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

COMMONWEALTH BRANDS, INC.; CONWOOD COMPANY, LLC; DISCOUNT TOBACCO CITY & LOTTERY, INC.; LORILLARD TOBACCO COMPANY; NATIONAL TOBACCO, 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 State Department of Health and Human Services,** **Defendants.**	**Civil Action No. 1:09CV-117-M** **(Electronically Filed)**

MEMORANDUM IN OPPOSITION TO
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION AND SUMMARY

On June 22, 2009, the President signed into law the Family Smoking Prevention and Tobacco Control Act of 2009 ("the Act"). The Act amends the Federal Food, Drug, and Cosmetic Act ("FDCA") to authorize the Food and Drug Administration ("FDA") to regulate tobacco products. The legislation followed years of exhaustive investigation by Congress, the executive branch and the courts that detailed the multi-faceted health hazards posed by tobacco use – risks that are rendered even more deadly because tobacco products are not only dangerous but also addictive.

Plaintiffs seek a preliminary injunction with respect to two of the Act's provisions. The first requires pre-market review by the FDA of "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." 21 U.S.C. § 387k(a), (b)(1). Marketing of such products is prohibited until the agency has determined, pursuant to standards set out in the Act, whether the product will in fact reduce such risks. The second challenged provision prohibits the marketing of a tobacco product "in combination with any other article or product regulated under" the FDCA. Id. § 321(rr)(4). Both challenges fail as a matter of law, because they are premised on misconceptions as to how the statutory provisions work and as to the governing First Amendment principles.

I. In enacting provisions for FDA review of "modified risk" tobacco products, Congress recognized the overwhelming evidence that consumers purchase certain tobacco products in the mistaken belief that the products reduce the health risks associated with tobacco use. Congress acknowledged, as well, that in the past such products largely escaped regulation. As a consequence, manufacturers have been able to market so-called "light" and "low tar" cigarettes as reduced risk

products, even though these products do not, in fact, reduce risk. As Congress found, the resulting impact on the public health has been devastating. See 21 U.S.C. § 387 Note, Findings 37-38.[1]

To close this regulatory gap, Congress enacted provisions requiring pre-market FDA review of tobacco products that purport to offer a reduced health risk. These provisions parallel existing provisions requiring pre-market review of drugs and certain medical devices. Under both the preexisting provisions and the new provisions, the requirement for pre-market FDA review depends on the purpose for which the product is marketed. Under both schemes, that purpose can be established by promotional claims, including claims made in labeling and advertising.

As the courts have explained, this examination of promotional claims to determine whether a product is subject to pre-market FDA review does not raise First Amendment concerns and thus does not require the further analysis used when reviewing the regulation of commercial speech. See, e.g., Whitaker v. Thompson, 353 F.3d 947, 952-53 (D.C. Cir. 2004). That reasoning applies equally here. After extensive consideration of the issue, Congress has decided to regulate the sale of "modified risk" tobacco products and, in determining whether a product falls within the scope of that provision, promotional claims about the product may – indeed, must – be considered, without implicating First Amendment concerns.

Even assuming, however, that the modified risk provisions are analyzed as commercial speech restrictions under Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557 (1980), they constitute a narrowly tailored means to further an enormously significant government interest. The health risks associated with tobacco use and nicotine addiction are

[1] The legislative findings are codified in a note to 21 U.S.C. § 387 and appear at 123 Stat. 1776, 1777-81 (2009).

overwhelming and incontrovertible. It is similarly beyond dispute that consumers, concerned about those risks, have turned to products such as "light" cigarettes on the mistaken belief that these products reduce the risks of tobacco-related disease. 21 U.S.C. § 387 Note, Findings 38-39. As Congress found, the "costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk" include "thousands of unnecessary deaths and injuries and huge costs to our health care system." Finding 37.

Plaintiffs cannot seriously dispute the urgency of establishing standards for the sale of modified risk tobacco products. Nor can plaintiffs credibly assert that the only means available to Congress to combat the industry's "dissemination of false or misleading information" are the measures that have consistently proved inadequate in the past. Mem. in Support of Pls. Mot. ("Pls. Mem.") at 24. The Constitution does not restrict Congress to regulatory measures that are demonstrably ineffective, and plaintiffs do not explain why Congress cannot employ here the same type of pre-market review procedures successfully used with regard to drugs and devices since 1962 and 1976, respectively.

Plaintiffs make little attempt to address the context and purpose of the modified risk provisions, and their objections to two aspects of the statutory scheme have no merit. First, they contend that in determining the intended use of their tobacco products, the only promotional claims that may be considered are those made in labeling and advertising, rather than messages directed to consumers through other media such as company websites. As reflected by case law and in accordance with common sense, the First Amendment imposes no such categorical limit.

Second, plaintiffs take issue with some of the statutory criteria to be considered by the FDA in determining whether to grant a manufacturer's application to market a modified risk tobacco

product. As discussed in the Argument, that claim also fails on the merits. Furthermore, as a threshold matter, it is unripe. No plaintiff has applied for an FDA order to market a modified risk tobacco product, and it is entirely speculative whether the criteria that they challenge would be the basis of an adverse agency decision.

II. Plaintiffs' challenge to 21 U.S.C. § 321(rr)(4), which prohibits the marketing of a tobacco product "in combination with any other article or product regulated under" the FDCA, misapprehends the scope of that section. That provision is directed at commercial conduct that links the sale of tobacco directly to the purchase of another regulated product. It thus applies to the physical combination of a tobacco product with a non-tobacco product, such as a soda enhanced with tobacco-derived nicotine, or the physical packaging of tobacco with another product. In addition, it applies to marketing practices that directly link the sale of tobacco to that of another product as, for example, a coupon offering $1 off the price of a soda upon the purchase of cigarettes, or vice versa. The provision thus targets commercial conduct, not speech, and raises no First Amendment concerns. In any event, the specific marketing practices that plaintiffs identify and seek to protect through issuance of a preliminary injunction, see Pls. Mem. 30-31, are not regulated under § 321(rr)(4).

III. The balance of harms and the public interest strongly militate against a grant of injunctive relief with respect to both of the provisions at issue. As noted, plaintiffs' challenge to the combined marketing provision rests on a misunderstanding of its effect. Their challenge to a subset of the criteria that would be used to evaluate an application to market modified risk product is a similarly unacceptable candidate for preliminary relief. Plaintiffs have not applied for an order to market any product under this provision and, as noted, it is entirely conjectural whether those criteria

would be the basis for an adverse ruling. Plaintiffs' contention regarding messages to consumers other than labeling and advertising likewise identifies no imminent, irreparable harm. The statute is not impermissibly vague and, contrary to plaintiffs' assertions, it does not criminalize speech. That one or more of plaintiffs' executives claim to have a good faith belief in the comparative safety of a modified risk tobacco product is not a ground for excusing compliance with Congress's administrative review scheme.

The threat to the public health, in contrast, is real and immediate. It has been documented beyond reasonable dispute. Tobacco use is not only deadly but also addictive. The harm created when a person commences tobacco use, as thousands do each day, is in the truest sense irreparable. Similar injury is inflicted on existing consumers who purchase "light" cigarettes and other ostensibly reduced risk products under the false belief that they are ameliorating health risks. Plaintiffs' motion should be denied.

STATEMENT

In few cases has a regulatory statute been preceded by such prolonged, intensive investigation of the products and industry to be regulated. The health risks associated with tobacco use and the marketing practices of the tobacco industry have been studied for more than four decades by the executive branch, Congress, and the courts, as well as by countless public health organizations.

A. The Marketing Of Ostensibly "Reduced Risk" Tobacco Products.

1. Beginning with the 1964 landmark report on "Smoking and Health," the Surgeon General issued a series of reports detailing the serious adverse health consequences of smoking and nicotine addiction. See United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1, 949 App. 2 (D.D.C. 2006) (listing and describing reports), aff'd in relevant part, 566 F.3d 1095 (D.C. Cir. 2009). In

response, tobacco manufacturers undertook a multi-pronged campaign to undermine the credibility of these studies, even though the companies had long understood the health risks associated with the use of tobacco products. These "efforts to deny and distort the scientific evidence of smoking's harms are demonstrated by not only decades of press releases, reports, booklets, newsletters, television and radio appearances, and scientific symposia and publications, but also by evidence of their concerted[] efforts to attack and undermine the studies in mainstream scientific publications such as the Reports of the Surgeon General." 449 F. Supp. 2d at 855.

At the same time, faced with growing public concern about the diseases and deaths caused by tobacco use, tobacco companies sought to develop "health reassurance" products that consumers would believe pose lower health risks, provide an alternative to quitting, or represent a step in decreasing the smoker's level of dependence. United States v. Philip Morris USA, Inc., 566 F.3d 1095, 1107 (D.C. Cir. 2009). The manufacturers understood, however, that these ostensibly "reduced risk" products in fact offered no health benefit. As the D.C. Circuit summarized, the manufacturers "marketed and promoted their low tar brands to smokers – who were concerned about the health hazards of smoking or considering quitting – as less harmful than full flavor cigarettes despite either lacking evidence to substantiate their claims or knowing them to be false." Ibid. Even as they did so, the manufacturers "were aware that lower tar cigarettes . . . do not actually deliver the low levels of tar and nicotine advertised." Ibid.

The reasons for the discrepancy lie in the nature of nicotine addiction and the phenomenon of smokers' compensatory behavior – the fact, long known to manufacturers, that smokers will alter the manner in which they smoke cigarettes to obtain their required level of nicotine. Ibid. Well before it was known to others, tobacco manufacturers knew from their internal research that smokers

of low tar cigarettes, in order "to satisfy their addiction [would] modify their smoking behavior to compensate for the reduced nicotine yields by 'taking more frequent puffs, inhaling smoke more deeply, holding smoke in their lungs longer, covering cigarette ventilation holes with fingers or lips, and/or smoking more cigarettes.'" Ibid. (quoting 449 F. Supp. 2d at 431). The manufacturers "understood this concept" of smokers' compensatory behavior even "while they promoted lower tar cigarettes as 'health reassurance' brands." Ibid.; see also id. at 1124.

Indeed, the manufacturers manipulated their ostensibly "reduced risk" products to exploit the phenomenon of smokers' compensatory behavior. Based on extensive internal research into the ways in which "the physical and chemical design parameters of cigarettes influence the delivery of nicotine to smokers," the manufacturers "engineered their products around creating and sustaining this addiction." Id. at 1107; see also id. at 1120 ("[I]nternal research reports and memoranda at the Defendant companies revealed that they understood the phenomenon of smoker compensation and studied how to manipulate it in order to make their light brands appealing to addicted smokers while continuing to be able to advertise the brands as low tar.").

The tobacco companies' deceptive tactics were successful. The market share for the "low tar and nicotine brands" rose from 2% in 1967 to 81.9% of total cigarette sales in 1998. 449 F. Supp. 2d at 508. In 2006, "low tar" brands accounted for 92.7% of the 343 billion cigarettes sold in the United States. Fed. Trade Comm'n, Cigarette Report for 2006, at 2, 7 (2009) (available at www.ftc.gov/os/2009/08/090812cigarettereport.pdf).

2. The manufacturers did not disclose their internal research on "low tar" cigarettes to the Surgeon General or government regulators. Instead, as part of the "scheme to defraud smokers," they "'withheld and suppressed their extensive knowledge and understanding of nicotine-driven

smoker compensation.'" Philip Morris, 566 F.3d at 1125 (quoting 449 Supp. 2d at 861); see also id. at 1108, 1119-20, 1125-26. As a result, the 1981 Surgeon General report concluded that "smokers who are unwilling or as yet unable to quit" were "well advised to switch to cigarettes yielding less 'tar' and nicotine, provided they do not increase their smoking or change their smoking in other ways." Philip Morris, 449 F. Supp. 2d at 445. "[H]ad the information available to the tobacco industry been available to the scientists preparing the 1981 Surgeon General's Report, that Report would not have drawn the erroneous conclusion that lower tar cigarettes produced lower risk or have made the recommendation that smokers who could not quit were 'well advised to switch to cigarettes yielding less "tar" and nicotine.'" Ibid.

Tobacco manufacturers also failed to disclose the results of their internal research to the Federal Trade Commission ("FTC"), which used machines to determine the tar and nicotine yield of different cigarette brands using a method called the Cambridge Filter Method. Based on their superior knowledge of compensatory behavior and nicotine addiction, the manufacturers understood that the machine-testing method did not reflect actual smoker behavior. They represented to the FTC, however, that smoker compensation was a "hypothesized" and "weakly documented phenomenon," id. at 504, without disclosing their contrary internal research, id. at 500. See also id. at 860-66. Accordingly, the Supreme Court, in rejecting the argument that the FTC had authorized tobacco industry claims about "light" cigarettes, noted that it would be "particularly inappropriate to read a policy of authorization into the FTC's inaction when that inaction is in part the result of petitioners' failure to disclose study results showing that Cambridge Filter Method test results do not reflect the amount of tar and nicotine that consumers of 'light' cigarettes actually inhale." Altria Group, Inc. v. Goode, 129 S. Ct. 538, 550 n.14 (2008).

3. Despite the tobacco industry's chronic deception, public understanding of the industry's deceptive marketing techniques grew steadily. The industry was forced to disclose much information in various lawsuits. And, in 1998, as part of a Master Settlement Agreement with 40 state attorneys general, plaintiffs Reynolds and Lorillard, along with Philip Morris and other manufacturers, were required to maintain publicly accessible physical and internet depositories of documents uncovered in tobacco litigation. See Philip Morris, 449 F. Supp. 2d at 843-44.

In 2001, the National Cancer Institute ("NCI") issued a major monograph titled "Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine," which concluded that scientific evidence did not support claims that changes in cigarette design and manufacturing had resulted in public health benefits. Id. at 446-47. One of the two scientific editors of the monograph testified before Congress in 2003. See Statement of David M. Burns before the Committee on Government Reform in the House of Representatives, Regulation of "Reduced Risk" Tobacco Products, June 3, 2003 (available at 2003 WL 21280495). In a section of the monograph later quoted by Senator DeWine, the authors explained that "[t]he use of these 'decreased risk' cigarettes has not significantly decreased the disease risk. In fact, the use of these cigarettes may be partly responsible for the increase in lung cancer for long-term smokers who have switched to the low-tar/low-nicotine brands." 150 Cong. Rec. S5962 (May 20, 2004) (emphasis added).[2]

The Surgeon General testified to Congress in 2003 that new evidence demonstrated that the promised health benefits of "low-tar" brands were illusory. Statement of Vice Admiral Richard H. Carmona, U.S. Surgeon General, to House Subcommittee on Commerce, Trade, and Consumer

[2] All citations to the Congressional Record herein are to the daily editions, and can be found at www.gpoaccess.gov/crecord/index.html.

Protection, June 3, 2003, reprinted at 155 Cong. Rec. S5999 (June 3, 2009).[3] The Surgeon General explained that "[l]ow-tar, low-nicotine cigarettes were introduced in the late 1960's and widely endorsed as a potentially safer substitute for the typical cigarette on the market at that time." Id. at S6000. "Within a decade, the low tar brands dominated the cigarette market," as "[m]any smokers switched to them for their perceived health benefits." Ibid. As the Surgeon General declared, "[w]e 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." Ibid. The Surgeon General admonished regulators to heed that experience in considering the marketing of purportedly reduced risk smokeless tobacco products, noting the significant risks presented by the use of smokeless tobacco. Ibid.

B. Legislative, Regulatory And Judicial Responses To Evidence Of The Deceptive Marketing Of Tobacco Products.

1. Despite the gradually increasing understanding of nicotine addiction, compensation, and industry marketing practices, no federal agency was empowered to regulate tobacco products until this year. In 1996, the FDA asserted authority under the Federal Food, Drug, and Cosmetic Act to regulate the marketing of tobacco products. See 61 Fed. Reg. 44396, 44418 (1996). The regulations would have established a minimum age to purchase cigarettes and smokeless tobacco, required age verification by tobacco sellers, and restricted placement of vending machines. They also would have established restrictions on youth-directed advertising, including requirements that such ads appear in a black-and-white, text-only format, and a ban on the sale and distribution of promotional products (such as hats and t-shirts) with the names or logos of tobacco companies. The Supreme Court

[3] The Surgeon General's statement was reprinted in the Congressional Record of June 3, 2009 at the request of Senator Merkley.

concluded, however, that Congress had not granted the FDA jurisdiction over tobacco products, although the Supreme Court recognized that tobacco use posed "perhaps the single most significant threat to public health in the United States." FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 161 (2000).[4]

In 2004, Senators DeWine and Kennedy introduced legislation that would have given the FDA the authority to regulate the manufacture and sale of tobacco products. As Senator DeWine explained, their bill sought to address the fundamental problem presented by a lack of oversight of tobacco products and their marketing: "tobacco products should not be able to imply that they may be safer or less harmful to consumers because they use descriptors such as 'light' or 'mild' or 'low' to characterize the level of a substance in a product." 150 Cong. Rec. S5962 (May 20, 2004). Senator DeWine observed that "[t]obacco companies are able to make these implied health claims about their products because they are not regulated." Ibid. Such claims, he declared, "should be examined, reviewed, and commented on by the Food and Drug Administration to determine whether it is appropriate for these products to be marketed as 'reduced-risk' products, so the public knows what they are choosing to consume." Id. at S5962-63.

Of particular concern was the possibility that smokeless tobacco might be marketed as a safe alternative to smoking, notwithstanding its own health risks and the danger that such marketing might "reduce cessation or delay cessation attempts" by current cigarette smokers and "increase the

[4] Senator Kennedy observed during the debates on the statute at issue here that the FDA's 1996 regulations were based on "the longest rulemaking proceeding in its history . . . . Seven hundred thousand public comments were received in the course of that rulemaking. At the conclusion of its proceeding, the Agency promulgated rules on the manner in which cigarettes are advertised and sold. Due to litigation, most of those regulations were never implemented." 155 Cong. Rec. S6407 (June 10, 2009).

rate of adolescent initiation of oral tobacco use, increasing rather than decreasing the fraction of the population using tobacco products." Statement of David M. Burns, supra, June 3, 2003 (available at 2003 WL 21280495).

Congress took no action on the DeWine-Kennedy bill and, in the regulatory vacuum, the tobacco industry continued the deceptive marketing of ostensibly reduced risk products.

2. While legislative efforts stalled, the District Court for the District of Columbia adjudicated claims against tobacco manufacturers under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961 et seq. ("RICO"), regarding a complex web of deceptive practices. The district court, after years of pretrial proceedings, conducted a nine-month bench trial that began in 2004. Philip Morris, 566 F.3d at 1106. The court heard live testimony from 84 witnesses, received written testimony from 162 witnesses, and received in evidence almost 14,000 exhibits. Ibid.

The district court made 4088 findings of fact in an opinion issued in 2006, concluding that tobacco manufacturers had maintained an unlawful racketeering enterprise and finding a reasonable likelihood that the manufacturers would continue to do so in the future. Id. at 1108-10. Among other forms of injunctive relief, the court ordered the manufacturers "to cease using any express or implied health message or health descriptor for any cigarette brand," including but not limited to terms such as "light" and "low tar." Id. at 1109. The court also ordered the manufacturers to make corrective communications in the same media that they had used to perpetrate the fraud, including newspapers, television, and company websites. Id. at 1138, 1142.

In a lengthy opinion, the D.C. Circuit affirmed the judgment of liability and the finding that the tobacco manufacturers were likely to continue to violate RICO in the future. It also approved much of the relief ordered by the district court, including the requirements described above. Id. at

1150. The D.C. Circuit rejected a variety of legal defenses, including those based on the First Amendment, explaining that the manufacturers' public statements were "clearly and deliberately false." Id. at 1124. The court of appeals stressed: "Defendants knew of their falsity at the time and made the statements with the intent to deceive." Ibid. "Thus, we are not dealing with accidental falsehoods, or sincere attempts to persuade; Defendants' liability rests on deceits perpetrated with knowledge of their falsity." Ibid. The court noted that "[a]s part of the Enterprise's scheme to defraud smokers, Defendants withheld and suppressed their extensive knowledge and understanding of nicotine-driven smoker compensation." Id. at 1125. And it explained that the "fraudulent activity surrounding 'light' cigarettes was not merely limited to the use of misleading descriptors." Ibid. "In addition to the misleading use of descriptors, the district court found '[Defendants'] public statements are blatantly false' in relation to the marketing of 'light' cigarettes." Ibid.

The D.C. Circuit also rejected First Amendment challenges to the injunction provisions requiring the manufacturers to make corrective disclosures about addiction, the adverse health effects of smoking and secondhand smoke, their manipulation of cigarette design and composition, and so-called "light" cigarettes. Id. at 1138. The court of appeals found no merit to the manufacturers' contention that "stand-alone corrective statements do not fall within the commercial speech doctrine because they are not attached to advertisements," explaining that "the district court clearly imposed these statements as a burden on Defendants' current and future commercial speech." Id. at 1143. As the court explained, "the reality that these corrective statements may tangentially burden noncommercial speech does not render the statements unconstitutional." Ibid. The court held that the requirement was adequately tailored to advance a substantial government interest because the

relief was designed to prevent manufacturers "from continuing to disseminate fraudulent public statements and marketing messages by requiring them to issue truthful communications." Ibid.[5]

C. The Family Smoking Prevention And Tobacco Control Act Of 2009.

On June 22, 2009, shortly after the D.C. Circuit issued its decision in the RICO case, the President signed into law the Family Smoking Prevention and Tobacco Control Act. Pub. L. 111-31, 123 Stat. 1776 (2009). The Act gives FDA explicit authority to regulate tobacco products and, as particularly relevant to plaintiffs' motion for a preliminary injunction, it "grants FDA the authority to strictly regulate so-called 'reduced harm' products and to prohibit unproven health claims by tobacco product manufacturers." H.R. Rep. No. 111-58(I) (2009). In the comprehensive legislative findings included in the statute, Congress declared that "[a]s the Federal Trade Commission has found, consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification." 21 U.S.C. § 387 Note, Finding 41. It further found that "[i]n August 2006 a United States district court judge found that the major United States cigarette companies have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction while also concealing much of their nicotine-related research." Finding 49 (citing the decision in United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1 (D.D.C. 2006)). Based on these and other findings, Congress determined 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

[5] The D.C. Circuit denied the tobacco manufacturers' petitions for rehearing and rehearing en banc on September 22, 2009.

manufacturers sold or distributed for risk reduction be reviewed in advance of marketing, and to require that the evidence relied on to support claims be fully verified." Finding 43.

Accordingly, Congress amended the FDCA to require, for "modified risk tobacco products," pre-market administrative review analogous to the pre-market review required under the FDCA for drugs and certain medical devices. Under the new statutory provisions, no person may introduce into interstate commerce any "modified risk tobacco product" without an FDA order permitting the marketing of the product. 21 U.S.C. § 387k(a). This restriction mirrors the FDCA provisions that bar any person from introducing a new drug or certain medical devices into interstate commerce without FDA approval. Id. §§ 355(a), 360e(a).

As with drugs and medical devices, the requirement of pre-market FDA review turns on the purpose for which the "modified risk tobacco product" is sold or distributed, as evidenced by promotional claims and other evidence of objective intent. Congress defined the term "modified risk tobacco product" to mean "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." Id. § 387k(b)(1) (emphasis added). And it defined the phrase "sold or distributed for use to reduce harm or the risk of tobacco-related disease" to mean a tobacco product–

> **(i)** the label, labeling, or advertising of which represents explicitly or implicitly that–
>
> > **(I)** the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;
> >
> > **(II)** the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or
> >
> > **(III)** the tobacco product or its smoke does not contain or is free of a substance;

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

Id. § 387k(b)(2)(A).

The Act provides that "[a]ny person may file with the Secretary an application for a modified risk tobacco product." Id. § 387k(d). Such an application must include a description of the proposed product and any proposed advertising and labeling; the conditions for using the product; the formulation of the product; sample product labels and labeling; all documents relating to research findings conducted, supported, or possessed by the manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health; data and information on how consumers actually use the tobacco product; and such other information as the Secretary may require. Ibid.

Once an application is filed, it is made available for public comment, id. § 387k(e), and referred to the Tobacco Products Scientific Advisory Committee, which must report its recommendation to the Secretary no later than 60 days after the date on which it is referred to the committee. Id. § 387k(f)(2). The Secretary shall 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 significantly reduce harm and risk of tobacco-related disease to

individual tobacco users; and 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). Special rules apply where scientific evidence cannot be made available without conducting long-term epidemiological studies. Id. § 387k(g)(2).

ARGUMENT

Plaintiffs seek a preliminary injunction to block implementation of an Act of Congress. As the Sixth Circuit has stressed, a "preliminary injunction is an extraordinary remedy involving the exercise of a very far-reaching power, which is to be applied only in the limited circumstances which clearly demand it." Leary v. Daeschner, 228 F.3d 729, 739 (6th Cir. 2000) (internal quotation marks and brackets omitted). In considering a request for a preliminary injunction, a court must consider (1) whether plaintiffs have established "a strong likelihood of success on the merits"; (2) whether they "would otherwise suffer irreparable injury"; (3) whether an injunction "would cause substantial harm to others"; and (4) whether an injunction would serve the public interest. Id. at 736 (internal quotation marks omitted); see also Winter v. Natural Resources Defense Council, Inc., 129 S. Ct. 365, 375 (2008).

Plaintiffs have not made the showing required for this extraordinary relief. Their legal challenges fail as a matter of law; the balance of harms clearly favors the government; and an injunction would have devastating consequences for the public health. Plaintiffs not only fail to establish the elements necessary for preliminary relief with respect to the two counts that are the subject of their motion; those counts also fail to state a claim upon which relief may be granted.

I. Congress Constitutionally Regulated The Marketing Of Modified Risk Tobacco Products.

A. Promotional Claims Are Properly Considered As Evidence Of A Product's Intended Use In Determining Whether The Product May Be Introduced Into Interstate Commerce.

Fully aware of the harm to the public health resulting from purportedly reduced risk tobacco products, Congress amended the FDCA to provide effective regulation of the sale of such products. In doing so, it adopted requirements for pre-marketing review that parallel established procedures applicable to drugs and certain medical devices. As the courts have recognized, those provisions regulate the marketing of drugs and devices in interstate commerce. Promotional claims made on a product's behalf are considered in order to determine the use for which the product is intended, and thus whether the product is subject to pre-market review. This use of speech to infer intent contravenes no First Amendment protections.

1. The FDCA defines "drugs" and "devices" to include articles "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1), (h)(2). To determine whether a product is a drug or medical device – and is thus subject to corresponding pre-market review requirements – FDA or a reviewing court looks to the product's intended use as may be established by the labeling and promotional claims made on its behalf. As the D.C. Circuit explained in Whitaker v. Thompson, 353 F.3d 947 (D.C. Cir. 2004), "[w]hen substances aimed at the treatment or prevention of disease are marketed, their regulation by [FDA] commonly turns on the nature of the claims made about the substance." Id. at 948. "In such cases, the label, advertising and other promotional materials are the evidence of the product's intended use." Ibid. Thus, "classification of a substance as a 'drug' turns on the nature of the claims advanced on its behalf."

Id. at 953. See also United States v. Article ... Consisting of 216 Cartoned Bottles, More or Less, Sudden Change, 409 F.2d 734, 739 (2d Cir. 1969) ("Regardless of the actual physical effects of a product, it will be deemed a drug for purposes of the [FDCA] where the labeling and promotional claims show intended uses that bring it within the drug definition.") (footnote omitted).

The Sixth Circuit's decision in United States v. 250 Jars ... "Cal's Tupelo Blossom U.S. Fancy Pure Honey", 344 F.2d 288 (6th Cir. 1965), illustrates the application of that principle. The Sixth Circuit held that jars of honey were properly seized as unapproved drugs because they were displayed for retail sale along with booklets and leaflets claiming that honey cures disease.[6]

In such cases, the product's labeling, advertising and other promotional materials "serve 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." Whitaker, 353 F.3d at 953 (citing Action on Smoking & Health v. Harris, 655 F.2d 236, 239 (D.C. Cir. 1980)). As the D.C. Circuit explained, the First Amendment poses no bar to using speech as evidence of unlawful conduct. Ibid. (citing Wisconsin v. Mitchell, 508 U.S. 476, 489 (1993) (use of speech to establish an element of a crime does not violate the First Amendment)); accord United States v. Article of Drug Designated B-Complex Cholinos Capsules, 362 F.2d 923, 927 (3d Cir. 1966) ("Thus it is constitutionally permissible for the FDA to use speech, in the form of labeling, to infer intent for purposes of determining that [the defendant's] proposed sale of [a product] would constitute the

[6] See also, e.g., Kordel v. United States, 335 U.S. 345 (1948) ("health food products" were drugs because they were claimed to ameliorate various ills); United States v. Writers & Research, Inc., 113 F.3d 8, 11 (2d Cir. 1997) (product was a drug because it was "promoted as a treatment or cure for cancer, AIDS, or other diseases"); United States v. Undetermined Quantities of Bottles of an Article of Veterinary Drug, 22 F.3d 235, 239 (10th Cir. 1994) (substances intended to be administered in dosages too low to cure or treat a disease are nonetheless drugs if "labeling and promotional materials" suggest that they cure or treat disease).

forbidden sale of an unapproved drug.") (sustaining condemnation of vitamins claimed to have therapeutic value and finding "nothing new or alarming in a ruling that statements made by a lecturer employed by a party and adopted by that party as its own representations may be taken in a civil action as evidence of that party's intention as to matters in which the intention is a material issue").[7]

2. In amending the FDCA, Congress provided that no person may introduce into interstate commerce a "modified risk tobacco product" without an FDA order permitting such marketing of the product. 21 U.S.C. § 387k(a). This restriction mirrors the FDCA provisions that bar any person from introducing a new drug or certain medical devices into interstate commerce without FDA approval. Id. §§ 331, 355(a), 360e(a). The application of the new pre-market review provisions turns on whether the tobacco product at issue "is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." Id. § 387k(b)(1) (defining "modified risk tobacco product") (emphasis added).[8] As under the

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[7] Indeed, Reynolds has acknowledged in a brief filed in the Supreme Court that "[c]laims in the market – oral or written; on labels, in advertising, or in salespersons' presentations – provide an objective, easily identifiable and administrable basis for determining FDA jurisdiction." Brief for Respondent R.J. Reynolds Tobacco Co. filed in FDA v. Brown & Williamson Tobacco Corp., No. 98-1152 (S. Ct.), 1999 WL 712566, at *15.

[8] Congress noted in the statutory fact-findings:

> The Food and Drug Administration is a regulatory agency with the scientific expertise to identify harmful substances in products to which consumers are exposed, to design standards to limit exposure to those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health. In connection with its mandate to promote health and reduce the risk of harm, the Food and Drug Administration routinely makes decisions about whether and how products may be marketed in the United States.

21 U.S.C. § 387 Note, Finding 44.

longstanding regulatory scheme for drugs and devices, promotional claims about a manufacturer's tobacco product are used as evidence of the product's intended use. See id. § 387k(b)(2)(A)(i)-(iii). And, as is the case with the drug and device marketing provisions, the regulation of modified risk tobacco products does not regulate lawful speech. Cf. Whitaker, 353 F.3d at 948, 952-53.

Plaintiffs get matters backwards when they urge that the purpose of the pre-market FDA review requirements is to block "truthful information." Pls. Mem. 22. The D.C. Circuit rejected precisely such a contention in Whitaker, where the manufacturer claimed that the pre-market approval requirement barred a "true and non-misleading statement about its [product's] salutary effects." 353 F.3d at 952. 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. Thus, under the drug and device provisions, the FDA reviews the evidence that a product will be safe and effective for its claimed purposes, such as in the treatment, prevention or diagnosis of a disease. 21 U.S.C. §§ 355(b), 360e(c). So too, under the tobacco provisions, the FDA will 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).

B. Even If Viewed As A Restriction On Speech, The Pre-Market Review Requirement Is Narrowly Tailored To Further The Government's Substantial Interest In Protecting Consumers From Misleading Tobacco Industry Claims.

As discussed above, the statutory provisions regulating modified risk tobacco products do not restrict speech; they restrict the distribution of certain products without FDA review. Under the Act, the tobacco manufacturer's communications to consumers are evidence of the product's

intended use, which presents no First Amendment issue. See Whitaker, 353 F.3d at 953; see also Wisconsin v. Mitchell, 508 U.S. 476, 489 (1993).

In any event, even if the provisions were regarded as restrictions on speech, they are easily sustained under the framework established in Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557 (1980). Under that framework, commercial speech enjoys First Amendment protection only if it concerns a lawful activity and is not misleading. Moreover, even if the speech in question concerns a lawful activity and is not misleading, the government may impose restrictions that advance a "substantial" government interest and are no "more extensive than is necessary to serve that interest." Id. at 566. As the Supreme Court has stressed, this standard does not require the legislature to employ "the least restrictive means" of regulation or to achieve a perfect fit between means and ends. Board of Trustees v. Fox, 492 U.S. 469, 480 (1989). It is sufficient that the legislature achieve a "reasonable" fit by adopting regulations "'in proportion to the interest served.'" Ibid. (quoting In re R.M.J., 455 U.S. 191, 203 (1982)); accord Pagan v. Fruchey, 492 F.3d 766, 771 (6th Cir. 2007) (en banc). The requirement of narrow tailoring is satisfied "so long as the . . . regulation promotes a substantial government interest that would be achieved less effectively absent the regulation." United States v. Albertini, 472 U.S. 675, 689 (1985). The provisions regulating modified risk tobacco products are plainly constitutional under this framework because they are narrowly tailored to advance the government's substantial interest in protecting consumers from misleading claims about the relative health risks of tobacco products.

1. The Modified Risk Provisions Advance An Extraordinarily Important Public Health Interest.

The health risks posed by tobacco use are incontrovertible. It is also beyond dispute that the sale of "light" cigarettes and other tobacco products that imply a reduced risk has contributed significantly to tobacco's toll on the public health, and the corresponding health care costs. As Congress found: "Unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk." 21 U.S.C. § 387 Note, Finding 37. "Those who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death." Ibid. "The costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system." Ibid.

Congress was fully aware of the impact of misleading claims about cigarettes on consumers. "As the National Cancer Institute has found, many smokers mistakenly believe that 'low tar' and 'light' cigarettes cause fewer health problems than other cigarettes." Finding 38. "As the National Cancer Institute has also found, mistaken beliefs about the health consequences of smoking 'low tar' and 'light' cigarettes can reduce the motivation to quit smoking entirely and thereby lead to disease and death." Ibid.; see also Finding 39. Congress determined: "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.

2. The Requirement Of Pre-Market FDA Review Is Narrowly Tailored To Accomplish Congress's Objective.

Congress further determined that the requirement of pre-market FDA review is narrowly tailored to protect consumers from misleading tobacco industry claims. In so doing, it specifically found that disclaimers would be inadequate, noting the FTC'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." Finding 41; see also Finding 42. Congress concluded 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 sold or distributed for risk reduction be reviewed in advance of marketing, and to require that the evidence relied on to support claims be fully verified." Finding 43 (emphasis added).

Congress plainly has the power to require that the manufacturer of a "modified risk tobacco product" make an evidentiary showing before introducing such a product into interstate commerce, just as evidentiary showings are required before a product may be marketed to mitigate, prevent, treat, or cure disease. As Senator Merkley observed during the debates on the new legislation, it is "frankly unbelievable that while we heavily regulate the production and sale of aspirin, a product that is not addicting and not destructive, tobacco, which is addictive and is destructive, goes without regulation." 155 Cong. Rec. S5999 (June 3, 2009).

Without acknowledging the congressional findings, plaintiffs declare that "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 . . . or an appropriately tailored disclosure[.]" Pls. Mem. 24 (citations omitted). This statement encapsulates many of the fundamental flaws in plaintiffs' analysis. The Constitution does not restrict Congress to regulatory mechanisms that have already proven to be ineffective. Congress determined that such existing measures are inadequate, and 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. Even if the tobacco industry had an unblemished record of probity and candor, it would have no greater right than the pharmaceutical industry has to market its products for uses not substantiated with scientific evidence before the FDA.

In light of the tobacco industry's actual record, it is altogether remarkable that plaintiffs insist that the government is constitutionally confined to regulatory methods tried and found wanting. Having perpetrated "[t]he largest disinformation campaign in the history of the corporate world," 155 Cong. Rec. S6408 (June 10, 2009) (Sen. Kennedy), the tobacco industry cannot plausibly assert that the public health is adequately protected using the same enforcement tools that have proved inadequate for decades. See also ibid. ("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 obtained through the discovery process proves that the companies not only knew of this addictiveness for decades, but actually relied on it as the basis for their marketing strategy.").

Plaintiffs mistakenly seek to rely on case law addressing the advertising of entirely truthful information. Such decisions are inapposite to the present case, which involves the regulation of commercial conduct rather than an effort to block the dissemination of easily verified and concededly accurate factual advertising. In Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976), and 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484 (1996), the Supreme Court invalidated blanket measures that prohibited the advertising of indisputably accurate pricing information about prescription drugs and alcoholic beverages, respectively. Thompson v. Western States Medical Center, 535 U.S. 357 (2002), likewise invalidated a ban on the unquestionably accurate advertising of drugs compounded by pharmacists.

Contrary to plaintiffs' suggestion, the modified risk provisions do not rest on "the 'paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely.'" Pls. Mem. 27 (quoting 44 Liquormart, 517 U.S. at 497 (plurality op.)). Instead, they work to ensure that a product is not marketed to reduce risks associated with tobacco use unless the manufacturer demonstrates through scientific evidence that the product will in fact reduce those risks. Congress properly committed the task of evaluating such evidence to the FDA, which already makes comparable assessments under the FDCA's drug provisions, see Finding 44, and whose administrative determinations will be subject to judicial review.

C. Plaintiffs' Objections Are Meritless.

1. The Communications That A Manufacturer Directs To Consumers About Its Product May Be Evidence Of The Product's Intended Use.

Plaintiffs fail to come to grips with the nature of the pre-market review requirement and offer arguments with regard to only two features of the requirement. First, plaintiffs take issue (Pls. Mem. 22-23) with the statutory provision that defines a modified risk tobacco product to include a product about which the "manufacturer . . . has taken any action directed to consumers through the media or otherwise . . . 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." 21 U.S.C. § 387k(b)(2)(A)(iii). They contend that this provision would make it a crime for a manufacturer's executive to participate in a public debate about the relative risks of different tobacco products, and that it therefore "prohibits core First Amendment speech." Pls. Mem. 23.

This argument is doubly flawed. As an initial matter, the provision that plaintiffs quote does not "prohibit speech." Instead, it identifies a form of evidence that may be considered in determining whether the manufacturer's product is intended to reduce the risk of tobacco-related disease and thus requires pre-market FDA review. The prohibition is on the sale or distribution of such a product in interstate commerce without an FDA order, 21 U.S.C. § 387k(a) – not on a manufacturer's speech.

Moreover, the evidence that may be considered under this provision is explicitly limited to those communications about a manufacturer's product that the manufacturer "direct[s] to consumers." 21 U.S.C. § 387k(b)(2)(A)(iii). Plaintiffs do not dispute that the claims a manufacturer

makes about its product through the "label, labeling, or advertising," id. § 387k(b)(2)(A)(i), constitute commercial speech. They contend, however, that other communications that a manufacturer directs to consumers about its product are not commercial speech unless they constitute "the 'proposal of a commercial transaction.'" Pls. Mem. 22 (quoting City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 423 (1993)). The contention is baseless. As the Sixth Circuit has explained, "[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). Even a publication in a trade journal can constitute commercial speech if it touts a company's products. Ibid. Thus, the fact that tobacco companies may "discuss cigarettes generically without specific brand names, or link cigarettes to an issue of public debate, does not change the commercial nature of the speech." Philip Morris, 566 F.3d at 1144 (citing Bolger v. Youngs Drug Products Corp., 463 U.S. 60, 66 n.13, 67-68 (1983)).

Tobacco companies have not restricted themselves to labels and advertising in misleading consumers about the health risks of their products; they have used a variety of means including false and misleading press releases, booklets, and television appearances. See, e.g., Philip Morris, 566 F.3d at 1121 (providing examples and noting hundreds more findings in the district court's opinion). Moreover, the companies have funded "special projects" designed "to produce favorable research results" that could be cited in support of their false claims. Id. at 1107.[9] Against this backdrop, Congress properly and prudently made clear that all claims that a manufacturer "direct[s] to

[9] See also, e.g., Philip Morris, 566 F.3d at 1108 (manufacturers sought to combat consumer concerns regarding secondhand smoke by creating organization "to coordinate and fund their secondhand smoke research with the appearance of independence," and created "a vast array of foreign or international entities to conduct their sensitive secondhand smoke research, generate 'marketable science' to use for public relations purposes, and coordinate their shared objectives and message").

consumers" about its product are relevant in determining whether the product is intended for use to reduce the risk of tobacco-related disease.

Plaintiffs fare no better in declaring that this aspect of the statutory definition is "unconstitutionally vague" in violation of due process. Pls. Mem. 28-29. As the Supreme Court has explained, 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). "[P]erfect clarity and precise guidance have never been required even of regulations that restrict expressive activity." Ibid. (quoting Ward v. Rock Against Racism, 491 U.S. 781, 794 (1989)). Plaintiffs' argument, at best, is that it is possible to posit circumstances that might give rise to uncertainty as to whether a manufacturer's claims about one of its products will constitute evidence of the product's intended use. They assert, for example, that evidence of intended use "could encompass the indisputable truism that smokeless tobacco does not produce second-hand smoke." Pls. Mem. 29. In fact, the statute explicitly provides that claims of this nature are not evidence of a "modified risk tobacco product." See 21 U.S.C. § 387k(b)(2)(C).[10] In any event, it is a "basic mistake" to believe "that the mere fact that close cases can be envisioned renders a statute vague." Williams, 128 S. Ct. at 1846.[11]

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[10] Section 387k(b)(2)(C) provides 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.'"

[11] See also Rendon v. TSA, 424 F.3d 475, 480 (6th Cir. 2005) (rejecting a vagueness challenge to a regulation that "prohibits conduct (which, of course, in certain cases, such as this, may include speech) that interferes with [airport] screeners in the performance of their duties"); Wilson v. State Bar of Ga., 132 F.3d 1422, 1430 (11th Cir. 1998) (upholding amendments to

2. Plaintiffs' Challenge To The Criteria That Will Be Applied By The FDA In Considering An Application To Market A Modified Risk Tobacco Product Is Premature And, In Any Event, Meritless.

Plaintiffs also take issue with an aspect of the statutory criteria to be applied by the FDA to determine whether to grant an application to market a modified risk tobacco product. As discussed above, the Act requires the FDA to consider whether an applicant has demonstrated that the product, as actually used by consumers, will (A) significantly reduce harm and risk of tobacco-related disease to individual tobacco users; and (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. 21 U.S.C. § 387k(g)(1). Plaintiffs do not take issue with the showing required under subsection (A). They contend, however, that Congress cannot constitutionally require the FDA to take into account the health benefits and risk to users and non-users as described in subsection (B).

As an initial matter, this argument is not a basis for a preliminary injunction because none of the plaintiff manufacturers has even applied to FDA for an order allowing the marketing of a modified risk tobacco product – much less demonstrated that one of its products will significantly reduce harm or the risk of tobacco-related disease to individual users and thus satisfy subsection (A). Under these circumstances, plaintiffs cannot claim that they will suffer imminent and irreparable injury unless the FDA is barred from making the inquiry required under subparagraph (B).

Indeed, plaintiffs' challenge to the criteria to be applied in the administrative review process is not ripe for judicial review at all. The ripeness doctrine's "basic rationale is to prevent the courts,

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attorney disciplinary code because "if lawyers or former lawyers of reasonable intelligence can derive a core meaning from the amendments, then the amendments 'may validly be applied to conduct within that meaning and the possibility of a valid application necessarily precludes facial invalidity'") (citation omitted).

through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies," as well as "to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." Abbott Labs. v. Gardner, 387 U.S. 136, 148-49 (1967). Ripeness "requires that the injury in fact be certainly impending." NRA v. Magaw, 132 F.3d 272, 280 (6th Cir. 1997) (internal quotation marks omitted). Without any FDA action on an application to market a modified risk tobacco product, there is no way to know whether the "population as a whole" inquiry will have any material consequence. Nor can the effect of that provision be assessed in the absence of a factual record based on action on a manufacturer's actual application. See Adult Video Ass'n v. DOJ, 71 F.3d 563, 568 (6th Cir. 1995).

Ripeness aside, there is no constitutional right to market a product that, on balance, would be detrimental to the public health. Thus, in determining whether to allow a drug or device to be marketed, the FDA may weigh the potential benefit to individual patients against potential hazards to others. Indeed, the FDCA "generally requires the FDA to prevent the marketing of any drug or device where the 'potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.'" Brown & Williamson Tobacco Corp., 529 U.S. at 134 (quoting United States v. Rutherford, 442 U.S. 544, 556 (1979)). In making such determinations, the FDA considers not only the risk that the drug will cause direct injury, but also the risk that an inefficacious drug may prompt individuals to "reject[] conventional therapy." Rutherford, 442 U.S. at 556. Similarly, the FDA considers the risk that a drug may not be taken as directed, or that it may be harmful if taken in combination with another product.

The inquiry into "benefit to the population as a whole" likewise ensures that the expected health benefit of a modified risk tobacco product is not outweighed by the expected harm that it would cause. Although plaintiffs declare that this provision entails "a subjective assessment for which the law provides no standards or guidance," Pls. Mem. 23 (emphasis added), the Act provides detailed standards by stating 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).

These considerations are crucial because tobacco products do not merely cause disease and death; they are also highly addictive. Thus, FDA properly may consider, for example, whether a smokeless tobacco product will be used as a supplement to (rather than substitute for) cigarettes, to "sustain nicotine addiction in those circumstances where smoking is prohibited" (such as in workplaces and on airplanes). Statement of David M. Burns, supra, June 3, 2003 (available at 2003 WL 21280495). Thus used, the product would reinforce rather than reduce the addiction to smoking. Ibid. Indeed, as Senator Durbin noted during the 2009 debates, "many of these new smokeless products are being marketed to smokers as a way to sustain their addictions in places where smoking

is no longer allowed." 155 Cong. Rec. S6149 (June 4, 2009). For example, Reynolds, on the website for its smokeless product "Camel SNUS," "boasts that 'snus can be enjoyed almost anywhere, regardless of growing smoking bans and restrictions.'" Ibid.

Similarly, the FDA may consider the "scientific evidence . . . that use of smokeless tobacco is a gateway to cigarette use," including the evidence that "youth are encouraged to experiment with low-nicotine starter products and subsequently graduate to higher-level nicotine brands or switch to cigarettes as their tolerance for nicotine increases." 155 Cong. Rec. S6000 (June 3, 2009) (quoting 2003 Statement of Surgeon General Carmona); see also 149 Cong. Rec. E1148 (June 4, 2003) (letter from Rep. Waxman describing U.S. Smokeless Tobacco Company's use of "a 'graduation strategy' to hook young users on low-nicotine products and then 'graduate' them to higher-nicotine products"). Likewise, the FDA may consider whether the marketing of a modified risk tobacco product would cause smokers to "reject[ ] conventional therapy," Rutherford, 442 U.S. at 556, such as FDA-approved smoking cessation products, and thus make it more difficult for the smokers to quit. See 21 U.S.C. § 387k(g)(4)(D).

D. The Balance Of Harms Favors The Government And An Injunction Would Be Contrary To The Public Interest.

The balance of harms overwhelmingly favors the government and a preliminary injunction would, without question, be against the public interest. It is crucial to the public health that tobacco products not be marketed as reduced risk products unless they will, in fact, reduce risks. As Congress found: "Tobacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking." 21 U.S.C. § 387 Note, Finding 13.

"Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease." Finding 14. "The costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system." Finding 37. The consequences of a preliminary injunction would be devastating because thousands of children start to smoke each day. See, e.g., 155 Cong. Rec. S6341 (June 9, 2009) (Sen. Dodd).

Moreover, Congress had particular reason to ensure that the tobacco industry does not replicate the history of "low tar" cigarettes by promoting smokeless tobacco as a reduced risk product without substantiating such claims before the FDA. "The National Cancer Institute, the American Cancer Society, the U.S. Surgeon General, and the Public Health Service have all concluded that smokeless tobacco products, as sold in the United States, are a cause of serious disease, including cancer." 155 Cong. Rec. S6154 (June 4, 2009) (Sen. Dodd). The Surgeon General specifically admonished Congress to heed the experience with "low tar" cigarettes in considering the marketing of purportedly reduced risk smokeless tobacco products, noting the significant risks presented by use of smokeless tobacco. 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).

As the Surgeon General testified, "[w]hile it may be technically feasible to someday create a reduced-harm tobacco product, the Institute of Medicine recently concluded that no such product exists today. When and if such a product is ever constructed, we would then have to take a look at

the hard scientific data of that particular product." Id. at S6000. He explained that "[o]ur 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." Ibid. The Surgeon General summarized: "[W]e simply do not have enough scientific evidence to conclude that any tobacco product, including smokeless tobacco, is a means of reducing the risks of cigarette smoking. . . . With the memory of our experience with low-tar cigarettes fresh in our minds, we must move extremely cautiously before making any statement or endorsement about the potential reduced risk of any tobacco product." Id. at S6000-01.

Plaintiffs have not identified the imminent and irreparable harm required to justify a preliminary injunction. They rely on a declaration of a Reynolds executive who states that it is "the company's firm conviction and belief that smokeless tobacco products, as compared to tobacco-combustion products such as cigarettes, do present less risk to adult tobacco consumers," and who baldly asserts that there is "overwhelming scientific evidence supporting this conclusion based on scientific research that has taken place over the past several decades in the United States and abroad." Payne Decl. ¶ 12, Ex. 1 to Pls. Mem.

These assertions miss the point. It may be assumed, for purposes of argument, that Reynolds would be able to demonstrate to the FDA that its smokeless products pose reduced risks of tobacco-related disease. That is no ground for setting aside the requirement that tobacco manufacturers – like drug manufacturers – make such an evidentiary showing to the agency before the ostensibly reduced risk products are unleashed on the public. The issue before the Court is not whether a particular tobacco product (or category of products) presents reduced risks. The issue is whether

Congress has the power to establish a pre-market review process for certain tobacco products similar to the pre-market review process for drugs and certain medical devices. Plainly, it does.

II. Congress Constitutionally Regulated The Marketing Of Tobacco Products In Combination With Other Products.

A. Plaintiffs Have No Likelihood Of Success On Their Challenge To The Combination Marketing Provision.

1. Section 101(a) of the Act amends Section 201 of the FDCA to prohibit the marketing of a tobacco product "in combination with any other article or product regulated under [the FDCA] (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement)." 21 U.S.C. § 321(rr)(4). Plaintiffs' contention that this provision violates the First Amendment is premised on a misunderstanding of its scope. Because this provision targets non-expressive commercial conduct, it does not implicate the First Amendment or provide any basis for preliminary relief.

Section 321(rr)(4) is directed at commercial conduct that links the sale of tobacco directly to the purchase of another regulated non-tobacco product. It thus applies to the marketing of an actual physical combination of a tobacco product with a non-tobacco product, such as a soda that contains nicotine derived from tobacco. See Draft Guidance for Industry and FDA Staff on The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act, Section II.A (Sept. 30, 2009) (noting that the provision applies when a tobacco and FDA-regulated non-tobacco product "are physically, chemically, or otherwise combined or mixed to produce a single entity that is marketed as containing both products").[12] Cf. 21 C.F.R. § 3.2(e)(1) (defining "combination products" with

[12] As required by agency rules, this guidance is issued in draft form for public comment. 21 C.F.R. § 10.115(c)(1), (g)(1). It is currently available for public inspection at the Office of the Federal Register, and also has been posted on the FDA's website at the following address:

regard to drugs, devices, and biological products to include "[a] product comprised of two or more regulated components . . . that are physically, chemically, or otherwise combined or mixed and produced as a single entity"). Section 321(rr)(4) also applies to a tobacco product that is physically packaged with another regulated non-tobacco product. See Guidance, Section II.A (addressing a scenario in which "[a] tobacco product and a non-tobacco product regulated under the FDCA are packaged together in a single package or as a unit"). Cf. 21 C.F.R. § 3.2(e)(2) (defining a "combination product" to include "[t]wo or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products").

Similarly, even where two products are not physically packaged together, they may be "marketed in combination" within the meaning of under § 321(rr)(4) if marketed in a way that directly links their sale: the combination marketing prohibition would apply, for example, to a coupon that offers 50 cents off the price of a particular mouthwash contingent upon the purchase of cigarettes, or vice versa. See Guidance, Section II.A. The combination marketing prohibition thus applies to both physical packages and "package deals." In this way, § 321(rr)(4) addresses longstanding concerns about the commercial practice of providing a financial incentive for the purchase of a tobacco product. Cf. 61 Fed. Reg. 44396, 44617-18 (1996) (provision of FDA rule

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www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm184283.htm. It is scheduled to be published in the Federal Register on October 5, 2009. Comments may be submitted to FDA for 90 days following publication in the Federal Register.

barring, in relevant part, a retailer from offering a non-tobacco product in consideration for the purchase of tobacco).[13]

2. Restrictions of this kind do not implicate the First Amendment because any burden on expression is at most incidental. Philip Morris USA Inc. v. City & County of San Francisco, No. 08-17649, 2009 WL 2873765, at *1 (9th Cir. Sept. 9, 2009) (unpub.) (upholding ordinance banning cigarette sales in retail stores that operate pharmacies because the restriction did not "involve conduct with a 'significant expressive element'") (quoting Arcara v. Cloud Books, Inc., 478 U.S. 697, 701-702, 706 (1986)). The provision challenged here bars certain commercial products and arrangements, not the flow of information about such goods. It by no means threatens to block the public's access to information about lawfully available products or consumer choices. Such regulation of commercial conduct raises no First Amendment concerns. See ibid. (noting that all civil and criminal regulations "'impose[] some conceivable burden on First Amendment protected activities'" and holding that a restriction on cigarette sales does not raise First Amendment concerns) (quoting Arcara, 478 U.S. at 706); see also, e.g., IMS Health Inc. v. Ayotte, 550 F.3d 42, 52 (1st Cir. 2008) (explaining that the First Amendment is not implicated when statutes "principally regulate conduct and, to the extent that they regulate speech at all, that putative speech comprises items of nugatory informational value"), cert. denied, 129 S. Ct. 2864 (2009). See generally Rumsfeld v. Forum for Acad. & Inst. Rights, Inc., 547 U.S. 47, 62 (2006) ("'[I]t has never been deemed an

[13] Smoking cessation products do not fall within the ambit of this provision. Products intended to be used to mitigate or treat nicotine addiction or to prevent, mitigate, or treat the withdrawal symptoms associated with nicotine addiction are separately regulated by FDA as drugs or, in some cases, as combination products (i.e., drug and drug-delivery device). See Act, § 101(a) (defining "tobacco product" to exclude articles regulated as drugs, devices, or combination products) (codified at 21 U.S.C. § 321(rr)(2)); see also 21 U.S.C. §§ 321(g)-(h), 331(d), 353(g), 355(a), 360(j).

abridgement of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.'") (quoting Giboney v. Empire Storage & Ice Co., 336 U.S. 490, 502 (1949)).

Even where the Supreme Court has invalidated restrictions on advertising, it has made clear that the government could validly regulate the underlying commercial conduct. Thus, in Thompson v. Western States Medical Center, 535 U.S. 357 (2002), the Court contrasted an invalid restriction on the advertising of compounded drug products with permissible restrictions on the manner of their sale. Among the examples suggested by the Court were a prohibition on "offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale," and a "limit [on] the amount of compounded drugs . . . that a given pharmacist or pharmacy sells out of state." Id. at 372 (internal quotation marks and citation omitted). Similarly, in 44 Liquormart, the Court invalidated local restrictions on the advertising of price information but emphasized that "higher prices can be maintained either by direct regulation or by increased taxation," noting that "[p]er capita purchases could be limited as is the case with prescription drugs." 517 U.S. at 507. Likewise, there is no question that Congress may prohibit or restrict commercial practices such as tobacco product price discounts and other package deals.[14]

[14] The burden is on the party seeking to engage in allegedly expressive conduct to demonstrate that the First Amendment applies. Clark v. Cmty. for Creative Non-Violence, 468 U.S. 288, 293 n. 5 (1984). Plaintiffs do not and cannot carry that burden here, as these activities plainly do not "fall into the broader category of expressive activity in which conduct itself can be said to convey a particularized message and, thus, be entitled to protection as symbolic speech." Wine & Spirits Retailers, Inc. v. Rhode Island, 418 F.3d 36, 49 (1st Cir. 2005) (citing United States v. O'Brien, 391 U.S. 367, 376-377 (1968), and Hurley v. Irish-Am. Gay, Lesbian & Bisexual Group, 515 U.S. 557, 569-70 (1995)).

B. The Conduct Cited In Plaintiffs' Irreparable Harm Declaration Is Not Covered By The Combination Marketing Provision.

The marketing practices cited in plaintiffs' declaration of irreparable harm are not covered by the combination marketing provision. See Pls. Mem. 30-31 (asserting that Reynolds mails communications that contain advertising both for tobacco products and for other retailers' products) (citing Cross Decl., Ex. 2 to Pls. Mem.). Section 321(rr)(4) does not ban advertisements for tobacco based on their proximity to advertisements for other products. In the sample mailing attached to plaintiffs' irreparable harm declaration, a discount coupon for bottled water merely appears on the same page as a discount coupon for cigarettes. See Cross Decl., Ex. 2 at 5. The utility of the coupon for water does not depend on the purchase of the cigarettes, or vice versa. Accordingly, that mailing does not fall within the scope of § 321(rr)(4). See Guidance, Section II.B.

Plaintiffs also attach to their declaration a coupon for a free tin of SNUS (a smokeless tobacco product) upon the purchase of a pack of Camel cigarettes. See Cross Decl., Ex. 2 at 6. This coupon too is not covered by § 321(rr)(4). Although Congress plainly has the power to regulate free offers of tobacco products (whether or not made in conjunction with the purchase of other tobacco products), § 321(rr)(4) applies to the marketing of tobacco products in combination with other (non-tobacco) FDA-regulated articles or products. See Guidance, Section II.B.

In sum, plaintiffs have identified no conduct in which they currently engage that falls within the scope of 21 U.S.C. § 321(rr)(4), much less the type of irreparable harm that would justify a preliminary injunction of an Act of Congress.

CONCLUSION

For the foregoing reasons, the motion for preliminary injunction should be denied.

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I hereby certify that on this 30th day of September, 2009, the foregoing document was served electronically upon the Court and upon the following:

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