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February 1, 2019

Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA-2018-N-3952 Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies

Dear Commissioner Gottlieb:

The American Lung Association appreciates the opportunity to provide comments on the Request for Comment, “Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies.”

The American Lung Association is the oldest voluntary public health organization in the United States and is committed to eliminating tobacco use and tobacco-related disease. Tobacco use is the leading cause of preventable death and disease in the United States, killing 480,000 Americans each year and another 16 million Americans live with a tobacco-caused disease.

The American Lung Association has decades of experience in helping smokers quit. Over a million Americans have quit smoking using the American Lung Association’s *Freedom From Smoking*® program. The program, often referred to as the gold-standard for tobacco cessation, is available as an in-person group clinic, a self-help guide, by telephone and online in our newest option, *Freedom From Smoking Plus*. In addition, the Lung Association’s Lung HelpLine is staffed by nurses, respiratory therapists and smoking cessation counselors and has operated the Illinois Tobacco Quitline since 2001. American Lung Association’s Not On Tobacco® (N-O-T) program is a smoking cessation/reduction program for high school-age youth, proven to help teens end their tobacco addiction for good.

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The best way to prevent tobacco addiction is to prevent youth and young adults from ever starting to use it in the first place. The Lung Association has long advocated to prohibit the sale of all flavored tobacco products, including mint and menthol flavored products, because flavors have been shown to encourage youth use.¹ In fact recent data show over half of all youth who use e-cigarettes use a mint or menthol flavored product. E-cigarettes and other flavored tobacco products also contain harmful ingredients, which can cause irreversible lung damage.²

As the result of the e-cigarette epidemic, parents, the public health community, medical providers and schools are truly struggling with what to do to help youth get the help they need to quit. It is clear that FDA must do more and do so systematically. The American Lung Association urges the FDA to work with the Centers for Disease Control and Prevention (CDC) and the public health and medical community to develop a set of guidelines on how to help youth end their addiction to nicotine and all tobacco products. These guidelines – coupled with meaningful actions from the Center for Tobacco Products to prevent youth from initiating – can help end the epidemic.

Prevention Must Be At the Heart of Ending This Epidemic

Use of e-cigarettes among kids and teenagers is an epidemic. Between 2017 and 2018, high school student use of e-cigarettes increased by 78 percent. During the same time period, middle school student use of e-cigarettes increased by 48 percent. The dramatic increases of youth e-cigarette use over the last year has reversed the trend of lower overall tobacco use among youth.³ This disturbing trend must not continue.

In 2016, the U.S. Surgeon General concluded that e-cigarettes are not safe for youth.⁴ There are a number of reasons to raise concern over the increasing number of kids and teenagers using e-cigarettes. First, nicotine, which is found in e-cigarettes, is extremely addictive and not a benign substance.⁵ The 2012 Surgeon General's Report, "Preventing Tobacco Among Youth and Young Adults," found that youth are more sensitive to nicotine and become addicted to nicotine faster than adults. Nicotine can also damage the adolescent brain, impacting cognition, mood and attention capabilities. Other chemicals found in e-cigarettes, – including propylene glycol and vegetable glycerin – are harmful to the lungs regardless of flavorings.⁶

Additionally, studies⁷ have shown that the earlier an individual starts smoking, the harder it is to quit. We know approximately 70 percent of smokers say they want to quit, but the addiction to nicotine is incredibly powerful.⁸

Studies have also shown that flavored tobacco use among youth and young adults frequently leads to use of combustible tobacco products.⁹ One of the major conclusions of the 2014 Surgeon General's report states, "The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will dramatically reduce this burden."¹⁰ Action is needed now to prevent another generation of addiction.



Next Steps

The Food and Drug Administration (FDA) has a clear mandate under the Tobacco Control Act to regulate all tobacco products in order to prevent non-users from ever starting to use any tobacco product. The American Lung Association urges FDA to take the following actions to respond to this public health crisis:

- 1) Finalize a product standard that would remove all flavored tobacco products, including menthol cigarettes from the marketplace;
- 2) Reinstate the pre-market review provisions for all newly deemed tobacco products;
- 3) Create best practice guidelines that include proven counseling programs for providers and parents to ensure youth are helped end their addiction for good;
- 4) Crack down on e-cigarette companies that make therapeutic/cessation claims without approval from the Center for Drug Evaluation and Research; and
- 5) Prioritize further research to increase e-cigarette cessation in youth.

FDA has already concluded that flavors should be prohibited. In its 2015 submission of the final “deeming” rule to the Office on Management and Budget (OMB), the FDA proposed to remove newly deemed flavored tobacco products unless a manufacturer could prove its product was appropriate for the protection of the public health.¹¹ Flavored cigarettes were eliminated in 2009 due to overwhelming evidence that flavored cigarettes were used primarily by kids.¹² Now, the evidence is clear that history is bound to repeat itself if all flavored tobacco products are not removed from the market. Each day of delay benefits the purveyors of these products who continue to prey on our nation’s children.

Since 80 percent of young people who have ever tried a tobacco product started with a flavored product, prohibiting the sale of flavored tobacco products, including mint and menthol, will reduce the attractiveness of e-cigarettes to youth.¹³ The American Lung Association strongly encourages the FDA to immediately take steps to prohibit the sale of all flavored tobacco products.

In addition, the preponderance of scientific evidence and studies indicate that e-cigarettes do not help adult smokers quit. A recent study found that there is no evidence that e-cigarettes helped smokers quit at rates higher than smokers who did not use these products.¹⁴ Instead, there are significant levels of dual use of cigarettes and e-cigarettes, with over half of adult current e-cigarette users continuing to be current cigarette smokers in 2016.¹⁵ The American Lung Association urges FDA to crack down on e-cigarette companies’ implied or direct therapeutic and health claims. These claims confuse adult consumers, as well as youth.

The American Lung Association strongly urges FDA to follow the process required in the deeming rule and require all newly deemed tobacco products to undergo pre-market review for any new tobacco product introduced after February 15, 2007. FDA must require manufacturers to submit products introduced after the 2007 date for pre-market review. The American Lung Association is also deeply troubled about the lack of clarity. In fact, two popular flavored Juul products, mango and cool cucumber, appear to have been introduced to the market after the August 8, 2016 date



without undergoing pre-market review or having received a marketing order from FDA. To prevent kids and teenagers from starting to use e-cigarettes and other tobacco products, FDA must adhere to the Tobacco Control Act and must immediately remove all tobacco products introduced to the market after August 8, 2016 that have not undergone premarket review.

Helping Youth End Their Addiction

Recent data from the Centers for Disease Control and Prevention (CDC) show over three million high school students and over half a million middle school students use e-cigarettes. There are currently no tobacco cessation pharmaceutical treatments FDA has found safe and effective in helping youth quit. The American Lung Association urges the FDA to work to incentivize the development and expedite the approval of cessation medications for people under the age of 18.

However, in the more immediate term, FDA can create guidelines for medical providers and parents on how to help youth end their addiction to nicotine. One key component of any guidelines should be tobacco cessation counseling. The United States Preventive Services Task Force (USPSTF) recommends preventive counseling for kids and tobacco use.¹⁶

In addition to taking the steps outlined above to prevent kids and teenagers from starting to use e-cigarettes, it is critically important that tobacco cessation programs are made available to prevent youth from a lifelong addiction to tobacco. Many such programs already exist. The utilization and promotion of these existing programs, including counseling should be a top priority when addressing the epidemic level of youth e-cigarette use in the United States, and the American Lung Association encourages FDA to include such evidence-based programs in guidelines created for helping youth end their addiction.

The Lung Association's N-O-T program, as well as other evidence-based programs, are grounded in proven-effective and established treatment plans that address the physical, behavioral and psychological aspects of addiction. The use of e-cigarettes models the same three aspects of addiction seen in more traditional forms of tobacco use. Consequently, the behavioral therapy principles utilized in programs that address traditional tobacco use can also be used to help e-cigarette users quit for good.

The Not On Tobacco® program (N-O-T) is the American Lung Association's voluntary smoking cessation program for teens ages 14 - 19. Over the 10-week program, participants learn to identify their reasons for smoking, healthy alternatives to tobacco use and people who will support them in their efforts to quit. This structured approach to smoking cessation is based on the social cognitive theory and addresses the physical, behavioral and psychological aspects of addiction.

Other tobacco cessation resources for teens recommended by the American Lung Association include Smokefree Teen, Smokefree TXT, 1-800-QUITNOW and the QuitSTART app. We encourage the FDA to consider including such programs in guidelines.



Conclusion

The U.S. Food and Drug Administration has an affirmative responsibility to protect children, teens and all young people from the addiction, disease and death caused by tobacco products. Recognizing that almost all tobacco users begin their use during their adolescence or young adulthood, tobacco companies have spent billions of dollars marketing their products and making them more attractive to young people. That has led to the industry using flavored tobacco products to lure youth, which has – tragically – been a successful strategy for the industry. The industry’s strategy has extended to targeting youth using e-cigarettes.

The American Lung Association urges FDA to take swift action to prevent youth from beginning their use of e-cigarettes, including removing all flavored tobacco products from the market and requiring a premarket review of all newly deemed tobacco products. We also urge FDA to develop a set of evidence-based guidelines to help providers and schools deal with this public health epidemic. Finally, FDA must also work to develop treatments that can help addicted youth end their addiction to nicotine for good.

Thank you for the opportunity to provide these comments. The American Lung Association looks forward to continue to work with FDA to stop e-cigarette use before another generation of America’s youth are lost to tobacco.

Sincerely,



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¹ Gammon, D.G., MS, King, B.A., PhD, MPH, Marynak, K.L., MPP, & Rogers, T. October 10, 2018. “Electronic Cigarette Sales in the United States, 2013-2017.” *JAMA Network*. Available at: <https://jamanetwork.com/journals/jama/article-abstract/2705175>

² Destailats, H., Gundel, L.A., Litter, M.I., Logue, J.M., Montesinos, V.N., Russell, M.L., & Sleiman, M. July 27, 2016. “Emissions from Electronic Cigarettes: Key Parameters Affecting the Release of Harmful Chemicals.” *Environmental Science & Technology*. Available at: <https://pubs.acs.org/doi/pdf/10.1021/acs.est.6b01741>

³ Ambrose, B.K., Apelberg, B.J., Cullen, K.A., Gentzke, A.S., Jamal, A., & King, B.A. 2018. “Notes from the Field: Use of Electronic Cigarettes an Any Tobacco Product Among Middle and High School Students – United States, 2011-2018.” *MMWR Morbidity and Mortality Weekly Report 2018*; 67: 1276-1277. DOI: https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_v

⁴ U.S. Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

⁵ Cross, S.J., Leslie, F.M., Loughlin, S.E., & Yuan, M. August 15, 2015. “Nicotine and the Adolescent Brain.” *The Journal of Physiology 2015*; 593: 3397-3412. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4560573/>

⁶ Destailats, H., Gundel, L.A., Litter, M.I., Logue, J.M., Montesinos, V.N., Russell, M.L., & Sleiman, M. 2016. “Emissions from Electronic Cigarettes: Key Parameters Affecting the Release of Harmful Chemicals.” *Environmental Science & Technology Monthly 2016*, 50(17): 9644-9651. DOI: 10.1021/acs.est.6b01741. Available at: <https://pubs.acs.org/doi/abs/10.1021/acs.est.6b01741>

⁷ Chen, X., Damaj, M.I., Kendler, K.S., & Myers, J. 2013. “Early Smoking Onset and Risk for Subsequent Nicotine Dependence: a Monozygotic Co-Twin Control Study.” *The American Journal of Psychiatry*, 170(4): 408-13.

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- ⁸ Asman, K., Babb, S., Jamal, A., & Malarcher, A. 2017. "Quitting Smoking Among Adults – United States, 2000-2015." *Morbidity and Mortality Weekly Report (MMWR)*, 65: 1457-1464. Available at: <https://www.cdc.gov/mmwr/volumes/65/wr/mm6552a1.htm>
- ⁹ Ambrose, B.K., PhD, MPH, Borek, N., PhD, Conway, K.P., PhD, Day, H.R., PhD, Hyland, A., PhD, Rostron, B., PhD, & Villanti, A.C., PhD, MPH. November 3, 2015. "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014." *JAMA Network*. Available at: <https://jamanetwork.com/journals/jama/fullarticle/2464690>
- ¹⁰ U.S. Department of Health and Human Services. January 2014. "The Health Consequences of Smoking-50 Years of Progress." *A Report of the Surgeon General*, 31: 7.
- ¹¹ U.S. Department of Health and Human Services and Food and Drug Administration. 2016. "TAB B 2014- 850 Deeming Final Rule Redline Changes. 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. 21 CFR Parts 1100, 1140, and 1143 [Docket No. FDA-2014-N-0189]." Retrieved from <https://www.regulations.gov/document?D=FDA-2014-N-0189-83193>
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- ¹⁵ Centers for Disease Control and Prevention. National Center for Health Statistics. National Health Interview Survey, 2016. Analysis performed by the American Lung Association Epidemiology and Statistics Unit using SPSS software.
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