The Proposed Two Year Phase in for Requiring Premarket Approval of Newly Deemed Tobacco Products is Too Long; 6 Months Would be More Appropriate

Docket No. FDA-2014-N-0189

Lauren M Dutra, ScD
Stanton A Glantz, PhD

Center for Tobacco Control Research and Education
University of California San Francisco

June 6, 2014

The FDA has proposed a 2-year delay in implementing the premarket approval provisions of the Family Smoking Prevention and Tobacco Control Act for newly deemed products. Products would be allowed to remain on the market, and the FDA would not "initiate enforcement action against the product for failing to have an FDA marketing authorization unless and until FDA issues an order denying the PMTA [premarket tobacco applications] under 910(c)" (p. 23176). The FDA also asked for public comment on the possibility of "extending the compliance period" for small manufacturers (p. 23177).

All of the FDA's requests for comments on this aspect of the proposed rule asked about the desirability of *lengthening* the compliance time period; the FDA did not even raise the possibility that the proposed period was too long and that a shorter compliance period could be more appropriate for protecting population health.

A two-year compliance period will result in large numbers of additional adolescents experimenting with e-cigarettes and becoming established e-cigarettes users. This is a real health cost of the delay. The FDA should not compromise the health of US adolescents by providing an overly generous compliance period for e-cigarette manufacturers. Such generosity will only result in the continued increase in nicotine addiction among US youths.

The compliance period should be 6 months for all products and manufacturers.

Using 2012 National Youth Tobacco Survey (NYTS)[1] estimates of 6.8% ever e-cigarette use among US middle and high school students and adjusting for population growth since 2012,[2] during proposed the 2-year delay in enforcing the law's premarket approval requirements, a minimum of 186,243 additional youth will try e-cigarettes[3] and be exposed to the addictive drug nicotine.

---

[1] 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.

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

[3] The supporting calculations are at the end of this comment.

Using 2012 NYTS estimates of 2.0% current e-cigarette use among youth and adjusting for population growth, at a minimum an additional 54,777 youth will become current e-cigarette users during the two year delay in enforcing the law's premarket approval requirement.

If the compliance period were shortened to 6 months, the FDA "only" 45,873 youth would experiment with e-cigarettes and 13,492 would become current e-cigarette users and therefore be more likely to become addicted to nicotine.

The actual number of youth that initiate e-cigarette use during the period before the FDA begins enforcing the premarket approval process is likely to be larger than these estimates. 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%) and there is every reason to expect that e-cigarette use will continue to accelerate among youth because of the rapid increases in mass marketing of e-cigarettes, including on television.[4] If we had assumed that ever and current e-cigarette use has continued to double among adolescents since 2012, which would be reasonable given existing trends, the rates of e-cigarette experimentation and regular use would be much higher.

The Regulatory Impact Analysis ignored these costs to the public's health in its assessment of different regulatory options. The RIA should be revised to include the health costs of delaying implementation as well as the public health benefits of shortening the delay in implementation. This analysis should not apply any consumer surplus discount because all the youth being considered here are below the age of reason.[5]

In addition, allowing products to remain on the market until the FDA issues an order approving or denying the premarket tobacco applications (PMTA) will create a situation that rewards e-cigarette companies for submitting incomplete applications that would lead the FDA to request clarification or additional information. More youth will begin using e-cigarettes and become addicted to nicotine during this time. **The final rule needs to state unequivocally that the return of an application due to incomplete information or a request for additional information constitutes a "decision" and that marketing of the subject product would have to end immediately and not resume until a complete application had been approved.**

In sum:

- The FDA should reduce the two-year compliance period to 6 months. Given the extended delays in issuing this rule, 6 months after the rule is finalized would still allow e-cigarette manufacturers ample time to comply while having a much smaller impact on the health of US youths.

---

[4] Duke J, Lee YO, et al. Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults. *Pediatrics* Published online June 2, 2014 doi: 10.1542/peds.2014-0269

[5] Song AV, Brown P, Glantz SA. When health policy and empirical evidence collide: the case of cigarette package warning labels and economic consumer surplus. *Am J Public Health* 2014 Feb;104(2):e42-51. doi: 10.2105/AJPH.2013.301737. Epub 2013 Dec 12.

- There should be no exception for "small manufacturers;" the cost of such an exemption will be paid by US youth. Establishing such an exemption would also open a loophole that larger companies might exploit by working through "third parties."
- The final rule should clearly state that the return of an incomplete application or request for additional information will merit an "enforcement action" (p.23148) that would end the grace period for marketing a product without specific premarket authorization.

Calculations:

The National Youth Tobacco Survey,[6] conducted by the CDC, estimated that 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.[7] In 2012, 42,378,395 people between the ages 10 and 19 lived in the US.[8] This segment of the population is growing 3% each year.[3] Assuming this rate of growth has continued since 2012, the youth population was 44,973,190 in 2014. Assuming e-cigarette use is the same in 2014 as it was in 2012 (6.8%), 3,058,177 US youths would be ever e-cigarette users in 2014.

Using the same assumptions, the population of youths ages 10 to 19 will be 46,322,386 in 2015. If we assume that e-cigarette use has remained stable since 2012 (6.8%), this means that 3,149,922 US adolescents will be e-cigarette experimenters in 2015. As a result, 91,745 US adolescents will try e-cigarettes for the first time between 2014 and 2015. In 2016, this segment of the population will number 47,712,057 youths. Assuming ever e-cigarette use is still 6.8% for this group in 2016, 3,244,420 adolescents will be ever e-cigarette users in 2016. As a result, 94,498 adolescents (3,244,420 minus 3,149,922) will try e-cigarettes for the first time between 2015 and 2016. If the FDA permits a 2-year waiting period for compliance, they will allow a minimum of 186,243 additional youth (91,745 between 2014 and 2015 plus 94,498 between 2015 and 2016) to try e-cigarettes.

If the compliance period were shortened to six months, the FDA would instead only be allowing 45,873 (91,745/2) youths to try e-cigarettes and therefore be exposed to the highly addictive chemical nicotine.

In 2012, 2.0% of US middle and high school students in the National Youth Tobacco Survey were current e-cigarette users[2] ("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%), 899,464 youths are current e-cigarette users in 2014.

---

[6] 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.
[7] 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.
[8] US Census Bureau. American Community Survey. Available at: http://www.census.gov/acs/www/data_documentation/public_use_microdata_sample/. Accessed May 16, 2014.

Estimating the youth population is 44,322,386 in 2015, 926,448 youths will be current e-cigarette users in 2015. As a result, 26,984 US adolescents will become current e-cigarette users between 2014 and 2015. Estimating the US youth population as 47,712,057 in 2016, 954,241 US youths will be current e-cigarette users in 2016. As a result, 27,793 adolescents would become current e-cigarette users between 2015 and 2016. If the FDA permits a 2-year waiting period for compliance, they are allowing at minimum an additional 54,777 youth (26,984 plus 27,793) to become current e-cigarette users. If the compliance period were shortened to 6 months, the FDA would instead only be allowing 13,492 youths (26,984/2) to become current e-cigarette users and therefore be more likely to become addicted to nicotine