BEFORE THE U.S. FOOD AND DRUG ADMINISTRATION

Petitions of the National Center for Tobacco Free Kids, et. al., and the Society for Research on Nicotine and Tobacco	)	Dkt. Nos. 01P-0571 and 02-0206

COMMENTS OF LORILLARD TOBACCO COMPANY

Pursuant to 21 C.F.R. § 10.30(d), Lorillard Tobacco Company ("Lorillard") submits the following comments on Citizen Petitions filed by the National Center for Tobacco-Free Kids, et al., dated December 18, 2001 (Docket No. 01P-0571) and by the Society for Research on Nicotine and Tobacco, dated April 23, 2002 (Docket No. 02-0206) relating to modified cigarette products. Although Lorillard does not market the cigarettes that are addressed in those Petitions, or any similar products, it may in the future decide to market its own modified cigarettes. It therefore has a strong interest in how cigarettes designed to reduce levels of, or smoker exposure to, toxic substances are regulated.

For the reasons that follow, the Petitions asking that FDA assert jurisdiction over modified cigarettes should, and must, be denied. Modified cigarettes include those with express or implied claims that the product exposes smokers to lower levels of toxic components (e.g., tar or specific smoke constituents), or poses less risk of one or more specific smoking-related diseases, than a conventional cigarette. These are not drug or device claims, and accordingly the products fall outside of FDA's jurisdiction.

01P-0571

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I. NATURE OF THE PETITIONS

These comments address the Petitions relating to "Advance" cigarettes, manufactured by Brown & Williamson Tobacco Corporation, "Eclipse" cigarettes, manufactured by R. J. Reynolds Tobacco Company, and "Omni" cigarettes, manufactured by Vector Tobacco Ltd. The Petitions request that the U. S. Food and Drug Administration ("FDA") regulate those cigarettes as "drugs" and/or "medical devices" under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (2000) (the "FDCA").

Advance, Eclipse, and Omni contain tobacco but are designed to yield lower levels of known, probable, or possible toxic substances in cigarette smoke. The Petitions base their requests that FDA regulate these cigarettes on the premise that they, expressly or implicitly, make claims that bring them within the FDCA's definition of "drug" and/or medical "device."

The Petitions, however, neglect three crucial facts. First, the Supreme Court has ruled that FDA has no authority to regulate cigarettes. See FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000). Second, even if, as the Petitions argue, the Court left open the possibility that FDA could regulate cigarettes that are portrayed as drugs, implied or express claims of "reduced risk" of smoking-related health effects are not "drug claims" as that concept has been applied by the FDA or recognized by the courts. Finally, as the Supreme Court stressed, Congress has established an entirely separate framework for regulation of cigarettes which includes labeling and advertising restrictions under the Federal Cigarette Labeling and Advertising Act, 15 U.S.C.S. § 1331, et seq., (the "FCLAA"), and false advertising regulation by the Federal Trade Commission ("FTC") pursuant to the Federal Trade Commission Act, 15 U.S.C.S. § 41, et seq., (the "FTC Act").

II. THE SUPREME COURT HAS CONFIRMED WHAT FDA LONG DECLARED: THE AGENCY LACKS JURISDICTION OVER CIGARETTES

Whether FDA possesses any authority to regulate cigarettes must be assessed in light of the Supreme Court's decision in Brown & Williamson, which repudiated the agency's claim that it could regulate cigarettes and smokeless tobacco products "as customarily marketed." FDA had based its claim on findings that the nicotine in tobacco is a "drug" and that cigarettes containing tobacco are, therefore, "drug delivery devices" because they are intended to provide nicotine to smokers. The Court rejected this theory on two related grounds. First, the Court found that faithful application of the FDCA would require FDA to ban cigarettes, a result clearly in conflict with Congress's understanding and intention. Second, the Court concluded that Congress had created a separate and exclusive regulatory regime for cigarettes in the FCLAA and related statutes, a regime that leaves no room for their regulation by FDA.

There are two relevant prongs of the definition of "drug" under the FDCA. The term "drug" means:

1. "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals", and
2. "articles (other than food) intended to affect the structure or any function of the body of man or other animals". [21 U.S.C. § 321(g)(1).][1]

The Supreme Court ruled in Brown & Williamson that FDA may not regulate cigarettes under the second prong of the drug definition. As explained in these comments, it is equally clear that FDA may not assert jurisdiction over cigarettes, including modified cigarettes, under the first prong of the FDCA drug definition.

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[1] The definition of "medical device" is comparable for purposes of this analysis.

A. The Narrow Exception To FDA's Lack Of Jurisdiction Over Cigarettes

The Supreme Court's decision reaffirmed the position FDA itself had taken for most of the 20th century. Prior to its dramatic repudiation by the agency in 1996, FDA's consistent position was that the FDCA gave it no jurisdiction to regulate cigarettes. The agency did recognize a narrow exception to its lack of jurisdiction, an exception based on two district court rulings from the 1950s, United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953), and United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959). If a seller of cigarettes labeled and promoted the product for therapeutic use, the product was subject to the FDCA's requirements for drugs. However, in the absence of such drug claims, FDA repeatedly made clear that it had no authority to regulate any cigarette.

As these two cases are the only instances in which a court has upheld FDA's exercise of jurisdiction over a tobacco product, their facts and reasoning merit close attention. In United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953), FDA seized a shipment of Fairfax cigarettes contending that the product was a "drug." The agency asserted that Fairfax's labeling claimed that the cigarette was effective in *preventing* a variety of diseases and conditions. The government's evidence showed that the leaflet accompanying Fairfax cigarette packets claimed that the product was effective in *preventing* "respiratory diseases, common cold, influenza, pneumonia, acute sinusitis, acute tonsillitis, scarlet fever, whooping cough, measles, meningitis, tuberculosis, mumps, otitis media (middle ear infection), meningopneumonitis psittacosis (parrot fever)." Fairfax, 113 F. Supp. at 337.

To the district court, the question of whether the seized product was a drug could be framed as "whether the public, having in mind the specious statements of the leaflets, would buy Fairfax cigarettes primarily for smoking enjoyment or with the hope of mitigating, curing or preventing disease." Id. at 338. Because it found that the "clear import of the leaflet is at least that the smoking of the cigarettes will make it less likely that the smoker will contract colds or other virus infections," the court concluded that Fairfax could be regulated as a drug. Id.

The product at issue in the second case, United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959), affirmatively claimed to be effective in helping users lose weight. Each cigarette package instructed purchasers to "[s]moke one cigarette shortly before meals . . . and whenever you are tempted to reach for a late evening snack. Trim reducing-aid cigarettes contain a patented appetite satient that takes the edge off your appetite." Trim, 178 F. Supp. at 849. The advertising campaign for the Trim cigarette made clear that weight loss, not smoking enjoyment, was the product's primary purpose. Indeed, advertisements suggested that Trim should be used in conjunction with, rather than as a replacement for, cigarettes smoked for pleasure. A typical radio advertisement stated:

> It's here . . . a great scientific discovery . . . Trim, reducing aid [sic] cigarettes that curb your appetite. Imagine . . . now you can lose up to twenty pounds or more, simply by smoking this delightful tasted cigarette . . . *without giving up your favorite brand.* Just light up a Trim reducing-aid cigarette before each meal. Watch your weight go up in smoke. Trim cigarettes contain a patented ingredient that stops that urge to eat fattening foods with your first puff. It's 'will-power' in tobacco form. Trim cigarettes have been clinically tested and medically approved. . . . The results are excellent. Patients have lost up to twenty pounds or more in eight weeks . . . the safe, simple way. Puff your pounds away with Trim cigarettes. Watch your weight go down, down, down. Harmless, non-habit forming. Light a Trim cigarette at night, when you're tempted to raid the ice box . . . they work instantly. Appease your appetite. *Even non-*

> *smokers can reduce with Trims*. You smoke only three a day. Trim reducing aid [sic] cigarettes make reducing fun. Get your first pack of Trim today at drug counters. Safely lose up to twenty pounds or double your money back.

Trim, at 849-50 (emphasis added).

Even the product's patent indicated that Trim was intended to be used as a weight reducer, not for smoking enjoyment. The fourth and fifth claims of Trim's patent refer to a "cigarette adapted upon smoking to cause reduction of appetite." Id. at 850.

Relying on the rationale of Fairfax, the district court concluded that because the Trim cigarette made affirmative weight loss claims, it was a drug.

> Not only does claimant concede that the labels on the immediate containers of its cigarettes were inductive of use of its product for the purpose of weight reduction, but an inspection of the copies of the panels of the display cartons of the cigarettes, the window display streamer and the salesmen's catalogue sheet relating thereto clearly discloses [sic] that the primary, if not the sole inducement intended by the claimant to the purchase and use of its product was the representation of the product's efficacy to reduce human avoirdupois.

Id. at 852.

B. Reduced Risk Claims Are Not "Drug" Claims

The marketing claims made for Fairfax and Trim cigarettes promised affirmative health benefits for users of the products. This is very different from the representations implied or made for cigarettes designed to eliminate or reduce toxic substances in tobacco smoke. Modified cigarettes marketed as presenting lower exposure to toxic smoke constituents, or a reduced risk of adverse health effects, as compared to other cigarettes, do not fall within the narrow exception recognized in these two cases. A claim that a product is less irritating or less risky than other similar products is not a drug claim.

This distinction was affirmed by the U.S. Court of Appeals for the Second Circuit only a year after the Fairfax decision in Federal Trade Commission v. Liggett & Myers Tobacco Co., 203 F.2d 955 (2d Cir. 1953). (The circuit court adopted the opinion of District Judge Irving Kaufman, 108 F.Supp. 573, who later served as Chief Judge of the Second Circuit.) The FTC had charged Liggett & Myers with violations of the FTC Act's prohibition against false or misleading advertisements for a "drug," defined in the Act in the same words it is defined in the FDCA. The complaint focused on Liggett & Myers' alleged representations that Chesterfield cigarettes could be smoked "without inducing any adverse affect [sic] upon the nose, throat, and accessory organs of the smoker." Id. at 575. According to the FTC, these representations made Chesterfield cigarettes "drugs" under the FTC Act. In an opinion later endorsed by the court of appeals, Judge Kaufman disagreed. He distinguished Chesterfield's representations from the claims made for Fairfax cigarettes:

> It is true, that cigarettes have in the past, been placed on the market and advertised as having therapeutic purposes [citing Fairfax]. However, that is toeto caelo from a representation by the defendant of a 'non-adverse' rather than beneficial effect.

Id. at 575.

In sum, the sparse pre-1965 case law that recognizes the possibility that a cigarette may be subject to FDA regulation if marketed as a drug also makes clear that representations that a cigarette may be less irritating or less risky than other cigarettes do not suffice. Only therapeutic claims – claims that a product will improve the user's health – could undermine a cigarette's immunity from FDA regulation.

C. The Fairfax And Trim Exception Confirms The Rule

For almost half a century, Fairfax and Trim represented a singular exception to FDA's repeatedly stated position that the FDCA gave it no jurisdiction over cigarettes. The agency adhered to this position in the face of repeated attempts to persuade it to change its view. A few examples from a larger body of precedents illustrate FDA's consistent position.

In response to the 1964 Surgeon General's report on the health dangers of smoking, Congress held hearings on the subject. At those hearings, Deputy FDA Commissioner Rankin testified that "the Food and Drug Administration has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, unless it bears drug claims." Cigarette Labeling and Advertising -- 1965: Hearings on H.R. 2248 before the House Comm. on Interstate and Foreign Commerce, 89th Cong., 1st Sess., 193 (1965).

In 1971, FDA's Bureau of Enforcement stated that "[t]obacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the Food, Drug, and Cosmetic Act for food, drug, device or cosmetic." Letter from Bureau of Enforcement to Directors of Bureaus (May 24, 1963), reprinted in Public Health Cigarette Amendments of 1971: Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce, 92nd Cong. 240 (1972). Similarly, in 1972, FDA Commissioner Charles Edwards testified before Congress that "cigarettes recommended for smoking pleasure are beyond the Federal Food, Drug, and Cosmetic Act." Id. at 242.

A few years later, Action on Smoking and Health ("ASH") filed a citizen petition with FDA requesting that FDA assert jurisdiction over cigarettes containing nicotine as a drug. FDA rejected this request, citing the Fairfax and Trim cases, which the agency said established

that it could assert jurisdiction over cigarettes "only when a jurisdictional basis for doing so exists, e.g., health claims." See Letter from Donald Kennedy, FDA Commissioner, to John F. Banzhaf, III, ASH (Dec. 5, 1977).

ASH immediately filed suit, challenging FDA's decision as arbitrary and capricious. In ASH v. Harris, 655 F.2d 236 (D.C. Cir. 1980), the Court of Appeals for the D.C. Circuit upheld the agency's decision. The court emphasized the agency's "consistent position that cigarettes will not be deemed a drug unless health claims are made by the vendors." ASH, 655 F.2d at 236. In explaining what was meant by "health claims," the court cited 1934 congressional testimony in which W. G. Campbell, Chief of the Food and Drug Administration, explained that the agency would not consider an item to be a drug unless the manufacturer "were to . . . say that [it] would *cure* various ills." Id. at 238 (emphasis added).

Significantly, shortly after it denied ASH's first petition, FDA rejected arguments that modification of traditional cigarette designs, including changes designed to reduce the presence or level of potentially toxic substances in tobacco smoke, e.g., by the addition or improvement of filters, could bring a cigarette within the Fairfax/Trim exception. In a second petition, ASH had asked FDA to assert jurisdiction over cigarette filters and filtered cigarettes as medical devices under the FDCA. ASH argued that cigarette filters are designed to remove tar, nicotine, and harmful gases from tobacco smoke. ASH further asserted that manufacturer claims that such filters reduced the health risks associated with smoking cigarettes were equivalent to "express or implied claims that the use of [filters] will mitigate, treat or prevent smoking-related diseases," thus bringing filters squarely within the definition of a "device."

On November 25, 1980, FDA Commissioner Jere E. Goyan responded to ASH's second petition (the "Goyan Letter"). Commissioner Goyan flatly rejected the argument that "reduced risk" claims could provide the basis for FDA jurisdiction:

> Representations in cigarette labeling or advertising of the nature of those in the record of Petition No. 2 as to the absolute or relative quantity of hazardous constituents of cigarette smoke or as to the safety of the cigarettes do not make the cigarettes or their filters intended for use in the mitigation, treatment, or prevention of disease.
>
> The representations in the filtered cigarette labeling and advertising in Petition No. 2 are made in the context of long-standing public discussion of potential health hazards of smoking and, in recent years, of warnings which have been statutorily required on cigarette packages.
>
> . . .
>
> Where, as here, attached filters are at most represented as making the cigarettes to which they are attached less hazardous to smoke, neither the cigarettes nor the filters are thereby intended for use in the mitigation, treatment, or prevention of disease.

See Goyan Letter, at P. 8 (internal citations omitted). Commissioner Goyan concluded with the following observations:

> [A] claim of general or comparative safety, without more, will not usually cause a product to be subject to the Act. Many products are designed and sold to be used to reduce the exposure of humans to hazardous substances. For example, catalytic converters and lead-free gasoline for use with automobiles are designed to reduce the exposure of humans to lead and hazardous by-products of gasoline combustion. These products, however, are not deemed to be within the Agency's jurisdiction. The determination that a product is properly regulated under the Act is not left to the FDA's unbridled discretion but must be in accordance with the statutory definition.

Id. at P. 11 (internal citations omitted).

Before 1995, FDA also frequently noted that Congressional legislation dealing specifically with tobacco reflected an intent to confine, if not cut off entirely, any FDA authority over cigarettes. In its 1977 rejection of ASH's petition, FDA acknowledged that Congress' adoption of the Product Safety Commission Improvements Act of 1976, 15 U.S.C. § 1261(f)(s) was "indicative of the policy of Congress to limit the regulatory authority over cigarettes by Federal Agencies." Similarly, in its Appellee Brief in ASH v. Harris, FDA maintained that Congress had "long been aware that the FDA does not consider cigarettes to be within its regulatory authority in the absence of health claims made on behalf of the manufacturer or vendor," and that Congress' failure to enact a legislative override of that interpretation demonstrated that it had "acquiesced in the FDA's interpretation of the statutory limits on its authority to regulate cigarettes." Brief for Appellee in ASH v. Harris, 9 Rec. in No. 97-1604 (CA4), Tab No. 4, pp. 23, 27, n. 23.

FDA's statements over more than forty years clearly indicated the agency's belief that it was for Congress, not the FDA, to regulate cigarettes. In Congressional hearings in 1983, HHS Assistant Secretary Edward Brandt testified that "the issue of regulation of tobacco . . . is something that Congress has reserved to itself, and we do not within the Department have the authority to regulate nor are we seeking such authority." Hearings on H.R. 1824 before the Subcomm. on Health and the Environment for the House Comm. on Energy and Commerce, 98th Cong., 1st Sess., 74 (1983). And in 1988, FDA Commissioner Frank Young testified that "it doesn't look like it is possible to regulate [tobacco] under the Food, Drug and Cosmetic Act." Rural Development, Agriculture, and Regulated Agencies Appropriations for 1989: Hearings before a Subcomm. of the House Comm. on Appropriations, 100th Cong., 2d Sess., 409 (1988).

D. FDA's Short-Lived Reversal Of Position

The foregoing history, summarized in the Supreme Court's opinion in Brown & Williamson, is not subject to serious dispute. Nor is the story of events commencing with FDA's publication in 1995 of proposed regulations governing cigarettes and smokeless tobacco products "as customarily marketed." The agency did not deny that it was abandoning its long-standing "no jurisdiction" policy. Instead, it contended that newly available evidence supported a different theory for asserting jurisdiction over cigarettes under the FDCA. Rather than focusing on the marketing claims made for a product, the customary evidence of a product's intended "therapeutic" use, FDA relied on the second prong of the FDCA's "drug" definition. Because, the agency said, nicotine itself has bodily effects and because sellers of cigarettes know that consumers smoke to get nicotine and design their products to provide nicotine, cigarettes are "intended" to provide the effects that nicotine produces and are, thus, "drug delivery devices" under section 201(h)(3) of the FDCA. In short, according to FDA, cigarettes that delivered nicotine were subject to regulation regardless of the claims made for them. And it did not matter that such products were also subject to, and marketed in compliance with, the laws Congress had enacted specifically for cigarettes.

FDA's new theory thus swept within it all cigarettes that delivered nicotine, regardless of the claims made for them. The agency drew no distinction between cigarettes that consisted solely or largely of tobacco leaf inside a paper wrapper and products that also included other ingredients or were equipped with other features, such as filters, designed to make them attractive to consumers. If a cigarette contained tobacco and yielded nicotine when smoked, it was within FDA's jurisdiction.

FDA's regulations would have applied to cigarettes engineered to reduce exposure to toxic substances in tobacco smoke. The regulations defined "cigarette" as:

> Any product which contains nicotine, is intended to be burned under ordinary conditions of use, and consists of: (1) any roll of tobacco wrapped in paper or in any substance not containing tobacco; or (2) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filter, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (a)(1) of this section.

61 Fed. Reg. 44,616 (Aug. 28, 1996).

In addition, FDA's statements about the nature of "cigarettes" make clear that FDA considered the term to encompass reduced risk cigarettes. In the preamble to its proposed regulations, FDA said:

> A cigarette is analogous to a metered-dose inhaler, an instrument that converts a drug into an aerosolized form for inhalation and delivery to the lungs for absorption into the bloodstream. . . . [Cigarettes] are carefully engineered, complex products that are designed to deliver a controlled amount of nicotine to the consumer using such device components as the tobacco, the paper, and the filter.

61 Fed. Reg. 41,347-8 (Aug. 11, 1995).

Modified cigarettes share this basic functional design with more conventional cigarettes. Both are products containing tobacco wrapped in paper that are lit with a flame and burned to release smoke that contains nicotine. Where FDA chose to draw a distinction between cigarettes covered by its regulations and those that were not, it did not do so on the basis of differences in design. Rather, it did so on the basis of the presence or absence of nicotine. "FDA would . . . consider a cigarette-like product that contains a pharmacologically active or addictive

substance *in place of nicotine* to be a 'new' drug delivery device that would be outside the scope of this regulation." 60 Fed. Reg. 41,322 (Aug. 11, 1995) (emphasis added).

Finally, FDA's discussion of Eclipse and Premier confirms that modified cigarettes would have been subject to its regulations just like other cigarettes. In discussing manufacturer attempts to develop such cigarettes, FDA observed:

> [T]the major similarity in the vapor from Premier and Eclipse and the smoke from a conventional cigarette is nicotine delivery. The implication of RJR's work on Premier and Eclipse is that nicotine delivery is the defining characteristic of a cigarette . . . Premier and Eclipse are thus evidence that conventional cigarettes are, in effect, simply nicotine delivery systems.

61 Fed. Reg. 44,879 (Aug. 11, 1996).

E. The Supreme Court Confirms That FDA Lacks Jurisdiction

In Brown & Williamson, the Supreme Court invalidated FDA's regulations and flatly rejected the agency's new theory to justify its assertion of jurisdiction over cigarettes. Accordingly, in the absence of new legislation, FDA may not exercise jurisdiction over any cigarette on grounds that are inconsistent with the Court's decision. That decision, and its rationale, are encapsulated in Justice O'Connor's statement:

> Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products. Such authority is inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the FDCA.

Brown & Williamson, 529 U.S. at 126.

As this statement reveals, the Court's ruling rests on two related but independent propositions. First, the FDCA's requirements for drugs and medical devices cannot be applied to tobacco cigarettes consistently with Congress's decision that such products should continue to be

lawful. Second, to address the health effects of cigarettes, Congress has created a separate, and exclusive regulatory regime, embodied in the FCLAA, a regime that leaves no room for FDA regulation.

The Supreme Court's decision establishes clear limits on FDA's regulatory authority, which can be summarized as follows:

1. Any cigarette is presumptively exempt from FDA regulation if it is subject to and complies with FCLAA.

2. This presumption is not limited to cigarettes that resemble products that were in commercial distribution in 1938 (when the FDCA was enacted), in 1965 (when FCLAA was enacted), or in 2000 (when the Supreme Court rendered its decision).

3. Justice O'Connor's frequent references to tobacco products "as customarily marketed" unquestionably refer to the manner in which products are labeled and promoted, and not to their design, structure, or ingredients. Justice O'Connor makes this interpretation inescapable when she describes FDA's regulations as applying to "tobacco products as customarily marketed – that is, without manufacturer claims of therapeutic benefit." Brown & Williamson, 529 U.S. at 127.

4. The regulations that the Supreme Court invalidated, predicated on the theory that a cigarette intended to deliver nicotine is a "drug delivery device," would have applied to all cigarettes, including products of novel design, as well as to cigarettes that incorporate more familiar features, such as improved filters or modified types of tobacco.

5. The Court squarely rejected FDA's theory that a cigarette may be regulated as a "drug" or "device" based on a showing that it contains nicotine and that consumers use it to obtain nicotine.

Together these indisputable propositions demonstrate that FDA would exceed its authority if it now were to attempt to assert jurisdiction over modified cigarettes similar to Advance, Eclipse, or Omni.

III. CIGARETTES DESIGNED TO REDUCE THE HEALTH RISKS OF SMOKING ARE NOT SUBJECT TO THE FDCA

In attempting to show that FDA may regulate cigarettes like Advance, Eclipse, and Omni, the Petitioners seek to expand the narrow "drug claim" exception that FDA had acknowledged was the only circumstance in which it could regulate a tobacco product. The Petitioners essentially contend that any suggestion, in labeling or advertising, that a cigarette has been designed to eliminate or reduce the concentration of possible toxins in tobacco smoke, or to reduce the risk of smoking related diseases, amounts to a "drug" claim that makes the product subject to the FDCA notwithstanding the Supreme Court's ruling.

This contention misconstrues the Supreme Court's decision and ignores the narrow limits of the exception to FDA's lack of jurisdiction.

A. Cigarettes Designed To Reduce The Health Risks Of Smoking Are Not "Drugs" Under The FDCA

The majority opinion in Brown & Williamson does not say that FDA retains any authority to regulate cigarettes that are marketed in compliance with the FCLAA, regardless of the claims made for such products. It is Congress's creation of this separate regime governing cigarettes that provided the bedrock for the Court's conclusion that the FDCA could not apply. Thus, it is an open question whether the Fairfax/Trim exception survives the Supreme Court's decision.

FDA successfully invoked this exception in only two cases, decided over fifty years ago, long before the enactment of the FCLAA. The two products involved were promoted as providing independent health benefits to users. Neither product was marketed for smoking pleasure. In its subsequent references to these court rulings – and the narrow circumstances in

which a cigarette could be subject to the FDCA – FDA repeatedly characterized the qualifying claims as "therapeutic claims" or "drug claims." See text at Part II(c), supra. In the absence of such claims, the agency declared, a cigarette was not subject to the FDCA. As Justice O'Connor emphasized, these repeated statements formed the basis for Congress's understanding that FDA lacked jurisdiction over cigarettes and supported Congress' decision to create a separate regime to address the health effects of cigarette use. See Brown & Williamson, 529 U.S. at 144.

FDA's historical treatment of cigarettes, Congress' enactment of the FCLAA and the Brown & Williamson decision combine to make clear that FDA has no jurisdiction over modified cigarette products, which make reduced risk but not therapeutic claims.

B. FDA's Lack Of Jurisdiction Over Modified Cigarettes Is Consistent With The Agency's Regulation Of Food Products

The distinction between reduced risk claims and therapeutic claims has been recognized by FDA and by Congress. Both have authorized reduced risk claims for foods, without requiring such foods to be regulated as drugs.

For example, FDA has permitted truthful claims that a food product does not contain, or contains a reduced amount of, a harmful constituent, without regulating such products as drugs. Thus, foods may expressly claim to be hypoallergenic, see 21 C.F.R. § 105.62, low in sodium, see 21 C.F.R. § 101.61, low in calories or calorie free, see 21 C.F.R. § 101.60, low in fat or fat free, see 21 C.F.R. § 101.62, or low in cholesterol or cholesterol free, see id. In addition, foods may claim to be "light," evidencing reduction of risk associated with the consumption of high fat or high calorie foods. See 21 C.F.R. § 101.56. All of these claims may be made without causing the foods to be regulated as drugs.

FDA's treatment of health claims for food illuminates why claims of reduced exposure or reduced risk for cigarettes are not therapeutic claims under the FDCA. In 1984, Kellogg began promoting All-Bran cereal as a good source of fiber that could reduce the risk of cancer, based on scientific studies cited in its advertising. FDA took no action with respect to the Kellogg product and did not seek to regulate the product as a drug.

Kellogg's product labeling and print advertisements included a statement that the National Cancer Institute had found evidence that a high fiber, low fat diet may lower the incidence of some kinds of cancer. The statement ended with the claim that no cereal (indeed no food) provided more fiber than Kellogg All-Bran cereal.[2]

The FTC's response to Kellogg's campaign was quick and supportive. Carol T. Crawford, then the director of FTC's Bureau of Consumer Protection, stated that it "is the type of advertisement that we believe should be encouraged." Mark Potts, FTC Official Backs Ad for All-Bran, The Washington Post, Dec. 5, 1984, at D-3. Ms. Crawford stated that Kellogg's advertisement was adequately qualified by simply pointing out the findings of the National Cancer Institute's study (that a high fiber, low fat diet can reduce an individual's risk of cancer), and noting that All-Bran is a high fiber cereal.

It merits emphasis that Kellogg's claims, supported by the FTC and countenanced by the FDA, were significantly broader than any current claims for modified cigarettes. Kellogg marketed its cereal as a source of protection against disease threatened by external factors. Modified cigarettes merely purport to reduce the risk presented by smoking itself.

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[2] Peter Barton Hutt, Government Regulation of Health Claims in Food Labeling and Advertising, 41 FOOD, DRUG COSM. L.J. 3 (1986).

In 1987, in response to increasing interest by both consumers and the public health community in the health promoting properties of some food constituents, FDA issued a policy statement setting forth criteria for allowing reduced risk claims for food. See Food Labeling; Public Health Messages on Food Labels and Labeling, 52 Fed. Reg. 28,843 (Aug. 4, 1987) (the "1987 Policy Statement"). The 1987 Policy Statement began by noting that:

> Consumers are becoming increasingly conscious of the relationship between diet and health. As a result, food manufacturers have begun to show an interest in developing a mechanism to inform consumers about this relationship and how specific foods may be used to improve one's diet, thereby promoting good health. FDA believes that it is important to consider ways to improve the public's understanding about the health benefits that can result from adhering to a sound and nutritious diet.

52 Fed. Reg. at 28,843-44 (Aug. 4, 1987).

Accordingly, FDA stated, manufacturers may make health-related claims on food labels without prior approval under the FDCA's drug provisions so long as the claims satisfied specified criteria, including the following.

1. Information on the labeling must be truthful and not misleading to the consumer. The information should not imply that a particular food be used as part of a drug-like treatment or therapy oriented approach to health care; and

2. The information should be based on and be consistent with valid, reliable, scientific evidence that is publicly available (prior to any health related claim being made).

Id. at 28,845.

Later that year, FDA Commissioner Frank Young and FDA Chief Counsel Thomas Scarlett defended FDA's policy in Congressional hearings.[3] Addressing the legal status of reduced risk claims for foods, Mr. Scarlett stated:

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[3] See FDA Proposals to Permit the Use of Disease-Specific Health Claims on Food Labels: Hearing before a Subcomm. of the Comm. on Government Operations, 100th Cong., 1st Sess.

> The premise for permitting health claims on food labeling without requiring premarketing clearance under the new drug provisions of the act is that there are statements that can be made describing accurately the relationship between a food and a physiological condition, including a disease condition, that are not drug-like and do not render the food a drug within the meaning of the Federal Food, Drug, and Cosmetic Act.

1987 Hearing, at 54-5.

In response to another question probing the legal rationale for FDA's proposal, Scarlett reiterated: "[T]he specific legal basis is that these are not, in fact, drug claims, mere mention of a disease condition does not, in and of itself, make a product that is otherwise a food product into a drug." Id. at 63.

Following public hearings and comments in 1990, FDA issued a revised proposal regarding food health claims.[4] The agency's preamble stressed that comments on the 1987 Policy Statement generally supported providing information to consumers about the diet and its impact on human health, but went on to say that "safeguards must be in place to limit the nature and scope of health statements that may be used on the food label or labeling and thus reduce the potential for false or misleading statements." Revised Proposal at 5,176. Accordingly, FDA limited the universe of permissible "health messages" to "statements concerning reducing the risk, or forestalling the premature onset, of certain chronic serious disease conditions (e.g., coronary heart disease, high blood pressure, cancer, osteoporosis) through changes in diet." Id.

This description of permissible non- "drug" health statements would clearly encompass the types of claims made for modified cigarettes. FDA's legal defense of its policy governing food health claims is thus consistent with the explanation the agency provided when it

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(1987) (hereinafter "1987 Hearing").

[4] See Food Labeling; Health Messages and Label Statements: Reproposed Rule, 55 Fed. Reg.

denied the 1979 ASH petition to regulate cigarette filters as medical devices. In its denial of the ASH petition, FDA rejected the argument that product changes designed to reduce the health risks of smoking brought a cigarette within the drug or device provisions of the FD&C Act. See Goyan Letter, at p. 5.

In the Nutrition Labeling and Education Act of 1990 ("NLEA"), 104 Stat. 2353, 21 U.S.C. § 343, Congress created a special statutory structure for allowing health claims for foods. The NLEA created a safe harbor from drug status for foods whose labels contain health claims so long as the claim has been certified by the FDA as supported by "significant scientific agreement." 21 U.S.C. § 343(p) & (q). Permitted food health claims include those that characterize the relationship of a nutrient to a disease or health-related condition. In the FDA Modernization Act (FDAMA) of 1997, Congress expanded the universe of permitted health claims, sanctioning claims without FDA approval that are based on an authoritative statement by a recognized scientific body. See Pub. L. No. 105-115, 111 Stat. 2296.

Reduced risk claims for cigarettes are narrower and even less like drug claims than health claims allowed for food because they describe only reduction in exposure to potentially harmful components of cigarette smoke and do not promise, implicitly or explicitly, any diminution in the overall risk of disease associated with exposure to harmful constituents of other products, or associated with other sources.

Regulation of reduced risk claims for tobacco products under the FTC Act, and not under the new drug provisions of the FDCA, is consistent with the law's treatment of food health claims, which are subject to a flexible regulatory structure that facilitates dissemination of

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5,176 (February 13, 1990) (the "Reproposal").

accurate health related information to consumers. The cumbersome new drug approval process is an inappropriate mechanism for evaluating either food health claims or reduced risk claims for tobacco products.

C. Recent FDA Actions Against Certain Non-Tobacco Products Do Not Support Assertion Of Jurisdiction Over Modified Cigarettes

FDA recently issued warning letters challenging the sale of nicotine lollipops and nicotine lip balm as unapproved drugs or food additives. See letter from David J. Horowitz, Director of CDER's Office of Compliance, to Larry and Pat Frieders, Techni-Med, Inc., (April 9, 2002). FDA also granted a petition to regulate nicotine water as a drug. See letter from Dennis E. Baker, FDA Associate Commissioner for Regulatory Affairs, to William Shultz and Matthew Meyers (July 1, 2002).

These products are clearly distinguishable from modified cigarettes and FDA's challenge to these products, even if ultimately successful, provides no support for the Petitioners' demand that the agency assert jurisdiction over modified cigarettes. These products contain no tobacco, are not marketed for smoking pleasure, were never covered by FDA's invalidated tobacco regulations, and are not marketed in compliance with FCLAA. Furthermore, like other non-tobacco products that FDA regulates, these products make express or implied smoking cessation claims. Modified cigarettes, by contrast, are marketed for smoking pleasure and regulated under FCLAA and, thus, clearly fall within the class of tobacco products that Congress intended to be beyond FDA's jurisdiction.

IV. REGULATION OF MODIFIED CIGARETTES UNDER THE FDCA WOULD CONFLICT WITH CONGRESSIONAL POLICY

A. Conflicts Between The FDCA And The FCLAA

Justice O'Connor's opinion identified numerous conflicts between the FDCA requirements for drugs and devices and the premises of Congress' separate regulatory regime for cigarettes. She specifically emphasized the collision between the FDCA's labeling requirements and the express language of the FCLAA:

> Not only did Congress reject the proposals to grant the FDA jurisdiction, but it explicitly preempted any other regulation of cigarette labeling: "No statement relating to smoking and health, other than the statement required by . . . this Act, shall be required on any cigarette package." The regulation of product labeling, however, is an integral aspect of the FDCA, both as it existed in 1965 and today.

Brown & Williamson, 529 U.S. at 148.

Justice O'Connor went on to examine mandatory FDCA labeling requirements that cigarettes could not satisfy or whose obligations would conflict with the explicit preclusion of the FCLAA. The same conflicts would arise if FDA sought to exercise jurisdiction over modified cigarettes.

For example, section 502(f) of the FDCA requires that all drugs bear "adequate directions for use," language that FDA has consistently interpreted as requiring adequate directions for safe use. But no cigarette, including a reduced risk cigarette, could be found "safe" within the meaning of the FDCA, which requires that a drug or device provide therapeutic benefits that offset the risks associated with its use. Cigarettes, conventional or modified, do not provide, and do not purport to provide, therapeutic benefits.

Section 502(f)(2) of the FDCA requires that all drugs provide "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health." And section 502(j) deems a drug misbranded "if it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j). FDA could not plausibly conclude that no warning was required on a modified cigarette or that such a cigarette was not "dangerous to health" when used for smoking – even if there were convincing evidence that it was less dangerous than other cigarettes. Hence the agency would be obligated to require the manufacturer to include on the label some statement about the risks of using the product – a statement that would be precluded by the FCLAA. The exclusive warnings for cigarettes are prescribed by FCLAA.

The conclusion Justice O'Connor reached in Brown & Williamson applies as fully to modified cigarettes as to conventional cigarettes. No cigarette that is marketed in compliance with the FCLAA can satisfy the requirements of the FDCA. As Justice O'Connor pithily wrote, cigarettes "simply do not fit" within the FDCA. See Brown & Williamson, 529 U.S. at 143.

B. Regulation As Drugs Or Devices Under The FDCA Would Doom Modified Cigarettes

Justice O'Connor recognized the inescapable conflict between the FDCA's requirements for drugs and devices and the conclusions Congress has reached regarding tobacco products. In the FCLAA and the other tobacco-specific statutes Congress has acknowledged the health risks of tobacco use and prescribed restrictions on labeling and advertising and imposed reporting requirements that achieve the balance it desired. This is not the same balance that the FDCA mandates, as Justice O'Connor emphasized.

> Viewing the FDCA as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is "safe" and "effective" for its intended use. . . . Thus the Act generally requires the FDA to prevent the marketing of any drug or device where "the potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." United States v. Rutherford, 442 U.S.544 (1979).

Brown & Williamson, 529 U.S. at 133 (quoting United States v. Rutherford, 442 U.S. 544 (1979)).

Cigarettes engineered to reduce smoking risks manifestly cannot satisfy this basic standard of the FDCA. While they may eliminate or reduce levels of toxic constituents in tobacco smoke, and may reduce the health risks of smoking, they cannot – and will not purport to – provide any offsetting therapeutic benefit. This in part explains why Congress decided, beginning in 1965, to construct, for this unique category of products, a different, separate regulatory regime.

Indeed, regulation of reduced risk cigarettes under the FDCA would produce a perverse result. Even if the Act could be interpreted to permit approval of a reduced risk (but no benefit) cigarette, the cost, in time and dollars, of collecting the evidence that FDA requires for drugs would stifle the incentive for any company to explore technologies for developing lower-risk products. The proceeds from even a very successful product could not conceivably repay the development costs. This reality would put an end to efforts to design cigarettes to reduce the health risks of smoking. At the same time, conventional cigarettes -- the only type the Petitioners acknowledge the Supreme Court's ruling exempts -- would occupy the entire market for smoking products.

The potential public health benefit of reduced risk cigarettes was recognized in the recent Institute of Medicine (IOM) Report: "Clearing the Smoke, Assessing the Basis for

Tobacco Harm Reduction" (2001). The Report concludes that "[f]or many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco toxicants is feasible" [page 5]. The incentive for continued technological improvements necessary to develop these products would be destroyed if they were regulated as new drugs.

V. REGULATION OF MODIFIED CIGARETTES UNDER THE FDCA WOULD OFFEND THE FIRST AMENDMENT

FDA would face yet another challenge if the agency asserted jurisdiction to regulate modified cigarettes. Assuming, contrary to the foregoing analysis, that Congress has not precluded FDA's exercise of jurisdiction, any controls that the agency sought to impose on cigarette promotion would have to satisfy the Supreme Court's stringent Central Hudson test. See Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n, 447 U.S. 557 (1980). As FDA has been forcefully reminded, this is a demanding test, and the agency's customary casual approach to fashioning advertising controls won't suffice.[5]

A. Concluding That FDA Lacks Jurisdiction To Regulate Modified Cigarettes Is Consistent with First Amendment Principles

In Central Hudson and several subsequent cases, the Supreme Court has made clear that restrictions on commercial speech must be no more extensive than necessary to

[5] FDA's restrictions on tobacco advertising were the centerpiece of its 1996 regulations. Lorillard and many others (including prominent First Amendment scholars and independent advocates for free expression) challenged those restrictions on First Amendment grounds. The District Court had no occasion to reach these arguments because it agreed with Lorillard's argument, above, that FDA had no authority to regulate tobacco advertising at all. The Fourth Circuit ignored the issue because it concluded that FDA had no jurisdiction whatever over cigarettes "as customarily marketed." And since the Supreme Court reviewed that question alone, the specific First Amendment issue was not resolved.

advance the government's legitimate interest. The Court has firmly rejected the paternalistic notion that government may prohibit truthful commercial speech to prevent citizens from making unwise decisions. Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n, 447 U.S. 557 (1980); Thompson v. Western States Medical Center, et al., 535 U.S. _____ (2002). If the government can achieve its goals by less restrictive means, it must do so.

As explained above, FDA regulation of reduced risk cigarettes as drugs would be tantamount to banning such products. This would not only contravene the Supreme Court's decision in Brown & Williamson, but it also would effectively deny the First Amendment rights of tobacco product manufacturers and consumers. Because FDA would be unable to approve the marketing of reduced risk cigarettes under the FDCA's stringent requirements for new drugs, smokers would never receive truthful health related information regarding such products.

The courts have rejected broad restrictions on speech respecting products regulated under the FDCA. The Supreme Court and the U.S. Court of Appeals for the D.C. Circuit recently overturned FDA prohibitions on advertising of pharmacist compounded drugs and health related claims for dietary supplements as inconsistent with the First Amendment. Thompson v. Western States Medical Center, _____ U.S. _____ (2002); Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), *reh'g denied en banc*, 173 F.3d 72 (D.C. Cir. 1999). Each court ruled that FDA's speech restrictions were more extensive than necessary to serve the government's interests, even though those interests were acknowledged to be substantial. In Pearson, the D.C. Circuit ruled that the government violated the First Amendment by prohibiting the dissemination of health claims for dietary supplements where a less draconian method - the use of disclaimers and qualifications - would have adequately served the government's interests. Consistent with

the principles articulated in Pearson, FTC regulation of advertising for modified cigarettes permits dissemination of truthful claims - subject only to appropriate scientific substantiation and qualification.

In response to these recent court decisions invalidating FDA regulations as violations of the First Amendment, FDA has taken the unusual step of seeking public comment on how it may regulate products within its jurisdiction consistent with the First Amendment. 67 Fed. Reg. 34,942 (May 16, 2002). This reflects the agency's recognition that it must rethink traditional regulatory approaches in order to assure adherence to the fundamental principles of free speech. These principles clearly support dissemination of accurate information to smokers regarding reduced risk cigarettes.

In Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001), the Supreme Court ruled that Massachusetts' outdoor and point-of-sale advertising regulations relating to smokeless tobacco and cigars violated the First Amendment. The Court held that the Massachusetts' regulations would impose a nearly complete ban on the communication of truthful information to adult smokers and that the State had failed to show that the regulations were no more extensive than necessary. The Court held that more narrowly tailored regulations were available to the government and stressed that regulation may not unduly impinge on a speaker's ability to propose a lawful commercial transaction or on adult listeners' opportunity to obtain such information.

FTC regulation of the claims made for reduced risk cigarettes satisfies the government's interest in assuring that such claims are factually accurate and not misleading without denying smokers potentially useful health related information. FTC regulation avoids

unduly intrusive restrictions on speech and honors the First Amendment preference for providing consumers more, rather than less, information.

B. The FDCA Would Not Allow FDA to Regulate Directly Advertisements for Reduced Risk Cigarettes

Our central argument is that FDA may not lawfully regulate cigarettes that have been modified to reduce toxic constituents of tobacco smoke. Even if FDA could assert jurisdiction, however, it could not restrict the advertising for such products. The explanation is simple: FDA lacks authority to regulate the advertising of any product – drug, device, or combination – that is sold over-the-counter.[6]

FDA acknowledges that it has no jurisdiction over advertisements for any non-prescription drug. That jurisdiction rests with the Federal Trade Commission pursuant to the compromise Congress enacted when it passed the FDCA in 1938 and simultaneously approved the Wheeler-Lea Amendments to the Federal Trade Commission Act. The original FDCA gave FDA no jurisdiction over the advertising of any product. In 1962 Congress amended the FDCA to give FDA jurisdiction over advertisements for prescription drugs, thereby reaffirming that the agency had (and has) no authority to regulate advertising for non-prescription drugs.

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[6] Lorillard and other manufacturers of cigarettes and smokeless tobacco made precisely this argument in comments submitted in response to FDA's 1995 proposed regulations. They repeated the argument in briefs before the U.S. District Court in which their ultimately successful challenge to FDA's final regulations began, and again in briefs before the Fourth Circuit. Neither the Fourth Circuit, which rejected the District Court's holding that FDA did have jurisdiction, nor the Supreme Court, which granted certiorari solely on that issue, had occasion to address the merits of the trial court's ruling. Hence the last word on the matter is that of the District Court. The Fourth Circuit vacated Judge Osteen's ruling on this issue but did not question his analysis.

Accordingly, even if reduced risk cigarettes could be classed as "drugs," as the Petitioners insist, FDA could not regulate their advertising.

The result would be no different if FDA were to claim that reduced risk cigarettes are "devices" for the delivery of nicotine. Section 360j(e) of the FDCA gives the agency power to "restrict" the sale, distribution, and/or use of a device if its safe use cannot otherwise be assured. In its original tobacco regulations, FDA contended that this language conferred power to limit the advertising of cigarettes and smokeless tobacco. But the District Court rejected this reading of that provision, first because 360j(e) does not mention "advertising" and, second, because another provision of the device law – which could not justify the restrictions FDA sought to impose – does, making clear that Congress knew the difference. A reading of the FDCA as a whole, therefore, leaves no doubt that the FDCA does not give FDA authority to regulate the advertising for any product sold over-the-counter, whether "drug" or "device."

This conclusion meshes perfectly with the compromise Congress fashioned when it enacted the FCLAA. In that law Congress imposed various requirements for cigarette labels and required the submission of certain information to the FTC and the DHHS. It also flatly prohibited advertising for cigarettes on electronic media. With respect to forms of advertising that cigarette manufacturers could engage in, Congress left regulatory responsibility where it had historically rested – with the FTC.

VI. MARKETING CLAIMS FOR MODIFIED CIGARETTES ARE APPROPRIATELY REGULATED BY THE FTC

Contrary to the Petitioners' claims, FDA's lack of jurisdiction over modified cigarette products does not create a regulatory gap. The FTC has been entrusted by Congress

with responsibility for administering the FCLAA. The Commission has broad authority to prevent false or misleading claims for consumer products, including tobacco products, and it has long experience in assessing scientific and health related claims, including claims for tobacco products. The FTC has vigorously policed tobacco product advertising and has frequently initiated enforcement actions challenging what it believed to be false or misleading tobacco product claims.

In overturning FDA's regulations the Supreme Court stressed that Congress has created a separate regulatory regime for tobacco products. For cigarettes, that scheme is embodied in FCLAA, which is administered by the FTC. The FTC has responsibility for overseeing the rotational presentation of health warnings on cigarette packaging and on advertising, and for enforcing the ban on advertising of tobacco products in electronic media. The Commission also regularly publishes the government's official report of tar and nicotine ratings. Congress gave the FTC, not FDA, authority to regulate tobacco product labeling and advertising claims. Only the FTC has the experience, the institutional structure, and the resources to perform this role.

The FTC has broad authority to prevent "unfair or deceptive acts or practices in or affecting commerce" (Section 5(a)(1) of the FTC Act, 15 U.S.C. § 45), including false or misleading advertising claims. Under the FTC advertising substantiation policy, articulated in Section 5 cases, an advertiser must have a reasonable basis for making an objective claim prior to dissemination of the claim. (Pfizer Inc., 81 F.T.C. 23 (1972); Thompson Medical Co., 104 F.T.C. 648 (1984), aff'd., 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987)). For health or safety claims, the Commission requires a high level of substantiation, including

competent and reliable scientific evidence. See, e.g., Brake Guard Products, Inc., 125 F.T.C. 138 (1998), Schering Corp., 118 F.T.C. 1030 (1994). Any exposure or health related claims for tobacco products, as well as other objective claims for such products, must comply with Section 5 of the FTC Act and the Commission's claims substantiation policy.

The FTC has a broad array of enforcement powers to prevent or correct false or misleading advertising claims, including cease and desist orders, corrective advertising, and redress or disgorgement of profits. The FTC has shown no hesitancy in employing its enforcement authority to prevent or correct false or misleading tobacco product advertising, including express or implied exposure or health related claims. Recent FTC enforcement actions with respect to tobacco product advertising include the following:

- Swisher International, Inc., C-3964; Havatampa, Inc., C-3965; Consolidated Cigar Corp., C-3966; General Cigar Holdings, Inc., C-3967; John Middleton, Inc., C-3968; Lane Limited, C-3969; and Swedish Match North America, C-3970 (Aug. 25, 2000) (consent orders) (requiring nation's seven largest cigar companies to include warnings about significant adverse health risks of cigar use in their advertising and packaging).

- Sante Fe Natural Tobacco Company, Inc., C-3952 (June 16, 2000) (consent order) (challenging claim that Natural American Spirit cigarettes are safer to smoke than other cigarettes because they contain no additives).

- R.J. Reynolds Tobacco Co., C-3892 (Aug. 27, 1999) (consent order) (challenging claims for Winston "no additives" cigarettes and requiring disclosures that "No additives in our tobacco does NOT mean a safer cigarette").

- American Tobacco Co., 119 F.T.C. 3 (1995) (consent order) (challenging claim that "10 packs of Carlton have less tar than one pack" of other brands).

- Pinkerton Tobacco Co., 115 F.T.C. 60 (1992) (consent order) (challenging as violations of the television advertising ban the display of Redman Tobacco brand name and selling message on signs, vehicles, uniforms, etc., at company-sponsored televised events).

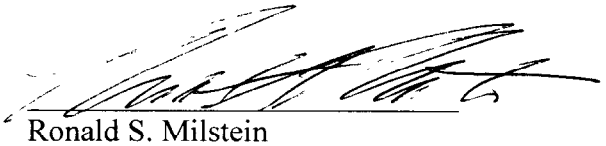
- R.J. Reynolds Tobacco Co., 113 F.T.C. 344 (1990) (consent order) (challenging deceptive claims regarding findings of scientific study on health effects of smoking).

The FTC is uniquely qualified to evaluate reduced risk claims for tobacco products. The FTC's statutory authority provides it the flexibility to allow truthful and scientifically documented claims and at the same time ample authority to prohibit, or require correction of, false, misleading or unsubstantiated claims.

VII. CONCLUSION

Congress and the Supreme Court have made clear that FDA has no jurisdiction over cigarettes, including cigarettes designed to reduce exposure to toxic smoke constituents, that are marketed for smoking pleasure and subject to regulation under FCLAA. The FTC has responsibility for assuring that cigarette advertising claims are accurate, scientifically substantiated and consistent with the requirements of FCLAA. Any alteration in the current regulatory regime for cigarettes can only be imposed by Congress, not FDA. For the foregoing reasons, the Petitions should be denied.

Respectfully submitted,



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