Summary of the Second Conference on Menthol Cigarettes:

Menthol in Cigarettes: It helps the poison go down easier

A Report to the Food and Drug Administration (FDA)

Prepared as Public Comment

Attention Dr. Lawrence Deyton

by

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Introduction

On October 19th and 20th, 2009, 143 tobacco control scientists and front-line tobacco control practitioners met in Washington, D.C. to discuss the state of the science regarding menthol cigarettes. The two day conference was held at the Academy for Educational Development located at 1825 Connecticut Avenue, NW Washington, DC. The conference consisted of 8 distinct panels: Menthol Pharmacology and Toxicity; Menthol and Tobacco Smoke Exposure; Menthol Epidemiology; Menthol and Addiction; Menthol and Cessation; Tobacco Industry Targeted Marketing; FDA and Menthol; and Population Behavioral Change. The conference also had two luncheon keynote addresses, one by Dr. Cheryl Healton President and CEO American Legacy Foundation and the other by the Honorable Louis Sullivan, past Secretary for Health and Human Services. In the afternoon of the second day 6 breakout groups met and more closely examined the question of menthol cigarettes among African Americans, American Indians/Alaska Natives, Asian and Pacific Islanders, Latinos, LGBT, Youth, Low SES, and Women. Eleven posters were displayed, reflecting recent research and scholarship around menthol cigarettes. The conference was convened by a broad planning committee representing academic institutions, tobacco advocacy and control groups; and federal agencies. Drs. Pamela Clark and Phillip Gardiner served as chairs of the conference. (A list of planning committee members, attendees, conference agenda and materials are all included in the appendix to this report).

Conference Objectives:

1. The first objective of this conference was to bring together the leading scientists and prevention specialists to collectively discuss and debate the latest developments in our understanding of the toxicology, pharmacology, epidemiology and addiction potential of menthol cigarette use.
2. The second objective was to update and prioritize the scientific research agenda that identifies the outstanding questions that must be answered.
3. The third objective was to, for the first time, identify a prevention and cessation agenda for tobacco control practitioners. Prior to the conference, there was not a strategy of how to tackle the issue of menthol cigarettes. Indeed, this conference would serve as the vehicle to begin the dialogue on this subject. Given the magnitude of menthol use by vulnerable sectors of our society, an agreed upon strategy, response and practice to mitigate the use of menthol cigarettes was long overdue.

This conference sought to present a broad public health perspective as it concerns menthol cigarettes. Not only was the issue of smoking menthol cigarettes and greater morbidity and/or mortality discussed, but the conference also dealt with menthol cigarettes' role in increasing the uptake of smoking as starter cigarettes, sustaining and increasing the addiction potential of tobacco products, making cessation more difficult, increasing the possibility of relapse and undermining social justice by the incessant targeted marketing of these products to youth, women, and communities of color.

Since the 1st Menthol Conference in 2002, over 70 peer-reviewed articles have been published, focusing on many of the issues and topic mentioned above, including the pharmacology, epidemiology and socio-behavioral aspects of menthol in cigarettes. The timing of the Conference this year was quite fortuitous, ideal indeed, coming just four months following President Barack Obama's signing of the historic Family Smoking Prevention and Tobacco Control Act (FSPTCA). Among the key elements of the act is that in October 2009, cigarettes will be prohibited from having candy, fruit and spice as their characterizing flavors. Menthol was specifically exempt from the ban. Thanks to the efforts of tobacco control front-line professionals, representatives from the Congressional Black Caucus, and work of Louis Sullivan, an amendment to the legislation was approved requiring that "Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee, the Secretary shall refer to the Committee for report and recommendation, under section 917(c)(4), the issue of the impact of the use of menthol in cigarettes on the public health, including such use among African Americans, Hispanics, and other racial and ethnic minorities." The organizers of this conference were keenly aware that our work and deliberations were taking place with this as a back drop. We are hopeful that the conference and the report below will be significant in informing the investigations, deliberations and the recommendations of the FDA.

Another noteworthy aspect of this conference was that in most cases, tobacco control scientists hold their meetings to elucidate the science, and front-line tobacco control practitioners hold their meetings to learn best practices from each other; both of these taking place at separate venues and at different times. What was unique about the Second Conference on Menthol Cigarettes is that it not only brought these two groups together to enhance each others' agendas, but it also was held at a time that could potentially alter national tobacco policy and practices.

Findings

There were no formal resolutions passed at this conference nor were there any voted on agreements. The Planning Committee was and is a very diverse group of individuals and organizations, all with differing views on whether menthol should be banned. Indeed, some members came to the conference believing one way and left the conference with different opinions. Still, as the proceedings below demonstrate, a consensus emerged that went far beyond looking narrowly at impact of the chemical menthol on heart disease and cancer rates. What materialized was a broader definition of the harm associated with menthol. The following points began to be repeated by speaker after speaker, and in the elegant words of Dr. Richard Hurt, it was concluded by many that we should not miss this historic opportunity to ban menthol and save millions of lives.

The following are the findings for the banning of menthol:

1. **Starter product for youth**. Drs. Cheryl Healton from the American Legacy foundation and James Hersey from RTI presented compelling data showing that a majority of youth start with menthol cigarettes because it masks the harsh taste of tobacco smoke. Since the conference, the latest report from SAMSHA, using the National Survey on Drug Use and Health, found that adolescents who recently starting smoking cigarettes were more likely to start with menthol cigarettes as opposed to non-menthol cigarettes

(Substance Abuse and Mental Health Services Administration, Office of Applied Studies. November 19, 2009: *The NSDUH Report: Use of Menthol Cigarettes.* Rockville, MD. Available at: http://www.oas.samhsa.gov/2k9/134/134MentholCigarettes.htm

2. **Promotion as a Healthier Cigarette.** Many speakers demonstrated with their slides that the tobacco industry promotes menthol cigarettes as a healthier alternative to non-menthol cigarettes.
3. **Greater Addiction Potential.** As it was clarified during the conference, we do not know if menthol is addicting in the way that nicotine is by replacing acetylcholine in the brain and activating the dopaminergic pathway. However, what was pointed out by many speakers is that menthol increases the addiction potential of cigarettes. Like the sub-title for this report says, menthol allows the poison to go down easier. Additionally, it was shown that, using standard nicotine dependence measures, that menthol smokers had higher dependence levels than non menthol smokers, even though menthol smokers on average smoke fewer cigarettes per day than non-menthol smokers. The "throat grab" associated with menthol (similar to that of nicotine) may be in itself reinforcing.
4. **Harder to Quit.** The Cessation Panel documented study after study that showed menthol cigarette smokers found it harder to quit than non-menthol cigarette smokers. And while not every study comparing menthol and non-menthol cigarettes had found the same outcomes, the majority of reported studies showed menthol cigarettes as harder to quit.
5. **Greater Potential for Relapse.** Evidence was presented that menthol smokers were more likely to relapse compared to non-menthol smokers. Additionally, it was shown that menthol smokers have greater problems quitting for a day, an important precursor to quitting.
6. **Poorer Mental Health.** There is increasing evidence that menthol smokers have poorer mental health functioning compared to smokers of non-menthol cigarettes.
7. **Unique Sensory Stimulation.** Speakers showed that menthol had unique properties that smokers become accustom to. It was pointed out that menthol is a mild anesthetic that stimulates cold receptors in the throat, bronchi, and lungs. Even though an irritant, menthol "soothes" the respiratory tract allowing the poisonous tobacco smoke to go down easier. Menthol also activates taste buds in the mouth the same way that capsaicin does.
8. **Inhibits Detoxification of NNAL.** Recent scholarship presented at the conference showed that menthol inhibits NNAL glucuronidation; that is menthol inhibits the body's detoxification mechanism for the powerful lung carcinogen NNAL.
9. **Inhibits Cotinine Clearance.** Speakers pointed out that menthol plays a role in inhibiting the clearance of cotinine (the main nicotine metabolite) from the body.
10. **Social Justice Issue.** Speaker after speaker pointed out that the predatory marketing of menthol cigarettes by the tobacco industry were aimed at the most vulnerable in our society; the least informed about the health effects of smoking; had the fewest resources with which to fight back; had the lowest amounts of social support; and had the least access to cessation services - this is indeed, a social justice issue. One speaker suggested that as it relates to the African American community, the crass marketing of menthols was prime example of environmental racism. La Tanisha Wright, past tobacco industry employee, informed all that the industry puts more menthol cigarettes in poorer African American and Latino communities at cheaper prices then they do in other communities.

It was for all the reasons above that many in the conference concluded that the FDA should ban menthol cigarettes.

Background

Menthol in Cigarettes

Menthol is one of the most widely used flavoring agents. It is a naturally occurring product processed from the flowering top of mint plants, *Mentha piperita* and *Mentha arvensis*, and can also be synthesized from other essential oils. It is a naturally occurring compound which gives plants of the *Mentha* species the typical mint flavor. Menthol, ($C_{10}H_{20}O$), cyclohexanol-5-methyl-2-(1- methylethyl), is a monocyclic terpene alcohol and is present in the volatile oil of mint plants. It occurs as four pairs of optical isomers: (+)- and (-)-menthol, (+)- and (-)-neomenthol, (+)- and (-)-isomenthol, and (+)- and (-)-neoisomenthol(1), of which (-)-menthol is the most naturally occurring isomer.

Menthol, because of its easy availability and unique property as a flavoring agent, is widely used in product manufacturing such as pharmaceuticals, oral hygiene products and tobacco. Pharmaceutically, menthol is used as an antipruritic, antiseptic, analgesic, in the symptomatic treatment of gastrointestinal disorders and also used as a flavoring agent in oral hygiene products(2).

In cigarettes, menthol is unique in that it is the only cigarette additive that is actively marketed to consumers. Virtually all cigarettes contain menthol, though most at subliminal levels. Use of menthol in manufacturing mentholated cigarettes varies from a relatively weak level of 0.1%–0.2%, to a strong application level of 0.2%–0.45% by tobacco weight. The use of menthol is generally higher in lower-yield cigarette brands, compared with regular-yield brands.(3)

Physiologic and Sensory Effects of Menthol in Cigarettes

Ferris-Wayne and Connolly(3) studied physiologic impacts of menthol such as cooling, smoothing, and anesthetic effects based on their internal tobacco documents search. Menthol has been used as an additive to increase the sensory effects i.e. increase smoothness and reduce harshness of cigarette smoke.(3) The likely reason for adding menthol in low concentrations (< 0.1 percent by weight; below recognition threshold) is to reduce smoke harshness.(3) The sensory effects enable deeper inhalation and increased uptake of cigarette smoke. As reported by Foley, Payne and Raskino,(4) a 1971 Brown & Williamson study claimed that menthol was the most important additive tested as a “smoke-soothing” agent. Similar claims have been made by some of the other tobacco companies. Even though the hypothesis has not been independently tested, R. J. Reynolds documents state that subliminal levels of menthol decrease harshness.(3)

The use of menthol has been promoted for the unique sensory properties that cool and mask the harsh properties of burning tobacco. Studies on menthol have shown that exposure to menthol is associated with a cooling sensation and the perception of increased nasal airflow, even though no changes in airway resistance were not detectable by objective airflow measurements.(5-7) Menthol selectively stimulates cold receptors to produce cooling effects and for this reason it is

also used as an expectorant to promote mucous clearance from the respiratory tract.(8) Other physiological effects associated with menthol are local anesthesia, increased drug absorption, bronchodilation, central nervous system effects (e.g. evoked potentials), and metabolic effects.(9)

The internal tobacco industry documents confirm the effectiveness of menthol in smokers' sensory preferences.(10) Industry researchers conducted studies on consumer preferences of different menthol concentrations in cigarettes and found that concentration of menthol was a major determinant of consumer liking. Ayya and De Wijk(11) (1995) studied the sensory perception in cigarettes with higher menthol concentration and found that smoking status was associated with liking of menthol concentration. Smokers with highest smoking frequency, measured as number of cigarettes per day, had preference for higher levels of menthol (0.8%), whereas smokers smoking fewer than 20 cigarettes per day preferred a moderate concentration (0.52%) of menthol.

An important component of the smoking experience is throat impact (also termed throat grab or bite). Menthol in cigarette smoke stimulates the trigeminal nerve endings in the mouth and throat in a manner similar, yet distinct, to that of nicotine, contributing to the perception of strength of the cigarette smoke.(3) In cigarettes with less than perceived threshold of menthol content, strength is dependent on nicotine delivery. In cigarettes with perceptible levels of menthol, the menthol contributes distinctly to sensory qualities of the smoke in mouth and throat. So, while the likely reason for adding menthol in low concentrations (< 0.1 percent by weight; below recognition threshold) is to reduce smoke harshness, the level of mentholation in low machine-yield brands is generally higher compared with regular-yield brands (Brown & Williamson, [not dated]; Cantrell, 1990).(3)

The "cooling" effect of menthol is also trigeminal.(3) Receptors at or near those associated with cold are stimulated by menthol producing irritation that is perceived as cold by the smoker. The same irritation has been described as stinging, burning or tingling, and increasing concentrations of menthol result in further irritation without increasing the sense of cold.(3) So, menthol can reduce nicotine irritation of the mouth and throat by way of its cooling effect at low concentrations, while contributing to an anesthetic effect by either counter-irritating or desensitizing at higher concentrations.

The literature on additional physiologic effects of menthol is mixed. Internal tobacco industry documents report a central nervous system (CNS) effect, referring to stimulation of the CNS "…at all levels. It is considered a brain stem stimulant".(3) On the other hand, a published industry study, using electroencephalography and heart rate response, failed to show pharmacologic effects of mentholated denicotinized cigarettes.(12) There have been anecdotal reports of CNS adverse effects of menthol, including a citation in a 1986 R J Reynolds document of CNS reactions to menthol "recorded by the British Committee on Safety of Medicines includ[ing] confusion, psychosis, and visual disturbances."(3)

Menthol and Targeted Marketing

Menthol cigarettes, though initially marketed to women, became by the 1960's and 1970's predominately an "African American" cigarette. Today, over 70% of African American smokers prefer menthol cigarettes, compared with 30% of White smokers. This unique social phenomenon was principally occasioned by the tobacco industry's masterful manipulation of the burgeoning Black, urban, segregated, consumer market in the 1960s. Through the use of television and other advertising media, coupled with culturally tailored images and messages, the tobacco industry "African-Americanized'' menthol cigarettes. They successfully positioned mentholated products, especially Kool, as young, hip, new, and healthy. During the time that menthols were gaining a large market share in the African American community, the tobacco industry donated funds to African American organizations hoping to blunt the attack on their products. Unfortunately, the long-term impact of the industry's practice in this community may be partly responsible for the disproportionately high tobacco-related disease and mortality among African Americans generally and African American males particularly" (Gardiner, 2004). Menthol is still used disproportionately by African Americans, but the tobacco industry has broadened its bad practices and promotes menthols widely, especially among youth, women and other communities of color.

Summary of the 1st Day of the Second Conference on Menthol Cigarettes

Panel 1. Menthol Pharmacology and Toxicity. Dr. Patricia Richter (CDC), Moderator

Panelist: Dr. Neal Benowitz, University of California San Francisco

Dr. Benowitz provided an overview of the pharmacology of menthol. He reported that menthol stimulates TRPM8 receptors (cooling sensation, local anesthesia), activates K-opioid receptors (antipruritic, analgesia), inhibits cutaneous sensory receptors (local anesthesia), increases cutaneous blood flow (analgesia), has antibacterial and antifungal activity (antiseptic, food preservative) and is a penetration enhancer (topical medications). Low dose menthol produces cold perception and analgesia, while high doses are irritating and produce pain. Menthol has been associated with ciliotoxicity, and at high doses, with eye, lung and dermal irritation. Dr. Benowitz found that menthol blunts the lowering of heart rate with mental and physical relaxation, most likely through the mechanism of vasodilatation.

Dr. Benowitz noted that virtually all cigarettes contain some menthol, but most at subliminal levels. Cigarettes that are characterized as menthol contain on average 3.0mg, of which 20% us absorbed, and a pack-a-day smoker absorbs approximately 12.5mg per day. This is similar to what is absorbed from food, but it is delivered directly to the lungs. It is not known what menthol does when it reaches the lungs, and it would be very difficult to study.

There are two major pathways of metabolism of menthol: conjugation to form glucaronides and oxidative pathways. The major pathway appears to be glucaronide formation. Menthol is metabolized very quickly so that it is difficult to measure unchanged menthol in the system. This raises an interesting question: If menthol has an effect on drug metabolism, is it having its effect in the lungs since so little is delivered to the liver? Fifty percent of orally ingested menthol appears as menthol glucaronide in urine, and the half life of menthol glucaronide is 43-56 minutes.

In a small cross-over study, Dr. Benowitz investigated the effect of menthol on nicotine metabolism. He found that menthol inhibited metabolism of nicotine, resulting in a reduction in nicotine clearance. Menthol use resulted in inhibition of the glucaronide formation. That may be important because some of the enzymes involved in glucaronidization of nicotine are also involved in the detoxification of tobacco specific nitrosamines, such as NNK and NNAL. If there is less glucaronide formation because of menthol, there may be impaired detoxification of carcinogens. That would result in lower conversion of carcinogens to metabolites. This is an important observation that must be pursued.

Dr. Benowitz thought it likely that lower quit rates among those who smoke menthol cigarettes is related to (1) the additional sensory, and therefore reinforcing, stimuli of menthol, (2) the cooling effect that can lead to greater intensity of smoking, and/or (3) menthol interaction with nicotinic cholinergic receptors. He does not believe that inhibition of nicotine metabolism is a likely cause because slow metabolism of nicotine may be protective against addiction.

Panelist: Dr. Joshua Muscat, Pennsylvania State University

Dr. Muscat discussed the seminal research reported in 1996 on the contribution of menthol cigarette smoking to increased body burdens of cotinine and carbon monoxide. He noted the difficulty in differentiating the effect of race/ethnicity from that of menthol use because of the very high prevalence of menthol smoking among racial minorities. In addition, because of the overwhelming harm caused by smoking, he agreed that using epidemiologic tools to parse out any additional harm that choosing menthol cigarettes presents would require a huge sample size. He reiterated that menthol does seem to inhibit the detoxification of important carcinogens delivered in cigarette smoke. He noted the paucity of information on the role of menthol in uptake of smoking by youth. The available information would be discussed later in the day by another panel.

Dr. Muscat discussed additional reasons for the difficulty of using epidemiologic studies to investigate the role of menthol in disease. He noted that there has been no way to control for people who switch between menthol and non-menthol, that with the increase in cost of cigarettes, people are smoking differently, and may be smoking the “brand of the week” (whichever may be cheapest).

Discussion

Clarification of the differences in actions of menthol applied topically and that delivered to the lungs was requested. Dr. Benowitz noted that we don’t know what happens when menthol is

delivered directly to the lungs. He stated that he was surprised when they found evidence of menthol influencing what is presumed to be liver metabolism, given the expectation that very little menthol is likely to be delivered to the blood stream. Whether the inhibition of both nicotine and NNAL metabolism by menthol is happening in the liver or actually in the lung is an important question.

One participant had two comments that were pertinent to FDA regulation. First, he noted the error of applying the language of "generally recognized as safe," established to describe ingested food products, to any ingredient added to cigarettes. Second, he explained that the FDA has the authority to request all internal industry documents relating to what the companies know about menthol and its toxicity.

Regarding the issue of whether menthol may promote nicotine compensation, it was noted that the fewer cigarettes smoked per day, the more the individual cigarette is smoked (higher smoke delivery per cigarette). Among African American smokers that relationship is even stronger than among Euro-American smokers.

Another question was raised about the likelihood of menthol acting in the lung as it does on the skin. A difficulty with studying that is that smoking itself increases permeability of the lung. For instance, if a smoker uses an inhaler to deliver a bronchodilator, (s)he receives a higher dose than does a non-smoker, independent of menthol. We don't know what menthol does in the lungs. If menthol does increase penetration of compounds, it is an important negative concern.

There was lengthy discussion of the problem of controlling for age in epidemiologic studies, given that age is so highly correlated with duration of smoking.

Suggestions were made for a research agenda. Included were larger cohort studies to examine harm, development of an adequate lung perfusion model, investigation of the potential role of genetics in menthol use and harm and a study of whether an inhaler with menthol would increase delivery of other substances. Several comments were made about the need for better and shorter-term models and better phenotyping of smokers.

Panel 2. Menthol and Tobacco Smoke Exposure. Dr. Mirjana Djordjevic (NCI), Moderator.

Panelist: Dr. David Ashley, CDC

Dr. Ashley posed seven mechanisms by which menthol could increase exposure and harm.

1. Increase intensity of smoking and volume of smoke inhaled
2. Increase permeability of cell membranes
3. Be a precursor of carcinogenic pyrolysis products
4. Affect the rate of nicotine metabolism, altering smoking behavior
5. Affect the rate of carcinogen metabolism, making absorbed carcinogens for effective
6. Enhance the addictiveness of smoking through sensory stimulation
7. Affect the absorption of nicotine

He first discussed the fate of menthol in the cigarette. Because of the way menthol is applied, concentrations are higher in the lit end of the rod than in the butt end, so that concentrations remain fairly constant while the cigarette is smoked down.

Studies performed more than 40 years ago resulted in conflicting results. One showed that at high temperatures, there is a breakdown of the menthol into phenols, benzene, toluene, ethyl benzene, styrene, biphenyl and polycyclic aromatic hydrocarbons. However, a study by Philip Morris found that 99 percent of the menthol is transferred into mainstream smoke, with no breakdown of the menthol within a cigarette. The most likely conclusion is that menthol is distilled during smoking, or there wouldn't be a menthol taste, but we don't know if there is another generation of toxic chemicals generated during smoking. That should be investigated using the more sophisticated technology available now.

Dr. Ashley reported on six studies comparing smoking topography while smoking menthol and non-menthol cigarettes. Four showed no difference in number of puffs or total puff volume, one showed lower total puff volume with menthols and one showed an increase in total puff volume with menthols. In his own small studies of solanesol levels in spent filters (a surrogate for mouth level exposure to nicotine), he found that people smoking Newport cigarettes (menthol) took in about 1.4 mg nicotine per cigarette compared to 1.1 mg smoking a Marlboro Red (non-menthol). In another larger study of 215 people, smoking menthol cigarettes resulted in higher intake of nicotine compared to non-menthol cigarettes. He concluded that most studies did not have a large enough sample size, given the huge range of smoking topography within and between subjects, and single measures of smoking topography do not adequately characterize how they smoked the products. It is not clear if there is a difference in smoking topography that is not related to other factors, such as race and gender.

There have been many studies of biomarkers of exposure comparing menthol and non-menthol smoking, with conflicting results. Three showed higher cotinine levels independent of race, but the effect of menthol on nicotine metabolism may be different for different sub-groups. Studies on other toxicant biomarkers have been very limited. Most have looked at carbon monoxide levels, with conflicting results. He noted that we need to do investigations of the impact of menthol on other biomarkers of toxicity.

Panelist: Dr. James Hebert, University of South Carolina

Dr. Hebert discussed the epidemiology of esophageal cancers. He noted that use rates for tobacco and alcohol are nearly identical among African Americans and Euro-Americans, but the prevalence of esophageal cancers is about four times higher for blacks. There is no conclusive epidemiologic evidence that menthol smoking contributes to that difference, or in differential rates of any cancers. He pointed out that their may be biases in that most of the studies involve patients treated at teaching hospitals, and most use the same American Health Foundation data base. He felt that the lack of African Americans in the study samples, the lack of an unambiguous definition of a menthol smoker and the lack of data on potential effect modifiers limited conclusions that could be reached.

Dr. Hebert reported on an in vitro study, using pig esophagus exposed to benzo-a-pyrene with and without a delivery vehicle of a mix of alcohol and menthol. He found very effective delivery of the BAP into the cells and into their nuclei in the present of alcohol and menthol. It may be that epidemiologic studies have been inadequate because they haven't considered mixtures, like drinking and smoking menthol cigarettes, and other interactions.

Discussion

Dr. Ashley re-iterated that there are a lot of variables not accounted for when looking at the relationship between menthol smoking and biomarkers of exposure and toxicity. When Dr. Hebert was asked if he had looked at menthol and alcohol vehicles separately, he said that he had and menthol alone was sufficient to promote transfer of BAP into the cell nuclei and that menthol was more important that alcohol.

When asked about the intra-individual variability of smoking topography, he said that they were getting that data but could not yet say how much variability there is over any day or between days.

One participant noted that there was a great deal of ambiguity in the relationships between menthol and diseases, and a good deal of time and money would be needed to come to supportable conclusions. If we tie ourselves to a particular kind of science we may not get out of that bind. We need to expand the concept of harm. Dr. Ashley noted that we cannot just wait for more science, we need to move forward with what we already know. If we all met again in another seven years (referring to the time elapsed between the first menthol conference and the second) we would still not have all the answers and would conclude that we need to meet in yet another seven years.

Key Note Speaker: Dr. Cheryl Healton, American Legacy Foundation

Dr. Healton noted that there are a lot of unanswered questions about menthol cigarettes, but that we do know three important things that make a strong case for banning menthol from cigarettes.

First, it is a starter product for youth. It is easy to figure out that if you want kids to smoke you should give them a cigarette that tastes like candy. Dr. Healton produced internal industry documents that demonstrate the tobacco companies' knowledge that menthol cigarettes are good starter cigarettes for youth, and of their need to increase the share of Kools among high school students. She showed that 44% of youth ages 12 to 17 who smoke prefer menthol cigarettes, dropping to 35% among smokers ages 18-24, and 30% for those over age 35 and older.

Dr. Healton stated that because menthol cigarettes facilitate youth uptake of smoking, the minty smooth smoke luring children into deadly addiction, this alone provides the key impetus for FDA to act now and ban menthol from cigarettes. If we can keep children from being the replacement smokers as the tobacco industry has described them, we actually have a chance of not only reducing tobacco-related disease but ultimately eliminating it. The seeds of the tobacco epidemic are born in the bodies of our children, and there is no more powerful argument that one could make to the FDA than to call the question on that.

Second, menthol cigarettes were promoted with health reassurance messages. Menthol has been the centerpiece of health reassurance messages, as you smoke or because you smoke. Her husband, who has since died of lung cancer, smoked Kool cigarettes because he wanted to protect his voice.

The tobacco companies use buzz words and innuendo that influence the way consumers feel about their smoking. Some of the code words are "smooth," "natural," and "fresh." When Kool was first launched, it was all about the penguin – she remembered that as a young child, it was the first Joe Camel. She was very attached to the penguin. It would be dressed in Christmas attire and sell cigarettes with Santa. She knew as a young girl that Kool cigarettes were safe. In advertising, menthol cigarettes are still aligned with health (e.g., "Alive with pleasure"), associated with refreshing ice, water and snow. She again showed internal industry papers that documented the intention to associate menthol cigarettes with medicinal properties.

And finally, it is a matter of social justice, as menthol cigarettes have been targeted at minorities relentlessly. The targeting of minority communities was no accident, rather an artifact of the type of marketing that has gone on. The clever marketing schemes were heavily focused on brand switchers (to change to menthol cigarettes) and on youth. Smoking is no longer for the life of the rich and famous, it is the death Nell for the poor and disadvantaged. Kool defined itself as the starter brand for young blacks and the dominant brand in the inner city.

Dr. Healton noted that Ebony Magazine was 10 times more likely the People Magazine to have ads for menthol cigarettes, and the Spanish language version of People was more than twice as likely as the English language version to contain ads for menthols. Magazines do not accept articles with anti-smoking messages because they will lose advertising dollars from the industry, so pro-tobacco advertising is not countered. She said that our government needs to take dramatic action to end the scourge of tobacco-related disease that disproportionately impacts communities of color, and banning menthol is the most immediate step in getting that ball rolling.

Panel 3. Menthol Epidemiology. Dr. Jasjit Ahluwalia (University of Minnesota), Moderator.

Panelist: Dr. Ralph Caraballo, CDC

Dr. Caraballo provided an overview of smoking prevalence by race/ethnicity, who is smoking menthol cigarettes and recent trends in menthol cigarette use. Smoking prevalence by group is shown in the table below.

Group	Prevalence of Smoking
White	27.3%
African American	27.6%
Hispanic	23.9%
Asian	14.5%
American Indian/Alaskan Native	37.1%
Native Hawaiian/Other Pacific Islander	31.4%

As can be seen prevalence varies greatly by group. He noted though that aggregating into groups often disguises important differences. For instance, if we look at “Asians” we find relatively low rates of smoking, but among Vietnamese and Korean men, for instance, the rates are much higher (32.5% and 37.4%, respectively).

The domestic market share of menthol cigarettes has remained stable at 27% to 29% throughout the 2000’s, but in 2005 it fell to 20%. Dr. Caraballo could not explain the reason for the drop. Self-report use of menthols was about 30.5% in 2002-2007. Use among whites was 19.3% to 23.2%, among blacks it was 77.3% to 82.2% and among Hispanics 29.7%. Approximately 18.5 million Americans smoke menthol cigarettes. Fifty-five percent of menthol cigarettes are smoked by whites, 28% by African Americans and 11% by Asian Americans. In every group, more women than men smoke menthol cigarettes. In each group, there is a tendency for younger ages to be more likely to smoke menthols. Menthol use is fairly uniform across education levels, except that it drops among college graduates. The lower the household income, the more likely smokers are to choose menthols.

The trend in menthol cigarette use from 2002 to 2007 has shown a significant increase, with a significant decrease in non-menthol use. The increase in menthol cigarette use is consistent across education groups and across income groups. There was also a significant increase among African Americans, Hispanics and whites over those years, as well as an increase in use of menthols by 12-17 year old smokers.

Panelist: Dr. Stephen Sidney, Kaiser Permanente Northern California

Dr. Sidney discussed the many smoking-related diseases that contribute to 400,000 deaths per year in the U.S. Heart disease causes about 31% of all deaths, all cancers combined about 23%, cerebrovascular disease 7% and COPD 4%, so that tobacco use is implicated in about two thirds of all deaths. Smoking doubles the risk of heart disease, increases the risk of lung cancer 10 times, stroke 2 times and COPD patients are usually cigarette smokers. Lung cancer rates are about the same for black women and white women, but much higher among black men than white men. Mortality from heart disease is higher among black men compared to white men and among black women compared to white women. The pattern is similar for mortality from cerebrovascular disease.

Dr. Sidney reported on six studies examining the relationship between menthol cigarette smoking and lung cancer. Kabat and Hebert reported a case-control study with 1044 histologically confirmed lung cancer and 1324 controls (patients with conditions not associated with smoking. The prevalence of menthol use was not different between cases and controls, and no association was seen for either short-term (1-14 years) or long-term (>14 years) menthol use and lung cancer. That study was extended by Stellman and co-workers, again finding no increased risk for lung cancer with menthol cigarette smoking. Kabat and Hebert using the same sample, found no association between menthol use and oropharyngeal cancers or esophageal cancer. In another case-control study, Carpenter and co-workers studied 337 incident cases of lung cancer and 478 population controls, and found no association between menthol cigarette use and lung cancer. Brooks and colleagues in another hospital-based study of 643 lung cancer cases

and 4110 controls, found that the lung cancer risk for long-term smokers of menthol cigarettes was similar to that for smokers of nonmenthol cigarettes (odds ratio = 0.97, 95% confidence interval: 0.70, 1.34). Murray and co-workers examined evidence from the prospective Lung Health Study and found that among the 5887 smokers in the clinical trial there were no differences in hazard ratios for coronary heart disease, other cardiovascular disease, lung cancer, or all-cause mortality. A limitation of the study was that the menthol smokers had on average fewer pack-years of smoking, which would put them at decreased risk of lung cancer.

The one study finding more lung cancer risk with menthol cigarettes was reported in 1995 by Dr. Sydney. He reported on 318 incident lung cancer cases among 11,761 smokers examined yearly for 6 years. Menthol/non-menthol cigarette use was well characterized. The relative risk of lung cancer associated with menthol cigarettes was 1.45 in men (95% confidence interval, 1.03-2.02) and it was 0.75 in women (95% confidence interval, 0.51-1.11), adjusted for age, race, education, number of cigarettes smoked per day, and duration of smoking. There was a significant trend in increasing duration of use of menthol and risk of lung cancer in men. The same group examined risk of cancers of other sites (upper aero-digestive, pancreas, renal, other urinary tract, uterine cervix, and all smoking-related) and found no association with menthol cigarette use.

Dr. Sydney summarized the studies of menthol use and non-lung cancer risks, finding no evidence of increased risk in two studies. Regarding cardiac disease, he reported that pre- to post-smoking heart rate increase was greater in smokers of menthol cigarettes compared to non-menthol cigarettes, that baseline heart rates were higher among those who preferred menthol cigarettes, but that there was no difference in blood pressure response to rapid smoking. Oral administration of menthol and of placebo capsules produced a lesser decrease in heart rate following ingestion of oral menthol compared to placebo. Menthol cigarette are associated with greater atrial stiffness, poorer coronary microvascular function, right ventricular Doppler velocities and relaxation and contraction indices. Dr. Sydney found no association of menthol smoking with deaths from coronary heart disease, cardiovascular disease, lung cancer or death from all causes.

Discussion

The question was raised whether African Americans on average smoke fewer cigarettes per day because the menthol allows them to smoke each cigarette more intensely. A comment was made that we need to study more proximal outcomes in epidemiologic studies, such as the impact of smoking menthol cigarettes on pregnancy outcomes. It was also noted that we tend to group people into categories that are too heterogeneous to be informative. There were comments of skepticism regarding the data on the drop in market share from 26% to 20% in the FTC report.

Panel 4. Menthol and Addiction. Dr. Bridgette Garrett (CDC), Moderator

Panelist: Dr. Karen Ahijevych, Ohio State University

Dr. Ahijevych discussed the addiction and exposure measures and their relationship to menthol cigarette use. She first discussed a study that she performed to characterize levels of menthol exposure, nicotine dependence, and selected biomarkers, controlling for race.

Menthol levels were obtained from collections of 24 hour urines while smoking usual cigarette brands *ad lib* in an inpatient, monitored facility. Higher menthol plus menthol glucuronide levels were significantly correlated with higher scores on the Fagerström Test for Nicotine Addiction, and inversely correlated with time to first morning cigarette. Menthol levels were also positively correlated with admission nicotine and with pre-cigarette nicotine for four cigarettes during the monitoring period. Total menthol concentration was significantly correlated with levels of NNAL and NNAL glucuronide, and with nine metabolites of polycyclic aromatic hydrocarbons. The implication is that because menthol content varies by cigarette brand, having actual menthol concentrations may provide better information in understanding the complex interactions between menthol use and exposure to carcinogens and likelihood of nicotine addiction.

Panelist: Dr. James Hersey, RTI International.

Dr. Hersey's presentation was based on two questions: Are menthol cigarettes starter products for youth, and do menthol cigarettes make it harder for youth to quit?

Dr. Hersey provided solid evidence that menthol cigarettes are starter products for youth. Understanding the role of smoking menthol cigarettes during adolescence is essential, as smoking usually begins at this age. He reported that the preference of adolescents for smoking menthol cigarettes has increased. There was a significant increase in the youth smoking prevalence rates during the early 1990s with a rise in the 30 day prevalence rates from 28% to 36% . Prevalence of daily smoking also increased at all grades level among the classes of 1989, 1990 and 1991. According to National Youth Tobacco Survey 2000, 42% of young smokers in 6-12 grades usually smoked a menthol brand. Furthermore, 74% African American and 58% Asian American youth reported smoking menthol cigarettes. Studies on menthol cigarette smoking in adolescents have suggested that menthol-smoking adolescents seeking cessation reported greater pleasure from smoking and fewer quit attempts than those who smoked non-menthol cigarettes.

Marketing strategies may have contributed to the increasing preference for menthol cigarettes by beginning smokers. Menthol cigarettes were marketed as having lower harshness and irritation which would appeal to new smokers. There are several studies that could be related to the changing strategies of the tobacco companies for marketing to a new population. It was reported that there was an increase in smoking among 9th grade students in Erie County, New York from 8% to 28% in African American teenagers, between 1996 and 2000. It was around the same time in 1999, that Philip Morris introduced the new menthol brand, Marlboro Mild that targeted younger African American smokers. Between 1998 and 2005, magazine advertising for non-menthol brands dropped, but increased from $36 million to $43 million for menthol brands, so that now 63% of all cigarette ads in magazines are for mentholated cigarettes.

Dr. Hersey noted that between 1994 and 2004, the cost of menthol cigarettes rose by 55%, but the nicotine content also rose, allowing people to smoke fewer cigarettes while maintaining the addiction. It is thought that smokers of menthol cigarettes are better able to tolerate higher nicotine and tar yield cigarettes.

To understand the issue of role of menthol cigarettes in youth, Dr. Hersey analyzed the data from the 2000 and the 2002 National Youth Tobacco Survey. The results showed that the percentage of smokers who used menthol regularly increased significantly, although the prevalence of smoking among youth had declined between 2000 and 2002. It was also reported that menthol cigarettes were most popular among "younger and newer" smokers. Similar trends were seen with middle school and high school teens being more likely to smoke menthol cigarettes if they had been smoking for less than a year. The same trend was not seen among students who had been smoking for more than a year. Further, menthol use was higher among middle school students than high school students in white (53.1% in middle school versus 37.4% in high school) and Hispanic youth (62.9% in middle school versus 52.4% in high school). However, among African Americans, students in both middle school and high school predominantly smoked menthol cigarettes (87.5% and 86.8% respectively). The results indicate that the proportion of smokers who smoke menthol cigarettes are of younger age and that menthol cigarettes are a starter product for adolescents.

Dr. Hersey reported a study that explored the use of menthol in cigarettes among teenagers by examining the internal tobacco industry documents. The internal documents revealed that tobacco companies have extensively researched controlling menthol levels as a way of increasing its sales. The research demonstrated that higher menthol levels and stronger perceived menthol sensation was suitable for long-term smokers of menthol cigarettes whereas lower menthol levels appealed to younger smokers. As a result, the industry started promoting lower menthol content to attract young smokers. This was further clarified when menthol cigarette brands popular among young adults showed low menthol levels when tested.

Dr. Hersey also reported that in his data adolescent menthol smokers found it harder to quit, were less likely to intend to quit and scored higher on an addiction scale compared to non-menthol smokers. Forty-five percent of menthol smokers smoked within 5 minutes of waking in the morning, compared to only 29 percent of non-menthol smokers.

Discussion

It was raised from the floor that we needed to adopt the terms the FDA will be using in looking at menthol, specifically the definition of abuse liability (addiction potential). It was noted that, for instance, acetaldehyde and nicotine in combination make cigarettes more addictive, and that we need animal and human abuse liability studies of menthol in cigarettes. There was a clarification that we need to ask not simply does menthol make smoking more addictive, but does menthol increase the abuse liability of cigarettes.

Panel 5. Menthol and Cessation. Ms. Linda Bailey, North America Quitline Consortium, Moderator

Panelist: Dr. Monica Webb, University of Miami

Dr. Webb noted that menthol cigarettes are associated with lower cessation rates among African Americans and Hispanics. There is also evidence the menthol is associated with greater risk of smoking relapse.

She reported a study of the association between preference for menthol cigarettes and nicotine dependence scores, quit attempts and physical and mental health. She found a statistically significant association between smoking menthol cigarettes and higher frequency of poor mental health days (OR 1.07, 95% CI 1.02-1.11, p = 0.005). She noted that this is a relatively crude measure of mental health, and urged that the study be replicated with more in-depth measures.

She also reported a study that looked at smoking cessation precursors. She found that menthol smokers were less likely to have cut down on their smoking or to limit their smoking. There was a non-statistically significant difference in having had a quit attempt for menthol versus non-menthol smokers (54% and 75% respectively), probably because of the small sample size.

Panelist: Dr. Kolawole Okevemi, University of Minnesota

Dr. Okuyemi reported a study of 600 smokers enrolled in a trial of bupropion for smoking cessation. Menthol smokers were more likely to smoke their first cigarette of the day in fewer than 30 minutes ($p<0.01$). Short term abstinence rates were lower for the menthol smokers. In another of his cessation trials, verified 7-day point-prevalence cessation at six months follow-up was significantly lower for menthol smokers.

In another study, Harris and co-workers reported on predictors of African Americans quitting in a large trial of bupropion. Among the predictors of cessation was not smoking menthol cigarettes (P = 0.006). In the Coronary Artery Risk Development in Young Adults (CARDIA) study, there was a trend toward lower cessation among menthol smokers (P = .06) There was a significant increase in the risk of relapse during the 15 year follow-up (odds ratio 1.89; 95% confidence interval 1.17-3.05; P = .009). Dr. Okuyemi also reported on a survey of African American smokers from an inner-city health center. Menthol and non-menthol smokers did not differ by number of past quit attempts, but the time since most recent quit attempt was shorter for menthol smokers. Duration of quit attempts were non-significantly shorter for menthol smokers. This is in concordance with the findings from the McCarthy et al study that the longest mean abstinence for menthol smokers was found to be four times less than non-menthol smokers. Menthol smokers were also observed to have a crude trend of fewer recent quit attempts as compared to non-menthol smokers, suggesting that menthol smokers are more nicotine dependent and less likely to attempt cessation.

Panelist: Dr. Jonathan Foulds, University of Medicine and Dentistry of New Jersey

Dr. Foulds reported a well-controlled cessation trial. He found that across all racial/ethnic groups, menthol smokers were less likely to successfully quit than were non-menthol smokers (36% versus 50%, $p < 0.001$). Even after controlling for a number of covariates, African American menthol smokers were less likely to be abstinent at 6 months compared to non-menthol smokers (OR = 0.48, 95% CI .25-.90). He found that a major determinant of failure to quit was being unemployed. The hypothesis is that if one has little money to spend, but is still addicted, (s)he will have to compensate by smoking more of each cigarette. Menthol may make that compensation easier, allowing taking in of more nicotine per cigarette, by masking the harshness of the smoke, and taking in more nicotine per cigarette makes quitting more difficult.

In other words, the elasticity of delivery is likely greater for menthol cigarettes compared to non-menthol cigarettes.

Panelist: Dr. Mark Pletcher, University of California, San Francisco

Menthol may exert its damage through either increasing damage per pack year of smoking, or by inducing more pack years of smoking (harder to quit). Dr. Pletcher reported on the impact of menthol cigarette smoking in the Coronary Artery Risk Development in Young Adults (CARDIA) study. He found the usual predictors of menthol smoking (younger age, female, lower education, unemployment, fewer cigarettes smoked per day). He reported a strong association between magnitude and duration of smoking and coronary calcification, but did not find a menthol effect. Nor did he find a statistically significant decrease in pulmonary function with menthol versus non-menthol cigarettes. He did find that sustained smoking cessation was less likely among menthol smokers. He also reported a strong association between menthol smoking and relapse.

Discussion

Dr. Foulds concluded that the cessation issues with menthol cigarettes may be confounded by other factors, such as un- or under-employment, but just on the basis of the greater uptake of smoking menthol cigarettes by adolescents' menthol should be banned. Dr. Webb reported that she has found a consistent trend in lower self-efficacy for quitting and higher scores on addiction scales among menthol smokers. It was suggested that the field would be best served by development of a detailed conceptual model of the relationship between menthol and quitting and all the additional variables that might modify that relationship. It was noted that perhaps we are learning more about menthol smokers than about menthol itself – Dr. Foulds concluded that it is the menthol that is driving the issue, but that might be because we can measure menthol smoking well. He also noted that his results from his clinic sample were replicated in a national sample of smokers who were not as likely to be treatment seeking as was his clinic sample.

Dr. Watson confirmed that findings from the CDC – solanesol levels in spent filters – consistently show higher volume of smoke through filters of menthol cigarettes. He noted that this confirms that menthol cigarettes have higher abuse potential. He also noted that someone who smokes two packs a day may be taking in the same volume as someone who smokes 15 cigarettes per day.

Dr. Henningfield explained the process by which the FDA would come to a conclusion about how to regulate menthol in cigarettes. He stated that there are a lot of unresolved issues, but that the conference may come to a consensus regarding menthol. The panel noted that the preponderance of evidence is that menthol makes it harder to quit, and that menthol makes it easier to start. Dr. Foulds stated that it would be reckless not to do something about it.

Dr. Ahluwalia still has doubts, and feels that because we do not have a biologic mechanism of action we need to be cautious, but the findings of menthol uptake by children is enough reason to ban it.

Summary of the 2nd Day of the Second Conference on Menthol Cigarettes

Panel 6. Tobacco Industry Targeted Marketing. Amber Thornton-Bullock, American Legacy Foundation, Moderator

This panel detailed through a plethora of exhibits, photos, and videos that the tobacco industry has specifically targeted the youngest and most vulnerable sectors of the United States population to promote the use menthol cigarettes. The tobacco industry realizing the special sensory, taste and anesthetic properties of menthol cigarettes have aggressively marketed them as healthier then their non-menthol brands. All speakers on this panel recognized that menthol was marketed broadly and widely through out the United States, but at its core, menthol products have been especially targeted to African Americans, other communities of color, women, and youth.

Panelist: Dr. Alan Blum, University of Alabama

Dr. Blum reviewed the history of mentholated cigarettes and the targeted advertising in the African American community. He demonstrated through numerous slides and video clips that the tobacco industry initially had developed the African Americanization of menthol cigarettes and continues to focus on this community with its marketing. While Joe Camel got a lot of advertising time in the 1990s, it was pointed out that the first cartoon character that promoted tobacco products was Willie the Penguin, the spokesperson for Kool mentholated cigarettes.

Dr. Blum went on to demonstrate that the tobacco industry focused most of their magazine advertising attention on 3 key magazines in the African American community: Jet, Ebony and Essence. The industry was quite aware that over 50% of African American females encountered Ebony on a weekly basis. Additionally, it was pointed out that the tobacco industry has gone out of its way to promote literacy, art, music, dance and college funds in the black community. In fact, R.J. Reynolds was able to get Benjamin Hooks, past president of the NAACP, to pose for a Salem billboard.

Panelist: Mr. George Crawford, Georgia Division of Public Health

Following Dr. Blum was Mr. George Crawford who brought the tobacco industry's tactics up-to-date by reviewing the use of Hip-Hop culture for tailored marketing to promote menthol cigarettes. Mr. Crawford began by saying that the tobacco industry knows that Hip-Hop is much broader than just Rap music, and that Hip-Hop culture appeals to both urban and suburban youth. Elements of Hip Hop culture identified and targeted by the tobacco industry include music, dance, graffiti, language, cars (rims particularly), clothes, jewelry (ice, bling) alcohol, drugs and of course tobacco.

Using the picture and images of well known rap artists to promote tobacco products has become standard fare. Rap artists dressed in Hip Hop attire including do-rags, cocked baseball hats, diamond ear studs, gold and silver chains (the bling-bling), sports t-shirts, tennis shoes and baggy pants are all decked-out to sell not only cigarettes but also blunt wrappers (i.e. a tobacco

sheet used to role marijuana joints). More often then not these blunt wraps, as they are called are candy and fruit flavored and some are mentholated. Some tobacco products have Hip Hop names, like *Bling Bling*, the brand name of a square cut cigar. Other tobacco products have Hip Hop drug names, like Kush and Chronic.

Mr. Crawford pointed out that the tobacco industry increasingly uses the colors of green and blue to promote their menthol products. It isn't even necessary to use the term menthol to promote menthol products; just the visuals, color and words; often the word menthol doesn't even appear on the cigarette packages of menthol cigarettes. Along with this, "ice" has emerged to connote freshness and coolness.

Panelist: Dr. Tess Boley Cruz, University of Southern California

Dr. Tess Boley Cruz looked behind the curtain and elaborated the underlying marketing theory guiding the tobacco industry's effort: product packaging, price, placement and promotion. Literature was reviewed that documented that menthol smokers choose menthol because of taste. A review of the tobacco industry documents has revealed that they (the tobacco industry) categorize menthol smokers into two distinct groups: those who worry about throat irritation on the one hand and those who seek specific menthol flavor on the other hand. Additionally, tobacco industry documents reveal that the tobacco industry has manipulated the level of menthol in cigarettes for years: low levels of menthol for beginners and youth to mask the harsh tobacco taste, like Newport Lights; greater amounts of menthol are placed in products for "seasoned" smokers, like Kool. The advertisements for Skoal Edge are revealing: "Skoal edge: it's not just bold, its one mean wintergreen." Another ad states: "They asked for a bolder wintergreen. Who are we to say no?"

Menthol Levels and Marketing (from Kreslake et al, AJPH 2008;98:1685-1693)

Menthol (% tobacco weight)	Brands	Target Groups
Low .32 - .37	Newport Marlboro Mild Salem Black Label	Younger smokers, Modern urban 21-34
Medium .44 - .48	Salem Green Label Camel Menthol Kool	Younger smokers Urban, multicultural young adults
High .55 - .63	Marlboro Menthol Kool Milds	Long term smokers 35+ Younger smokers

As is detailed in the chart above, the tobacco industry pays particular attention to youth and young adult's use of menthols: 44% of all youth smokers; 78% of African American youth smokers; and 48% of Asian American youth smokers. Women were identified as the largest

group of menthol smokers. Dr. Cruz pointed out that, from her own work, the largest tobacco advertising expenditures in women's magazines were found to be for menthol brands. In discussing retailing menthol products, Dr. Cruz stated that research has shown that menthol smokers were twice as likely to use promotional offers as non-menthol users). Moreover, menthol is playing a role in new tobacco products. The emergence of orbs, strips, sticks (RJ Reynolds) and the like all have menthol (types, iterations, brands, etc).

Dr. Cruz went on to say that research continues to show that the tobacco industry specially target African Americans smokers with menthol products, and continue giving donations to a vast array of Black civic, cultural and social causes. However, the industry also targets Asian and Latinos through graphic advertisements and donations to their social causes.

Dr. Cruz made a series of recommendations:

- ✓ Require plain packaging - the pack is part of the marketing mix.
- ✓ Remove menthol to help deter starters.
- ✓ Menthol appears to function like other flavors - restrict it to protect pediatric health.
- ✓ Menthol may be used when there is throat irritation so it should be restricted to avoid masking signs of illness.
- ✓ Require reporting of tar, nicotine and menthol levels on packs, like food labeling, so users can make informed choices, and professionals can tailor quit efforts by strength of tobacco.
- ✓ Make warning labels interactive, on each page of brand password-protected websites, so they are noticed and read.
- ✓ Extend regulations to non-cigarette tobacco products.
- ✓ Menthol is a social justice issue. Ban it to reduce disparities.

Panelist: Ms. La Tanisha Wright, National African American Tobacco Prevention Network

Ms. Wright, an ex-tobacco industry representative, described first-hand knowledge of how targeted marketing was done at R.J. Reynolds. Ms. Wright discussed an array of predatory retail practices conducted by the tobacco industry towards communities of color. R.J. Reynolds used the term "focus" communities and/or stores to designate areas with urban characteristics, high menthol sales and low income clientele; predominately minority and most often African American or Latino communities. Correspondingly "non-focus" areas were suburban, low-menthol sales and, for the most part, white communities. The tobacco industry places the highest quantities of mentholated products in "focus" retail stores.

Retail stores in "focus" areas receive higher discount rates on mentholated cigarettes compared to other brands. For example, Ms. Wright pointed out that in "non-focus" communities menthol products were discounted $.50 a pack; on the other hand in "focus" communities, mentholated cigarettes are discounted between $1.00 and $1.50 per pack. Other promotions were more attractive in "focus" stores compared to "non-focus" stores. In "focus stores *buy 1 get 1 free* promotions predominated, while in "non-focus" stores *buy 2 get 1 free* was the general rule.

The tobacco industry places a higher quantity of interior and exterior signs at "focus" retails stores compared to "non-focus" retail stores. On average during the earlier part of this decade, R.J. Reynolds placed 4-8 exteriors signs in "non-focus" retail stores. Conversely, in "focus" retail stores upwards of 20 exterior signs was the normal practice. Similarly, tobacco advertisements have a higher profile in "focus" retail outlets compared to "non-focus" retail outlets.

Ms. Wright continued by stating that the tobacco industry has been increasing the nicotine yield in their cigarettes since the MSA in 1998 and menthol cigarettes were no exception. Between 1998 and 2006, Newport had increased nicotine yield by 10% while Kool was increased by 30%. During this time period, the tobacco industry also established brand-specific websites targeted toward youth. These websites feature juvenile games, prizes and accessories. For example, at the R.J. Reynolds Kool website, green and white Kool tennis shoes can be purchased.

Panelist: Mr. William Rucker, University of Missouri St. Louis

Mr. Rucker began his talk by tracing his involvement in high school and college in developing anti-tobacco programs. He pointed out that the school / University partnership that was developed focused on academic excellence on the one hand and countering tobacco in the community on the other hand. Working with a team of young people in the community, Mr. Rucker observed many of the phenomena associated with menthol cigarettes in the African American community that had been described previously and during the conference. He stated that all along the route to school, there were advertisements for tobacco products with the overwhelming majority of them for menthol cigarettes. Additionally, the convenience stores near the school sold "loosies" (single cigarettes); selling loosies is against the law in Missouri. Mr. Rucker stated that the tobacco industry and their retailers purposefully sold single cigarettes knowing that it would attract youth who often would not be able to afford a pack of cigarettes. It was also pointed out that loosies were not being sold in more affluent communities.

Mr. Rucker and his team presented their findings about tobacco advertising and loosies to a statewide meeting. Law enforcement agencies were compelled to join in the anti-smoking effort. Mr. Rucker's team developed an action plan that called for:

1. Enforcing city and state ordinances that prohibit the sell of tobacco products to minors
2. Enforcing the prohibition on the sell of single cigarettes

To date Mr. Rucker has involved 42 school districts in Missouri in the tobacco control efforts. These efforts have included developing public service announcements (PSAs), recording hip-hop songs with an anti- tobacco messages and producing videos with the slogan: Stop the Loose; Stop the Use.

Panelist: Mr. Kwasi Harris, Behavioral Health Center, Chicago

After acknowledging his ancestors and elders, Mr. Harris turned his attention to what he called the war taking place in the African American community where the real weapons of mass destruction, cigarettes, were being dropped everyday. In this regard, Mr. Harris pointed out that

one of the most egregious expressions of targeted marketing in the last decade was the Brown & Williamson / R.J. Reynolds *Kool Mixx* campaign. Here the tobacco industry, using hip-hop vernacular, images, DJs and rappers, sought to host a series of events around the country to popularize their cigarette brand, culminating with a major event/party in Chicago. Mr. Harris, who was working with the National African American Tobacco Prevention Network at the time, said that the community organizing that they undertook in Chicago was a case study in a community speaking out and fighting back.

Mr. Harris argued that the tobacco industry was not only *using* Black culture, but desecrating it. While claiming to be celebrating hip-hop, the tobacco industry was in reality using this cultural expression to push their deadly product. In fact, the tobacco industry was in effect killing the very people who had created hip-hop in the first place. Mr. Harris pointed out that even before folks organizing against the Kool Mixx campaign in Chicago stopped the event, the tobacco industry already had their next predatory marketing scheme in place: The New Jazz Philosophy Tour.

Mr. Harris said that many lessons were learned from the Kool Mixx campaign:

1. Big tobacco knows what we in the community like
2. Organizing the community requires bringing all segments together to fight the tobacco industry, including the faith community, street organizations (gangs), health voluntaries, legal representatives, elected officials, tobacco control activists and regular community folk.
3. Establishing a common denominator that all can rally around. In the case of the Kool Mixx campaign in Chicago, that common denominator was health and the health of our community.
4. Identification of three parameters that guided all of their work:
    a. Grassroots organizing
    b. Litigation
    c. Legislation
5. Community activists involved in the fight with the tobacco industry must develop their own marketing campaign to counter the insidious presence of pro-tobacco messages in our communities. Mr. Harris provided copies to conferees of some the counter marketing materials that were developed in the fight in Chicago.
6. The last lesson that Mr. Harris shared with the conference was that since their organizing efforts had been successful in stopping the Kool Mixx party, the organizers threw a party of their own.. Mr. Harris also noted that not only was the Kool Mixx campaign thwarted, but they were successful in shutting down the House of Menthol website.

Mr. Harris concluded his remarks by stating that indeed the predatory marketing of menthol was a social justice issue, as the previous day's luncheon keynote speaker Dr. Cheryl Healton had stated. Mr. Harris said that the marketing of menthol to the African American community was not only targeted marketing, but also it was a question of environmental racism. He pointed that these products were marketed to the least informed about the health effects of smoking, had the

fewest resources with which to fight back, had the lowest amount of social support and had the least access to cessation services - this is indeed, a social justice issue.

Discussion

Because of the length of this panel, discussion was postponed until the afternoon break-out session reports.

Panel 7. FDA and Menthol. Dr. William Robinson, National African American Tobacco Prevention Network, Moderator.

Panelist: Stephanie Foster, American Legacy Foundation

An overview of the FDA legislation was provided by Ms. Foster. She re-iterated that tobacco industry documents show that this industry has historically and continues today to view menthol as a starter product for youth initiation and that menthol products are especially targeted to minority communities. Ms. Foster highlighted that lawyers at the American Legacy Foundation had reviewed the recent legal case against Philip Morris (U.S. v. Philip Morris et al.) and excerpted all mentions and references to menthol. She provided conference participants will copies of these findings.

Ms. Foster stated that the American Legacy Foundation concluded that menthol should be considered analogous to other candy-flavorings in cigarettes that were banned from sale in September of 2009. Moreover, it was pointed out that the FDA had recently sent a letter to tobacco producers stating that the ban on characterizing flavors applied not only to cigarettes but also to all other tobacco products that meet the definition of a cigarette; the implication being that little cigars that are flavored should be treated in the same way as cigarettes.

Ms. Foster explained to the conference about the tobacco products scientific advisory committee. She noted that menthol was just one of its charges, along with review of dissolvable tobacco products, nicotine level alterations, and oversight of modified risk products applications from the industry. The scientific advisory committee will have 12 members, 9 voting 3 non-voting, with the tobacco industry having the 3 non-voting positions. Specifically, as in concerns menthol, the scientific advisory committee is charged to:

1. Determine the impact of the use of menthol cigarettes on public health among African Americans, Hispanics, and other racial and ethnic minorities.
2. Determine the scientific risks and or benefits associated with increases and/or decreases in menthol in tobacco products.
3. Determine if menthol use is likely to increase starting and uptake of use of tobacco products.
4. Provide recommendations on whether to ban menthol, or take other actions or whether future study is needed.

This scientific advisory committee findings on menthol should be completed within 1 year.

Ms. Foster concluded by alerting the audience that the period of public comment had been extended to December 28, 2009 and she encouraged participants to express their views to the FDA, more then once if possible, to help build a credible record around menthol.

Panelist: Ms. Sharon Eubanks, formerly with the United States Department of Justice.

Ms. Eubanks, former lead attorney in the United States v. Philip Morris, pointed out to the conference that the FDA, like other government agencies, takes statutes passed by Congress and creates regulatory authority that often fills gaps or addresses issues not covered in the original statute. As it concerns menthol, Ms. Eubank stated that the FDA had created a process of how it intends to deal with this issue; much of this was reviewed by Ms. Foster. Ms. Eubanks alerted the participants to key distinctions in the legal and regulatory language of the FDA Bill. She pointed out the difference in the phrasing the "FDA shall" (required language) and "FDA may" (giving power to the agency).

Ms. Eubanks noted that the FDA had posted on its website a Charter for the Tobacco Products Scientific Advisory Committee in August of 2009 and it was worth all participants' reading. Even though it have been pointed out by many speakers that the Advisory Committee had a year to give their report to the FDA, Ms. Eubank warns that there was no time frame that the agency or the Secretary was mandated to take action on the regulation of menthol. It was stated that the squeaky wheel is the one that gets attention and the menthol issue will have stiff competition, from other pressing important needs like the FDA dealing with new tobacco products, especially from dissolvable nicotine products, among many others. s. Eubanks was encouraged by the fact that the Charter states that $2,512, 812 had been set aside for the advisory committees work, meaning that there is actually a substantial amount of money to tackle the issue of menthol.

While there have rightfully been concerns voiced about the tobacco industry being on the scientific advisory committee, Ms. Eubanks pointed out that the Secretary and/or the head of the FDA had the ability and the discretion to create sub-committees that might include only voting (read non-industry) members to address specific topics or concerns. Ms. Eubanks warned conferees that the industry will probably bring more law suits not so much challenging the FDA overall authority, rather the legal attack will focus on *how* the FDA is exercising its regulatory authority.

Ms. Eubank concluded that while we may not know whether menthol increases cancer risk, or whether menthol increases the absorption of tobacco toxins in the lungs, or whether by a strict medical definition menthol products were more addicting, what we do know is formidable: Menthol has its own special sensory stimulation that serves to re-enforce smoking behavior; we know it intensifies the smoking experience; we know that tobacco industry uses menthol as a starter product; we know that menthol is often presented as a healthful alternative; and we certainly know that menthol has been targeted to minority communities through an array of predatory marketing practices. It was her sense that just the social justice issues alone should compel the FDA to ban menthol.

Attendees were admonished to realize that this process will minimally take 2 years and that is a liberal estimate.

Panelist: Dr. Pamela Clark, University of Maryland College Park

Dr. Clark, Co-Chairperson of the Menthol Conference, reviewed what we had learned over the past day about menthol and what the FDA needed to do given these findings. Dr. Clark stated that we have reports and evidence that menthol inhibits nicotine clearance. Moreover, menthol inhibits NNAL glucuronidation; that is, menthol inhibits the body's detoxification mechanism for the powerful lung carcinogen NNAL. Other studies have shown that menthol produces greater cardiac reactivity with menthol smokers exhibiting higher heart rates while smoking and while resting compared to non-menthol smokers. She noted a Turkish study that found smoking menthol cigarettes to cause greater decreases in cardiac systolic function compared to non-menthol cigarettes.

Dr. Clark stated that the evidence presented over the past day was compelling and that it had altered her opinions about the prohibition of menthol; she now agreed that sufficient evidence exists to prohibit its use in tobacco products characterized as menthol for the following reasons:

1. Clearly the menthol seen by the tobacco industry as a starter product, aimed directly at America's youth, middle-schoolers, and the least experienced smokers. If fact, Dr. Clark suggested that this might be our best argument for why menthol should be banned.
2. Menthol is marketed specifically with "health" messages that research is shown to resonate with the targeted audience.
3. The social justice issues are wholly apparent; focusing a deadly product on the poorer and most vulnerable sectors of the society is egregious.
4. While most sales of cigarettes have declined, menthol sales have only leveled off, meaning that people are still taking up menthol cigarettes, while not other brands.
5. There is increasing evidence that menthol cigarette users have poorer mental health functioning compared to smokers of non-menthol cigarettes.
6. There is evidence that menthol smokers have greater problems quitting for a day, a marker that we know is one precursor to quitting.
7. Studies show that menthol smokers have higher nicotine dependence levels compared to non-menthol smokers. Even thought the average menthol smoker smokes fewer cigarettes a day compared to non-menthol smokers, they still have higher dependence measures.
8. As it was shown in the Cessation panel, there is increasing evidence that menthol smokers have poorer quit rates and higher rates of relapse.
9. Interestingly, as it was pointed out during the conference that unemployed menthol smokers had a harder time quitting compared to those where unemployed but smoked regular cigarettes.

Dr. Clark concluded stating that the tobacco industry's claims that menthol used be viewed through the lens of the GRAS; is not only irrelevant, but also irresponsible. What is Generally Regarded As Safe (GRAS) is qualitatively different for topical solutions and ingested products, compared to products that are burned, and inhaled into the lungs. Given all of what has been said above there is ample evidence to prohibit the use of menthol in tobacco products.

Several additional issues need to be resolved. The conclusion is that cigarettes with characterizing levels of menthol should be banned. That would result in immediate cessation of the relentless predatory marketing of menthol cigarettes. However, she noted that subliminal levels of menthol in cigarettes contribute to smoke smoothing, and consideration should be given to banning all menthol. In addition, there are a large number of odorless, tasteless menthol analogues already patented by tobacco manufacturers, that would produce menthol-like effects. A consideration of examining all tobacco additives that make smoking more attractive is in order. A further consideration if menthol is banned is the likely proliferation of "add-your-own" menthol products on the market.

Panelist: Dr. Jack Henningfield, Pinney Associates and John Hopkins University

Dr. Henningfield started his remarks by reminding the audience that many of the new folks at the FDA and those in the new tobacco products section were committed to public health and referred attendees to a recent New England Journal of Medicine article. Dr. Henningfield targeted 3 areas where he felt that the conference was on solid ground in calling for a prohibition of menthol characterized cigarettes:

1. Youth initiation; menthol as a start up drug
2. Inhibiting cessation
3. Increases addiction potential

Dr. Henningfield clarified that while menthol is not as far as we know addictive in its own right and more research needs to be done on this issue, it seems pretty clear from the many studies and presentations in this conference that menthol increases the addiction risk and potential of tobacco products. Having said this, Dr. Henningfield proceeded to list a series of questions that he said must be considered by the FDA.

1. Should menthol be completely banned in all cigarettes or just banned in those cigarettes that are "characterized" as menthol products? The distinction here is that menthol is added to most tobacco products (pipe, roll-your-own, smokeless, etc), however only some cigarettes are characterized as "menthols;" they of course have significantly greater amounts of menthol.
2. If the FDA were to agree to alter or lower menthol levels, how will that be handled in the marketing and packaging of these products? If ingredients are listed on tobacco products, should menthol levels be disclosed?
3. What should the FDA do with menthol analogues? In this regard it was pointed out by Dr. Clark that the tobacco industry was developing menthol analogues that could potentially replace menthol as we know it and still have the same sensory effects and continue to increase the addiction potential of tobacco products.
4. What should be the time frame for prohibiting menthol in tobacco products? In this regard it was pointed out that the prohibition of menthol would have to be accompanied by a massive educational campaign among menthol smokers. Many will feel that there "best friend" has been taken away from them. Indeed, the population of menthol smokers needs to be enfranchised and empowered and offered increased cessation opportunities.
5. Contraband operations must be monitored.

Dr. Henningfield asserted that the FDA will have to develop performance standards in addressing the issue of menthol. He re-iterated that those standards must include initiation and appeal to children; the potential for increasing dependency and addiction; and the inhibition of cessation. Even though there is some evidence about the toxic effects of menthol, the FDA needs to know what solid evidence we have and what evidence is not solid. Additionally, it was pointed out that even after prohibition, studies will still need to be conducted on a whole range of topics and issues. The FDA will have to ask the basic question: has the banning of menthol slowed initiation and increased cessation; are there more quitters and fewer starters?

Dr, Henningfield concluded stating that a greater burden needs to be put on the tobacco industry to disclose the information that they know about menthol. We in the tobacco research and tobacco control movement will need to generate greater community support analogous to the Town Hall meeting on menthol and the FDA conducted at Howard University the previous evening. It might be prudent for the FDA to focus initially on the advertising issues and not allow the promotion of menthol products.

Discussion:

It was pointed out by Dr. Alan Blum that he testified against the FDA legislation at the congressional hearings because he felt that the congress should have banned cigarettes outright and because of the menthol exemption. He went on to say that it was the failure of the congress to prohibit menthol along with other candy favors that laid the conditions for the 2nd Conference on Menthol Cigarettes.

Dr. Gardiner, one of the conference Co-Chairs responded that while the congress may have laid down on its job, we, this conference need not. He pointed out that Dr. Clark and he have agreed to prepare a detailed report on the proceedings of this conference. While no formal consensus has been reached, it does seem clear that menthol's use by youth as a starter product, the documented problems associated with menthol and cessation; the constant bombardment of quasi-health messages about menthol; and menthols propensity to promote addiction - for all these reasons it seemed reasonable that the FDA should prohibit the use of menthol in tobacco products. Dr. Gardiner also suggested that menthol prohibition needs to put into the context of the overall health care debate taking place in this country. If there is to be prohibition of menthol then it needs to be accompanied by a nation-wide increase in cessation services, since we know that where menthol cigarettes are used, cessation services are the most diminished.

Dr. Clark stated that just stopping the predatory advertising of menthol products would be a big step in and of itself. Still, the question remains should the FDA ban any and all amounts of menthol in cigarettes or should it just ban cigarettes that are characterized as menthols? Dr. Jack Henningfield suggested that there was greater evidence for banning characterizing menthol cigarettes and that there wasn't at this time sufficient evidence for banning of sub-threshold levels of menthol in cigarettes. He continued stating that if cigarettes characterized as menthols are banned there of course will be unintended consequences; how the ban is carried out will be very important. FDA will have to minimize the risks and maximize the benefits. Indeed a grassroots movement will have to be developed to ensure that the ban is implemented as well as it can be.

Dr. Pebbles Fagan of the National Cancer Institute stated that more often then not, researchers and tobacco control folks alike did not confront the real possibilities of unintended consequences of tobacco policies and legislation. Dr. Clark responded that researchers and advocates were more ready and better prepared to face this issue. She noted that the experience with "light" cigarettes had taught the whole movement a sobering lesson. Ms. Eubanks added that the legislation takes the question of unintended consequences into account, where several places in the legislation states that the FDA must balance the risks and the benefits of their actions and understanding the likelihood of increased use or decreased use. Additionally, Dr. Henningfiled added that the FDA will be monitoring all of its actions since surveillance was a strong part of the legislation.

Dr. Valerie Yerger pointed out that since studies show that nicotine accumulates in melanin cells in the body, it will be important to determine if menthol adds to this process. This is vitally important since menthol has been shown to inhibit the glucuronidation of the powerful lung carcinogen NNAL and if it is accumulating in the body, it could be a very unhealthy consequence for all people of color.

Mr. McGoldrick from the Campaign for Tobacco Free Kids suggested that FDA had the ability right now to restrict the marketing and advertising of menthol products. He encouraged conference participants to take advantage of the FDA's public comment period and let them know about the tobacco industry's marketing in your community.

Lastly, one participant suggested that we should call for the prohibition of all flavorings in tobacco products since after menthol is prohibited the tobacco industry will just come up with something new.

Luncheon Keynote Speaker: The Honorable Louis Sullivan, past Secretary of the Department of Health and Human Services

The conference was honored to the have the Honorable Lois Sullivan, past Secretary of the Department of Health and Human Services as the second day keynote speaker. Dr. Sullivan began by saying that it was not only people in Washington and the congress that make laws, but it is people from around the country that also play a vital role, and in this context was pleased to see all the people from across the United States in attendance at the conference. He went on to say that smoking and tobacco use is ingrained in our society and in our culture and that tobacco use is supported by a very smart, rich and determined industry.

Dr. Sullivan suggested that Congress ducked its responsibility by not including menthol as one of the laundry list of candy-favor additives to be banned in the FDA oversight legislation. Rather they "punted" the responsibility to the FDA, an agency that has seldom had the resources to truly effectively carry out its job. Having said this, Dr. Sullivan went on to tell the conference about the *Uptown* story. Uptown was a new menthol product introduced by R.J. Reynolds in 1989-1990 that was proposed to be test-marketed in the Philadelphia African American Community. A community group lead by Dr. Bob Robinson and others had organized the

Philadelphia Black community to oppose the introduction of this product to a population already over-burdened with a myriad of health concerns.

Dr. Sullivan became aware of this initiative and, on a trip to Philadelphia, agreed with the local organizers and championed the calls for not test marketing this product in the Philadelphia African American community. Dr. Sullivan did this with great risk to his reputation and job, since there were many in the Bush administration that were supportive of the tobacco industry. Still, he felt that if he is really the Secretary of Health then he needed to speak out on this issue. Before traveling to Philadelphia, Dr. Sullivan wrote a letter to the president of R.J. Reynolds outlining his concerns about testing this product in a community already suffering disproportionately from tobacco-related diseases and other maladies. His comments in Philadelphia received national headlines and a week following his remarks he received a letter from the president of R.J. Reynolds stating that they were cancelling their plans to test market uptown in the Philadelphia Black Community. He pointed out that often public health officials in order to do the right thing have to take stands that are not guaranteed popular.

In closing, Dr Sullivan talked about the work of outlawing smoking in government building and the difficulties he encountered. He did applaud the move on the part of newly elected president Bill Clinton for outlawing smoking in the White House, though small, still was an important symbolic move for great public health. He warned conferees that having the FDA ensure the safety of cigarettes was a contradiction in terms and that the industry will probably try to use this fact against us.

Panel 8. Population Behavioral Change, Dr. Phillip Gardiner, University of California, Office of the President, Moderator.

Panelist: Ms. Makani Themba-Nixon, The Praxis Project

Ms. Themba-Nixon alerted the audience that her organization, The Praxis Project, had been initially dismayed that the issue of prohibiting menthol was not included as one of the many candy-flavored additives banned in the FDA legislation. In many respects she argued that not having menthol on the table reflected a separation between what was taking place on the ground at the community level and what was taking place on the national tobacco policy level. She stated that as we move forward we need to create an inter-disciplinary space for activists and scientists alike so that this gap can be narrowed.

Ms. Themba-Nixon went on to say that menthol was symbolic of many other public health issues where one group is most impacted, but does not have the political voice, positioning or clout to bring to the fore their thoughts and ideas about how to deal with it. She applauded the work of the National African American Tobacco Prevention Network and Dr. Louis Sullivan for getting the menthol amendment, which forces the FDA to deal with the question of menthol. She opined that we hopefully will learn from the experience of menthol so that in 5 years issues disproportionately facing a given community will be central to the deliberations of new tobacco regulation, and not peripheral. In the case of menthol, the main flavoring ingredient in tobacco, it was excluded from prohibition in the bill, something that would not have taken place if the people most affected where part of the deliberations. In many respect, she stated that some of us

in the tobacco control movement had been blindsided by the exclusion of menthol from the banned additives in the FDA Bill.

Ms. Themba-Nixon pointed out that there was a huge power disparity where urban communities are grossly under-represented in the political process. She gave examples where cities like Milwaukee, Wisconsin have 23% of the state population, but only have 16% of the elected officials in the State House. This type of disparity should signal to tobacco control folks that we need to make common cause with other groups, like those working on proportional representation. She concluded by saying that probably only a dozen or so people were involved in the discussion and formulation of the FDA legislation, determining what should and should not be included. We stand now at a point where we can democratize our own processes in tobacco control to ensure that the people most affected are checked engaged.

Panelist: Dr. Frances Stillman, John Hopkins University

Dr. Stillman focused her remarks on community-based participatory research. Dr. Stillman encouraged the audience to learn from the community when doing tobacco control work and not take the time worn academic approach of showing up in the community and saying I know the science therefore I know what should be done. Dr. Stillman admitted that she had not worked around the issue of menthol, per se, but her work in Baltimore's African American community provided fertile ground and many lessons on how to take up the fight against menthol at the community level.

Dr. Stillman went on to say that not only should the community be part and partial of determining the strategy and tactics in the fight against menthol, but academics together with the community needed to develop a political movement to expose the predatory nature of the tobacco industry's ongoing targeted marketing campaign. She continued by saying that the grassroots initiative undertaken on the local level must be replicated and augmented on a national level. Dr. Stillman concluded saying that the community must be the leader in the norm change that we are seeking; we in the tobacco control and research movements must join with the community to change the norms around menthol use, must learn how to change the community's loyalty toward menthol, turn it around, and we can learn this from the community itself.

Panelist: Dr. Robert Robinson, Centers for Disease Control and Prevention (retired)

Dr. Robinson, past associate director for health equity at the Centers for Disease Control and Prevention Office on Smoking and Health, began by returning to Louis Sullivan's remarks concerning the campaign against Uptown cigarettes, stating that in the short 13 days not only was R.J Reynolds defeated, but it fundamentally changed the dynamics of the tobacco control movement: it heralded African American activists beginning to play nationally leading roles and giving ethical foundation to the movement itself. Dr. Robinson also noted that there were more people of color at this conference than white people, an extraordinary event for a tobacco control and tobacco research meeting.

Dr. Robinson stated that we not only need to ban menthol in tobacco products, but more importantly we need to broaden our definition of harm. As it has been said by many speakers

before, we cannot solely look at the morbidity and mortality associated with menthol, rather we have to expand our perspective to include uptake and initiation, increased risk of addiction, inhibitions to cessation and increased relapse. He thanked the National African American Tobacco Prevention Network and the American Legacy Foundation for calling for the prohibition of menthol cigarettes. He asserted that if we are to take up the issue of banning menthol then the question of cessation needs to move to the center of our discussions. In this regard, Dr. Robinson suggested that the tobacco control movement needed to go beyond cultural competency and adopt a broader approach of community competency. Given the complexity of the communities we work in, we must deal with issues broader than just culture, including history, geography, context, language literacy, positive imagery, diversity and gender roles among others. Only a paradigm this broad can begin to address the issues of cessation that we face in our various communities.

Dr. Robinson pointed out that the tobacco industry understood the complexity of the communities that they are targeting, which is why they have been so effective in their penetration. He noted that quitlines while necessary were insufficient in solving cessation issues. It is unfortunate that money has sometimes been taken away from community-based efforts and gone to quitlines. It was also suggested that the pamphlet Pathways to Freedom be more widely distributed by quitlines to African American smokers seeking to quit. This could be an important step in quitlines increasing their competency in dealing with communities of color. It was also noted that quitlines funding, services and materials offered clients varied from state to state.

Dr. Robinson implored all scientists and activists to promote the continued research around menthol, make sure menthol questions are on all national surveys, monitor the tobacco industry's continual promotion of menthol, focus on health disparities and inequities and replicate cessations efforts that have been shown to work in all communities. Dr. Robinson admonished epidemiologist that, even though there may be a relatively small number of persons in the native Hawaiian community, with menthol use at 38% of smokers of this population, the overall toll on the community is quite significant and that tobacco control folks need to move this to the top of their agenda.

In closing Dr. Robinson challenged conferees to not only develop new materials, but also use existing materials to address menthol use. He called on all at the conference to join in the process being launched by the NAATPN to oversee the FDA's work around menthol. He called for the oversight process to be transparent and inclusive. He reminded the audience that the lack of transparency and accountability is what led to the controversy around menthol over the past two years, that ultimately was the context that gave rise to this conference. He encouraged all not to repeat that process – we need to learn from past mistakes.

Breakout Workgroups – Report Back Summaries

Each Group met for an hour on the afternoon of the second day of the conference and they were charged with addressing four questions:

1. If menthol is removed from tobacco products, how would its removal impact your community?

2. What did you learn from the presentations at the conference that will help you address the issues of menthol in your community?
3. What prevention and/or cessation actions will you personally commit to once you leave the conference?
4. What would you advise the FDA to do about the issue of menthol?

Breakout Group 1. American Indian/Alaska Native, Dr. Felicia Hodge

Dr. Hodge pointed out to the participants that more often then not cigarettes were very cheap on reservations, $1 a pack in many cases.

1. If menthol is removed from tobacco products, how would its removal impact your community?

Dr. Hodge stated quite frankly that her group of 2 people did not know what the impact would be. She did point out that American Indians like other communities saw menthol brands as less harmful and that menthol products tasted good.

2. What did you learn from the presentations at the conference that will help you address the issues of menthol in your community?

Dr. Hodge said that she had learned a lot from the conference and it will be important to get this information to American Indians and Alaska Natives.

3. What prevention and/or cessation actions will you personally commit to once you leave the conference?

Dr. Hodge said that she would continue her cessation work among American Indians.

4. What would you advise the FDA to do about the issue of menthol?

Dr. Hodge pointed out that American Indians lived in sovereign nations and that many of the processes proposed in the FDA legislation that states would use to implement the new FDA policy would not and does not apply to American Indians. Dr. Hodge called for the FDA to open up a dialogue with tribes to ensure that their needs are met.

Breakout Group 2. Low SES, Ms. Janet Porter

1. If menthol is removed from tobacco products, how would its removal impact your community?

Ms. Porter reported that her group was not clear on what the actual impact of removing menthol from cigarettes would be on people of low socioeconomic status. She said that the poor and the homeless don't have the same brand loyalty that more stable parts of the population have; people often just smoke what is available.

2. What did you learn from the presentations at the conference that will help you address the issues of menthol in your community?

Ms. Porter said that her group had learned a lot from the conference, especially about cessation and menthol. She stated that the group felt that low SES individuals must be empowered and be a part of any and all cessation activities aimed at them.

3. What prevention and/or cessation actions will you personally commit to once you leave the conference?

In this regard Ms. Porter stated that the low SES group would talk to physicians that work with the homeless. Additionally, this group said that it had in the past missed opportunities to get menthol questions on national surveys and said that they would try to remedy that in the future. Last Ms. Porter said that her group would seek greater collaboration with other groups to tackle the question of menthol.

4. What would you advise the FDA to do about the issue of menthol?

Ms. Porter stated that she wished that the FDA would provide her group and others more data on low SES populations. Additionally, her group suggested that the same scrutiny be brought to other ingredients in tobacco products. Last, she just wanted the FDA to be aware that the tobacco industry has set aside money to circumvent the legislation and the FDA needed to ear-mark funds to deal with that.

Breakout Group 3. Women and Menthol, Dr. Tess Boley Cruz

Dr. Cruz stated that even though women were the main consumers of menthol cigarettes, there had been a dearth of information presented at the conference about this important constituency.

1. If menthol is removed from tobacco products, how would its removal impact your community?

Dr. Cruz stated that her group felt that there could be both positive and negative consequences in removing menthol. Since women are the majority of menthol smokers this change will impact women the most. Women may want to smoke to keep their weight low, the tobacco industry will try to frame the issue as negatively as possible to create a backlash, and people may want to quit but may lack the opportunity or resources. Greater protection needed to be provided for women. On the other hand, it is possible that will the removal of menthol there will be more women quitters and this should be taken into account also. Dr Cruz stated that on the positive side removal of menthol could further protect women by reducing the burden of illness, serving as a good catalyst for dialogue using the tobacco industry's own words, and could make tobacco use less palatable and raise consciousness about how to quit, provide better ways of coping with stress, healthier ways to lose weight and the opportunity to raise healthier daughters.

2. What did you learn from the presentations at the conference that will help you address the issues of menthol in your community?

Dr. Cruz reported that her group had learned a lot from the conference, especially the testimonies from community activists, which were inspiring.

3. What prevention and/or cessation actions will you personally commit to once you leave the conference?

Dr. Cruz reported that this group was committed to placing more emphasis on menthol in their tobacco control and tobacco research work, especially as it pertains to women. She pointed out that there needs to be more community activism that focuses on women and is tailored for various types, class levels, locations, religions, race/ethnicities, ages and disabilities.

4. What would you advise the FDA to do about the issue of menthol?

Dr. Cruz reported that her group felt that the FDA should remove menthol as an additive from ALL tobacco delivery devices to make it less palatable, and this should be a high priority. Moreover, the FDA should get the tobacco industry to fully disclose all information that they have on menthol and similarly functioning additives or analogs.

Breakout Group 4. Latino/Hispanic, Asian/Pacific Islander, LGBT and menthol, Dr. Jeannette Noltenius

As with the previous reporters, Dr. Noltenius began her comments by alerting the audience that the great diversity represented by her group had not been addressed at the conference. Other then some epidemiological studies that break out Latino/Hispanic populations, little research scholarship has been devoted to menthol use among the API and LGBT communities. She encouraged the conference to embrace its diversity, and in doing it will lay the basis for joint work together.

1. If menthol is removed from tobacco products, how would its removal impact your community?

Dr. Noltenius reported that the API members of her group felt that in the short-term removal could discourage youth uptake especially at middle/high school levels. On the other hand, group members were cognizant that in the long-term the tobacco industry will create new products and addictives to replace menthol. Additionally, some people may take up smokeless tobacco and then others may start using kreteks, possibly using these products interchangeably as some are already using both (kreteks and cigarettes). Among Latino's it was pointed out that Puerto Ricans were the heaviest of menthol users. Similar to African Americans, Puerto Ricans are targeted with menthol advertisements. It was also noted that not only is it possible that smuggling will increase, but that people may add alcohol, cardamom seeds and other additives to non-menthol cigarettes. She continued saying that people adapt to change, but whatever we do must support cessation and proactively go after smokers with resources. We must do the work in every community – this is an opportunity to push for quitting.

2. What did you learn from the presentations at the conference that will help you address the issues of menthol in your community?

Dr. Noltenius stated that her group had learned a lot from the conference. However, there remained a lack of understanding about menthol use in the Latino, LGBT, and API communities. With the decline in funding for tobacco control, many groups in communities where priority populations reside have taken money from the tobacco industry, thus diminishing their ability to take up the issue of smoking generally and menthol in particular. Another thing that was learned was that menthol is in all tobacco products, this is something that many in the group did not know before this conference. Additionally, Dr. Noltenius stated that conference had shown that other, new additives and analogues will come along and that we must be prepared to combat them. Another lesson from the conference was that community campaigns need to be developed to educate our communities about the hazards of menthol.

3. What prevention and/or cessation actions will you personally commit to once you leave the conference?

This group agreed that they planned to inform their various communities about what they had learned at the menthol conference. This group recognized that one size does not fit all and the prevention and cessations services needed to be culturally appropriate and tailored to fit each different community. An attendee from Guam added that they planned to get menthol questions added to the WHO surveys that are conducted in the Pacific Rim. Dr. Noltenius stressed that her group really saw the need to develop community capacity and that we needed to get the quitlines to add menthol questions to their data collection efforts. Representatives of the API community said that they were going to develop a menthol fact sheet.

4. What would you advise the FDA to do about the issue of menthol?

Dr. Noltenius pointed out that any and all policies developed by the FDA should apply equally in all US territories, including Guam, the Marianna Islands, Puerto Rico, and the US Virgin Islands.

Breakout Group 5. Youth and Menthol, Ms. Auriel Rolle-Polk and others

1. If menthol is removed from tobacco products, how would its removal impact your community?

Ms. Auriel Rolle-Polk reported that the youth group needed to get prepared for youth cessation, in the event that menthol is banned. She went on to say that the industry will probably step up its advertising aimed at youth, pushing their new goods like smokeless and dissolvable products. It is possible that you will begin to make their own cigarettes and this would not be a welcomed development. She suggested that people may use the internet to order menthol products from other countries, if menthol cigarettes were no longer available in the United States.

2. What did you learn from the presentations at the conference that will help you address the issues of menthol in your community?

Mr. David Bowen stated that there needed to be much more research regarding youth, but that all in the group had learned a lot from the conference especially how the tobacco industry targets youth. However, since youth are targeted a lot, it seems that youth need to have a greater voice in tobacco control efforts and certainly a bigger voice at a conference like this.

3. What prevention and/or cessation actions will you personally commit to once you leave the conference?

One member, reporting for the group, stated that he and others would share what they learned at this conference with Historical Black Colleges.

4. What would you advise the FDA to do about the issue of menthol?

It was stated that the Youth Breakout session thought that menthol should be banned, and should lead to investigation into what else the tobacco industry is putting into cigarettes. Also, possibly menthol cigarettes should be more expensive or have a higher tax and the revenues flowing from that could go to fund menthol cessation programs.

Breakout Group 6. African Americans and Menthol, Mr. William Robinson

1. If menthol is removed from tobacco products, how would its removal impact your community?

Mr. Robinson said that if menthol were removed, the African American group felt that there would be major push back. It was suggested that people in the community would be looking for something to replace it. The cessation needs are great. It is possible that the tobacco industry will try to recapture previous menthol smokers with new products. Mr. Robinson said this state of affairs highlighted the need to actively combat the tobacco industry.

2. What did you learn from the presentations at the conference that will help you address the issues of menthol in your community?

Mr. Robinson reported that they had learned a lot about menthol being a starter product for youth. The other lesson the group mentioned was that seeing menthol as a social justice issue was driven home by many speakers at the conference.

3. What prevention and/or cessation actions will you personally commit to once you leave the conference?

Mr. Robinson said that there needed to be a continuing dialogue around menthol by his and other organizations that serve the African American community. He called on conferees to join with the African American Tobacco Prevention Network to set up a formal process to monitor the work of the FDA around menthol. Mr. Robinson suggested that there might be a listserve dedicated to menthol that comes out of this conference and the oversight measures.

4. What would you advise the FDA to do about the issue of menthol?

Mr. Robinson joined others at the conference in calling for the FDA to ban menthol. At the same time, Mr. Robinson stated that his group said that we should know about the new compounds and additives that the tobacco industry will inevitably be using to replace menthol. Lastly, he suggested that an explicit social justice warning be placed on all menthol cigarette packs, e.g. over the last 10 years tens of thousands of African Americans have died from using mentholated cigarettes.

Closing Discussion

While there was much praise given to conference organizers and some concerns voiced about the absence of more discussion on women and youth for example, for the most part conferees were satisfied with the conference. However, the last speaker from the floor, Dr. Richard Hurt, Director of the Nicotine Dependence Center at the Mayo clinic, a general internist, and a well known tobacco control advocate brought the 2nd Conference on Menthol Cigarettes to an appropriate end with these forceful remarks:

"While some may fret about unintended but unknown consequences of eliminating menthol from tobacco products, the very real and predictable consequences of no action or equivocation are more young people addicted to tobacco and more tobacco-caused deaths in smokers. It could not be clearer that the time for action is now. We have ample evidence at hand to change tobacco products to make them less enticing to our children. I agree with Greg Connolly that the way forward with FDA regulation is to make tobacco products less attractive by removing additives that make them more palatable. Let us start by eliminating menthol.

"Whether or not menthol directly causes lung cancer or emphysema is in many ways irrelevant. After all cigarettes clearly cause these as well as a myriad of other diseases and menthol is added to make them easier to use, thus leading to more people initiating and maintaining their tobacco dependence. This is explicitly stated in the DOJ case by Judge Kessler in the Court's Finding: 'The tobacco companies took menthol into consideration as part of their program to manipulate nicotine levels to create and sustain addiction.' Could this be stated more clearly or more emphatically?

"To frame this we must focus and have the support of the public health community, but also support from grass root communities which have been targeted by the tobacco industry. The focus could be on the three areas noted by Dr. Healton which are indisputable from a factual standpoint about how the tobacco companies have used the additive menthol:

- Menthol is used to make cigarettes a starter product your youth
- Menthol is used for health reassurance
- This is a social justice issue as menthol cigarettes have been targeted to certain populations

"Thus I believe we need broad support to move forward and the time is now**. If we have to have a 3rd Conference on Menthol, we will have failed this historic moment and will allow Philip**

Morris to have bought another decade. That would be an inexcusable legacy to leave our children and grandchildren.

“To link together quotes from two esteemed contemporary politicians I would say, ‘When history calls, history calls’ and ‘Yes we can.’”

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Appendix A

Planning Committee Members

Planning Committee Members

Cathy Backinger
National Cancer Institute

Danny McGoldrick
Campaign for Tobacco Free-Kids

Amber Thornton-Bullock
American Legacy Foundation

Makani Themba-Nixon
The Praxis Project

Pamela Clark
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National Latino Tobacco Control Network

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Ines Alex Parks
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Stephenie Foster
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Eva Sharma
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Bridgette Garrett
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Allison Rose
National Cancer Institute

Allison Hoffman
National Institute on Drug Abuse

Patricia Sosa
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Susan Marsiglia
Substance Abuse and Mental Health

Mitch Zeller
Pinney Associates

Appendix B

Conference Sponsors

Sponsors, Second Conference on Menthol Cigarettes

- Academy for Educational Development
- American Cancer Society
- American Heart Association
- American Legacy Foundation
- American Lung Association
- Campaign for Tobacco Free Kids
- Centers for Disease Control/Office on Smoking and Health
- National African American Tobacco Prevention Network
- National Cancer Institute
- National Institute on Drug Abuse
- National Latino Tobacco Control Network
- North American Quitline Consortium
- The Praxis Project
- Novartis Consumer Health
- University of California, Office of the President – Tobacco Related Disease Research Program
- University of Maryland, School of Public Health

Appendix C

Participants

Sponsored Attendees				
Last Name	**First Name**	**Title**	**Badge Name**	**Organization**
Adams-Simms	Denise		Denise Adams-Simms	California Black Health Network
Adhikari	Surendra Bir	Planning, Outcomes, Research	Surendra Adhikari	Ohio Dept of Alcohol & Drug Addiction Services
Ahijevych	Karen	Professor	Karen Ahijevych	The Ohio State University
Ahluwalia	Jasjit S.	Executive Director, NIH Center for Minority Health	Jas S. Ahluwalia	Univ. of Minnesota Medical School
Allen, Jr	Bruce	Assistant Professor	Bruce Allen, Jr. Dr. P.H.	Charles Drew University of Medicine and Science
Bell Caffee	Brenda	Executive Director	Brenda Bell Caffee	Caffee Caffee and Associates, Public Health Foundation Inc.
Benowitz	Neal L.	MD	Neal Benowitz	University of California San Francisco
Blum	Alan	Director	Alan Blum, MD	Univ. of Alabama Center for study of Tobacco and Society
Bolden	Gregory A.		Greg Bolden	State of Georgia
Bowen	David	Youth Coordinator	David Bowen	Urban Underground

Braithwaite	Ronald	Evaluator	Ronald Braithwaite	Evaluation and Research Associates, Inc
Brown	Linda Early		Linda Early Brown	Sothern University Ag Center, Communities of Color
Brown	Jesse	Reverend	Jesse Brown	The Onyx Group
Carpenter	Catherine L.	Associate Professor	Catherine Carpenter, PhD	David Geffen School of Medicine at UCLA- Clinical Nutrition
Carter	Lawrence	Chief, Division of State Tobacco Control Initiatives	Lawrence Carter	Maryland Department of Health and Mental Hygiene
Castine	Ritney A.	Youth Consultant	Ritney A. Catine	Louisiana Tobacco Control Program
Clark	Pamela	Research Professor	Pamela Clark	Univ. of Maryland, College Park School of Public Health
Cooper-Ashford	Shelley	Executive Director	Shelley Cooper-Ashford	Center for MultiCultural Health
Crawford	George	Consultant	George Crawford	
Cruz	Tess	Assistant Professor	Tess Cruz, PhD, MPH	University of Southern California
Eaton	Amberly P.	Youth Advocate	Amberly Eaton	

Essuon	Aba D.	Researcher/Evaluator	Aba Essuon	Evaluation and Research Associates, Inc
Fernander	Anita F.	Assistant Professor	Anita F. Fernander	Univ. of Kentucky, College of Medicine-Dept. of Behavioral Science
Foulds	Jonathan	Professor	Jonathan Foulds	UMDNJ-School of Public Health
Gandhi	Kunai K.	Psychiatry	Kunal K. Gandhi	UMDNJ-RWJMS Division of Addicition Psychiatry
Gardiner	Phillip	Tobacco Related Disease Research Program	Phil Gardiner	Univ. of Calif. Office of the President
Giovino	Gary	Professor and Chair	Gary Giovino	School of PH and Health Professions, Univ @ Buffalo, SUNY
Hardy Thornton	Amber	Executive VP, Program Development	Amber Hardy Thornton	American Legacy Foundation
Harris	Kwesi Ronald	Servant Leader	"Kwesi" Ronald Harris	Khepera & Associates Networking Services
Hebert	James R.	Director Cancer Prevention and Control Program	James R. Hebert	Univ. of South Carolina, Dept. of Epidemiology and Biostatistics

Hodge	Feleica		Felicia Hodge	UCLA-School of Nursing
Hoffmann	Robert	Chronic disease Management	Robert Hoffmann, M.A.	Tri County Cessation Center for NYS DOH
King	Gary		Gary King	Penn State University, Dept. of Biobehavioral Health
Lew	Rod	Executive Director	Rod Lew	Asian Pacific Partners for Empowermnet, Adv. and Leadership (APPEAL)
Lewis	Yvonne	Chair	Yvonne Lewis	National African American Tobacco Prevention Network (NAATPN)
Matthews	Alicia	Associate Professor	Alicia Matthews	Univ. of Illinois at Chicago, College of Nursing and LGBT Tobacco Control Network
McGruder	Carol	Project Director	Carol McGruder	The URSA Institute
Moore	Tonia R	Program Manager	Tonia R. Moore, MSHCM	Louisiana Campaign for Tobacco-Free Living (TFL)
Muilenburg	Jessica Legge		Jessica Muilenburg, PhD	Univ of Georgia

Muscat	Joshua	Professor	Joshua Muscat	Penn State Cancer Institute-Public Health Sciences
Okuyemi	Kola	MD, MPH	Kola Okuyemi	Univ. of Minnesota Medical School
Parga	Francisco Javier	Clinical Psychologist	Fracisco Javier Parga,	Coalition for a Tobacco Free Puerto Rico
Pletcher	Mark	Epidemiology and Biostatistics	Mark Pletcher, MD, MPH	University of California San Francisco
Polk	Auriel Rolle	Youth Advocate	Auriel	Campaign for Tobacco Free Kids
Robinson	Robert G.		Bob Robinson	National African American Tobacco Prevention Network (NAATPN)
Robinson	William S.	Executive Director	William S. Robinson	National African American Tobacco Prevention Network (NAATPN)
Rogers	Chris	State Coordinator	Chris Rogers	African American Tobacco Network (AATEN)
Rucker	Billy	Project Support	Billy Rucker	Youth Empowerment in Action-Division of Educational Psychology

Shivappa	Nitin		Nitin Shivappa	Northern Illinois University
Sidney	Stephen	Associate Director for Clinic Research	Steve Sidney	Kaiser Permanente Northern California
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Walker	D'Elbie	Statewide Cessation Field Representative	D' Elbie Walker	Oklahoma State Dept of Health
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Abram	David B.	Executive Director	David Abrams	American Legacy Foundation
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Annand	Debra		Debra Annand	American Lung Association of DC-Health Education Services
Apelberg	Benjamin	Assistant Scientist	Ben Apelberg	Johns Hopkins Bloomberg Sch. of PH
Bailey	Linda	President and CEO	Linda Bailey	North Americn Quitline Consortium
Biener	Lois	Senior Research Fellow	Lois Biener	University of Massachusetts Boston
Billings	Paul	Vice President National Policy & Advocacy	Paul Billings	American Lung Association
Bishop	Susan	Regulatory Affairs Manager	Susan Bishop	American Heart Association

Blount	Linda	National VP, Office of Health Disparities	Linda Blount	American Cancer Society Department of Health Disparities
Boonn	Ann		Ann Boonn	Campaign for Tobacco-Free Kids
Brinkman	Marielle		Ms. Marielle Brinkman	Battelle
Canova	Diane	Managing Senior Fellow	Diane Canova	Partnership for Prevention
Clopton	Tracy	Tobacco Program Consultant	Tracy Clopton	Office of Healthy Ohio, Tobacco Use Prevention and Cessation Program
Cullen	Jennifer	Director, Research & Evaluation	Jennifer Cullen	American Legacy Foundation
Davila-Garcia	Martha I.	PhD	Martha Davila-Garcia	Howard University College of Medicine
Eubanks	Sharon Y.	Attorney	Sharon Y. Eubanks	
Forbes	Ripley	Dir. Legistative & Policy Adv.	Ripley Forbes	Partnership for Prevention
Foster	Stephanie	Sr. VP Government Affairs	Stephanie Foster	American Legacy Foundation
Glynn	Thomas		Thomas Glynn	American Cancer Society
Gordon	Sydney	Doctor	Dr. Syd Gordon	Battelle Memorial Institute-Hynab Exposure Assessment
Haifley	Gregg	Associate Director Federal Relations	Gregg Haifley	American Cancer Society Cancer Action Network (ACS CAN)
Hatstukami	Dorothy		Dorothy Hatstukami	Univ. of Minnesota, Tobacco Use Research Center

Healton	Cheryl	President/CEO	Cheryl G. Healton, Dr.P.H.	American Legacy Foundation
Henningfield	Jack E.		Jack Henningfield	Johns Hopkins Univ. School of Medicine and Pinney Associates
Hersey	James		Jim Hersey	RTI International
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Joyce	Caroline	Senior Director, Government Affairs	Caroline Joyce	American Legacy Foundation
Jump	Zach		Zach Jump	American Lung Association, Epidemiology and Statistics
Keneipp	Krisrten D.	Policy Associate	Kristen D. Keneipp	NYC Dept. of Health and Mental Hygiene
Koka	Sara	Senior analyst for Tobacco and Chronic Disease	Sara Koka	ASTHO
Lazarus	Philip	Associate Director-Professor	Philip Lazarus, PhD	Penn State Cancer Institute-Pharmacology
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Mahony	Ann G.	APHA ATOD Section Chair	Ann G. Mahony	American Public Health Association-Alcohol, Tobacco and Other Drugs Section

Marsiglia Gray	Susan J.		Susan Marsiglia Gray	Substance Abuse and Mental Health Services Adm-Center for Substance Abuse Prevention
Martin	Karen	Senior Director, Collaboration & Outreach	Karen Martin	American Legacy Foundation
McGoldrick	Danny		Danny McGoldrick	Campaign for Tobacco-Free Kids
McMahon	Catherine J.	Senior Policy Analyst	Catherine McMahon	American Cancer Society Cancer Action Network (ACS CAN)
Moore	Reggie	Youth Activism	Reggie Moore	American Legacy Foundation
Morris	Debra G.	Director of Technical Assistance	Debra Morris	Tobacco Technical Assistance Consortium (TTAC)
Myers	Matthew L.	President/CEO	Matthew Myers	Campaign for Tobacco-Free Kids
Noltenius	Jeanette	National Coordinator	Dr. Jeanette Noltenius	National Latino Tobacco Control Network
Nwaigwe	Chinedu		Chinedu Nwaigwe	Health Education Council, Dept. NAATEN
Parks	Inez	Sr. Manager, Priority Populations	Alex Parks	American Legacy Foundation
Patterson	Bennie	Youth Activism Coordinator	Bennie Patterson	American Legacy Foundation
Payton	John	President and Director-Counsel	John Payton	NAACP-Legal Defense and Educational Fund, Inc.

Pendleton	LaRoux	Program Consultant	La Roux Pendleton	California Tobacco Control Program-California Dept. of Public Health
Porter	Janet	Program Director	Janet Porter, MPH	Health Education Council, Break Free Alliance
Rawlett	Kaitlyn	Corporate and Public Affairs	Kaitlyn	Levick Strategic Communications
Riordan	Meg		Meg Riordan	Campaign for Tobacco-Free Kids
Robinson	Leslie A.	Doctor	Leslie A. Robinson, Ph.D.	Center for Health Promotion and Evaluation
Ross	Ashley	Program Manager, DC Tobacco Control	Ashley Ross	DC Department of Health, Community Health Adm.
Sharma	Eva	Public and Community Health	Eva Sharma	University of Maryland
Stillman	Frances	Associate Professor	Fran Stillman	The Johns Hopkins Bloomberg Sch. Of PH/Institute for Tob Control
Themba-Nixon	Makani	Executive Director	Makani Themba-Nixon	The Praxis Project
Thomas	Yonette F.	Assoc. VP for Research Compliance	Yonette F. Thomas, Ph. D.	Howard University
Vallone	Donna	Senior VP Research & Evaluation	Donna Vallone, PhD	American Legacy Foundation
Williams	Jill M.	Addiction Psyschiatrist	Jill M. Williams, M.D.	UMDNJ-RWJMS Division of Addiction Psychiatry
Williams	Carla D.	Assistant Professor of Medicine	Carla D. Williams	Howard University
Zeller	Mitch		Mitch Zeller	Pinney Associates

Government Attendees				
Last Name	**First Name**	**Title**	**Badge Name**	**Organization**
Abdul-Salaam	Shadeed	Contractor		Battelle/ERAT/NCEH/DLS/CDC
Ashley	David L.	Chief, ERAT	David L. Ashley	CDC-National Center for Environmental Health
Backinger	Cathy	Branch Chief	Dr. Cathy Backinger	NCI-Tobacco Control Research Branch
Caraballo	Ralph S.	Branch Chief	Ralph S. Caraballo	CDC-OSH
Collins	Kevin			Kevin Collins
Davis	Shane	Health Scientist	Shane Davis	CDC-OSH
Djordjevic	Mirjana V.	PhD	Mirjana V. Djordjevic, Ph.D	NCI-Tobacco Control Research Branch
English	Lorna	Deputy Director, Office on Smoking and Health	Lorna English	CDC-OSH
Fagan	Pebbles	Health Scientist	Pebbles Fagan	NCI-Behavioral Research Program, Tobacco Control Research Branch
Garrett	Bridgette	PhD	Bridgette Garrett	CDC-OSH
Hartman	Anne M.		Anne Hartman	NCI/NIH; Reisk Factor Monitoring & Methods Br; Applied Research Program; Division of Cancer Control and Population Sciences
Hoffman	Allison	Program Director	Allison C. Hoffman	National Insititue to Drug Abuse, NIH

Lawrence	Deirdre	Doctor	Dr. Dee Lawrence	NCI-NIH
McKenna	Matthew	Director, Office on Smoking	Matthew McKenna	CDC-OSH
Miner	Lucinda	Deputy Director, OSPC	Lucinder Miner	6001 Executive Blvd
Parker	Karen L.	Sr Health Science Analyst and Women's Health Officer	Karen Parker, MSW	NCI-Office of Science Planning and Assessment
Pechacek	Terry	Dr.	Terry Pechacek	CDC-Office on Smoking and Health
Richter	Patricia	Toxicologist	Patricia Richter	CDC-OSH, Center for Disease Control and Prevention
Rock	Valerie J.	Health Scientist	Valerie J. Rock	CDC-OSH
Rose	Allison	Special Projects Administration	Allison Rose	SAIC-Frederick Inc. Contractor to National Cancer Institute
Shelton	Dana	Associate Director of Policy	Dana Shelton	CDC/NCCDPHP/OSH
Shiu	Nathan	MPH	Nathan Shiu	CDC-OSH/Northrop Grumman
Taylor	Shani	Ms.	Shani Taylor	NCI-Tobacco Control Research Branch
Watson	Clifford	Lead Research Chemist	Cliff Watson	CDC - National Center for Environmental Health, Division of Laboratory Sciences

Appendix D

Final Agenda

SECOND CONFERENCE ON MENTHOL CIGARETTES
OCTOBER 19 – 20, 2009

Conference Agenda

Academy for Educational Development
1825 Connecticut Avenue, NW Washington, DC 20036
Academy Hall, 8th floor

Monday, October 19, 2009

7:30am – 8:30am **Registration Open / Continental Breakfast**

8:30am – 8:50am **Welcome**

Phillip Gardiner, *University of California Office of the President*

Introduction, Acknowledgements

- Conference Purpose and Goals
- Agenda review
- Ground rules & logistical announcements

8:55am - 9:35am **Summation of Menthol Science Post 2002**

Pamela Clark, *University of Maryland College Park*

- 1st Menthol Conference Outcomes
- Post First Conference Review: scientific progress and gaps since 2002
- Review of papers published by tobacco manufacturers

9:40am – 10:45am **Menthol Pharmacology and Toxicity**

This panel will cover research developments related to menthol pharmacologic properties metabolic pathways, and interactions with other tobacco toxins.

Moderator: Patricia Richter, *Centers for Disease Control & Prevention*

Panelists: Neal Benowitz, *University of California San Francisco* and Joshua Muscat, *Pennsylvania State University*

10:45am – 11:00am **Morning Break / Poster Viewing**

11:00am -12:00 pm **Menthol and Tobacco Smoke Exposure**

Current research findings, including depth of inhalation, lung residence time, airway patency and second-hand smoke considerations will be covered in this session.

Moderator: Mirjana Djordjevic, *National Cancer Institute*

Panelists: David Ashley, *Centers for Disease Control & Prevention* and James Hebert, *University of South Carolina*

12:05pm – 1:30pm **Lunch**

Guest Speaker: Cheryl Healton, President and Chief Executive Officer, *American Legacy Foundation*

1:35pm – 2:35pm **Menthol Epidemiology**

Epidemiological considerations will be the focus of this panel presentation. Research related to who smokes menthol cigarettes, the evolving and changing historical context of mentholated product use, and linkages to tobacco-related diseases will be explored.

Moderator: Jasjit Ahluwalia, *University of Minnesota*

Panelists: Ralph Caraballo, *Centers for Disease Control & Prevention* and Steve Sidney, *Kaiser Permanente*

2:40pm – 3:40pm **Menthol and Addiction**

Menthol's influence on smoking initiation and the interaction of menthol and nicotine on sensory perception and neurosensory impact will be discussed.

Moderator: Bridgette Garrett, *Centers for Disease Control & Prevention*

Panelists: Karen Ahijevych, *Ohio State University* and James Hersey *RTI International*

3:40pm – 4:00pm **Afternoon Break / Poster Viewing**

4:00 pm – 5:30 pm **Menthol and Cessation**

This panel will discuss the relationships between menthol smoking and smoking maintenance and cessation, including the issue of relapse.

Moderator: Linda Bailey, *North American Quitline Consortium*

Panelists: Jonathan Foulds, *University of Medicine and Dentistry of New Jersey*; Kolawole Okuyemi, *University of Minnesota*; Mark Pletcher, *University of California San Francisco*, and Monica Webb, *University of Miami*

5:35 pm – 6:00 pm **Summation of Day One**

Phil Gardiner and Pamela Clark

****

7:30pm – 9:30pm Town Hall Event & Reception Howard University

This ancillary event is hosted and coordinated by Howard University. Menthol conference attendees are invited to attend. Logistical and programming details are available at the Registration Desk.

<u>Tuesday, October 20, 2009</u>

7:30am- 8:00 am **Continental Breakfast**

8:00am – 8:15am **Welcome**

Amber Thornton-Bullock, *American Legacy Foundation*

Introduction and remarks related to working towards prevention and community action oriented outcomes.

8:15am – 10:15am **Tobacco Industry Targeted Marketing**

This panel will explore various tactics that have been, and continue to be, utilized by the industry, and some specific counter-marketing and community organizing efforts that have been successful.

Moderator: Amber Thornton-Bullock

Presenters: Alan Blum, *University of Alabama*; George Crawford, *Georgia Division of Public Health*; Tess Cruz, *University of Southern California*; Kwesi Harris, *Behavioral Health Center Chicago*; Billy Rucker, *University of Missouri St. Louis*, and La Tanisha Wright, *National African American Tobacco Prevention Network*

10:15am – 10:25am **Morning Break / Poster Viewing**

10:25am – 12:00pm **FDA and Menthol**

This panel will provide an overview of the Family Smoking and Tobacco Control Act with a focus on requirements related to menthol, potential legal implications, the role of the FDA Tobacco Products Scientific Advisory Committee, and what science is needed to guide the regulatory processes.

Moderator: William Robinson, *African American Tobacco Prevention Network*

Presenters: Pamela Clark; Sharon Eubanks, formerly with the *United States Department of Justice*; Stephenie Foster, *American Legacy Foundation*, and Jack Henningfield, *Pinney Associates and Johns Hopkins University*

12:05pm – 1:30pm **Lunch**

Guest Speaker: The Honorable Louis Sullivan, *Past Secretary, United States Department of Health and Human Services*

1:30pm – 2:30pm **Population Behavioral Change**

This Panel will examine population level strategies to prevent the uptake of mentholated tobacco products. The theory behind a community level focus and the practical needs for activists on the ground will be discussed.

Moderator: Phillip Gardiner

Panelists: Robert Robinson, *Centers for Disease Control & Prevention* (retired); Frances Stillman, *Johns Hopkins University*, and Makani Themba-Nixon, *The Praxis Project*

2:30 pm – 3:30 pm **Breakout Work Groups**

For this afternoon session, conference participants will be asked to self-select into one of eight population-specific workgroups to further explore and share community-based prevention and control strategies and tactics. Breakout groups include:

African American –*National African American Tobacco Prevention Network Representative*
American Indian Alaska Native – *Intertribal Center of Michigan Representative*
Asian Pacific Islander – *Asian Pacific Community Health Organization (AAPCHO) Representative*
Latino- *Indiana Latino Institute Representative*
LGBT – *Fenway Institute/ GLBT Representative*
Youth- *Reginald Moore, American Legacy Foundation*
Low SES – *Health Education Council-Low SES Representative*
Women - TBA

3:30 pm – 3:45 pm **Afternoon Break / Poster Viewing**

3:45pm – 4:45pm **Breakout Leaders Report Back**

4:45 pm – 5:30 pm **Conference Summation & Adjournment**

Pamela Clark
Phillip Gardiner
Amber Thornton-Bullock