



March 27, 2014

Mitchell Zeller
 Director, Center for Tobacco Products
 Food and Drug Administration
 9200 Corporate Dr.
 Rockville, MD 20850

Dear Director Zeller:

The recently-issued report of the Surgeon General, *The Health Consequences of Smoking – 50 Years of Progress* (the SG Report), provides a comprehensive review of the progress our nation has made against the tobacco epidemic. Disturbingly, although the SG Report documents a sharp decline in the incidence of adult smoking in the decades since the historic 1964 Surgeon General’s Report, it also finds that smokers are at a far greater risk of developing lung cancer than they were 50 years ago. Moreover, the Report concludes that this outcome is the result of changes made during that time in the design and composition of U.S. cigarettes.

For the first time in history, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) gives the Food and Drug Administration (FDA) the authority to require changes in the content and design of cigarettes “appropriate for the protection of public health.” The SG Report makes clear that FDA needs to act and act quickly to use this broad authority to require the tobacco companies to reverse the changes that have actually made their products even more dangerous. No manufacturer of any other product would have been allowed to make product changes that increased the risk of fatal disease to its users. In light

of the Surgeon General's unequivocal finding that today's cigarettes do just that, we write to urge FDA to respond decisively by requiring whatever changes are needed in the design and composition of cigarettes to eliminate the increased risk of disease and death identified by the Surgeon General.

The SG Report provides compelling evidence of the increased risk to smokers: "Although the prevalence of smoking has declined significantly over the past one-half century, the risks for smoking-related disease and mortality have not. In fact, *today's cigarette smokers – both men and women – have a much higher risk for lung cancer and chronic obstructive pulmonary disease (COPD) than smokers in 1964, despite smoking fewer cigarettes.*" (emphasis added).

The Surgeon General found that, during the period 1959-2010, the risk of lung cancer to smokers increased 10-fold for women and more than doubled for men, whereas the risk of lung cancer for those who had never smoked remained the same. Thus, the Report concludes: "The evidence is sufficient to infer that the relative risk of dying from cigarette smoking has increased over the last 50 years in men and women in the United States."

The SG Report also establishes that the increased risk of lung cancer to smokers is due to the tobacco industry's changes in the design and composition of cigarettes. Specifically, the Report finds that the increase in lung cancer risk is driven largely by a dramatic increase in the risk of adenocarcinoma of the lung, which has become an increasing proportion of all lung cancers. In turn, the Report finds that "the increased risk of adenocarcinoma of the lung in smokers *results from changes in the design and composition of cigarettes since the 1950s.*" (emphasis added). The Report notes two specific changes in design and composition that may be responsible for the increased risk of adenocarcinoma of the lung: an increase in highly carcinogenic tobacco-specific nitrosamines in U.S. cigarettes and the use of ventilation holes in filters that enable smokers to inhale more vigorously, thereby drawing carcinogens in the smoke more deeply into the lungs.

The Surgeon General's conclusion that the increased risk of lung cancer to smokers is due to changes in cigarette design and composition has critical implications for FDA's regulation of tobacco products. As the SG Report observes, "[a]bove all, if the risk of lung cancer has increased with changes in the design and composition of cigarettes, then the potential exists to reverse that increase in risk through changes in design and composition." Under § 907 of the Tobacco Control Act, FDA has the authority to adopt standards for tobacco products "appropriate for the protection of the public health." In short, FDA has the authority to require cigarette manufacturers to change the design and composition of cigarettes to reduce the risk of disease and death. The need for exercising this authority is particularly compelling when the scientific evidence demonstrates that changes in the design and composition of cigarettes unilaterally made by manufacturers have increased that risk.

It should also be noted that the SG Report incorporates the findings of U.S. District Judge Gladys Kessler in *United States v. Philip Morris*, 449 F.Supp. 2d 1 (D.D.C. 2006), and of the U.S. Congress in enacting the Tobacco Control Act, that the cigarette companies "have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction." Indeed, in the Consumer Guide to the SG Report, issued by the Department of Health and Human Services, it is noted that "[s]ome of today's cigarettes are more addictive than those from earlier decades." The Surgeon General observes that "[c]igarettes are highly engineered products." It would appear that the cigarette companies have engineered products that are both more lethal and more addictive.

The Surgeon General calls for "effective implementation of FDA's authority for tobacco product regulation in order to reduce tobacco product addictiveness and harmfulness." It is imperative that FDA

respond to the SG Report by moving decisively to exercise its statutory authority to require cigarette manufacturers to make necessary life-saving changes in the design and composition of their products.

Over the past 50 years, smoking has killed more than 20 million Americans. We cannot afford to give the tobacco industry another 50 years to make cigarettes even more dangerous and addictive than they are today.

Respectfully,

American Academy of Family Physicians
American Academy of Oral Medicine
American Academy of Otolaryngology – Head and Neck Surgery
American Academy of Pediatrics
American Association for Cancer Research
American Association for Respiratory Care
American Cancer Society Cancer Action Network
American College of Cardiology
American College of Preventive Medicine
American Congress of Obstetricians and Gynecologists
American Heart Association
American Lung Association
American Medical Association
American Psychological Association
American Public Health Association
American Society of Addiction Medicine
American Society of Clinical Oncology
American Thoracic Society
Association of State and Territorial Health Officials
Association of Women's Health, Obstetric and Neonatal Nurses
Campaign for Tobacco-Free Kids
Cancer Prevention and Treatment Fund
Community Anti-Drug Coalitions of America
Legacy
Lung Cancer Alliance
National African American Tobacco Prevention Network
National Association of County & City Health Officials
National Latino Alliance for Health Equity
North American Quitline Consortium
Oncology Nursing Society
Partnership for Prevention
Society for Cardiovascular Angiography and Interventions
Society for Research on Nicotine and Tobacco

cc: The Honorable Kathleen Sebelius
The Honorable Margaret Hamburg