

U.S. Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm. 1061
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Aug. 31, 2015

The Association of State and Territorial Health Officials (ASTHO) thanks FDA for the opportunity to provide comments regarding the Advanced Notice of Proposed Rulemaking for nicotine exposure warnings and child-resistant packaging for liquid nicotine, nicotine-containing e-liquids, and emerging tobacco products including dissolvable products, lotions, gels, and drinks. ASTHO strongly supports child-resistant packaging and proper warning labels for tobacco products sold in the United States, including e-cigarette liquid containers, dissolvable products, lotions, and gels, in order to prevent injuries and deaths from accidental nicotine poisoning.

ASTHO is the national nonprofit organization representing public health agencies in the United States, the U.S. Territories, and the District of Columbia. Our members, the chief health officials of these jurisdictions, formulate and influence sound public health policy and ensure excellence in state-based public health practice. ASTHO members and our key public health partners and 20 affiliate organizations represent public health leaders across state, territorial, and local health departments. ASTHO serves as a resource to state health agencies and national and federal partners on public health perspectives, capacities, challenges, and opportunities to implement state-based prevention initiatives.

ASTHO's Tobacco Prevention and Control project provides support to state public health agencies as they develop policies that encourage healthy environments and reduce tobacco use and tobacco related mortality. ASTHO supports FDA's implementation of the Family Smoking Prevention and Tobacco Control Act and values FDA's authority to regulate tobacco product manufacturing, labeling, distribution, and sale. ASTHO also supports policies that improve the health of women, children, and families and limit children's access to harmful substances like nicotine and tobacco smoke. Comprehensive interventions to prevent unintentional injuries and promote safe and healthy homes, including secured storage for poisons, is critical for children's health and safety.

Achieving health equity nationwide requires valuing everyone equally with focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health disparities.¹ The lack of warning labels and child-resistant packaging on emerging tobacco products contributes to health inequity because it puts vulnerable populations like pregnant women and children at risk. ASTHO urges FDA to use its authority to warn the public about the dangers of nicotine poisoning through labeling and to require tobacco products be sold in child-resistant packaging.

Tobacco use remains the leading preventable cause of death in the United States, accounting for approximately 480,000 deaths annually.² Tobacco use also results in \$157 billion in direct and indirect medical costs each year.³ CDC reports that between 2011 and 2013 smoking prevalence among adults in the United States decreased in 26 states.⁴ However, the use of emerging tobacco products like e-cigarettes is on the rise: U.S. adults who have ever used e-cigarettes increased from 3.3 percent in 2010

to 8.5 percent in 2013.⁵ Although the United States has made progress in reducing tobacco use and tobacco related mortality, the lack of regulation for emerging products such as e-cigarettes and liquid nicotine packages threatens to undermine the progress the public health community has made on tobacco control.

More adolescents are using e-cigarettes as youth-targeted advertisements and colorful packaging have made the devices appealing to minors.⁶ In addition, e-cigarette liquid nicotine is offered in more than 7,000 flavors, such as gummy bear, strawberry, and chocolate, making e-cigarette liquid packages attractive to both young children and adolescents.⁷ Moreover, e-cigarettes are advertised using celebrities and at youth based sport and music events.⁸ E-cigarette use among high school students increased from 660,000 students in 2013 to 2 million students in 2014, and use among middle school students increased from 120,000 students in 2013 to 450,000 students in 2014.⁹

Liquid nicotine poisoning is an emerging public health issue given that liquid nicotine containers are appealing to youth and are not required to be sold with child-resistant packaging. Nicotine is an acute toxin that can cause nausea, vomiting, bradycardia, trouble breathing, and death when swallowed or absorbed through the skin.¹⁰ Some e-cigarette liquid manufactures report nicotine concentrations up to 5.4 percent.¹¹ Just a teaspoon of 1.8 percent nicotine liquid can be fatal, even for an individual weighing 200 pounds.¹² The American Association of Poison Control Centers (AAPCC) reported 3,783 liquid nicotine poisoning cases in 2014, an increase of approximately 1,300 percent since 2011, when there were 271 reported cases.¹³ According to AAPCC, more than half of these liquid nicotine exposures involved children under the age of 6.¹⁴

The growing body of evidence about the dangers of nicotine products warrants providing pregnant women and adolescents with warnings about using smokeless tobacco and dissolvable and e-cigarette products.¹⁵ Safety requirements for products containing liquid nicotine have the potential to prevent accidental liquid nicotine poisoning. Children and pregnant women are particularly vulnerable to nicotine because even in small concentrations nicotine exposure during developmental years impairs brain and lung development.¹⁶ Effective labeling policies should require products to display safety warnings, nicotine concentration, and an ingredient list.¹⁷

In addition, child-resistant packaging could protect children from accidentally ingesting liquid nicotine. A legislative approach to prevent e-cigarette liquid poisoning would require that liquid nicotine is sold in child-resistant packages, as set forth by the Poison Prevention Packaging Act.¹⁸ Child-resistant packaging is defined as a container that is difficult for children under five to open, given a reasonable amount of time, but not difficult for a normal adult to use.¹⁹ These packaging standards are used for household packages that contain toxic substances, and are applicable to liquid nicotine containers.²⁰ Several states have already implemented child-resistant standards for liquid nicotine containers, including Minnesota, Vermont, Virginia and North Carolina.²¹ Virginia legislature recently approved a bill requiring that liquid nicotine is sold in child-resistant packaging that includes warning labels stating that containers must be kept out of children's reach.²²

ASTHO strongly supports comprehensive policy approaches requiring that tobacco products, including e-cigarette liquid containers, dissolvable products, lotions, and gels, are sold in child-resistant packaging

and contain proper warning labels. Comprehensive policies that include both warning labels and child-resistant packaging are necessary to prevent e-liquid poisoning. Comprehensive tobacco control programs that combine regulatory, clinical, and educational strategies have been shown to reduce smoking rates and tobacco related mortality. FDA's ability to assert jurisdiction over emerging tobacco products will improve the health of the nation, and prevent accidental nicotine poisoning.

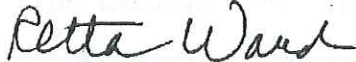
Sincerely,



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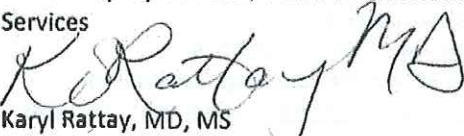
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