Docket No. FDA-2012-D-0071

COMMENTS

of

THE WASHINGTON LEGAL FOUNDATION

to the

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH & HUMAN SERVICES

Concerning

DRAFT GUIDANCE FOR INDUSTRY:
MODIFIED RISK TOBACCO PRODUCT APPLICATIONS

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED
AT 77 *FED. REG.* 20026 (April 3, 2012)

Richard A. Samp
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

June 4, 2012

WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Avenue, NW
Washington, DC 20036
202-588-0302

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Via Email and U.S. Mail
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: FDA Draft Guidance for Industry:
Modified Risk Tobacco Product Applications
77 Fed. Reg. 20025 (April 3, 2012)

Dear Sir/Madam:

The Washington Legal Foundation (WLF) very much appreciates this opportunity to comment on the Food and Drug Administration's (FDA) draft guidance to industry entitled "Modified Risk Tobacco Product Applications." The guidance describes the types of information that must be included in any application for authorization to market a modified risk tobacco product (MRTP) pursuant to the Family Smoking Prevention and Tobacco Control Act, 123 Stat. 1776, enacted on June 22, 2009 ("FSPTCA" or "the Act"). As WLF has expressed in previous filings, it has grave concerns regarding a number of the provisions of the Act as they relate to MRTPs; it is concerned that those provisions cannot be enforced in a manner that is consistent with the First Amendment.

In light of those serious First Amendment issues, WLF is disappointed that FDA's draft guidance does not appear to have made any allowance for free-speech rights. Indeed, although the draft guidance is devoted almost entirely to restrictions on what manufacturers are permitted to say about their tobacco products, the phrase "First Amendment" appears nowhere in the document.

Because Congress has delegated to FDA responsibility for implementing the FSPTCA, it is incumbent on the agency to devise means of implementing the Act in a manner that minimizes intrusions on First Amendment rights. The Act creates a new Section 911 of the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 387k, entitled, "Modified risk tobacco products." Section 387k imposes severe restrictions on the right of manufacturers of tobacco products to speak truthfully regarding the relative health risks of their products.

Of course, any such restrictions on truthful speech raise significant First Amendment concerns. WLF believes that there are strong arguments that § 387k impinges on First

Amendment rights in three significant ways. First, even assuming that the manufacturer speech at issue qualifies as "commercial speech" in all instances and thus is subject to review under the somewhat relaxed standards applicable to commercial speech restrictions, § 387k appears to contemplate speech restrictions far broader than anything heretofore upheld under Supreme Court commercial speech case law. Second, § 387k appears to contemplate a system of prior restraint of truthful speech that is anathema to the First Amendment. Third, the vagueness of § 387k is constitutionally problematic because it does not provide clear guidance regarding precisely what forms of speech are to be prohibited.

FDA is charged with responsibility for adopting rules to implement § 387k, including (as here) guidance to industry regarding the filing of applications for authorization to market MRTPs. This guidance thus provides FDA an opportunity to mitigate the shortcomings of § 387k – by providing definitions that eliminate the statute's vagueness and by establishing application standards that minimize the extent to which it impinges on First Amendment freedoms. WLF does not believe that the proposed guidance serves either of those goals.

I. *Interests of WLF*

The Washington Legal Foundation is a public interest law and policy center with members and supporters in all 50 States. WLF regularly appears before federal and State courts and administrative agencies to promote economic liberty, free enterprise, and a limited and accountable government. In particular, WLF has devoted substantial resources over the years to promoting the free speech rights of the business community, appearing before numerous federal courts in cases raising First Amendment issues. *See, e.g., Nike v. Kasky*, 539 U.S. 654 (2003). WLF has successfully challenged the constitutionality of FDA restrictions on speech by pharmaceutical manufacturers. *Washington Legal Found. v. Friedman,* 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd,* 202 F.3d 331 (D.C. Cir. 2000). As a result of that litigation, FDA is subject to a permanent injunction limiting FDA authority to suppress manufacturer dissemination of certain journal articles/medical texts discussing off-label uses of their FDA-approved products.

WLF also regularly participates in FDA administrative proceedings in support of expanded First Amendment rights. *See, e.g.,* FDA Docket No. 2009-N-0294 (Sept. 29, 2009) (response to FDA request for public comments regarding implementation of FSPTCA); FDA Docket No. 2008-D-0053 (April 21, 2008) (response to FDA's draft guidance for industry on good reprint practices); FDA Citizen Petition No. 2006P-0319/CPI (August 11, 2006) (documenting repeated First Amendment violations by FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) and calling on DDMAC to conform to constitutional constraints on its activities); FDA Docket No. 02N-0209 (October 28, 2002) (response to FDA's request for public comments on First Amendment issues).

II. *FDA's Statutory Authority*

Congress adopted the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. §§ 301 *et seq*., in 1938 to regulate the sale of drugs and medical devices to the public. Asserting that tobacco products as customarily marketed are "medical devices" and "drugs" within the meaning of the FDCA, FDA in 1996 asserted authority to regulate tobacco products. Among other things, FDA claimed the right to regulate what manufacturers of tobacco products could say about their products. The U.S. Supreme Court ruled in 2000 that FDA was overstepping its authority – that Congress had not intended, when it adopted the FDCA, to permit FDA to regulate tobacco products. *FDA v. Brown & Williamson Tobacco Corp.,* 529 U.S. 120 (2000).

On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act, which for the first time grants FDA regulatory authority over tobacco products. The FSPTCA cannot be deemed a congressional effort to legislatively overrule *Brown & Williamson*, in that it does not authorize FDA to treat tobacco products as "drugs" or "medical devices." Rather, the Act creates a new Chapter IX of the FDCA that establishes a wholly new regulatory regime for "tobacco products."

Among the provisions of the Act is a new § 911(a) of the FDCA, 21 U.S.C. § 387k(a), which provides, "No person may introduce into or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product." The section goes on to provide a detailed definition of what constitutes a "modified risk tobacco product," or "MRTP." See, e.g., 21 U.S.C. § 387k(b)(1) ("The term 'modified risk tobacco product' means 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."). It also sets out the procedures for obtaining and maintaining an FDA order permitting the marketing of a MRTP. 21 U.S.C. §§ 387k(g), 387k(h), and 387k(i).

Even a cursory reading of § 387k makes plain, however, that Congress was not principally seeking to control the marketing of a new class of products designed "to reduce harm or the risk of tobacco-related disease" among those using an existing tobacco product. Rather, Congress sought to control what the manufacturers of existing tobacco products could say about the relative harms caused by their products. *See, e.g.,* 21 U.S.C. § 387k(b)(2)(A)(iii) (imposing restrictions on speech regarding a tobacco product "that would reasonably be expected to resulting 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."). In other words, despite the language of § 387k(b)(1), Congress did not contemplate that businesses would seek to market products designed to be used by a consumer for the purpose of reducing harm or the risk of tobacco-related disease caused by a

separate tobacco product also being used by the consumer.

Accordingly, § 387k is *not* a statute designed to regulate what products are to be distributed in interstate commerce; in general, it does not contemplate doing anything to prevent the sale of any tobacco product, regardless of the danger to public health posed by the product. Rather, § 387k is a pure speech regulation: it is designed to regulate what manufacturers can say about existing tobacco products. The statute contemplates that those manufacturers who say health-related things about their existing products without FDA permission may be subjected to severe civil and criminal penalties.

III. Section 387k Contemplates Broad Constraints on Truthful Commercial Speech That Severely Impinge on First Amendment Rights, but FDA Can Ameliorate Constitutional Concerns by Focusing on Speech It Has Determined to Be False or Misleading

A. Principles of First Amendment Protection

The First Amendment comprehensively safeguards freedom of speech. U.S. Const. amend. I. In determining the degree of protection accorded, however, the Supreme Court has drawn a distinction between "commercial speech" and other forms of protected speech. *E.g., Ohralik v. Ohio State Bar Association*, 436 U.S. 447, 455-56 (1978). Noncommercial speech (pure speech) that expresses ideas, communicates information or opinions, or disseminates views or positions is extended protection of the highest order. In contrast, commercial speech is extended less, but certainly not insubstantial, protection than expressions that are noncommercial in nature. *E.g., Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York*, 447 U.S. 557, 562-63 (1980). For purposes of First Amendment analysis, "commercial speech" is identified as communication that principally "proposes a commercial transaction." *E.g., Board of Trustees of the State University of New York v. Fox*, 492 U.S. 469 (1989) [hereinafter "*Board of Trustees of SUNY*"] (quoting *Virginia State Board of Pharmacy Board v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976)). The communication relates "solely to the economic interests of the speaker and its audience." *Central Hudson*, 447 U.S. at 561.[1]

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[1] FDA should not make the mistake of assuming that any statements issued by a tobacco company should be deemed "commercial" speech simply because they are the utterances of a commercial entity. The fact that a speaker has an "economic motivation" for speaking is not by itself sufficient to classify the speech as "commercial." *Bolger v. Youngs Drug Products Corp.,* 463 U.S. 60, 67 (1983). Indeed, in one of its most famous First Amendment decisions, the Supreme Court granted full First Amendment protection to a paid newspaper advertisement soliciting donation of funds. *New York Times Co. v. Sullivan,* 376

The First Amendment "protects commercial speech from unwarranted governmental regulation." *Central Hudson*, 447 U.S. at 561. The government is empowered to prohibit commercial speech that is false or misleading; however, in order to be entirely prohibited, the subject communication must be either inherently misleading or actually misleading, as opposed to only potentially misleading. *See Peel v. Attorney Registration and Disciplinary Comm'n of Illinois*, 496 U.S. 91, 109-110 (1990); *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 640 n. 9 (1985); *In re R.M.J.*, 455 U.S. 191, 202-03 (1982). Information that is only potentially misleading may not be completely banned if the information can be presented in a manner that is not deceptive. *See Peel*, 496 U.S. at 100; *In re R.M.J.*, 455 U.S. at 203. Commercial speech that is not misleading also may be regulated; however, interference must be in proportion to the governmental interest served, and may be regulated only to the extent that such regulation furthers a substantial interest. *See In re R.M.J.*, 455 U.S. at 203-04.

The Supreme Court set forth a four-part test for determining permissible regulation of commercial speech in *Central Hudson*:

> At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.

447 U.S. at 566. The test is no less applicable in assessing the constitutionality of restrictions on speech in the context of tobacco marketing, a lawful activity, than in other contexts; there is no "vice" exception to the First Amendment based on the nature of the product being sold. *E.g., 44 Liquormart v. Rhode Island*, 517 U.S. 484, 513-14 (1996); *Rubin v. Coors Brewing Co.,* 514 U.S. 476, 482 n.2 (1995); *Lorillard Tobacco Co. v. Reilly,* 533 U.S. 525, 564 (2001).

While restrictions imposed under the *Central Hudson* test need not be the least severe

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U.S. 254 (1964). Any efforts by tobacco companies to speak out on issues of public importance – such as speech on issues related to the relative health risks of specific tobacco products, not uttered for the purpose of inducing a specific sales transaction – are fully protected by the First Amendment and thus are largely off-limits to government regulation. For purposes of these comments, however, WLF assumes that all the speech that Congress and FDA seek to regulate under 21 U.S.C. § 387k qualifies as "commercial speech."

needed to meet the regulatory objective, the means chosen must be "narrowly tailored." *Board of Trustees of SUNY*, 492 U.S. at 477-478; *In re R.M.J.*, 455 U.S. at 203. In order to be "narrowly tailored," restrictions on commercial speech must be aimed at eliminating false or misleading communication "without at the same time banning or significantly restricting a substantial quantity of speech that does not create the same evils." *Ward v. Rock Against Racism,* 491 U.S. 781, 800 n. 7 (1989). The Supreme Court expressly directed that "the free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful." *Zauderer*, 471 U.S. at 646.

The Supreme Court further has indicated that in choosing between a highly paternalistic regulatory approach and one that fosters open communication, regulators must choose the latter because "[i]t is precisely this kind of choice, between the dangers of suppressing information, and the dangers of misuse if it is freely available, that the First Amendment makes for us." *Virginia State Board of Pharmacy*, 425 U.S. at 770. "The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." *Thompson v. Western States Medical Center,* 535 U.S. 357, 375 (2002) (quoting *44 Liquormart,* 517 U.S. at 503). "The premise of our system is that there is no such thing as too much speech – that the people are not foolish but intelligent, and will separate the wheat from the chaff." *Austin v. Michigan State Chamber of Commerce*, 494 U.S. 652, 695 (1990) (Scalia, J., dissenting). This being the case, requirements for disclosure, disclaimer, or explanation are highly favored over regulations that would entirely prohibit commercial speech. *See Zauderer*, 471 U.S. at 650-51; *In re R.M.J.*, 455 U.S. at 203.

For the *Central Hudson* test to be satisfied, the Court must be persuaded that the cost of the regulation has been "carefully calculated." *City of Cincinnati v. Discovery Network, Inc.,* 507 U.S. 410, 416 n.12 (1993). As with fully protected speech, the burden of justifying its restrictions rests squarely with the government agency seeking to impose the restriction. *Bolger v. Youngs Drug Products Corp.,* 463 U.S. 60, 71 n.20 (1983) ("party seeking to uphold a restriction on commercial speech carries the burden of justifying it"); *Western States,* 535 U.S. at 373.[2]

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[2] The evidentiary burden is not light; for example, the government's burden of showing that a commercial speech regulation advances a substantial government interest "in a direct and material way . . . 'is not satisfied by mere speculation or conjecture; rather, a government body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restrictions will alleviate them to a material degree.'" *Rubin v. Coors Brewing Co.,* 514 U.S. 476, 487 (1995) (quoting *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993)).

B. Section 387k Is in Serious Tension with Constitutional Limitations on Regulation of Commercial Speech

A principal focus of § 387k is the truthfulness of claims by a tobacco manufacturer that use of one of its products poses a lower risk of tobacco-related disease than use of other commercially available tobacco products. WLF strongly supports prevention and elimination of false health-related claims and thus applauds any FDA efforts in that regard.

However, there is language in § 387k suggesting that Congress believes that the burden of proof falls on a tobacco company to demonstrate that health-related claims are truthful. As the case law discussed above makes clear, the burden of proof runs the other way – if a government agency seeks to regulate or ban speech on the ground that it is false or misleading, the First Amendment burden of proof falls on the agency to demonstrate falsity. Moreover, § 387k includes language suggesting that FDA may impose an outright ban on health claims that are merely *potentially* misleading, without regard to whether disclaimers might serve to prevent consumers from being misled.

The courts have repeatedly made clear that FDA enforcement activity is subject to the First Amendment rules regarding allocation of burden of proof in First Amendment cases. For example, the U.S. Court of Appeals for the District of Columbia Circuit held recently that the First Amendment imposes strict limitations on FDA's power to restrict health claims made by manufacturers of dietary supplements, even when the claims are made on the product label. *Pearson v. Shalala,* 164 F.3d 650 (D.C. Cir. 1999) ("*Pearson I*"). In overturning a district court decision that had upheld FDA's outright ban on such claims when use of disclaimers might have responded fully to FDA's concerns, the appeals court stated:

> The government insists that it is never obliged to utilize the disclaimer approach, because the commercial speech doctrine does not embody a preference for disclosure over outright suppression. Our understanding of the doctrine is different. . . . In more recent cases, the [Supreme] Court has . . . repeatedly point[ed] to disclaimers as constitutionally preferable to outright suppression.

Id. at 657. The court added, "[W]hen government chooses a policy of suppression over disclosure – at least where there is no showing that disclosure would not suffice to cure misleadingness – government disregards a 'far less restrictive' means" of achieving its policy interests. *Id.* at 658 (quoting *Bd. of Trustees of SUNY,* 492 U.S. at 479).

On remand, FDA's First Amendment arguments were again rejected. The district court granted a preliminary injunction against FDA's continued violation of First Amendment rights; the court required FDA to approve a health claim (for inclusion on product labeling for folic acid) regarding the positive relationship between consumption of folic acid and prevention of

birth defects. *Pearson v. Shalala,* 130 F. Supp. 2d 105 (D.D.C. 2001) ("*Pearson II*"). The district court was harshly critical of FDA's continued resistance to court orders that it comply with the First Amendment; the court said:

> [I]t is clear that the FDA simply failed to comply with the constitutional guidelines outlined in *Pearson* [*I*]. Indeed, the agency appears to have at best, misunderstood, and at worst, deliberately ignored, highly relevant portions of the Court of Appeals Opinion.

Pearson II, 130 F. Supp. 2d at 112. The court held that under the First Amendment, FDA "must shoulder a very heavy burden if it seeks to totally ban a particular health claim." *Id.* at 118. The court held that FDA had failed to meet that burden; it held that "[t]he mere absence of significant affirmative evidence in support of a particular [health] claim . . . does not translate into negative evidence 'against' it." *Id.* at 115. In other words, the court held, any FDA efforts to regulate manufacturer dissemination of unapproved health claims must take the form of disclaimer requirements rather than outright bans on the claims, unless FDA can demonstrate that the claims are "against" the great weight of the scientific literature.[3] The district court later denied FDA's motion for reconsideration of the preliminary injunction order. Noting that FDA's "arguments contained in the motion for reconsideration further demonstrate Defendants' reluctance to fully comply with *Pearson I,*" the court reiterated its conclusion:

> [T]he philosophy underlying *Pearson I* is perfectly clear: that the First Amendment analysis in *Central Hudson* . . . applies in this case, and that if a health claim is not inherently misleading, the balance tilts in favor of disclaimers rather than suppression. In its motion for reconsideration, the FDA has again refused to accept the reality and finality of that conclusion by the Court of Appeals.

Pearson v. Thompson, 141 F. Supp. 2d 105, 112 (D.D.C. 2001).

The U.S. Supreme Court has been equally dismissive of FDA's defenses to First Amendment claims. That court held that a FDCA provision that restricted pharmacists from advertising the availability of compounded drugs could not survive the final two prongs of the

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[3] Significantly, the district court simply ignored FDA's argument that its efforts to ban the folic acid health claims were not subject to First Amendment review because FDA was not banning speech *directly* but rather was simply using the speech as evidence that the manufacturer intended to market its product as a drug. (And, of course, FDA was asserting that dissemination of the health claims would render the folic acid subject to seizure as an unapproved new drug, because FDA has never approved the marketing of folic acid as a drug.)

Central Hudson test and thus violated the First Amendment. *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002). Noting that the FDCA provision at issue allowed pharmacists to initiate discussions about a compounded drug once a patient presented a prescription for another drug, the district court in that same case found it "difficult to see how the communication of the same information can both serve and undermine the public health, depending on which party initiates the contact or the method used to communicate it." *Western States Medical Center v. Shalala*, 69 F. Supp. 2d 1288, 1299 (D. Nev. 1999).

Nor does the First Amendment permit FDA to regulate or ban commercial speech on the grounds of falsity on the basis of an assertion that FDA has not yet certified the speech as being truthful. The theory that statements lacking FDA approval were inherently misleading was considered and rejected in *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998) ("*WLF I*"), *appeal dism'd,* 202 F.3d 331 (D.C. Cir. 2000). There, FDA argued that manufacturer-funded or manufacturer-disseminated speech about off-label uses is inherently misleading because the FDCA "prescribes a specific system for determining the 'truth' of claims about drugs and devices." *WLF I*, 13 F. Supp.2d at 67. The court concluded that FDA had no power to impose a "specific system for determining truth," holding that:

> In asserting that any and all scientific claims . . . regarding prescription drugs are presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them, FDA exaggerates its overall place in the universe.

Id.

There may be rare occasions on which restrictions on truthful, non-misleading commercial speech are permissible when the transaction being proposed is legal, although the U.S. Supreme Court has never directly endorsed commercial speech restrictions under those circumstances. WLF finds § 387k to be particularly problematic because it appears to endorse *widespread* government suppression of truthful commercial speech. *See, e.g.,* § 387k(g)(1)(B) (prohibiting FDA from permitting health-related claims unless it determines that doing so will "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."). The assumption underlying any determination that truthful speech might not "benefit the health of the population as a whole," of course, is that some consumers will respond to the speech in a manner that the government deems bad for those consumers health (*e.g.,* a consumer who does not use any tobacco products might respond to a truthful less-harmful-to-health claim by deciding to use the advertised product). But as the Supreme Court has made clear, government bans on commercial speech are anathema to the First Amendment when designed not to guard consumers from false or misleading information, but rather as an indirect means of regulating conduct. Such bans are premised on the assumption that the government knows best what is good for consumers and that they are better off if they are denied access to certain information,

even though it is not in any way misleading. The Court has labeled such assumptions "offensive" to First Amendment values:

> Precisely because bans against truthful, nonmisleading commercial speech rarely seek to protect consumers from either deception or overreaching, they usually rest solely on the offensive assumption that the public will respond "irrationally" to the truth. *Linmark,* 431 U.S., at 96. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. That teaching applies equally to state attempts to deprive consumers of accurate information about their chosen products.

44 Liquormart, 517 U.S. at 503 (plurality); *see also id.* at 517 (Scalia, J., concurring in part); *id.* at 526-27 (Thomas, J., concurring in part); *Virginia State Board of Pharmacy,* 425 U.S. at 762 ("the general rule is that the speaker and the audience, not the government, assess the value of the information presented.").

The Supreme Court has categorically rejected all arguments that there can be a government interest in depriving consumers of truthful commercial information, even when the government fears that consumers might somehow misuse the information:

> We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful information in order to prevent members of the public from making bad decisions with the information. In *Virginia Bd. of Pharmacy,* the State feared that if people received price advertising from pharmacists, they would "choose the low-cost, low-quality service and drive the 'professional' pharmacist out of business" and would "destroy the pharmacist-customer relationship" by going from one pharmacist to another. We found these fears insufficient to justify a ban on such advertising. 425 U.S. at 769.

Western States, 535 U.S. at 374-75.

Western States went on to quote *Virginia Bd. of Pharmacy* at length, to emphasize the inappropriateness of ever restricting speech for the purpose of suppressing truthful information:

> There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them. . . . But the choice among these alternative approaches is not ours to make or the Virginia General Assembly's. It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First

> Amendment makes for us. Virginia is free to require whatever professional standards it wishes of its pharmacists; it may subsidize them or protect them from competition in other ways. But it may not do so by keeping the public in ignorance of the entirely lawful terms that competing pharmacists are offering.

Id. at 375 (quoting *Virginia Bd. of Pharmacy*, 425 U.S. at 770).

Central Hudson permits the government to suppress speech that proposes an illegal transaction. It is true, of course, that the sale of tobacco products to youths is illegal in all States, and thus the government has an interest in suppressing advertising designed to encourage youths to purchase and use tobacco products. Indeed, by enacting the FSPTCA, the government ostensibly seeks to reduce youth smoking. But § 387k cannot be deemed a narrowly tailored effort to combat youth smoking; nothing in that provision focuses on lower-risk-of-disease claims that are particularly likely to be seen by youths and to persuade them to use tobacco products. Other means, such as targeted anti-smoking advertising or educational programs, would seem to be much more narrowly tailored to the purpose of discouraging youth smoking. The possibility that commercial speech might be seen by some audiences who may not legally purchase the product being advertised has never been deemed sufficient to sufficient to justify total suppression of the speech. *See Lorillard*, 533 U.S. at 564. As the Court explained:

> The State's interest in preventing underage tobacco use is substantial, and even compelling, but it is no less true that the sale and use of tobacco products by adults is a legal activity. We must consider that tobacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products. In a case involving indecent speech on the Internet we explained that "the government interest in protecting children from harmful materials . . . does not justify an unnecessarily broad suppression of speech to adults." *Reno v. ACLU,* 521 U.S. 844, 875 (1997) (citations omitted). *See, e.g., Bolger v. Youngs Drug Products Corp.,* 463 U.S. 60, 74 (1983) ("The level of discourse reaching a mailbox simply cannot be limited to that which would be suitable for a sandbox"); *Butler v. Michigan*, 352 U.S. 380, 383 (1957) ("The incidence of this enactment is to reduce the adult population . . . to reading only what is fit for children"). As the State protects children from tobacco advertisements, tobacco manufacturers and retailers and their adult consumers still have a protected interest in communication.

Id.

In sum, because § 387k does not provide adequate allowance for truthful speech regarding the relative safety of competing tobacco products, its strict application would raise

serious First Amendment concerns.

C. FDA Has an Opportunity to Mitigate § 387k's Constitutional Infirmities

FDA is empowered to issue guidance regarding how it intends to enforce § 387k and, in particular, how it anticipates handling applications for approval of MRTPs. WLF respectfully submits that FDA should use this opportunity to mitigate § 387k's constitutional infirmities. In order to avoid court decisions striking down the agency's enforcement activities on First Amendment grounds, WLF recommends that FDA substantially amend the guidance document before issuing it in final form.

First, the guidance document should interpret § 387k so as to make clear that the statute does not alter the constitutionally mandated allocation of the evidentiary burden; *i.e.*, the burden of proof regarding speech regulation remains on the government at all times. Just as the Federal Trade Commission (in connection with its enforcement of the Federal Trade Commission Act) requires business to be able to substantiate claims made in advertisements, FDA is constitutionally entitled to require tobacco companies making comparative health claims to substantiate those claims – meaning that they must provide evidence suggesting that the claim is more likely than not to be accurate. If despite such substantiation, FDA personnel are concerned that closer study (*e.g.*, a well-controlled epidemiological study conducted over the course of several years) might reveal that the claims are inaccurate, the guidance document should provide that the burden of proof is on FDA to produce evidence that the claims are inaccurate. In the absence of such evidence, the guidance ought to provide that the speech may not be suppressed on grounds of falsity.

The FSPTCA does not unequivocally mandate that the evidentiary burden be imposed on applicants. It states that the seller of tobacco product may make MRTP claims if:

> The Secretary determines that the applicant has demonstrated that such product, as it is 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). Nothing in that provision requires any particular level of proof from manufacturers. Provided that the manufacturer of a tobacco product can support reduced-health-risk claims (in the manner set forth in § 387k(g)(1)) with substantial evidence (*i.e.*, the evidence demonstrates the truth of the proposed statements by a preponderance of the

evidence), nothing in the statute requires FDA to impose a higher evidentiary burden – and First Amendment case law prohibits FDA from doing so.

The proposed guidance document would impose significantly more exacting evidentiary requirements. *See, e.g.,* Draft Guidance at 16-29. Those requirements cannot be squared with the First Amendment. By imposing such exacting standards on MRTP claims, FDA is essentially claiming the right to ban speech even when the preponderance of the evidence suggests that the speech is truthful and even though FDA does not claim to have any evidence suggesting that the evidence is false. As the U.S. District Court for the District of Columbia held in striking down FDA efforts to suppress speech that it could not demonstrate to be false, "FDA exaggerates its overall place in the universe" when it asserts the right to ban speech which it has no reason to believe is false, simply because FDA has not yet determined that the speech is truthful. *WLF I*, 13 F. Supp.2d at 67.[4]

Second, as noted above, even if commercial speech is not false, the government is entitled to regulate the speech on the ground that the speech is potentially misleading to some consumers. But in such instances, the First Amendment provides that the speech may not be suppressed entirely unless the government can demonstrate that no amount of disclaimers would suffice to eliminate the potentially misleading nature of the speech. Accordingly, the draft guidance ought to specify that comparative safety claims will not be subject to prohibition under § 387k unless FDA first determines that disclaimers would be insufficient to dissipate the misleading aspects of the speech. *See, e.g., Pearson v. Shalala,* 164 F.3d at 657.

For example, the Act requires FDA to take into account the health effects of comparative safety claims may have on those "who do not currently use tobacco products." 21 U.S.C. § 387k(g)(1)(B). Congress apparently was concerned that non-users might be misled by such claims into believing that the MRTP poses no safety risks, and thus would be induced to begin using product when they might otherwise never have used a tobacco product. Accordingly, FDA would be justified in including within its draft guidance a requirement that manufacturers include disclaimer statements, setting out in no uncertain terms that the MRTP poses safety risks and that while the product may pose fewer risks than other tobacco products,

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[4] To repeat what we stated above, FDA cannot plausibly assert that it is simply regulating conduct, not speech. The products at issue are products that are already being distributed and sold in interstate commerce. In adopting its guidance document, FDA is not asserting a right to prevent those distribution and sales; rather, it seeks to restrict the right of manufacturers of those products from making health-related claims regarding their products. Such restrictions can only be deemed speech restrictions – subject to First Amendment restraints. FDA's failure to mention the First Amendment in its draft guidance suggests that FDA does not fully grasp that basic tenet of constitutional law.

the safest course is to use no tobacco product at all. But assuming that the disclaimer is sufficient to dissipate the possibility of confusion, the guidance should make clear that FDA may not ban a comparative health claim altogether simply because a fully informed consumer might voluntarily choose – after hearing the claim – to begin using the product.

Third, it will virtually never be the case that a prohibition of truthful, non-misleading commercial speech regarding the relative safety of a tobacco could pass First Amendment muster. Accordingly, WLF recommends that FDA amend the guidance document to make clear that FDA will not seek to suppress truthful speech based on fears that consumers might misuse the speech. In particular, FDA should interpret § 387k(g)(1)(B) (which limits relative safety claims by tobacco manufacturers to speech that would "benefit the health of the population as a whole") to require no more than that the speech be truthful. In that way, FDA would be adhering to the Supreme Court's admonition that truthful speech may not be banned simply because government regulators "seek to keep people in the dark for what the government perceives to be their own good." *Western States,* 535 U.S. at 375.

IV. Any System of Prior Restraints on Speech, Such as the One Contemplated by Section 387k, Raises Severe First Amendment Problems. FDA Has an Opportunity Through Its Guidance to Minimize Those Constitutional Concerns

A. Prior Restraints on Speech Are Disfavored

In those instances in which the Supreme Court has indicated that regulation of speech is consistent with the First Amendment, the Court has held that the preferred approach is to regulate the speaker by imposing sanctions after the speech has been uttered, rather than imposing any sort of prior restraint. The Court has made clear in no uncertain terms that "[a]ny system of prior restraints of expression comes to this Court bearing a heavy presumption against its constitutional validity" and that the government "carries a heavy burden of showing justification for the imposition of such a restraint." *New York Times Co. v. United States*, 403 U.S. 713, 714 (1971). A system of prior restraint is no less suspect because it simply delays speech rather than attempting to prohibit the speech indefinitely. *Nebraska Press Ass'n v. Stuart*, 427 U.S. 539, 560 (1976). Indeed, that was precisely the claim rejected in *New York Times* – the Court rejected the federal government's argument that it should be permitted to delay publication of the "Pentagon Papers" until after the papers had undergone a national security scrutiny. Nor is the presumption of invalidity lessened simply because the speech at issue is commercial speech. *See, e.g., Lowe v. Securities and Exchange Comm'n*, 472 U.S. 181, 234 (1985) (White, J. concurring in result). Systems that require speech to be delayed to provide regulators an opportunity to review its contents uniformly have been struck down unless the mandated delay is of extremely short duration. *See, e.g., Freedman v. Maryland*, 380 U.S. 51 (1965).

Prior restraints must overcome a heavy presumption against constitutionality and *must* include certain procedural safeguards. *Bantom Books Inc. v. Sullivan*, 372 U.S. 58, 72 (1962); *Southeastern Promotions, Ltd. v. Conrad,* 420 U.S. 546, 548, 562 (1975). First, the government – not the speaker – must bear the burden of proving the speech is impermissible under the law. *Id*. Second, the law must create a specified "brief period" during which the agency must decide whether or not to allow the speech in question. *Freedman,* 380 U.S. at 59. Third, a prior restraint must lay out objective touchstones or standards that are to guide the agency's decision to allow or disallow the speech. *Lakewood v. Plain Dealer Pub. Co.* 486 U.S. 750, 769-71 (1988).

B. Section 387k Includes None of the Safeguards Demanded of a System of Prior Restraints

Section 387k falls short of providing the constitutionally required safeguards. First, it places the burden of proof on the speaker to prove that a less-likely-to-cause-tobacco-disease claim is true, by stating that FDA will grant an application to market an MRTP only if the applicant has "demonstrated" both that the product will "significantly reduce" health risks to consumers and will "benefit the health of the population as a whole." 21 U.S.C. § 387k(g)(1). Second, not only does the statute not require rapid decision-making, it explicitly tolerates delays by granting advisory committees a 60-day period within which to make recommendations to FDA regarding MRTP applications. 21 U.S.C. § 387k(f)(2). It grants FDA a full two years before it must issue regulations establishing a timetable for reviewing MRTP applications, 21 U.S.C. § 387k(*l*)(1), yet the statute's speech prohibitions are are already in effect. 21 U.S.C. § 387k(b)(3). Third, the review standards specified by the statute are inherently vague. For example, by authorizing FDA to reject an MRTP application based on a conclusion that permitting the less-likely-to-cause-tobacco-disease claim would not "benefit the health of the population as a whole," § 387k(g)(1)(B), the statute grants FDA virtually unlimited discretion to deny an MRTP application.

Freedman is illustrative. In that case, the Supreme Court struck down a Maryland law that prohibited theaters from exhibiting films without first obtaining approval from the State Board of Censors, because the law did not require prompt review of approval applications and did not require the Board to initiate judicial review on its own in cases in which it denied approval. *Id*. at 59-60. While holding that "any system of prior restraint of expression comes to this Court bearing a heavy burden against its constitutionality validity," *id*. at 57, the Court recognized that such systems are not *per se* unconstitutional. *Id*. at 53. But the Court said that such systems are never permissible unless they ensure prompt review by the government agency and immediate judicial review from any adverse decision. *Id*. at 59-60. The Court held up as an acceptable model a New York law regarding obscene books that: (1) delayed any restraint until after a local municipality determined that the book was, in fact, obscene and sought judicial enforcement of that determination; (2) required that a trial be held "within one

day after joinder of issue"; and (3) required the judge to issue his/her decision within two days thereafter. *Id.* at 60 (citing *Kingsley Books v. Brown*, 354 U.S. 436 (1957)).

Section 387k includes none of the safeguards outlined in *Freedman*. Instead, safety claims are *automatically* blocked for an *indefinite* period while FDA decides whether to approve the claims. It contains no mechanism that would allow a manufacturer to appeal to FDA officials to allow for immediate dissemination – all without any determination from FDA that the advertisement is in any way false or misleading, or otherwise potentially injurious to public health or safety. Even though the Supreme Court has placed on government agencies the burden of justifying the need for a prior restraint on speech, § 387k neither imposes a requirement on FDA to initiate a federal court proceeding at which it would be required to justify its speech restraint, nor creates a special mechanism by which manufacturers could seek to lift the restraint on an expedited basis. While a manufacturer is, of course, entitled to file suit in federal court alleging that the application of § 387k's prior restraint to its proposed claim is unconstitutional as applied because the claim is truthful and non-misleading, the availability of a federal court lawsuit – which can take months or years to resolve – is not the sort of contemporaneous review mechanism that the First Amendment demands of a valid system of prior restraints.

It is no answer to these constitutional arguments to assert that because it is constitutionally permissible for FDA to pre-approve labeling claims for drugs and medical devices, it should be similarly permissible to institute a pre-approval process for safety-related claims made by manufacturers of tobacco products. Despite the unusual language of § 387k(b)(1) – which seems to suggest that manufacturers might actually contemplate the sale of products designed to be used by a consumer for the purpose of reducing the health risk caused by a separate tobacco product also being used by the consumer – Congress clearly did not have such products in mind. Rather, the Act simply seeks to regulate the speech of manufacturers of existing tobacco products. As such, federal regulation of that speech is not comparable to federal regulation of drugs and medical devices. In the latter instance, FDA has repeatedly disavowed any intent to regulate the speech of drug and device manufacturers. Rather, it has asserted (as, for example, in *Washington Legal Found. v. Friedman*) that it merely uses the product labeling as evidence that the manufacturer intended to market its product as a drug, and that such marketing may violate the FDCA if the manufacturer does not have FDA approval to market the drug for the listed indication. Under those circumstances, FDA can plausibly claim that it is regulating commerce, not speech. No such claim is plausible here. Section 387k does not grant FDA authority to prohibit the sale of existing tobacco products under ordinary circumstances; rather, it authorizes FDA to suppress the speech of the manufacturers of those products. Accordingly, that speech regulation is subject to all the First Amendment limitations normally imposed on government regulation of commercial speech.

C. FDA Should Use Its Guidance Document as an Opportunity to Mitigate the Constitutional Infirmities of § 387k's Prior Restraint System

Because FDA is empowered to issue regulations setting forth how it intends to enforce § 387k, it has an opportunity to mitigate the constitutional infirmities of § 387k's prior restraint system. First, FDA should suspend its prior-restraint system until it has in place an effective review system that meets minimum constitutional standards, as set forth above.

Second, as explained in Section III above, FDA should specify that an MRTP application will be approved if the manufacturer can demonstrate that the claim is well-substantiated – meaning it is more likely than not, based on evidence normally accepted by scientists, that the claim is true. The guidance document should specify that reasonable disclaimers must to be added to the claim if FDA believes that additional studies are warranted – and it may require post-approval studies and surveillance – but FDA may not reject an application on that basis if a reasonable scientist would conclude on the basis of existing evidence that the claim is not false or misleading. Obviously, the guidance should specify that the claim must be withdrawn if the later studies or surveillance undermine its validity.

Third, the guidance document should establish a timetable for completion of FDA review, with a maximum review period of no more than 15 days. If FDA has been unable to determine within the specified period that the claim is false or misleading, then FDA has no constitutional authority to suppress the speech and should stand aside until it can complete its review. As court decisions cited above make clear, FDA has no authority to declare speech to be false based solely on the fact that it has not yet determined the speech to be true. In order to ensure that manufacturers do not take advantage of any backlogs that may develop at FDA, the guidance should specify that any manufacturer that goes ahead with its safety-related claims during the pre-approval period does so at its own risk. That is, if FDA later determines that the claim was not well-substantiated, and that determination is upheld in the courts, then the manufacturer would be subject to all of the penalties set forth in the Act for those who violate its provisions.

Finally, the guidance must provide clear and objective standards to guide FDA's discretion. The statute fails to do so; it merely states that the product must "significantly reduce the risk of tobacco-related disease" among users. FDA guidance not only must provide clear guidelines regarding what constitutes a "significant[]" reduction, but also must be written so as to authorize all truthful claims that provide significant health information to consumers. For example, if users of one product are shown to develop cancer at a significantly lower rate than users of another product, the guidance must permit a truthful statement to that effect – even though the manufacturer has not also developed information comparing the incidence of heart disease among the two groups of users.

V. Section 387k Is Impermissibly Vague Regarding the Types of Speech Covered by the Statute, but FDA Can Ameliorate Those Vagueness Concerns by Specifying Precisely What Types of Speech are Covered

A. Section 387k Fails to Provide Clear Notice Regarding What Speech is Regulated

A statute is impermissibly vague, and thus violates Fifth Amendment due process rights as well as the First Amendment, if it "fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits." *Hill v. Colorado,* 530 U.S. 703, 732 (2000). A statute can also be impermissibly vague "if it authorizes or even encourages arbitrary and discriminatory enforcement." *Id.*

Section 387k fails to provide the constitutionally required clear notice. It seeks to regulate "any action directed to consumers through the media or otherwise . . . 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." § 387k(b)(2)(iii). That provision potentially covers virtually anything an employee of a tobacco manufacturer says with respect to product safety, yet a person of ordinary intelligence would have significant difficulty understanding its intended scope. For example, it could be construed as covering conversations with journalists, or the publication of a scientific study in a peer-reviewed journal regarding the relative safety of tobacco product manufactured by the author's employer.

B. The Guidance Document Should Provide Precise Definitions That Eliminate Vagueness Concerns

FDA can eliminate these void-for-vagueness concerns by providing precise definitions of the speech subject to regulation under § 387k. The most logical means of differentiating between covered speech and speech not subject to regulation would be to draw a line between commercial and non-commercial speech. FDA should make clear that speech uttered in a non-commercial setting – *i.e.,* speech neither directly nor indirectly intended to propose a commercial transaction – is not subject to regulation under § 387k, even if it is possible that the speech might be communicated to a substantial number of consumers. For example, a speech or paper given to a professional society that discusses the lower instance of tobacco-related disease among users of smokeless tobacco than among cigarette smokers would constitute non-commercial speech and thus would not be subject to regulation under § 387k. It would not be subject to regulation even if it could be shown that the speech was reported in newspapers and the newspaper article ultimately was read by a substantial number of consumers. Conversely, any product labeling or advertising constitutes commercial speech and thus would be covered.

Drawing the line so as to exempt non-commercial speech from regulation also has the advantage of reducing First Amendment concerns. To the extent that § 387k(b)(2)(iii) were interpreted as applying even to non-commercial speech, it would be subject to strict scrutiny and its speech restrictions could be upheld only under the most compelling of circumstances. On the other hand, limiting § 387k(b)(2)(iii) so that it applies only to commercial speech will ensure that judicial challenges to FDA's authority will be subject to the less demanding First Amendment standards normally applied to government regulation of commercial speech.

VI. FDA Should Take the Initiative and Determine for Itself Whether Using Smokeless Tobacco Poses a Lower Risk to Health Than Smoking Cigarettes

The draft guidance suggests that FDA is content to wait for others to come to the agency with evidence that some tobacco products pose substantially lower health risks than do other tobacco products. WLF respectfully suggests that FDA is abdicating its responsibilities to public health by adopting that hands-off approach. As FDA is well aware, numerous scientific studies lend substantial support to claims that use of smokeless tobacco, while posing substantial health risks, is far less dangerous than smoking cigarettes. FDA ought to begin immediately with its own comprehensive examination of that health issue. Unless it does so, it will not be equipped to respond in a timely manner to MRTP applications for smokeless tobacco products. Without its own evidence, FDA will have no basis for declining to accept industry studies purporting to demonstrate that it is more likely than not that smokeless tobacco products pose a reduced health risk.[5]

WLF does not claim the scientific expertise to evaluate the numerous studies indicating that smokeless tobacco poses a lesser health risk. The existence of such studies from reputable groups nonetheless strongly suggests that smokeless tobacco poses reduced risks. WLF lists just a few of those studies: (1) K. Stratton, P. Shetty, R. Wallace, S. Bondurant, editors, *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*, National Academies Press (Washington, 2001) (smokeless tobacco does not cause respiratory disease or lung disease, suggesting that there would be at least 60% fewer deaths from smokeless tobacco than from cigarettes, and noting epidemiological analyses suggesting that the health risk from smokeless tobacco is only 2% of the risk from cigarettes); (2) Kjell Asplund, *Smokeless Tobacco and Cardiovascular Disease*, 45 Progress in Cardiovascular Diseases 383 (April

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[5] In response to a question specifically raised by the draft guidance: WLF opposes the IOM's Recommendation 10 that research studies should be undertaken only by FDA-approved, independent third-party researchers. FDA is entitled to look carefully at studies submitted by MRTP applicants to ensure that they are well-controlled. But FDA has no basis for refusing to accept otherwise-adequate studies simply because it disapproves of the identify of the researchers.

2003) (regular users of smokeless tobacco do not have permanent changes of hearty rate or blood pressure when exposed to tobacco); J. Foulds, *Effect of Smokeless Tobacco (Snus) on Smoking and Public Health in Sweden*, Tobacco Control (June 2003) (no association between use of smokeless tobacco and cancer or respiratory disease).

If FDA does not believe that such studies demonstrate that use of smokeless tobacco products poses a significantly lower health risk than use of cigarettes, it should disclose the basis of that belief. If FDA has no reason to doubt the accuracy of those studies, then it has no constitutional basis for seeking to prevent manufacturers from asserting such claims. If FDA's only concern is that allowing manufacturers to make such claims (accompanied with appropriate disclaimers regarding the increased health risks of smokeless tobacco use in comparison to using no tobacco products) may induce some nonusers to begin using smokeless tobacco, then any FDA effort to suppress truthful speech runs afoul of *Western States* – which states in no uncertain terms that the First Amendment does not permit the Government to suppress truthful speech about a product based solely on a fear that consumers will respond to the speech by acting in a manner disfavored by government regulators. In light of that clear constitutional command, § 387(g)(1)'s provision barring reduced-risk claims unless they "benefit the health of the population as a whole" must be interpreted as excluding consideration of health risks voluntarily assumed by fully informed consumers.

CONCLUSION

WLF has significant concerns that 21 U.S.C. § 387k authorizes speech suppression that violates the First and Fifth Amendments. WLF respectfully suggests that FDA ameliorate those constitutional concerns by revising the guidance along the lines outlined in these comments.

Sincerely,

/s/ Richard A. Samp
Richard A. Samp
Chief Counsel