

**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, *

v. *

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

Defendants. *

CIVIL ACTION
NO. 1:09CV-117-M
(Electronically Filed)

RESPONSE TO THE MEMORANDUM OF AMICI CURIAE

There is an ongoing, vigorous scientific and public debate over tobacco control and harm reduction. On the one side of that debate are certain opponents of tobacco use, including some Amici, who apparently believe that smokeless tobacco products should play *no* role in that strategy, because by promoting such products, existing tobacco users may be encouraged to switch to smokeless tobacco products rather than quitting altogether. On the other side of the debate are individuals and entities, including some Plaintiffs, who believe that, since millions of American adults continue to smoke cigarettes despite long-standing efforts to persuade them not to, public health would be furthered by encouraging adult smokers to switch to smokeless tobacco.

Amici spend much of their brief denigrating Plaintiffs' motives and accusing them of a history of deception. *See, e.g.*, Mem. of Amici Curiae in Opp. to Mot. for Prelim. Inj. of Pls. at 12,

15. This attack does not aid the Court. First, the findings upon which Amici rely—those in *United States v. Philip Morris*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in part, vacated in part*, 566 F.3d 1095 (D.C. Cir. 2009)—are currently on appeal. Second, and for present purposes more important, they are entirely irrelevant to this case. These findings go to the assertion that Plaintiffs' use of descriptors such as "light" and "low tar" on cigarettes was misleading, even though manufacturers (1) used a uniform, Federal Trade Commission-sanctioned method of measuring tar levels in cigarettes and (2) advised the FTC when the test was adopted *in 1967* that it could not replicate human smoking patterns. *See id.* at 436-37. But in *this* case, Plaintiffs are *not* challenging the constitutionality of the Modified Risk Tobacco Product Requirement's ("MRTPR") prohibition on these descriptors. *See* 21 U.S.C. § 387k(b)(2)(A)(ii). Instead, Plaintiffs' challenge is limited to the *other* speech restrictions imposed by the MRTPR, including:

- labels, labeling, and advertising that "explicitly or implicitly" represents that one tobacco product "presents a lower risk of tobacco-related disease or is less harmful than" another, that a tobacco product or its smoke "contains a reduced level of a substance or presents a reduced exposure to a substance," or that a tobacco product or its smoke "is free of a substance," *id.* § 387k(b)(2)(A)(i)(I)-(III); and
- "any action directed to consumers through the media or otherwise" that could "result in consumers believing that [a] tobacco product or its smoke may" be less harmful than other products or have reduced levels or be free of certain substances, *id.* § 387k(b)(2)(A)(iii).

Notably, none of the Amici—representing the leading public health organizations—assert that the statements on Plaintiff Reynolds' website identified in the declaration submitted by Tommy J. Payne are false or misleading.

The MRTPR seeks to silence Plaintiffs in this important scientific and public policy debate regarding tobacco use and harm reduction. It is therefore an impermissible viewpoint-based restriction on Plaintiffs' core protected speech.

1. There is unquestionably a very serious, ongoing public debate about the role smokeless tobacco products should play in a larger public health strategy aimed at addressing the health consequences of smoking.

a. One side of that debate believes that, while quitting is the best way to reduce risk, if an existing smoker will not quit, that individual is far better off switching to a product that poses fewer health risks than cigarettes. As the Tobacco Advisory Group of the Royal College of Physicians has explained:

[C]omplete abstinence from smoking is the obvious best option for health. However, . . . this option is not realistically achievable in the short-term or medium-term future for a substantial proportion of smokers in populations in which smoking is already established. In this context, since tobacco smoking is driven primarily by addiction to nicotine, but the harm from smoking is caused by other smoke constituents, the rational next-best option is to reduce the harm arising from nicotine use by providing it in a form that does not involve inhaling smoke.¹

Dr. Lynn Kozlowski is another prominent advocate of this position. According to Dr. Kozlowski:

[There is a] human right of individuals to receive information relevant to their health and their health choices [Some smokeless tobacco], based on present evidence, make[s] dramatic reductions in health risks to individual smokers; . . . there is an established right to information that affects health; and . . . the potential public harm is not clear and convincing enough to justify suspension of advice about reduced risks to individuals from these products.²

The Royal College of Physicians' Tobacco Advisory Group further explains:

In an environment in which smokers are informed and believe that smokeless tobacco is just as harmful to health as smoking, one would not expect many to switch for health reasons. . . . The epidemiology of tobacco use in Sweden[, however,] suggests that if the public is offered a substantially less harmful smokeless tobacco product along with access to accurate information on relative risks, a substantial proportion can switch to the less harmful product.

¹ Tobacco Advisory Group, Royal College of Physicians, *Harm Reduction in Nicotine Addiction* 223 (2007) (hereinafter "*Harm Reduction*").

² Lynn T. Kozlowski, *Harm Reduction, Public Health, & Human Rights*, 4 *Nicotine & Tobacco Research* S55, S56 (2002).

Harm Reduction at 159-61.

This position is also adhered to by some Plaintiffs. Thus, as set forth in the declaration that Plaintiff Reynolds has submitted in this case, Reynolds believes that while “[n]o tobacco product has been shown to be safe and without risks,” “[t]he health risks associated with cigarettes are significantly greater than those associated with the use of smoke-free tobacco and nicotine products.” Payne Decl. ¶ 11. Consequently, Reynolds believes:

The best course of action for tobacco users concerned about their health is to quit. Adults who continue to use tobacco products should consider the reductions of risks for serious diseases associated with moving from cigarettes to the use of smoke-free tobacco or nicotine products.

Id. Reynolds further believes:

Significant reductions in the harm associated with the use of cigarettes can be achieved by providing accurate information regarding the comparative risks of tobacco products to adult tobacco consumers, thereby encouraging smokers to migrate to the use of smoke-free and nicotine products, and by developing new smoke-free tobacco and nicotine products and other actions.

Id.

b. Of course, as is invariably the case on important issues of public health, there is another side to this debate. Many opponents of tobacco use, including Amicus American Cancer Society, apparently believe that smokeless tobacco products should play little or no role in a larger public health strategy addressed to the negative effects of tobacco use because they discourage smokers from ceasing to use tobacco products altogether. According to the American Cancer Society:

[Ads for smokeless tobacco] encourage smokers to use these products to meet their nicotine cravings in settings where they cannot smoke. This wipes out one of the benefits of smoke-free laws. Smokers who delay quitting by using smokeless products while continuing to smoke increase their risk of lung cancer. How long a person smokes is by far the most important factor in lung cancer risk.³

³ American Cancer Society, *Smokeless Tobacco & How to Quit*, available at http://www.cancer.org/docroot/PED/content/PED_10_13X_Quitting_Smokeless_Tobacco.asp?sitearea=PED (last visited Oct. 4, 2009).

This position has also been adopted by some government officials, and apparently by the Government in this case. Thus, in 2003, Scott J. Leischow, then Chief of the Tobacco Control Research Branch of the National Cancer Institute, testified that “even if a tobacco product is shown to reduce disease risk in an individual, the availability of products that claim reduced harm may have harmful consequences on the population” since “smokers may see reduced harm products as a viable alternative to quitting.”⁴ And in its brief in this case, the Government gives voice to this same “concern” about “the possibility that smokeless tobacco . . . marketing might ‘reduce cessation or delay cessation attempts’ by current cigarette smokers.”⁵

c. As the foregoing makes clear, there is a vigorous, ongoing debate about the role of smokeless products that some Plaintiffs currently manufacture and sell in a larger public health strategy addressing the health effects of tobacco use. This Court need not decide which side of this debate is correct, but Plaintiffs respectfully request that this Court preserve their right to present their position in a forthright fashion.

2. Amici spend pages upon pages accusing Plaintiffs of deception. But this assertion is based entirely on a separate question of whether the sale of “light” and “low tar” cigarettes falsely implies that such cigarettes are less harmful than full flavor cigarettes. Plaintiffs vigorously dispute that their past practices were misleading. But for present purposes, this sideshow is irrelevant. In *this* case, Plaintiffs are not challenging the MRTPR’s prohibition on the use of descriptors such as “light” and “low tar.” See 21 U.S.C. § 387k(b)(2)(A)(ii). Rather, they are challenging the MRTPR’s *other* speech restrictions. And as to these, Amici cannot deny that the overwhelming

⁴ *The Science of Reduced Risk Tobacco Products: Statement Before the H. Comm. on Gov’t Reform*, 108th Cong. (June 3, 2003) (Statement of Scott J. Leischow, Chief of the Tobacco Control Research Branch, Nat’l Cancer Inst., Nat’l Insts. of Health, U.S. Dep’t of Health and Human Servs.), available at <http://www.hhs.gov/asl/testify/t030603a.html>.

⁵ Mem. in Opp. To Pls.’ Mot. for Prelim. Inj. at 11-12 (quoting *Regulation of “Reduced Risk” Tobacco Products: Statement Before the H. Comm. on Gov’t Reform*, 108th Cong. (June 3, 2003) (Statement of David M. Burns, Professor of Med., Univ. of Cal.), available at 2003 WL 21280495).

weight—indeed, quite arguably the *uniform* weight—of independent scientific evidence establishes that smokeless tobacco poses substantially fewer health risks than cigarettes.

It is well-established that the “process” that makes tobacco use particularly dangerous is combustion—the burning of tobacco in cigarettes. *Harm Reduction* at 18. For a cigarette user, the act of smoking leads to a greatly increased risk, compared to non-users of tobacco, of heart disease, heart attack, stroke, oral cancer, cancers of the lung and gastrointestinal tract, and chronic pulmonary diseases. *Id.* at 14, 107-13. Because smokeless tobacco does not involve combustion, the overwhelming scientific evidence establishes that smokeless tobacco is substantially less dangerous to a user’s health than cigarettes. Tobacco Advisory Group, Royal College of Physicians, *Protecting Smokers, Saving Lives* 5 (2002) (hereinafter “*Protecting Smokers*”).

Indeed, some scientists have opined that smokeless tobacco is “at least 90% less hazardous than cigarette smoking.” C. Bates et al., *European Union Policy on Smokeless Tobacco*, 12 *Tobacco Control* 360, 361 (2003); accord Peter N. Lee & Jan S. Hamling, *Systematic Review of the Relation Between Smokeless Tobacco and Cancer in Europe and North America*, 7 *BMC Med.* 36⁶ (2009) (“any effect of [smokeless tobacco] on risk of cancer, if it exists at all, is quantitatively very much smaller than the known effects of smoking”); Marita Broadstock, *Systematic Review of the Health Effects of Modified Smokeless Tobacco Products*, 10 *New Zealand Health Tech. Assessment Report* 1, 23-56 (2007) (finding no strong evidence linking *snus* use to oral, neck, and gastrointestinal cancers or to an increased risk of cardiovascular disease, heart attack, and stroke); David T. Levy et al., *The Relative Risks of a Low-Nitrosamine Smokeless Tobacco Product Compared with Smoking Cigarettes*, 13 *Cancer Epidemiology, Biomarkers & Prevention* 2035, 2038 (2004); *Protecting Smokers* at 5 (“[T]he consumption of non-combustible tobacco is of the

⁶ This article has “page numbers not for citation purposes.” For the Court’s convenience, however, Plaintiffs offer specifically page 48 of the 53-page document, available at <http://www.biomedcentral.com/content/pdf/1741-7015-7-36.pdf>, for its consideration.

order of 10-1,000 times less hazardous than smoking, depending on the product.”); *see also* Scientific Comm. on Emerging & Newly Identified Health Risks, Health & Consumer Protection Directorate-General, European Commission, *Health Effects of Smokeless Tobacco Products Preliminary Report 107* (2007).

To be sure, researchers have found that smokeless tobacco products do not *eliminate* health risks. *See generally* Dorothy K. Hatsukami et al., *Changing Smokeless Tobacco Products*, 33 Am. J. Preventive Med. S368, S373-76 (2007). But these *reductions* in risk to individual users are so substantial that it is virtually undisputed that public health would improve greatly relative to the *status quo* if smokers switched to smokeless tobacco. Lynn T. Kozlowski, *Effect of Smokeless Tobacco Product Marketing & Use on Population Harm from Tobacco Use*, 33 Am. J. Preventive Med. S379, S383 (2007). Indeed, as Dr. Kozlowski notes, the number of non-tobacco users that would have to begin using smokeless tobacco would have to be monumental for the public health risks to equal the danger presented by smoking cigarettes. For example, assuming that twenty percent of the population smokes: “[f]or a product that is 80% less dangerous than cigarettes, an impossible 100% of the population (*i.e.*, 5 times greater) would need to use the product to equal the early death from smoking.” *Id.* “It is doubtful that close to 100% of the population would come to use any tobacco product,” smokeless or not. *Id.*

3. Notwithstanding this overwhelming evidence, under the MRTPR, Plaintiffs are barred from engaging in truthful speech as part of the scientific and public policy debate over tobacco use and harm reduction. In short, this statutory regime has taken one side of a public policy debate and simultaneously seeks to shut down the other side. For unlike Plaintiffs, opponents of smokeless tobacco products are completely free to advance their position at any time and in any forum. This “[v]iewpoint discrimination is censorship in its purest form.” *R. A. V. v. City of St. Paul*, 505 U.S. 377, 430 (1992) (quotation omitted) (Stevens, J., concurring). Indeed, “[t]o permit one side of a

debatable public question to have a monopoly in expressing its views . . . is the antithesis of constitutional guarantees.” *City of Madison, Joint School Dist. No. 8 v. Wisconsin Employment Relations Comm’n*, 429 U.S. 167, 175-76 (1976).

CONCLUSION

For the reasons herein, and those in Plaintiffs’ principal brief and reply brief, this Court should preliminarily enjoin the challenged provisions of the MRTPR.

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

/s/ Charles E. English

CHARLES E. ENGLISH
CHARLES E. ENGLISH, JR.
D. GAINES PENN
E. KENLY AMES

ATTORNEYS FOR PLAINTIFFS

- and -

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

- and -

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

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

- and -

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

ATTORNEYS FOR PLAINTIFF
COMMONWEALTH BRANDS, INC.

- and -

LeAnne Moore
NATIONAL TOBACCO COMPANY, L.P.
3029 W. Muhammad Ali Boulevard
Louisville, KY 40212
Telephone: (731) 364-5419, ext. 4155
E-mail: lmoore@nationaltobacco.com

ATTORNEYS FOR PLAINTIFF
NATIONAL TOBACCO COMPANY, L.P.

860379