

**Prepared Statement of  
The Federal Trade Commission**

**Before the**

**Committee on Energy and Commerce  
Subcommittee on Commerce, Trade, and Consumer Protection  
United States House of Representatives**

**Washington, D.C.**

**June 3, 2003**

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Mr. Chairman and members of the Committee, I am Timothy J. Muris, Chairman of the Federal Trade Commission ("Commission" or "FTC"). The Commission is pleased to have this opportunity to provide information concerning the potential advertising of reduced risk tobacco products.<sup>(1)</sup> This statement discusses the Commission's mission, our activities in the tobacco area, and then addresses the process the Commission would use in examining the advertising of these products.

**FTC Jurisdiction Over Tobacco Advertising and Marketing**

The FTC's mission is to prevent unfair competition and unfair or deceptive acts or practices in the marketplace. The Commission regulates national advertising, including the advertising and promotion of cigarettes, smokeless tobacco, and other tobacco products, pursuant to Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, which prohibits "unfair or deceptive acts or practices in or affecting commerce." The Commission's activities promote informed consumer choice.

The FTC's law enforcement activities involving tobacco advertising and promotion date back to the 1930s.<sup>(2)</sup> In 1962, the FTC's request for technical guidance from the U.S. Public Health Service was among the factors that led the then-Surgeon General of the United States to establish an advisory panel to undertake a comprehensive analysis of the data on smoking and health. The work of the advisory panel, in turn, led to the historic 1964 Report of the Surgeon General finding that cigarette smoking presented significant health risks. In that same year, the Commission issued a regulation requiring tobacco companies to include health warnings in cigarette advertising and on packages.<sup>(3)</sup> The FTC's regulation was superseded in 1965, before it went into effect, by the Federal Cigarette Labeling and Advertising Act ("Cigarette Act"),<sup>(4)</sup> which required such warnings on cigarette packages.

In 1972, the Commission once again addressed the issue of health warnings in cigarette advertising. Pursuant to its Section 5 authority, the FTC issued consent orders mandating for the first time that the major cigarette manufacturers place health warnings in cigarette advertisements.<sup>(5)</sup>

Today, the Commission administers the Cigarette Act, and administers and enforces the Comprehensive Smokeless Tobacco Health Education Act ("Smokeless Tobacco Act").<sup>(6)</sup> The Cigarette Act instructs the Commission to take certain steps to implement the mandated Surgeon General's health warnings.<sup>(7)</sup> The Smokeless Tobacco Act directs the FTC to promulgate regulations governing the health warnings on packaging and advertising for smokeless tobacco products. The Commission's regulations specify the placement and rotation of the warnings, and require companies to submit plans to the Commission setting forth their rotation schedules.<sup>(8)</sup> Finally, the FTC enforces the ban in the Smokeless Tobacco Act on broadcasting smokeless tobacco advertisements on radio and television.

The Commission also publishes periodic reports on advertising and promotion activities in the cigarette and smokeless tobacco industries.<sup>(9)</sup> Those reports provide information on sales and on expenditures for various categories of marketing expenditures. The Commission issued its first report on the cigarette industry in 1967 and on the smokeless tobacco industry in 1987.

In addition to its administrative and law enforcement responsibilities under the Cigarette Act and the Smokeless Tobacco Act, the Commission also has authority under Section 5 of the FTC Act to prevent unfair or deceptive acts or practices in connection with the marketing and sale of tobacco products. Pursuant to that authority, the Commission

has taken a number of law enforcement actions against unfair or deceptive tobacco advertising and promotional practices. For example, in 1983, the Commission sued the Brown & Williamson Tobacco Corporation over ads that continued to describe Barclay as a 1 mg. of tar brand, even though the Commission had revoked Barclay's 1 mg. rating because the cigarette's unusual design prevented the cigarette test method from measuring Barclay's yields on a basis comparable to other cigarettes.<sup>(10)</sup> Moreover, in 1997, the Commission issued a complaint against the R.J. Reynolds Tobacco Co. alleging that the company's Joe Camel advertising campaign caused or was likely to cause many young people to begin or continue to smoke, thereby exposing them to significant health risks.<sup>(11)</sup> In 1999 and 2000, the Commission entered into consent agreements with several cigarette manufacturers, resolving charges that their advertisements implied that their "no additive" cigarettes were safer than otherwise comparable cigarettes because they did not contain additives.<sup>(12)</sup> In 2000, the Commission also entered into a consent agreement with a company claiming reduced health risks for its herbal cigarettes.<sup>(13)</sup>

Testing for the tar and nicotine yields of cigarettes is also conducted by the tobacco industry under a methodology adopted by the Commission in 1967. For the past several years, the FTC has also actively sought the views of the Federal government's public health agencies about what changes should be made in that methodology.<sup>(14)</sup> The agency has also recommended to Congress that authority for cigarette testing be given to one of the government's science-based public health agencies<sup>(15)</sup> and we renew that recommendation here.

### **"Reduced Risk" Tobacco Claims**

As with other products, the Commission's primary role for tobacco products is to ensure that products are marketed in a manner that is truthful, not misleading, and adequately substantiated. The Commission does not pre-screen advertising claims for tobacco or any other product. Instead, the agency addresses deception in the marketing of tobacco largely through post-market law enforcement actions targeted against specific false or misleading claims or unfair practices, just as it does for other products.

Despite coordinated efforts of the government and the public health community, tobacco use in the United States continues to cause substantial health risks. Products that could significantly reduce those risks could provide a substantial health benefit. For example, products that satisfy a smoker's craving for nicotine with substantially fewer risks to health than cigarettes would have the potential to benefit consumers. At the same time, consumers may be injured if advertisers make harm reduction claims that turn out to be untrue or that exaggerate the benefits or safety of their products.

There are currently a variety of products being developed or already in test markets that are intended to reduce the risks associated with smoking. These products include Eclipse (an R. J. Reynolds Tobacco Company product that heats, rather than burns, tobacco) and Accord (a Philip Morris USA system in which special cigarettes are smoked in an electronic lighter); cigarettes and other tobacco products with reduced levels of nitrosamines (one category of constituents in tobacco that have been classified as known carcinogens), such as that developed by Star Scientific, Inc.; and Omni, which Vector Tobacco, Inc. has marketed as "the first reduced carcinogen cigarette."

There are also products termed "nicotine replacement therapies" ("NRT") that the Food and Drug Administration currently allows to be marketed for smoking cessation purposes: nicotine gums, transdermal patches, lozenges, inhalers, and nasal sprays. These nicotine delivery devices have been studied and approved only for short-term use to help smokers quit smoking, rather than for long-term "harm reduction" use by people who are unable or unwilling to quit smoking.

Finally, in February 2002, the United States Smokeless Tobacco Company ("USST") petitioned the Commission for an advisory opinion regarding the acceptability of communicating in advertising a harm reduction claim for smokeless tobacco. USST withdrew the petition in August 2002, stating that it would provide the Commission with information from two upcoming scientific conferences that would be addressing issues relevant to the petition. On May 9, 2003, USST provided this additional information to the Commission, and asked that the Commission place this new information on the public record and hold a "public forum" to discuss these issues.

In considering advertising or other marketing claims by potential reduced risk tobacco products, the Commission would consider whether harm reduction claims may be deceptive using the same legal framework that it uses for all consumer products under Section 5 of the FTC Act: whether the advertising conveys a message that is likely to mislead reasonable consumers to their detriment, including claims for which the advertiser did not have adequate substantiation. The Commission's experience suggests that harm reduction claims are likely to raise difficult questions of advertising interpretation, as well as complex scientific and public health issues.

In examining a harm reduction claim, the first question that the Commission would address is what messages consumers take away from the advertising in question. Taking into account the full context of the advertising in which the claim appears,<sup>(16)</sup> the Commission would seek to identify the range of messages - both express and implied - that consumers would take from the advertisement. These would include: (1) whether claims about a reduction in carcinogens and toxins in the product conveys risk reduction messages; and (2) whether consumers might take away from a harm reduction representation the message that a product containing known carcinogens was not just safer than cigarettes, but that it poses no risk or only a minimal risk.

Once the Commission has determined what messages consumers take away from a particular ad, the next issue is whether those claims are truthful and substantiated. The FTC Act requires that objective claims about products and services be substantiated before the ad is disseminated. When the advertisement does not claim to have a specific level of substantiation supporting its claims, the Commission determines what constitutes a reasonable basis for those claims by analyzing the so-called "Pfizer factors": the type of claim; the benefits if the claim is true; the consequences if the claim is false; the ease and cost of developing substantiation for the claim; the type of product; and the level of substantiation experts in the field would agree is reasonable. *Pfizer, Inc.*, 81 F.T.C. 23 (1972). In the context of safety claims, the FTC has typically required a substantiation standard of "competent and reliable scientific evidence."

Analyzing the evidence whether any particular tobacco product is safer than traditional cigarettes, or whether a reduction in exposure to known carcinogens is associated with reduced health risks, requires expertise in biology, chemistry, toxicology, and epidemiology, among other fields. Moreover, the scientific issues raised by purported reduced risk products are often not only extremely complex, but may take years to develop.<sup>(17)</sup> The Commission brings a unique market-based expertise to its scrutiny of consumer protection matters and our work often requires review and analysis of scientific literature. Because the Commission is an agency of lawyers and economists, however, and not a science-based agency, we rely on assistance from other experts in evaluating scientific evidence.<sup>(18)</sup> Just as the Commission has requested the assistance of the Department of Health and Human Services in connection with the test method that produces cigarette tar and nicotine ratings, the Commission would require similar assistance in evaluating the substantiation for advertising claims made for reduced-risk tobacco products.

Finally, although a determination that an individual risk reduction claim is truthful and substantiated would end the Commission's deception inquiry, broader public health issues may remain.<sup>(19)</sup> For example, some commenters on the USST petition focused on the overall impact on public health from the marketing of these products; these comments argued that smokeless tobacco promoted as a reduced risk product might degrade overall public health, depending on how consumers react.<sup>(20)</sup> Similarly, some commenters questioned whether such advertising and promotion might promote more widespread use of smokeless tobacco, rather than just as a replacement for smoking.<sup>(21)</sup> Others, however, believe that notwithstanding this empirical question, the potential harm to public health is not clear enough to justify depriving individuals of information they might use to reduce risks to their own health.<sup>(22)</sup> This debate on the public health effects of these alternative tobacco products is an important one the appropriate science-based agencies of the government need to address.

Health claims in advertising, including tobacco advertising, are of particular importance to the Commission. The Commission welcomes the Committee's interest in the role that this agency will play in ensuring that the marketplace works efficiently to provide consumers with information that may enable them to reduce their risks of smoking-related disease, while protecting them from claims that are not supported by sound scientific evidence. The agency is committed to reviewing advertising for potential reduced risk tobacco products on a case-by-case basis to try to ensure that the information consumers receive about reduced risk products is truthful and non-misleading.

## Conclusion

The Commission thanks this Committee for focusing attention on this important and evolving public health issue, and for giving us an opportunity to present our views.

## Endnotes:

1. The written statement presents the views of the Federal Trade Commission. Oral testimony and responses to questions reflect my views and do not necessarily reflect the views of the Commission or any Commissioner.
2. See, e.g., *Julep Tobacco Co.*, 27 F.T.C. 1637 (1938) (stipulation prohibiting claims that Julep cigarettes help counteract throat irritations due to heavy smoking and never make the throat dry or parched).

3. See Trade Regulation Rule for the Prevention of Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 Fed. Reg. 8324, 8354 (1964).

4. Pub. L. No. 89-92, 79 Stat. 282 (1965), as amended by Pub. L. No. 98-474, 98 Stat. 2204 (1984), and by Pub. L. No. 99-92, § 11, 99 Stat. 393, 402-04 (1985), current version at 15 U.S.C. § 1331 (1994).

5. See *Lorillard et al.*, 80 F.T.C. 455, 460-65 (1972) (consent orders). Under the orders entered into with six tobacco manufacturers, the companies were required to disclose the Surgeon General's warning in identified forms of advertising. The consent orders were modified in 1981, when the Commission sought civil penalties in federal district court against each of the cigarette companies for failure to comply with the 1972 orders. See *United States v. Lorillard*, No. 76-Civ. 814 (JMC) (S.D.N.Y. July 13, 1981).

In 1982, the Bureau of Consumer Protection notified the House Committee on Energy and Commerce that the staff supported a new system of rotational health warnings. Letter from Timothy J. Muris, Director, Bureau of Consumer Protection, *Federal Trade Commission*, to The Honorable John D. Dingell, Chairman, Committee on Energy and Commerce, *U.S. House of Representatives* (Sept. 1, 1982). In May 1984, the Commission sent letters to Congress endorsing the concept of federal legislation to require a system of rotational health warnings that would appear in cigarette advertisements and on cigarette packages. Shortly thereafter, Congress amended the Cigarette Act to require rotational warnings for both advertising and package labeling.

6. 15 U.S.C. §§ 4401-4408.

7. Although the Commission administers the Cigarette Act, the Department of Justice enforces it.

8. 16 C.F.R. § 307.

9. In addition, the Commission issued a report on cigar advertising and promotion in 1999.

10. *F.T.C. v. Brown & Williamson Tobacco Corp.*, 580 F. Supp. 981 (D.D.C. 1983), *aff'd in part, remanded in part*, 778 F.2d 35 (D.C. Cir. 1985).

11. *R.J. Reynolds Tobacco Co.*, 127 F.T.C. 49 (1999). The Commission's complaint was issued on May 28, 1997. On January 26, 1999, the Commission dismissed the complaint without prejudice because the relief sought had been achieved through, *inter alia*, the master settlement between the major tobacco companies and the attorneys general for 46 states.

12. *Santa Fe Natural Tobacco Co.*, Docket No. C-3952 (2000) (consent); *Alternative Cigarettes, Inc.*, Docket No. C-3956 (2000) (consent); *R.J. Reynolds Tobacco Co.*, Docket No. C-3892 (1999) (consent).

13. *Alternative Cigarettes, Inc.*, Docket No. C-3956 (June 14, 2000) (consent). See also *Alan V. Phan*, 116 F.T.C. 162 (1993) (consent order settling allegations that advertisements misrepresented the health risks of smoking certain non-tobacco cigarettes).

14. Letter from Donald S. Clark, Secretary, *Federal Trade Commission* to the Honorable Donna E. Shalala, Secretary, *Department of Health and Human Services* (Nov. 19, 1998).

15. *Federal Trade Commission Report to Congress For 1998 Pursuant to the Federal Cigarette Labeling and Advertising Act* 6 (2000) ("the Commission strongly recommends that Congress give cigarette testing authority to one of the Federal government's science-based, public health agencies"); *Federal Trade Commission Report to Congress For 1997 Pursuant to the Federal Cigarette Labeling and Advertising Act* 5-6 (1999).

16. The messages consumers take away from a particular statement in an advertisement depend on the overall context in which that statement appears. Accordingly, the Commission ordinarily evaluates each advertisement in its entirety. It is difficult to determine what messages consumers take away from a generic statement about a particular class of products without placing that statement in the context of an actual advertisement.

17. The history of low tar cigarettes provides an example. One recent survey of current evidence concludes that although low tar cigarettes were initially marketed as safer alternatives than regular cigarettes, recent evidence suggests that they may convey no such benefit. See National Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*, Smoking and Tobacco Control Monograph No. 13, at 9 (2001) ("When all of the epidemiological evidence is considered in the context of what is currently known about cigarette design and compensation, it does not support the conclusion that a reduction in disease risks has occurred in the population of smokers due to the design changes that have occurred in cigarettes over the last 50 years.").

18. Tobacco is not the only category of products for which the Commission turns to other federal entities that possess specialized scientific expertise. For example, the FTC works closely with the Food and Drug Administration in the dietary supplement field, and with the Environmental Protection Agency in the areas of energy conservation, gasoline marketing, and claims for pesticides.

19. *E.g.*, Institute of Medicine, *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction* 6 (2001) (potential reduced-exposure products "are potentially beneficial, but the net impact on population health could, in fact, be negative. The effect on public health will depend upon the biological harm caused by these products and the individual and community behaviors with respect to their use.").

20. *E.g.*, Letter from Matthew L. Myers, President, *Campaign for Tobacco-Free Kids* to The Honorable Donald S. Clark, Secretary, *Federal Trade Commission* (Feb. 25, 2002) (comparative health claims made for smokeless tobacco must not only be truthful, but should promote the public health); Letter from Henry A. Waxman, U.S. House of Representatives and Senator Richard J. Durbin, United States Senate to The Honorable Donald S. Clark, Secretary, *Federal Trade Commission* (June 4, 2002) (noting that the potential health benefits that might result from smokers switching to smokeless tobacco were offset by the risks that some smokers who would have quit might, instead, switch to smokeless tobacco; that smokeless tobacco might become more attractive to nonsmokers; and that some of those nonsmokers - once addicted to nicotine - might switch to cigarettes). See also, *e.g.*, WHO Scientific Advisory Committee on Tobacco Product Regulation, *Recommendation on Smokeless Tobacco Products* 3 (2003) (listing arguments against the use of smokeless tobacco for purposes of harm reduction); .

21. *E.g.*, Letter from Matthew L. Myers, *supra* note 20 (despite USST's stated interest in making harm reduction claims to addicted adult smokers, FTC approval of petition would permit it "to disseminate these claims in ads whose primary appeal could be to young non-tobacco users"); Letter from Dileep G. Bal, M.D., Chief, Cancer Control Branch, *State of California Health and Human Services Agency - Department of Health Services* to The Honorable [Donald] S. Clark, Secretary, *Federal Trade Commission* (March 8, 2002) ("While USSTC [sic] claims that this health advisory is meant to claim harm reduction for the benefit of addicted adults, it would allow USSTC [sic] and other companies to market their products with this claim to young, non-tobacco users as well).

22. L. Kozlowski, *Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options*, *Nicotine & Tobacco Research* S55-S60 (2002) (noting that nicotine replacement therapies and snus [Swedish moist snuff] are much safer than cigarettes; that there is a basic human right to information that affects one's health; and that when the health risks from a product are relatively small, "the level of increased use needed to maintain a public health equilibrium (no changes in population-level problems) becomes very high.") (citation omitted). See also Tobacco Advisory Group of the Royal College of Physicians, *Protecting smokers, saving lives: The case for a tobacco and nicotine regulatory authority* 2-5 (2002) (supporting comprehensive regulatory approach to tobacco in order to promote public health and noting that emergence of reduced risk products presents multiple challenges for regulators; smokeless tobacco is "10-1,000 times less hazardous than smoking, depending on the product" but its potential marketing as a harm reduction option raises various questions that must be addressed, including minimizing its use as a starter product for young smokers).