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

COMMONWEALTH BRANDS, INC.; CONWOOD COMPANY, LLC; DISCOUNT TOBACCO CITY & LOTTERY, INC.; LORILLARD TOBACCO COMPANY; NATIONAL TOBACCO COMPANY, L.P.; and R. J. REYNOLDS TOBACCO COMPANY,	*	
Plaintiffs,	*	CIVIL ACTION NO. 1:09CV-117-M
v.	*	
	*	(Electronically Filed)
UNITED STATES OF AMERICA; UNITED STATES FOOD AND DRUG ADMINISTRATION; MARGARET HAMBURG, Commissioner of the United States Food and Drug Administration; and KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,	*	
Defendants.	*	

MEMORANDUM OF AMICI CURIAE
CAMPAIGN FOR TOBACCO-FREE KIDS,
AMERICAN CANCER SOCIETY, AMERICAN CANCER SOCIETY
CANCER ACTION NETWORK, AMERICAN HEART ASSOCIATION,
AMERICAN LEGACY FOUNDATION, AMERICAN LUNG ASSOCIATION,
AMERICAN MEDICAL ASSOCIATION, AMERICAN PUBLIC HEALTH
ASSOCIATION, KENTUCKY MEDICAL ASSOCIATION,
ONCOLOGY NURSING SOCIETY,
AND PUBLIC CITIZEN IN OPPOSITION TO
MOTION FOR PRELIMINARY INJUNCTION OF PLAINTIFFS
COMMONWEALTH BRANDS, INC., ET AL.

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INTRODUCTION

The legal arguments in this case cannot be considered in isolation from the public health context in which they arise: For more than 30 years, tobacco use has been the nation's leading preventable cause of death, disease, and disability. It causes nearly one out of every three deaths from cancer; one out of every five deaths from heart disease; and nearly nine out of ten deaths from lung cancer. Tobacco alone kills more people each year in the United States than AIDS, car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined. The nicotine in tobacco products is highly addictive, and 77% to 92% of smokers are addicted to nicotine.

Although the tobacco industry has long had extensive knowledge of these facts, it has for years lied about the health hazards and addictive nature of its products. Particularly relevant here, the tobacco industry long made unsubstantiated health claims that certain tobacco products were less harmful than others. Not only were the claims proved false, but the industry long knew that they were false. These unsubstantiated claims misled millions of tobacco users and were responsible for millions of preventable diseases and premature deaths.

Although the complaint in this case is far broader, the Tobacco Companies' preliminary injunction motion challenges only two provisions of the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 (2009): the restriction on promoting products as "modified risk tobacco products" (MRTP) without FDA approval, 21 U.S.C. § 387k, and the provision that prohibits marketing tobacco products "in combination with any other article or product regulated under" the Food, Drug, and Cosmetic Act. 21 U.S.C. § 321(rr)(4). The latter provision is not a speech restriction at all, but a restriction on selling "combination products." *See* 21 C.F.R. § 3.2(c) (FDA definition of "combination products"). We understand that this point will be explained in the

Government's memorandum in opposition to the preliminary injunction motion. Accordingly, in this memorandum, amici focus on the MRTP provision. As discussed below, the MRTP marketing restriction is an important tool for protecting public health and is consistent with 70 years of FDA regulatory authority.

INTEREST OF AMICI

Amici curiae are eleven non-profit public health organizations and consumer advocacy groups that for decades have worked to educate the public about and protect the public from the devastating health and economic consequences of tobacco use. Amici are particularly well qualified to assist the Court in understanding the substantial public interest advanced by the restrictions challenged here and have broad knowledge about the regulatory schemes implemented by the Food and Drug Administration. A fuller description of each organization is included in the motion for leave to file this memorandum as amici curiae, which is being filed concurrently with this memorandum.

BACKGROUND

Although the memorandum of plaintiffs Commonwealth Brands, Conwood Company, Discount Tobacco City and Lottery, National Tobacco Company, and R.J. Reynolds Tobacco Company (hereafter referred to collectively as Tobacco Companies) makes almost no mention of the public health imperative that lies at the heart of this case, the Family Smoking Prevention and Tobacco Control Act was enacted to stem the constant tide of severe and deadly preventable health problems caused by tobacco use in this country and to curtail the abusive marketing practices that perpetuate these problems. Pub. L. No. 111-31 at § 2 (Findings). The statistics are grim: More than 400,000 people in this country die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease. 61 Fed. Reg. 44396, 44398 (1996); CDC, *Smoking and Tobacco Use:*

Fast Facts, www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm (May 2009) (smoking is responsible for 443,000 deaths per year). An overwhelming majority of adult smokers started smoking before age 18. And one out of every three children who becomes a regular smoker will die prematurely from a tobacco-related disease. 61 Fed. Reg. at 44399.

Despite laws in all 50 states banning the sale of tobacco products to anyone under age 18, one in five high school students smokes cigarettes. CDC, *Cigarette Use Among High School Students—United States, 1991-2007*, www.cdc.gov/mmwr/preview/mmwrhtml/mm5725a3.htm (June 2008). Each day, approximately 3,600 young people under age 18 try smoking. *Id.*; *see also* 61 Fed. Reg. at 44568 (more than one million minors try their first cigarette each year*).* And each day, "an estimated 1,100 young people become daily cigarette smokers." CDC, *Cigarette Use Among High School Students, supra.* After the industry began targeting youth in advertising for smokeless tobacco products, minors' use of smokeless tobacco products greatly increased. *Id*. at 41318; 60 Fed. Reg. 41314, 41331 (1995). Today, 13% of male high school students use smokeless tobacco. CDC, *Smoking and Tobacco Use: Youth and Tobacco Use: Current Estimates*, www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm (May 2009).

Although for many years the tobacco industry feigned ignorance of the addictive nature of its products, the Food and Drug Administration (FDA) tobacco rulemaking in 1995 and 1996, *see* 60 Fed. Reg. 41314 (1995); 61 Fed. Reg. 44396 (1996), and the extensive findings of Judge Kessler in *United States v. Philip Morris*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), presented overwhelming evidence that the industry's public statements were lies. For example, a 1972 R.J. Reynolds report stated that "[n]icotine is known to be a habit-forming alkaloid, hence the confirmed user of tobacco products is primarily seeking the physiological

'satisfaction' derived from nicotine," *id*. at 232, and acknowledged that the user's "choice of product and pattern of usage are primarily determined by his individual nicotine dosage requirements." *Id.*

The tobacco industry not only lied about the risks of smoking generally, but for decades implemented a scheme to convince smokers that so-called "light," "low-tar," or "low-nicotine" cigarettes were less harmful than regular cigarettes—which the industry knew to be false. *Id*. at 445, 468, 531. The companies promoted their low-tar brands to smokers who were concerned about cigarettes' health hazards or considering quitting, to encourage them not to quit. *Id.* at 508; *see United States v. Philip Morris*, 566 F.3d 1095, 1107 (D.C. Cir. 2009). The scheme was highly successful: Sales of purportedly "low-tar" and "low-nicotine" brands increased from 2% of total cigarette sales in 1967 to almost 92.7% in 2006. 449 F. Supp. 2d at 508; FTC, *Cigarette Report for 2006* at 7 (2009), *available at* www.ftc.gov/os/2009/08/090812cigarettereport.pdf. As recently as 2006, the companies were "continu[ing] to make[] false and misleading statements regarding low-tar cigarettes in order to reassure smokers and dissuade them from quitting." *Philip Morris*, 449 F. Supp. 2d at 507-08.

Based on the industry's history of misrepresentation, as documented by the court in the *Philip Morris* case and a 2001 National Cancer Institute monograph on the risks of "light" cigarettes,[1] Congress expressly found that the only way effectively to protect the public from the dangers of unsubstantiated reduced-risk claims is to create a system of pre-market review, to ensure that the evidence cited to support such claims is verifiable. Pub. L. No. 111-31 at § 2 (Findings 36-43). On

[1]National Cancer Institute, Smoking and Tobacco Control Monograph 13, *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine* (Oct. 2001), *available at* http://cancercontrol.cancer.gov/tcrb/monographs/13/index.html (hereinafter "NCI Monograph").

this motion for a preliminary injunction, the Tobacco Companies' First Amendment challenge fails on the basis of this lengthy history of industry deceit and the tragic public health consequences that resulted from the industry's purposely misleading marketing.

ARGUMENT

Unlike government restrictions on "core" speech (such as political, artistic, or scientific speech), which are reviewed under a strict scrutiny standard, government restrictions on commercial speech are analyzed under the test set out in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). Under *Central Hudson*, commercial speech that concerns an unlawful activity or is false or misleading receives no First Amendment protection. *Id*. at 566. Commercial speech that is not false or misleading may be restricted to the extent that the restrictions are narrowly tailored to advance a substantial government interest. *Id*.

Here, the pre-approval requirement for claims that a product is a reduced-risk tobacco product is consistent with the FDA's long-established pre-approval authority over the content of drug and medical device labeling and promotion, as well as the pre-approval requirement for health claims made for foods. Like the pre-approval scheme Congress enacted for these other products, the MRTP provision—which allows the sale of the products but requires FDA approval of reduced-risk health claims before tobacco companies can make those claims to consumers—serves as a check against unproven, and therefore misleading, health claims about tobacco use. As a means of preventing false or misleading commercial speech, the provision should be upheld under *Central Hudson*.

Moreover, even if the restricted speech were truthful, the provision would satisfy *Central Hudson* because there is a reasonable fit between the government's substantial interest and the restriction. In particular, the industry's documented deceit with respect to marketing "low-tar" and

"low-nicotine" cigarettes, as well as the public's inability to assess the truth or falsity of such claims, demonstrates the need for extra caution before permitting advertising of other purportedly reduced-risk products.

I. The MRTP Provision Is Supported By The FDCA's Long-Standing Regulation Of Health Claims For Drugs, Medical Devices, And Foods.

The MRTP provision provides, in essence, that if a tobacco company wants to promote a tobacco product as less hazardous than other tobacco products, it must obtain the FDA's permission to do so. Although the Tobacco Companies present the MRTP provision as an extraordinary restraint on speech, it in fact mirrors the statutory schemes that have long provided for FDA regulation of potentially dangerous drugs and medical devices and of health claims for foods.

For example, under the Food, Drug, and Cosmetic Act (FDCA), a pharmaceutical company cannot sell a new drug without prior approval of the FDA. *See generally* 21 U.S.C. § 355; *see also id.* § 360c (approval of medical devices). To obtain permission to market a new product, a drug company must first submit a "new drug application" (NDA) for FDA's review and approval. 21 U.S.C. § 355(a), (b). An NDA must include information about the clinical trials that demonstrate the safety and effectiveness of the product, proposed labeling, and other information. *Id*. § 355(b), (d). If, after reviewing the application, the FDA finds that the drug is safe and effective for its intended use or uses and that the labeling is not false or misleading, the FDA will send an approval letter to the applicant. *Id*. § 355(c)(1)(A). FDA approval includes approval of the labeling, which specifies the approved uses of the products, as well as warnings, precautions, and other information. 21 C.F.R. §§ 201.56, 201.57, 201.80.

After a drug is approved for sale, the manufacturer is permitted to market it only for the specific use for which the company sought and obtained approval. 21 U.S.C. § 331(a), (d); *id.* § 352(a). If the company wants to promote the product for an additional use, it must submit an application and again receive FDA approval before doing so. 21 U.S.C. § 314.70. If the company markets the drug for unapproved uses or makes health claims not pre-approved by the FDA, it can face severe penalties. For example, Pfizer recently agreed to pay $2.3 billion to settle felony charges brought by the government for promoting the drug Bextra for an unapproved use. HHS, *Justice Department Announces Largest Health Care Fraud Settlement in its History*, www.hhs.gov/news/press/2009pres/09/20090902a.html (Sept. 2 2009). Like the FDCA's drug provisions, the MRTP provision does not bar truthful speech, but rather provides a mechanism for objective pre-marketing evaluation of health and safety claims for a category of products that pose great potential for harm.[2]

Tobacco products' primary active ingredient and mechanism of addiction is the drug nicotine. Accordingly, as R.J. Reynolds once stated, "the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry." 449 F. Supp.

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[2]The Tobacco Companies (at 24) suggest that *Washington Legal Foundation v. FDA*, 13 F. Supp. 2d 51 (D.D.C. 1998), *vacated by*, 202 F.3d 331 (D.C. Cir. 2000), held that the FDCA restriction on off-label promotion of drugs violates the First Amendment. That suggestion is incorrect. *Washington Legal Foundation* did not address the heart of the restriction on promoting drugs for unapproved uses; it addressed only distribution to physicians of reprints of medical textbooks and peer-reviewed journal articles and manufacturer involvement in continuing medical education seminars and symposia. *Id.* at 54. Nothing in that district court decision draws into question the bar on promoting unapproved uses to *consumers*—and speech "directed to consumers" is the speech addressed in the MRTP provision. *See* 21 U.S.C. § 387k(b)(2)(A)(3). And nothing in that opinion draws into question the FDA's authority to bar other types of promotion of unapproved uses—such as through direct pitches by pharmaceutical salespeople, advertisements, and statements on drug labels. Indeed, as the Pfizer example shows, the bar on promoting unapproved uses remains powerfully in effect. *Cf. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) (en banc) (rejecting due process challenge to FDCA restriction on selling investigational but unapproved new drugs to terminally ill patients).

2d at 232 (quoting R.J. Reynolds internal report). And like the MRTP provision, the FDCA's drug provisions were enacted because Congress was "concerned about unsafe drugs and fraudulent marketing." *Wyeth v. Levine*, 129 S. Ct. 1187, 1195 (2009). The analogy to drug regulation is thus particularly apt.

Even standard foods, however—which have far less potential to cause harm—must obtain FDA approval before making promotional health claims. Under the food labeling provisions of the FDCA, food manufacturers may make health claims for their products only after authorization by the FDA and subject to substantive and procedural criteria set forth in the statute. 21 U.S.C. § 343(r)(1), (3).[3] In addition, the FDA sometimes chooses to allow "qualified" health claims that cannot satisfy the statutory standard ("significant scientific agreement"). *See* 68 Fed. Reg. 41387 (2003). In these instances as well, the FDA requires that the health claim be submitted to it in advance, along with all supporting documentation, and that the claim be made only after FDA authorization and only with a disclaimer approved by the agency. *Id.* Under the pre-approval scheme for foods, for example, a food company can assert that its high-fiber cereals may reduce the risk of some types of cancer only because the FDA has approved that claim. 21 C.F.R. § 101.76. And dairy companies are permitted to advertise that milk may reduce the risk of osteoporosis because the FDA has approved that claim. *Id*. § 101.72.

[3]Specifically, the FDCA permits FDA approval of food health claims only when the agency "determines, based on the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." 21 U.S.C. § 343(r)(3)(B)(i).

Moreover, just as the Pfizer example shows that violation of the FDCA pre-approval requirement for making health claims about drugs has real consequences, recent action by the FDA against General Mills shows that the agency likewise takes seriously the approval requirement and marketing restriction concerning health claims for foods. Last May, the FDA sent General Mills a warning letter complaining about two unauthorized health claims made on Cheerios Whole Grain Oat Cereal. The FDA wrote that the Cheerios were misbranded because the placement and wording of the claims suggested that Cheerios "is intended for use in lowering cholesterol, and therefore in preventing, mitigating, and treating the disease hypercholesterolemia" and "for use in the treatment, mitigation, and prevention of coronary heart disease through, lowering . . . cholesterol." Letter from FDA to General Mills, May 5, 2009, *available at* www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm162943.htm. In other words, although health claims associating oats with lower cholesterol are FDA-approved, the company ran afoul of the FDCA when it made related but unapproved health claims.

The MRTP provision falls comfortably in line with these other well-established regulatory schemes. Similar to the food provisions of the FDCA, the MRTP provision allows tobacco companies to market their products without FDA approval if they make no claims about health, but a company must seek FDA approval before touting a tobacco product as healthy or healthier than others. The Tobacco Companies presentation of the MRTP provision as outside the mainstream of long-established regulatory schemes is off-base.

II. The MRTP Provision Imposes A Permissible Check On False Or Misleading Speech.

A. Ignoring the long history of FDA approval of health claims—both for products that pose serious risks (*e.g.,* prescription drugs) and for products that do not (*e.g.* breakfast cereal)—the Tobacco Companies argue that barring them from marketing some tobacco products as healthier than others is a ban on "core speech," reviewed under a strict scrutiny standard rather than under the less demanding *Central Hudson* test. This argument is disingenuous. As the marketing of "light" cigarettes demonstrates, *see supra* p. 4, *infra* pp. 17-19, the primary purpose of a tobacco company touting a particular tobacco product as less dangerous than others is to encourage people to purchase that product. *Cf. Bolger v. Young Drugs Prods. Corp.*, 463 U.S. 60, 68 (1983) (contraceptive manufacturer's pamphlet about preventing venereal disease is commercial speech, even though it discusses an important public issue).

A "core speech" argument similar to the Tobacco Companies' argument here was made—and rejected—in *Washington Legal Foundation*, a case on which the Tobacco Companies rely. There, the plaintiff argued that FDA limitations on manufacturers' sponsoring continuing medical education seminars at which their products would be discussed, and on distributing materials at such seminars, was scientific or educational speech entitled to the highest degree of First Amendment protection, not commercial speech subject to the *Central Hudson* test. 13 F. Supp. 2d at 59, 65. The court disagreed, noting that the main purpose of disseminating the articles was to promote sales. *Id*.

The same reasoning applies even more strongly in this case. Unlike the record before the court in *Washington Legal Foundation*, here, the Court can look to judicial, congressional, and executive branch findings to see how the tobacco industry has lied about scientific conclusions, denied the evidence of addiction and health risks, and manipulated scientific evidence, all to boost

and maintain sales. For example, evidence at trial in the government's RICO case against certain tobacco companies, including plaintiffs R.J. Reynolds and Lorillard Tobacco Company, "revealed that at the same time [the companies] were disseminating advertisements, publications, and public statements denying any adverse health effects of smoking and promoting their 'open question' strategy of sowing doubt, they internally acknowledged as fact that smoking causes disease and other health hazards." *Philip Morris*, 566 F.3d at 1106. The companies also created entities to "conduct[] the manufacturers' joint public relations through false and misleading press releases and publications." *Id*. at 1107. Although they "intimately understood" that nicotine was highly addictive and, in fact, "engineered their products around creating and sustaining this addiction," they for decades "publicly denied and distorted the truth about the addictive nature of their products, suppressed research revealing the addictiveness of nicotine, and denied their efforts to control nicotine levels and delivery." *Id*. And particularly relevant to the marketing of products as reduced risk, the companies "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." *Id.; see also* Pub. L. No. 111-31 at § 2 (Findings 47-49).

The overwhelming evidence about the industry's "scheme to defraud smokers and potential smokers" by denying the health effects of smoking, denying the addictiveness of nicotine, "falsely representing that light and low-tar cigarettes deliver less nicotine and tar and therefore present fewer health risks than full flavor cigarettes," "falsely denying that they market to youth," "falsely denying that secondhand smoke causes disease," and "suppressing documents, information, and research to prevent the public from learning the truth about these subjects and to avoid or limit liability in litiga-

tion," *id*., demonstrates that the Tobacco Companies' discussion of reduced risk products is intended to promote use of the dangerous products they sell. *See also Board of Trustees of State University of New York v. Fox*, 492 U.S. 469, 473 (1989) (rejecting argument that when core speech and commercial speech are "intertwined," the entirety must be classified as noncommercial).

In short, the MRTP focuses on speech "directed to consumers." 21 U.S.C. § 387k(b)(2)(A)(3). A manufacturer describing to consumers the purportedly beneficial aspects of its product fits squarely within the scope of commercial speech. *See Bolger*, 463 U.S. at 67-68 (advertising that "'links a product to a current public debate' is not thereby entitled to the constitutional protection afforded noncommercial speech") (quoting *Central Hudson*, 447 U.S. at 563 n.5).

B. Not only does the MRTP provision address commercial speech, but the history of tobacco industry marketing of "low-tar" and "low-nicotine" tobacco products—products for which it fostered and exploited a misconception that the products were less dangerous than other cigarettes to discourage smokers from trying to quit—shows that this provision is a means of preventing false or misleading commercial speech that has great potential for harm, by an industry with a documented record of deceit.

In 2006, the court presiding over the RICO suit brought by the United States against numerous tobacco companies and two tobacco trade organizations found that tobacco companies such as plaintiffs R.J. Reynolds and Lorillard "were reasonably likely" to continue their deceptive conduct in the future "because they continued to make false and misleading statements at the time of trial." *Philip Morris*, 566 F.3d at 1109. In light of the industry's history of deceptive marketing of tobacco products falsely claimed to pose fewer health risks and the substantial public health concerns at issue, the Court should defer to Congress's determination that the Tobacco Companies'

reduced-risk claims are misleading until such time as the FDA has evaluated them for scientific accuracy, found them to be truthful, and approved them for use in marketing. *See United States v. Edge Broadcasting Co.*, 509 U.S. 418, 434 (1993) ("Within the bounds of the general protection provided by the Constitution to commercial speech, we allow room for legislative judgments."). Thus, like claims for other products with potentially significant health consequences, claims that some tobacco products pose a reduced health risk can lawfully be subject to FDA pre-approval, and potential disapproval, under *Central Hudson*. *See Edenfield v. Fane*, 507 U.S. 761, 768 (1993) ("[O]ur cases make clear that the State may ban commercial expression that is fraudulent or deceptive without further justification."); *Friedman v. Rogers*, 440 U.S. 1, 9-10, (1979) (government may restrict commercial speech that is "not provably false, or even wholly false, but only deceptive or misleading").

That the MRTP provision may delay some reduced-risk promotional statements that could be true presents no First Amendment impediment. First, there is no way of knowing prior to FDA review which reduced-risk claims that a company wants to make will be justified. Again, the FDA's regulation of drug and health claims for foods demonstrates the point: The FDA has rejected applications for approval to market drugs for particular uses because it determined that the applications did not substantiate that the products were safe and effective for those uses, and the FDA has denied requests from food companies seeking to make health claims that were not adequately supported. *See*, *e.g.*, FDA, Letter of Denial - Alkaline and Earth Alkaline Citrates Minimizing the Risk of Osteoporosis (Docket Number 2007P-0301), Oct. 30, 2007, *available at* www.fda.gov/Food/LabelingNutrition/LabelClaims/HealthClaimsMeetingSignificantScientificAgreementSSA/ucm121764.htm; FDA, Qualified Health Claims, Letters of Denial, *available at* www.fda.gov/Food/

LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072751.htm. Here, Congress's findings made it so skeptical that tobacco companies' reduced-risk claims would be accurate that, even for claims that obtain FDA approval, Congress required post-marketing studies to verify that the FDA's pre-marketing findings are backed up by post-marketing reality. 21 U.S.C. § 387k(i). As Congress recognized, because of the potential for addiction and serious illness caused by ungrounded health claims associated with tobacco products, post-marketing review cannot alone adequately serve the substantial public interest.

Second, commercial speech restrictions may be justified by a record of abuse (such as the extensive record of the tobacco industry's conduct over many decades) and the government's interest in protecting the public (such as its substantial interest in protecting the public health). *See Florida Bar v. Went for It, Inc.*, 515 U.S. 618 (1995) (historical evidence of abuse may justify broad prophylactic restraints on speech); *Friedman*, 440 U.S. at 15 (same); *Mainstream Marketing Serv., Inc. v. FTC*, 358 F.3d 1228, 1233 (10th Cir. 2004) (restriction on commercial telemarketing justified by government's interest in combating abusive telemarketing). That principle applies fully here, where the restriction is not a ban, but a mechanism to assure that statements concerning the health effects of tobacco products are reviewed for accuracy *before* consumers are deluged with them. *Cf. Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 562 (2001) (striking down state tobacco regulation that "would constitute nearly a complete ban on the communication of truthful information").

Third, when the FDA is assured that a claim is truthful—that it is not another "knowing[] and intentional[]" effort "to defraud smokers and potential smokers, for purposes of financial gain, by making false and fraudulent statements, representations, and promises," *Philip Morris*, 566 F.3d at 1117 (quoting district court finding, 449 F. Supp. 2d at 852)—the MRTP provision provides a

process for approval of the reduced-risk claim. The public health imperative justifies the delay to allow the FDA to ensure that the companies do not make false or misleading claims.

C. Even if the MRTP provision were a restriction on non-misleading speech, the provision would satisfy *Central Hudson* because the provision is narrowly tailored to directly advance a substantial government interest. 447 U.S. at 566. The tobacco industry's history of deliberate misuse of evidence to support inaccurate health claims demands special skepticism of future claims, and requiring tobacco companies to demonstrate the validity of claims before presenting those claims to the public is a reasonable way to prevent further deception and public harm. For the same reasons, plaintiffs are wrong that the MRTP provision unconstitutionally prohibits health claims that do not benefit the population as a whole. Tobacco companies have in the past successfully used health claims to discourage smokers from trying to quit and to falsely allay the concerns of people thinking about starting, with devastating consequences for public health. Given this unique history of deception and intentional harm, Congress reasonably crafted an approval requirement to ensure that tobacco companies do not misuse health claims to further use of an addictive and deadly product.

There can be no legitimate dispute that the government has a substantial interest in protecting the public health, and that restricting the promotional tools used by tobacco companies advances that interest. As discussed above, *supra* pp. 2-4, tobacco use is a leading cause of preventable death, disability, and disease in the United States, and advertising is a crucial tool in the industry effort to draw in new, young customers. With respect to purportedly reduced-risk products in particular, tobacco companies have long "used so-called brand descriptors such as 'light' and 'ultra light' to communicate reassuring messages that these are healthier cigarettes and to suggest that smoking low-tar cigarettes is an acceptable alternative to quitting," and they "used sophisticated marketing imagery"

to reinforce the misconception that these "low-tar" brands were less harmful. *Philip Morris*, 449 F. Supp. at 430. The Tobacco Companies' memorandum does not take issue with these facts.

The issue then, as in many commercial speech challenges, is the fit between the governmental interest and the means chosen to accomplish it. In discussing this aspect of the *Central Hudson* test, the Supreme Court has emphasized that the restriction should be "no more extensive than is necessary," *id.* at 566, but that it need not be "perfect," only "reasonable." *Fox*, 492 U.S. at 480. Here, the history of promotional practices employed by the tobacco industry over the past 30 years shows the reasonableness of the fit between the substantial public interest and the MRTP provision.

The first scientific studies linking cigarette smoking with lung cancer appeared in the early 1950s and led to the publication in 1962 of the Royal College of Physicians' report on "Smoking in Relation to Cancer of the Lung and Other Diseases" and in 1964 to the U.S. Surgeon General's report on smoking and health. *See* NCI Monograph at 1-2, 199, 204. As the public began to understand the link between smoking and disease, cigarette companies, seeking to stave off a massive loss in sales, scrambled to develop products that would ease consumers' fears about the health effects of smoking. *Id.* at 5-6, Ch. 7. Developing products to ease fears, however, did not mean developing products to ease health risks. As one tobacco company stated in an internal report, "[t]he illusion of filtration is as important as the fact of filtration." *Id*. at 206 (citing 1966 Philip Morris report entitled *Market Potential of a Health Cigarette*).

To reassure and retain consumers, the companies introduced "low-tar" and "light" cigarettes. For health-conscious adults who wanted to quit smoking but were unable to do so because they were addicted, switching to cigarettes with lower reported tar and nicotine yields seemed an attractive alternative, allowing them to maintain their addiction while supposedly mitigating the health risk.

Industry advertising promoted and reinforced this belief. As a result, over the past twenty-five years or so, most smokers in developed countries began to use "light" and "low-tar" products as a substitute for what they perceived to be riskier products. *See*, *e.g.*, L. Kozlowski, *et al.*, "*Smokers' Misperceptions of Light and Ultra-Light Cigarettes May Keep Them Smoking*," 15 Am. J. of Preventive Med. 9-16 (July 1998); *see generally* NCI Monograph at Ch. 1, Ch. 6. In the United States, for example, 92.7 percent of cigarettes currently sold are low-tar brands marketed with descriptions such as "light" and "ultra-light." FTC, *Cigarette Report for 2006*, *supra*, at 7.

In fact, however, "light" and "lowered tar and nicotine" cigarettes are not any safer than regular cigarettes. As the National Cancer Institute reported in 2001, although changes in cigarette design reduced the amount of tar and nicotine measured by smoking machines, machine measurements do not accurately show how much tar and nicotine smokers actually take in. *See* NCI Monograph at 1, 4. Despite claims that certain brands of cigarettes deliver lowered tar and nicotine, there is no meaningful difference in exposure from smoking low-tar brands as compared to regular brands, and therefore no difference in disease risk. *Id.* at 10. Although "many smokers switch to lower yield cigarettes out of concerns for their health believing these cigarettes to be less risky or to be a step towards quitting," *id.*, "current evidence does not support either claims of reduced harm or policy recommendations to switch to these products." *Id.*

Although the NCI Monograph is only eight years old, the industry has been aware for decades that smoking machines do not accurately measure the behavior of actual smokers. As a 1982 R.J. Reynolds report stated, "smokers compensate to obtain a consistent amount of nicotine. Relevant to this, it should be noted that all cigarettes experienced a marked reduction in nicotine filter efficiency under human smoking conditions compared to the nicotine filter efficiencies obtained under

standard FTC conditions." *Philip Morris*, 449 F. Supp. 2d at 468. Nonetheless, tobacco companies decided to use labels touting "light" and "lowered tar and nicotine" cigarettes, and fostered and then exploited widespread public misperception about both the true exposure to tar and nicotine, and the relative health risks of products. For example, R.J. Reynolds tailored its advertising for "low-tar" cigarettes to smokers "seriously concerned about the alleged hazards of smoking." *Id*. at 531.

These facts form the backdrop against which Congress enacted the MRTP provision. *See* Pub. L. No. 111-31, § 2 at ¶¶36-43 (Findings). These facts more than justify Congress's conclusion that "[p]ermitting manufacturers to make unsubstantiated statements concerning modified risk tobacco products . . . would be detrimental to the public health," *id*. ¶ 42, and demonstrate the reasonable fit between significant public health concerns and the MRTP provision. On a motion for preliminary injunction, where the public interest plays into the balance of factors, the tobacco industry's history of deceit and Congress's determination that pre-market review by the FDA is the "only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products," *id*. ¶ 43, provide a firm basis for denial of the Tobacco Companies' motion.

CONCLUSION

For the foregoing reasons and the reasons stated in the government's memorandum, the motion for a preliminary injunction should be denied.

September 30, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

On September 30, 2009, I electronically filed this document through the ECF system, which will send a notice of electronic filing to counsel for all parties in this case.

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