



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

**In re Proposal to Rescind FTC  
Guidance Concerning the Current  
Cigarette Test Method**

**No. P944509**

**COMMENTS OF PHILIP MORRIS USA INC.**

Philip Morris USA Inc. ("PM USA") hereby submits the following comments in response to the Federal Trade Commission's *Proposal to Rescind FTC Guidance Concerning the Current Cigarette Test Method*, 73 Fed. Reg. 40,350 (July 14, 2008) ("FTC Proposal").

For more than forty years, the Federal Trade Commission ("FTC") has taken the position that "factual statements of the tar and nicotine content of the mainstream smoke of cigarettes would not be in violation of legal provisions administered by the FTC," as long as such statements were adequately supported by "tests conducted in accordance with the Cambridge Filter Method." See FTC Proposal, 73 Fed. Reg. at 40,351. However, over the course of the past four decades – both before and after the FTC issued its guidance in 1966 – the FTC, the public health community, and members of the cigarette industry all have raised questions and concerns regarding the adequacy of the Cambridge Method. In 1966, various tobacco companies commented to the FTC that 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.”<sup>1</sup> In 1966 and throughout its more than forty-year period of guidance, the FTC itself acknowledged the limitations of the method, recognizing that the method “does not and cannot measure [the] many variations in human smoking habits.” See Press Release, FTC to Begin Cigarette Testing (Aug. 1, 1967).

More recently, as noted in its Proposal, the FTC in 1994 “asked the National Cancer Institute (“NCI”) to convene a consensus conference to address cigarette testing issues,” and in 1997 the FTC issued a notice for comment on proposed revisions to the testing methodology. See FTC Proposal, 73 Fed. Reg. at 40,351 n.4. 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.” HHS in turn asked NCI to review the evidence of the relationship between machine-measured cigarette yields and disease risk. In September 2002 (following the issuance of “Monograph 13” by NCI), PM USA submitted a Petition for Rulemaking noting issues that have been raised regarding the limitations of the Cambridge Method, and requesting, among other things, that the FTC “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.” See *In re Petition for Rulemaking Concerning Tar and Nicotine Testing and Disclosure* 5 (Sept. 18, 2002) (“2002 Petition”). PM USA continues to support action by the FTC or other federal authorities to identify and implement a standardized testing methodology that addresses the concerns raised regarding the Cambridge Method.

---

<sup>1</sup> Supplemental Observations Following November 30, 1966 Hearing Before the Federal Trade Commission 2-3 (emphasis omitted). Cigarette manufacturers 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 17 (July 16, 1981) (Ex. 1).

That the Cambridge Method has shortcomings – a fact undisputed for decades – does not lead inexorably to the conclusion that the public interest would be best served by immediate rescission of the FTC’s longstanding guidance. If the current guidance were simply rescinded – thereby eliminating any standardized methodology for tar and nicotine yield measurements – the FTC would effectively create a regulatory vacuum.<sup>2</sup> To the extent that tar and nicotine yields are disclosed in this unregulated environment, such disclosures could lead to substantially greater consumer confusion than any possible confusion that may exist under the current guidance.

Accordingly, PM USA respectfully submits that the FTC should take a measured approach in its Proposal. Rather than abruptly rescinding its guidance after more than forty years and leaving nothing in its place, the FTC should retain its guidance pending consideration by appropriate federal authorities of alternative standardized testing methods to replace (or to supplement) the Cambridge Method. As indicated in its 2002 Petition, PM USA stands ready to work with the FTC in the development of an alternative to the Cambridge Method.

The retention of a uniform testing method – even a method with the limitations inherent in the Cambridge Method – during the search for an alternative method is preferable to the total abandonment of any uniform method.<sup>3</sup> The fact that many other jurisdictions – including the European Union – continue to rely upon a virtually identical version of the Cambridge Method

---

<sup>2</sup> We recognize that legislation is currently pending that would give FDA authority to regulate tobacco products, including authority to require disclosures relating to the results of the testing of tar and nicotine through labels or advertising. PM USA has supported such legislation, and the House of Representatives recently passed its version of this legislation. However, it is not clear whether or when such legislation may be enacted.

<sup>3</sup> If the FTC decides to rescind its guidance concerning the Cambridge Method without providing guidance concerning an alternative method, PM USA urges the Commission to set a future effective date for such a rescission with a reasonable lead-time of not less than one year, to provide manufacturers with time to make any change that they may determine is appropriate in packaging and other materials.

(the ISO Method)<sup>4</sup> supports the view that the FTC's current guidance should be retained pending adoption of an alternative testing method. Moreover, during the period prior to the adoption of an alternative testing method, the FTC could reduce any perceived risk of consumer confusion by taking one or more of the following steps: (1) explain the limitations of the Cambridge Method in a "Consumer Alert" (as the FTC did in 2000); and/or (2) require cigarette manufacturers to include specific disclaimers about the Cambridge Method when they disclose tar and nicotine yields (similar to PM USA's disclaimers, discussed *infra*). Furthermore, if it deems it important, the Commission can address its additional stated concern that "consumers are likely to interpret [the term 'FTC Method'] as FTC approval, ownership or endorsement of the Cambridge Filter Method," FTC Proposal, 73 Fed. Reg. at 40,352, by amending its guidance to preclude references to "FTC Method." This approach would deal effectively with this expressed concern without fostering the greater consumer confusion that could result from opening the door to non-uniform test methods.

Below we (1) provide background information about current use of the Cambridge Method and alternative testing methodologies that have been adopted or are being considered by the public health community and by other government entities, and (2) discuss the importance of having a uniform testing methodology, rather than opening the door to claims made in a regulatory vacuum.

---

<sup>4</sup> For purposes of this comment, PM USA uses "Cambridge Method" to include the ISO Method.

I. **The Creation of the Cambridge Method, Its Current Use, and Research Into Alternative Methods**

A. **Creation of the Cambridge Method**

The Cambridge Method has been the official standardized methodology for measuring tar and nicotine yields in the United States since 1966, despite the fact that the FTC from the beginning has recognized that the method does not model individual smoking behavior. As the FTC Proposal notes, the Cambridge Method was, from the outset, “intended to produce uniform, standardized data about the tar and nicotine yields of mainstream cigarette smoke, *not* to replicate actual human smoking.” FTC Proposal, 73 Fed. Reg. at 40,351 (emphasis in original). “Because no known test could accurately replicate human smoking, the FTC believed that the most important objective was to ensure that cigarette companies could present tar and nicotine information to the public based on a standardized method that would allow comparisons among cigarettes.” *Id.* In other words, the FTC historically recognized that the limitations on the adequacy of the Cambridge Method to replicate actual smoking behavior did not destroy the consumer benefits that could be derived from requiring tar and nicotine yields to be based on a uniform standard.

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.” CCH Trade Regulation Reporter 39,012, at 41,602 (Sept. 22, 1955). The result was that different manufacturers employed different methodologies to support claims regarding tar and nicotine yields. In its February 16, 1958 Press Release, FTC Seeks Uniform Testing of Cigarette Smoke (Ex. 2), Charles E. Grandley (Director of the Bureau

of Consultation) noted the public confusion that had arisen from the use of “widely varying tests conducted by cigarette manufacturers and private laboratories” and concluded that “discrepancies in testing are not in the interest of the public.” Accordingly, in December 1959, the FTC notified cigarette manufacturers that it considered “all representations of low or reduced tar . . . to be health claims” and advised each manufacturer to cease making such representations. *See, e.g.*, Letter from William H. Brain to Addison Yeaman (Dec. 17, 1959). In essence, the FTC took the position that, given the absence of a standardized method, disclosures of tar and nicotine yields were *inherently* deceptive and would not be allowed.

At about the same time, however, scientific evidence was emerging indicating that lowered yields of tar and nicotine reduce the risk of contracting certain types of disease, such as lung cancer. 2002 Petition at 8-9. In 1966, a technical committee of scientific experts convened by the U.S. Public Health Service “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.”<sup>5</sup> As a result of the growing scientific evidence, the FTC in March 1966 reversed its position and allowed disclosure of tar and nicotine yields in cigarette advertisements. The FTC declared that “factual statements of the tar and nicotine content of the mainstream smoke of cigarettes would not be in violation of legal provisions administered by the FTC,” as long as such statements were adequately supported by “tests conducted in accordance with the Cambridge Filter Method.” *See* FTC Proposal, 73 Fed. Reg. at 40,351.

In so doing, however, the FTC expressly acknowledged that the Cambridge Method had limitations. Consistent with the cigarette manufacturer’s own comments on the method, the FTC

---

<sup>5</sup> *Reviewing Progress Made Toward the Development and Marketing of a Less Hazardous Cigarette: Hearings Before the Consumer Subcomm. of the S. Comm. on Commerce, 90<sup>th</sup> Cong. 7-8 (1967) (Ex. 3).*

recognized in 1966 that “[n]o two human smokers smoke in the same way” and that the test “does not and cannot measure” human smoking habits. The FTC noted further that its method does not even attempt to determine “the amount of smoke, or tar and nicotine, which the ‘average’ smoker will draw from any particular cigarette.” 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.” See Press Release, FTC to Begin Cigarette Testing (Aug. 1, 1967).

Yet, notwithstanding the Cambridge Method’s shortcomings, the FTC made it clear that it was in the public’s interest to adopt that method and disseminate its results publicly. The FTC declared 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.” *Id.* at 1-2. 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.” *Id.* at 1. 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.” *Id.* 2-3.

Since adopting the Cambridge Method, the FTC has repeatedly recognized the limitations of the testing methodology, but has retained the method as in the public interest.<sup>6</sup> In an advisory

---

<sup>6</sup> See, e.g., FTC Report to Congress for the Year 1977, at 6 & n.8 (“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. 5); FTC, *Determination re Barclay Cigarettes* 4 (1984) (“If consumers who switch to lower yield cigarettes change their smoking pattern, for

Footnote continued on next page

opinion rejecting one company's request to advertise tar and nicotine yields higher than the most recent Cambridge Method results because of the inaccuracy of those results, the FTC stated that "consumer confusion might be generated" by any deviation from the standard test results and declared that "tar values which are set forth in cigarette advertisements must be consistent with the latest applicable FTC tar number." *See* 92 F.T.C. 1035 (1978) (Ex. 4). In 1983, the FTC expressly determined to retain the Cambridge Method "even though the limitations on the predictiveness of the FTC Method caused by compensatory smoking were clearly recognized."<sup>7</sup>

More recently, in 1994, the FTC asked NCI to convene a conference to evaluate the Cambridge Method, and, in response to NCI's recommendations, issued a notice for comment on proposed revisions to the testing methodology that "would require that each cigarette variety be tested under two different sets of smoking conditions." FTC Report to Congress for 1996, at 2 (Ex. 10). Finally, in 1998, the FTC asked HHS to "conduct a complete review of the FTC's cigarette testing methodology."<sup>8</sup> Throughout the decades, however, the FTC has not made any changes to its testing methodology (other than adding measurements for carbon monoxide to be reported solely to the FTC).

---

Footnote continued from previous page

example, by smoking more cigarettes per day, they may receive a greater yield than suggested by the FTC test results." (Ex. 6); FTC Report to Congress for 1993, at 2 ("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. 7); 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 ratings can't predict the amount of tar and nicotine you get from any particular cigarette.") (Ex. 8).

<sup>7</sup> C.L. Peeler, *Cigarette Testing and the Federal Trade Commission: A Historical Overview, 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*, at 3 (1996) (Ex. 9).

<sup>8</sup> Letter from Donald S. Clark to the Honorable Donna L. Shalala (Nov. 19, 1998).



**B. The Current Use of the Cambridge or Similar  
Standardized Methods and Continued Research into New Methods**

The FTC has hardly been alone in recognizing that the Cambridge Method serves important public interests, despite the method's well-recognized limitations. Other jurisdictions are currently relying on the Cambridge Method, while at the same time actively researching modifications to that method. For example, the Cambridge Method remains mandatory in numerous countries outside of the United States for reporting tar and nicotine yields in labeling.<sup>9</sup> In addition, the EU and other countries rely on the Cambridge Method to impose regulatory limits on maximum yields.<sup>10</sup> Indeed, the European Commission recently considered the “pros and cons” of different test methods, but reported that “Member States widely wished to continue using the current ISO smoking regime on an obligatory basis until solid evidence shows that better methods exist to replace them.”<sup>11</sup> Elsewhere – such as Canada – alternative test methods are being used (or considered) as a supplement to the Cambridge Method.

---

<sup>9</sup> According to the World Health Organization, the EU and at least seven other European countries use the Cambridge Method. See *The European Tobacco Control Report 2007*, at 59-60, <http://www.euro.who.int/document/e89842.pdf>. In addition, South Africa requires use of the Cambridge Method, and in Australia manufacturers disclose yields using the Cambridge Method pursuant to a voluntary agreement. See D. Swart and S. Panday, *The Surveillance and Monitoring of Tobacco Control in South Africa 7*, [http://www.who.int/tobacco/training/success\\_stories/en/best\\_practices\\_south\\_africa\\_surveillance.pdf](http://www.who.int/tobacco/training/success_stories/en/best_practices_south_africa_surveillance.pdf); Voluntary Agreement for the Disclosure of the Ingredients of Cigarettes (Dec. 2000), [http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-drugs-tobacco-ingredients.htm/\\$FILE/agreement.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-drugs-tobacco-ingredients.htm/$FILE/agreement.pdf).

<sup>10</sup> See Directive 2001/37, 2001 O.J. (L194) 26, 29 (EC). See also *The European Tobacco Control Report 2007*, at 59-60 (listing jurisdictions outside of 2006 EU member countries that set limits on maximum yields: Bulgaria (joined EU 2007), Croatia, Georgia, Iceland, Israel, Norway, Montenegro, Romania (joined EU 2007), Serbia, and Switzerland).

<sup>11</sup> See *Second Report on the Application of the Tobacco Products Directive, Brussels 2007*, at 4, [http://ec.europa.eu/health/ph\\_determinants/life\\_style/Tobacco/Documents/tobacco\\_products\\_en.pdf](http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/tobacco_products_en.pdf). See also *First Report on the Application of the Tobacco Products Directive, Brussels 2005*, at 4, [http://ec.europa.eu/health/ph\\_determinants/life\\_style/Tobacco/Documents/com\\_2005\\_339\\_en.pdf](http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/com_2005_339_en.pdf) (“The Commission does not propose to revise the current standards set out in the Directive until solid evidence shows that better methods exist to replace them.”).

Two U.S. jurisdictions have adopted their own alternative machine smoking regimens that are more intensive than the Cambridge Method. Massachusetts and Texas require manufacturers to report nicotine using a modified Cambridge Method with a stronger and more frequent puff (45 mL puff volume, once/30 seconds, 50 percent of vent holes blocked), as compared to the Cambridge Method (35 mL puff volume, once/minute, no vent holes blocked). *See* 105 MASS. CODE REGS. 660.500(D) (2008); 25 TEX. ADMIN. CODE § 101.5(a)(1) (2008). Canada also requires a more “intense” testing regimen (55 mL puffs, once/30 seconds, and all of the filter vent holes blocked) as a supplement to the Cambridge Method (rather than replacing the Cambridge Method).<sup>12</sup> This Canadian supplemental “intense” method has been described as approximating a “maximum” exposure.<sup>13</sup>

At the same time, numerous organizations and individuals are involved in extensive research into the development of an alternative means of testing tar and nicotine yields that more accurately estimates the yields experienced by an individual smoker. The FTC Proposal acknowledges that “representatives from agencies within DHHS are continuing to look into these issues.” FTC Proposal, 73 Fed. Reg. at 40,352 n.4. The World Health Organization (“WHO”) Framework Convention on Tobacco Control (“FCTC”), to which the United States is a signatory, directs the parties to propose guidelines for the testing, measurement and regulation of the contents and emissions of tobacco products and for public disclosure of the toxic constituents

---

<sup>12</sup> Health Canada, Tobacco Control Programme, *Determination of “Tar,” Nicotine and Carbon Monoxide in Mainstream Tobacco Smoke 2* (1999), [http://www.hc-sc.gc.ca/hl-vs/alt\\_formats/hecs-sesc/pdf/tobac-tabac/legislation/reg/indust/method/\\_main-principal/nicotine-eng.pdf](http://www.hc-sc.gc.ca/hl-vs/alt_formats/hecs-sesc/pdf/tobac-tabac/legislation/reg/indust/method/_main-principal/nicotine-eng.pdf).

<sup>13</sup> *See* World Health Organization, *Guiding Principles for the Development of Tobacco Research and Testing Capacity and Proposed Protocols for the Initiation of Tobacco Product Testing* (2004), [http://www.who.int/tobacco/global\\_interaction/tobreg/goa\\_2003\\_principles/en/index.html](http://www.who.int/tobacco/global_interaction/tobreg/goa_2003_principles/en/index.html).

and emissions of tobacco products.<sup>14</sup> Accordingly, WHO has taken an interest in the development of an alternative test method. At the first meeting of the FCTC Conference of Parties (“COP”) in February 2006, the COP established a “working group” to work with the WHO Tobacco Free Initiative (“TFI”) and Study Group on Tobacco Product Regulation (“TobReg”) to develop guidelines for testing and measuring tobacco product contents and emissions based on the work already completed under the auspices of TFI and TobReg.<sup>15</sup> The working group has met several times since 2006 and is currently reviewing options for a new testing regimen with the assistance of the WHO Tobacco Laboratory Network (“TobLabNet”).<sup>16</sup> The working group tasked TobLabNet with identifying the advantages and disadvantages of a number of testing methods, including the Cambridge, Massachusetts, and Canadian methods, at a November 2006 meeting.<sup>17</sup> In 2007, TobReg determined that the Canadian “intense” method was “the method with the best fit for measuring constituents for use in the proposed regulatory strategy.”<sup>18</sup> A COP meeting is scheduled for November 2008 and the COP working group is expected to report on its progress or make recommendations at that meeting.<sup>19</sup>

---

<sup>14</sup> World Health Organization, Framework Convention on Tobacco Control art. 9-10 (2003), [http://www.who.int/tobacco/framework/WHO\\_FCTC\\_english.pdf](http://www.who.int/tobacco/framework/WHO_FCTC_english.pdf) (Articles 9 & 10).

<sup>15</sup> World Health Organization, *Elaboration of Guidelines for Implementation of the Convention: Article 9 Product Regulation* 1, ¶ 1 (2007), [http://www.who.int/gb/fctc/PDF/cop2/FCTC\\_COP2\\_8-en.pdf](http://www.who.int/gb/fctc/PDF/cop2/FCTC_COP2_8-en.pdf).

<sup>16</sup> See International Standardization Organization, Minutes of Meeting of WHO, BSI (“British Standards Institute”), ISO/TC 126 (Feb. 22, 2007) (on file).

<sup>17</sup> World Health Organization, *Results of Elaboration of Article 9 and 10, Regulation of the Contents of Tobacco Products and Tobacco Product Disclosures* (2007), <http://www.wpro.who.int/NR/rdonlyres/8007934C-52FF-453E-A3B2-977047D8866D/0/ResultsofElaborationofArticles9and10.pdf>.

<sup>18</sup> World Health Organization, *The Scientific Basis of Tobacco Product Regulation: Report of a WHO Study Group* 83 (2007), <http://repositories.cdlib.org/context/tc/article/1235/type/pdf/viewcontent/>.

<sup>19</sup> See Third Session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control (WHO FCTC), [http://www.who.int/fctc/cop/third\\_session\\_cop/en/index.html](http://www.who.int/fctc/cop/third_session_cop/en/index.html) (last visited Sept. 11, 2008).

The International Organization for Standardization (“ISO”) has also sought to develop recommendations for alternatives to the Cambridge Method. In 2004, after discussions with WHO, ISO created a working group (Working Group 9, ISO Technical Committee 126, thus known as “TC 126 WG9” or simply “WG9”) to develop recommendations for a test that “as far as possible is representative of smokers’ behaviour.”<sup>20</sup> WG9 evaluated human smoking behavior, uptake studies, and smoking methods in order to provide advice on a machine smoking method that would be “more relevant to smoking behavior which could reflect maximum yields” than the Cambridge Method, and that had acceptable reproducibility and variability.<sup>21</sup> Although WG9 was not able to reach a consensus on a single new machine smoking method, it proposed the Canadian “intense” method and an “Option B” (with puff volume of 60 mL, puff frequency of twice/minute, and 50 percent filter blockage) as two alternatives for ISO consideration.<sup>22</sup> WHO subsequently asked ISO to postpone any further work on an intense cigarette smoking regime until a decision is reached by WHO COP.<sup>23</sup> In the spring of 2007, ISO members voted to create a new working group (WG10) to examine “an intense smoking regime.”<sup>24</sup> It has been reported that WG10 is planning to perform preparatory work, including discussion of data and information about a future “intense smoking regime.”<sup>25</sup>

---

<sup>20</sup> See ISO, *Smoking Methods for Cigarettes: Final Report 2* (Mar. 2006) (on file).

<sup>21</sup> See ISO, Resolutions from the 1st Meeting of ISO/TC 126/WG9, Smoking Methods for Cigarettes (Apr. 2005) (on file).

<sup>22</sup> See ISO, Resolutions from the 3rd Meeting of ISO/TC 126/WG9, Smoking Methods for Cigarettes (Dec. 2005) (on file).

<sup>23</sup> See Letter from Yumiko Mochizuki to Henning Lutz and ALL ISO TC 126 (Nov. 17, 2006) (Annex 2, Minutes of WHO/BSI meeting on 2007-02-22 at 12-13) (on file).

<sup>24</sup> See Voting results and comments on N882 Intense Smoking, ISO/TC 126 N903, at 1 (Apr. 2007) (on file).

<sup>25</sup> *Id.*

In addition to these international organizations, academic investigators have proposed variants on a supplemental machine smoking test to be more representative of human smoking behavior. One such proposal involves a so-called “compensatory” regimen in which puff volume and frequency are increased by a set amount for each incremental decrease in nicotine yield as measured by the Cambridge Method.<sup>26</sup> For example, the investigators suggested that under the “compensatory” regimen, the puff volume would rise by 4 mL and the puff frequency would increase by 4 seconds for every decrease of 0.1 mg nicotine as measured by the Cambridge Method.<sup>27</sup>

In short, numerous jurisdictions have adopted or are searching for alternative methods for measuring tar and nicotine yields. In fact, the current draft of the bill providing FDA jurisdiction over cigarettes contemplates that FDA will develop a new methodology for testing tar and nicotine yields. *See Family Smoking Prevention and Tobacco Control Act*, H.R. 1108, 110th Cong. §§ 101 & 206 (passed by House of Rep., July 30, 2007) (proposed 21 U.S.C. § 915 & 15 U.S.C. § 1333(e)). But the ongoing assessment of possible testing methods to supplement or replace the Cambridge Method does not provide support for the FTC Proposal to abandon the Cambridge Method while the search for an alternative test method continues. To the contrary, the widespread search for alternative test methodologies underscores the importance of avoiding a regulatory vacuum.

---

<sup>26</sup> Lynn T. Kozlowski & Richard J. O'Connor, *Official Cigarette Tar Tests Are Misleading: Use a Two-stage, Compensating Test*, LANCET 2159-61 (2000).

<sup>27</sup> David Hammond et al., *Revising the Machine Smoking Regime for Cigarette Emissions: Implications for Tobacco Control Policy*, TOBACCO CONTROL 2007, at 12 (2007).

## II. The Need For A Uniform Standard

As noted above, the FTC explained at the time it adopted the Cambridge Method in 1967 that “the public interest requires that all test results presented to the public be based on a uniform method used by all laboratories” because “use of more than one testing method would produce different results which would only serve to confuse or mislead the public.” Press Release, FTC to Begin Cigarette Testing (Aug. 1, 1967) (Ex. 11). The FTC also noted that “statements or representations based on non-standardized tests having no official or governmental sanction would tend to confuse and mislead the public.” See Letter from FTC Secretary Joseph W. Shea to Howard Bell (Oct. 25, 1967) (Ex. 12).

The FTC’s adoption of a uniform testing methodology for measuring tar and nicotine yields – notwithstanding the known limitations of that method – is consistent with how the FTC has acted outside of the cigarette context. Lessening consumer confusion, empowering consumer choice, and encouraging competition have been longstanding general goals of the Commission. These goals have been achieved in numerous other regulatory contexts through FTC rules imposing uniform disclosure and testing requirements.<sup>28</sup> Moreover, the FTC has

---

<sup>28</sup> See, e.g., 73 Fed. Reg. 10,403, 10,403 (Feb. 27, 2008) & 72 Fed. Reg. 13,052, 13,052 (Mar. 20, 2007) (FTC’s “Amplifier Rule,” which establishes standards for measuring amplifier performance characteristics “to aid consumers in making meaningful comparisons,” was adopted “in response to sellers making misleading or confusing power distortion and other performance claims based on differing or unrecognized test procedures.”); 71 Fed. Reg. 78,057, 78,059 (Dec. 28, 2006) (“A uniform label on every ceiling fan package should make it easier for consumers to locate and compare information for different models as they shop.”); 71 Fed. Reg. 34,247, 34,247 (June 14, 2006) (“The purpose of the [Picture Tube] Rule is to prevent deceptive claims regarding the size of television screens and to encourage uniformity in measuring television screens, thereby aiding comparison shopping.”); 60 Fed. Reg. 26,926, 26,926 (May 19, 1995) (“The purpose of the [alternative fuel and alternative fueled vehicles] labeling requirements is to enable consumers to make reasonable choices and comparisons.”); *id.* at 26,930 (“Although in the absence of such requirements sellers could be expected to identify the fuels sold, they may not do so in a standardized format that assists consumers in identifying the proper fuel quickly.”).

acknowledged that these goals can be furthered even when the test method it has adopted is an imperfect one.

For example, the FTC's "R-value Rule" requires certain disclosures on insulation products "based on uniform, industry-adopted standards" to "enable[] consumers to evaluate how well a particular insulation product is likely to perform, to determine whether the cost of the insulation is justified, and to make meaningful, cost-benefit based purchasing decisions among competing products." 70 Fed. Reg. 31,258, 31,258 (May 31, 2005). The R-value Rule was motivated in part by the conduct of sellers, who did not adequately explain the meaning or importance of the R-value, who exaggerated R-values, or who did not account for factors that could degrade insulation performance. *Id.* at 31, 259. During the FTC's recent consideration of changes to the R-value Rule, two public comments expressed concerns about insulation performance in very cold temperatures. 70 Fed. Reg. at 31,262. The FTC recognized that the testing standards mandated by the rule did not account for all variables that may affect insulation performance in a real home setting, but decided against making any changes, because accounting for these additional factors "would significantly complicate both compliance and communication to consumers, without necessarily providing a commensurate level of benefit." *Id.* In short, the FTC recognized limitations in its uniform testing method, but nevertheless retained that method in light of the consumer benefits it conferred.

The retention of the guidance relying upon the Cambridge Method until a new method is adopted would also be consistent with the approach that other agencies have taken under analogous circumstances. For example, many years after adopting standard test methods for calculating automobile fuel economy (miles-per-gallon) information provided to consumers on new vehicle window stickers and often used in advertising, the Environmental Protection

Agency (“EPA”) concluded that, as a result of changes in driving behavior and technology, the existing test methods did “not fully represent current real-world driving conditions” and thus did not adequately provide consumers with accurate information about the fuel economy they should expect.<sup>29</sup> Accordingly, in 2006, EPA revised the test methods for calculating fuel economy to account better for real-world conditions and behaviors. However, rather than abandoning immediately the existing test methods, EPA decided to phase in the new test methods gradually to provide automobile manufacturers with sufficient lead time to account for the new test requirements. Moreover, EPA acknowledged that “even with the improved fuel economy test methods we are finalizing today, some consumers will continue to get fuel economy that is higher or lower than the new estimates. No single test or set of tests can ever account for the wide variety of conditions experienced by every driver.”<sup>30</sup> In essence, EPA concluded that a test may retain its utility even if it does not adequately account for real world variations in consumer experiences.

If the Cambridge Method were jettisoned after more than forty years, without any uniform testing method in its place, there would be no standardized basis upon which consumers could evaluate tar and nicotine yields. The FTC would return the cigarette industry and market to the regulatory vacuum of the 1950s, which the FTC previously found resulted in substantial consumer confusion. This regulatory vacuum seems to be recognized by the FTC Proposal:

---

<sup>29</sup> “[T]here have been many changes affecting the way Americans drive — speed limits are higher, road congestion has increased, vehicle technologies have changed markedly, and more vehicles are equipped with energy-consuming accessories like air conditioning.” 71 Fed. Reg. 77,872, 77,874 (Dec. 27, 2006).

<sup>30</sup> *Id.* at 77,876. EPA also stated that “fuel economy varies from driver to driver for a wide variety of reasons, such as different driving styles, climates, traffic patterns, use of accessories, loads, weather, and vehicle maintenance. Even different drivers of the same vehicle will experience different fuel economy as these and other factors vary. Therefore, it is impossible to design a ‘perfect’ fuel economy test that will provide accurate real-world fuel economy estimates for every consumer . . . .” *Id.* at 77,874.



“Upon withdrawal of this guidance, factual statements about tar and nicotine yields would be evaluated the same as any other advertising or marketing claims subject to the Commission’s jurisdiction: the statements could be made as long as they were truthful, non-misleading, and adequately substantiated.” FTC Proposal, 73 Fed. Reg. at 40,352. Each cigarette company that wished to provide information to adult smokers concerning tar and nicotine levels would need to determine its own testing methodology, and claims would be based upon a variety of testing methodologies involving smoking cigarettes to varying butt lengths, with different frequencies of puffs, and different solvents to determine smoke ingredients. See Press Release, FTC Seeks Uniform Testing of Cigarette Smoke (Feb. 16, 1958) (Ex. 2); C.L. Peeler, *Cigarette Testing and the Federal Trade Commission: A Historical Overview* at 1 (describing 1950’s “tar derby”) (Ex. 9).<sup>31</sup> Smokers interested in information on tar and nicotine yields would face greater confusion, and, indeed, the FTC’s own information collection activities would be subject to substantial question.<sup>32</sup> PM USA believes the FTC’s original policy considerations and goals underlying its uniform standard for measurement of tar and nicotine remain valid notwithstanding the known limitations of the Cambridge Method, at least pending consideration of alternative test methods.

---

<sup>31</sup> It is by no means certain that only one testing method would become the exclusive reasonable basis for any tar and nicotine claim, particularly if the companies use disclaimers or explanations in connection with their differing methodologies. The FTC has long held that there may be more than one reasonable basis upon which to substantiate a claim. See *In re Bristol-Meyers Co.*, 102 F.T.C. 21, 376-77 (1983) (holding that “the amount of substantiation necessary to constitute a reasonable basis must be determined case-by-case” and that while two well-controlled clinical tests would provide a reasonable basis, the FTC could not “rule out the possibility that other types of evidence might be adequate”) (citing *In re Pfizer, Inc.*, 81 F.T.C. 23, 64 (1972)).

<sup>32</sup> The Commission’s recently published Notice seeking comments on its proposed request for authority, through January 31, 2012, to collect data from tobacco companies notes that the FTC plans to ask cigarette manufacturers for data regarding “the tar, nicotine, and carbon monoxide ratings for their cigarettes, to the extent they possess such data.” 73 Fed. Reg. 46,006, 46,007 (Aug. 7, 2008). The value of that data would be substantially undermined if each company’s ratings were derived from a different test protocol.

Maintaining the current guidance until an alternative method is adopted should not cause any consumer confusion in light of the widespread dissemination of information to consumers about the limitations of the Cambridge Method. The FTC has published an alert advising consumers about the Cambridge Method's limitations since 2000. *See* FTC Consumer Alert, *Up In Smoke: The Truth About Tar and Nicotine Ratings* (May 2000) (Ex. 8). Consumers have received other information about the limits of the Cambridge Method from other sources, as well. For example, following the issuance of the FTC Consumer Alert, PM USA placed a statement in its cigarette brand advertisements that states: "The amount of 'tar' and nicotine you inhale will vary depending on how you smoke the cigarette." The statement refers people to the PM USA website for more information. The PM USA website since 1999 includes information on low tar cigarettes, stating that the FTC tar and nicotine disclosures do not necessarily reflect the amount of tar and nicotine an individual smoker might get and that the amount inhaled will vary depending on how the cigarette is smoked. The website further states that smokers should not assume that low tar cigarettes are safer than full flavor cigarettes. Moreover, since 2002, PM USA has provided similar information in other ways, such as in periodic inserts on cigarette packages. (Examples of these communications are attached as Ex. 13).

Furthermore, the FTC may require additional disclaimers or qualifications to the extent necessary to avoid consumer confusion. In this respect, if the FTC is concerned that the use of the term "FTC Method" to describe the Cambridge Method may be a source of consumer confusion, FTC Proposal, 73 Fed. Reg. at 40,352, it can effectively address that concern without a total rescission of its guidance. The FTC could provide that the guidance will only apply to factual statements of tar and nicotine measured by the Cambridge Method that do not include the statement "per FTC Method" or other phrases that might imply FTC endorsement of the

Cambridge Method (or other test methods). Unlike the FTC Proposal in its current form, which could increase rather than decrease consumer confusion, a proviso prohibiting any reference to the FTC should not result in adverse consumer effects.

The FTC in its proposal acknowledges the importance of weighing the potential impact of the proposed action on consumers. *See* FTC Proposal, 73 Fed. Reg. at 40,352. In its effort to disavow the Cambridge Method, the FTC should be careful not to re-create the regulatory vacuum that gave rise to the “tar derby” decades ago. PM USA respectfully submits that the FTC should not rescind its guidance until after a suitable alternative to the Cambridge Method has been identified.<sup>33</sup>

---

<sup>33</sup> Because the FTC Proposal does not address the use of “descriptors” – and because descriptors are currently the subject of ongoing litigation – we have not addressed descriptors in our comments.

### Conclusion

For many years, in other industries as well as the cigarette industry, the FTC has recognized the strong public interest justifications for the adoption of uniform standards for disclosure of product characteristics. The goal of eliminating consumer confusion by requiring cigarette companies to produce uniform, standardized data about tar and nicotine yields is as important today as it was in 1966. Efforts to develop an alternative to replace (or to supplement) the Cambridge Method are ongoing. No sound public purpose would be served by the abrupt abandonment of the current guidance prior to the development of a new protocol to replace or supplement the Cambridge Method. The FTC's goal should be the substitution of the current guidance with a new guidance, not the elimination of any guidance at all.

Respectfully submitted,

Jerome I. Chapman  
ARNOLD & PORTER LLP  
555 Twelfth Street, N.W.  
Washington, DC 20004  
(202) 942-5000  
(202) 942-5999 (fax)

*Counsel for Philip Morris USA Inc.*

September 12, 2008