January 29, 2015

The Honorable Sylvia M. Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Burwell:

We are writing to affirm the public health importance of applying the new product provisions of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) to products the Food and Drug Administration (FDA) proposes to deem subject to its authority.

The Tobacco Control Act established a premarket review process for new tobacco products, which the statute defines as products introduced into interstate commerce after February 15, 2007 and products modified after that date. Tobacco companies that want to market a new tobacco product must first file a new product application seeking to demonstrate that their product is "appropriate to the protection of

public health" or a substantial equivalence application seeking to show that their product is substantially equivalent to a grandfathered product on the market prior to February 15, 2007.

Several tobacco companies, as well as some Members of Congress, have expressed concern about how FDA has proposed applying the new product provisions to products that it is deeming subject to its authority. They have urged FDA to change the "grandfather date" in Section 910 of the statute from February 15, 2007 to the date of the proposed or final deeming rule, a request that also has been made by several members of Congress. We urge you to reject calls to change the new product "grandfather date" of the Tobacco Control Act. FDA has no statutory authority to alter the grandfather date and doing so would weaken FDA regulation of tobacco products with adverse consequences for the public health.

Premarket review of new tobacco products is central to the public health protections afforded by the Tobacco Control Act. The premarket review provisions were enacted as a response to the tobacco industry's long history of introducing new products that are more addictive and more appealing, particularly to young people, while carrying a greater risk of disease. Any change in the grandfather date would exempt a wide variety of electronic cigarettes and other deemed products from any agency review to determine whether they pose a threat to public health.

The statute does not allow the FDA to alter the February 15, 2007 date in Section 910 and leaves FDA no discretion to either expand or contract the range of products subject to its review as "new tobacco products" by adjusting this date. If FDA were to alter this grandfather date, the effect would be to exempt a wide range of e-cigarettes, cigars and other tobacco products from any oversight or review to determine whether they constitute threats to public health, even though they deliver highly addictive nicotine. In recent years, we have witnessed the results of the unregulated e-cigarette market including a tripling of youth use of e-cigarettes in the last two years. Teen use of e-cigarettes now surpasses use of regular cigarettes, with over 16% of 10^{th} graders and over 17% of 12^{th} graders reporting use of e-cigarettes, according to recent data from the government-sponsored Monitoring the Future survey. E-cigarette manufacturers have used marketing tactics similar to cigarette manufacturers to reach children and also used flavorings such as "Cherry Crush" and Pina Colada" that appeal to children. One study found that by January 2014 there were 466 brands of e-cigarettes and over 7700 unique flavors, a flood of new products that have not been reviewed by FDA. Furthermore, there have been significant reports of nicotine poisonings – mostly in those under 5 years old – from exposure to these products, including, tragically, one death. Grandfathering these products would make their exemption from new product review permanent.

FDA's proposed deeming rule would afford manufacturers of e-cigarettes ample opportunity to meet the statutory standards for new products, while continuing to sell their products currently on the market, as well as introducing new products. FDA has proposed to use its enforcement discretion to give manufacturers of e-cigarettes and other deemed products a two year "compliance period" beyond the date of the final deeming rule. During this time manufacturers could file a new product application under Section 910 or a substantial equivalence application. Manufacturers would also be free to

introduce new products during this time, as long as they file either a new product or substantial equivalence application prior to expiration of that period. FDA has also proposed to allow the new products for which applications have been filed during the two-year period to remain on the market until FDA acts on the application.

The Tobacco Control Act effectively created a similar compliance period for cigarettes, smokeless tobacco and roll-your-own tobacco, allowing manufacturers to introduce new products into commerce for a 21-month period following the June 22 effective date of the statute, as long as they filed substantial equivalence applications prior to expiration of that period (i.e. prior to March 22, 2011). However, the statute did not permit a "new tobacco product" to remain on the market, or be introduced into the market, unless the manufacturer alleged that it met the conditions for substantial equivalence. In contrast, the proposed deeming rule would permit the marketing of a new product even though no claim of substantial equivalence is made. Under the deeming proposal, e-cigarette manufacturers may keep their products on the market, and introduce new products, by filing for a new product marketing order before the new compliance period ends. These provisions already give e-cigarettes more favorable treatment under the statute than that accorded to currently regulated tobacco products.

One of the major purposes of the Tobacco Control Act was to end the ability of the tobacco companies to introduce new, addictive products without any review or oversight. An expansion of the number of products excluded from review by the agency would be contrary to this purpose. FDA's concern should not be that its proposed deeming rule denies market opportunities to e-cigarettes, but rather that its proposed rule would allow e-cigarette manufacturers to continue to target children for years into the future without any regulatory review of their products or their conduct. [i]

FDA should reject any request to modify the grandfather date for deemed products.

Sincerely,

American Academy of Family Physicians
American Academy of Pediatrics
American Association for Respiratory Care
American Cancer Society Cancer Action Network
American College of Cardiology
American College of Occupational and Environmental Medicine
American College of Preventive Medicine
American Congress of Obstetricians and Gynecologists
American Heart Association
American Lung Association
American Psychological Association
American Public Health Association
American Society of Clinical Oncology
American Thoracic Society
Association of Maternal & Child Health Programs

Association of State and Territorial Health Officials
Campaign for Tobacco-Free Kids
Cancer Prevention and Treatment Fund
Legacy
National African American Tobacco Prevention Network
National Association of City and County Health Officials
National Latino Alliance for Health Equity
Oncology Nursing Society
Partnership for Prevention
Prevent Cancer Foundation
Prevention Institute
RiverStone Health
Society for Cardiovascular Angiography and Interventions
Society for Research on Nicotine and Tobacco
South Carolina Tobacco-Free Collaborative
United Methodist Church – General Board of Church and Society

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[i] In comments filed in the docket in which FDA proposed to extend its regulatory authority, the undersigned groups urged FDA to shorten the compliance period during which such products could remain on the market in the absence of a new product or substantial equivalence application. We also urged FDA to allow manufacturers of deemed products to benefit from the agency's enforcement forebearance in creating a compliance period only if they abide by various conditions to prevent marketing to youth.