

FDA TPSAC's Menthol Theater Closing Its Doors

The TPSAC is moving toward completion of its assigned task, producing a report on menthol in cigarettes—with all the drama inherent in Broadway Theater. What will be their ultimate decision?

Does anyone know? At this writing even TPSAC may not know.

Does anyone care? The real question is, who should care?

Above all, who should care most are the parents of youths who, in event of a menthol ban, would purchase counterfeit menthol cigarettes which have been proven to be far more toxic, even by an order of magnitude, than legal cigarettes.

African-Americans should also care; African-American communities would bear the brunt of the health effects from the counterfeit cigarettes' higher toxicity as well as the increased crime associated with the sale of illegal cigarettes.

The non-smoking public should also care because the counterfeit cigarette trade would fuel violent crime. Terrorist organizations are already involved in the transport and sale of counterfeit cigarettes and, if the government increases the size of the market by banning menthol, these groups would expand their activities and it can be expected that violent drug cartels would move into counterfeit cigarette business.

Three Controlling Issues

Three issues dominate the menthol cigarette debate:

1. Do menthol cigarettes increase mortality/morbidity relative to legal cigarettes?
2. Do menthol cigarettes make it easier to start smoking and more difficult to stop smoking?
3. Would a menthol ban lead to an increase in the “black market” for menthol cigarettes?

Morbidity/Mortality

- ▶ The TPSAC has been presented with a wide range of studies – the hard science – dealing with morbidity/mortality.
- ▶ The overwhelming weight of the evidence suggests that menthol does not increase morbidity/mortality relative to non-menthol cigarettes.

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Initiation/Cessation

- ▶ The data on initiation/cessation – the soft science – is mixed, tending toward no effect.
- ▶ One of the problems with developing initiation/cessation conclusions is that the underlying studies were not focused on the initiation/cessation issue and, consequently, subsequent reviews had to force fit a new study design into old study objectives.
- ▶ CRE [examined](#) in detail a number of initiation/cessation studies identified by the FDA and concluded they were not compliant with the [Data Quality Act](#) which makes it illegal for FDA to use the studies as a basis for a federal decision.
- ▶ CRE filed a petition under the [Data Quality Act](#) requesting that FDA correct the record to notify the public that a number of the initiation/cessation studies they have identified must be classified as DQA non-compliant.
- ▶ FDA should act on the aforementioned petition prior to issuing its report on menthol; failure to do so could suggest that the agency is being less than transparent on its review of the underlying science.
- ▶ Two statistically powerful studies on initiation/cessation were performed; one by Dr. Hyland of the Roswell Park Cancer Institute and the other by Dr. Muscat under contract to the Public Health Service.
- ▶ Dr. Hyland concluded:

“Despite the biologic mechanism that suggests that menthol may facilitate greater nicotine transfer to the smoker, these data indicate that mentholated cigarette smokers do not exhibit greater signs of nicotine dependence as measured by the likelihood of future cessation, time to first cigarette in the morning, or number of cigarettes smoked per day”.
- ▶ Dr. Muscat concluded:

“Cigarette mentholation was not associated with continued smoking”.

“The findings suggest that menthol does not increase the addictive properties of tobacco nicotine.”
- ▶ Therefore one can readily conclude that there is no basis for regulation of menthol on the behavioral data presently before the Committee.

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Contraband

- ▶ Recently, the federal contraband expert, The Bureau of Alcohol, Tobacco and Firearms, [ATF](#), issued a Notice of Proposed Rulemaking which contained the three following conclusions:
 - (1) Cigarette smuggling profits fund terrorism and other deadly criminal groups
 - (2) Counterfeit cigarettes pose health hazards over and above those of genuine cigarettes.
 - (3) Illegal cigarette trafficking makes it easier for children to smoke.
- ▶ Of particular importance, the ATF concluded:

“The trafficking of contraband cigarettes is a worldwide problem. Billions of dollars of tax revenue are lost by all levels of government throughout the world due to the smuggling of cigarettes. Much of the illicit profit gained by organized crime and terrorist groups is used in furtherance of their criminal enterprises.”

“The trafficking in counterfeit and contraband tobacco products also poses a serious health risk to our society. There are no standards of production in counterfeit product. This allows for such things as biological or chemical contamination of the product.”

“contraband cigarettes are more likely to be sold to underage persons than legitimate product.”

Conclusions

- ▶ The aforementioned conclusions reached by FDA’s federal colleague, ATF is the “game changer”
- ▶ There is no science-based justification for a menthol ban.

Final Curtain Call

- ▶ ATF take a bow!