

MEMORANDUM

To: Governor Andrew M. Cuomo

From: Howard A. Zucker, M.D., J.D.
Commissioner of Health

Date: September 26, 2019

Subject: Recommendation on Menthol Flavor

Under your leadership, New York State (NYS) has launched an aggressive and rapid response to the alarming increase of e-cigarette use among New York's youth. The Public Health and Health Planning Council's approval on September 17, 2019 of emergency regulations prohibiting flavored e-cigarette products other than tobacco and menthol flavors was a critical action that will save lives. At your direction, the Department of Health has reviewed the research and gathered new data on menthol flavoring and now confidently recommends that it be included in the list of flavors that are prohibited.

The rationale for including menthol flavor in the prohibition includes the following:

E-cigarettes are harmful to health.

- Most e-liquids contain nicotine, the highly addictive chemical in all tobacco products. Nicotine can harm the developing brain of adolescents and young adults, which can lead to lower impulse control and mood disorders; disrupt attention and learning and prime the developing brain for addiction to alcohol and other drugs, such as cocaine.¹
- E-cigarette aerosol can contain 1) fine and ultrafine toxic particles that can interfere with lung functioning and increase the risk of heart disease, lung cancer and asthma attacks; 2) heavy metals such as lead, tin and nickel which can cause reduced lung function and lung cancer; 3) chemicals used for flavoring such as diacetyl, a chemical linked to the serious lung disease bronchiolitis obliterans; and 4) volatile organic compounds that can cause long-term health effects including cancer.¹
- The Food and Drug Administration (FDA) is currently investigating the possible link between e-cigarettes and seizures. As of August 7, 2019, the agency has received 127 reports of seizure or other neurological symptoms that occurred between 2010 and 2019. It is not known if there is a direct relationship between the use of e-cigarettes and the risk of seizures. However, seizures or convulsions are known potential side effects of nicotine poisoning.²

Youth in NYS are using e-cigarettes at high rates that are increasing.

- Between 2014 and 2018, the rate of current e-cigarette use among NY high school youth increased 160%, from 10.5% to 27.4%. E-cigarettes are the most commonly used tobacco product among youth, surpassing cigarettes, cigars, smokeless tobacco, and hookah.³
- More than five times as many high school students in New York State use e-cigarettes than smoke cigarettes.³

Flavors are a principal reason that youth initiate and maintain e-cigarette use.

- Flavors are a key marketing strategy that appeal to youth and young adults. Most youth go straight to using e-cigarettes. This supports the assertion that e-cigarette marketing is aimed at attracting new, young customers to nicotine use, as opposed to adult smokers interested in assistance with quitting smoking combustible tobacco.
- Data from the 2016-2017 FDA's Population Assessment of Tobacco and Health (PATH) study found that 96.1% of 12- to 17-year-olds who had initiated e-cigarette use since the last survey wave started with a flavored product.⁴
- Additionally, the study found that 97% of current youth e-cigarette users had used a flavored e-cigarette in the past month and 70.3% said they use e-cigarettes "because they come in flavors I like."⁴

Youth in NYS are using menthol flavored e-cigarettes at high rates that are increasing.

- A recently conducted Spring 2019 survey of 15- to 17-year-old e-cigarette users in NYS found their preference for menthol or mint flavored e-cigarettes was 34.1%, second only to fruit flavors (51.8%).⁵ (*Note: this is a new analysis received last week*)
- Adolescent vapers' preference for menthol or mint increased from 19.9% in 2017 to 34.1% in 2019, a statistically significant difference.⁵
- When asked, "How harmful to your health do you think menthol or mint flavors of e-liquids are," alarmingly, nearly half of the youth (47.8%) believed menthol flavored e-liquid was less harmful than tobacco flavored e-liquid.⁵
- Among adolescent vapers in Spring 2019, 80% report using Juul products even though Juul stopped selling flavored pods in most retail stores in November 2018; Juul continues to sell menthol-flavored pods in stores.⁵

Studies confirm menthol flavoring in e-liquids is harmful to health.

- In a study performed at the Stanford University School of Medicine, scientists found that menthol and cinnamon flavored e-liquids, specifically, caused the most damage to endothelial cells (the cells that line the interior of blood vessels). Some of the effects of the e-liquid flavors were independent of the nicotine concentration. Researchers concluded that flavoring liquid used in e-cigarettes may increase the risk of heart disease.⁶
- In a study at the Duke University School of Medicine, high levels of a carcinogenic oil banned in the U.S. as a food additive were found in samples of menthol-flavored e-cigarette liquids and smokeless tobacco products. Concentrations of the additive pulegone were 100 to more than 1,000 times higher than the concentrations considered safe for ingested food products by the FDA.⁷

There is inadequate evidence to support menthol vaping products for smoking cessation.

- There are important lessons that we can learn from decades of experience and research on menthol in combustible tobacco. This research has shown that menthol products are easier to start and harder to quit.⁸
- The Department could not find adequate evidence to support the effectiveness of menthol e-cigarettes as a cessation strategy for smokers of menthol cigarettes. And, given the evidence pointing to serious health concerns related to the menthol flavoring in e-cigarettes, smoking cessation recommendations should continue to focus on the seven FDA-approved medications.
- According to the January 2018 National Academies of Sciences, Engineering and Medicine, *Consensus Study Report on the Public Health Consequence of E-Cigarettes*, there is insufficient evidence from randomized controlled trials about the effectiveness of e-cigarettes as cessation aids compared with no treatment or to FDA-approved smoking cessation treatments.⁹
- A more recent literature review (June 2019) concluded that “even under well-controlled conditions, when offered e-cigarettes with supportive counseling, 82% of smokers do not switch to e-cigarettes, that is, they switch back and forth between tobacco products rather than achieve nicotine abstinence.”¹⁰ In fact, a spokesperson for Juul was recently quoted in the Wall Street Journal on 9/18/19 confirming this: “We are a switching product - our product contains nicotine and is intended to switch adult smokers from one nicotine delivery system to another - not a cessation product and that is clear in all of our marketing and communications.”
- The Department encourages all individuals to look into coaching options and talk with their health care providers about alternative cessation options.

Youth who use e-cigarettes are at increased risk for starting to smoke, and continuing to smoke, combustible cigarettes.

- E-cigarette use does not prevent youth from smoking combustible tobacco.
- The National Academy of Science, Engineering, and Medicine (NASEM) report, *Public Health Consequences of E-Cigarettes*, concluded that there is:
 1. “...**substantial evidence** that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults,” and
 2. “...**moderate evidence** that e-cigarette use increases the frequency and intensity of subsequent combustible tobacco cigarette smoking” among youth and young adults.⁹

Recommendation

Including menthol in the emergency regulation will send a strong message that menthol flavored e-cigarettes are anything but safe or acceptable for use by anyone in our state. I recommend that the Department proceed to expand the current ban to include menthol at the next meeting of the Public Health and Health Planning Council on October 10, 2019.

References:

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