November 17, 2016

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
Washington, DC 20510

The Honorable Harry Reid
Minority Leader
U.S. Senate
Washington, DC 20510

The Honorable Paul Ryan
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Senate Majority Leader McConnell, Senate Minority Leader Reid, House Speaker Ryan, and House Minority Leader Pelosi:

As organizations representing U.S. physicians, we write to express our strong opposition to a provision in a House appropriations bill that would exempt e-cigarettes, cigars, and certain other tobacco products that were on the market prior to August 8, 2016, from a scientific review by the Food and Drug Administration (FDA).

An important part of the Family Smoking Prevention and Tobacco Control Act, which Congress enacted with bipartisan support in 2009, was a requirement that new tobacco products undergo a scientific review by FDA. This requirement enables FDA to assess the

risks that a new tobacco product poses to public health, including its risk for causing disease, its addictiveness, and the likelihood that youth and non-tobacco users will use it. Based on its scientific assessment, FDA is able to prohibit new tobacco products that are harmful to public health from the marketplace.

The House Agriculture appropriations bill (H.R. 5054) would exempt thousands of tobacco products, including many candy- and fruit –flavored products, from this scientific product review. Under the House provision, tobacco products that FDA just began to regulate this year, including e-cigarettes and cigars, would be exempted from a product review if they were on the market prior to August 8, 2016. Supporters of the House provision have argued that a product review of these e-cigarettes is not appropriate because these products could benefit public health if they help smokers quit using cigarettes. They often point to a report on e-cigarettes by the Royal College of Physicians and the organization's support for encouraging smokers who are unlikely to quit to instead switching to less harmful sources of nicotine, including e-cigarettes.

The Royal College of Physicians' recommendations on e-cigarettes are not an appropriate standard for establishing U.S. policy for several reasons. First, the Royal College of Physicians is making its recommendations in the context of a much stricter European tobacco regulatory environment, including advertising restrictions and health warnings on e-cigarettes, policies that have not yet been fully implemented in the U.S. Second, rates of U.S. youth e-cigarette use are much higher than UK youth rates. Since 2011, the U.S. has seen a 10-fold increase in e-cigarette use among high schoolers. There are now an estimated 3 million middle school and high school students in the U.S. who currently use e-cigarettes. Third, the Royal College of Physicians' position is an outlier amongst medical and public health organizations as well as the position of most developed nations. Developed nations like Australia, New Zealand and most members of the European Union have taken a far more restrictive approach to e-cigarettes than the Royal College Physicians' recommendations. Lastly, currently available data do not support the use of e-cigarette products as a smoking cessation strategy.

The undersigned U.S. physician organizations want to make clear that we believe FDA oversight of e-cigarettes, including a product review, is necessary to protect public health. Our position is based on our assessment of the existing data on the potential risks and benefits of e-cigarettes, including the United States' experience with e-cigarettes. The long-term risks of using e-cigarettes are unknown, but they are not likely to be risk free. The aerosol generated by some e-cigarettes has been found to contain carcinogens and toxins. Of particular concern is use of e-cigarettes by American youth.

Any use of nicotine by youth is troubling because adolescents are especially vulnerable to nicotine addiction and nicotine use during adolescence may have lasting adverse

consequences for brain development. Furthermore, initial research has raised concerns that e-cigarette use may have adverse health effects, particularly on the lungs.

When Congress enacted the Family Smoking Prevention and Tobacco Control Act it specifically created a process for FDA to evaluate the risks of new and revised tobacco products. A scientific product review by FDA will help to answer remaining questions about e-cigarettes and provide the agency with an important tool to protect public health. Manufacturers will be required to provide FDA with information about the products they wish to sell, including what their products contain, how they are made, what the health risks of using them are, and whether they are likely to increase use by youth or non-tobacco users. With this information, FDA can make sure e-cigarettes remaining on the market are made in a way that minimizes their appeal to youth, minimizes their risk to health, and maximizes whatever potential they may have to reduce the tremendous burden of death and disease.

As you and leaders on the Appropriations Committees work to finalize appropriations bills for Fiscal Year 2017, we urge you to reject this provision. FDA oversight of these products, including a scientific review of the risks that a new product poses to individuals and the broader population, is appropriate for a nicotine-containing product and should not be weakened.

Sincerely,

American Thoracic Society
American College of Preventive Medicine
American Medical Association
American Society of Addiction Medicine
American Osteopathic Association
American Association of Clinical Endocrinologists
American College of Cardiology
American Society of Clinical Oncology
American Academy of Family Physicians
American Academy of Pediatrics
Society of Thoracic Surgeons
American College of Chest Physicians
National Association for the Medical Direction of Respiratory Care