

# FDA Should Prohibit E-cigarette Marketing that Promotes False Health Claims

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The proposed FDA rule fails to propose effective restrictions on the marketing of e-cigarettes. The FDA must immediately prohibit marketing that promotes unsubstantiated health and therapeutic claims that position e-cigarettes as safe, healthier than tobacco cigarettes, and useful for smoking cessation. These are actions that the FDA can take now because the e-cigarette companies are making unsupported therapeutic claims.

In addition to enforcing current law, under the current rule making the FDA rule should issue regulations that restrict the marketing of these nicotine-delivery devices to prohibit health and therapeutic claims. **E-cigarettes are falsely advertised as smoking cessation aids.**

In fact, in a previous comment to the FDA,<sup>1</sup> several of the authors of this comment outlined multiple instances of e-cigarette companies making therapeutic health claims about their products. **E-cigarette advertisements make misleading health claims**

As reported in a published systematic content analysis of e-cigarette website marketing:<sup>2</sup>

"Ninety-five percent of the websites made explicit or implicit health-related claims, 64% had a smoking cessation-related claim, 22% featured doctors, and 76% claimed that the product does not produce secondhand smoke. Comparisons to cigarettes included claims that e-cigarettes were cleaner (95%) and cheaper (93%). Eighty-eight percent stated that the product could be smoked anywhere and 71% mentioned using the product to circumvent clean air policies."

E-cigarette companies are marketing e-cigarettes as smoking cessation aids (Figure 1).<sup>3,4,5,6</sup>  
In response to these marketing messages, many people use e-cigarettes to try to stop

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<sup>1</sup> Grana, R., Ling, P.M., Barnes, R.L., Lempert, L., Glantz, S.A. (2013). Comment submitted regarding Food and Drug Administration actions related to Nicotine Replacement Therapies and smoking-cessation products; report to Congress on innovative products and treatments for tobacco dependence; public hearing; extension of comment period. Racking # 1jx-835b-n9ph.

<sup>2</sup> Grana R, Ling P. Smoking Revolution? A content analysis of electronic cigarette retail websites. *American Journal of Preventive Medicine*. 2014;46(4):395-403.

<sup>3</sup> Lee et al, 2011, Public Health Challenges of Electronic Cigarettes in South Korea. *Journal of Preventive Medicine and Public Health*, 44 (6): 235-241.

<sup>4</sup> de Andrade and Hastings, 2013, The Marketing of E-Cigarettes: A UK Snapshot *BMJ Group Blogs*. <http://blogs.bmj.com/tc/2013/04/06/the-marketing-of-e-cigarettes-a-uk-snapshot/>. Accessed April 16, 2013.

<sup>5</sup> Yamin et al, 2010, E-Cigarettes: A Rapidly Growing Internet Phenomenon. *Annals of Internal Medicine*, 153 (9): 607-609.

<sup>6</sup> Grana & Ling, 2014, Smoking Revolution? A content analysis of electronic cigarette retail websites. *American Journal of Preventive Medicine*, 46 (4): 395-403.

smoking.<sup>7,8,9,10</sup> Despite these marketing messages, in the proposed rule the FDA observes that “There is no evidence to date that e-cigarettes are effective cessation devices” (p.23152). In fact, “the number of cigarette smokers who actually quit tobacco product use with e-cigarettes is low” (p. 23147).

One longitudinal population study of adult smokers in four countries (including the US) found that e-cigarette use was not significantly associated with quitting conventional cigarettes.<sup>11</sup> In another longitudinal study of US smokers, at one year there was no relationship between e-cigarette use and quitting tobacco cigarettes, even after accounting for dependence (number of cigarettes smoked per day, how early in the day a smoker has first cigarette) and intention to quit smoking.<sup>12</sup> A third longitudinal study of young adults in the US also found that e-cigarette use did not predict quitting smoking at follow-up (one year).<sup>13</sup> A fourth longitudinal study of quit-line users in the US found that e-cigarette users were less likely to have quit smoking than non-e-cigarette users at 7 months follow-up.<sup>14</sup> A cross-sectional US study also found that unsuccessful cigarette quitters were significantly more likely to have ever tried e-cigarettes than individuals who had never tried to quit.<sup>15</sup> A meta-analysis of these five population studies found significantly lower odds of quitting (OR = 0.61, 95% CI 0.45–0.83) among adult smokers who had used e-cigarettes, compared to those who had not.<sup>16</sup>

Another cross-sectional study found that, among US adolescents, e-cigarette users were more likely to plan to quit smoking cigarettes but were less likely to have recently abstained from e-



Figure 1: NE Where Electronic Cigarettes Blog promotes e-cigarettes as smoking cessation devices. <http://newhere.com/blog/quit-smoking-electronic-cigarettes/>. Accessed May 2014.

<sup>7</sup>Etter, 2010, Electronic cigarettes: a survey of users. *BMC Public Health*, 10: 231.

<sup>8</sup>Pearson et al, 2012, e-Cigarette Awareness, Use, and Harm Perceptions in US Adults. *American Journal of Public Health*, 102 (9): 1758-1766.

<sup>9</sup>Pokhrel et al, 2013, Smokers who try e-cigarettes to quit smoking: Findings from a multiethnic study in Hawaii. *American Journal of Public Health*, 103(9): e57-e62.

<sup>10</sup>Vickerman et al, 2013; Use of electronic cigarettes among state tobacco cessation quitline callers. *Nicotine Tob Res*, 15 (10): 1787-1791.

<sup>11</sup>Adkison et al, 2013, Electronic nicotine delivery systems: International tobacco control four-country survey. *American Journal of Preventive Medicine*, 44(3):207-215.

<sup>12</sup>Grana RA, Popova L, Ling PM. A longitudinal analysis of electronic cigarette use and smoking cessation. *JAMA Internal Medicine*. 2014;174(5):812-813.

<sup>13</sup>Choi, K., Forster, L, 2014. Response to Letter to the Editor Regarding “Beliefs and Experimentation with Electronic Cigarettes: A Prospective Analysis Among Young Adults.” *American Journal of Preventive Medicine*, 46 (6): e58-359.

<sup>14</sup><sup>14</sup>Vickerman et al, 2013; Use of electronic cigarettes among state tobacco cessation quitline callers. *Nicotine Tob Res*, 15 (10): 1787-1791.

<sup>15</sup>Popova and Ling, 2013, Alternative tobacco product use and smoking cessation: A national study. *American Journal of Public Health*, 103 (5): 923-930.

<sup>16</sup>Grana R, Benowitz N, Glantz SA, 2014. E-cigarettes: A scientific review. *Circulation*, 129: 1972-1986

cigarettes.<sup>17</sup> Similar results were observed in a large cross-sectional study of Korean adolescents.<sup>18</sup>

A recent focus group study of older smokers (>45 years old) revealed that many had false conceptions about e-cigarettes, likely due to misleading advertising techniques. More than half had tried e-cigarettes, and most were interested in using them for smoking cessation, despite the lack of evidence to support this idea. Most agreed that current marketing strategies promoted the renormalization of smoking, and they viewed the absence of warnings as an endorsement of their safety.<sup>19</sup>

## Overall Conclusions

E-cigarettes are advertised with unsubstantiated claims and in ways that undermine cessation attempts of adults. In fact, some e-cigarette companies have even unlawfully placed a FDA label on their products (Figure 2). The FSPTCA<sup>20</sup>, final Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents<sup>21</sup> and the Master Settlement Agreement<sup>21</sup> already prohibit many of these exploitive techniques for cigarettes and smokeless tobacco. Section 903 of the FSPTCA provides that a tobacco product shall be considered misbranded if its labeling is false or misleading in any way, and section 911 prohibits the sale or distribution of tobacco products for which the labeling or advertising represents either *explicitly or implicitly* that the product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products. FDA should use its authority under the FSPTCA to extend these restrictions to e-cigarettes and all newly covered products.<sup>22</sup> The FDA has the authority under sections 906(d) and 907 of the Family Smoking Prevention Tobacco Control Act<sup>23</sup> to issue regulations requiring restrictions on the sale and distribution of tobacco products for the protection of the public health.



Figure 2. E-cigarette liquid refill bearing the FDA label. <http://www.fasttech.com> Accessed May 2014

### Based on this evidence, the FDA should take the following actions:

1. In the current rulemaking, amend the regulations at 21 C.F.R. Part 1140 *et seq* concerning labeling and advertising restrictions to include *all tobacco products*, including newly

<sup>17</sup>Dutra and Glantz, 2014, Electronic cigarettes and conventional cigarette use among US adolescents a cross-sectional study. *JAMA Pediatrics*, 2014 Mar 6. doi: 10.1001/jamapediatrics.2013.5488 [Epub ahead of print].

<sup>18</sup> Lee S, Grana R, Glantz S, 2014. Electronic-cigarette use among Korean adolescents: A cross-sectional study of market penetration, dual use, and relationship to quit attempts and former smoking. *Journal of Adolescent Health*, 54 (6): 684-690.

<sup>19</sup> Cataldo, J.K. Sheon, N., Hunter, M., Petersen, M.A. (2014) Risk and Benefit Perceptions in the Use of Conventional and Emerging Tobacco Products Among Older Smokers, NIH/FDA Tobacco Regulatory Science Conference, Bethesda, MD, April 28, 2014

<sup>20</sup> Public Law 111-31; 123 Stat. 1776

<sup>21</sup> 75 FR 13225 (March 19, 2010)

<sup>22</sup> Master Settlement Agreement, (May 2014). Available at: <http://publichealthlawcenter.org/topics/tobacco-control/tobacco-control-litigation/master-settlement-agreement>

<sup>23</sup> Pub.L. 111-31, H.R. 1256 (June 22, 2009)

covered products such as electronic cigarettes, cigars, hookah, and other products by substituting the words “tobacco products” in all places where the phrase “cigarette or smokeless tobacco” occurs in Subpart D sections 1140.30, 1140.32, and 1140.34; by deleting subsection 1140.30(c); and by adding the words “in any media, including, but not limited to, online, internet, cellular applications, and social media” after the phrase “audio or video format” in subsection 1140.32(b).

2. In the current rulemaking, prohibit youth targeting and amend 21 C.F.R. section 1140.30(2) by adding the following words after the phrase “persons younger than 18 years of age”: “Manufacturers, distributors, and retailers are prohibited from advertising or labeling any tobacco product in any publication or event where the audience is composed of fifteen percent (15%)<sup>24</sup> or more persons younger than 18.”
3. Use its existing authority to enforce against any company or manufacturer that makes false or misleading health claims in its labeling or advertising or that explicitly or implicitly implies in their labeling or advertising that their products are effective smoking cessation devices or therapies until such time as the company or manufacturer submits a proper application to the FDA supporting such a claim.

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<sup>24</sup> Master Settlement Agreement, (May 2014). Available at: <http://publichealthlawcenter.org/topics/tobacco-control/tobacco-control-litigation/master-settlement-agreement>