

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: JLN 3

(A-17)

Introduced by: American Association of Public Health Physicians
Subject: **Urging FDA to Allow Designation of Smoking as a Behavior**
Referred to: Reference Committee ____

WHEREAS: For regulatory purposes, FDA currently considers smoking to be a disease, not a behavior;^{1,2} and

WHEREAS: This designation appears to be based on a marketing decision made by major pharmaceutical firms about 40 years ago to market their nicotine products as drugs rather than consumer products.

WHEREAS: Based on this designation, made within FDA and not specified in law, any claim by an e-cigarette or smokeless tobacco manufacturer or vendor that the product may be of value in helping smokers reduce cigarette consumption or quit smoking is considered a drug claim and currently requires that the product be pulled from the market until licensed as a drug;³ and

WHEREAS: Smokers who perceive smoking as a behavior have no interest in taking a drug to help stop smoking, but are willing to consider lower risk alternatives to cigarettes, and

WHEREAS: E-cigarettes are the only products demonstrated to recruit smokers not interested in quitting to quit smoking;⁴ and

WHEREAS: The first likely personal and public health benefit of e-cigarettes and smokeless tobacco products is to enable smokers who are unable or unwilling to quit to satisfy their urge to smoke while switching to a product that is far less hazardous and easier to quit than cigarettes;⁵ and

WHEREAS: The second major personal and public health benefit of e-cigarettes and smokeless tobacco products is to divert teens who otherwise would have become smokers to a product that is far less hazardous and easier to quit than cigarettes;⁵ and

WHEREAS: Compelling evidence suggests that the availability of e-cigarettes and related vapor products may be playing a significant role in helping to reduce the prevalence of smoking among both teens and adults in recent years;^{6,7} and

WHEREAS: While many non-smoking teens experiment with e-cigarettes, very few continue e-cigarette use on a regular basis, and even fewer transition from consistent use of e-cigarettes to smoking;^{6,7} and

WHEREAS: The FDA Center for Tobacco Products (CTP) has proceeded with both its research and regulatory regimens on the presumption that there can be no personal or public health benefit to any tobacco-related product not licensed as a drug, thus denying manufacturers and vendors of e-cigarettes, related vapor products, and smokeless products from marketing their products as alternatives to cigarettes;¹ and

WHEREAS: for FDA to allow e-cigarettes and smokeless products to claim benefits for smoking reduction and cessation without being licensed as drugs, FDA will need to recognize the possibility that smoking, at least for some smokers, might be a behavior, not a disease,

THEREFORE, BE IT RESOLVED that our AMA urge FDA to allow manufacturers to decide whether their products shall be licensed as a drug or as a consumer product to be marketed as a relatively low risk alternative to cigarettes.

Fiscal Note: not yet determined

Received:

References:

1. Ashley DL, Backinger CL, van Bommel DM, Neveleff DJ. Tobacco regulatory science: Research to inform regulatory action at the Food and Drug Administration's Center for Tobacco Products. *Nicotine & Tobacco Research*. 2014;16(8) (August):1045-1049.
2. Ashley DL. How science informs FDA's regulatory decisions: Deeming, PMTA and MRTPA. In: *Special Symposium*. Chicago, Ill. 2/March; 2016. Society for Research on Nicotine and Tobacco, 2016 Program.
3. Food and Drug Administration. Clarification of when products made or derived from tobacco are regulated as drugs, devices, or combination products; amendments to regulations regarding "intended uses"; further delayed effective date; request for comments. In: *A Rule by the Food and Drug Administration*. 82 Federal Register pages 2193 to 2217. March 20; 2017. March 24, 2017.
4. Polosa Rea. Effect of an electronic nicotine delivery device (e-cigarette) on smoking reduction and cessation: A prospective 6-month pilot study. *BMC Public Health*. 2011;11(11) (11 October):786.
5. Nitzkin JL. The case in favor of e-cigarettes for tobacco harm reduction. *International Journal of Environmental Research and Public Health*. 2014;11:6459-6471.
6. Monitoring The Future Survey. Overview of Findings 2015. National Institute of Drug Abuse. December; 2016. 17 July 2016.
7. McNeill A, Brose L, Calder R, Hitchman S. E-cigarettes: An evidence update. A report commissioned by Public Health England. London, England. August; 2015. A an Evidence Update Plus Policy Implications; vol. Public Health England. 19 August 2015.

RELEVANT AMA POLICY

JLN Note: AMA has no standing policies as to whether smoking should be regulated as a disease or a behavior and no standing policies as to when a tobacco-related product should be regulated as a drug or as a tobacco product.