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
Slver Spring, MD 20993

Dear Commissioner Gottlieb:

As you have repeatedly emphasized, the increased youth use of e-cigarettes, including Jul, 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

We have followed dosely the statements you have made and the actions FDA has taken so far.

The 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 dearly as possible our views about what will be necessary to address this problem. We believe

- 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 daimed they are capable of self-regulation. Today some of the same companies and the e-cigarette companies make the same daim. It has never worked before and it will not work now. Qaims 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

themselves reverse the epidemic of youth use of e-cigarettes. FDA each of the four areas discussed below.

must address

3. It is essential to address the problem of youth use of other tobacco products as well as ecigarettes. 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 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

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.

Snœrely,

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