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IN THE FOOD AND DRUG ADMINISTRATION

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Comments on First Amendment Issues )  
(67 Fed. Reg. 34942 (May 16, 2002)) )  
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Docket No. 02N-0209

**Comments on First Amendment Issues Submitted on Behalf of  
The National Center for Tobacco-Free Kids**

SEPTEMBER 13, 2002

02N-0209

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The Food and Drug Administration has requested comments on the issue of whether the First Amendment limits the Agency's authority to regulate the advertising and promotion of products under its jurisdiction. 67 Fed. Reg. 34942 (May 16, 2002) (hereafter, "the Request"). The National Center for Tobacco-Free Kids, Inc. ("Tobacco-Free Kids") submits these comments to address two questions implicated by the Request. The first question is whether the First Amendment limits FDA's authority to review and regulate advertising/promotion as part of the Agency's statutory duty under the Federal Food Drug and Cosmetic Act ("FFDCA")<sup>1</sup> to ensure that new products that qualify as drugs are approved by the Agency prior to marketing and that such products are safe and effective. The answer to this question is no. The second question is, if FDA is granted authority over traditional tobacco products as proposed by legislation currently pending in Congress, whether the First Amendment limits FDA's ability to regulate advertising for traditional tobacco products (cigarettes, cigars, and smokeless tobacco) in the manner contemplated in that legislation. The answer to this question, too, is no.

The first question is of immediate significance because of the emergence in the marketplace of so-called "reduced risk" tobacco products. As a general matter, such products are claimed to provide users of traditional tobacco products with a source of nicotine and/or tobacco that (1) reduces the risk to those individuals of contracting diseases that are normally associated with the use of the traditional products and (2) with respect to smokers in particular, satisfies their cravings for nicotine when they cannot smoke. In December 2001, Tobacco-Free Kids and 16 other organizations filed joint citizens petitions with FDA requesting that the Agency regulate as unapproved new drugs five such products -- Ariva tobacco lozenges, OMNI and Advance "low carcinogen" cigarettes, Nicotine Water, and Eclipse, all of which have been marketed to

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<sup>1</sup> 21 U.S.C. § 301 *et seq.*

consumers of traditional tobacco products in general as safer, healthier alternatives to these products, and to smokers in particular as a substitute for cigarettes when they cannot light up.<sup>2</sup> Tobacco-Free Kids has asserted in its Petitions that because of these claims (and for other reasons, including the unique nature of some of these products), Ariva, OMNI, Advance, Nicotine Water and Eclipse all meet the FFDCAs definition of “drugs” and are subject to FDA preapproval for safety and effectiveness.<sup>3</sup> These comments explain why the First Amendment does not stand in the way of the kind of FDA review called for in the Tobacco-Free Kids Petitions.

The second question is relevant because, as noted, Congress is currently considering legislation, including S. 2626 and H.R. 1097, that would confer upon FDA jurisdiction over traditional tobacco products and authorize FDA to regulate advertising for those products . These pending bills would legislatively overcome the Supreme Court’s decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (1998), in which the Court held that Congress had not granted FDA such jurisdiction. If S. 2626 or H.R. 1097 were to become law and therefore were to provide FDA with authority to regulate traditional tobacco products, the next question would be whether the FDA advertising restrictions for such products that are contemplated in these bills are constitutional. By these comments, Tobacco-Free Kids seeks to

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<sup>2</sup> FDA Docket Nos. 01P-0570, 01P-0571, 01P-0572, 01P-0573 (hereafter referred to as “the Tobacco-Free Kids Petitions”). Detailed descriptions of these products and of the health claims made on their behalf appear in the Tobacco-Free Kids Petitions. The Petitions for Ariva and Nicotine Water argued in the alternative that those products were foods containing unapproved food additives and were therefore subject to regulation under the FFDCAs. 21 U.S.C. § 348.

<sup>3</sup> FDA has already granted the Petition relating to Nicotine Water, agreeing that the product is an unapproved drug and subject to safety and effectiveness review under the FFDCAs. See July 1, 2002 Letter to William B. Schultz *et al.* from Dennis E. Baker, Associate Commissioner for Regulatory Affairs, FDA. The other three Petitions are pending with the Agency.

emphasize that the First Amendment would not preclude the kinds of advertising restrictions contemplated under S. 2626 or H.R. 1097.

I. FDA'S REVIEW AND REGULATION OF PROMOTIONAL CLAIMS AS PART OF ITS DETERMINATION AS TO WHETHER A PRODUCT IS AN UNAPPROVED DRUG, OR AS TO WHETHER THE PRODUCT IS SAFE AND EFFECTIVE, DOES NOT VIOLATE THE FIRST AMENDMENT.

Under the FDCA, a new drug may not be marketed unless the FDA has approved it as safe and effective for each of its intended uses. 21 U.S.C. § 355(d). A product is defined as a drug under the FDCA if it is intended to be used as a drug – e.g., to mitigate, treat, or prevent a disease, or to affect the structure or function of the human body. 21 U.S.C. § 321(g)(1)(B), (C). In order to determine a product's intended uses and the related question of whether a product that meets the definition of drug is safe and effective for such uses, FDA may consider, among other things, the circumstances surrounding distribution of the product, including “advertising matter.” 21 C.F.R. §201.128; *see also Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980) (intent may be determined from a product's “label, accompanying labeling, promotional claims, advertising, and any other relevant source.”). Thus, FDA's review and regulation of claims made on behalf of a particular new drug product are critical to the Agency's ability to determine whether (1) the product qualifies as a drug and (2) if so, whether it meets the statutory requirements of safety and effectiveness. As such, this regulation and review is an indispensable part of the FDCA's new drug approval regime in general.

FDA's review and regulation of claims made on behalf of products that have not been approved as drugs are consistent with the First Amendment and neither the Agency's past interpretations of the First Amendment nor judicial commercial speech decisions suggest otherwise. Indeed, as discussed below, both FDA and the courts have recognized that to read the

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First Amendment as prohibiting the FDA from taking into account advertising claims as part of its evaluation as to whether a product qualifies as a drug or as to whether that product is safe and effective would be to eviscerate the FFDCAs entire system of drug regulation and to fundamentally endanger the public health. The commercial speech doctrine does not require this result.

As a threshold matter, it is important to note that the FDA's Request does not raise issues regarding or request comment on whether *the FFDCAs*, which defines and sets forth FDA's authority to regulate drug claims, is consistent with the First Amendment. The Request, in fact, expressly states that FDA "intends to defend [the FFDCAs] against any constitutional challenges" (67 Fed. Reg. at 34943) and emphasizes that the Agency's review is confined to whether its "*regulations, guidances, policies, and practices* comply with the First Amendment." *Id.* (emphasis added). Whether FDA may, consistent with the First Amendment, regulate commercial speech as part of its determinations as to whether a product is an unapproved drug or as to whether such a product is safe and effective is a question that implicates the statute, not the Agency's regulations, guidances, policies, or practices. And if the Agency, as it suggests, does not intend by its Request to invite comment on the constitutionality of the FFDCAs, that question is not currently before it.

Even if the Agency does intend to review its ability under the FFDCAs to regulate commercial speech as part of its determination as to whether a product is an unapproved drug, or as to whether that product is safe and effective, the FDA's authority in this area is consistent with the First Amendment, for several reasons.

1. *There is no restriction on commercial speech, and therefore no First Amendment violation where, as here, the government merely uses commercial speech as evidence of a*

*manufacturer's intent*. Under the FDCA, FDA reviews manufacturers' claims on behalf of their products in order to determine whether the products are intended to be used as drugs. And it is this *intent*, not the claims *per se*, that determines whether a manufacturer must submit a product to FDA for safety and effectiveness review under the FDCA. The First Amendment "does not prohibit the evidentiary use of speech . . . to prove motive or intent." *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993). *See also Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 495-96 (1982) (upholding against First Amendment challenge village ordinance treating the proximity of drug-oriented literature as evidence that items were being marketed for use with illegal drugs). Lower courts have applied this rule in the very context at issue here – *i.e.*, to uphold FDA's reliance on commercial speech as a basis for determining whether a product meets the statutory definition of a "drug." *E.g., United States v. Article of Drug Designated B-Complex Cholinol Capsules*, 362 F.2d 923, 925-927 (3d Cir. 1966) (manufacturer's intended use of drug determined on the basis of claims made in radio broadcast and in manufacturer's promotional material).

FDA's stance on this issue is consistent with these court decisions. Less than three years ago, the Agency issued a proposed rule that limited the claims that could be made on behalf of dietary supplements (65 Fed. Reg. 1000 (January 6, 2000)) and at that time addressed whether its regulation was consistent with the First Amendment. The Agency found that where "it is the intent and not the speech that triggers a regulatory burden on the speaker, there is no First Amendment violation." 65 Fed. Reg. at 1038. The Agency thus concluded that where commercial speech demonstrated an intent on the part of the manufacturer that the supplement be used as a drug, this speech could trigger FDCA preapproval requirements without causing a First Amendment problem. *Id.*

FDA's First Amendment analysis in the dietary supplement context applies foursquare to the Agency's reliance on drug claims as a basis for regulating reduced-risk tobacco products and any other products that are intended to be used as drugs. The claims made on behalf of these products evince an intent on the part of the manufacturer that the products be marketed and sold as drugs. It is this intent – and the claims themselves – that triggers FDA regulation of these products, and such regulation is fully consistent with the constitution.

2. *Even if FDA's regulation of claims for products not approved as drugs were found to restrict commercial speech, the restricted speech is not protected by the First Amendment.*

A. Speech Relating to an Illegal Activity. The marketing or sale in interstate commerce of an unapproved product that is properly classified as a drug under the FFDCRA is illegal. 21 U.S.C. §§ 331(a), 331(d), and 355. The government may prohibit commercial speech that promotes illegal activity without running afoul of the First Amendment. *Central Hudson Gas & Elec. Corp., v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 563-564 (1980). *See also Thompson v. Western States Medical Center*, \_\_\_ U.S. \_\_\_, \_\_\_, 122 S.Ct. 1497, 1504 (2002) (commercial speech that “concerns unlawful activity” is not protected under the First Amendment); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 497 n.7 (1996) (“[T]he First Amendment does not protect commercial speech about unlawful activities.”); *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 623-624 (1995) (“[T]he government may freely regulate commercial speech that concerns unlawful activity.”); *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 69 (1983) (“The State may also prohibit commercial speech related to illegal behavior”). To the extent, therefore, that a manufacturer engages in commercial speech to promote an unapproved product as a drug, it is engaging in such speech to promote an illegal activity and is not entitled to First Amendment protection.

The fact that the commercial speech at issue in the unapproved drug context not only promotes illegal activity but also furnishes the principal evidence of unlawful intent and therefore can be said to have a more direct relationship to the underlying illegal conduct does not change the analysis. The Supreme Court's decision in *Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations*, 413 U.S. 376 (1973), is particularly instructive on this point. There, the Court addressed a municipal ordinance that prohibited (1) employers from engaging in gender discrimination and from publishing, or causing to be published, a hiring advertisement that indicated gender discrimination, and (2) newspapers from publishing such discriminatory advertising. The Court held that advertisements placed in sex-designated columns (*e.g.*, "Jobs – Male Interest") furnished evidence of the employer's discriminatory intent and that the advertising disallowed by the ordinance related to the illegal activity of discriminatory hiring. In the end, the Court held that these limitations on advertising were "incidental to a valid limitation on economic activity" – *i.e.*, the ban on discriminatory hiring – and upheld the Pittsburgh ordinance. *Id.* at 389.

The FDA has already employed this very same analysis in the context of drug claims – specifically, drug claims made on behalf of dietary supplements. The Agency concluded that such claims, where made on behalf of unapproved products, promoted an unlawful activity and therefore were not entitled to First Amendment protection. *See*. 65 Fed. Reg. at 1038. As part of this analysis, FDA cited, among other decisions, *Pittsburgh Press* and noted that restrictions on drug claims made on behalf of unapproved products, like the restrictions on advertising at issue in that case, were restrictions on commercial speech that were merely "incidental to a valid limitation on economic activity" and therefore in no way inconsistent with the Constitution. *Id.*

(citing *Pittsburgh Press*, 413 U.S. at 389).<sup>4</sup> FDA’s analysis in the dietary supplement context is applicable in the context of unapproved new drugs, including reduced-risk tobacco products.

B. FDA Premarket Review of Potentially Misleading Speech. Just as the First Amendment does not protect speech relating to illegal activity, it also does not protect speech that is deceptive or misleading. *Central Hudson*, 447 U.S. at 566 (“For commercial speech to come within [First Amendment protections], it at least must concern lawful activity *and not be misleading.*”) (emphasis added). See also *Western States*, 122 S.Ct. at 1504; *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 553 (2001). It is, of course, one of the purposes of FDA safety and effectiveness review to determine whether drug claims are in fact not misleading – *i.e.*, whether a drug that claims to treat, mitigate, or prevent a disease or to affect the structure and function of the body in fact does these things, and does them in a way that does not pose additional, unstated harms to consumers.<sup>5</sup> Thus, FDA premarket review of unapproved products is in fact an integral part of the process of determining whether claims related to those drugs are in fact entitled to *any* First Amendment protection *at all*. The Supreme Court has held

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<sup>4</sup> Indeed, the *Pittsburgh Press* Court found the restrictions on commercial speech at issue in that case to be merely “incidental” to restrictions on underlying unlawful activity even though the Pittsburgh ordinance *directly banned the commercial speech in addition to the underlying illegal conduct*. As FDA has itself noted (65 Fed. Reg. at 1038), drug claims are not *per se* illegal, but merely furnish evidence of unlawful intent, which is permissible under the First Amendment. See *Wisconsin v. Mitchell*, *supra*; *Hoffman Estates*, *supra*. Thus, limits on drug claims are even more “incidental” to restrictions on underlying unlawful activity than the limits imposed on advertising in *Pittsburgh Press*.

<sup>5</sup> With respect to at least some of the reduced-risk tobacco products that are the subject of the December 2001 Tobacco-Free Kids Petitions, there is evidence that in fact those products do not effectively mitigate smoking-related diseases and are *not* safe. For example, there is evidence that Eclipse contains a higher percentage of cancer-causing agents than certain ultralight cigarettes currently on the market and that it may actually pose *new* health problems for consumers relating to inhalation of the fiberglass particles that are part of the product’s unique nicotine delivery system. See Eclipse Petition, p. 21 and n.33.

that nothing in the First Amendment prevents the government from ensuring “that the stream of commercial information flow[s] cleanly as well as freely.” *Edenfield v. Fane*, 507 U.S. 761, 768 (1993) (quoting *Va. Pharmacy Bd. v. Va. Consumer Council*, 425 U.S. 748, 771-772 (1976)). FDA’s review of drug claims to determine their accuracy and completeness seeks to achieve this very objective and for this additional reason does not violate the First Amendment.

The Supreme Court’s recent decision in *Thompson v. Western States Medical Center*, *supra*, does not change the above analysis, either as to illegal speech or deceptive/misleading speech. *Western States*, to which FDA points in its Request in order to explain the need for its First Amendment review, concerned whether FDA could impose advertising restrictions on pharmacists who engaged in the process of drug compounding as a condition of not subjecting the compounded drugs to the FDCA’s new drug approval process. FDA did not argue in *Western States*, as it can argue in the context of claims relating to drugs that *are* subject to FDCA premarket review, that the speech it was seeking to restrict either concerned unlawful activity or was potentially misleading. And, indeed, the Supreme Court in that case presumed that the information about compounded drugs that the public was denied as a result of the advertising restrictions would be truthful and non-misleading. *See* 122 S.Ct. at 1507 (FDA’s concern about advertising of compounded drugs “amounts to a fear that people would make bad decisions if given truthful information about [these] drugs.”) The Court in *Western States* at no point held, or even suggested, that the FDCA’s new drug approval process itself was constitutionally problematic. It held only that restrictions on advertising in conjunction with *the exemption* of certain products from FDCA approval requirements were not constitutionally permissible. There is no First Amendment problem associated with the regulation of products that remain under FDA jurisdiction, including reduced-risk tobacco products.

3. *Even if claims relating to unapproved drugs were protected under the First Amendment, the burdens placed on that speech by FDA do not violate the Constitution.*

If claims for unapproved products which qualify as drugs are deemed to be First Amendment-protected speech, the test to determine whether restrictions on such commercial speech are unconstitutional is set forth in *Central Hudson Gas & Elec. Corp., v. Public Serv. Comm'n of N.Y.*, *supra*. Under the *Central Hudson* test, a restriction on commercial speech is valid if (1) the speech is truthful, neither actually or inherently misleading, and concerns lawful activity; (2) the government interest in regulating the speech is substantial; (3) the regulation directly advances the government interest; and (4) the regulation is narrowly tailored to serve that interest. 447 U.S. at 556. As discussed above, Tobacco Free Kids' view, which FDA appears to share, is that the *Central Hudson* test is inapplicable here because, first, the "speech" at issue here serves only as evidence of intent, and second, the speech concerns unlawful activity and is at least potentially misleading, and therefore does not satisfy the first *Central Hudson* prong. But if the first *Central Hudson* prong is met and the test in its entirety applies here, it is clear that regulation of claims related to unapproved drugs is constitutional under that test.

As to the second and third *Central Hudson* prongs, there can be no question that regulation of claims relating to unapproved products which qualify as drugs "directly advances the substantial government interest in protecting and promoting the public health by helping to ensure that products intended to have an effect on a disease are safe and effective for that intended use." 65 Fed. Reg. at 1039 (upholding regulation of drug claims for dietary supplements under *Central Hudson* test). The government has a vital interest in "promoting the health, safety, and welfare of its citizens." *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485 (1995). And the notion that this interest is advanced by requiring manufacturers to prove the safety and

effectiveness of their drug products before marketing and making health claims about them lies at the very heart of the drug regulation regime established by Congress in the FFDCA. As FDA itself has observed, regulation of claims associated with unapproved products which qualify as drugs is critical to this regime, “both in preventing direct harm from such products – i.e., protecting the public from adverse events that such products might cause – and in preventing the indirect harm to health that is caused when an ill person foregoes medical care in favor of ineffective self-treatment.” 65 Fed. Reg. at 1039.

Regulation of claims for unapproved products which qualify as drugs also furthers another substantial government interest – the interest in protecting consumers from fraud: “If products are marketed for disease uses only after they have been demonstrated to be safe and effective for such uses, consumers will not suffer economic harm from spending money on worthless remedies.” *Id.* See *Edenfield v. Fane*, 507 U.S. at 769 (“[T]here is no question that [the government’s] interest in ensuring the accuracy of commercial information in the marketplace is substantial”). See also *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999) (noting that “the government’s interest in preventing consumer fraud/confusion may well take on added importance in the context of a product . . . that can affect the public’s health.”) In order to regulate reduced-risk products like Ariva, OMNI, Advance, Nicotine Water, and Eclipse, for example, FDA does not have to demonstrate that these products are “worthless remedies” for tobacco/nicotine addiction. Regardless of what the value of these products *might* be, the government’s substantial interest in preserving the public health is advanced by ensuring that drug claims made for these products (and others) are objectively and rigorously evaluated by FDA, the nation’s principal public health agency, before the public is subjected to those claims.

The fourth *Central Hudson* prong is also met here because FDA’s approach to the regulation of claims associated with unapproved drugs is narrowly tailored to advance the substantial government interests at issue. Requiring products for which drug claims are made to undergo safety and effectiveness review before those products are allowed to go to market, or before drug claims can be made for them, is a reasonable accommodation between commercial speech rights and the government’s goals of preserving the public health and preventing consumer fraud. In fact, as the FDA itself recognized in the context of its regulation of drug claims for dietary supplements, the current regime satisfies not only the “narrow tailoring” test but also the more rigorous “least restrictive means” test<sup>6</sup> because the current approach is no more extensive than necessary to serve the government’s interests – that is, there is no less restrictive approach that would advance these interests. 65 Fed. Reg. at 1040.

It has been suggested that in certain contexts, the First Amendment might require FDA to use disclaimers (*e.g.*, “this product has not been approved by the FDA”) in conjunction with drug claims for unapproved products, instead of prohibiting outright such claims absent agency review. There is, however, no room in the FFDCA for the use of disclaimers as part of FDA’s premarket drug review; when it enacted the FFDCA, Congress adopted a regime that relies on premarket review of products for which drug claims are made and this regime simply does not provide for the alternative use of disclaimers. Thus, if FDA were to examine whether disclaimers are required by the First Amendment as an alternative to premarket review, it would of necessity be passing on the constitutionality of the FFDCA. As noted above, the issue of disclaimers in the drug regulation context is not before the Agency.

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<sup>6</sup> The “least restrictive means” test requires a “perfect fit” between the government’s means and its ends; the “narrow tailoring” test requires a fit that is “not necessarily perfect, but reasonable.” *Board of Trustees of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989).

In any event, the First Amendment does not require the use of disclaimers in the context of unapproved drugs. Even in the dietary supplement context, the lone court that has viewed disclaimers as an appropriate means of regulating speech has held that this analysis *does not* apply to drugs. *See Pearson v. Shalala*, 164 F.3d at 656 n.6 (holding that “[d]rugs . . . appear to be in an entirely different category [from dietary supplements] – the potential harm presumably is much greater”).<sup>7</sup> This same court also held that disclaimers may not suffice to cure claims that are not supported by the weight of the evidence. *Id.* at 659 (“Nor do we rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban [the claim] outright.”). *See also id.* at 659 n.10 (noting that there is “no problem with the FDA imposing an outright ban on a claim where evidence in support of the claim is qualitatively weaker than evidence against the claim – for example, where the claim rests on only one or two old studies”). Even if disclaimers were found to be a constitutionally necessary way of regulating drug claims, the claims would still have to be evaluated by the Agency, as it does now, in order to determine the evidentiary support for the claim and whether the claim was so insupportable that it could not be “cured” by a disclaimer. FDA itself has recognized that to allow manufacturers to circumvent FDA safety/effectiveness review simply by adding disclaimers to their labels would completely destroy the regulatory structure enacted by Congress in the FFDCA:

If companies could avoid the time and expense of complying with the new drug provisions of the [FFDCA] merely by attaching a disclaimers to a disease treatment or prevention claim, *the longstanding system of drug regulation in this country would be eviscerated, with serious public health consequences.*

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<sup>7</sup> Tobacco Free Kids questions the correctness of *Pearson* and the specific First Amendment analysis undertaken by the court in that case, but assumes that *Pearson* is the law for the purpose of these Comments.

65 Fed. Reg. at 1040 (emphasis added).

Finally, even if FDA were at some juncture to decide to evaluate whether disclaimers are an alternative to the current regime in some circumstances, there should be an affirmative burden to show that any disclaimers would be sufficient to protect the public health and to avoid consumer confusion regarding the safety of unapproved products. As discussed above, the use of disclaimers in the drug context would be a dramatic departure from past history and practice. And the effect of disclaimers on drug labels is a largely uncharted subject.<sup>8</sup> Before the Agency undertakes to authorize disclaimers as an alternative to safety and effectiveness review, it would have to conduct thorough consumer comprehension studies, the results of which enable it to reach the conclusion that consumers understand and will take into account such disclaimers. Further, as the court in *Pearson* suggested, it should fall to the Agency to evaluate each claim for which a disclaimer is proposed, in order to determine whether the claim is so insupportable that it could not be cured by the proposed disclaimer.

A final argument sometimes made against FDA's regulation of drug claims is that such regulation imposes an unconstitutional prior restraint on that speech. Even assuming that such drug claims are in fact protected speech, this argument is misplaced. First, as FDA has recognized, numerous courts, including the United States Supreme Court, have suggested that the prior restraint doctrine does not apply to commercial speech. *See Central Hudson*, 447 U.S. at 571 n.13 (“[C]ommercial speech is such a sturdy brand of expression that traditional prior

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<sup>8</sup> To the extent that the issue has been studied, there is evidence to suggest that disclaimers are, in fact, ineffective in eliminating misleading impressions or in remedying consumer confusion. On this point, we refer the Agency to the Comments of the Association for the Advancement of Retired Persons (“AARP”), which contain a detailed discussion of the scientific literature regarding the effectiveness of disclaimers.

restraint doctrine may not apply to it.”). And the courts that have applied prior restraint analysis to FDA’s regulation of drug claims have found that the restrictions on such claims passed constitutional muster. *See Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 227-228 (2d Cir. 1998) (upholding drug claims authorization process for dietary supplements where process was narrowly tailored and contained built-in procedural safeguards, such as a decisionmaking standard to limit agency discretion), *cert. denied*, 525 U.S. 1040 (1998). Indeed, *some* prior restraint in the context of drug claims is essential if FDA is to fulfill its statutory obligation to protect the public health and to ensure that, as to drug claims, “the stream of commercial speech flow[s] cleanly as well as freely.” *Edenfield*, 507 U.S. at 768 (citation, internal quotation omitted).

No court has ever held that the FFDCA’s new drug approval process violates the First Amendment. Nor does FDA appear to be inviting such a challenge in its recent request for comments. Indeed, the Agency has in other contexts recognized that this process (1) is an integral component Congress’ scheme for the regulation of drugs and for the protection of the public health and (2) does not violate the First Amendment. It is critical that FDA not lose sight of these fundamental facts as it review the comments it receives in response to its Request. Ariva, OMNI, Advance, Nicotine Water, and Eclipse will not be the last products that are touted for their treatment or mitigation of disease without any scientific basis or independent verification for these claims. And if it is to protect the public health, FDA must continue to ensure that such claims are accurate and contain all material information, and that the products on whose behalf the claims are made are safe and effective, before the products reach the market. Anything less would be unnecessary as a matter of constitutional law and would seriously jeopardize the public health.

## II. THE FIRST AMENDMENT DOES NOT PREVENT FDA FROM REGULATING THE ADVERTISING OF TRADITIONAL TOBACCO PRODUCTS.

In *FDA v. Brown & Williamson Tobacco Corp.*, *supra*, the Supreme Court struck down FDA's efforts to regulate traditional tobacco products as those products are customarily marketed, on the grounds that Congress had not conferred such regulatory authority on the Agency. The impact of the Court's decision was to invalidate the FDA regulations placing limitations on the advertising of traditional tobacco products – limitations that were principally aimed at preventing underage use of such products and the adverse health consequences flowing from such use. 61 Fed. Reg. 44615, 44617 (August 28, 1996) (hereinafter "Final Tobacco Rule"). Because the Supreme Court's decision was based on the lack of congressional authorization for FDA's regulation in this area, the Court did not address whether the proposed advertising restrictions on traditional tobacco products violated the First Amendment, nor did the district court or circuit court of appeals in that case.

The First Amendment question, however, may soon become ripe because Congress is currently considering bipartisan legislation that would expressly confer on FDA statutory authority to regulate traditional tobacco products under the FFDCFA. *See* S. 2626, H.R. 1097 (107<sup>th</sup> Cong. 2d Sess.) As part of the regulatory scheme set forth in S. 2626 and H.R. 1097, the bills also expressly approve the advertising limitations set forth in the Final Tobacco Rule (*e.g.*, S.2626 at § 2, Findings (30)-(32)) and provide that that Rule – including the advertising limitations -- shall become law. *Id.* at § 102; H.R. 1097 at § 6. Thus, it is possible that in the near future, FDA will face a First Amendment challenge to its ability to regulate advertising for traditional tobacco products in the manner contemplated in the Final Tobacco Rule.

It is Tobacco Free Kids' position that the authority to regulate tobacco marketing as well as the specific limitations on the advertising of traditional tobacco products that are contained in the Final Tobacco Rule and that are endorsed in S. 2626 and H.R. 1097 are consistent with the First Amendment. In this respect, Tobacco-Free Kids endorses the exhaustive First Amendment analysis contained in the Preamble to FDA's Final Tobacco Rule. *See* 61 Fed. Reg. 44465-44538 (August 28, 1996). As part of that analysis, the Agency determined that:

- (1) The advertising restrictions arguably did not burden protected speech at all because the restrictions were designed to address speech promoting illegal conduct – that is, the sale of traditional tobacco products to persons under 18.<sup>2</sup>
- (2) Even if the speech burdened by the advertising restrictions were entitled to First Amendment protection, the advertising restrictions set forth in the Final Tobacco Rule did not impermissibly burden such speech under the *Central Hudson* test because:
  - The government interest in preventing underage use of traditional tobacco products and in avoiding the adverse health consequences of such use is substantial and compelling;<sup>10</sup>
  - The advertising restrictions directly advanced the substantial government interest, given the direct link between advertising for traditional tobacco products and underage use of those products;<sup>11</sup> and
  - The advertising restrictions were narrowly tailored so as to not burden any more speech than necessary to advance the government's interest – *i.e.*, the restrictions

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<sup>2</sup> 61 Fed. Reg. 44470-44472. *See* pp. 6-7, above, for a discussion of the caselaw relating to First Amendment protections for commercial speech that relates to unlawful activity.

<sup>10</sup> 61 Fed. Reg. 44472-44474. *See also* S. 2626 § 102 (31) (noting the government's "substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use.")

<sup>11</sup> 61 Fed. Reg. 44474-44495. *See also* S. 2626 § 102 (31) (noting that advertising restrictions contained in Final Tobacco Rule "directly and materially advance" the substantial government interests at stake).

did not *ban* the advertising of traditional tobacco products, but rather simply placed reasonable time, place and manner restrictions on such advertising.<sup>12</sup>

The Supreme Court's decision in *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) is not to the contrary. There, the Supreme Court held that certain of the advertising restrictions imposed on manufacturers of traditional tobacco products by the State of Massachusetts violated the First Amendment. The Court explained that, while the goal of the State in preventing underage tobacco use (the same goal advanced by the advertising limitations in the Final Tobacco Rule) was undoubtedly compelling and the State's restrictions undoubtedly advanced this goal, the restrictions were not narrowly tailored. 533 U.S. at 553-570. The Court also emphasized, however, that the question of narrow tailoring must be resolved on a case-by-case basis. *Id.* at 563 ("The degree to which speech is suppressed – or alternative avenues for speech remain available – under a particular regulatory scheme tends to be case specific.") Indeed, as an example of the case-specific nature of the narrow tailoring inquiry, the Court specifically distinguished the regulatory regime suggested by the FDA's Final Tobacco Rule from the regime adopted in Massachusetts, suggesting that the former, like the latter, would have to be judged on its own merits. *Id.* Thus, existing Supreme Court law provides no basis for the FDA to declare that a federal statute authorizing regulation of tobacco advertising violates the First Amendment.

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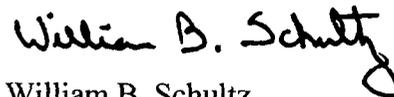
The central mission of FDA is to "protect unwary customers in vital matters of

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<sup>12</sup> 61 Fed. Reg. 44496-44500. *See also* S. 2626 § 102(32) ("the regulations . . . impose no more extensive restrictions on communication by tobacco manufacturers and sellers as are necessary to reduce the number of children and adolescents who use cigarettes and smokeless tobacco and to prevent the life-threatening health consequences associated with tobacco use. Such regulations are narrowly tailored to restrict those advertising and promotional practices which are most likely to entice them into tobacco use, while affording tobacco manufacturers and sellers ample opportunity to convey information about their products to adult consumers.")

health . . . .” *United States v. 216 Cartoned Bottles, More or Less, of . . . Sudden Change*, 409 F.2d 734, 741 (2d Cir. 1969). The First Amendment gives the Agency a wide berth to accomplish this mission, permitting the regulation of commercial speech on several different grounds. This is no less true in the context of tobacco and nicotine products – both traditional versions of such products like cigarettes and smokeless tobacco, should Congress confer jurisdiction over those products on FDA, and newer, so-called “reduced risk” products, over which the Tobacco-Free Kids has argued the Agency currently has jurisdiction. Indeed, given the broad risks posed to the public health by the use of tobacco and nicotine, both in the underage and adult populations, FDA bears a heightened responsibility to protect the public health in this context. The First Amendment does not stand in the way of the Agency’s ability to do so.

Respectfully submitted,



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