



July 16, 2018

Scott Gottlieb, MD  
Commissioner  
Food and Drug Administration  
5630 Fishers Lane  
Rm. 1061  
Rockville, MD 20852

**Re: FDA-2017-N-6189, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes**

Dear Commissioner Gottlieb:

The American College of Physicians (ACP) is pleased to offer comments on the Tobacco Product Standard for Nicotine Level of Combusted Cigarettes advance notice of proposed rulemaking (ANPRM). ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 152,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

**ACP supports the Food and Drug Administration (FDA) using its authority under Section 907 of the Tobacco Control Act to issue a product standard to set the maximum nicotine level for tobacco products consistent with evidence that suggests that doing so would reduce the risk of addiction and protect public health.** Nicotine is a highly addictive substance. Evidence is sufficient to conclude that nicotine negatively affects maternal and fetal health and it may also have a lasting impact on adolescent brain development (i). Reducing nicotine levels to minimally addictive or non-addictive levels could have a profound public health benefit and “save millions of lives and tens-of-millions of life years over the next several decades” (ii). If an effective product standard is adopted, current tobacco users may lower the number of cigarettes smoked, limit nicotine exposure and dependence (iii) and be encouraged to engage in tobacco cessation. Young people, who are most likely to experiment with tobacco, could be less likely to start using tobacco and develop tobacco use disorder.

ACP provides the following comments regarding the issues raised in the ANPRM:

Scope: ACP strongly recommends that the nicotine tobacco product standard be extended to all tobacco products, including but not limited to, cigarettes (including kreteks and bidis), cigars (including little cigars, cigarillos and so-called premium cigars), cigarette tobacco, roll-your-own tobacco, pipe tobacco and waterpipe tobacco. No tobacco product is safe; however, many smokers believe that other tobacco products, such as cigars and smokeless tobacco products, are safe alternatives to cigarettes (iv). ACP strongly supports comprehensive efforts to reduce use of all tobacco products. If a maximum nicotine level is not set for other tobacco products, current users and those experimenting with tobacco could migrate to products with higher nicotine levels, furthering their nicotine addiction and undermining the intent of the product standard. By requiring all products to have the same nicotine level, the agency can prevent potential countervailing effects including dual use and product switching.

Countervailing Effects: The tobacco industry has attempted to market certain cigarettes as safer than others by applying filters, offering “low-tar” or “light” cigarettes, and promoting brands as having lower nicotine. However, a monograph of the National Cancer Institute (NCI) determined that cigarettes marketed as “low-tar,” “mild,” or “light” offer no health advantages over regular cigarettes. Smokers of such products often compensate by smoking more or adjusting their method of smoking, thereby exposing themselves to similar amounts of nicotine, tar, and other harmful compounds found in products with higher levels of nefarious substances. Some evidence shows that a gradual reduction in cigarette nicotine level does not result in compensatory smoking (v,vi). Since the product standard would represent a new policy implemented on a broad scale, ongoing surveillance is necessary to ensure that the product standard does not have unintended consequences such as compensatory smoking, dual use, or product switching, that undermine its intent. While it is unclear if tobacco users would add liquid nicotine to very low nicotine tobacco content products, it would be sensible to apply the maximum nicotine level product standard to existing or emerging products designed to supplement nicotine levels. One study found that after 12 months of using very low nicotine cigarettes, smokers who were not interested in quitting continued to have nicotine dependence, possibly because they may have supplemented their nicotine intake with higher nicotine cigarettes (vii). Although such products would presumably not exist under the product standard, the evidence suggests that migration to higher-nicotine products is possible.

Other considerations: Implementation of a maximum nicotine level must be part of a comprehensive effort to reduce tobacco use. ACP policy recommends that states and the federal government establish and adequately fund comprehensive tobacco control efforts to prevent smoking and other tobacco use; provide objective information about the dangers of cigarettes, cigar, pipe, smokeless, and other tobacco products; minimize exposure to secondhand smoke; and help tobacco users quit (viii). On the latter point, ACP specifically recommends that public and private insurers as well as state, community, and employer-based

entities provide effective tobacco cessation and treatment benefits, such as counseling and medication, to all qualifying individuals. This effort would include a public education campaign to explain why a maximum nicotine level is needed, provide information on smoking cessation resources, and prevent unintended consequences (ix). It is crucial that if a maximum nicotine level product standard is established, that tobacco users have easy access to FDA-approved, evidence-based tobacco cessation products and services.

Additionally, ACP strongly supports FDA regulation of electronic nicotine delivery systems (ENDS), also known as electronic cigarettes (x). ENDS use among young people has been designated a “public health concern” by the United States Surgeon General (xi) and substantial evidence shows that young people who use ENDS are more likely to ever use combustible cigarettes (xii). Recent evidence shows that electronic cigarette use among non-smokers increased over the 2014-2016 period, raising concern that non-smokers are being exposed to nicotine (xiii). Some people use ENDS as a way to quit smoking combustible cigarettes, but current evidence is insufficient to recommend ENDS for tobacco cessation in adults (xiv), and some people use both devices due to the addictive nature of nicotine. Therefore, we urge the FDA to reverse its decision to extend the compliance deadline for review of ENDS products until 2022.

ACP is encouraged by the ANPRM and urges the agency to issue a proposed rule on the tobacco product standard for nicotine level of tobacco products swiftly. If you have questions, please contact Ryan Crowley, Senior Associate for Health Policy at [rcrowley@acponline.org](mailto:rcrowley@acponline.org).

Sincerely,



Ana María López, MD, MPH, FACP  
President  
American College of Physicians

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<sup>i</sup> U.S. Department of Health and Human Services. *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*. Atlanta, GA: U. S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Printed with Corrections, January 2014.

<https://www.surgeongeneral.gov/library/reports/50-years-of-progress/sgr50-chap-5.pdf>

<sup>ii</sup> Apelberg AJ, Feirman SP, Salazar E, Corey CG, Ambrose BK, Paredes A, et al Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States. *N Engl J Med*. 2018; 378:1725-1733.

<https://www.nejm.org/doi/10.1056/NEJMSr1714617>

<sup>iii</sup> Donny EC, Denlinger RL, Tidey JW, Koopmeiners JS, Benowitz NL, Vandrey RG, et al. Randomized Trial of Reduced-Nicotine Standards for cigarettes. *N Engl J Med*. 2015;373:1340-1349.

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- <sup>iv</sup> O'Connor RJ et al. Smokers' beliefs about the relative safety of other tobacco products: Findings from the ITC Collaboration. *Nicotine & Tobacco Research*. 2007;9(10):1033-1042.
- <sup>v</sup> Benowitz NL, Hall SM, Stewart S, Wilson W, Dempsey D, and Jacob P 3<sup>rd</sup>. Nicotine and Carcinogen Exposure with Smoking of Progressively Reduced Nicotine Content Cigarette. *Cancer Epidemiol Biomarkers Prev*. 2007;16(11):2479-2485. <http://cebp.aacrjournals.org/content/16/11/2479.long>
- <sup>vi</sup> Benowitz N, Dains KM, Hall SM, Stewart S, Wilson M, Dempsey D, Jacob P 3<sup>rd</sup>. Smoking Behavior and Exposure to Tobacco Toxicants During 6 Months of Smoking Progressively Reduced Nicotine Content Cigarettes. *Cancer Epidemiol Biomarkers Prev*. 2012; 21(5):761-769. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3348427/>
- <sup>vii</sup> Benowitz NL, Nardone N, Dains KM, Hall SM, Dempsey D, Jacob P 3<sup>rd</sup>. Effect of Reducing the Nicotine Content of cigarettes on Cigarette Smoking Behavior and tobacco Smoke Toxicant Exposure: Two Year Follow Up. *Addiction*. 2015;110(10):1667-1675. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4565734/>
- <sup>viii</sup> American College of Physicians. Tobacco Control and Prevention. Philadelphia: American College of Physicians; 2010: Policy Monograph. [https://www.acponline.org/system/files/documents/advocacy/current\\_policy\\_papers/assets/control\\_tobacco.pdf](https://www.acponline.org/system/files/documents/advocacy/current_policy_papers/assets/control_tobacco.pdf)
- <sup>ix</sup> Benowitz NL and Henningfield JE. Reducing the nicotine content to make cigarettes less addictive. *Tob Control*. 2013;22(Suppl 1):i14-i17. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3632983/>
- <sup>x</sup> Crowley RA. Electronic Nicotine Delivery Systems: Executive Summary of a Policy Position Paper from the American College of Physicians. *Ann Intern Med*. 2015;162(8):583-584. <http://annals.org/aim/fullarticle/2275390/electronic-nicotine-delivery-systems-executive-summary-policy-position-paper-from>
- <sup>xi</sup> U.S. Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016. [https://e-cigarettes.surgeongeneral.gov/documents/2016\\_sgr\\_full\\_report\\_non-508.pdf](https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf)
- <sup>xii</sup> National Academies of Medicine. Public Health Consequences of E-Cigarettes. January 23, 2018. <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx>
- <sup>xiii</sup> Bao W, Guifeng X, Lu J, Snetselaar LG, Wallace RB. Changes in Electronic Cigarette Use Among Adults in the United States, 2014-2016. *JAMA*. 2018;319(19):2039.
- <sup>xiv</sup> Siu AL. Behavioral and Pharmacotherapy Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Women: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med*. 2015;163(8):622-634. <http://annals.org/aim/fullarticle/2443060/behavioral-pharmacotherapy-interventions-tobacco-smoking-cessation-adults-including-pregnant-women>