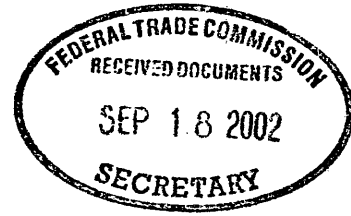


BEFORE THE
FEDERAL TRADE COMMISSION
Washington, D.C. 20580



)
In Re: Petition for Rulemaking)
Concerning Tar and Nicotine)
Testing and Disclosure)
_____)

Docket No. _____

PETITION FOR RULEMAKING

PRELIMINARY STATEMENT

Philip Morris Incorporated ("PM"), by counsel and pursuant to 16 C.F.R. § 1.9 and Section 18 of the Federal Trade Commission Act ("FTCA"), 15 U.S.C. § 57(a)(1)(B), hereby petitions the Federal Trade Commission ("FTC") to promulgate rules governing:

- (1) the disclosure of average tar and nicotine yields of cigarette brands,
- (2) the use of disclaimers with respect to average tar yield and the health effects of "low-yield" cigarettes,¹ and
- (3) the use of descriptors, such as "light" and "ultra light."

¹ The FTC has historically defined "low-yield" cigarettes by tar range. For instance, as early as 1968, the FTC established three "categories" of tar yields: 15 mg and under; 16-21 mg; and 22 mg. The FTC characterized low-yield cigarettes as those having 15 milligrams of tar or less. FTC Report to Congress at 18-19 (June 30, 1968) (Ex. 1). As the industry succeeded in reducing average tar yields, standardized industry practices in the use of descriptors is reflective of those reductions. Today, continuing to rely on the FTC method, the industry standard for full-flavor cigarettes are those with an average yield of 15 mg or more tar per cigarette; light cigarettes those with an average yield of 7 to 14 mg of tar per cigarette; and ultra lights an average yield of less than 7 mg of tar per cigarette.

The requested action by the FTC is appropriate in light of recent scientific developments, described below, culminating in the release of the National Cancer Institute's *Risk Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*, Smoking and Tobacco Control Monograph No. 13, Bethesda, MD: U.S. Department of Health and Human Services, NIH Pub. No. 02-5074 (Oct. 2001) (Ex. 2) ("Monograph 13").

By this petition, PM is requesting that the FTC take immediate action in response to evolving scientific information about low-yield cigarettes. Historically, the FTC has played a central role in developing the method for measuring average tar and nicotine yields and in determining what communications would be permitted regarding those yields. Beginning in the 1950s, credible scientific evidence began appearing suggesting that reductions in tar and nicotine yields in cigarettes would reduce the risk of certain diseases, such as lung cancer.² Based on this evidence, the public health community urged tobacco companies to develop and market low-yield cigarettes and repeatedly advised smokers who would not quit to smoke low-yield cigarettes.³

In March 1966, consistent with the position of the public health community, the FTC announced that it would permit statements of average tar and nicotine yield, but

² See, e.g., E.L. Wynder, et al., A Study of Tobacco Carcinogenesis. II. Dose-Response Studies, *Cancer* 10(6): 1193-1200 (1957) (Ex. 3); E.C. Hammond, et al., 'Tar' and Nicotine Content of Cigarette Smoke in Relation to Death Rates, *Environmental Research* 12:263-74 (1976) (Ex. 4); E.A. Zang & E.L. Wynder, Cumulative Tar Exposure: A New Index for Estimating Lung Cancer Risk among Cigarette Smokers, *Cancer* 70(1):69-75 (1992) (Ex. 5).

³ See, e.g., Monograph 13 at 69 (Ex. 2); Smoking and Health – A Report of the Surgeon General, xiv (1979) (Ex. 6); The Health Consequences of Smoking: The Changing Cigarette – A Report of the Surgeon General v (1981) (Ex. 7).

only if such statements were based on the results of a standardized test method – the Cambridge Method:

On the basis of the facts now available to it, the Commission has determined that a factual statement of the tar and nicotine content . . . would not be in violation of [FTC] Guides, or of any of the provisions of law administered by the Commission, so long as (1) no collateral representation (other than factual statement of tar and nicotine contents of cigarettes offered for sale to the public) are made, expressly or by implication, as to reduction or elimination of health hazards, and (2) the statement of tar and nicotine content is supported by adequate records of tests conducted in accordance with the Cambridge Filter Method⁴

The FTC made clear that the measurements provided by the Cambridge Method should be the only measurements communicated to the public: “statements or representations” of tar or nicotine yield based on other testing methodologies “would tend to confuse and mislead the public.”⁵ Three years later, the FTC proposed a trade regulation rule requiring the disclosure of tar and nicotine ratings in cigarette advertisements.⁶ The tobacco industry responded by voluntarily agreeing to disclose average tar and nicotine yields as measured by the Cambridge Method in cigarette advertising – and has continued to do so to this day.⁷

⁴ Trade Regulation Reporter ¶ 39,012, at 41,603 (CCH 1995) (Ex.8).

⁵ Letter from Joseph W. Shea to Howard H. Bell of 10/25/67 at 3 (2023098313) (Ex. 9).

⁶ 35 Fed. Reg. 12,671 (Aug. 8, 1970) (Ex. 10).

⁷ FTC Report to Congress at 18-19 (Dec. 31, 1970) (Ex. 11). This new requirement was “strongly” supported by prominent U.S. public health organizations, such as the American Cancer Society. Letter from E. Cuyler Hammond to Miles Kirkpatrick of 10/29/70 at 3 (TIMN 0069530) (Ex. 12).

Throughout the last several decades, the FTC continued to monitor the tobacco companies' statements regarding average tar and nicotine yields. The FTC has specifically permitted the use of descriptors, such as "low," "lower," and "reduced" tar that reflect the Cambridge Method's yield measurements.⁸ In September 1997, the FTC most recently raised the issue of whether the use of the Cambridge Method test is potentially misleading to smokers who might think that the average per cigarette yields disclosed reflect actual smoker intake. Accordingly, the FTC issued a notice for comment on proposed revisions to the testing methodology.⁹ At the same time, the FTC expressed concern about descriptive terms such as "light" and "ultra light" and asked for comment: "Is there a need for official guidance with respect to the terms used in marketing lower rated cigarettes? If yes, why? If no, why not?"¹⁰ In 1998, the FTC requested that the Department of Health and Human Services ("HHS") "conduct a complete review of the FTC's cigarette testing methodology." The HHS in turn asked the National Cancer Institute ("NCI") to review the evidence of the relationship between machine-measured cigarette yields and disease risk. Three years later, on November 27, 2001, the NCI issued Monograph 13. In response to the Monograph, the FTC stated that it would be "working with" HHS "to fix the current cigarette tar and nicotine testing methodology." No timetable has been set, and the matter is pending.

⁸ See, e.g., Decision and Order, In the Matter of American Brands, Inc., No. 8799 (Aug. 20, 1970) (Ex. 13); 59 Fed. Reg. 51,980, at 51,981 (Oct. 13, 1994) (Ex. 14).

⁹ FTC Report to Congress for 1996 at 1 (Ex. 15); see also 62 Fed. Reg. 48,158 (Sept. 12, 1997) (Ex. 16).

¹⁰ 62 Fed. Reg. 48,158, at 48,163 (Ex. 16).

In short, the FTC for the last five years has been considering what action, if any, to take on the subject matter of low tar cigarettes. Meanwhile, since 1997, concerns have increased with respect to (1) whether the FTC's Cambridge Method provides meaningful information to consumers and (2) whether descriptors, such as "light" and "ultra light," are potentially misleading to some consumers.¹¹ Recently emerging scientific analyses, such as those presented in NCI's Monograph 13, have placed into doubt the premise under which the FTC previously acted in this area: that low-yield cigarettes reduce the risk of harm. NCI's Monograph 13 concludes that "[t]here is no convincing evidence that changes in cigarette design between 1950 and the mid 1980s have resulted in an important decrease in the disease burden caused by cigarette use either for smokers as a group or for the whole population."¹²

Against this backdrop, PM respectfully files this petition asking the FTC to take immediate and appropriate action in light of the current state of the science in this area. Specifically, PM submits that, in response to recent criticism of the Cambridge Method, the FTC should reconsider its use of the Cambridge Method and consider whether a new method for determining tar and nicotine yields will more accurately estimate tar and nicotine delivery to the smoker. PM stands ready to assist the FTC in attempting to develop such a method. Further, PM submits that the FTC should require disclosure of tar and nicotine yields (as measured by the Cambridge Method or, if adopted, an

¹¹ See, e.g., Monograph 13 at 10 ("Measurements of tar and nicotine yields using the FTC method do not offer smokers meaningful information on the amount of tar and nicotine they will receive from a cigarette.") (Ex. 2); *id.* at 197 ("many consumers use the terms 'Light' and 'Ultra Light' as a guide to the riskiness of particular brands of cigarettes").

¹² *Id.* at 81.

alternative method) and require that any such disclosure be accompanied by certain disclaimers. The purpose of these disclaimers would be to communicate to the public uniform and consistent messages: (1) that the amount of tar delivered by any cigarettes depends on how a person smokes the cigarette, (2) that smokers may intake more tar and nicotine than estimated by the Cambridge Method, (3) that low-tar cigarettes have not been established to be safer than other cigarettes, and (4) that smoking low-tar cigarettes does not make quitting smoking easier. Finally, PM submits that the FTC – while requiring the above-described disclaimers – should continue to allow the use of descriptors to differentiate among brands and brand styles, particularly within a single brand family, and to provide information relating to differences in taste. The FTC, however, should promulgate appropriate regulations to ensure that descriptors are used in a uniform manner throughout the industry and are defined by specific tar and nicotine ranges as prescribed by the FTC.

BACKGROUND

I. CURRENT REGULATORY SCHEME RELATING TO TAR AND NICOTINE TESTING AND DISCLOSURE

For more than three decades, the FTC has collected and published average per cigarette tar and nicotine yields using the Cambridge Testing Method. At the FTC's request, the cigarette companies entered into an agreement requiring the disclosure of these average yields in advertisements. Consistent with the FTC's policy, the cigarette companies have used descriptors such as "light" and "ultra light" to refer to taste characteristics as well as to ranges of average tar and nicotine yields.

The instant petition is submitted against the backdrop of the FTC's actions and regulations in this area, which we outline below.

A. The FTC's Decision to Ban Tar and Nicotine Disclosures

In the mid-1950s, in response to what it perceived as a rising number of health claims in cigarette advertising, the FTC issued Cigarette Advertising Guidelines. Among other things, the Guidelines prohibited claims “that any brand of cigarette or the smoke therefrom is low in nicotine or tars . . . when it has not been established by competent scientific proof . . . that such difference or differences are significant.”¹³ In December 1959, the FTC notified the industry that it considered “all representations of low or reduced tar . . . to be health claims” and advised each manufacturer to cease making such representations.¹⁴ In short, the FTC took the position that disclosures of tar and nicotine yields were inherently deceptive and would not be allowed. A month later, the FTC negotiated an agreement with the industry banning tar and nicotine advertising.¹⁵

Although the agreement was technically voluntary, the Chairman of the FTC subsequently explained that, if necessary, the Commission would have enforced the agreement with litigation:

[The Guidelines] constituted, in effect, informal advice and guidance to industry with respect to the regulatory posture which the Commission had reason to believe would be established as a basis for issuance of complaints, and

¹³ Trade Regulation Reporter ¶ 39,012, at 41,602 (CCH 1995) (Ex. 8).

¹⁴ See, e.g., Letter from William H. Brain to Addison Yeaman of 12/17/59 at 1 (521058489) (emphasis added) (Ex. 17).

¹⁵ Trade Regulation Reporter ¶ 7853.51, at 11,730 (CCH 1988) (“[T]here will be no more tar and nicotine claims in cigarette advertising.”) (Ex. 18); see also Annual Report of the FTC for the Fiscal Year Ended 82 (June 30, 1960) (“In the most important achievement under [the guidelines] the seven major manufacturers agreed to delete all tar and nicotine claims from cigarette advertising – a noteworthy example of industry-government cooperation to eliminate a practice considered deceptive and confusing to the public.”) (Ex. 19).

subsequent proceedings under Section 5(B) of the Federal Trade Commission Act. . . .

In 1960, then, the Commission was informing the industry that in its opinion the evidence then available would support a complaint against any marketer who made any reference to tar and nicotine content, charging that such a reference was false and misleading.¹⁶

B. Growing Evidence in Support of Lower Tar and Nicotine

At the same time that the FTC was banning disclosure of tar and nicotine yields, scientific evidence began to emerge indicating that lowered yields of tar and nicotine reduce the risk of contracting certain types of disease, such as lung cancer. For example, in the 1950s, scientists discovered a dose-response relationship between skin tumors in laboratory animals and exposure to cigarette tar.¹⁷ Scientists inferred from this evidence that reducing the tar yields of cigarettes might reduce the risk of lung cancer. In 1957, Dr. Ernst Wynder – one of the pioneers of smoking and health research – advocated a 40% reduction in tar yields based on the findings in the mouse skin painting experiments.¹⁸ Dr. Wynder's historic recommendation led the way to a public health consensus that tar and nicotine reductions were an important potential means of reducing the health risks associated with smoking.

¹⁶ Letter from Chairman Paul Rand Dixon to the Honorable Warren G. Magnuson of 4/11/66 at 2-3 (Ex. 20).

¹⁷ See, e.g., E.L. Wynder, et al., A Study of Tobacco Carcinogenesis. II. Dose-Response Studies, Cancer 10(6): 1193-1200 (1957) (Ex. 3).

¹⁸ E.L. Wynder & J. Mann, A Study of Tobacco Carcinogenesis. III. Filtered Cigarettes, Cancer 10(6): 1201-05, 1204 (1957) (Ex. 21); see also E.L. Wynder, et al., A Study of Tobacco Carcinogenesis. II. Dose-Response Studies, Cancer 10(6): 1193-1200, 1199 (1957) (Ex. 3).

In 1966, the U.S. Public Health Service convened a technical committee of scientific experts to consider whether tar and nicotine reductions should be encouraged.

After evaluating the evidence, the committee concluded that:

[t]he preponderance of scientific evidence strongly suggests that the lower the 'tar' and nicotine content of cigarette smoke, the less harmful would be the effect.

The committee "recommend[ed] to the Surgeon General that action be encouraged which will result in the progressive reduction of the 'tar' and nicotine content of cigarette smoke."¹⁹

In an effort to obtain additional evidence as to whether reductions in tar would be beneficial, in the mid-1960s scientists began to conduct epidemiological studies that examined the effects of smoking low-yield cigarettes. The scientists compared the disease rates for smokers of low-yield or filtered cigarettes to the disease rates for smokers of high-tar, non-filtered or "full-flavored" cigarettes. The NCI published the first study of this kind in 1968. The study showed that smokers who switched to filtered cigarettes had a 40% reduced risk of lung cancer as compared to smokers of other cigarettes. The author concluded that further tar and nicotine reductions could provide even greater protection:

These findings provide the first human evidence that redesign of the product can reduce health hazards. They indicate that, if full advantage were taken of existing filter

¹⁹ Reviewing Progress Made Toward the Development and Marketing of a Less Hazardous Cigarette, Hearing Before the Consumer Subcomm. of the S. Comm. on Commerce, 90th Cong. 7-8. (1967) (Ex. 22). The committee's written report was circulated in 1966, but was not formally submitted to Congress until 1967.

and other cigarette technology, a greater protection could be provided immediately.²⁰

This finding was confirmed almost immediately in a 1970 epidemiological study conducted by Dr. Wynder, who found that filtered cigarette smokers had a reduced risk of lung cancer compared to non-filtered cigarette smokers.²¹

C. The FTC Reverses Its Position

As a result of this growing scientific evidence that filtered cigarettes reduce the risk of certain types of disease, the FTC in March 1966 reversed its position and allowed the disclosure of tar and nicotine yields in cigarette advertisements – albeit only under certain conditions. The FTC sent letters to each of the manufacturers explaining that “a factual statement of the tar and nicotine content (expressed in milligrams) of the mainstream smoke from a cigarette would not be in violation” of the 1955 Guidelines, so long as the measurements are “supported by adequate records of tests conducted in accordance with the Cambridge Filter Method.”²² Its goal was “to encourage cigarette manufacturers to provide consumers with comparative information about their products’ tar and nicotine yields.”²³ The FTC subsequently explained that this decision to “augment information available to the public on the tar and nicotine content of cigarettes”

²⁰ I.D.J. Bross, Effect of Filter Cigarettes on the Risk of Lung Cancer, NCI Monograph 28: 35-40, 38 (1968) (Ex. 23).

²¹ E.L. Wynder, et al., The Epidemiology of Lung Cancer – Recent Trends, J. Amer. Med. Ass’n 213(13): 2221-28 (1970) (Ex. 24).

²² Trade Regulation Reporter ¶ 39,012, at 41,603 (CCH 1995) (Ex. 8).

²³ C.L. Peeler, Cigarette Testing and the Federal Trade Commission: A Historical Review, in The FTC Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes: Report of the NCI Expert Committee, Smoking and Tobacco Control Monograph 7: 1-8, 1 (1996) (Ex. 25) (hereinafter, “Peeler”).

was “[b]ased on the proposition that lower yield cigarettes present a lessened hazard to the American public.”²⁴ The FTC admonished, however, that “statements or representations” of tar yield “based on non-standardized tests having no official or governmental sanction would tend to confuse and mislead the public”²⁵ – and thus would not be allowed.

At about the same time, the FTC issued a notice seeking comment as to “what action, if any, should be taken in the public interest with respect to modifying or amplifying the Cambridge Filter Method” and announced that it would hold a hearing on the subject.²⁶ Before the hearing, the tobacco industry made a submission advising the FTC about the difficulties that are inherent in measuring the tar that any individual smoker will intake: “Cigarette smokers vary greatly in their manner of smoking – puffing rate, volume, frequency, length of cigarette smoked, etc.”²⁷ After the hearing, the industry again pointed out the limitations of the proposed testing methodology:

The [Cambridge] Method does not measure the volume of smoke – or the PM [particulate matter] or nicotine in the volume of smoke – that any human being will draw from smoking any particular cigarette. Each smoking characteristic is leveled or averaged out by the standard method.

No two human smokers smoke in the same way.
No individual smoker always smokes in the same
fashion. . . .

²⁴ FTC Report to Congress at 17 (June 30, 1968) (Ex. 1).

²⁵ Letter from Shea to Bell of 10/25/67 at 3 (2023098311) (Ex. 9).

²⁶ 31 Fed. Reg. 14,278 (Nov. 4, 1966) (Ex. 26).

²⁷ Before the Federal Trade Commission, Technical Data and Recommendations at 18 (Nov. 28, 1966) (1005115719) (Ex. 27).

The [Cambridge] Method does not and cannot measure these many variations in human smoking habits.²⁸

Notwithstanding the industry's observations regarding the limitations of the testing method, the FTC began testing cigarettes by the Cambridge Method in August 1967.²⁹ The FTC justified its use of the Cambridge Method in a press release, in which the Commission acknowledged the limitations of its method.³⁰ At times copying the industry's statements verbatim, it advised that "[n]o two human smokers smoke in the same way" and that its test "does not and cannot measure these many variations in human smoking habits."³¹ The FTC noted further that its method does not even attempt to

²⁸ Supplemental Observations Following November 30, 1966 Hearing Before the Federal Trade Commission at 2-3 (emphasis in original) (Ex. 28). The industry continued to point out the limits of the test method even after the Cambridge method was adopted. For instance, in the context of the Barclay dispute, discussed below, Brown & Williamson advised the FTC that "[a]ny one smoker can and may reduce the dilution by the way he or she holds the cigarette with hand or lips." Letter from Martin London to Matthew L. Myers of 7/16/81 at 17 (03531854) (Ex. 29).

²⁹ See 32 Fed. Reg. 11,178 (Aug. 1, 1967) ("issu[ing] directions . . . to commence the first formal test") (Ex. 30).

³⁰ See Press Release, FTC to Begin Cigarette Testing (Aug. 1, 1967) (Ex. 31) (hereinafter, "Press Release").

³¹ *Id.* at 2. The FTC has repeated this warning about the limitations of its testing methodology on numerous occasions. See, e.g., FTC Report to Congress for the Year 1977 at 6 & n.6 ("implication" that cigarettes with lower tar ratings may be safer is correct only "as long as the smoker does not smoke more cigarettes, smoke further down on the cigarettes smoked, inhale more deeply, or otherwise modify his or her smoking behavior") (Ex. 32); FTC Report to Congress for the Year 1981, Attachment at 4 ("If consumers who switch to lower yield cigarettes change their smoking pattern, for example, by smoking more cigarettes per day, they may receive a greater yield than suggested by the FTC test results.") (Ex. 33); FTC Report to Congress for 1993 ("The Commission alleged that consumers would not necessarily get less tar because the ratings shown in the ads were obtained by smoking machines that did not reflect actual smoking, partly because they did not account for 'compensatory smoking.'") (Ex. 34); FTC Consumer Alert, Up in Smoke: The Truth about Tar and Nicotine Ratings (May 2000) ("The Federal Trade Commission wants you to know that cigarette tar and nicotine

[Footnote continued on next page]

determine “the amount of smoke, or tar and nicotine, which the ‘average’ smoker will draw from any particular cigarette,” because “there are too many variables as to both smokers and smoking conditions for any average to be meaningful.” Indeed, the FTC was concerned that any attempt to determine results for an “average” smoker “could be misleading to the public, because a smoker has no way of knowing how closely his smoking habits conform to those of the purportedly ‘average’ smoker.”³²

Nonetheless, the FTC made clear that it would require the use of the Cambridge Method. The FTC concluded that “the public interest requires that all test results presented to the public be based on a uniform method” because “use of more than one testing method . . . would only serve to confuse or mislead the public.”³³ The FTC chose the Cambridge Method to be the “uniform method” because it provides a “reasonable standardized method” that was “capable of being presented to the public in a manner that is readily understandable.”³⁴ Finally, the FTC promised that it would “continue evaluating its results, and on that basis may determine in the future to change the number of cigarettes tested or any other testing procedures as may be found necessary.”³⁵

[Footnote continued from previous page]
ratings can’t predict the amount of tar and nicotine you get from any particular cigarette.”) (Ex. 35).

³² Id.

³³ Id. at 1-2.

³⁴ Id. at 1; see also Peeler at 2 (Ex. 25) (“[T]he Commission believed that the most important thing was to make certain the results presented to the public were based on a reasonable, standardized method and could be presented to consumers in an understandable manner.”).

³⁵ Press Release at 2-3 (Ex. 31).

Three years later, the FTC went a step further and proposed a trade regulation rule requiring the disclosure of tar and nicotine ratings in cigarette advertisements.³⁶ Thus, in just 10 years, the FTC went from a position of banning tar and nicotine disclosures to a position of requiring such disclosures. In justifying its proposal, the FTC explained that “responsible medical opinion indicates that the reduction of tar and nicotine content in cigarette smoke decreases the hazard to the health” and thus “[t]o promote the public interest, advertisers should not be discouraged from promoting these varieties which rank low in tar and nicotine.”³⁷ The FTC believed that requiring tar and nicotine disclosures would serve two purposes. First, disclosures would “lead those smokers who are unable to kick the habit to greater interest in obtaining a low tar and nicotine cigarette.” Second, disclosures would encourage “competition among the cigarette companies to meet that interest.”³⁸

Notwithstanding its proposed regulations, the FTC sent a letter to the industry expressing its willingness “to explore . . . the possibility of reaching an agreement with all of the cigarette manufacturers on the inclusion of a statement of tar and nicotine

³⁶ 35 Fed. Reg. 12,671 (Aug. 8, 1970) (Ex. 31). In 1969, Surgeon General Dr. William Stewart testified before Congress in favor of a law requiring the disclosure of tar and nicotine yields in advertisements and on packaging. Dr. Stewart explained that “[w]e believe the consumer is entitled to know the tar and nicotine levels of his cigarette. . . . It is the view of the Public Health Service that this is useful information; that the lower these levels are, the less hazardous is the cigarette likely to be.” Cigarette Labeling and Advertising, Hearings on H.R. 643, H.R. 1237, H.R. 3055 & H.R. 6543 Before the House Comm. on Interstate and Foreign Commerce, 91st Cong. 86 (1969) (statement of Dr. William H. Stewart) (Ex. 36).

³⁷ FTC Report to Congress at 14 (Dec. 31, 1970) (Ex. 11).

³⁸ *Id.* at 15. Prominent public health organizations such as the American Cancer Society “strongly” supported the proposed trade rule. Letter from Hammond to Kirkpatrick of 10/29/70 at 3 (TIMN 0069530) (Ex. 12).

contents in cigarette advertising," so long as the agreement would include an "effective method of insuring compliance with the terms of any agreement."³⁹ In response, five of the six major manufacturers submitted a written plan agreeing to include tar and nicotine disclosures in advertising, and the FTC suspended its proposed trade rule indefinitely.⁴⁰ The FTC explained that relying on the industry's plan would free its resources to pursue other matters, and at the same time warned that it would return to the proposed trade rule if necessary:

It appears to be in the public interest to afford the tobacco industry an opportunity to implement the letter and spirit of the amended plan which it has proposed. In taking this action, the Commission is retaining the unconditional right to reschedule the trade regulation rule proceedings and to take any other action relating to this subject at any time it deems such action to be necessary or desirable in the public interest.

The Commission believes that if the amended plan operates satisfactorily, the Commission will be able to employ substantial manpower and funds which would otherwise have been devoted to hearings and court proceedings to dealing with the serious problems relating to cigarette advertising.⁴¹

³⁹ Letter from FTC to Horace R. Kornegay (Sept. 16, 1970) (TIMN 0101668) (Ex. 37).

⁴⁰ FTC Report to Congress at 18-19 (Dec. 31, 1970) (Ex. 11); see also Letter from Horace R. Kornegay to FTC (Dec. 17, 1970) (TIMN 0063404) (Ex. 38).

⁴¹ FTC Report to Congress at 19 (Dec. 31, 1970) (quoting December 22, 1970 press release, attached as Appendix D) (Ex. 11).

**D. The Scientific and Public Health Community
Continued to Support Lower Tar and Nicotine Yields**

1. Scientific Evidence and Public Health Recommendations

Following the FTC's adoption of the Cambridge Method, scientific evidence continued to accumulate indicating that reductions in tar yield would reduce the risk of certain diseases, such as lung cancer.

Most notably, in 1976, the American Cancer Society ("ACS") published an epidemiological analysis of its groundbreaking Cancer Prevention Study ("CPS-I"). CPS-I tracked over one million Americans for a 12-year period. The study categorized its subjects as either "high," "medium," or "low" yield smokers, as determined by the Cambridge Method's measurements. The study found that, compared to smokers of high-tar and nicotine cigarettes, people who smoked low-yield cigarettes were 26% less likely to die from lung cancer. The study also found that the health benefits from low-yield cigarettes were not limited to lung cancer. Smokers of low-yield cigarettes had a 14% reduced risk of dying from heart disease and a 16% reduced total mortality rate. Encouraged by these findings, the ACS concluded "we think it fair to say that switching from 'high' [tar] to 'low' [tar] cigarettes was at least a small step in the right direction for those who continued to smoke cigarettes."⁴²

Numerous other studies in the United States and Europe similarly found that smokers of filtered or low-yield cigarettes as identified by the FTC or similar testing method had a reduced risk of disease:

⁴² Hammond, 'Tar' and Nicotine Content of Cigarette Smoke in Relation to Death Rates, *Environmental Research* 12: 263-74, 273 (1976) (Ex. 4).

- In 1981, an English study found that smokers of filtered cigarettes had less than 50% the lung cancer incidence of higher tar, non-filtered cigarette smokers.⁴³
- In 1984, an epidemiological study based on seven locations in Western Europe found that male smokers of filtered cigarettes had a 41% reduction in lung cancer risk as compared to non-filtered smokers and that female smokers of filtered cigarettes had a 51% reduced risk. The authors concluded “our findings indicate that lifetime filter smokers have a lower risk relative to lifetime nonfilter smokers than previously thought . . . smoking cessation must be the primary goal of efforts to prevent lung cancer, although changing to low tar (filter) cigarettes should help in reducing the risk.”⁴⁴
- In 1992, an epidemiological study conducted by Dr. Wynder projected a 15-20% reduction in lung cancer risk for every 10-mg reduction in tar yields.⁴⁵
- In 1995, a combined analysis of four British epidemiological studies found that “about a quarter of deaths from lung cancer, coronary heart disease, and possibly other smoking related diseases could be avoided by switching from higher tar cigarettes (30mg/cigarette) to lower tar ones (15mg/cigarette).”⁴⁶

As recently as 2001, researchers found that lung cancer mortality rates in young Australian women had declined despite increases in smoking prevalence, concluding that “[r]eductions in tar yields . . . may be responsible.”⁴⁷

⁴³ J. Rimington, The Effect of Filters on the Incidence of Lung Cancer in Cigarette Smokers, *Environmental Research* 24: 162-66 (1981) (Ex. 39).

⁴⁴ J.H. Lubin, et al., Patterns of Lung Cancer Risk According to Type of Cigarette Smoked, *Int'l J. Cancer* 33: 569-76, 575 (1984) (Ex. 40).

⁴⁵ Zang & Wynder, Cumulative Tar Exposure: A New Index for Estimating Lung Cancer Risk among Cigarette Smokers, *Cancer* 70(1): 69-75 (1992) (Ex. 5).

⁴⁶ J.L. Tang, et al., Mortality in Relation to Tar Yield of Cigarettes: A Prospective Study of Four Cohorts, *Brit. Med. J.* 311: 1530-33, 1533 (1995) (Ex. 41).

⁴⁷ L. Blizzard & T. Dwyer, Declining Lung Cancer Mortality of Young Australian Women Despite Increased Smoking is Linked to Reduced Cigarette ‘Tar’ Yields, *Brit. J. Cancer* 84(3): 392-96, 396 (2001) (Ex. 42)

Relying on these and other studies, public health officials concluded that low tar cigarettes did reduce disease risk. In a 1981 comprehensive review, the Surgeon General concluded that “[t]oday’s filter-tipped, lower ‘tar’ and nicotine cigarettes produce lower rates of lung cancer than do their higher ‘tar’ and nicotine predecessors.”⁴⁸ In 1986, the International Agency for Research on Cancer (“IARC”) similarly concluded that the epidemiological evidence “suggest[ed] that prolonged use of non-filter and high-tar cigarettes is associated with greater lung cancer risks than prolonged use of filter and low-tar cigarettes.”⁴⁹ More recently, in 1996, the NCI concluded that the “more recent” scientific evidence continued to support the Surgeon General’s 1981 conclusion that “[t]oday’s filter-tipped, lower ‘tar’ and nicotine cigarettes produce lower rates of lung cancer than do their higher ‘tar’ and nicotine predecessors.”⁵⁰

Consistent with these conclusions, the public health community throughout the world called for cigarette manufacturers to reduce tar and nicotine yields in their cigarettes:

⁴⁸ U.S. Department of Health and Human Services, The Health Consequences of Smoking: The Changing Cigarette – A Report of the Surgeon General, 18 (1981) (Ex. 7).

⁴⁹ IARC Working Group, IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans: Tobacco Smoking 38: 1-421, 313 (1986) (emphasis added) (Ex. 43).

⁵⁰ J.M. Samet, The Changing Cigarette and Disease Risk: Current Status of the Evidence, in The FTC Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes: Report of the NCI Expert Committee, Smoking and Tobacco Control Monograph 7: 77-92, 86 (1996) (Ex. 44).

- In 1983, the U.K. Independent Scientific Committee on Smoking and Health concluded that it was “encouraged by the decrease in tar yields over the last few years and recommend a continued reduction.”⁵¹
- In 1985, the Fourth Scarborough Conference on Preventive Medicine – an international conference of public health authorities – issued a consensus statement declaring that “the policy [of encouraging tar and nicotine reductions] has been beneficial and that tar yields should be further reduced.”⁵²
- In 1988, the U.K. Independent Scientific Committee on Smoking and Health again concluded that “Government and the tobacco industry should consider what further action could be taken to persuade more smokers to favour low tar brands.”⁵³
- In 1991, Dr. Wynder reaffirmed the position he had advocated since the mid-1950s, explaining that “a strong social case is made for further developments in the low-yield cigarette.”⁵⁴
- In 1998, the U.K. Scientific Committee on Tobacco and Health again addressed the issue, recommending that a “policy of further tar reduction in manufactured cigarettes should be pursued.”⁵⁵
- In 2000, the Health Committee of the House of Commons focused on the fact that, notwithstanding evidence of compensation, in the U.K. “cancer rates have fallen faster than can be explained by changes in smoking prevalence and overall consumption of tobacco.” The Committee considered this trend to be evidence that “tar reduction is responsible for

⁵¹ Department of Health and Social Security, et al., Third Report of the Independent Scientific Committee on Smoking and Health, Chairman: Dr. Peter Froggatt, 11 (1983) (Ex. 45).

⁵² Participants of the Fourth Scarborough Conference on Preventive Medicine, Is There a Future for Lower-Tar-Yield Cigarettes, *The Lancet* II(8464): 1111-14, 1111 (1985) (Ex. 46).

⁵³ Department of Health and Social Security, et al., Fourth Report of the Independent Scientific Committee on Smoking & Health, Chairman: Sir Peter Froggatt, 11 (1988) (Ex. 47).

⁵⁴ D. Hoffmann, I. Hoffmann, E.L. Wynder, Lung Cancer and the Changing Cigarette, in Relevance to Human Cancer of N-Nitroso Compounds, Tobacco and Mycotoxins 449-59 (I.K. O’Neill, J. Chen, H. Bartsch, eds., 1991) (Ex. 48).

⁵⁵ Department of Health, et al., Report of the Scientific Committee on Tobacco and Health, Chairman: Professor David Poswillo, 7.21 (1998) (Ex. 49).

the health improvement,” leading it to “support further reduction in tar levels.”⁵⁶

Furthermore, the public health community went one step further and expressly urged smokers who would not quit to switch to a lower tar brand:

- In the 1960s and 1970s, the U.S. Government issued a pamphlet for smokers, entitled “If You Must Smoke,” that advised them to “[c]hoose a cigarette with less tar and nicotine.”⁵⁷
- In 1974, the U.S. Department of Health, Education, and Welfare issued a poster listing the tar and nicotine yields of commercially available cigarettes and advising smokers to switch to the cigarette with the lowest yield: “The Cigarette World is divided into the bad and the worse. You can buy as much as 34 mgs. of tar in a cigarette, or as little as 2. As much as 2.1 mgs. of nicotine, or as little as 0.2. There’s a Tar & Nicotine list below that tells you which is which. Look them up. If you must smoke, at least bad is better than worse.”⁵⁸
- In 1988, the Health Departments of the U.K. issued a poster recommending that smokers choose “a brand of cigarette in a lower tar group than the brand you smoke at present.”⁵⁹
- In 1989, the American Cancer Society issued a brochure, “Cancer Facts & Figures,” that recommended that “those who are not yet able to quit would be well advised to switch to brands with the lowest possible tar and nicotine (T/N) content.”⁶⁰

2. Compensation

In making these findings and recommendations, the scientific and public health community was always well aware of issues surrounding possible “compensation” – i.e.,

⁵⁶ 2000 U.K. House of Commons Report at ¶¶ 129, 137 (Ex. 50).

⁵⁷ U.S. Department of Health, Education, and Welfare, If You Must Smoke . . . (1973) (Ex. 51); see also U.S. Department of Health, Education, and Welfare, If You Must Smoke . . . (1969) (Ex. 52).

⁵⁸ U.S. Department of Health, Education, and Welfare, The Cigarette World is Divided into the Bad and the Worse (1974) (Ex. 53).

⁵⁹ Health Departments of the United Kingdom, Tar, Carbon Monoxide and Nicotine Yields of Cigarettes (Jan. 1988) (Ex. 54).

changes in smoking behavior accompanying a switch to a cigarette with reduced tar and nicotine yields. In leading the call for low-yield cigarettes in 1957, Dr. Wynder made clear that any potential health benefit could be eliminated by compensation, such as increasing the number of cigarettes smoked.⁶¹ Similarly, as early as 1964, the U.S. Surgeon General expressed his concern to the public – reported in a popular U.S. newsmagazine – that “removing tar [and] nicotine . . . might also lead to different levels of cigarette consumption and different amounts of inhalation, and so forth.”⁶²

Nevertheless, the scientific community generally believed that the epidemiologic findings of a reduced risk would be valid even if smokers of low-yield cigarettes compensate. The reasoning was that the studies compare the risks of smokers of low-tar cigarettes to the risks of smokers of high-tar cigarettes – and thus would inherently take into account differences in how each category of smoker smokes and the extent to which those differences in smoking behavior may affect risk. Thus, the scientific community believed epidemiological findings of reduced risk from low-yield cigarettes were valid even if the smokers of low-yield cigarettes in the studies compensated.⁶³ For example,

[Footnote continued from previous page]

⁶⁰ American Cancer Society, Cancer Facts & Figures – 1989, 21 (1989) (Ex. 55).

⁶¹ Wynder & Mann, A Study of Tobacco Carcinogenesis. III. Filtered Cigarettes, *Cancer* 10(6): 1201-05, 1204 (1957) (Ex. 21).

⁶² Answers on Filters, *U.S. News & World Report*, Jan. 27, 1964, at 38 (Ex. 56).

⁶³ Further, scientists generally believed that most smokers did not compensate by smoking more cigarettes when switching to a lower-yield brand. In 1980 scientists from the ACS analyzed CPS I and found that “over a long period of time people tend to smoke the same number of cigarettes a day regardless of the tar and nicotine level.” L. Garfinkel, Changes in Number of Cigarettes Smoked Compared to Changes in Tar and Nicotine Content over a 13-Year Period, *Banbury Report* 19 (G.B. Gori, F.G. Bock eds., 1980) (Ex. 57). Based on this and numerous other studies, in 1984 the U.S. Surgeon General concluded that smokers do not generally compensate by increasing the number

[Footnote continued on next page]

epidemiologist Dr. Jonathan Samet, in a 1996 review for NCI, explained that epidemiology was particularly important in assessing the health effects of low-yield cigarettes because it took compensation into account:

Epidemiologic research has had a central role in characterizing the consequences of the changing cigarette because it supplies direct information on the consequences of varying tar and nicotine yield products. Thus, the findings inherently consider compensatory changes in inhalation patterns or in numbers of cigarettes smoked and provide the evidence needed to answer the question of immediate public health relevance: whether disease risk varies with cigarette tar and nicotine yield as determined by the FTC method.⁶⁴

E. The FTC Continued to Re-evaluate Its Testing Methodology

Since 1970, and in light of the evolving scientific evidence, the FTC has frequently reevaluated the propriety of its tar and nicotine rating, choosing in each instance to retain it. In 1976, the FTC tentatively rejected as “inappropriate” a request by Lorillard that its Kent Golden Lights be measured at a 5 mm depth of insertion into the smoking machine (as opposed to 11 mm required by the Cambridge Method).⁶⁵ In a separate letter to Lorillard, the FTC reaffirmed its view that “it would be deceptive to

[Footnote continued from previous page]
of cigarettes smoked: “most studies agree that smokers rarely increase their daily cigarette consumption upon switching from higher to lower-yield brands.” U.S. Department of Health and Human Services, The Health Consequences of Smoking: Chronic Obstructive Lung Disease – A Report of the Surgeon General 342 (1984) (Ex. 58).

⁶⁴ J.M. Samet, The Changing Cigarette and Disease Risk: Current Status of the Evidence, in The FTC Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes: Report of the NCI Expert Committee, Smoking and Tobacco Control Monograph 7: 77-92, 79-80 (1996) (Ex. 44).

⁶⁵ 42 Fed. Reg. 21,155 (Apr. 11, 1977) (Ex. 59).

advertise a tar figure which is higher than the latest applicable FTC tar figure.⁶⁶ At the same time, however, the FTC acknowledged its concerns about whether its testing methodology adequately accounted for the possibility of ventilation blocking:

Of special concern when considering any such modification of the standard 11 mm. insertion is whether the insertion depth would and should be decreased beyond the point consumers cover the cigarette with their lips, fingers, or both when they puff. The Commission believes that additional information is necessary before deciding whether further action should be taken in connection with this matter.

42 Fed. Reg. 21,155.

Based on these concerns, the FTC solicited further comments from the industry concerning whether the depth of insertion should be varied to account for the placement of ventilation holes, and Lorillard responded by arguing in favor of a varied depth of insertion.⁶⁷ The FTC rejected Lorillard's position, explaining that "a change in the insertion depth would cause a lack of continuity with previous test results" and that it would thus be inappropriate to change the procedure "in the absence of information indicating that a new insertion depth would be more consistent with the manner in which smokers insert cigarettes in actual use."⁶⁸

In 1981, at the request of several competitor manufacturers, the FTC commenced an investigation into allegations that Brown & Williamson's Barclay cigarette "was

⁶⁶ Letter from Carol M. Thomas to Michael I. Gastman of 9/26/79 at 1 (TIMN 0063432) (emphasis added) (Ex. 60).

⁶⁷ 43 Fed. Reg. 11,856 (Mar. 22, 1978) (Ex. 61).

⁶⁸ Id. at 11,857.

assessed inaccurately by the current FTC cigarette testing methodology.”⁶⁹ In June 1982, the FTC concluded that Barclay’s tar rating was “inaccurate” because “the unique construction of the Barclay filter resulted in it delivering less tar and nicotine during smoking by the testing machine than would be delivered to an actual smoker.”⁷⁰ In April 1983, after Brown & Williamson’s attempt to enjoin the FTC from taking action had failed,⁷¹ the agency announced that it would no longer accept Barclay tar ratings based on the Cambridge Method.⁷² The FTC sought comment regarding alternate methods of measuring the tar yield of Barclay and whether it should continue using the Cambridge Method for other cigarette brands.⁷³ Ultimately, the FTC retained the Cambridge Method. “[E]ven though the limitations on the predictiveness of the FTC method caused by compensatory smoking were clearly recognized,” the FTC did not have a “sufficient basis for changing the protocol.”⁷⁴ There was “no clear consensus as to specific action the Commission could (or should) take to eliminate the limitations of the test method” and “abandoning the testing system without instituting another method would have been premature because then-current epidemiological evidence suggested that there had been a

⁶⁹ FTC Report to Congress for the Year 1981 at 3 (Ex. 33).

⁷⁰ *Id.*

⁷¹ The history of litigation between the FTC and Brown & Williamson regarding Barclay is described in *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35 (D.C. Cir. 1985) (Ex. 62).

⁷² 48 Fed. Reg. 15,953, at 15,954 (Apr. 13, 1983) (Ex. 63).

⁷³ *Id.* at 15,954-55.

⁷⁴ Peeler at 3 (Ex. 25).

reduction in lung cancer deaths that might be attributable to declines in average tar levels.”⁷⁵

Approximately a decade later, in July 1994, the FTC revisited the propriety of its rating system by asking the National Cancer Institute to convene a conference to evaluate the Cambridge method.⁷⁶ The conference recommended certain changes, set forth in NCI Monograph 7, “The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes,” published in 1996.⁷⁷ These recommendations included:

- that the “system should also measure and publish information on the range of tar, nicotine, and carbon monoxide yields that most smokers should expect from each cigarette”
- that the “system must be accompanied by public education to make smokers aware that individual exposure depends on how the cigarette is smoked and that the benefits of switching to lower yield cigarettes are small compared with quitting”
- that “[b]rand names and brand classifications such as ‘light’ and ‘ultralight’ represent health claims and should be regulated and accompanied, in fair balance, with an appropriate disclaimer”

NCI Monograph 7 at vii.

In response to these recommendations, the FTC in September 1997 issued a notice for comment on proposed revisions to the testing methodology that “would require

⁷⁵ Id. at 7.

⁷⁶ FTC Report to Congress for 1993 at 3 (Ex. 34); see also FTC News Release, FTC Seeks Study of Low-Tar Cigarette Testing Method for Your Information, 1994 WL 378961 (F.T.C. July 20, 1994) (“[T]he Commission is aware of concerns that have been raised about the limitations of the current testing methodology.”) (Ex. 64).

⁷⁷ See FTC Report to Congress for 1995 at 2 (Ex. 65).

that each cigarette variety be tested under two different sets of smoking conditions.”⁷⁸

Finally, in 1998, the FTC sought expert scientific advice again, requesting that HHS “conduct a complete review of the FTC’s cigarette testing methodology.”⁷⁹ The FTC explained that it “has been concerned for some time that the current test method may be misleading to individual consumers who rely on the ratings it produces” because the “current ratings tend to be relatively poor predictors of tar and nicotine exposure.”⁸⁰

The FTC has not made any changes to its testing methodology (other than adding measurements for carbon monoxide). That methodology has now with the publication of Monograph 13 become the subject of more intense scrutiny and appears to have few, if any, supporters in the public health community. As discussed below, PM now formally petitions the FTC to once again review the testing methodology and, if possible, develop a more appropriate methodology supportable by scientists and the public health community.

F. The FTC Scrutinized Use of Descriptors

Since 1970, the FTC has also scrutinized the manner in which the cigarette companies could use descriptors such as “light” and “lower” tar to characterize their cigarettes in advertisements. During this time period, the FTC made clear that manufacturers could use such descriptors provided that the advertisements also included the average tar measurements determined by the FTC method.

⁷⁸ FTC Report to Congress for 1996 at 1 (Ex. 15); see also 62 Fed. Reg. 48,158 (Sept. 12, 1997) (Ex. 16).

⁷⁹ FTC Report to Congress for 1997 at 5 (Ex. 66).

⁸⁰ Id. at 4.

In September 1969, the FTC issued a complaint against American Brands, Inc.'s ("American") advertisements that its Pall Mall Gold brand was "lower in tar than ever before" and that it was "[l]ower in tar than the best selling filter king."⁸¹ The FTC contended that this advertising was deceptive because American:

has represented and created the impression that its cigarettes are low in tar when in truth and in fact its Pall Mall Gold 100's and Lucky filters contain approximately 20 and 21 milligrams of tar, amounts which rank them 56th and 77th higher among the 122 brands tested than the brand containing the lowest tar level of 4 milligrams.⁸²

The dispute ultimately resulted in a consent order, in which the FTC prohibited American from:

Stating in advertising that any cigarette manufactured by it, or the smoke therefrom, is low or lower in "tar" by use of the words "low," "lower," or "reduced" or like qualifying terms, unless the statement is accompanied by a clear and conspicuous disclosure of:

1. The "tar" and nicotine content in milligrams in the smoke produced by the advertised cigarette; and
2. If the "tar" content of the advertised brand is compared to that of another brand or brands of cigarette, (a) the "tar" and nicotine content in milligrams of the smoke produced by that brand or those brands of cigarette, and (b) the "tar" and nicotine content in milligrams of the lowest yield domestic cigarette; provided that a comparison to a class of cigarettes, or to many or most of the cigarettes of a class, shall not be deemed a comparison to another brand or brands of cigarette.⁸³

⁸¹ Complaint ¶ 4, In the Matter of The American Tobacco Co., No. 8799 (Sept. 29, 1969) (Ex. 67).

⁸² Id.

⁸³ Decision and Order, In the Matter of American Brands, Inc., No. 8799 (Aug. 20, 1970) (first emphasis added; emphasis of "provided" in original) (Ex. 13).

Thus, in this consent decree, the FTC specifically permitted American to use “qualifying terms” such as “low” and “lower” provided that those terms were accompanied by a “conspicuous disclosure of [t]he tar and nicotine content in milligrams in the smoke.”

In the mid-1990s, the FTC again challenged an American advertisement, which represented that “consumers will get less tar by smoking 10 packs of Carlton than by smoking a single pack of the other brands shown in the ads, each of which was rated as having an average of more than 10 milligrams of tar per cigarette.”⁸⁴ The FTC complained that the advertisements were deceptive because “consumers would not necessarily get less tar because the ratings shown in the ads were obtained by smoking machines that did not reflect actual smoking, partly because they did not account for ‘compensatory smoking.’”⁸⁵ In January 1995, the FTC reached a consent agreement with American,⁸⁶ under which American agreed to forgo any such comparative claims.⁸⁷ Nonetheless, the agreement permitted American to use descriptors to make the “express . . . representation that [American’s] brand is ‘low,’ ‘lower,’ or ‘lowest’ in tar.”

Id.

It was not until 1997 that the FTC asked for comment regarding descriptive terms such as “light” and “ultra light” per se: “Is there a need for official guidance with respect to the terms used in marketing lower rated cigarettes? If yes, why? If no, why not?”⁸⁸ The FTC noted that descriptors “appear to be used by the industry to reflect ranges of

⁸⁴ FTC Report to Congress for 1993 at 2 (Ex. 34).

⁸⁵ Id.

⁸⁶ See FTC News Release, 1995 WL 6995 (F.T.C. Jan. 10, 1995) (Ex. 68).

⁸⁷ 59 Fed. Reg. 51,980, at 51,981 (Oct. 13, 1994) (Ex. 14).

⁸⁸ 62 Fed. Reg. 48,158, at 48,163 (Ex. 16).

FTC tar ratings.”⁸⁹ Disclaimers were also considered. The FTC has not modified its test method or required additional disclosures.

G. Monograph 13

In 1998, the FTC formally requested HHS to further review its testing method and include recommendations on whether the system should be continued and, if so, what specific changes should be made to the testing methodology.⁹⁰ HHS, in turn, asked NCI to review the evidence of the relationship between machine-measured cigarette smoke and disease risk. The result, released November 27, 2001, was Monograph 13, *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*. Monograph 13 represents “the first step in [HHS’s] response to the [FTC’s] 1998 request for assistance in developing recommendations to fix” the Cambridge Testing Method.⁹¹ Its purpose was to determine whether the scientific evidence showed that the changes in cigarette design over the last 50 years resulted in reduced disease risks for smokers.⁹²

Monograph 13 represents a fundamental departure from the scientific and public health community’s prior thinking about the health effects of low yield cigarettes. Contrary to the conclusions of the Surgeon General and the IARC – and even the NCI as recently as 1996 – Monograph 13 concludes that “there is no convincing evidence that

⁸⁹ Id.

⁹⁰ Letter from Donald S. Clark to the Honorable Donna E. Shalala of 11/19/98 at 1-2 (Ex. 69).

⁹¹ Id.

⁹² News Release, The National Cancer Institute, Questions and Answers, Monograph 13: Risks Associated with Smoking Cigarettes with Low Machine-Yield Measured Yields of Tar and Nicotine (Nov. 27, 2001). (Ex. 70).

changes in cigarette design between 1950 and the mid-1980s have resulted in an important decrease in the disease burden caused by cigarette use either for smokers as a group or for the whole population.”⁹³ The Monograph further concludes:

- The FTC Method does not provide consumers with “meaningful information” about the amount of tar and nicotine they will receive from a cigarette, either standing alone or in comparison to other brands.⁹⁴
- “Existing disease risk data do not support making a recommendation that smokers switch cigarette brands. The recommendation that individuals who cannot stop smoking should switch to a low yield cigarette can cause harm if it misleads smokers to postpone serious efforts at cessation.”⁹⁵
- “Epidemiological and other scientific evidence, including patterns of mortality from smoking-caused diseases, does not indicate a benefit to public health from changes in cigarette design and manufacturing over the last fifty years.”⁹⁶
- For people who switch to low yield brands, “there appears to be complete compensation for nicotine delivery,” on a per cigarette basis, “reflecting more intensive smoking of low yield cigarettes.”⁹⁷

In addition, Monograph 13 also notes that, notwithstanding the major modifications in cigarette design between 1950 and 1975, “there have been few substantive changes toward a further reduction of the toxic and carcinogenic potential of cigarette smoke.”⁹⁸

The Monograph also notes that the levels of tobacco-specific nitrosamines in cigarette

⁹³ Monograph 13, at 81 (Ex. 2). Notably, this conclusion is expressed in terms of changes in cigarette design between 1950 and the mid-1980s. There is very little data about the effects of more recent, “ultra low” cigarettes.

⁹⁴ Id.

⁹⁵ Id. at 146.

⁹⁶ Id. at 10.

⁹⁷ Id.

⁹⁸ Id. at 184.

smoke have increased over the years and may be responsible for the rising rates of adenocarcinoma:

Changes in the agricultural, curing, and manufacturing processes of cigarettes have resulted in an increase over the last several decades in the amounts of tobacco-specific nitrosamines in cigarette smoke. These changes are considered to have contributed to the increase in adenocarcinoma of the lung observed over the past several decades.⁹⁹

Finally, the Monograph concludes that, in comparison to the smoke generated by the Cambridge Method, “the inhaled smoke of one cigarette contains 2 to 3 times the amount of tar, nicotine, and carbon monoxide and 1.6 to 1.8 times the level of biomarkers for the major lung carcinogens BaP, and NNK.”¹⁰⁰

Although PM does not agree with all aspects of Monograph 13, it accepts the significance of its conclusions regarding low-yield cigarettes.¹⁰¹ PM agrees that smokers should not assume that lower-yield cigarettes are less harmful than other cigarettes and that there is no such thing as a safe cigarette. Every cigarette, irrespective of its tar yield, can cause cancer and other fatal diseases. Quitting is by far the best alternative for reducing those risks. PM has publicly made these statements on its website and elsewhere.¹⁰²

⁹⁹ Monograph 13 at 184 (Ex. 2).

¹⁰⁰ Id.

¹⁰¹ Id. at 146.

¹⁰² See www.pmusa.com/tobacco_issues (Ex. 71).

II. PROPOSED RULEMAKING

Following the issuance of Monograph 13, the FTC indicated that it intends to reevaluate the Cambridge Method. In a November 27, 2001 press release, the FTC announced that it will be “working with” HHS “to fix the current cigarette tar and nicotine testing methodology.”¹⁰³ PM believes that the FTC should take immediate and appropriate action with respect to attempting to improve the method by which tar and nicotine yields are measured. Furthermore, PM submits that Monograph 13’s conclusions compel the FTC, without waiting for the final selection of the appropriate testing method, to consider whether disclaimers should be required to accompany any disclosure of tar and nicotine yields and, if so, what those disclaimers should say.

PM submits the following proposals for rulemaking:

A. Reconsider the Cambridge Method

Under the current regulatory scheme, which mandates the exclusive use of the Cambridge Method, consumers are being presented with information regarding tar and nicotine yields that members of the scientific and public health community have come to regard as inaccurate. PM proposes that the FTC immediately solicit the opinions of scientists and public health professionals in order to determine whether there is an alternative method of measuring tar and nicotine yields that will more accurately estimate the amount of tar and nicotine actually delivered to the smoker. PM further proposes that, if such an alternative method is not currently in existence, the FTC develop such a method if technically feasible, and PM stands ready to work with the FTC to develop

¹⁰³ FTC, Statement of the Federal Trade Commission’s Bureau of Consumer Protection on the National Cancer Institute’s Report on Cigarette Testing Method (Nov. 27, 2001) (Ex. 72).

such a method. Finally, PM proposes that the FTC replace the current Cambridge Method in the event the FTC finds a superior method available.

B. Consider Requiring Additional Information

Regardless of the testing methodology adopted, the FTC should require the disclosure of tar and nicotine ratings along with the provision of mandatory disclaimers for all low-yield brands. These disclaimers, which should be required for low-yield brands tested under the Cambridge Method or under a new method if one is adopted, should communicate to the public in substance that:

- (1) low-yield cigarettes have not been proven to be less hazardous than other cigarettes and are not a substitute for quitting;
- (2) the amount of tar and nicotine that a smoker obtains from a cigarette depends on how the individual smokes the cigarette;
- (3) that smokers may intake more tar and nicotine than measured by the FTC testing methodology;
- (4) that low tar cigarettes do not make quitting smoking easier than other cigarettes.

Until the FTC determines the appropriate wording and placement for disclaimers, PM intends to continue and expand its efforts to communicate with its consumers on this issue. PM already provides information on this topic on its website and includes the disclaimer, "The amount of tar and nicotine you inhale will vary depending on how you smoke the cigarette," next to the tar and nicotine disclosure in cigarette advertising. In addition, PM is considering additional communication vehicles for the information set forth in attachment A to this Petition.

C. Clarify Use of Descriptors

Cigarette manufacturers have historically used descriptors such as “light” and “ultra light” to differentiate brands on the basis of their machine-measured average tar and nicotine yields as well as taste. In light of the importance of descriptors in product differentiation, the FTC should adopt a rule expressly authorizing the industry to continue to use such descriptors, provided two conditions are met. First, the use of descriptors should be accompanied by the disclaimers generally described above to minimize consumer confusion. As long as the public is informed that “light” cigarettes are not safer than other brands of cigarettes and that tar delivery ultimately depends on the degree to which a smoker compensates, cigarette companies should be allowed to continue to use the descriptors to differentiate among brands and provide information relating to taste. Second, the use of these descriptors should be allowed, provided that words such as “light” and “ultra light” are used in a uniform fashion and correspond to ranges of average per cigarette yields as estimated by the Cambridge Method now or whatever improved method is selected by the FTC in the future. Use of descriptors in a uniform manner, accompanied by disclaimers, will further the FTC’s goal of informing smokers about the relative yields reported by the testing method, enabling them to make educated decisions about whether and what brands to smoke.

It is worth emphasizing that the continued use of descriptors is particularly important given the extent to which consumers associate descriptors with taste considerations. As Monograph 13 reports, for example, a recent telephone survey found that the most cited reason for smoking light cigarettes – 81% of those surveyed – was


“prefer taste.”¹⁰⁴ Consumers should be permitted to use descriptors to accommodate taste preferences, so long as they are also informed that the descriptors do not indicate that any cigarette has been proven to be safer or that any cigarette is a suitable alternative to cessation. Accordingly, there is no reason to deny consumers the opportunity to use descriptors to distinguish among brands for reasons other than health.

CONCLUSION

For all the above reasons, we petition the FTC to promulgate rules governing (1) the disclosure of average tar and nicotine yields of cigarette brands, (2) the use of disclaimers with respect to average tar yields and health effects of low yield cigarettes, and (3) the use of descriptors.

Respectfully submitted this September 18, 2002,

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¹⁰⁴ Monograph 13 at 195 (reporting on 1999 Kozlowski study) (Ex. 2).

ATTACHMENT A

Information for Smokers:

1. There is no such thing as a safe cigarette.
2. The terms “Ultra Light”, “Light”, “Medium” and “Mild” are used as descriptors of the strength of taste and flavor. These terms, as well as “low tar,” or “lowered tar and nicotine” also serve as a relative indication of the average tar and nicotine yield per cigarette, as measured by a standard government test method.
3. The tar and nicotine yield numbers are not meant to communicate the amount of tar or nicotine actually inhaled by any smoker, as individuals do not smoke like the machine used in the government test method. The amount of tar and nicotine you inhale will be higher than the stated tar and nicotine yield numbers if, for example, you block ventilation holes, inhale more deeply, take more puffs or smoke more cigarettes.
4. Similarly, if you smoke brands with descriptors such as “Ultra Light”, “Light”, “Medium” or “Mild”, you may not inhale less tar and nicotine than you would from other brands. It depends on how you smoke.
5. You should not assume that cigarette brands using descriptors like “Ultra Light”, “Light”, “Medium” or “Mild” are less harmful than full-flavor cigarette brands or that smoking such cigarette brands will help you quit smoking.

If you are concerned about the health effects of smoking, you should quit. For more information about the numbers, brand descriptors or quitting smoking, please go to www.pmus.com or call 1-800-xxx-xxxx.