June 4, 2014

Sylvia Mathews Burwell
Director
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Director Burwell:

We appreciate that this letter will reach you during a transitional period, but it concerns a matter of critical importance to the public health that demands careful attention by both the Department of Health and Human Services (HHS) and the Office of Management and Budget (OMB).

On April 25th the Food and Drug Administration (FDA) released a long overdue proposed rule to deem electronic cigarettes, cigars and other tobacco products within its regulatory authority under the Family Smoking Prevention and Tobacco Control Act. Until FDA issues a final deeming rule, these tobacco products will remain without regulation, with significant adverse consequences for public health.

Given the importance of making this rule effective as quickly as possible, we have written to HHS and FDA to urge the adoption of a final deeming rule no later than 12 months from the April 25 issuance of the proposed rule. (See attached letter).

In addition, there are matters vital to the protection of the public health that are not addressed in the proposed deeming rule. Prominent among them is the availability of characterizing flavors and marketing that appeal to youth. We have urged FDA to begin the investigation of these issues immediately, include these matters in the final "deeming" rule or, at the very least, issue proposed rules on characterizing flavors and additional marketing restrictions within 12 months of publication of the proposed deeming rule, to be made final shortly after the deeming rule becomes final.

Finally, E-liquid is being shipped and sold in containers that are not childproof. As a result there has been a disturbing rise in children being poisoned by liquid nicotine. We have called on FDA to issue a proposed rule to address the urgent threat to our children from nicotine poisoning within the next 90 days, and a final rule to require child-resistant packaging on nicotine e-liquids by the date of the final deeming rule.

In order for FDA and the Administration to meet these goals the Office of Management and Budget (OMB) and the White House must also make the review and approval of these

matters a priority. The three years it took FDA, HHS, and OMB to develop and approve the proposed deeming rule was too long. The public health consequences of the delay in issuing the proposed deeming rule have been significant.

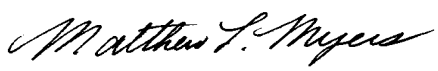
Recognizing the important role OMB plays in the review of regulations, all agencies within the Administration must work together to ensure that these deadlines are met. We urge that OMB and all others within the Administration take swift action and commit to the approval of the deeming rule and whatever additional rules are needed to eliminate the use of flavorings and marketing that appeal to children and to prevent child poisonings from e-liquid no later than April 25, 2015. The promise of the Tobacco Control Act will only be fulfilled if the regulatory process proves capable of generating strong public health rules in a timely manner.

Sincerely,

Christopher W. Hansen
President
American Cancer Society Cancer Action Network

Nancy A. Brown
Chief Executive Officer
American Heart Association

Harold Wimmer
National President and CEO
American Lung Association



Matthew L. Myers
President
Campaign for Tobacco Free Kids

Robin Koval
President and CEO
Legacy

cc: Kathleen Sebelius, Secretary, Department of Health and Human Services