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October 4, 2019

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

Re: Docket No. FDA-2012-N-0143, "Harmful and Potentially Harmful Constituents in Tobacco Products; Established List; Proposed Additions; Request for Comments," 84 Fed. Reg. 38032 (August 5, 2019)

Our organizations submit these comments in the above-designated docket concerning FDA's proposed changes to the harmful and potentially harmful constituents (HPHC) list. The reporting of this information is a fundamental requirement for the effective performance of FDA's statutory responsibilities.

Section 904(e) of the Tobacco Control Act requires FDA to establish and periodically revise as appropriate a list of harmful and potentially harmful constituents and requires tobacco product manufacturers to report the content of such constituents in their cigarettes to FDA. As such, FDA has designated 96 constituents in cigarettes and smokeless tobacco as harmful or potentially harmful. Since FDA established the HPHC list, FDA's tobacco product authorities have been extended to include other tobacco products, including electronic nicotine delivery systems (ENDS). Consistent with Section 904 of the Tobacco Control Act, FDA is considering revising the HPHC established list to reflect the current range of tobacco products now under the Agency's jurisdiction.

We support revising the HPHC established list to include HPHCs in all of the tobacco products regulated by FDA, including e-cigarettes. Without current and accurate information about the level of these substances in e-cigarettes, FDA cannot meet its statutory responsibilities.

The process of aerosolization creates chemical constituents beyond the ingredients initially found in the e-liquid. Thus, it is difficult for consumers to know what chemicals are actually present in e-cigarette products. A report from the National Academies of Sciences, Engineering, and Medicine found conclusive evidence that "in addition to nicotine, most e-cigarette products contain and emit numerous potentially toxic substances."¹

It is critical that FDA continue to monitor these products and keep the HPHC list accurate, complete and up to date. Having current and accurate information about the levels of these constituents in tobacco products is essential for FDA to exercise its jurisdiction effectively. This information is critically important to FDA in determining whether to grant applications to market tobacco products, in evaluating applications for modified risk tobacco products and in the establishment of product standards.

In addition, we agree with FDA's initial conclusion that constituents identified by the National Institute for Occupational Safety and Health (NIOSH) as having adverse respiratory effects should be another criterion used to determine if a constituent should be included on the HPHC established list. When

aerosolized, humectants in e-cigarettes (mostly propylene glycol and glycerol) emit extremely high levels of fine particles into the respiratory system.² Many years ago, researchers raised concerns that the chemicals found in some e-cigarettes and e-liquids could cause respiratory damage when the e-cigarette aerosol is inhaled deeply into the lungs, even though some of the chemicals may generally be recognized as safe by FDA for ingestion.³ The Surgeon General's Report in 2016 noted that some of the flavoring chemicals found in e-cigarettes have been shown to cause serious lung disease when inhaled.⁴ FDA officials also recognized that aerosol exposure is "a major health concern" because the aerosol particles can penetrate deeply into the respiratory system. According to FDA, "That means some of the toxic chemicals and other substances contained in e-cig aerosols have the potential to go deep into the lungs and may pose risk for diseases not usually seen in smokers."⁵ This criterion is particularly important in light of the recent reports of serious respiratory illnesses and deaths associated with e-cigarette use.

There is still much to learn about these newer tobacco products and we understand that FDA is continuing to develop its scientific expertise with respect to these products. As such, it is important for FDA to continue to assess the appropriateness of the criteria used to determine whether a chemical or chemical compound is an HPHC and if additional or different criteria are needed. Further, it is important for FDA to continue to review other disease outcomes and assess if additional constituents should be added to the HPHC list.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

¹ National Academies of Sciences, Engineering, and Medicine (NASEM), *Public Health Consequences of E-Cigarettes*, Washington, DC: The National Academies Press, 2018, doi: <https://doi.org/10.17226/24952>.

² National Academies of Sciences, Engineering, and Medicine (NASEM), *Public Health Consequences of E-Cigarettes*, Washington, DC: The National Academies Press, 2018, doi: <https://doi.org/10.17226/24952>.

³ Barrington-Trimis, JL, Samet, JM, & McConnell, R, "Flavorings in Electronic Cigarettes: An Unrecognized Respiratory Health Hazard?" *The Journal of the American Medical Association*, doi:10.1001/jama.2014.14830, published online November 10, 2014.

⁴ HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

⁵ FDA, Gottlieb, S. and Abernethy, A., "Understanding the Health Impact and Dangers of Smoke and 'Vapor,'" <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/understanding-health-impact-and-dangers-smoke-and-vapor>. Accessed September 25, 2019.