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ABSTRACT

Publicly available internal tobacco industry documents were analyzed to answer the following questions regarding the sensory qualities of menthol and its possible effects on topography: 1) What properties does menthol contribute to the smoking experience? 2) Does menthol contribute to the sensory qualities of the smoke and affect smoking topography? 3) Do changes in smoking topography lead to greater exposure to toxic substances, increased nicotine dependence, or greater chance of tobacco-related disease? 4) What are the various ways menthol is measured and how are menthol yields determined? 5) Does the menthol content and/or yield have an effect on how the cigarette is smoked or cigarette preference? 6) What is the relationship between menthol and intensity in use of cigarettes (i.e., does menthol lead to a higher delivery of smoke per cigarette)? A final collection of 252 documents was analyzed for this report, of which 67 were deemed relevant to one or more of the research questions and cited in this paper. Our analyses of the documents indicate the following: 1) Menthol has cooling and anesthetic properties that moderate the harshness and irritation of tobacco; 2) Menthol contributes to the sensory qualities of the smoke and affects smoking behavior and cigarette preference depending on the level of menthol and nicotine in the cigarette; 3) It is unclear whether menthol's effect on smoking behavior leads to greater exposure to toxic substances; 4) Menthol is measured in milligrams or micrograms that are distilled from a cigarette before and after smoking; 5) It is unclear whether the menthol content and/or yield have an effect on how a cigarette is smoked because most testing that we were able to locate in the documents was done on new mentholated products by in-house smoker panels; and 6) It is unclear what the tobacco industry knew about the relationship between menthol and intensity in use of cigarettes. The documents provide

evidence that cigarette manufacturers not only use menthol as a flavorant, but also as an ingredient that has physiological effects, and synergistically interacts with nicotine.

INTRODUCTION

The Family Smoking Prevention and Tobacco Control Act (Act) gives the US Food and Drug Administration (FDA) regulatory authority over tobacco products. On September 22, 2009, the FDA exercised this authority when it announced the ban of some cigarette flavorings. However, this ban did not include menthol, as it was excluded from the list of banned flavorings originally identified in the Act. Menthol's exclusion from the list of prohibited flavor additives in cigarettes has promoted discussion among many in the public health arena.[1] The Act included a requirement to create the Tobacco Products Scientific Advisory Committee (TPSAC) within the FDA's Center for Tobacco Products. TPSAC is charged with advising the FDA Commissioner on the regulation of tobacco products, including the use of menthol as a characterizing flavor in cigarettes and the impact of mentholated cigarettes on public health, with special attention given to children, African Americans, Hispanics and other racial and ethnic minorities.

The wide use of menthol in cigarettes is due to its minty flavor, aroma, and cooling characteristics, and physiological effects on the smoker.[2, 3] The isomer l-menthol is the largest component of peppermint oil extracted from the two significant types of peppermint plants, Mentha piperita and Mentha arvensis. There are significant taste differences among the various isomers. Only 1-menthol imparts the well-known mint-like taste and desired cooling effect.[3] Depending on the product and desired flavor, the amount of menthol will vary, but is present in 90% of all tobacco products, both "mentholated" and "non-mentholated."[3, 4] The market-share of filter-tipped mentholated products has ranged from 1.1% in 1956 to 27.3% in 1983 to 20% in 2006.[3, 5] Available data currently show that past month use of mentholated brands among cigarette smokers aged 12 or older varies by race and ethnicity:[6]

- 82.6% African American
- 53.2% Native Hawaiian

- 32.3% Hispanic
- 31.2% Asian
- 24.8% American Indian/Alaska Native
- 23.8% non-Hispanic white

Although menthol is an FDA-approved food additive, the FDA is now considering the fate of menthol's use as a characterizing flavor in cigarettes (menthol cigarettes) and has requested a review of tobacco industry documents to answer questions regarding a number of menthol-related topics. This paper will address the following questions asked by the TPSAC related to the role of menthol in smoking topography (the puffing and inhalation behaviors experienced while smoking)[7]:

1. What properties does menthol contribute to the smoking experience?
2. Does menthol contribute to the sensory qualities of the smoke and affect smoking topography?
3. Do changes in smoking topography lead to greater exposure to toxic substances, increased nicotine dependence, or greater chance of tobacco-related disease?
4. What are the various ways menthol is measured and how are menthol yields determined?
5. Does the menthol content and/or yield have an effect on how the cigarette is smoked or cigarette preference?
6. What is the relationship between menthol and intensity in use of cigarettes (i.e., does menthol lead to a higher delivery of smoke per cigarette)?

The goal of this research is to determine what the tobacco industry knows about the potential effects menthol may have on smoking topography.

METHODS

In this qualitative research study of the digitized repository of previously internal tobacco industry documents, a snowball sampling design[8] was used to search the Legacy Tobacco Documents Library (LTDL) (http://legacy.library.ucsf.edu). We systematically searched the LTDL between June 01, 2010 and August 09, 2010, utilizing standard documents research techniques. These techniques combine traditional qualitative methods[9] with iterative search strategies tailored for the LTDL data set.[10]

Based on the FDA staff-supplied research questions (see Introduction above), initial keyword searches combined terms related to: menthol, topography, smoking behavior, menthol yield, menthol intensity, inhaled volume, and carbon monoxide level. This initial set of keywords resulted in the development of further search terms and combinations of keywords (e.g., depth inhalation, puff number, puff volume, bustle-injected, menthol release agent). Of the approximately 11 million documents available in the LTDL, the iterative searches returned tens of thousands of results. (See Appendix A for full list of search terms and number of results returned.) For example, a search of all tobacco industry document collections on the LTDL for the keyword "menthol" alone would yield over 800,000 documents. The results that are returned in the LTDL include multiple copies of many documents, so researchers must decide which irrelevant and duplicate documents to exclude. Relevance was based on whether, upon electronically searching or reading a document, it included content related to the topic or the specific questions presented by the FDA staff. Tobacco companies investigated issues in order to increase their share of market, rather than to understand public health issues; thus, many of the tens of thousands of returned documents with these search terms did not appear to be directly relevant.

For each set of results, the researchers reviewed the first 100-200 documents. If documents did not appear to be relevant to the research questions, or if there was a repetitive pattern of documents, the researchers moved on to the next search term. Among the reports, correspondence, and studies conducted by product development and research departments of the major tobacco companies (American Tobacco, British American Tobacco (BAT), Brown & Williamson, Lorillard, Philip Morris, and RJ Reynolds), relevant documents were found in the following subject areas: 1) menthol's contribution to the smoking experience and smoking topography; 2) how menthol is measured and yields determined; and 3) menthol's effect on smoke delivery. A final collection of 252 documents were deemed relevant to one or more of the research questions. Memos were written to summarize the relevant documents to further narrow down to the 67 relevant documents that are cited in this white paper. Appendix A details the results of the searches and the number of documents screened and further reviewed.

Limitations

Tobacco industry document research presents unique challenges,[8] and results should be interpreted within the context of known limitations, such as the vast number of available documents, time restrictions, and the use of code words and acronyms. The sheer quantity of available documents (over 60 million pages) forces researchers to make decisions about which search terms retrieve the most relevant material. Further, the LTDL is frequently updated as tobacco companies provide additional material and documents become available through litigation. The document searches were conducted over a ten-week period. Given the short period of time for conducting this project (LTDL archival research often takes a year or more to complete), the research team had to strategically screen the documents through the process discussed above.

In analyzing the documents during a limited timeframe, context may have been lost and, therefore, this white paper cannot be a comprehensive report of all documents related to the influence of menthol on smoking topography. Understanding the time period when a document was written, who wrote a document, why a document was written, or why a study was performed requires time for reviewing and linking documents together. It is also difficult to compare statistics gathered using different methodologies used by numerous companies over several decades.

Even if there had been more time for searching, it is unlikely that a complete picture of the tobacco industry's research about menthol and smoking topography could be compiled. There is evidence that the industry tried to hide its findings, although it is unclear from whom. For example, in a 1974 BAT memo about a visit to BIBRA, a toxicology consulting firm, it was noted that "Reference to menthol should be omitted from such documents [invoices], which should refer generally to toxicity studies."[11] Brown and Williamson used the code terms, such as "Kintolly," "Tolkin," "Harpat," "Polar Bear," and "Cenmap" when referring to menthol.[12] However, the search of these code terms did not return results relevant to smoking and topography. Acronyms were also commonly used, which are often unclear if the context is unknown.

Research in the LTDL typically involves repeating the iterative search process (including searching all code words and acronyms we learn through the process) until we reach saturation of both keywords and documents. Unfortunately, we could not reach saturation for this white paper; however, the documentary evidence presented in this paper supports our primary findings.

RESULTS

Table 1 presents the research questions and summarizes the basic findings.

Table 1: RESEARCH QUESTIONS AND BASIC FINDINGS

Question	Summary of finding based on review
1) What properties does menthol contribute to the smoking experience?	Menthol has cooling and anesthetic properties that can moderate the harshness and irritation of tobacco.
2) Does menthol contribute to the sensory qualities of the smoke and affect smoking topography?	Yes, menthol contributes to the sensory qualities of the smoke, and affects smoking behavior and cigarette preference depending on the level of menthol and nicotine in the cigarette.
3) Do changes in smoking topography lead to greater exposure to toxic substances, increased nicotine dependence, or greater chance of tobacco-related disease?	Based on our limited research of the publicly available internal tobacco industry documents, it is unclear whether menthol's effect on smoking behavior leads to greater exposure to toxic substances. What internal documents disclose about the role menthol may play in nicotine dependence is discussed elsewhere.[13]
4) What are the various ways menthol is measured and how are menthol yields determined?	Menthol is measured in milligrams or micrograms that are distilled from a cigarette before (product) and after smoking (smoke). Menthol is highly mobile and volatile, and tobacco companies sought patents to reduce the mobility and volatility to improve the smokability of menthol cigarettes.
5) Does the menthol content and/or yield have an effect on how the cigarette is smoked or cigarette preference?	It is unclear whether the menthol content and/or yield have an effect on how a cigarette is smoked because most testing that we were able to locate in the documents was done on new mentholated products by in-house smoker panels.
6) What is the relationship between menthol and intensity in use of cigarettes (i.e., does menthol lead to a higher delivery of smoke per cigarette)?	Based on our limited research of the publicly available internal tobacco industry documents, it is unclear what the tobacco industry knew about a relationship between menthol and intensity in use of cigarettes.

i. What properties does menthol contribute to the smoking experience (i.e., anesthetic, cooling, etc.)?

Menthol has cooling and anesthetic properties that are dose-sensitive. The menthol properties moderate the harshness and irritation of tobacco, affecting a smoker's experience of smoking.

Tobacco manufacturers have done extensive consumer research on mentholated cigarettes, often testing qualities of new products against existing menthol products or competitor products. Mentholated products were promoted to offer an alternative to the heavy, harsh, hot, and many times unpleasant experience of non-mentholated products.[14] During the course of several years, tobacco manufacturers tested menthol's effect on consumer attributes.[15] A 1978 memo from market researchers Shirley Wilkins and Bud Roper (of the Roper Organization) to Jon Zoler and Al Udow of Philip Morris' marketing and consumer research departments addressed menthol properties:

> The Richmond [VA] meeting confirmed certain theses that we had—that there are physiological effects from menthol, and that the taste of a menthol cigarette lasts longer than that of a non-menthol. [The meeting] added the information that menthol has a slightly "local anesthetic" effect.
>
> We already have a number of known facts about menthol smokers—that they tend to be young, black, female and lighter smokers…we should focus…on <u>why</u> [emphasis in original] certain smokers are attracted to menthol when others are not...[16]

The following year the Roper Organization conducted the focus group study "Smoker's habits and attitudes with a special emphasis on low tar and menthol cigarettes."[17] One of the purposes of this study was to assess the menthol market in terms of usage and smokers' attitudes. The study consisted of interviews of a "representative nationwide cross section of 4016 people

18 years of age and over, which yielded 1367 smokers."[17] Interviews were also conducted among an oversample of menthol smokers. Survey results revealed,

> [T]here were no unique or distinctive taste preferences that distinguish menthol smokers from other smokers—aside from their liking for menthol. What differences exist in taste preferences are either minor or contradictory or both…The survey suggests that the appeal of menthol cigarettes is more in terms of their effects than their tastes.[17]

Key terms regarding menthol properties described by tobacco companies included "cooling effect," "irritation," "analgesia," "amelioration," and "slightly numbing, anesthetic effects."[17, 18] According to a 1981 Philip Morris document, tobacco manufacturers interchanged "*physiological effects*" with "*taste*" [emphasis in original]."[19] Taste is important to the industry as the viability of their products in the market is dependent on taste.

Menthol elicits a sensation of coolness, which may then lead the smoker to experience the cigarette as "refreshing."[20] The cooling effect appears not to be a result of volatilization of menthol, but rather a result of the chemical action that occurs at or near nerve endings associated with the sensation of cold and located in the nasal, oral, and skin membranes.[13] As a report from a tobacco chemists' research conference described, menthol activates these cold receptors by interfering with the calcium conductance of the neuronal sensory membranes.[21] The report indicates that menthol has been clearly demonstrated to affect the response of many receptors to stimulation.[21] Duke University's neurobiology researchers Sidney Simon, PhD and Miguel Nicolelis, MD, PhD, who were funded by Philip Morris, demonstrated menthol's diverse abilities to evoke sensory pathways, affecting differently cold fibers, taste receptors and trigeminal ganglion neurons.[22, 23]

The olfactory (smell) and gustatory (taste) senses are especially sensitive to menthol. When menthol is added to cigarettes and smoked, its cooling sensation is also experienced in the lungs.[21] The response to menthol is enhanced in small concentrations. However, large concentrations of or chronic exposure to menthol will depress receptor response to menthol.[21] For example, the cooling sensation is dose-sensitive, up to a point, after which there generally would not be any further degree of cooling. Instead, an increase in the menthol level would lead to an increase in unintended sensations such as tingling, stinging, and burning.[24]

Menthol has the ability to "undeniably impart a cooling influence," and in doing so, reduces both harshness and tobacco taste.[25] In addition to contributing to a minty, refreshing, and cooling taste experience, RJ Reynolds chemical and sensory evaluation research team showed menthol moderated the negative sensations, such as the irritation that comes with the smoking of tobacco.[26] Between 1982 and 1986, RJ Reynolds conducted several sensory studies examining nicotine as an independent continuous variable in relation to mainstream smoke sensory characteristics.[27] According to its own review of the company's sensory studies done on test cigarettes containing different levels of nicotine, RJ Reynolds observed strength and aftertaste to be measurable responses to any change in nicotine delivery. As the yield of nicotine delivered by a cigarette is lowered, so is the amount of satisfaction to the smoker. This noticeable change in satisfaction is offset by the presence of menthol, as "menthol will effectively mask the changes in nicotine delivery."[27] These findings suggest adding menthol as a flavoring allowed tobacco manufacturers not only to design cigarettes with less nicotine, but as RJ Reynolds pointed out about Brown & Williamson, to "mask a multitude of sins behind menthol."[28]

RJ Reynolds conducted taste tests with non-menthol Winston cigarettes, which had been added with 1 to 2 µg/puff of menthol. The test was designed to see if low or subliminal levels of menthol would enhance smoke quality.[29] Although smokers did not detect the menthol, they did notice a reduction in nasal sting, tongue bite, and harshness, which demonstrates menthol's non-flavor-related effects on unfavorable aspects of smoking cigarettes. Smokers participating on smoke panels for British American Tobacco reported that the test prototype cigarette with "strong menthol intensity throughout" masked tobacco flavor.[30]

RJ Reynolds used Quantitative Data Analysis (QDA)[*] to test mentholated full flavor low tar (FFLT) products.[31] In a 1983 study where menthol and nicotine levels were varied, panelists found menthol to contribute to the taste of menthol, a cooling effect, and a coating aftertaste.[31] Smoke menthol, and not nicotine level, was found to be the major contributor to the organoleptic (i.e., relating to the senses) perception experienced by the panelists when smoking mentholated low tar cigarettes. Smoke nicotine level was found to play a relatively minor role.[31] In 1984, RJ Reynolds conducted a subsequent study with six groups,[20] where three of the groups were asked to smoke full flavor cigarettes and the other three groups were asked to smoke what RJ Reynolds identified as "full flavor low tar" cigarettes. Focus group participants identified menthol descriptors, leading RJ Reynolds to make the following observations:

> Coolness is a function of menthol. Coolness is a sensation more than a taste. It can be negative in terms of too much menthol. Refreshing is an element of coolness.
>
> . . .
>
> Different consumer groups want different balances between tobacco and menthol taste. Both elements are extremely important. Balance is critical…Tobacco taste is critical – it relates to strength.
>
> . . .
>
> Tobacco taste is the driver among Newport smokers. Tobacco taste is very important, but they want some menthol.
>
> …

* This method involved "trained subjects who identify sensory characteristics and indicate the relative intensity of their perception of a set of products."[31]

> High menthol levels ([menthol] taste and [menthol] intensity) can lead to harshness perceptions because of related, undesirable sensations.[20]

By making cigarettes smoother and less harsh, menthol alleviates nicotine's irritating effect. For decades, the tobacco industry has known that younger, inexperienced smokers have lower tolerance for irritation and tobacco taste than do older and more experienced smokers.[32, 33] A 1983 confidential RJ Reynolds memo written by the company's chemists may provide insight as to how the interaction between nicotine and menthol is taken into account when engineering tobacco products.

> "Nicotine…[is] a major irritant in cigarette smoke while menthol is known to produce a cooling effect and is often used to alleviate sensations of irritation. Thus, in mentholated cigarette smoke, a balance between the irritation of nicotine and soothing of menthol might be important in the perception of these products. For instance, in the case of two cigarettes at the same nicotine [level] but different menthol levels, the product with more menthol might appear to be less irritating. Likewise, for two cigarettes at the same menthol [level] but different nicotine levels, the product containing more nicotine might be perceived to have less menthol-related attributes"[34]

More than ten years after the Roper Report, Philip Morris was still attempting to "understand … taste and performance dimensions of menthol cigarettes" for development of a new menthol product.[35] In a 1992 focus group study intended to collect data to be used for developing a new menthol product, participants reportedly "seem to like menthol because <u>it buffers/masks the taste of tobacco</u> [emphasis in original]," and Philip Morris decided that "further exploration of <u>positive</u> ways to leverage this masking effect may be warranted [emphasis in original]."[35] However, the menthol smokers in the study (panelists) also noted that inhaling cigarettes with too much menthol elicited a "bite" that actually hurts.[35] Furthermore, the panelists made a distinction between inhaling and exhaling menthol cigarettes.[35] Panelists perceived inhaling a menthol cigarette to be "cool" or "minty," and that the "rush" of menthol was more pronounced during inhalation.[35] In contrast, panelists perceived the sensation of exhaling menthol cigarettes to be "less about the menthol taste and more about the absence of cigarette taste."[35] It is during the exhalation phase, according to the panelists, that menthol masks the taste of tobacco, making the smoke "smoother."[35]

Tobacco manufacturers knew, not only from their own internal studies but also from tracking studies published in peer-reviewed journals, that menthol has cooling and anesthetic properties that moderate the harshness and irritation of tobacco.[36] One of the concluding remarks made by The Creative Research Group in its 'Project Crawford' report, presented in 1982 to the Imperial Tobacco Company, succinctly states how menthol's properties affect the smoking experience.

> The whole smoking experience, for the committed menthol smoker, thus becomes much more pleasant. Negatives are minimized (tobacco taste and harshness); positive attributes are superimposed (coolness and menthol taste). In fact, given the menthol smoker's explanation, it becomes difficult to understand why everyone would not switch to a menthol brand![25]

ii. Does menthol contribute to the sensory qualities of the smoke and affect topography? What are the effects and what is the mechanism? (i.e., Increased breath holding? Larger puff volumes? Reduced perception of cigarette smoke irritation? Expired carbon monoxide levels?)

Yes, menthol contributes to the sensory qualities of the smoke and affects smoking behavior and cigarette preference depending on the level of menthol and nicotine in the cigarette.

Menthol's "nicotine-like" electrophysiological effects and menthol's "synergistic interaction"[37] with nicotine affect smokers' perceptions of their smoking experience, measured by impact and liking scores. The results of these industry studies have been described elsewhere.[13, 38] A number of factors collectively account for smoking topography, or how a person smokes a cigarette. There are both intra- and inter-individual differences in smoking behavior, resulting in differences in the number of puffs, puff volume, and frequency; how deeply one inhales; how long one holds smoke in the lungs; and how much of the cigarette the smoker smokes. Following is a list of the smoking behavior parameters, provided by RJ Reynolds' scientists as part of the company's New Product Technologies and Human Smoking Behavior programs [emphasis in original].[39]

- MEAN and PEAK PRESSURE…how hard the subject is drawing on the cigarette. Mean is the average over a puff, and peak is the maximum.
- FLOW RATE…the rate of airflow through the mouth end of the cigarette.
- PUFF DURATION…how long [in seconds] the subject draws on the cigarette during a puff.
- PUFF VOLUME…the volume of air that flows through the mouth end of the cigarette during the puff.
- NUMBER OF PUFFS…simply the number of distinct puffs the subject takes while smoking the cigarette.
- TOTAL PUFF VOLUME…the total volume of air that flows through the mouth end of the cigarette during all puffs of the cigarette smoking. It is simply the sum of the puff volumes of each puff.
- CYCLE TIME…the length of time in seconds from the <u>beginning</u> of a puff until the <u>beginning</u> of the next puff.
- STATIC TIME…the length of time in seconds form the <u>end</u> of a puff until the <u>beginning</u> of the next puff.
- FREQUENCY...the reciprocal of cycle time, expressed in puffs per minute.

No two smokers smoke the same; furthermore, a smoker is not likely to smoke in the same way all the time.[40, 41] When collecting data on topography parameters of test cigarettes or prototypes, RJ Reynolds deleted all puffs that began during the first three seconds of smoking (which were referred to as "lighting puffs"), because these initial puffs were based on expected product performance and not on actual performance of a test cigarette.[39]

According to studies cited in a Philip Morris report on the evaluation of the use of menthol as a cigarette ingredient:

> Smokers not only smoke different brands differently, but they also smoke the same brand differently depending upon a host of human, social and environmental variables. Sensory cues, such as smoke taste and impact [the "kick" or "grab" in the back of the mouth and throat.[38]] all contribute to a smoking profile, and ultimately relate to the yield of a variety of smoke constituents in the puff (Reeves and Dixon, 1995). Smoking parameters are variable between individual human smokers ranging from 20 to 80 cm^3 for puff volume, 0.8 to 3.0 sec for puff duration, 20 to 100 sec for puff interval and 19 to 28 mm for butt length of unfiltered cigarettes (e .g. Creighton and Lewis, 1978; Schulz and Seehofer, 1978; Darrall, 1988).
>
> …
>
> Smokers generally reduce their puff volume and duration as they consume the cigarette in order to reduce the sensory effects of yields which would otherwise increase with puff number (Nemeth-Coslett and Griffiths, 1985; Guyatt et al., 1989; Kolonen et al., 1992; Bentrovato et al., 1995; Reeves and Dixon, 1995).[40] [Cited articles can be located in this tobacco document.]

Several smoking studies examining the relationship between mentholation and smoking topography have been published in peer-reviewed journals,[2, 42-46] including articles written by industry researchers.[47-49] A recent review conducted by one of Lorillard's researcher cites methodological weaknesses in many of the published studies on menthol cigarette smoking topography.[48] For example, measurements of exhaled breath carbon monoxide (CO) as a biomarker to assess smoking intensity is "somewhat" compromised by "its lack of specificity, its protracted and variable elimination half-life, and its variable quantitative relationship to other smoke constituents across cigarette designs."[41] Referencing the work of Jarvik et al. (1994) that demonstrated mentholated cigarettes decrease puff volume, Lorillard noted:

> In this repeated-measures cross-over design study white subjects were found to take significantly more puffs than African American smokers, yet there was no racial difference in carbon monoxide levels, systolic or diastolic blood pressure, or heart rate. There was also no difference in number of puffs taken from regular or mentholated cigarettes.[41]

Lorillard also took notice of the 2004 Ahijevych and Garrett study that found that the anesthetic effect of menthol increased the depth of inhalation.[2] An industry document was created to dispute Ahijevych and Garrett's conclusion that menthol is "another additive which might be suspected of facilitating inhalation, by numbing the throat."

> Menthol from either pharmaceutical products or cigarettes, [sic] has a local sensory effect in the nasopharynx. However, there is no evidence that smoking a mentholated cigarette has any effect on smoking behaviour or respiratory dynamics that would lead to increased intake of smoke.[36]

In its confidential document titled "Menthol Allegations," Philip Morris concluded from its analysis of the published literature that menthol's effect on smoking topography and CO exposure is inconclusive due to "the complex interplay of smokers' taste preferences, ethnicity of subject, and selection of cigarettes to be smoked under experimental conditions."[50] This document was created in response to a civil lawsuit filed against Philip Morris and other tobacco companies. However, in 1973-1974 Philip Morris had already conducted a number of its own internal smoker simulation studies, collecting data on smoking behavior parameters such as puff count, puff volume (cc), flow (cc/min), puff duration (sec), and puff interval (sec). Data were collected from actual human subjects and not smoking machines. One of these smoking simulation studies compared the smoking parameters of menthol smokers with non-menthol smokers.[51] Philip Morris initiated this small study to determine if menthol smokers smoked differently than non-menthol smokers.[51] Twelve smokers participated in the study; half of whom were menthol smokers and the other half non-menthol smokers.[51] The model cigarettes were

Benson & Hedges Menthol and Benson & Hedges Regular. Each subject smoked each model cigarette six times.[51] The quantities of the ingredients of the menthol and non-menthol cigarettes were slightly different, but the tar, nicotine, and puff counts were higher in the menthol cigarettes (see figure below).[51]

Figure 1: Analysis of Ingredients in Regular and Menthol Benson & Hedges[51]

Benson & Hedges Regular	Analysis	Benson & Hedges Menthol
18.9	TPM, mg/cigt.	20.8
14.9	FTC Tar, mg/cigt.	16.5
1.14	Nicotine, mg/cigt.	1.33
1.9	Water, mg/cigt.	2.0
8.8	Puff Count, puffs/cigt.	9.1
4.7	RTD, in. of H_2O	4.8
	Menthol	
	Smoke, mg/cigt.	0.46
	Filter, mg/plug	1.57
	Rod, mg/cigt.	1.68

The higher puff volumes noted in this menthol vs. non-menthol study were associated with smokers smoking their usual cigarette type. The menthol smokers had higher puff volumes when smoking menthol cigarettes, whereas the non-menthol smokers had higher puff volumes when smoking non-menthol cigarettes. Table 2 was created for this paper using the data on the smoking parameters collected in this Philip Morris study.[51]

Table 2: Smoking Parameters of Menthol and Non-menthol Smokers in Philip Morris Study[51]

	Puff #	Puff Volume (cc)	Avg. Flow (cc/min)	Puff Duration (sec)	Puff Interval (sec)
MENTHOL SMOKERS					
Menthol cig 1st	10.6	54.0	1843	1.76	31.11
Menthol cig 2nd	8.7	44.0	1665	1.63	51.67
All menthol smokers smoking	9.6	49.0	1754	1.70	41.39

menthol					
Non-menthol cig 1st	9.1	41.9	1505	1.72	47.52
Non-menthol cig 2nd	10.9	53.2	1704	1.87	27.90
All menthol smokers smoking non-menthol cigs	10.0	47.6	1605	1.80	37.71
NON-MENTHOL SMOKERS					
Non-menthol cig 1st	13.9	45.5	1604	1.82	31.30
Non-menthol cig 2nd	9.0	49.5	1801	1.74	54.57
All non-menthol smokers smoking non-menthol cigs	11.5	47.5	1703	1.78	42.94
Menthol cig 1st	9.6	47.7	1779	1.66	50.07
Menthol cig 2nd	13.9	45.7	1586	1.85	29.55
All non-menthol smokers smoking menthol cigs	11.7	46.7	1683	1.76	39.81

With this small group, Philip Morris found that the data indicated no apparent differences among the two groups of smokers. The smoking parameters of the menthol smokers smoking both types of cigarettes were very similar to those of the non-menthol smokers. The difference in puff count between the two groups of smokers is apparently attributed to the high puff count of one particular subject (see subject #30, Table XIII in document).[51] While smoking a menthol cigarette may not have been significantly different, Philip Morris, however, noted that the menthol smokers may have developed a pattern of higher puff volume and average flow over time than the non-menthol smokers.

After a decade of its internal studies on menthol and smoking topography, which were often conducted with a small sample size, Philip Morris maintained its earlier views that:

> [S]moking behavior is comprised of a complex set of behaviors that involve psychosocial, sensory, and pharmacological factors. We also believe these factors to be influenced by adult smokers' demographic characteristics as well as their smoking history.[52]

RJ Reynolds also conducted studies on menthol's effect on human smoking behavior. One such study compared existing menthol brands Salem Light 85 and NOW Menthol 85 with five menthol NPT (new product technology) products.[39] The five menthol NPT prototypes differed from one another by the level of nicotine and menthol and smoking behavior attributes. (See tables 3, 4.) The configuration of the NPT products were 1) low nicotine and low menthol; 2) low nicotine and high menthol; 3) medium nicotine and low menthol; 4) medium nicotine and medium menthol; and 5) medium nicotine and high menthol. The low and medium nicotine yields were about 0.45 and 0.75 mg, respectively, and the low, medium, and high menthol yields were about 0.26, 0.45, and 0.70 mg respectively. These tables show the sensory qualities identified in RJ Reynolds' human smoking behavior studies.

Table 3 Nicotine and menthol levels in HSB Study[39]

Cigarette	Nicotine	Menthol	Notes
Salem Light 85	1.430	.725	Satisfying; easy to draw and light; menthol and cool taste
Now Menthol 85	.456	.410	Satisfying; easy to draw and light; menthol taste; cool

			taste, aftertaste; stays lit
NPT low nicotine/low menthol	.423	.263	Menthol taste; stays lit; less harsh
NPT low nicotine/high menthol	.472	.678	Less harsh; menthol taste; cool taste and aftertaste
NPT medium nicotine/low menthol	.745	.268	Least harsh; not easy to draw or light; less satisfying
NPT medium nicotine/medium menthol	.730	.449	Less harsh; least satisfying; not easy draw or light
NPT medium nicotine/high menthol	.759	.619	Less satisfying; not easy to draw or light; menthol taste

Table 4 Selected Attributes of Menthol Products in HSB Study[39]

Attribute	Salem	Now Menthol	L/L	L/H	M/L	M/M	M/H	Ideal
Harsh	118	116	101	90	77	94	98	139
Satisfying	68	83	147	138	170	173	162	108
Easy to Draw	50	57	115	105	120	114	126	89
Easy to Light	46	53	133	115	141	132	137	94
Stays Lit	42	45	96	85	101	92	100	98
Menthol Taste	62	66	93	82	113	98	77	90
Cool Taste	56	66	100	87	128	108	89	82
Cool Aftertaste	66	70	102	88	130	109	91	86

In addition to collecting qualitative data on attributes such as taste, aroma, coolness, and the cigarette's lightability (the ease by which a cigarette is lit and stays lit), RJ Reynolds collected measurements of the puffing parameters. RJ Reynolds primarily used these data to develop new products, but secondarily analyzed the data to examine the effects of nicotine and menthol levels upon smoking behavior. The smoking behavior results showed that smokers applied higher pressures to the NPT products, indicating that smokers were working harder to "get something" out of those products. All NPT products had a higher flow rate than Now Menthol and Salem Light; Now Menthol had a higher flow rate than Salem Light. The NPT products with the highest menthol levels resulted in highest flow rates and less time between puffs. As the menthol level increases to a certain point, the time between puffs also increases. Increased time between puffs is associated with satisfaction from the last puff. This finding suggests menthol level is associated with satisfaction from the last puff, "so that the NPT products are less satisfying, followed by NOW MENTHOL, then SALEM LIGHT on this basis."[39] Therefore, the product with a menthol level not too low and not too high would be the most satisfying to a smoker.

The number of puffs, according to RJ Reynolds, suggests how well liked a cigarette is or how satisfied the smoker is with that product. The low nicotine NPT products were associated with a higher puff count than the medium nicotine NPT products, which were rated higher in consumer acceptance. The fewer the puffs, the more satisfying and accepted a cigarette is. Menthol had an effect on some of the findings on smoking behavior; however, RJ Reynolds could not explain why.[39] RJ Reynolds also noted that the NPT products lacked the "sensory cues" to give study smokers sensations similar to those delivered by SALEM LIGHT or NOW MENTHOL.[39]

The sensory qualities differ depending on the level of menthol as well as nicotine. Levels that are unfamiliar to a smoker will affect his or her smoking behavior, making it more difficult to smoke a new product. A balance of medium levels of menthol tends to be preferred by the smokers on the tobacco companies' test panels.

iii. Does menthol's contribution to sensory qualities of smoke and menthol's effect on topography lead to greater exposure to toxic substances, increased nicotine dependence or greater chance of tobacco-related diseases?

Based on our limited research of the publicly available internal tobacco industry documents, it is unclear whether menthol's effect on smoking behavior leads to greater exposure to toxic substances. What internal documents disclose about the role menthol may play in nicotine dependence is discussed elsewhere.[13]

Although it has been reported in peer-reviewed literature that mentholation of cigarettes appears to increase exposure of smokers to toxic effects of carbon monoxide,[44] the industry did not appear to address this issue according to the current searches. Documents showing a link between menthol and increased nicotine dependence[13] and menthol's role in the health effects of smoking are presented elsewhere.[53]

iv. What are the various ways menthol is measured and how are menthol yields determined?

Menthol is measured in milligrams or micrograms that are distilled from a cigarette before and after smoking. Menthol is highly mobile and volatile, and tobacco companies sought patents to reduce the mobility and volatility to improve the smokability of menthol cigarettes.

For decades, tobacco manufacturers have struggled to stabilize and prevent fluctuations in the menthol yields of their menthol brands,[54] as the delivery mechanism for menthol in cigarettes is not well understood.

> Menthol has long been a major cigarette flavorant and several investigators have reported limited smoke distribution data. There is a continuing need for

> investigation into the mechanism(s) by which menthol is delivered to the smoke. Once these mechanisms are understood perhaps the efficiency of menthol delivery can be enhanced.[14]

During the late 1960s and 1970s, tobacco manufacturers were paying close attention to the concepts of increased filter efficiency and ventilation in filter tips, and as hundreds of products were being introduced, the full flavor (FF) cigarette category became segmented into two additional categories - full-flavor low tar (FFLT) and ultra low tar (ULT).[14] Cigarette construction parameters and menthol load had an impact on the performance of mentholated products. A study referenced by RJ Reynolds' Perfetti[14] indicated that increasing levels of ventilation while decreasing levels of filtering efficiency would allow RJ Reynolds to design a mentholated cigarette that delivered more menthol to the smoker. It had been previously demonstrated that as the air dilution increased, menthol had the lowest reduction in percentage yield compared to the other major smoke components such as tar and nicotine.

To achieve a desired level of menthol delivered by its products, tobacco manufacturers attempted to adjust the levels of ventilation and filtering efficiency "to improve the efficiency of the menthol available for delivery to the smoker."[14] For example, as filter draft and ventilation levels were increased, menthol deliveries decreased.[14] Menthol transfer efficiency decreases as filtration and ventilation increase. Therefore, lower nicotine delivery products require higher menthol levels to maintain "perception" of menthol.[14]

Table 5: Menthol Transfer Efficiency[14]

Tar Range	% Transfer Efficiency	% Menthol Applied
Full Flavor	15 – 16	0.35 – 0.45
Milds	12 – 13	0.45 – 0.55
Lights	8 – 10	0.60 – 0.80
Ultras	1 – 5	0.80 – 1.25

Measuring menthol content

According to an undated report on product development in the Brown & Williamson collection, the level of menthol in U.S. domestic products by weight was reported in to be 0.34 – 1.25%, with lower levels for "emerging" menthol markets.[55] Menthol is applied to cigarettes by a number of methods: either sprayed onto cut tobacco or tobacco stream, applied to paper, "printed" on pack foil or dissolved in filter plasticizer. Smoke studies on mentholated cigarettes have shown similar results for the amount of unchanged menthol in mainstream smoke, side stream smoke, and in filters and butts. Total amount of menthol available to mainstream smoke ranges from 30 to 35% of the applied level.[24] Tobacco manufacturers measured the menthol content by isolating menthol by steam distillation, followed by gas-liquid chromatography.[14, 56, 57] BAT developed a process that is described here:

> The tobacco from five cigarettes is transferred to distillation flask . . . along with the paper wrapping (since menthol equilibrates over the entire cigarette, it is necessary to include cigarette paper with the tobacco in order to obtain a total value). . . . The menthol concentration is determined by comparing peak areas of the sample and standard menthol solutions . . . .[57]

To determine the menthol in smoke, the following procedure was employed.

> Five cigarettes are smoked to the desired butt length (usually 23 mm) under I.T. Co. [Imperial Tobacco Company] standard smoking conditions of a 35 cc puff of 2 seconds duration taken once a minute. The mainstream smoke is collected in a glass spiral trap, wetted prior to use with ethanol, and cooled with a dry-ice/acetone mixture.[57]

RJ Reynolds used a "combination of steam distillation and liquid-liquid partition through gas chromatography on polypropylene glycol with an FID detector" to measure menthol.[14] Menthol was measured by percentage[56, 57] of the cigarette ingredients or in milligrams per cigarette (mg/cig).[14, 58, 59]

Measuring menthol yields

To determine menthol yields, the tobacco companies used smoking machines.[14, 60] Mathematical models were developed to estimate smoker intakes of nicotine, tar, and total particulate matter (TPM) because smoking machines do not accurately reflect actual human smoking conditions.[51] Data collected from the smoking machine in a Philip Morris study illustrate this point (see table 6). Although the example is for non-mentholated Marlboro 85mm cigarettes, the comparative data show the differences between actual human smoking data and values obtained on the smoking machine.

Table 6: Delivery Data of Marlboro 85[51]

Estimated Intake of Subjects		Smoking Machine
41.6	TPM, mg/cigt (total particulate matter)	20.6
28.8	FTC Tar, mg/cigt.	17.0
1.79	Nicotine, mg/cigt.	1.15
11.04	Water, mg/cigt.	2.40

While these data may only be estimates, what is evident is that smokers are getting greater amounts of TPM, tar, and nicotine.[51] "In fact, on a percentage basis, the smoker would receive 100% more TPM, 70% more FTC tar, 60% more nicotine, and 360% more water than the nominal values."[51] It may be important to keep these differences in mind when considering data on menthol levels collected from smoking machines. The searches in the tobacco documents archives did not return evidence of how tobacco manufacturers may have measured menthol content and yield in humans.

Menthol yields are measured in milligrams per puff (mg/puff) or micrograms per puff (µg/puff).[56, 57, 61] An example of menthol measurements in two menthol brands follows:[60]

Figure 2: Menthol Measurements and Smoke Delivery[60]

A. Cigarette Specifications and Smoke Delivery[a]

Cigarette	Wt[b] (mg)	Pressure Drop[b] (mm)	Puff Count	TPM on Pad (mg/cig)	H_2O on Pad (mg/cig)	Nicotine on Pad (mg/cig)	CO (mg/cig
SALEM[c]	1011 ± 23	123 ± 11	8.6[c]	19.6 ± 0.6	2.7 ± 0.2	1.11 ± 0.04	15.8
REAL[d] Menthol	960 ± 16	106 ± 8	7.8[d]	10.5 ± 0.3	0.8 ± 0.1	0.82 ± 0.02	8.9

a Analyses by Analytical Department, 35-cc puff, 2.00-sec duration, 1/60-sec frequency

b Average of 100 cigarettes from 10 packs, not conditioned

c 28-mm butt

d 33-mm butt

Cigarette	Menthol on Pad (mg/cig)	Initial Menthol in Tobacco Rod (mg/cig)	Initial Menthol in Filter (mg/cig)	Total Menthol in Cigarette (mg)	% Transfer to Smoke
SALEM[c]	0.39	1.60 ± 0.06	0.85 ± 0.05	2.45	16
REAL Menthol[d]	0.40	2.45 ± 0.04	1.47 ± 0.01	3.92	10

The following table from a Brown & Williamson document[62] provides the range of menthol content and smoke menthol by brand:

Figure 3: Menthol Content by Brand[62]

TABLE 3
TAR, NICOTINE AND MENTHOL DELIVERY VS. CIG. MENTHOL CONTENT

BRAND	MENTHOL CONTENT (%)	TAR (mg/cig)	NIC (mg/cig)	SMOKE MENTHOL (mg/cig)	# of PUFFS
KOOL KS	0.42	17	1.2	0.50	6.8
KOOL XL KS (Japan)	0.34	9	0.8	0.24	7.6
KOOL MILDS KS	0.52	12	0.9	0.50	7.3
KOOL DELUXE LTS KS	0.70	9	0.8	0.50	7.8
NEWPORT KS	0.34	17	1.3	0.44	7.2
SALEM KS	0.42	18	1.4	0.58	7.3
SALEM LTS KS	0.58	8	0.7	0.40	6.9
ALPINE KS	0.42	17	1.1	0.48	7.3
NOW MENTHOL KS	1.90	1	0.2	0.15	6.3

Factors affecting menthol delivery

There are several factors that affect menthol yields.

> [A]ging time, plasticizer type and level, humectant type and level, environmental storage conditions, moisture level, packaging types, blend formulation and tobacco types, wrapper type, porosity, basis weight, permeability, tipping porosity or use of laser technology for filter ventilation, filter type ….[63]

In 1968, American Tobacco's research on its menthol competitors indicated that higher menthol yields came from ammonium salts in reconstituted tobacco,[64] which could explain the larger market share of other menthol brands. Brown & Williamson also noted that Philip Morris had changed Marlboro Menthol to an ammoniated reconstituted tobacco to attract KOOL and Newport menthol smokers,[62] demonstrating the importance of companies investing in menthol cigarettes.

Tobacco manufacturers knew it was not enough to know total menthol content and yields. Other variables to be considered included the method by which the cigarette was prepared and the age of the product.[65] Tobacco companies sought to understand menthol delivery and knew that smoker acceptability was based on the perception of menthol, that is, whether a smoker recognized menthol in the cigarette. For example, RJ Reynolds internal research revealed major factors affecting smoker perception and smoking behavior, including cigarette preparation, menthol migration and delivery, and aging time before cigarette was smoked.

> Understanding in the areas of menthol delivery and smoker acceptability based on the perception of menthol is very important for the development of new products and the maintenance and improvement of existing brands.
>
> …
>
> Aging time is a very important factor since major changes in smoke menthol delivery and, presumably, perception occur during the initial three to four weeks after the product is prepared.[66]
>
> …
>
> [T]here are three different phases that a [conventionally prepared] menthol cigarette goes through in its expected shelf-life …. During Phase 1, the freshly prepared cigarette has essentially no menthol on its filter and, thus, initially delivers smaller amounts of menthol to the mainstream smoke because of its high filter efficiency. Further along in time, in Phase 1, menthol very rapidly migrates to the filter and effectively decreases the cigarette filtering efficiency for menthol. Greater deliveries in smoke menthol result. Finally, there comes a time where the efficiency of the filter for menthol remains relatively constant and, thus, smoke menthol deliveries likewise are relatively constant…During Phase 2, the amount of menthol found in the smoke remains essentially constant in spite of the loss in

> menthol during storage and despite the decrease in the percentage of menthol entering the filter. This is because these effects are over-compensated for by the great decrease in filter efficiency resulting from the increasing pre-loading of the filter with menthol. As the length of storage time increases, there is eventually a decrease in the amount of menthol in the smoke - Phase 3. During this period, menthol is believed to be more deeply sorbed into the filter and, thus, not available for elution. Menthol is also sorbed into the tobacco and either chemically altered or pyrolyzed on smoking and, thus, not analyzed as smoke menthol. In either or both cases a decrease in smoke menthol has been observed on long storage.[66]

Menthol cigarettes packaged in a box delivered a lower amount of menthol than do menthol cigarettes contained in a soft pack, as the box absorbs menthol faster.[67] In addition to noting how packaging influences menthol delivery, tobacco manufacturers appreciated that the way menthol was applied to cigarettes had an impact on menthol perception. Tobacco documents disclose there were three different methods for applying menthol to cigarettes when they are made. In most cases, a menthol solution was sprayed onto the cut tobacco. Menthol was also applied directly to the filters by dissolving the menthol in the triacetate that was used in the manufacture of cellulose acetate filters. Finally, the aluminum packing foil was sprayed with menthol before it was used for packing. The foil released the menthol to the cigarettes during storage. Regardless of how menthol was applied, tobacco manufacturers recognized the need to continue their investigation "into the mechanism(s) by which menthol is delivered to the smoke,"[14] and once those mechanisms were understood, tobacco manufacturers attempted to increase the efficiency of menthol delivery.

Because menthol is highly volatile, preventing the loss of menthol from cigarettes presented major challenges to the tobacco manufacturers, who have tried, sometimes with great difficulty, to keep menthol in a single location within the cigarette pack. To deal with "the menthol problem," tobacco manufacturers have sought ways to tame the volatile nature of menthol.[68] For example, BAT sought novel approaches to stabilize menthol in their mentholated products. However, attempts to use common fixative materials such as benzyl benzoate offered no significant improvement in menthol retention by the tobacco rod or increased delivery to the smoker.[69]

In whatever ways possible, inventors - often affiliated with the tobacco industry - sought to "control the natural volatility" of menthol, whether it was coming up with an innovative way to incorporate it into the smokable material of the tobacco rod, encapsulate it within gelatin, affix it to activated charcoal or other adsorbent substance, or impregnate plastic pellets with it. If a tobacco manufacturer or individual developed a unique technology pertaining to the use of menthol, then it was likely that a patent application was filed to prevent individuals or corporations from employing similar technologies.[70]

Effect of aging on puff-by-puff yields of smoke menthol

It was common practice during the late 1970s and early 1980s to make mentholated products and ship them as quickly as possible to panelists who would evaluate the products. Measurements of smoke menthol yields per cigarette, if measured at all, were done on mentholated product less than one week old. In 1981, RJ Reynolds became aware that mentholated cigarettes needed to be aged before being sent to panelists for testing. To determine the minimum aging time necessary for sensory evaluation of mentholated products, RJ Reynolds conducted internal studies on the effects of aging on puff-by-puff yields of smoke menthol.[66, 71]

> The objective…was to determine the minimum aging time necessary prior to sensory/consumer evaluation to insure consistent puff-to-puff yields of smoke menthol to consumers and, most important, to insure reliable sensory/consumer evaluations of mentholated products."[72]

Though the total menthol content in a cigarette may remain constant over time, the amount of menthol in the cigarette rod and filter changes due to the migrational distribution of the volatile menthol, which affects smoker perception and is dependent on how the cigarette is prepared. RJ Reynolds researchers, who had been demonstrating since 1962 menthol migrated from the cigarette rod to the filter, showed that a conventionally prepared menthol cigarette goes through three different phases during its shelf-life.[66] In phase 1, there was essentially no menthol in the filter of a freshly prepared cigarette. Menthol cigarettes in this initial phase deliver small amounts of menthol to the mainstream smoke. During the later part of phase 1, menthol will rapidly migrate to the filter, resulting in greater delivery in smoke menthol. Phase 2 represents a constant delivery of smoke menthol, though the migration of menthol from the rod to the filter continues with time. This is despite the loss in menthol during the storage and despite the decrease in the percentage of menthol entering the filter. As the length of storage time increases, there is a corresponding decrease in smoke menthol.

1982 RJ Reynolds inter-office memos describe the migratory nature of menthol observed in a four-month study of mentholated products.[73-75] Three products—Salem King Size 85 mm, Salem 100 mm, and Salem Slim 100 mm —were conventionally prepared with mentholated tobacco. The other three mentholated products were "bustle-injected," where the menthol is "injected into the filter tow while it is in the blooming area of the bustle."[76] Bustle-injected menthol products contained the same amount of pack menthol as their conventionally prepared counterparts, but 30% of the total pack menthol had been bustle-injected into the filter.

The test cigarettes were stored at room temperature and under freezer conditions. Cigarettes stored under freezer storage showed no appreciable menthol migration nor caused any significant changes in the smoke or tobacco analyses. Freezer storage proved to be a viable approach to stockpiling mentholated cigarettes.[73] Approximately 35% (although the memo's conclusion and other RJ Reynolds documents state variations on the order of 20-30%) of the total menthol applied to tobacco in conventionally prepared cigarettes migrated from the rod to the filter over the four-month testing period. Menthol migration from the cigarette rod to the filter was not uniform. Just as was noted with the conventionally prepared cigarettes, menthol in the bustle-injected cigarettes was depleted in the portion of the rod closest to the filter but to a much smaller extent.[73]

The total menthol remained essentially constant in all test cigarettes during the four-month testing period, regardless of whether the cigarettes were conventionally prepared or bustle injected.[73] However, an analysis of the smoke menthol delivery indicated there were significant differences in puff-by-puff menthol smoke between conventionally made mentholated products and bustle-injected products.

The 85 mm (king size) configuration "did not behave like the 100 mm and 100 mm slim configurations,"[66] which had an overall greater menthol delivery.

> The 85 mm configuration has an available menthol level of only 50% and an air dilution of only 37.1% of that of the 100 mm configurations. These less ventilated products result in overall greater deliveries of smoke menthol per puff. The ratio of available menthol to air dilution suggests a smoke menthol delivery level of 35% higher for the 85 mm products. The actual smoke menthol delivery is 52.5% higher... Hence, the observed greater menthol delivery may be totally consistent with the construction parameter differences…primarily due to the shorter filter length that must be equilibrated.[66]

In the 1991 RJ Reynolds study,[72] puff-by-puff smoke menthol yields were measured in six different mentholated products over a period of five weeks. Like the 1981 study, three of the mentholated products were the conventionally prepared Salem 85mm, Salem 100mm, and Salem Slim 100m, and the other three were bustle-injected with menthol. Smoke menthol yields were measured at four time periods: within 24 hours of making, during the second week of aging, during the third week of aging, and during the fifth week of aging. The following are the conclusions:

> The data indicate that prior to 14 days of aging…, the puff-by-puff yields of menthol are significantly depressed compared to puff-by-puff smoke menthol yields at times past the initial two weeks of aging… The puff-by-puff smoke menthol yields at 3 weeks…and at 5 weeks… of aging are not significantly different… The puff-by-puff menthol yields of the bustle-injected products were significantly greater only at the initial…periods due to pre-loading of menthol on the filter elements.[72]

In a 1993 sensory evaluation study of aging, RJ Reynolds also found that the tobacco/menthol balance, decreased over time.[77]Based on these data and prior company research in sensory perception of smoke menthol and analytical smoke menthol yields, RJ Reynolds management was advised by their internal scientists to age conventionally prepared mentholated products a minimum of two full weeks prior to submission for routine sensory or consumer evaluations. This observation was also made in 1981, along with the recommendation that bustle-injected menthol cigarettes require only one day of aging[78] and again in 1983 when a study on the effects of long-term storage of mentholated products[79] showed there was no "fundamental difference in the mechanism of smoke menthol delivery for conventional and bustle injected products."[80]

What is not discussed in the findings of the 1991 RJ Reynolds study, but evident in the accompanying charts showing menthol delivery against puff count, is how the menthol level in all the prototypes increased with each subsequent puff. Lorillard also found menthol delivery to increase with each puff.[81] Whether a menthol cigarette is conventionally prepared and bustle injected, the amount of menthol delivered to a smoker increases with each subsequent puff.

Figure 4: Menthol Delivery in Conventionally Prepared 85mm Cigarettes[72]

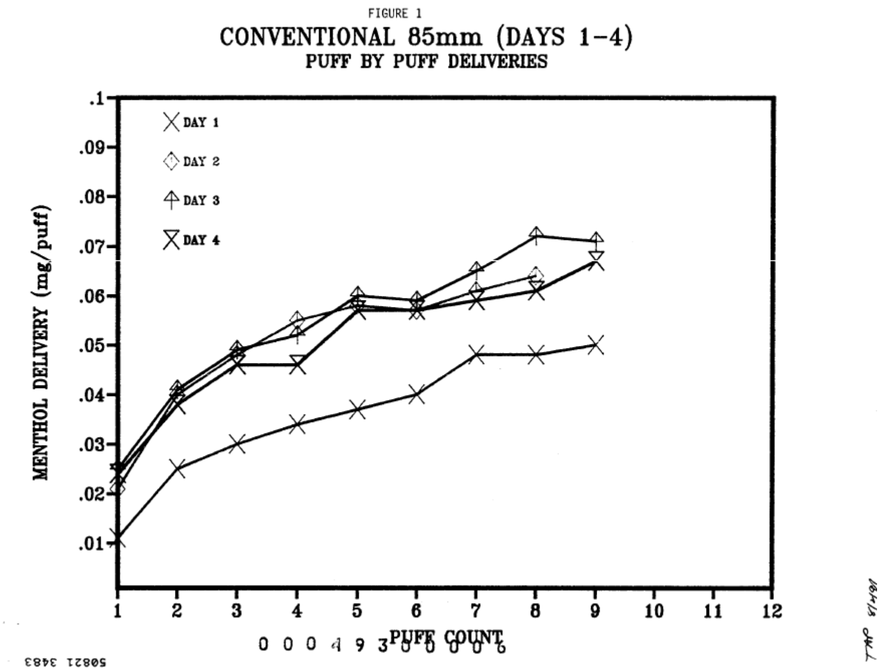


Figure 5: Menthol Delivery in Bustle Injected 85mm Cigarettes[72]

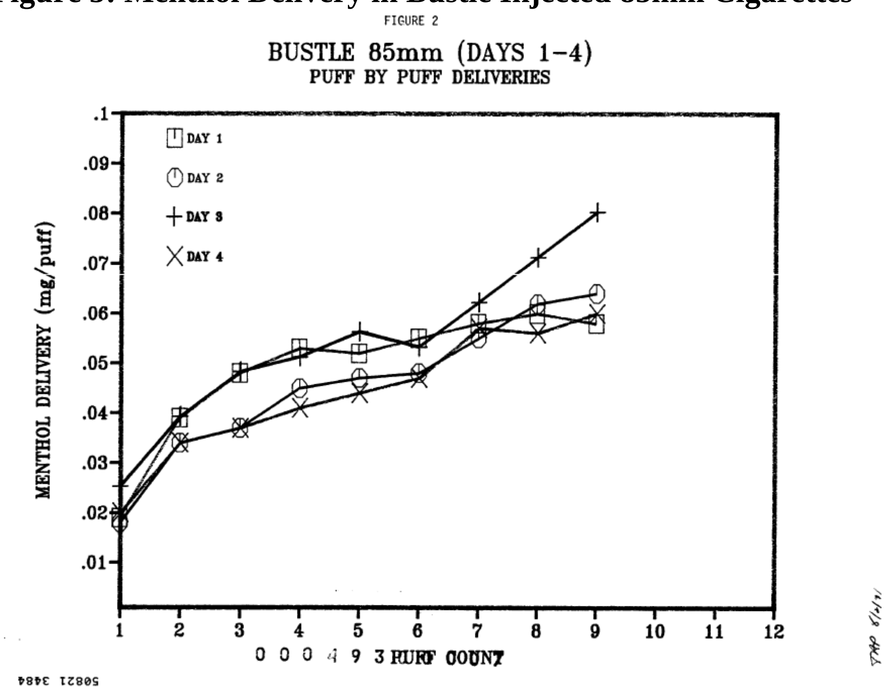


Figure 6: Menthol Delivery in Conventionally Prepared 100mm Cigarettes[72]

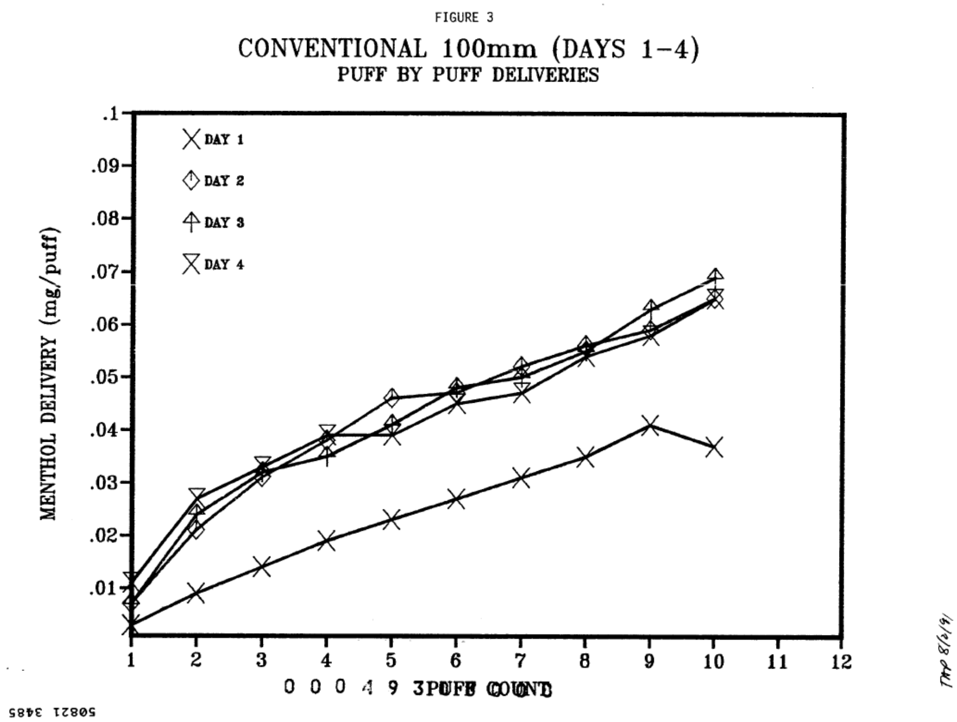
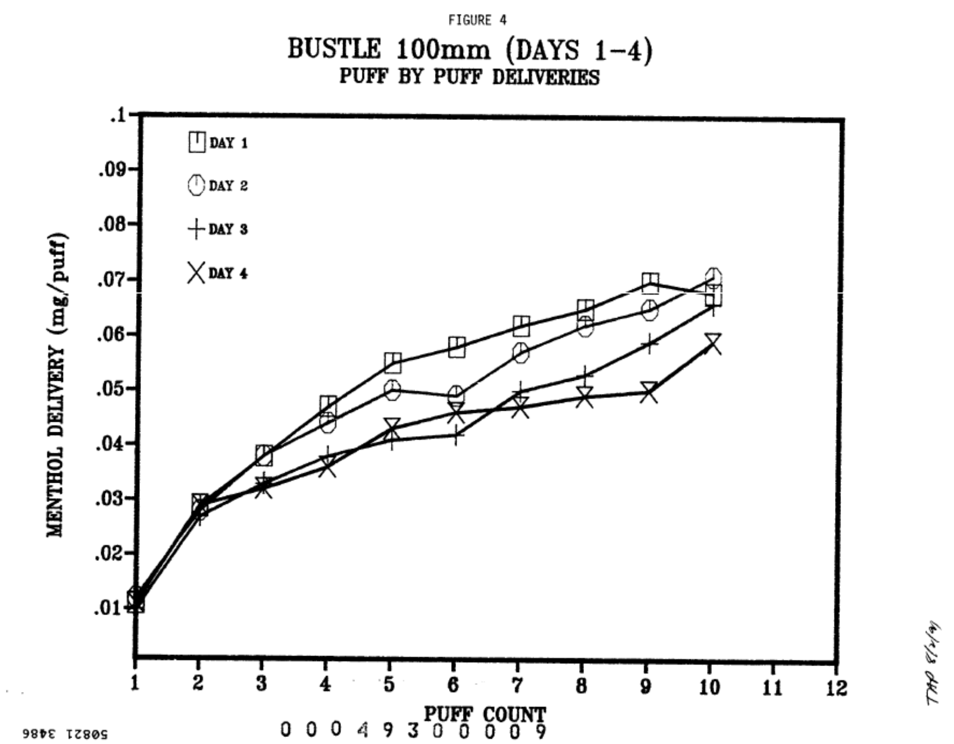


Figure 7: Menthol Delivery in Bustle Injected 100mm Cigarettes[72]



However, a Philip Morris special scientific report appears to contradict the preceding RJ Reynolds graphs.

> [M]enthol can have a high delivery in the first few puffs, then a lower delivery as the rod is smoked. The puff profile for menthol depends on (1) whether the menthol was initially applied to the filler or to the filter, and (2) on the age of the cigarette. The more menthol applied to the filter, [sic] and the shorter the age of the cigarette, the higher menthol delivery in the first puffs. Thus, the same amount of menthol applied to two different cigarettes can result in entirely different deliveries . . . [67]

Lorillard[82] and Philip Morris[83] also understood menthol's volatility and migration tendencies. In his report on menthol cigarettes and menthol's migrational tendencies and transfer to smoke, Robert Ikeda, Philip Morris scientist, noted that the migrational properties of menthol affects the puff-by-puff menthol delivery.[83] The loss of menthol was problematic and not only due to menthol's migration from the cigarette rod to the filter. As filtered menthol cigarettes were perishable products, the storage time and storage temperature were variables that affected menthol delivery.

To address the main question, menthol is measured in milligrams or micrograms that are distilled from a cigarette before and after smoking.

v. Does the menthol content and/or yield have an effect on how the cigarette is smoked or cigarette preference?

It is unclear whether the menthol content and/or yield have an effect on how a cigarette is smoked because most testing that we were able to locate in the documents was done on new mentholated products by in-house smoker panels.

Menthol delivery is not necessarily the amount the smoker actually consumes. What the smoker consumes is dependent on the amount of menthol absorbed from the inhaled smoke and how the smoker smokes the cigarette.[2] Menthol content and yield have an effect on cigarette preference, but it is unclear from the available tobacco industry documents whether these affect how the cigarette is smoked. Tobacco manufacturers experimented during the 1980s and 1990s to discover the "most desirable levels of menthol,"[21] but according to industry documents, "the levels of menthol have changed very little over the years."[21] 90% of all cigarettes contain at least a very small amount of menthol, which is added to enhance the tobacco taste. Unless cigarettes contain 0.3% to 1.0% of their tobacco weight in menthol, they will lack the minty, cooling characteristics associated with menthol.[21]

BAT compared L&M, L&M Lights, L&M Ultra Lights, and L&M Menthol from the Middle East and determined the menthol brand to have a higher puff number (10.0) compared to the others as well as more CO (carbon monoxide) per cigarette (10.1 mg/cigarette), but concluded:

> Although L&M Menthol is a longer cigarette than the other products, and the blend nicotine is similar to L&M, the smoke yield is only marginally higher than L&M. This is probably due to the longer filter and overtip length than L&M and also the increase in filter efficiency.

Brown & Williamson studied Philip Morris products that allow for twisting the filter so tar intake can adjust between 5 and 15 mg/cigarette.[84] The menthol puffs per cigarette were: 7.5 for maximum tar and 8.6 for minimum tar.[84] There was more tar per cigarette in the menthol brand as well as more nicotine at the minimum tar level and more CO at both maximum and minimum tar levels (14.8 mg versus 13.1 mg for maximum and 5.9 mg versus 2.6 mg for minimum).[84]

Figure 8: Brown & Williamson Smoking Results of Dial-a-Tar Prototypes[84]

Smoking Results at Maximum and Minimum Tar Dial Settings

	Concord KS		Concord KS Men.	
	Max Tar	Min Tar	Max Tar	Min Tar
SMOKING (/CIG)				
PUFFS	7.6	9.0	7.5	8.6
TAR (MG)	13.7	3.6	15.4	7.2
NICOTINE (MG)	1.05	0.37	1.04	0.63
CO (MG)	13.1	2.6	14.8	5.9
FILTER EFFICIENCY (%)	39.6	53.7	37.8	43.7
SMOKE MENTHOL (MG)			0.63	0.45
PER PUFF SMOKE MENTHOL (MG)			0.084	0.053
VENTILATION (%)	9.3	70.0	5.2	62.0

Based on the industry studies, the amount of menthol in a cigarette affects preference of smokers, but there is great variability in what the preference is. RJ Reynolds tested new prototypes of its Salem brand and found the full flavor low tar menthol smokers wanted "cigarettes with less nicotine delivery and more menthol delivery," whereas full flavor menthol smokers wanted "high levels of nicotine deliveries and low or moderate deliveries of menthol."[85] Full flavor low tar menthol smokers wanted more menthol taste as compared to other smokers.[85] In studying Newport and other competing brands, Philip Morris found that "smokers who perceive their cigarette as being more acceptable may also perceive that cigarette as having a medium level of menthol."[86] RJ Reynolds tested the preferences of women, grouping them into 18-34 and 35 and over.[87] The study concluded that:

> Younger adult women [18-34] desire more menthol sensation than older women [35+]. However, it may take less absolute menthol delivery (micrograms/puff) for the younger adult group to achieve this higher menthol sensation. Given the data currently in-house, exact menthol delivery levels which coincide with female smoker ideals are unavailable. However, a range of 40-65 micrograms/puff seems appropriate for the younger adult female group while a range of 50-70 micrograms seems appropriate for the older group. . . . Age related perception differences of menthol delivery occur across all menthol cigarette brands and

> categories. Younger adult female smokers tend to perceive more menthol delivery than older female smokers irrespective of what brand they are smoking [emphasis in original].[87]

They also found "it takes less absolute menthol delivery to achieve the younger group's higher ideal than it takes to achieve the older group's lower ideal."[87] Therefore, smoking preference was affected, but it was not as simple as stating that menthol, or more menthol over less menthol, is preferred.

Menthol cigarettes were tested against competitor menthol brands and not just compared to non-menthol cigarettes. In 1990 Philip Morris had observed in its "Smoker Response Study of Competitive Menthol Brands" that menthol smokers smoked their regular menthol brand differently than they did competitive menthol brands.[88] There were nine panelists in the study; five regularly smoked Merit 85 Menthol and one smoked Benson & Hedges 100's Menthol; there were no data available on the regular brand smoked by the remaining three panelists. Panelists were observed smoking their regular brand and competitor brands Kool 85, Salem 85, and Salem Lights. Patterns were noted when panelists smoked competitor brands and there were differences in the smoking parameters depending on what brand was smoked.

> [I]t was stated in the summary that "the panelists' tendency for backoff [decreased puff count, shorter puff duration, and decreased puff volume] of the Kool 85 may indicate a possible dislike for this cigarette." The question you raised was "Were they really backing off or is this the way they smoked their regular brand?"
>
> …
>
> In comparing the smoking parameters of their regular brands versus the Kool 85, all the smokers took more puffs and higher maximum flow rates on their regular brand than they did on the Kool 85. All but one of the smokers took a higher puff volume and puffs of longer duration on their regular brand. Five of the six smokers also showed shorter intervals between puffs on their regular brands.
>
> …
>
> In the case of their regular brands versus the Salem 85, all except one smoker took more puffs on their regular brands with higher volumes and lower maximum flow

> rates than on the Salem 85. The regular brand as compared to Benson and Hedges Menthol showed a similar situation.
>
> …
>
> The Salem Lights were smoked differently. More puffs with higher volumes and maximum flow rates plus longer intervals were taken on the Salem Lights than their regular brands.[88]

In a 1990 RJ Reynolds human smoking behavior (HSB) study, when new products were tested, products were considered unsuitable if they "lacked the 'sensory cues' to give subjects the sensations similar to other cigarettes' deliveries."[39] Such sensory cues included menthol taste, smoothness, "lightability," aroma (toward lighter, more tobacco, and less artificial).[39] Lower menthol content was preferred over higher menthol content,[62, 89] particularly for the non-menthol smokers if they were to switch to menthol.[62]

On balance, it is unclear from the industry documents whether the menthol content and/or yield have an effect on how a cigarette is smoked because most testing that we were able to locate in the documents was done on new mentholated products by in-house smoker panels.

vi. What is the relationship between menthol and intensity in use of cigarettes (i.e., does menthol lead to a higher delivery of smoke per cigarette)?

Based on our limited research of the publicly available internal tobacco industry documents, it is unclear what the tobacco industry knew about the relationship between menthol and intensity in use of cigarettes.

In searching the documents, terms related to intensity of cigarette use and menthol did not return results related to this question posed by the TPSAC. Therefore, based on our limited research of the publicly available internal tobacco industry documents, it is unclear what the tobacco industry knew about the relationship between menthol and intensity in use of cigarettes.

DISCUSSION

The use of menthol as a flavorant has been very important to the tobacco industry, especially due to the increased preference for filters, for low delivery cigarettes, and easier to smoke tobacco products. From RJ Reynolds' T.A. Perfetti's menthol cigarette design treatise:

> In almost every instance, the mentholated brand style was developed, produced, and introduced after the non-mentholated brand style. This was a consequence of the smaller market for menthol but an important trend was developing. In most cases, the mentholated product was not developed with the menthol smoker in mind. Instead, it was developed based on the wants and ideals of the general smoking population which consisted of mainly non-mentholated smokers. During the 1960's and 1970's, a defined menthol smoking population finally became established. From that period on, researchers had clearer direction for designing mentholated products.[14]

Analyses of publicly available internal tobacco industry documents indicate that tobacco manufacturers studied mentholated cigarettes, often comparing their company's brands with new prototypes or competitor brands rather than comparing menthol and non-menthol brands. The industry found that menthol content has an effect on cigarette preference and a medium level of menthol content is preferred, but it varies greatly as smoking behavior varies by individual.

There have been significant efforts made to develop a menthol cigarette that reflects the latest in technology. Menthol has been used as an ingredient in cigarettes since the 1920s, but it was not until after the 1960s, when mentholated cigarettes found their place in the tobacco market, that the number of patents related to the use of menthol exploded. Tobacco manufacturers, likewise, increased their in-house studies of menthol. Tobacco companies put in a great deal of effort to put menthol into cigarettes, and delivering menthol as a flavorant in a controlled manner proved difficult, but important. The popularity of menthol cigarettes, according to industry studies, is intimately tied to menthol's physiological effects, which have an impact on smoking topography. The tobacco manufacturers applied their findings to cigarette design and product development.

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APPENDIX

Appendix A: Smoking Topography Search Term (listed alphabetically) and Results from Legacy Tobacco Documents Library

Search Terms	# Results	# Docs Screened	# Docs Retrieved
"Alcohol flavorant" menthol	90	90	22
Bustle-injected + menthol	181	142	30
"Carboxyhaemoglob menthol" ~ 50	93	93	4
"Depth inhalation" ~ 10 menthol	2,079	150	3
Dt: patent Grubbs, Auken, Johnson	43	43	11
"Human smoking behavior" or HSB menthol	4,023	150	2
Inhaled volume	223	223	6
"Larger puff volume" menthol	182	182	1
"Menthol anesthetic" ~ 10 not non-menthol	223	223	6
"Menthol intensity" ~ 25 delivery	998	200	22
(menthol not non-menthol) and "carbon monoxide level"	624	100	0
Menthol vs non menthol inhalation	5,858	33	33
"Menthol yields" not non-menthol	238	238	75
"Organoleptic evaluation" and menthol	688	100	0
"Post cigarette CO" menthol	6	6	0
"Puff duration" menthol not "non-menthol"	4,023	50	5
"Puff number" menthol not dt: public* not "non-menthol"	5,928	100	13
"Puff volume" menthol not dt: public*	8,542	100	6
Smoking behavior ~ dif bet menthol and Non menthol smokers ~ inhalation, # puffs, volume	16	16	15
"Smoking behavior" "menthol yield"	29	29	0
Topography	1,419	250	4
("Yield in use" OR "yin") menthol studies	188	100	0
TOTALS:	35,694	2,518	252

Notes: (1) An asterisk (*) indicates a "wildcard" search, such that the stem of the word indicated will yield results containing that stem. For instance, "menthol*" will yield "menthol," "mentholated," "mentholation," etc. (2) A string of words in quotation marks ("") indicates a "phrase" search, such that the string included in order within the quotation marks will be searched. For instance, "puff duration" as a single phrase will be searched. (3) A tilde (~) indicates a "proximity" search such that words appearing within a specified proximity to each other in a document will be searched. For instance, "nicotine menthol ~25" will yield documents in which the words "nicotine" and "menthol" appear within 25 words of each other.