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

Re: Docket Number FDA-2010-N-0001-0093

Menthol Report Subcommittee of Tobacco Products Scientific Advisory Committee Public Comments

Legacy appreciates the opportunity to submit these comments to the Menthol Report Subcommittee of the Tobacco Products Scientific Advisory Committee (TPSAC) on the subject of the timelines and structure of the TPSAC's required report to the Secretary of Health and Human Services regarding the impact of use of menthol in cigarettes on the public health. The comments are submitted pursuant to the notice in the Federal Register published on August 24, 2010.

These comments will focus on the structure of the report and, in particular, the importance of aligning it to the specific mandate set out in the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) to the TPSAC. We are not addressing the question of timelines since we are fully confident that the TPSAC Subcommittee and TPSAC itself will complete their work within the statutory timeframe.

Legacy is a national, independent public health foundation created in 1999 out of the landmark Master Settlement Agreement ("MSA") between the tobacco industry, 46 state governments and five U.S. territories. Our mission is to build a world where young people reject tobacco and anyone can quit. Legacy does not lobby or take positions on specific legislation. Our programs include:

truth® - A national youth smoking prevention media campaign responsible for preventing approximately 450,000 youth from initiating smoking from 2000 through 2004.

EX® - An innovative smoking cessation public education campaign designed to help smokers "re-learn" life without cigarettes.

Research Initiatives – Examining the various causes and effects of tobacco use in the United States.

Outreach to Priority Populations – Priority Populations Initiatives and grants provide critical interventions using methods that are culturally competent and tailored for the specific needs of communities disproportionately affected by the toll of tobacco.



As TPSAC considers the impact of the use of menthol in cigarettes on the public health, we urge it to remain mindful of its specific statutory mandate and to assure that its report and recommendations are framed within that context. TPSAC is tasked to examine the scientific evidence regarding:

- The use of menthol cigarettes among children, African-Americans, Hispanics, and other racial and ethnic minorities;
- In connection with a ban or other regulation of menthol cigarettes:
 - The risks and benefits that would be posed to the population as a whole including users and nonusers of tobacco products;
 - The increased or decreased likelihood that existing users will stop using such products; and
 - The increased or decreased likelihood that those who do not use tobacco products will start using such products; and
- Countervailing effects of a ban or other regulation of menthol cigarettes on the health of adolescent tobacco users, adult tobacco users, or non tobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of the Tobacco Control Act and the significance of such demand.

As is evident, TPSAC is charged in principal part with carefully assessing what the scientific evidence shows with regard to the impact of the use of menthol cigarettes on the public health, including the risks and benefits of menthol regulation along with whether tobacco cessation and initiation is more or less likely in the event of a ban or other regulation of menthol. In addition, TPSAC is explicitly charged with considering the public health impact of menthol cigarettes on particular populations, notably children and minorities.

We emphasize the importance of aligning the report and recommendations to these statutory provisions because some have suggested that TPSAC address and base its recommendations on a very different set of questions. In particular, there have been suggestions that a ban on menthol can only be justified if it is *conclusively established* that menthol tobacco products *cause* greater morbidity and mortality to *established users* than is *caused* by non-menthol tobacco products. This view has been accompanied by withering critiques of the current state of the science. But as set out above, this position finds no support in the Tobacco Control Act's clearly articulated, public health-driven charge to TPSAC which focuses on *risks* and *benefits* and *likelihoods* and is as concerned with impacts on initiation and cessation as it is with health effects on established smokers who will continue to smoke.

Legacy will make a detailed submission setting out its views regarding both the law and science regarding the regulation of menthol at the appropriate time. We certainly agree that TPSAC's recommendations must be exclusively based on its best, expert and independent understanding of the science. But TPSAC's report and recommendations must be responsive to the questions asked by the statute and not by those who would impose a much narrower test that would undercut the Tobacco Control Act's over-arching public health standard. By maintaining its focus on the statute's specific questions, the TPSAC will properly discharge its important statutorily assigned mission.

Legacy would like to thank the FDA for providing the opportunity to express its views on this important subject. Please contact Stephenie Foster, Senior Vice President of Government Affairs at 202-454-5559 or sfoster@legacyforhealth.org if you have questions or need more information.