AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Norman E. Sharpless, MD
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to recommend that the U.S. Food and Drug Administration (FDA) include a comprehensive list of ingredients and nicotine contents on applicable packaging for e-cigarette components, which include, but are not limited to, e-cartridges, e-liquid vials, and e-liquid refills.

The AMA has comprehensive policy supporting further clinical and epidemiological research on e-cigarettes, efforts to deter youth use of electronic nicotine delivery systems (ENDS), and the extension of FDA's regulatory jurisdiction to electronic cigarettes, cigars and other tobacco products not previously included in the Federal Food, Drug, and Cosmetic Act. The rising utilization of e-cigarettes, particularly by the youth population, is of great concern and recently resulted in a Public Health Advisory by the U.S. Surgeon General.[1] In 2018, it was estimated that more than 3.6 million U.S. youth, including 1 in 5 high school students and 1 in 20 middle school students, currently use e-cigarettes. Evidence suggests that these products not only contain nicotine, the addictive drug present in combustible cigarettes, but also release formaldehyde, ethylene glycol, diacetyl and acetyl propionyl, and other substances that may be associated with respiratory illness.[2] Nicotine exposure during adolescence has also been associated with negative impacts on neurocognitive development and can result in an increased risk for future addiction to combustible cigarettes and other drugs.[3]

In accordance with the FDA's Final Rule[4] released in May 2016, e-cigarettes and other ENDS are required to include advertising and package warnings that display information regarding potential addictiveness and harm to overall health. However, the regulation did not require disclosures related to nicotine content and product ingredients. Even when nicotine content on e-cigarette labels is included, it may not accurately reflect the amount inhaled during vaping, a finding that has previously been recognized by the agency during the rulemaking process.[5] Future research efforts seeking to elucidate the public health implications and smoking cessation potential of e-cigarettes rely on the ability to collect and assess data for both nicotine content and ingredient composition. Therefore, we strongly encourage the

[1] https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf
[2] https://www.nejm.org/doi/10.1056/NEJMra1502466
[3] https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf
[4] https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the
[5] http://gestor.papsf.cat/_Adm3/upload/docs/ITEMDOC_3818.pdf

FDA to issue tobacco product manufacturing practice regulations for e-cigarettes, in order to mitigate potential adverse health consequences in the setting of globally increased usage of such products, and their related components.

Thank you for considering the AMA's views. If you have any questions, please contact Shannon Curtis, Assistant Director, Federal Affairs, at shannon.curtis@ama-assn.org or 202-789-8510.

Sincerely,

James L. Madara, MD