



August 13, 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

To Whom It May Concern:

The National Physicians Alliance (NPA) welcomes this opportunity to comment on the U.S. Food and Drug Administration's (FDA) proposed rules to extend its authority to regulate electronic cigarettes under the Tobacco Control Act. The NPA is a multispecialty physician organization that works to increase engagement of physicians in their communities to improve health. These comments were prepared by the NPA's FDA Task Force.

The NPA supports the FDA proposal to extend its regulatory authority to other tobacco products, especially electronic cigarettes (e-cigs). E-cigs have rapidly expanded into a \$1-2 billion annual industry with the potential to grow far larger. Of significant concern is the impact the increasing size of the industry may have on children and adolescents.

The potential for e-cigs to be a bridge product for other tobacco use is of immense concern. The CDC has released data indicating that the percentage of high school students who have ever used e-cigarettes increased from 4.7 to 10 between 2011 and 2012.¹ A recent study published in the *Journal of the American Medical Association Pediatrics* demonstrated that adolescents who used e-cigs were more likely to use traditional cigarettes.² In addition to restricting sales to minors, the FDA should use its authority to regulate marketing to children. Also, it is unclear whether or not these devices can be used to vaporize other illegal drugs with minor modifications to the device. This could pose another significant public burden as this unique delivery system could be created.

1. Notes from the Field: Electronic Cigarette Use Among Middle and High School Students — United States, 2011–2012. *Morbidity and Mortality Weekly Report*. 2013. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm>. Accessed August 11, 2014.

2. Dutra LM, Glantz SA. Electronic cigarettes and conventional cigarette use among us adolescents: A cross-sectional study. *JAMA Pediatr*. 2014;168(7):610-617. doi:10.1001/jamapediatrics.2013.5488.

Moreover, the variety of flavors in e-cigarettes are alarming given the increasing reports of nicotine poisoning being reported to poison control centers. These flavors can be especially appealing to youth. The FDA should regulate flavors in e-cigarettes as it has traditional cigarettes. Furthermore, e-cigarettes have been marketed extensively as products that seek to replace cigarette use but yet mimic cigarettes in many ways from the shape, the light at the end, and the vapor emitted. As a result, e-cigarettes as a whole should be regulated as cigarettes.

The Tobacco Control Act prohibits manufacturers of products to claim that they have a lower risk of tobacco related disease or illness unless these claims have been substantiated by the FDA. The NPA believes it is essential that the FDA use the modified risk provisions especially because these devices have been marketed as tobacco cessation tools or devices. These modified risk provisions can help protect the public from adverse consequences that misleading health claims provide. In addition, there is no medical justification that would allow these devices to be marketed as a premium cigar. Any exemption of these products would be contrary to the public health. It is clearly evident by recent CDC reports that smoking cigars have increased at an exponential rate in teenage boys. It would be prudent that the FDA not allow any lag in regulation of these e-cigs as has happened with premium cigars.

The NPA supports the inclusion of all ingredients and the reporting of any possible harmful constituents. The components of e-cigs remain unregulated and the compositions of vapors have not been delineated. While further research is needed, precautions must be taken to ensure safety. Including health warnings are an essential part of this process.

The NPA believes that the FDA should proceed forward to implement the proposed rule in order to protect the people of the United States from the dangers of electronic-cigarettes and other tobacco products. In addition, we would like the rule to be strengthened by adopting the recommendations above.

Respectfully,



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