

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: JLN 2

(A-17)

Introduced by: American Association of Public Health Physicians

Subject: **Regulation of E-cigarettes and Related Vapor Products**

Referred to: Reference Committee ____

WHEREAS: Recently promulgated FDA Deeming Regulations require that every e-cigarette and related vapor (e-cig) product now on the market submit a Premarket Tobacco Product Application (PMTA) by November 2018 or be removed from the market;^{1,2} and

WHEREAS: FDA estimates the cost of each such application to be approximately \$350,000, plus costs of mandated research, with a separate application required for each combination of a device, flavor and strength of nicotine;^{1,3} and

WHEREAS: This cost will be sufficient to drive all e-cig-related small and medium sized businesses from the market due to the inability to bear such a cost; and

WHEREAS: FDA has stated as a goal of these regulations their intent to sharply reduce the number of e-cig manufacturers;^{1,3}

WHEREAS: FDA has not, to date, offered any clarification as to what research findings would be acceptable for FDA approval of any given product, and has not promulgated any manufacturing or safety guidelines;³ and

WHEREAS: FDA, by specifying that any modification of a current e-cig product would require that the product be immediately removed from the market, pending approval of a PMTA application,³ has prohibited e-cig manufacturers from taking steps that would enhance the battery-related safety aspects of their products, and

WHEREAS: Cigarettes, the most addictive and most hazardous of tobacco-related products bear no such regulatory burden;^{4,5} and

WHEREAS: The Surgeon General has estimated that e-cig product present no more than 5% the risk of potentially fatal tobacco-related illness than cigarettes;⁶ and

WHEREAS: Data currently available from multiple sources suggest the possibility that recently accelerated reductions in smoking prevalence in teens may be due to availability of e-cig products;⁷ and

WHEREAS: Elimination of the PMTA requirement, at least for e-cig products currently on the market would enable FDA to immediately begin to regulate manufacturing and marketing of these products, should FDA opt to do so.

THEREFORE, BE IT RESOLVED That our AMA urge Congress to adopt legislation that would:

1. Eliminate the PMTA requirement for currently marketed e-cig products

2. Allow modifications to improve battery safety without requiring immediate removal of the product from the market or imposing a PMTA requirement for the modified product.
3. Require FDA to immediately proceed to specify the research requirements and findings that would be sufficient for acceptance of a PMTA application on a newly proposed e-cig product
4. Immediately proceed to develop manufacturing, safety and marketing regulatory guidelines for e-cig products.
5. Allow e-cig products to claim less risk than cigarettes without requiring a separate Modified Risk Tobacco Product (MRTP) application for each e-cig product.
6. Re-align the regulatory burdens placed on each class of tobacco-related product so that the most hazardous and most addictive products bear the greatest regulatory burden.

Fiscal Note: not yet determined

Received:

References:

1. Food and Drug Administration. Final Rule: Deeming Tobacco Products To Be Subject to the Federal Food, Drug and Cosmetic Act, As Amended by the Family Smoking Prevention and Tobacco Control Act. In: *21 CFR Parts 1100, 1140 and 1143; Docket No. FDA-2014-N-0189; RIN 0910-AG38*. May 10; 2016. Deeming Regulations - E-Cigarettes and Cigars. May 10, 2016.
2. Tobias L, Lindsay.Tobias@fda.hhs.gov. . May 1; 2017. extends compliance deadlines three months to enable new administration to address issues raised by multiple lawsuits in federal court.
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. Waxman HA, <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm262084.htm>. Family Smoking Prevention and Tobacco Control Act. Public Law 111-31, 111th Congress. Washington DC: Library of Congress; 2009. Text of Legislation. 29 September 2010.
5. Fagerstrom K. Dependence on tobacco and nicotine. In: *Nicotine Science and Policy*. 14/Dec; 2013. 2Jan2014.
6. A Report of the Surgeon General. *E-Cigarette Use Among Youth and Young Adults*. Washington, DC: U.S. Department of Health and Human Services; 2016.
7. Johnston L, Miech R, O'Malley P, Bachman J, Schulenberg J. Table 2. Trends in prevalence of use of cigarettes in grades 8, 10 and 12. University of Michigan. December 13; 2016. February 4, 2017.

RELEVANT AMA POLICY

FDA to Extend Regulatory Jurisdiction Over All Non-Pharmaceutical Nicotine and Tobacco Products H-495.973

Topic: Tobacco Products

Policy Subtopic: NA

Meeting Type: Annual

Year Last Modified: 2016

Action: Reaffirmation

Type: Health Policies

Council & Committees: NA

Our AMA: (1) supports the U.S. Food and Drug Administration's (FDA) proposed rule that would implement its deeming authority allowing the agency to extend FDA regulation of tobacco products to pipes, cigars, hookahs, e-cigarettes and all other non-pharmaceutical tobacco/nicotine products not currently covered by the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act; and (2) supports legislation and/or regulation of electronic cigarettes and all other non-pharmaceutical tobacco/nicotine products that: (a) establishes a minimum legal purchasing age of 18; (b) prohibits use in all places that tobacco cigarette use is prohibited, including in hospitals and other places in which health care is delivered; (c) applies the same marketing and sales restrictions that are applied to tobacco cigarettes, including prohibitions on television advertising, product placement in television and films, and the use of celebrity spokespeople; (d) prohibits product claims of reduced risk or effectiveness as tobacco cessation tools, until such time that credible evidence is available, evaluated, and supported by the FDA; (e) requires the use of secure, child- and tamper-proof packaging and design, and safety labeling on containers of replacement fluids (e-liquids) used in e-cigarettes; (f) establishes manufacturing and product (including e-liquids) standards for identity, strength, purity, packaging, and labeling with instructions and contraindications for use; (g) requires transparency and disclosure concerning product design, contents, and emissions; and (h) prohibits the use of characterizing flavors that may enhance the appeal of such products to youth.

JLN Note on AMA Policy: AMA endorses extension of FDA authority over e-cigarettes and related vapor products, but has no standing policies dealing with the Premarket (PMTA) or Modified Risk (MRTP) application processes