Should the FDA Regulate Menthol?

The Family Smoking Prevention and Tobacco Control Act of 2009 gave the Food and Drug Administration the authority to regulate the manufacture, distribution, and marketing of tobacco products in order to protect public health. The legislation also banned cigarettes containing characterizing flavors; however, the Act did not include menthol in this ban. As a result, menthol cigarettes are not regulated. The FDA retains authority of its own to regulate menthol and recently requested public comment as to whether the agency should move forward with their own restrictions on the flavor additive. The Ochsner Institute for Wellness and Health Policy submitted formal comments on the matter, where we expressed our strong opinion that menthol should indeed be categorized as a characterizing flavor, because menthol, like other characterizing flavors, increases the chance that children will initiate and eventually become addicted to smoking. The following is a copy of the letter that was submitted to the FDA in 2013. 
Mitchell Zeller, J.D.
Director, Center for Tobacco Products
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: Docket No. FDA-2013-N-0521 – Advanced Notice of Proposed Rulemaking, Menthol in
Cigarettes, Tobacco Products; Request for Comments

Dear Director Zeller:

Thank you for the opportunity to comment as the Food and Drug Administration determines
whether to regulate menthol in cigarettes and other tobacco products. Ochsner Health System is
Louisiana’s largest private sector healthcare provider with a network of nine hospitals and more
than 40 health centers located throughout rural and urban Louisiana. In 1939, Ochsner’s
founder, Dr. Alton Ochsner, co-wrote a groundbreaking paper linking tobacco use with lung
cancer. To honor his legacy, we have created the Ochsner Institute for Wellness and Health
Policy. One of the Institute’s foremost missions is to advocate for policy changes that will
eradicate tobacco addiction and its devastating consequences once and for all.

Simply put, the Ochsner Institute for Wellness and Health Policy supports a full ban on menthol
in not only cigarettes, but tobacco products as a whole. One of the primary goals of the Family
Smoking Prevention and Tobacco Control Act is to prevent and reduce tobacco use by young
people. As Congress noted in the legislation, virtually all new tobacco users are addicted before
they are old enough to understand the risks and consequences of addiction and the probability
that they will die early because of it. As the FDA noted in its December 2009 guidance on the
Tobacco Control Act, one “important way to reduce the death and disease caused by smoking is
to prevent children and adolescents from starting to smoke” in the first place.

The Tobacco Control Act banned characterizing flavors in cigarettes because of the statistic that
17-year-old smokers are three times as likely to smoke flavored cigarettes as smokers over the
age of 25. Flavored cigarettes make it easier for young people to start smoking by masking the
bad taste of tobacco, and studies have demonstrated that young people believe flavored tobacco
products are safer than unflavored tobacco products. Congress rightly recognized that removing
these flavored products from the market is important because it eliminates an attractive method
For decades, the tobacco industry has relied upon menthol as a flavor to lure young people and other targeted populations to initiate smoking, recognizing that its strong and distinctive taste has the capability to overpower the harsh taste of tobacco. The Scott vs. American Tobacco Company trial exposed a multitude of evidence, including written internal memos drafted by tobacco employees, which revealed the extent to which tobacco companies have used menthol flavoring to target certain populations. One such memo written by a tobacco company employee outlined a couple of theories he thought should inform the company’s advertising campaigns. The employee wrote of menthol, “isn’t it really analogous to the taste sensation of peppermint? (In this regard, peppermint supposedly is the largest-selling flavor in Harlem, and Mason Mints, a chocolate-covered peppermint candy bar, sell as if they were being endorsed by [Congressman] Adam Clayton Powell.)” The same memo theorized that women would be attracted to the minty flavor of menthol because of its “breath-freshening” capabilities. Another memo written by a member of a tobacco company’s research and development team detailed experiments which used a “smoke panel” to sample cigarettes that contained varying amounts of sugar, nicotine, and a “finishing flavor” of menthol in an effort to determine which blend would most positively affect the cigarette’s “taste”. This is only a small sample of the many ways the tobacco industry has for years used menthol as a characterizing flavor in order to target certain customers.

In addition to relying on menthol as flavoring, tobacco companies use menthol because its anesthetic properties reduce throat irritation, enabling the smoker to overcome the body’s natural resistance to toxins. This is of particular benefit to first-time users. Indeed, the National Survey on Drug Use and Health found that 47.7% of all adolescent smokers smoke menthol, a higher percentage than any other age group. This preference carries over into young adulthood and disproportionately affects particular populations. African Americans smoke mentholated cigarettes at much higher rates than whites.

Tobacco companies know which populations are most likely to become addicted to mentholated tobacco, and they continue to market to these groups. For example, according to the 2012 Surgeon General’s report on “Preventing Tobacco Use Among Youth and Young Adults”, menthol cigarettes are more likely to be marketed in stores near schools with a higher proportion of African American students. Camel No. 9’s “In Stiletto” campaign, which features pink lettering and pink smoke, is intended to reach young women. Camel’s Snus menthol dip features an ad campaign promoting individuality, using slogans such as “Avoid the Mainstream”, “One Size Should Never Fit All” and “Ironically, Individuality is not a Trait Shared by Everyone”. This theme is intended to appeal to youth and young adults who are just learning to carve out their own identity. These are just some of the many examples of marketing tactics tobacco companies have used in the last few years, all of them after the Master Settlement Agreement.

We believe that a total ban on menthol in tobacco products is necessary to prevent more of our youth from becoming addicted to tobacco. Recent CDC reports indicate that the ban on characterizing flavors in cigarettes did not go far enough to curb tobacco consumption in youth; other tobacco products such as candy-flavored cigarretlos have seen a dramatic rise in the last
couple of years. If a menthol ban is only limited to cigarettes, we believe the same outcome will occur.

In short, menthol should have never been excluded from the Tobacco Control Act. It is used as a characterizing flavor in the same manner as strawberry, grape, clove, or any other flavor that was specifically banned in the legislation. Its public health impact has been great; evidence shows that menthol aids in creating and strengthening cigarette addiction because it enhances nicotine delivery. Young people who take up menthol cigarettes are 80% more likely to become lifelong smokers than those who consume regular cigarettes. For those smokers who attempt to quit smoking, relapse rates are considerably higher for menthol cigarette smokers than regular cigarette smokers.

Nearly 39% of menthol smokers report that if menthol cigarettes were banned, they would try to quit smoking. In fact, researchers estimate that if a menthol ban had gone into effect in 2011, at least 320,000 deaths would be averted by 2050. Please consider fully banning menthol from all tobacco products as quickly as possible. We cannot afford to wait any longer – our children’s lives are at stake.

Sincerely,

Patrick J. Quinlan, M.D.
Executive Director, Ochsner Institute for Wellness and Health Policy