November 10, 2018

Dr. Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
White Oak Building One
10903 New Hampshire Ave., Room 2217
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

As you have repeatedly emphasized, the increased youth use of e-cigarettes, including Juul, is alarming and cause for urgent action by the Food and Drug Administration (FDA). As the leaders of major public health and medical organizations that for decades have been leading the effort to end tobacco use in the United States, we agree completely and stand ready to support action that will ensure that we don't addict another generation of American youth.

We have followed closely the statements you have made and the actions FDA has taken so far. The *Washington Post* and other media sources have now reported that FDA is preparing to announce new restrictions on e-cigarettes. The organizations signed below want to express as clearly as possible our views about what will be necessary to address this problem. We believe that FDA's actions must address three core principles and that to be effective FDA needs to take action in four specific areas.

Core Principles Essential to Reducing Tobacco Use

1. Voluntary action by the industry - including the e-cigarette industry – is insufficient. Industry wide regulatory action is essential. For more than 60 years the tobacco companies have claimed they are capable of self-regulation. Today some of the same companies and the e-cigarette companies make the same claim. It has never worked before and it will not work now. Claims of voluntary self-regulation have always been simply a tactic to divert attention from the companies' wrongful conduct. Voluntary actions are no substitute for mandatory, industry-wide regulatory action by FDA.

2. **FDA's approach must be comprehensive and not be limited to sales restrictions to prevent illegal sales to youth.** While it is important to enforce the rules and to impose new requirements to prevent the illegal sale of e-cigarettes and other tobacco products to youth, or even to restrict the type of stores where flavored products are sold, such sales restrictions have never been sufficient to prevent youth initiation of tobacco products and they won't by

themselves reverse the epidemic of youth use of e-cigarettes. FDA's approach must address each of the four areas discussed below.

3. It is essential to address the problem of youth use of other tobacco products as well as e-cigarettes. The easy availability of menthol cigarettes, flavored cigars and flavored hookah is contributing to the current youth problem and needs to be addressed. It is encouraging to see recent media reports that FDA says it will propose prohibiting menthol in cigarettes. It is critical that FDA move swiftly to accomplish that goal. We strongly support that effort.

FDA's Plan Must Include Meaningful Action Against Youth Usage

Consistent with these principles, we are unified in our conclusion that to be effective FDA's actions - including its regulations - need to address the following four specific areas:

1. FDA must enforce pre-market review. FDA must actively enforce the legal requirement preventing products that were not commercially marketed as of August 8, 2016, or that were modified after that date, from being sold without premarket review. FDA must also rescind the four-year suspension of premarket review for newly deemed products on the market as of that date. One of the most important authorities FDA has is to review new tobacco products to ensure that they benefit public health. It is the tool that enables FDA to review any product and the proposed marketing of any product to ensure that they do not unduly appeal to youth and to set conditions for their sale to ensure that they do not contribute to youth use. Indeed, a primary lesson of the Juul disaster is the only way to prevent youth tobacco use is *before* a product enters the market in huge volumes, not after. Furthermore, it appears that many new products delivering very high nicotine levels have entered the market after August 8, 2016. This must stop immediately.

2. FDA needs to require the immediate removal of all flavored tobacco products that have not been thoroughly vetted in advance by FDA to assess their public health impact. The unregulated introduction of flavored products is a major contributor to the current crisis and FDA should take action to require the immediate removal of newly-deemed flavored products, other than those with tobacco flavor, that have not been thoroughly vetted in advance by FDA through the premarket review process. FDA can do this now by enforcing the premarket review authority even while it moves forward on product standards.

3. FDA needs to institute restrictions on e-cigarette marketing, including on social media, that are at least as stringent as those applied to cigarettes. E-cigarette companies have adopted many of the same marketing tactics to attract young people that the cigarette companies have employed for decades. Prohibitions on branded non-tobacco product sales, sports and other event sponsorships, and measures such as prohibiting self-service displays and instituting minimum pack sizes reduce youth access of these products.

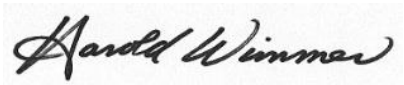
4. FDA needs to restrict internet sales of these products and continue to aggressively enforce the law against sales to minors. Many online tobacco sales sites lack robust age verification

methods, making it easy for youth to access these products. In addition, no restrictions covering delivery are in place to ensure that products are only delivered to adult consumers. Until sufficient protections against youth access are in place, on-line sales should be prohibited. We also encourage the FDA to limit the brick and mortar retailers who may sell these products. Purchases at convenience stores appear to be a major source of supply for youth. Restricting sales to adult only tobacco stores would limit youth access.

As you have acknowledged, the use of e-cigarettes by youth is a public health crisis. We urge FDA to take these actions as critical first steps. We look forward to working with you to ensure that a new generation does not become addicted to tobacco.

Sincerely,

Colleen A. Kraft, MD, MBA, FAAP
President
American Academy of Pediatrics



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