

September 17, 2010

Ms. Cristi Stark  
Office of Science  
Center for Tobacco Products  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

**COMMENTS OF LORILLARD TOBACCO COMPANY AND  
R. J. REYNOLDS TOBACCO COMPANY**

RE: Notice of Meeting of the Menthol Report Subcommittee of the Tobacco Products Scientific Advisory Committee (TPSAC)

Dear Ms. Stark:

The attached comments are respectfully submitted on behalf of Lorillard Tobacco Company (Lorillard) and R. J. Reynolds Tobacco Company (Reynolds) in response to FDA's Notice of Meeting for the September 27, 2010 meeting of the Menthol Report Subcommittee of the TPSAC. 75 Fed. Reg. at 52008.

The notice provides that interested parties may provide written submissions by September 17, 2010 for consideration by the TPSAC. Lorillard and Reynolds designate the submission as background material in order for it to be provided to members of the TPSAC and to be made available to the public through its posting to FDA's Scientific Advisory website with other briefing materials for the meeting.

Respectfully submitted,



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## Comments of Lorillard Tobacco Company and R.J. Reynolds Tobacco Company

### TPSAC Report Regarding the Impact of Menthol in Cigarettes

These comments are respectfully submitted in response to the September 3, 2010 request for comments in connection with the September 27, 2010 meeting of the Tobacco Products Scientific Advisory Committee (TPSAC). As announced by FDA, the September 27, 2010 TPSAC meeting is intended to focus on the timeline, structure and process to be used by TPSAC in developing its report to FDA regarding the impact of menthol in cigarettes on the public health (hereinafter “Report”), as required under the Family Smoking Prevention and Tobacco Control Act (FSPTCA).<sup>1</sup>

FDA has publicly stated that in drafting its Report, TPSAC will employ a process that is transparent and inclusive of the input of various stakeholders, and strictly relies on robust scientific data, as opposed to speculation. We certainly agree with these objectives and encourage FDA and TPSAC to take steps to ensure that these goals are met. In order to ensure transparency, it is vital for TPSAC to encourage public participation, not only in meetings and comments, but also in the Report drafting process. This requires that TPSAC provide sufficient opportunity to permit public review of and comment on drafts prior to the Report being finalized. Furthermore, to engender public confidence in both the TPSAC and its final report, FDA must rigorously screen for and address the appearance of and actual conflicts of interest. This is critical to ensuring that preconceived opinions and agendas do not influence the analysis of scientific data. TPSAC must develop and apply rigorous standards for the evaluation of scientific literature, and should evaluate data in an evenhanded manner based solely on those standards – not the source of the data. Finally, TPSAC must evaluate the totality of the information available to it, including the documents and submissions provided by members of the industry.

#### **I. THE PROCESS TO DRAFT THE REPORT MUST BE OPEN, TRANSPARENT AND INCLUSIVE OF VARIOUS STAKEHOLDERS**

Since the passage of the FSPTCA, the FDA has consistently conveyed its intentions to employ an open, transparent and inclusive process when determining whether to impose regulations on tobacco manufacturers. As stated on FDA’s website, “[a]s FDA implements the Tobacco Control Act, the Center [for Tobacco Products] is committed to ensuring that our actions are grounded in sound science, that we are open and transparent, and that we give stakeholders the opportunity to comment and participate in the regulatory process.”<sup>2</sup> Dr. Lawrence Deyton, Director of the Center for Tobacco Products, stated at the March 30, 2010 TPSAC meeting, “[w]e’re also striving to create a transparent process that Americans know they

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<sup>1</sup> 21 U.S.C. § 387g(e) (2009).

<sup>2</sup> U.S. Food and Drug Administration Center for Tobacco Products, 2009-2010: Inaugural Year in Review, *available online at* <http://www.fda.gov/downloads/TobaccoProducts/NewsEvents/UCM216374.pdf>.

can trust. That's always critical in any regulatory system, but history tells us it is absolutely fundamental to regulating tobacco products.”<sup>3</sup> These views were reiterated by Dr. Jonathan Samet, the Chairperson of TPSAC, who stated that “[o]ur goal is that today’s meetings will be a fair and open forum for discussion of these issues, and that individuals can express their views without interruption.”<sup>4</sup>

While these public statements of intention from FDA and TPSAC have been laudable, TPSAC must honor its commitment to ensure that it follows a procedure that will allow for an open and transparent process that will engender public trust in the Report that it issues.

***A. TPSAC must permit public review and comment on drafts of the Report.***

Transparency and inclusiveness demand that the public, including regulated industry, are provided with meaningful opportunities to participate in the science evaluation and Report drafting process. FDA and TPSAC have provided opportunities for participation in TPSAC meetings and comments to the docket. But given its critical nature, drafts of the Report itself should be subject to extensive review and comment by the public. In order to permit an orderly and open process, we propose that TPSAC adopt the following schedule:

- November 15, 2010 -- TPSAC summary of its review of documents that TPSAC requested be produced by tobacco companies
- December 15, 2010 -- TPSAC First Draft of Report Circulated For Public Comment
- January 15, 2011 -- TPSAC Second Draft Showing Changes and Additions To First Draft
- February 15, 2011 -- TPSAC Third Draft Showing Changes and Additions
- March 23, 2011 -- TPSAC Final Report

***B. Non-voting TPSAC members should be permitted to meaningfully participate.***

The FSPTCA provided for a diversity of membership on the TPSAC, including representatives of regulated industry and growers as non-voting members of the Committee. Dr. Deyton stated in the March 30, 2010 meeting, “[a]s you know, the [FSPTCA] requires that this Committee have three non-voting members representing the tobacco industry. And there is a reason for that. A precondition for designing effective regulatory measures is understanding the industry to be regulated, and the tobacco industry is no exception. So successful implementation

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<sup>3</sup> Food and Drug Administration, Center for Tobacco Products, Tobacco Products Scientific Advisory Committee Meeting, at 37 (March 30, 2010).

<sup>4</sup> Food and Drug Administration, Center for Tobacco Products, Tobacco Products Scientific Advisory Committee Meeting, at 6 (March 30, 2010).

of [FSPTCA] requires engaging the various components of the tobacco industry directly, fairly and with transparency.”<sup>5</sup>

For these non-voting members to adequately represent the interests of their constituencies – and to provide TPSAC the benefit of their extensive, industry-specific scientific knowledge and experience -- they must be provided with a meaningful opportunity to contribute. This means at the very least that non-voting members of the committee must be given full access to all committee materials on the same timeframe as other TPSAC members, so that non-voting members may fully participate in the proceedings.<sup>6</sup> This treatment is required by FDA’s own regulations, which provide that non-voting members have the “same rights as any other committee member,” subject to limited exceptions that would not apply to drafting the menthol Report.<sup>7</sup>

**C. *Voting members must be screened for all conflicts of interest, including opposition to the industry.***

Fostering an open and transparent process also requires FDA to abide by conflict of interest laws to ensure that members of TPSAC do not have prior or existing relationships that may undermine the legitimacy of the process. FDA has stated that members of its advisory committees “[a]re subject to the conflict of interest laws and regulations . . . as special government employees.”<sup>8</sup> As special government employees (SGE), TPSAC members must comply with various federal conflicts of interest laws, which prohibit, among other things, “financial” and “appearance” conflicts of interest. It is unlawful for an SGE to participate in any “particular matter” in which he or she has a “financial interest” that could be affected by the government action under consideration, or where circumstances “would raise a question regarding” an SGE’s “impartiality.”<sup>9</sup> Numerous questions have previously been raised with respect to at least four members of TPSAC who appear to have either “financial” conflicts of interest or “appearance” conflicts of interest. These members have testified in smoking and health cases against tobacco companies and/or consulted with drug companies that manufacture smoking cessation products.<sup>10</sup> For TPSAC’s Report to be legitimate and accepted by the public,

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<sup>5</sup> Food and Drug Administration, Center for Tobacco Products, Tobacco Products Scientific Advisory Committee Meeting, at 37 (March 30, 2010).

<sup>6</sup> The non-voting members have often received meeting materials several weeks after the voting members and only a few days prior to the meeting, leaving them unable to digest the information, get constituent feedback and participate in a substantive way.

<sup>7</sup> 21 C.F.R. § 14.86(a). The limited exceptions only concern (1) voting, and (2) access to trade secrets or confidential commercial information.

<sup>8</sup> 21 C.F.R. § 14.80(a)(2).

<sup>9</sup> 5 C.F.R. § 2635.502(a)(2).

<sup>10</sup> These issues were addressed at length in the letter submitted by Reynolds to FDA’s open docket on disclosure of conflicts of interest for special government employees (FDA-2002-D-0094).

these conflicts need to be properly reviewed and addressed in a full and transparent manner by FDA.

***D. Industry findings and industry-funded studies should receive fair consideration.***

Tobacco industry studies and findings have been regularly discounted by TPSAC and by FDA without explanation. In contrast, referenced studies that were conducted or sponsored by tobacco control organizations, some of which were not peer-reviewed or contained no primary scientific data, have been accepted unquestioningly despite their origins. As TPSAC reviews the science, it may prove that individual studies will be found lacking in some regard, and such studies should indeed be excluded from consideration. However, the widespread negating of peer-reviewed, published scientific papers as “tobacco industry-funded studies” without noting the potential biases and weaknesses in tobacco control studies is inappropriate and compromises the objective science base of the TPSAC process. Some of the most significant and advanced analyses and laboratory assessments of tobacco products have been conducted by tobacco industry interests or performed by these interests at independent extramural laboratories. This body of work must be considered in a balanced manner alongside similar work from non-industry investigators.

Any arbitrary discounting of industry studies and viewpoints contravenes FDA’s own statements regarding objectivity and inclusion.

**II. TPSAC’S REPORT ON MENTHOL MUST BE BASED ON RIGOROUS AND OBJECTIVE SCIENTIFIC STANDARDS.**

A cornerstone of any FDA proceeding is adherence to a rigorous scientific process. The FSPTCA requires TPSAC’s Report to be based solely on the science of menthol.<sup>11</sup> Moreover, addressing TPSAC at its first meeting, Dr. Margaret Hamburg, FDA Commissioner, explained, “I want to underscore it once again, that the FDA regulation of tobacco products is a science based, science driven process. It must be.”<sup>12</sup> Dr. Lawrence Deyton echoed Dr. Hamburg, stating, “the work of this committee is so fundamental to FDA’s mission. The advice you give us based on the science and the science alone will help us at FDA shape regulations and programs that will literally save people’s lives.”<sup>13</sup> The letter of the law, along with numerous pronouncements by FDA leadership, makes it clear that sound science alone must form the foundation for TPSAC’s Report.

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<sup>11</sup> See Pub. L. No. 111-31, § 907(a)(3)(B)(i).

<sup>12</sup> Food and Drug Administration, Center for Tobacco Products, Tobacco Products Scientific Advisory Committee Meeting, at 29 (March 30, 2010).

<sup>13</sup> Food and Drug Administration, Center for Tobacco Products, Tobacco Products Scientific Advisory Committee Meeting, at 39 (March 30, 2010).

**A. *TPSAC must conduct a comprehensive evaluation of the relevant data.***

If FDA is to truly adopt a science-based approach, TPSAC must evaluate all available and verifiable data and studies on the health effects of menthol cigarettes. In doing so, TPSAC should give greater weight to those studies that demonstrate sound methodology. This includes industry-funded studies, which often constitute the largest and most scientifically rigorous studies on menthol.

To date, TPSAC has undertaken only a cursory analysis of a limited set of scientific data and studies regarding menthol. In forming opinions on other important topics, TPSAC members appear to have primarily relied on data presented to the committee, accepting conclusions without analyzing the data underlying those conclusions. As an example, the TPSAC was recently asked to assess a list of harmful and potentially harmful constituents in tobacco products and tobacco smoke. Rather than making an independent assessment of the scientific data and literature, TPSAC adopted the recommendations of the International Agency for Research on Cancer, the Environmental Protection Agency and the National Toxicology Program with barely any critical analysis.

As TPSAC moves to the core of its review of menthol in cigarettes, it must strive to avoid the seemingly superficial process used to develop its recommendations on constituents. Only a robust and scientifically valid process should be used to impose regulations on manufacturers of mentholated cigarettes.

**B. *The scientific data that forms the basis for the Report must be data presented before the committee.***

TPSAC has permitted the influx of opinion and innuendo formed from data and studies external to TPSAC. For instance, to bolster their arguments during meetings, voting TPSAC members have often referred to studies that they have personally conducted or reviewed outside of the committee but that have not been formally presented to TPSAC. Such practices do not permit either the public or other members of TPSAC to evaluate the studies and verify their accuracy.<sup>14</sup>

These instances confirm that there must be a single rigorous, scientific standard applied to both the selection of the data and studies that TPSAC reviews and to the evaluation of particular studies and conclusions concerning the health effects of menthol cigarette use. At the very least, the standard must include: objectivity in considering data; inclusion of all available

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<sup>14</sup> As an example, when discussing a study before the committee which demonstrated that menthol cigarette users smoked fewer cigarettes-per-day than non-menthol cigarette smokers, Dr. Neal Benowitz referred to external evidence to make a counter point: “[i]n my research and most of the research I’ve ever seen, if you look at menthol cigarettes in general, they tend to have higher tar and higher nicotine deliveries than non-menthol cigarettes.” Video at 01:35:40, Food and Drug Administration, Center for Tobacco Products, Tobacco Products Scientific Advisory Committee Meeting (March 30, 2010).

data; and consideration for the full spectrum of worthy interpretations of the data and the weight of the evidence.

***C. An objective assessment of the science demonstrates that menthol does not adversely impact the public health.***

There is no meaningful difference between the health effects related to smoking menthol and nonmenthol cigarettes. An overwhelming body of epidemiology findings indicates that chronic smoking-related disease risks are unrelated to cigarette mentholation. These findings are powerfully supported by and consistent with available chemistry, toxicology and biomarkers data that indicates that menthol and nonmenthol cigarettes do not differ in terms of public health impacts. Levels of biomarkers of exposure, which are quantitative measures of smokers' systemic exposures that reflect the combined influences of all aspects of smoking behavior, are not elevated among menthol smokers. Biomarkers findings to date are consistent with similar smoking behaviors and inhalation intensities between menthol and nonmenthol cigarette smokers. Both the epidemiology and biomarkers results are consistent with equivalent smoking cessation by menthol and nonmenthol cigarette smokers in the general population of the US. (See written submissions and presentations summarizing the science related to menthol in cigarettes provided by Lorillard Tobacco Company and R. J. Reynolds Tobacco Company in connection with TPSAC meetings on March 30-31 and July 15-16 (available at [www.fda.gov](http://www.fda.gov))).

Major surveys of cigarette brand preferences in the United States among adolescent and adult smokers show that the top three largest-selling brands are the same across all age categories of both occasional and regular smokers. African-American adolescent smokers report a higher preference for menthol cigarettes than do White adolescent smokers, and yet those African-American adolescents have, for many years, reported a much lower rate of smoking than their White counterparts. This and other information indicates that menthol does not facilitate smoking among youth. In fact, a state-by state comparison of youth smoking rates and menthol cigarette sales shows a modest but statistically-significant inverse correlation. Menthol is not a causal factor in youth smoking initiation.

**III. TPSAC MUST FAIRLY CONSIDER ALL OF THE ISSUES SURROUNDING USE OF MENTHOL PRODUCTS.**

FDA and TPSAC have focused extensively on the marketing practices of the tobacco industry to explain the preference for menthol cigarettes in certain racial or ethnic segments of the community. TPSAC has requested an extraordinary amount of documents from industry on marketing practices, and industry has responded by submitting millions of pages of documents (and for some companies, additional documents are to be submitted in coming weeks). In addition, industry has made numerous written submissions and presentations to TPSAC demonstrating that the industry's marketing practices for menthol cigarettes are no different than those for nonmenthol cigarettes. It does not appear that TPSAC or FDA has reviewed these documents or evaluated these submissions. Rather than understanding the actual practices employed by the industry today, in public meetings to date the agency and committee have seemed focused on historical practices. As TPSAC moves forward with its menthol Report, it must develop and implement a systematic process to review the information provided by industry and integrate this review into its final Report.

Moreover, the trends surrounding the use of menthol products are very complex and TPSAC must resist the temptation to oversimplify the issue and place all of the responsibility for current menthol cigarette use on industry practices. There are many forces and issues that impact consumer preferences and brand life dynamics for any consumer product, including menthol cigarettes. The market share of menthol products has varied historically, rising and falling in accordance with consumer preferences, as opposed to industry marketing practices.<sup>15</sup> If TPSAC believes that menthol cigarette use is impacted by current industry marketing practices, TPSAC must establish such a connection.

#### IV. CONCLUSION

TPSAC must take pains to ensure that the Report drafting process is open, inclusive and founded on sound science. Political and media attention concerning TPSAC's work will be intense. It is critical that the Committee and FDA rise above the fray and adhere to the science -- not any political agenda. TPSAC must use an evenhanded and transparent process that permits a fair consideration of all of the available evidence concerning menthol cigarettes. We believe that if TPSAC adheres to the available science, it will conclude that menthol cigarettes cause no more harm to the public health than non-menthol cigarettes. For the committee's benefit, Appendix A provides a proposed outline for the menthol Report, which emphasizes the science-based nature of TPSAC's task and the necessity to be inclusive of various viewpoints.

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<sup>15</sup> See, e.g., presentations of Lorillard and Reynolds to TPSAC (July 15, 2010), *available at*: <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm220024.htm>; submissions to TPSAC for March 30, 2010 meeting, *available at*: <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm220024.htm>.

## APPENDIX A

### PROPOSED OUTLINE FOR REPORT AND RECOMMENDATION ON THE IMPACT OF THE USE OF MENTHOL IN CIGARETTES ON THE PUBLIC HEALTH

#### I. INTRODUCTION

- A. Statutory Authority

#### II. LISTING OF TPSAC MEMBERS AND BACKGROUND ON EACH

#### III. SUMMARY OF TPSAC MEETINGS AND WORK OF TPSAC

- A. Schedule of Meetings
- B. FDA Review of Industry Document Production
  - 1. Industry legacy documents/publicly available/cited in publications
  - 2. Newly produced documents in response to TPSAC/FDA requests
- C. TPSAC Review of Company Submissions
  - 1. Process Followed
  - 2. Discussions of Company Presentations
- D. Research Solicited by Center for Tobacco Products and Results
- E. Scientific Method Followed to Analyze Studies, Data, Documents and Determine Weight of Evidence

#### IV. HISTORY AND FEATURES OF MENTHOL CIGARETTES

- A. Discovery of Menthol Cigarettes
- B. Menthol Levels
- C. How Menthol Cigarettes Are Made
- D. Menthol in Non-Menthol Cigarettes

#### V. HEALTH EFFECTS AND BIOMARKERS

- A. Results of 13 Epi Studies
- B. Summary of Biomarker Studies

- C. Summary of Chemistry, Toxicology and Smoking Topography Studies
- D. Summary of All Written Submissions and Presentations, Including by Industry

**VI. ADDICTION AND CESSATION**

- A. Studies on Addiction
  - 1. Limitations of Addiction Studies
- B. Studies on Cessation
  - 1. Limitations of Cessation Studies
- C. Summary of All Written Submissions and Presentations, Including by Industry

**VII. DEMOGRAPHICS OF MENTHOL SMOKING**

- A. General Population
- B. African- Americans and Hispanics
- C. Age Groups
- D. Summary of All Considered Reviews of Demographics Based on National Survey Data, Including Submissions and Presentations by Industry

**VIII. ADOLESCENT SMOKING**

- A. Rates of Adolescent Smoking
- B. Adolescent Smoking Among African-Americans
- C. Limitations on Survey Data and Inferences Regarding Smoking Initiation

**IX. CURRENT MARKETING OF MENTHOL CIGARETTES**

**X. EFFECTS OF POTENTIALLY TREATING MENTHOL AND NON-MENTHOL CIGARETTES DIFFERENTLY**

- A. Impact on the Demand for Contraband
- B. Technical Achievability of Compliance with Standard

**XI. RECOMMENDATIONS**