

FDA should deny requests to extend the public comment period for this rule

Comment Submitted in Response to FDA Regarding Proposed 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; Regulations on the Sale
and Distribution of Tobacco Products and Required Warning Statements for
Tobacco Products

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E-cigarette and cigar companies and trade associations have petitioned the FDA to extend the comment period by up to an additional 105 days, bringing the total comment period to 180 days. There is a real health cost to granting such a delay. Based on 2012 use patterns of e-cigarettes alone, we estimate that during the requested 105 day extension we estimate that an additional 26,000 youth will start experimenting with e-cigarettes and 8,000 youth will become established e-cigarette users.

These estimates are probably low because they do not account for the fact that e-cigarette market penetration continues to accelerate. These estimates do not include new experimenters and established users for cigars and other products covered by the proposed deeming rule.

The FDA needs to include these health costs when evaluating the industry's request and deny it. This rule has been years in the making and 75 days is enough time for industry to respond.

DETAILS OF CALCULATIONS:

From the National Youth Tobacco Survey,¹ the most recent estimate for ever e-cigarette use among middle and high school students in the US, (“Have you ever tried Electronic Cigarettes or E-cigarettes, such as Ruyan or NJoy?”) was 6.8% in 2012.²

In 2012, 42,378,395 people between the ages 10 and 19 lived in the US.³ Based on the population trends from 2011 to 2012, this segment of the population is growing 3% each year.³ Assuming such growth continues, the population of youths ages 10 to 19 is 44,973,190 in 2014. If we assume that e-cigarette use has remained stable since 2012 (6.8%), this means that 91,745 US adolescents will try e-cigarettes for the first time between 2014 and 2015. This figure translates into 26,392 adolescents trying e-cigarettes for the first time every 105 days in 2014. By delaying the public comment period another 105 days, the FDA would allow an additional 22,392 adolescents to start experimenting with e-cigarettes, exposing them to the addictive drug nicotine.

In 2012, 2.0% of US middle and high school students in the National Youth Tobacco Survey were current e-cigarette users² (“During the past 30 days, have you used Electronic Cigarettes or E-cigarettes, such as Ruyan or NJoy” on at least one day?”¹). Assuming the population of youths ages 10 to 19 is 44,973,190 in 2014 and that current (30-day) e-cigarette use has remained the same since 2012 (2.0%), 26,984 US adolescents will become current e-cigarette users between 2014 and 2015. This figure translates to 7,763 youths becoming current e-cigarette users every 105 days in 2014. By delaying the comment period another 105 days, the FDA would allow an additional 7,763 US adolescents to become regular e-cigarette users, making them very likely to become addicted to nicotine.

Given that ever e-cigarette use more than doubled among US middle and high school students between 2011 and 2012 (3.3% to 6.8%), and current e-cigarette use almost doubled during this same time period (1.1% to 2.0%), the actual effects of delay in 2014 would be substantially larger than our estimates, which are based on 2012 behavior.

¹ Centers for Disease Control and Prevention. National Youth Tobacco Survey. Available at: http://www.cdc.gov/TOBACCO/data_statistics/surveys/NYTS/index.htm. Accessed May 16, 2014.

² Corey C, Wang B, Johnson SE, et al. Electronic cigarette use among middle and high school students- United States, 2011-2012. *Morbidity and Mortality Weekly Report*. 2013;62(35):729-730.

³ US Census Bureau. American Community Survey. Available at: http://www.census.gov/acs/www/data_documentation/public_use_microdata_sample/. Accessed May 16, 2014.