



March 22, 2010

Ms. Cristi Stark
Center for Tobacco Products
Food and Drug Administration
9200 Corporate Boulevard, Room 120L
Rockville, MD 20850-3229

Dear Ms. Stark:

On behalf of our organizations, we are pleased to offer the following comments to the Tobacco Products Scientific Advisory Committee. The Food and Drug Administration's determination of what action to take with regard to menthol and menthol tobacco products will be guided by Section 907 of the Family Smoking and Tobacco Prevention Act. This will be the first time that FDA applies the "public health" standard as set forth in Section 907 of the statute and will establish a precedent for how the "public health" standard is to be applied in future comparable situations.

According to Section 907(e) of the Family Smoking and Tobacco Prevention Act, the FDA Tobacco Science Advisory Committee is required to review "the impact of the use of menthol in cigarettes on the public health." FDA is authorized to issue a tobacco product standard if the Secretary "finds" that a product standard "is appropriate for the protection of the public health." Section 907(a)(3)(A).

While Section 907(a)(3)(B) and 907(b) instruct FDA to "consider" a number of other factors, it is the Secretary's "finding" that a proposed tobacco product standard "is appropriate for the protection of the public health" that governs whether a proposed tobacco product standard may be adopted.

One issue FDA will need to resolve is what the statute requires FDA to "consider" and what the statute requires FDA to "find" in determining whether a product standard should be issued with regard to menthol.

Lorillard Tobacco, the largest manufacturer and marketer of menthol tobacco products has already attempted to narrow what is meant by the phrase "appropriate for the protection of the public health" to whether individual smokers show a differing health risk compared to users of non-menthol tobacco products and whether individual smokers of menthol smokers have comparable cessation rates.

This is a distortion of what the statute requires. Under the Family Smoking Prevention and Tobacco Control Act, FDA is authorized to review and consider the evidence regarding the role of menthol added to tobacco products by the tobacco manufacturers related to:

- the toxicity/harm/disease risk of the product to tobacco users
- the addictiveness of the product to tobacco users
- Initiation, including among non-users
- Cessation or Relapse, including among former users

And, at least as long as tobacco products cause harm, Section 907 authorizes FDA to issue a proposed product standard to promote the public health by prohibiting tobacco companies from adding ingredients or taking other steps that increase the number of new smokers and those who relapse as well as decreases the number of people who are able to quit.

Background

The plain language of the statute requires FDA to consider the impact of the use of menthol on the “public health”, including such use among children, African Americans, Hispanics, and other racial and ethnic minorities.” The Public Health standard is one that focuses more broadly than on current tobacco users.

The statute provides further guidance to the FDA. FDA is also instructed to address the considerations listed in Section 907 (a)(3)(B)(i) and (b).

Section 907(a)(3)(B)(i) states that in considering what is appropriate for the protection of the public health, the FDA shall consider scientific evidence concerning:

- The “risks” and “benefits” to the population as a whole, including users and non-users of tobacco products;
- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products.

Section 907(b) states that the Secretary “shall consider” information submitted “regarding the technical achievability of compliance” with a proposed standard and “information concerning the countervailing effects” of a proposed product standard.

The relevant provisions of Section 907 are consistent with the “Purposes” section of the legislation that states that it is Congress’ intent to give FDA authority, *inter alia*, to address issues relating to

- “dependence on tobacco” and

- that “promote cessation to reduce disease risk”.

Pub. L. No. 111-31 (June 22, 2009), section 3.

The additional considerations in section 907(a)(3)(B)(ii) do not alter the requirement that FDA is authorized to act whenever it “finds” that a proposed standard “is appropriate for the protection of the public health.”

The Section 907 tobacco “public health” standard differs from the traditional standard of review for FDA and the requirement that human drugs and medical devices be “safe” and “effective.” The drug and device safety standard focuses on the risks and benefits to the individual using the drug, but there is generally no occasion to consider risks to other individuals. The same is true of other standards in the Federal Food, Drug and Cosmetic Act (FFDCA), such as the requirements governing food and food additives. These standards focus on the “safety” to the individual using the product, and there is no requirement that the FDA look at other members of the population because the products are not expected to have any impact beyond its users. The one exception is animal drugs, where the agency, in deciding whether a drug is safe, must consider “the cumulative effect on man or animal of [the] drug.” FFDCA section 512(d)(2)(B), 21 U.S.C. 360b(d)(2)(B).

The basic requirement of the public health standard in section 907 is that the agency is instructed to look at the entire population. As the statute states, FDA is instructed to consider the beneficial and detrimental health effects on tobacco users as well as persons who do not use tobacco but may be more or less likely to use tobacco products in the future as a result of any proposed standard. This means FDA is both authorized and required to review the evidence concerning the impact of an ingredient, like menthol, that is added to a tobacco product on the risk and/or rate of initiation and risk and/or rate of relapse of a former tobacco user.

The argument that the public health standard in Section 907 only permits FDA to consider whether an ingredient or constituent increases the toxicity or disease risk to tobacco users is also inconsistent with the ban on cigarettes with “characterizing flavors” in Section 907(a). The ban on “characterizing flavors” was not based on Congress’ conclusion that these products increase the risk of disease among tobacco users. It was based on Congress’ conclusion that these products appeal to young people, therefore may increase initiation.

Application of Public Health Standard to Section 907 for the purpose of dealing with menthol:

This means that in addressing the menthol issue the mandate to “protect the public health” obligates the FDA to look at the impact of any proposal on the entire population, including current users, never users and former users.

To accomplish this goal the FDA must necessarily look at both the impact of the product on current smokers and the impact of the product on prospective and former smokers. It is not possible to comply with the public health mandate without also examining product characteristics that impact the number of users.

Thus, in conducting its evaluation of what action, if any, to take with regard to the menthol added to tobacco products, FDA's scientific inquiry should consider whether the added menthol:

- Increases the toxicity/harm/disease risk of the product and/or exposure to harmful ingredients or constituents
- Increases the addictiveness of the product or leads to more rapid addiction
- Increases or is likely to increase initiation
- Decreases or is likely to decrease cessation

In evaluating the overall public health impact of a proposed standard regarding menthol on the population as a whole, FDA should also "consider" both the anticipated beneficial and the anticipated countervailing effects of the proposed standard.

Role of Marketing

The impact of menthol in tobacco products should not be addressed in isolation from the marketing of menthol products. To fully address the problems caused by menthol tobacco products, it is important to understand and evaluate both the impact of menthol in the product and how menthol products are marketed and to address both issues in determining what action should be taken to best protect the public health. This marketing, often targeted at minority communities, has been instrumental in the use of menthol products and in the disproportionate use of menthol products by minority groups.

Since the 1960s, the tobacco industry has developed specific strategies to addict African Americans to menthol cigarettes, including capitalizing on misperceptions about menthol cigarettes being healthier, piggy-backing on popular African American cultural references, and forming close relationships with smaller neighborhood tobacco outlets to improve advertising and sales.¹ Through market research and aggressive advertising, the industry has successfully penetrated this population. Eighty-four percent of all African American smokers smoke menthol cigarettes, as compared to 24 percent of all Caucasian smokers.² The industry's "investment" in the African American community has had a destructive impact: African Americans suffer the greatest burden of tobacco-related mortality of any ethnic or racial group in the United States.³

Research shows that cigarette company advertising and other marketing efforts greatly influence tobacco use initiation among adolescent non-smokers and maintenance among those youths who have already become regular smokers.⁴ More than 80 percent of all smokers start before the age of 18 and, not surprisingly, the vast majority of kids smoke the three most heavily advertised brands.^{5,6} One of these heavily advertised brands, Newport, is the cigarette brand leader among African American youth in the United States.⁷ Eight out of every ten black youth smokers smoke Newport cigarettes.⁸

The tobacco industry has historically targeted the African American community through intense advertising and promotional efforts, especially at the community level.

- A 2008 study of retail outlets in California found that the number of cigarette ads per store and the proportion of stores with at least one ad for a tobacco sales promotion are increasing more rapidly in neighborhoods with a higher proportion of African Americans.⁹
- An article reviewing studies spanning from 1924 to 2002 found that there were 2.6 times more tobacco advertisements per person in areas with an African American majority compared to white-majority areas. In addition, the odds that billboards were tobacco-related in African American communities were 70 percent higher than in white communities.¹⁰
- African American communities have been bombarded with cigarette advertising. Since the MSA, the average youth in the United States is annually exposed to 559 tobacco ads, every adult female 617 advertisements, and every African American adult 892 ads.¹¹
- There are more interior and exterior tobacco advertising in retail outlets in low-income communities and communities with larger African American populations.¹²
- Expenditures for magazine advertising of mentholated cigarettes, popular with African Americans, increased from 15 percent of total tobacco magazine ad expenditures in 1998 to 50 percent in 2005.¹³
- In the two years after the Master Settlement Agreement (MSA) in November 1998, the average annual expenditures for Newport in magazines with high youth readership increased 13.2 percent (from \$5.3 to \$6.0 million).¹⁴
- A study looking at magazine advertising between 1998 and 2002 found that Black magazines were almost 10 times more likely to contain advertisements for menthol cigarettes compared to White magazines.¹⁵
- Additionally, before the MSA's ban on tobacco billboard advertising in 1999, there were higher densities of tobacco ad billboards in ethnic communities than in predominantly white communities.¹⁶

The ubiquitous tobacco marketing in minority communities is characterized by slogans, messages, and images that have a great appeal in the black community and that depict African Americans using tobacco in an appealing light. Cigarette ads portray images of African American smokers who are happy, confident, successful and wealthy, in love, attractive, strong and independent.¹⁷ The tobacco industry has used symbols and events held in high esteem by community members as another tactic to reach this community.¹⁸

In 2004, Brown & Williamson started an ad campaign for their Kool brand cigarettes clearly aimed at youth, and African American youth, in particular. The Kool Mixx campaign featured images of young rappers, disc jockeys and dancers on cigarette packs and in advertising. The campaign also included radio giveaways with cigarette purchases and a Hip-Hop disc jockey competition in major cities around the country. The themes, images, radio giveaways and music involved in the campaign all clearly have tremendous appeal to youth, especially African American youth. Simultaneously, Brown & Williamson promoted a new line of cigarette flavors like Caribbean Chill, Mocha Taboo, and Midnight Berry using images of African Americans and themes attractive to African American youth. These cigarettes were promoted through dance clubs and hip-hop music venues.

The targeting of African American communities by menthol and other tobacco brands may be intensified by the increased reliance by tobacco companies on marketing at the point of sale. As advertising on television, on billboards, and in magazines has declined or even disappeared (in the case of television) the importance of advertising in and on the outside of retail outlets has grown dramatically. Studies have shown interior and exterior tobacco advertising is far more prevalent in predominantly minority, low-income communities than in non-minority, higher income communities.¹⁹

The aggressive advertising of these mentholated brands by the major cigarette companies seems to have paid off. Menthol cigarettes are highly attractive to younger teens and can be considered a starter product.²⁰ Among adult and teen African American smokers, the most popular brands are Newport, Kool, and Marlboro. However, while about 42 percent of black adults smoke Newport, 80.4 percent of black kids smoke this brand. Newport also appears to be more attractive to youth than to adults in the general population. While 23 percent of 12-17 year old smokers prefer Newport, just 17.8 percent of 18-25 year old smokers and only 8.7 percent of smokers over age 25 prefer Newport.²¹

Conclusion

The Tobacco Science Advisory Committee's consideration of menthol and menthol tobacco products is extremely important. Congress mandated that the menthol issue be a priority because of its wide spread use among the African American community and concern about its impact on the number of people who die from tobacco use. The concern focuses both on the product and the impact

of its marketing. Menthol does not appear naturally in tobacco products. It is added knowingly and intentionally by manufacturers and menthol tobacco products are heavily promoted, especially in African American and low income communities.

The Tobacco Science Advisory Committee's consideration is also important because it represents the first time the FDA will apply the Section 907 "public health" standard. While it is the responsibility of the Science Advisory Committee to apply the science to the questions put to it, it is the responsibility of the FDA to set forth the parameters of the questions the Science Advisory Committee is to consider. It is vital that those parameters be set forth clearly and unambiguously. How the FDA sets forth those parameters in the case of menthol will set a precedent for its actions in future comparable situations.

Respectfully submitted,

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¹ Gardiner, PS, "The African Americanization of menthol cigarette use in the United States," *Nicotine & Tobacco Research* 6(Suppl 1):S55-S65, February 2004. Yerger, VB, Przewoznik, J & Malone, RE, "Racialized geography, corporate activity, and health disparities: Tobacco industry targeting of inner cities," *Journal of Health Care for the Poor and Underserved* 18:10-38, 2007.

² Substance Abuse and Mental Health Administration. The NSDUH Report. Use of Menthol Cigarettes. November 19, 2009. <http://www.oas.samhsa.gov/2k9/134/134MentholCigarettes.htm>

³ CDC, "African Americans and Tobacco," 1998, http://www.cdc.gov/tobacco/data_statistics/sgr/sgr_1998/sgr-min-afr.htm; U.S. Department of Health and Human Services (HHS), *Tobacco Use Among US Racial/Ethnic Minority Groups—African Americans, American Indians and Alaskan Natives, Asian Americans and Pacific Islanders, and Hispanics: A Report of the Surgeon General*, 1998, http://www.cdc.gov/tobacco/data_statistics/sgr/sgr_1998/index.htm.

⁴ National Cancer Institute, *The Role of the Media in Promoting and Reducing Tobacco Use*, Smoking and Tobacco Control Monograph No. 19, NIH Pub. No. 07-6242, June 2008, http://cancercontrol.cancer.gov/tcrb/monographs/19/m19_complete.pdf. See also, Pucci, LG & Siegel, M, "Exposure to brand-specific cigarette advertising in magazines and its impact on youth smoking," *Preventive Medicine* 29(5):313-20, November 1999; Sargent, JD, et al., "Effect of seeing tobacco use in films on trying smoking among adolescents: a cross sectional study," *British Medical Journal* 323(7326):1394-7, December 15, 2001.

⁵ Calculated based on data in National Survey on Drug Use and Health, 2007. See also, HHS, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General*, 1994, http://www.cdc.gov/tobacco/data_statistics/sgr/sgr_1994/index.htm.

⁶ Substance Abuse and Mental Health Services Administration (SAMHSA), HHS, *Results from the 2005 National Survey on Drug Use and Health: Detailed Tables*, 2006, <http://www.oas.samhsa.gov/nsduh/2k5nsduh/tabs/Sect7peTabs58to67.pdf>.

⁷ SAMHSA, HHS, *Results from the 2005 National Survey on Drug Use and Health: Detailed Tables*, 2006, <http://www.oas.samhsa.gov/NSDUH/2k5nsduh/tabs/Sect7peTabs58to67.pdf>. See also, CDC, "Cigarette Brand Preference Among Middle and High School Students Who Are Established Smokers – United States, 2004 and 2006," *Morbidity and Mortality Weekly Report (MMWR)* 58(5), February 13, 2009 <http://www.cdc.gov/mmwr/PDF/wk/mm5805.pdf>; Sutton, CD, "Newport: 'Fastest Growing Cigarette in the Country,'" The Onyx Group, [updated] January 30, 2002, <http://www.onyx-group.com/Newport.htm>; Johnston, LD, et al., *Cigarette Brand Preferences Among Adolescents*, Monitoring the Future Occasional Paper 45, Institute for Social Research, The University of Michigan, 1999, <http://monitoringthefuture.org/pubs/occapers/occ45.pdf>.

⁸ SAMHSA, HHS, *Results from the 2005 National Survey on Drug Use and Health: Detailed Tables*, 2006. See also, CDC, "Cigarette Brand Preference Among Middle and High School Students Who Are Established Smokers – United States, 2004 and 2006," *Morbidity and Mortality Weekly Report (MMWR)* 58(5), February 13, 2009 <http://www.cdc.gov/mmwr/PDF/wk/mm5805.pdf>.

⁹ Feighery, EC, et al., "An examination of trends in amount and type of cigarette advertising and sales promotions in California stores, 2002-2005," *Tobacco Control* (published online), February 26, 2008.

¹⁰ Primack, BA, et al., "Volume of Tobacco Advertising in African American Markets: Systematic Review and Meta-Analysis," *Public Health Reports* 122(5):607-615, September/October 2007.

¹¹ Connolly, GN, Testimony before the Senate HELP Committee, February 27, 2007.

¹² Laws, MB, et al., "Tobacco availability and point of sale marketing in demographically contrasting districts of Massachusetts," *Tobacco Control* 11:71-73, 2002. See also, Luke, D, Esmundo, E, & Bloom, Y, "Smoke signs: Patterns of tobacco billboard advertising in a metropolitan region," *Tobacco Control* 9:16-23, 2000.

¹³ Kreslake, JM, et al., "Tobacco industry control of menthol in cigarettes and targeting of adolescents and young adults," *American Journal of Public Health* 98(9):1685-92, September 2008.

¹⁴ King, C, et al., "The Master Settlement Agreement with the tobacco industry and cigarette advertising in magazines," *New England Journal of Medicine* 345(7):504-11, August 2001.

¹⁵ Landrine, H, et al., "Cigarette advertising in Black, Latino, and White magazines, 1998-2002: an exploratory investigation," *Ethnicity & Disease* 15(1):63-67, Winter 2005.

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- ¹⁶ Stoddard, JL, et al., "Target Tobacco Markets: Outdoor Advertising in Los Angeles Minority Neighborhoods," *American Journal of Public Health (AJPH)* 87:1232-3, July 1997.
- ¹⁷ Villarosa, L, "Body and Soul," *Women's Review of Books* 11(10-11):13-4, 1994.
- ¹⁸ HHS, *Tobacco Use Among US Racial/Ethnic Minority Groups: A Report of the Surgeon General*, 1998, http://www.cdc.gov/tobacco/data_statistics/sgr/sgr_1998/index.htm.
- ¹⁹ Laws, MB, et al., "Tobacco availability and point of sale marketing in demographically contrasting districts of Massachusetts," *Tobacco Control* 11:71-73, 2002.
- ²⁰ Hersey JC, et al., "Are menthol cigarettes a starter product for youth?" *Nicotine & Tobacco Research* 8(3):403-413, 2006.
- ²¹ SAMHSA, HHS, *Results from the 2005 National Survey on Drug Use and Health: Detailed Tables*, 2006, <http://www.oas.samhsa.gov/NSDUH/2k5nsduh/tabs/Sect7peTabs58to67.pdf>.