



August 28, 2013

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

Re: Docket ID FDA-2013-N-0521

To Whom It May Concern:

The National Association of Convenience Stores (NACS) is highly concerned about the adverse impact of overly restrictive federal regulations on menthol cigarettes, including a possible prohibition on manufacture or sale. A ban on menthol in cigarettes risks giving rise to an entire industry of unregulated cigarette products that would create significant health concerns detailed below.

NACS submits these comments in response to an Advance Notice of Proposed Rulemaking (ANPRM) published July 24, 2013 in the Federal Register. The ANPRM requested comment and information about a FDA preliminary scientific evaluation and "any other information" related to a series of questions. In this submission, NACS focuses its reply on Question C3:

"If menthol cigarettes could no longer be legally sold, is there evidence that illicit trade in menthol cigarettes would become a significant problem? If so what would be the impact of any such illicit trade on public health? How would any such illicit trade compare to the existing illicit trade in cigarettes?"

The National Association of Convenience Stores (NACS)

NACS is uniquely qualified to speak about the existence and ramifications of illicit tobacco markets.

NACS is an international trade association representing more than 2,200 retail company members. Our member companies do business in nearly 50 countries worldwide, with the majority of members based in the United States. The U.S. convenience store industry, with some 145,000 stores across the United States, posts approximately \$624 billion in total sales on an annual basis. The majority of our members are small, independent operators. More than 70 percent of our total membership is companies that operate 10 stores or less. Over 60 percent are owned and operated by someone who only has one store.

The number one in-store item for our industry is by far tobacco products. Tobacco is also one of the most regulated products that the industry sells. Our members are on the front lines of the illicit tobacco war. Our members also are active in verifying the age of tobacco purchasers. As a result, NACS has played a prominent role in studying and developing U.S. tobacco policy and illicit markets for the last two decades; our members have a deeply vested interest in the outcome of the policy choices that FDA makes.

Illicit Cigarette Markets Are A Significant Problem Today, and Will Worsen if Menthol Cigarettes are Outlawed.

As a predicate, there is ample evidence from the existence of current illicit markets that illicit trade in menthol cigarettes would become a significant problem if the FDA outlaws menthol cigarettes.

It is simply not reasonable to expect that the menthol market, which accounts for roughly 30 percent of cigarette sales today, will vanish overnight or could be phased out over time if menthol cigarettes are banned. Combined with the relative ease of obtaining menthol flavorings, black market manufacturers will sprout up or expand quickly.

We are troubled that the FDA has asked only broad questions (such as Question C3) about illicit trade instead of developing a fact-based foundation to understand the current extent of illicit trade as Congress intended, and then seeking comment from interested parties on those findings.

Consequently we offer below an overview of facts and studies that give a hint at the current problem and how this problem would be aggravated and worsened with a prohibition of menthol. But we urge the FDA strongly to not regard our comments and the comments of others as a substitute for genuine study of the issue as Congress intended. In fact, we encourage the FDA to develop a robust research agenda to assess the health impacts of today's illicit tobacco market.

The Canadian Example

The real world experience of Canada is one clear example of the dangers of fueling a black market.

A large portion of the cigarettes purchased in Canada is illegal.¹ My counterpart, Dave Bryans, at the time president of the Canadian Convenience Stores Association, noted in 2011 that Canadian youth have easy access to cheap tobacco, which undermines well-accepted strategies to reduce youth smoking: "The Canadian market is flooded with

¹ Because of its nature, illicit tobacco markets are hard to measure. But as one indication, as of late 2008, nearly 50 percent of the cigarettes consumed in Ontario and more than 40 percent of those consumed in Quebec were contraband.

untested and unregulated contraband cigarettes. ... The government's inability to curb illicit tobacco is going against public health policies. Our studies conclude that those under 19, who are prohibited from purchasing cigarettes, have no trouble getting their hands on cheap, illegal cigarettes." One study in 2010 found that 43 percent of all cigarettes smoked among Ontario high school daily smokers were cheap, illicit cigarettes.

A special task force on the status of contraband tobacco that is advising the Minister of Public Safety put the problem in stark terms: "Persons involved in contraband tobacco, including the end users, are undermining global and domestic health objectives, contributing to the proliferation of organized crime, inviting criminals into their communities, undermining the local legitimate economy, and evading taxes that support Canada's programs."²

Canada offers a cautionary tale for the United States, demonstrating how an already enormous black market can easily be intensified when a government creates overly restrictive policies or outlaws a previously legal product. Canada is but one example of how an illicit cigarette market, propelled by well-intentioned government policies, led to the unintended consequences of a widespread and pervasive black market.

Global Capabilities Exist to Manufacture Unregulated Counterfeit Cigarettes.

There is abundant evidence that points to a well-developed global black market infrastructure to manufacture, distribute and sell counterfeit cigarettes. The global manufacturing capability can quickly ramp up to meet the increased demand a ban on menthol would create.

- Numerous studies, reports and other sources point to robust contraband manufacturing capabilities in countries like China and in regions like Eastern Europe. Among other resources is a series of articles by the public interest group, Center for Public Integrity, that shine a spotlight on the tobacco underground.³
- In a report to Congress, the Government Accountability Office cited multiple arrangements and structures to profit from the black market trade in tobacco. "Schemes can range from individual consumers purchasing tax-free cigarettes from Internet Web sites, to larger-scale interstate trafficking of tobacco products, to smuggling cigarettes into the country by criminal organizations."⁴

² "Report on the Status of the Contraband Tobacco Situation in Canada," Report presented to the Minister of Public Safety by the Task Force on Illicit Tobacco Products; July 2009. <http://www.publicsafety.gc.ca/prg/le/ct-rpt-eng.aspx>

³ "The Counterfeit Cops," by Te-Ping Chen. Report of the Center for Public Integrity, Updated February, 2012. <http://www.publicintegrity.org/2010/01/27/6339/counterfeit-cops>

⁴ ILLICIT TOBACCO: Various Schemes Are Used to Evade Taxes and Fees, (United States Government Accountability Office, March, 2011) 2. <http://www.gao.gov/new.items/d11313.pdf>

- A report of the Virginia State Crime Commission, “Illegal Cigarette Trafficking,” describes the existing and robust infrastructure in contraband cigarettes. “Cigarette trafficking can occur at all points along the normal production and distribution channels, with cigarettes being diverted outside normal commercial streams and into the black market.”⁵
- The Virginia Crime Commission study also reported: “To achieve lower costs, traffickers can arrange for their cigarettes to be manufactured overseas. Frequently, these cigarettes are counterfeits. The packaging used in popular brands of cigarettes is duplicated; however, the cigarettes inside will differ substantially from the genuine articles. A number of recent studies have reported that the manufacturing facilities used in the production of counterfeit cigarettes have little or no quality control; the counterfeit cigarettes, in turn, have alarmingly high levels of contaminants, including dangerous levels of toxic metals. *In short, counterfeit cigarettes present a serious public health risk.*” (emphasis added.)
- A 2009 Inspector General report for the Department of Justice said the diversion of tobacco today costs federal and state governments more than \$5 billion a year in unpaid excise taxes. Other reports say enforcement efforts have not kept pace with increasingly complex schemes.

The Virginia Crime Commission’s three policy recommendations are all centered on enhancing law enforcement efforts including providing more resources. With an already robust national black market and under-resourced law enforcement agencies with a range of competing priorities, one can only imagine the amount of resources needed to effectively police an increased market in counterfeit cigarettes. We need only to look at today’s flourishing drug trade or the abysmal results of Prohibition to envision what would be in store should the government take so careless a step as to ban menthol in cigarettes thus create the incentives for an expanded black market.

Illicit Markets Create Significant Public Health Concerns

We respect the FDA’s mission to address the public health issues raised by cigarettes. In its most recent scientific assessment, the FDA concluded that menthol cigarettes are no different in health impact than non-menthol cigarettes: “From the available studies, the weight of evidence supports the conclusion that menthol in cigarettes is not associated with an increase in disease risk to the user compared to non-menthol cigarette smokers.”⁶

⁵ “Illegal Cigarette Trafficking.” Report of The Virginia State Crime Commission, 2013. <http://leg2.state.va.us/dls/h&sdocs.nsf/4d54200d7e28716385256ec1004f3130/dba061dea0fa878b852579c8006e00a4?OpenDocument>

⁶ “Preliminary Scientific Evaluation Of The Possible Public Health Effects Of Menthol Versus Nonmenthol Cigarettes” (U.S. Food and Drug Administration, July, 2013) 6.

Given that conclusion, it is difficult to understand how an FDA edict to outlaw menthol in cigarettes would have credibility with smokers. Upon reading this scientific conclusion, it is equally possible to believe that smokers will turn to a street-corner vendors who offers low-price cigarettes, readily available in baggies for the price of a pack of gum.

By singling out a portion of the market that is “not associated with an increase in disease risk,” FDA would exacerbate an existing and growing illicit market and thus undermine public health objectives.

Illicit Markets will Undermine Retailers' Efforts to Prevent Underage Smoking

Convenience stores are on the front lines of the nation's efforts to prevent underage smoking. We check age identifications and our establishments undergo frequent reviews to assure compliance. A report released by the Substance Abuse and Mental Health Administration ⁷ shows that the rate of tobacco sales to underage youth at retailers nationwide has fallen significantly from about 40 percent in 1997 to 9.1 percent in the last fiscal year. An illicit market would reverse that trend.

It is impossible to assume that a menthol ban will reduce underage smoking, which is the announced objective of, and justification for, virtually every provision of the Tobacco Control Act. If anything, a ban on menthol will aggravate underage smoking problems, as demonstrated by the Canadian experience. Unlike legitimate retailers who take seriously their responsibility to curb tobacco sales to underage youth, the purveyors of illicit menthol cigarettes, operating outside of the law, will not discriminate among their customers based on age.

If menthol is banned or severely restricted, retailers will be competing with a greatly expanded black market for cigarettes. Cigarette sales won't occur across the counter in our stores. Instead they will take place down the street, outside our stores, and you can be sure that these street-corner vendors won't be checking IDs for birthdates. If this occurs, it will severely impede the progress the United States has made toward reducing access to cigarettes for minors.

Illicit Cigarettes Often Contain Unregulated or Even Toxic Ingredients

We are struck by the limited nature of the questions posed by the FDA in the Advance Notice of Proposed Rulemaking. It is well known from studies that counterfeit cigarettes often elevate health hazards because of dangerous impurities or other unregulated or even toxic ingredients like lead.

We wrote to the Tobacco Products Scientific Advisory Committee in July 2010:

<http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/UCM361598.pdf>

⁷ <http://www.samhsa.gov/newsroom/advisories/1308265455.aspx>

“That black market creates health concerns, first and foremost. Current manufacturers operate within the full scrutiny of the FDA in satisfying customer demand. Illegal manufacturers, obviously, will not, meaning that cigarette contents, purity, nicotine and tar levels, to name just a few issues, all will be subject to their whims. Congress specifically recognized in the Tobacco Control Act that the FDA should play a role in regulating the manufacture of cigarettes; banning menthol will eliminate the important public health safeguards that Congress intended in that Act.”

Unfortunately, the Advisory Committee did not study the health effects of counterfeit cigarettes. We urge the FDA not to make the same omission. Unregulated, hazardous ingredients in counterfeit cigarettes can have a significant impact on consumers beyond the health consequences associated with smoking. In asking about the “impact any such illicit trade on public health,” we urge the FDA to commission studies about the ingredients of counterfeit cigarettes so it can factor these findings into its science-based decision on menthol in cigarettes.

Economic Impact of Outlawing Menthol Cigarettes

It stands to reason that a black market will have severe adverse effects on small businesses and jobs. The jobs of our employees and owners will be at risk as powerful criminal networks drive more sales underground.

Thousands of working Americans rely upon menthol sales beyond the factory workers who actually manufacture them. According to a study submitted by Altria Client Group on behalf of Philip Morris, “Nearly 500,000 American jobs depend at least in part on the legal sale of menthol cigarettes...Job losses would vary by stage in the tobacco value chain, but are likely to have a disproportionate impact on small, independent convenience store owners, tobacco growers and independent distributors to convenience stores.”⁸

Many of the thousands of jobs lost in the United States due to a ban on menthol cigarettes would be replaced by jobs overseas manufacturing counterfeit and unregulated cigarettes, while many more would be replaced by illegal traffickers domestically. Banning menthol will trade good paying, legal jobs and taxes for illegal jobs and a thriving illicit market with no corresponding benefit to human health.

Conclusion

NACS encourages the FDA to undertake a thorough analysis of the potential for an illicit market, its potential size and the degree to which it would impact public health and jobs. We hope that the FDA will not be satisfied with simply receiving responses as part of the

⁸ “Countervailing effects of a ban on menthol cigarettes.” (Report submitted by Altria Client Services on behalf of Phillip Morris USA to the Tobacco Products Scientific Advisory Committee, January, 2011) 80.
<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM246043.pdf>

ANPRM process. Instead, we urge the FDA to assemble the responses of NACS and others to develop a robust research agenda into the existence today of illicit markets, the impact on youth smoking, the ingredients in counterfeit cigarettes and other issues.

There is a very real fear that banning menthol in cigarettes will worsen today's unregulated and unhealthy illicit market. Thank you for your time.

Respectively,

A handwritten signature in blue ink that reads "Lyle Beckwith". The signature is written in a cursive, flowing style.

Lyle Beckwith
Sr. Vice President, Government Relations