



February 9, 2015

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Mr. Howard Shelanski
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 7th St., NW
Washington, DC 20503

Dear Secretary Burwell and Administrator Shelanski:

We, the American Psychological Association, the College of Problems of Drug Dependence, and the Society for Research on Nicotine and Tobacco, are writing as the principal organizations dedicated to the advancement, understanding, and dissemination of research on the behavioral and psychological sciences, substance use and dependence, and nicotine and tobacco, respectively. Collectively, we represent thousands of scientists working on all aspects of drug dependence and addiction, from molecular neuroscience and gene expression to social and cultural determinants of substance use behavior.

We are alarmed and dismayed over what was likely a well-intentioned cost-benefit analysis conducted by FDA staff economists in the proposed tobacco deeming rule. This analysis vastly over-estimated the cost to consumers of "lost pleasure" in the unlikely event they were fortunate enough to be able to quit the use of tobacco products. We say "unlikely," since nearly 70 percent of adult smokers want to stop smoking and more than half attempt to quit every year. Because nicotine addiction is so strong, each year only about 4-6 percent of smokers successfully quit.¹ Unfortunately, the extremely aversive and well-documented sequelae of nicotine withdrawal were apparently lost on the FDA economists who may not be knowledgeable about substance use dependence. Those of us who study the phenomena that maintain drug use behavior would never include those entirely negative experiences on the "loss of pleasure" side of the equation.

Further, the majority of chronic tobacco product users develop dependence on these products before reaching the legal age to use them. It is estimated that 95 percent of adult smokers began smoking

¹ U.S. Department of Health and Human Services, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*, Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

before the age of 21.² Putting the issue of legal access aside, a large and compelling body of research on adolescent development has demonstrated that both the physical and cognitive maturation of the brain, including forebrain executive functioning related to motivation, self-control, judgment, and decision-making, are still in a formative stage when most adolescents are first exposed to and subsequently become dependent on nicotine. As adolescents are not meant to use tobacco products and lack sufficient foresight to evaluate the long term health impact of tobacco use, there is really no rationale for assessing even minimal "loss of pleasure," if any, in a cost-benefit assessment of tobacco product regulations.

An alternative approach, detailed by Chaloupka et al. in the December 2014 issue of *Tobacco Control*, appropriately challenges the FDA analysis and presents a framework we believe should guide the process for tobacco product regulation moving forward.³ The concept of consumer surplus simply cannot be applied to a product that produces dependence in the majority of users.

FDA has substantial resident expertise in behavioral science and addiction in the Center for Tobacco Products and on the Tobacco Product Scientific Advisory Committee (TPSAC). We respectfully request that you review the process and approach FDA has used in evaluating its cost-benefit analysis as applied to tobacco product regulation, and we strongly urge FDA to include expertise in behavioral science and addiction in a re-evaluation of the impact of the deeming rule. Finally, we believe that all future regulatory actions related to tobacco products should likewise include such expertise so as to prevent the misapplication of economic principles to products that routinely result in lifelong dependence, morbidity, and mortality in those who use them.

Sincerely,

American Psychological Association
The College on Problems of Drug Dependence
Society for Research on Nicotine and Tobacco

cc: Richard Frank, Assistant Secretary for Planning and Evaluation,
Department of Health and Human Services
Margaret Hamburg, Commissioner, U.S. Food and Drug Administration
Mitchell Zeller, Director, FDA Center for Tobacco Products

² Calculated based on data found in the National Survey on Drug Use and Health, 2012.

³ Chaloupka, F.J., Warner, K.E., Acemoglu D, et al. (2014). An evaluation of the FDA's analysis of the costs and benefits of the graphic warning label regulation. *Tobacco Control*, 2014; 0:1–8.