April 17, 2018

The Honorable Richard Shelby
Chair
Senate Appropriations Committee
U.S. Senate
Washington, DC 20510

The Honorable Patrick Leahy
Ranking Member
Senate Appropriations Committee
U.S. Senate
Washington, DC 20510

The Honorable Rodney Frelinghuysen
Chair
House Appropriations Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Nita Lowey
Ranking Member
House Appropriations Committee
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Shelby, Ranking Member Leahy, Chairman Frelinghuysen and Ranking Member Lowey:

As Congress begins work on fiscal year 2019 appropriations bills, we, the physicians of America, strongly urge Congress to oppose any provisions to weaken or delay the Food and Drug Administration's (FDA) authority to regulate all tobacco products.

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.

In recent years, the House has included provisions in the Agriculture-FDA appropriations bill to exempt thousands of tobacco products, including many candy- and fruit-flavored products, from

this scientific product review. Under these House provisions, many tobacco products that FDA just began to regulate, 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 U.K. Royal College of Physicians and the organization's support for encouraging smokers who are unlikely to quit to instead switch 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 recommendation 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, U.S. youth e-cigarette rates are much higher than UK youth rates. In the U.S., 11.3 percent of high school students in 2016 reported using e-cigarettes during the past 30 days. E-cigarettes have become the most commonly used tobacco product among youth. There are more than 2 million middle school and high school students in the U.S. who currently use e-cigarettes. This is particularly concerning in light of the National Academies of Sciences, Engineering, and Medicine's (NASEM) recent report that found substantial evidence to conclude that youth who use e-cigarettes have an increased risk of ever using combustible cigarettes. Third, the Royal College of Physicians' position is an outlier amongst most developed nations. Developed nations like Australia, New Zealand and the European Union have taken far more restrictive approaches to e-cigarettes than the Royal College of Physicians recommendations.

Lastly, the ability of e-cigarettes to help smokers to quit cigarettes has not been established. The NASEM concluded there was only limited evidence that e-cigarettes may help people to stop smoking cigarettes and insufficient evidence from randomized controlled trials to assess the effectiveness of e-cigarettes as a smoking cessation aid compared to FDA-approved smoking cessation medications or quitting on one's own without treatment.

The undersigned U.S. physician organizations want to make clear that we believe FDA oversight of e-cigarettes, including pre-market 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. E-cigarettes may be less harmful than cigarettes, but they are not risk-free. The aerosol generated by some e-cigarettes has been found to contain carcinogens and toxins. Initial research has raised concerns that e-cigarette use may have adverse health effects, and the long-term risks of using e-cigarettes are unknown. Moreover, nearly 60 percent of adult e-cigarette users in the U.S. continue to smoke cigarettes, which elevates their health risks compared to switching completely to e-cigarettes or quitting use of all tobacco products. Of particular concern is the use of e-cigarettes by American youth. In addition to the higher potential for progressing to combustible cigarette smoking, 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.

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 the 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 related to tobacco products.

As you work to enact appropriations bills for fiscal year 2019, we strongly urge you to reject any provisions to weaken or delay FDA's authority to regulate all tobacco products. 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 any nicotine-containing product and should not be weakened.

Sincerely,

American Academy of Allergy, Asthma and Immunology
American Academy of Family Physicians
American Academy of Pediatrics
American College of Cardiology
American College of Chest Physicians
American College of Physicians
American College of Preventive Medicine
American College of Radiology
American Medical Association
American Thoracic Society
National Association for the Medical Direction of Respiratory Care
National Council of Asian Pacific Islander Physicians
National Hispanic Medical Association
National Medical Association
Society of Thoracic Surgeons