

August 8, 2014

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

Re: Docket No. FDA-2014-N-0189—Proposed Rule, Deeming Tobacco Products Subject to Regulation

To Whom It May Concern:

On behalf of our 157,000 members, we are pleased to comment on the proposed Food and Drug Administration (FDA) rule governing the regulation of nicotine delivery products it deems to be covered by the Family Smoking Prevention and Tobacco Control Act. We offer these comments in response to your Federal Register notice of April 25, 2014 (79 FR 23142).

Preventing oral cancer and other tobacco-related diseases has been a longstanding priority for the ADA. About 9 out of 10 people who die from oral (mouth) and pharyngeal (throat) cancers use tobacco, and the risk of developing these cancers is related to how much (and how often) they use.¹ On average, 40 percent of those with the disease will not survive more than 5 years.² Tobacco products are also causally associated with higher rates of gum disease, one of the leading causes of tooth loss in adults.³

As a matter of public health, dentists have become increasingly alarmed by recent attempts to market smokeless tobacco products as healthier (or less harmful) alternatives to cigarettes. There is currently not enough evidence—and certainly no scientific consensus—to support claims that smokeless tobacco products are safer than combustible tobacco products and will magically reduce the number of smokers.^{4,5} The vast body of credible, peer-reviewed science actually suggests that smokeless tobacco products may be a “gateway drug” that can lead users to a lifetime of cigarette smoking.^{6,7,8,9}

We are extremely pleased with the rule FDA has proposed. At a minimum, it would clarify the agency's authority to regulate products it deems to be made or derived from tobacco and intended for human consumption. It would also foster a science-based process for regulating the latest generation of nicotine delivery products, such as dissolvable tobacco, tobacco gels, hookah tobacco, electronic cigarettes, electronic cigarette cartridges, cigars, and pipe tobacco.

We applaud you for proposing a rule that would subject the latest generation of nicotine delivery products to regulation, and are pleased to offer our enthusiastic support. If you have any questions, please contact Mr. Robert J. Burns at 202-789-5176 or burnsr@ada.org.

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Sincerely,

/s/

Charles H. Norman, D.D.S.
President

/s/

Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director

CHN:KTO:rjb

¹ American Cancer Society, "Detailed Guide: Oral Cavity and Oropharyngeal Cancer (2007)," http://www.cancer.org/docroot/CRI/content/CRI_2_4_2X_What_are_the_risk_factors_for_oral_cavity_and_oropharyngeal_cancer_60.asp, Accessed September 25, 2009.

² National Institute for Dental and Craniofacial Research, "Oral cancer," <http://www.nidcr.nih.gov/OralHealth/Topics/OralCancer/OralCancer.htm>, Accessed September 25, 2009.

³ "The Health Consequences of Smoking: A Report of the Surgeon General", 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; Washington, D.C., 2004.

⁴ Richard H. Carmona, *Can Tobacco Cure Smoking? A Review of Tobacco Harm Reduction*, testimony before the Subcommittee on Commerce, Trade, and Consumer Protection of the House Committee on Energy and Commerce, 108th Cong., 1st sess., June 3, 2003.

⁵ The Clinical Practice Guideline Treating Tobacco Use and Dependence 2008 Update Panel, Liaisons, and Staff. A clinical practice guideline for treating tobacco use and dependence: 2008 update. A U.S. Public Health Service report. *Am J Prev Med* 35, no. 2 (2008): 158–176.

⁶ Institute for Social Research, The University of Michigan, "Monitoring the Future," <http://monitoringthefuture.org/pressreleases/00cigpr.pdf>.

⁷ American Academy of Pediatrics, "Things You Should Know about Smokeless Tobacco," <http://www.aap.org/advocacy/chmchew2.htm>.

⁸ CDC, "Is smokeless tobacco safer than cigarettes?" *SGR4Kids*, www.cdc.gov/tobacco/sgr/sgr4kids/smokless.htm.

⁹ H.H. Severson, K.K. Forrester, and A. Biglan, "Use of smokeless tobacco is a risk factor for cigarette smoking," *Nicotine Tob Res.* 2007 Dec; 9(12):1331-7.