



American Association
for Cancer Research

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American Society of Clinical Oncology

IASLC
INTERNATIONAL ASSOCIATION FOR THE STUDY OF LUNG CANCER



Conquering Thoracic Cancers Worldwide

May 2, 2016

The President
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Mr. President:

Sunday, April 24th, marked two years since the release of the U.S. Food and Drug Administration's (FDA) proposed "deeming" regulation which would expand its authority over tobacco products. This proposed regulation will implement provisions of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which you signed in 2009, that significantly reduces the 480,000 annual deaths and \$170 billion expense attributable to tobacco-caused diseases. This proposed regulation gives the FDA immediate authority over "deemed" products including electronic cigarettes, cigars, pipe tobacco, certain dissolvables that are not "smokeless tobacco," gels, and waterpipe tobacco. It also authorizes the Secretary of Health and Human Services to "deem" other tobacco products as subject to FDA jurisdiction.

This proposed regulation to "deem" authority over all currently unregulated tobacco products has now been under review at the White House Office of Management and Budget (OMB) for more than six months. As representatives of the nation's leading cancer organizations, the American Association for Cancer Research (AACR), the American Society of Clinical Oncology (ASCO), and the International Association for the Study of Lung Cancer (IASLC), we write to you today to urge your Administration to finalize this regulation so that the health of our youth and of all Americans is protected.

Over a year ago, during a Congressional hearing, the Secretary of Health and Human Services, Sylvia Mathews Burwell, indicated that the "deeming" regulation would be finalized by the end of summer 2015. We are now approaching the summer of 2016 and these delays continue to put public health at risk. Tobacco is clearly recognized as the leading preventable cause of adult mortality and has been causally associated with 18 different cancers. Tobacco abuse accounts for 30 percent of all cancer deaths and is attributable to at least 80% of the 155,000 lung cancer deaths in the US in 2015.

Recently introduced novel tobacco related products pose potentially significant risks as well as possible benefits. At present, the FDA cannot exercise authority to regulate the flavors in new tobacco products, or to require manufacturers to disclose their ingredients. The public, particularly youth, will continue to be the target of irresponsible marketing of unregulated e-cigarettes and cigars if FDA does not act. Because there are currently no restrictions on e-

cigarettes we cannot analyze their significance as a potential tool for sorely needed smoking mitigation therapy. We have seen the profound impact that federal regulation has had on conventional cigarette use, and now, with the ever increasing use of cigars and e-cigarettes, FDA should operate with full authority to regulate all tobacco products.

The unregulated cigar industry, its manufacturing standards, ingredients, and labeling should be placed under FDA jurisdiction. The smoking of cigars has greatly increased among youth and young adults after the addition of flavorings was banned in conventional cigarettes. Small cigars are now essentially conventional cigarettes. According to the Centers for Disease Control and Prevention (CDC), high school boys now smoke cigars at nearly the same rate as cigarettes (10.8 percent for cigars and 10.6 percent for cigarettes), and the CDC also estimates based on a 30-day use that there were 2.4 million occasional youth e-cigarette users in 2014. Allowing the FDA to regulate these products will help protect those who use these products as well as those who are exposed to secondhand smoke or vapor.

Release of the proposed “deeming” regulation asserting jurisdiction over all tobacco products is long overdue. We ask for your leadership in advancing this regulation for the protection of all Americans, especially our cherished yet vulnerable populations, youth and young adults.

Sincerely,



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Fred R. Hirsch, MD, PhD
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Cc: Robert M. Califf, MD, MACC, Commissioner, U.S. Food and Drug Administration
Mitch Zeller, JD, Director, Center for Tobacco Products, U.S. Food and Drug Administration