

## **Recent Research, some conducted by the FDA, Reinforces Need for Regulation of ALL Tobacco Products to Protect Health**

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Two recent supplements to peer-reviewed journals have provided additional support for the need for the FDA to regulate all tobacco products, including e-cigarettes. The August 2014 supplement in the *American Journal of Preventive Medicine* that was entirely devoted to publishing research conducted by or with FDA scientists, revealed high levels of use of both conventional and nonconventional tobacco products among youth in the U.S., including e-cigarettes and cigars. Likewise, the July 2014 *Tobacco Control* supplement showed high levels of exposure to e-cigarettes in the media. This recent evidence supports the need for the FDA to provide improved warning labels for all tobacco products; regulate all types of cigars as addictive products that endanger the health of youth; and regulate the advertising, product design, and sales of all tobacco products, including e-cigarettes.

### **Samples for supplements**

The *AJPM* supplement uses data from the National Youth Tobacco Survey (NYTS), a questionnaire administered annually to a nationally representative sample of middle and high school students in the US. The *Tobacco Control* supplement contains information gathered by the National Cancer Institute State and Community Tobacco Control Research Initiative (SCTC) from a number of data sources.

### **Cigar use is increasing rapidly among youth and was likely underestimated in the past**

In 2012, 21.2% of middle and high school students had ever smoked cigars, 8.4% were current cigar smokers in 2012, and even higher prevalence was observed among ethnic and racial minorities.<sup>1</sup> Ever cigar use increased among high school students between 2011 and 2012.<sup>1</sup> ***By failing to regulate all cigars, the FDA would be contributing to high levels of cigar use among youth.***

### **Conventional and nonconventional tobacco product use (especially dual use with cigarettes) is rapidly increasing among youth**

Wang et al<sup>2</sup> found high levels of dual use of conventional and nonconventional tobacco products among youth in the NYTS. Apelberg et al<sup>3</sup> found that use of more than one type of tobacco product (polytobacco use) was associated with tobacco dependence among adolescents in the NYTS. ***It is therefore very important that the FDA regulate all tobacco products,***

*including e-cigarettes, to help decrease levels of polytobacco product use and thereby decrease the risk for nicotine dependence among youth.*

### **Youth who perceive tobacco products as being lower risk are more likely to use them**

Most middle and high school students in the 2012 NYTS sample believed that lower frequency and intensity of smoking yielded lower risks of negative health effects from smoking.<sup>4</sup> Youth who perceived such a continuum of harm to exist for cigarettes were also more likely to perceive e-cigarettes as less harmful, suggesting high levels of susceptibility to e-cigarette use among youth. Because e-cigarette use exposes youth to nicotine and is highly associated with current smoking,<sup>5</sup> the FDA must regulate both cigarettes and e-cigarettes to protect youth from nicotine addiction.

### **Current warning labels are ineffective for youth**

Johnson et al<sup>6</sup> found that current warning labels are not effective for adolescents, less than one third of whom said these labels made them think “a lot” about the health risks of tobacco products.<sup>6</sup> *These results highlight the importance of the FDA substantially improving the proposed warning labels to use stronger and more direct language.*

### **Advertising exposure increases curiosity about tobacco products among youth**

Portnoy et al<sup>7</sup> found that adolescents exposed to higher levels of tobacco marketing had higher levels of curiosity about using cigarettes, cigars and smokeless tobacco. Curiosity about one type of tobacco product was strongly associated with higher levels of curiosity about other products. High levels of curiosity are linked to a higher risk of tobacco product use among adolescents.<sup>8-9</sup>

### **E-cigarette advertising uses media channels frequented by youth**

Duke et al<sup>10</sup> confirmed that increased spending on TV advertising by e-cigarette companies has resulted in higher exposure of adolescents (12 to 17 years old) and young adults (18 to 24 years old) to e-cigarette TV ads in the U.S. Between 2012 and 2013, e-cigarette ads appeared on several TV programs that were rated among the top 100 youth programs for that year.

E-cigarette advertising is also prevalent on other media formats frequented by youth, such as the internet and social media sites such as Twitter. Huang et al<sup>11</sup> found that over 73,000 tweets posted by 23,700 separate users mentioned e-cigarettes between May 1 and June 30 of 2012. 89.7% of these tweets were commercial (as opposed to organic). Although data on users under 18 is scarce, 26% of internet users 18 to 29 years old are members of Twitter- nearly double the percentage of users between 30 and 49.<sup>12</sup>

Emery et al's<sup>13</sup> analysis of over 17,500 adults ages 18 and older suggest that much of the exposure to e-cigarette advertising is not sought out by the user. While only 5% of participants had searched for information on e-cigarettes online and through other avenues, over 50% had been exposed to e-cigarette ads on TV, radio, in print or online between February and March of 2013, and 66% of those who had been exposed were exposed through TV.

The advertising techniques currently used by e-cigarette companies are increasing interest in trying e-cigarettes among adults.<sup>14</sup> Ads that emphasize the differences between e-cigarettes and cigarettes are particularly effective, especially those that advertise e-cigarettes as healthier than cigarettes, less expensive, or helpful to quit smoking.

***The FDA should prohibit advertising and promotion that claims or implies that e-cigarettes are safer than cigarettes or effective smoking cessation devices until manufacturers submit convincing evidence to the FDA that these claims are true.***

### **The number of brands and flavors of e-cigarettes is increasing**

The number of brands of e-cigarettes is also skyrocketing, and along with them, the number of flavors that are available for e-cigarette liquid.<sup>15</sup> In January of 2014, there were 466 brands, and in the 17 months prior, an average of 10.5 new brands per month. Newer brands (released between May 2012 and January 2014) had a significantly higher mean number of flavors than older brands (pre-May 2012). Newer brands were more likely to sell e-liquid separately, which may increase risk of accidental exposure to nicotine liquid, which can be life threatening. In addition, flavors particularly appeal to youth.

***This information adds to the case for the FDA acting to prohibit flavors in e-cigarettes as part of the current rulemaking process.***

### **The FDA has a responsibility to regulate all tobacco products (including e-cigarettes) in order to protect the health of youth**

The Family Smoking Prevention and Tobacco Control Act (FSPTCA) gives the FDA the authority to regulate tobacco products in order to protect public health.<sup>3</sup> Therefore, the FDA also bears the responsibility of protecting the public (especially adolescents) from products such as e-cigarettes that may lead them to initiate the use of other tobacco products. By failing to regulate certain types of products, such as premium cigars and e-cigarettes, the FDA would be undermining their own efforts to prevent and promote cessation of tobacco products, such as the "Real Cost" campaign, because the use of these products is associated with the use of other tobacco products. The FDA needs to act quickly and surely to protect the nation's youth. If the FDA's efforts to regulate existing and new and emerging products continue at the current pace, they may have little effect on prevalence of use among adolescents.<sup>16</sup>

## Overall Conclusions

Youth are using many types of tobacco products at high levels, making it necessary to regulate all products, including all cigars and e-cigarettes. Both youth and adults are being exposed to high levels of e-cigarette advertising. *The FDA should use its authority under the FSPTCA to extend the current advertising prohibitions in place for cigarettes to e-cigarettes and all newly covered products.*<sup>1</sup>

**The FDA should take the following actions as a result of the information in this comment:**

1. Apply all of the same advertising restrictions to all tobacco products (including e-cigarettes and premium cigars) that are already in place for cigarettes, including TV, radio, billboards, venues, etc.
2. Prohibit e-cigarette marketing at events (all events open to youth under age 18), magazines, and other media (media with a 10% or higher youth readership).<sup>31</sup>
3. Prohibit all flavored tobacco products.
4. Prohibit sports sponsorship or advertising of tobacco products at sports events attended by youth under age 18.
5. Develop more effective warning labels for all nicotine containing products.
6. Treat all cigars as dangerous products that threaten youth health, i.e., reject "Option 2".

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<sup>1</sup> Master Settlement Agreement, (May 2014). Available at: <http://publichealthlawcenter.org/topics/tobacco-control/tobacco-control-litigation/master-settlement-agreement>

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