State Attorneys General

A Communication from the Chief Legal Officers of the Following States and Territories:

Alaska * Arizona * California * Colorado * Connecticut Delaware * Guam * Hawaii * Idaho * Illinois * Indiana * Iowa Maine * Maryland * Mississippi * Montana *New Hampshire * New Mexico New York * Northern Mariana Islands * Ohio * Oregon * Pennsylvania Puerto Rico * Rhode Island * Vermont * Washington

November 8, 2013

Division of Dockets Management (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Re: Docket No. FDA-2013-N-0521 Menthol in Cigarettes

The undersigned Attorneys General (hereinafter "the Attorneys General") submit this comment in response to the FDA's Advance Notice of Proposed Rulemaking, 78 Fed. Reg. 44484 (July 24, 2013), to support a ban on menthol flavored cigarettes.

1. Youth smoking

The Attorneys General seek to prevent young people from smoking. The FDA's report on menthol, "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes" (hereinafter "the Report"), concludes that menthol in cigarettes is likely associated with increased initiation and dependence on smoking and with reduced cessation. It also indicates that younger populations have the highest rate of smoking menthol cigarettes and that such cigarettes have been marketed in ways that promote youth smoking. Consequently, sales of menthol cigarettes impede efforts to deter adolescents from smoking.

The States devote considerable resources to the prevention of sales of cigarettes and other tobacco products to minors. In fact, federal law requires the States to do so. Because flavored cigarette products attract young smokers, flavors other than menthol were banned by the Tobacco Control Act in 2009. The exception of menthol from the flavor ban undermines the States' attempts to curb youth smoking.

2. Disparate impact

The Report concludes that menthol is favored by discrete segments of the population. A majority of African-American smokers smoke menthol cigarettes, and other minority groups are also more likely to use them. Moreover, menthol cigarettes are associated with increased dependence on smoking and reduced success in smoking cessation among African-Americans. Use of

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menthol cigarettes is more prevalent among younger smokers than older smokers, lower-income smokers than higher-income smokers, and female smokers than male smokers. The Report also indicates that menthol cigarettes have been marketed in ways that promote their use by African-Americans and adolescents.

Considering these facts, it is clear that the FDA's exception for this one flavor disproportionately endangers young people, women, African-Americans and other minorities, and people of lower socioeconomic status. The Attorneys General have a duty to protect *all* the residents of their States, and the continued sale of menthol cigarettes interferes with that objective.

3. International Trade Implications

When Congress banned all flavors except menthol in 2009, it charged the FDA to study whether menthol should also be banned. Banning other flavors, but not menthol, threatens to undermine state and federal tobacco control efforts, because the United States is a party to numerous treaties and trade agreements that render the distinction between menthol and other flavors subject to challenge. Such challenges threaten the viability of the existing flavor ban.

In April 2010, Indonesia sought consultations with the United States about the menthol flavor exception, arguing that the exception for menthol-flavored cigarettes manufactured in the United States unfairly discriminated against clove-flavored cigarettes manufactured in Indonesia. (World Trade Organization Dispute DS 406: *United States — Measures Affecting the Production and Sale of Clove Cigarettes.*) An arbitration panel subsequently ruled in favor of Indonesia and determined that the United States had violated the Technical Barriers to Trade agreements. Including menthol in the ban on flavors would reduce the potential for other countries to allege that the United States has violated its international trade agreements.

4. Complete Ban v. Product Standard

The FDA is considering a product standard for menthol as an alternative to an outright ban. A product standard would set a maximum allowable level of menthol in cigarettes. The Attorneys General agree with the many institutions and individuals that have voiced cogent arguments as to why a complete ban, rather than a product standard, should be enacted to protect the public health.

The Attorneys General also support a complete ban because a ban would greatly facilitate their ability to enforce against contraband menthol cigarettes. Cigarette packs bearing the name of a well-known menthol brand, labeled as "menthol" or "wintergreen," or decorated in prominent green colors, would be easily identifiable as contraband by visual surveillance alone. Enforcing a product standard, however, would require difficult and costly chemical analysis to ascertain whether the quantity of menthol contained in particular cigarettes exceeds the allowable maximum.

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5. Contraband Concerns

The specter of a black market is often raised to oppose regulation or taxes, but the threat of the emergence of a black market in menthol cigarettes should not be permitted to override the protection of public health.

Although contraband cigarettes are a serious problem, there are numerous law enforcement tools that can be used to combat production or importation of unlawful tobacco products. Moreover, the quantity of menthol cigarettes that could be made available on the black market would be far less than the quantity that will be available if menthol remains legal. Therefore, a ban on menthol would dramatically decrease public access to menthol cigarettes.

On behalf of the undersigned Attorneys General, we thank the FDA for the opportunity to comment on this important topic.

Sincerely yours,

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