with the FDA, it seems unlikely that they would be suffering irreparable harm at this point because a delay of 540 days in a similar context has been found to satisfy the First Amendment, Nutritional Health Alliance v. Shalala, 144 F.3d 220, 225 (2d Cir. 1998), and the Court could always require the FDA to provide a time limit if necessary. See, e.g, Nutritional

Health Alliance v. Shalala, 953 F.Supp. 526, 532 & n. 17 (S.D.N.Y. 1997) (citing Gonzalez v. Freeman, 334 F.2d 570, 577-580 (D.C. Cir.1964); Blankenship v. Secretary of HEW, 587 F.2d 329, 336 (6th Cir. 1978)). Accordingly, the Court concludes that Plaintiffs have not shown the irreparable harm required for a preliminary injunction.

C.

The next factor is whether an injunction poses a "substantial harm to others." The government says that enjoining the MRTP provision will cause tremendous harm to others because "[t]he costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system." (Government's Response, p. 33) (quoting Finding 37). In support of this proposition, it cites the tobacco industry's history of marketing "low tar" cigarettes, which caused numerous smokers to believe they were using a less harmful product when in fact they were not. U.S. v. Philip Morris USA Inc., 566 F.3d 1095, 1107 (D.C. Cir. 2009); Statement of Vice Admiral Richard H. Carmona, U.S. Surgeon General, to House Subcommittee on Commerce, Trade, and Consumer Protection, June 3, 2003, reprinted at 155 Cong. Rec. S5999-6000 (June 3, 2009) ("Our nation's experience with low-tar, low-nicotine cigarettes is instructive to the issue at hand. . . . We now know that low-tar cigarettes not only did not provide a public health benefit, but they also may have contributed to an actual increase in death and disease among smokers."). In light of this

evidence, the Court concludes that the "harm to others" factor weighs against the Plaintiffs' request for injunctive relief.

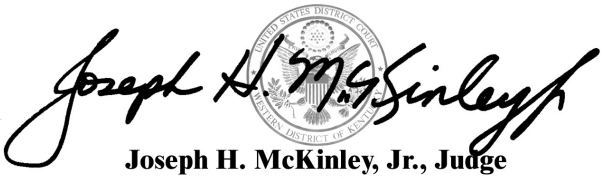
D.

The final factor is whether an injunction would serve the "public interest." Plaintiffs rightly observe that "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); see also Gannett Co., Inc. v. DePasquale, 443 U.S. 368, 383 (1979). However, they wrongly conclude that that rule applies here. Because Plaintiffs' only likelihood of success on the merits involves the lack of a time limit for FDA review, an injunction against enforcement of the MRTP provision is not necessary to prevent a violation of their constitutional rights. On the other hand, as the government observes, it is clearly and substantially in the public interest to uphold the MRTP provision and prevent the sale or distribution of purportedly reduced health risk tobacco products that do not in fact reduce such risk. See generally Edenfield v. Fane, 507 U.S. 761, 769 (1993). The Court therefore concludes that this factor also weighs in the government's favor.

Having considered each of the required factors, the Court finds that the "extraordinary remedy" of a preliminary injunction is unwarranted.

III. CONCLUSION

For the foregoing reasons, Plaintiffs' motion is **DENIED**.



Joseph H. McKinley, Jr., Judge
United States District Court

November 5, 2009

cc. Counsel of Record