August 11, 2008

In Regards To: "Cigarette Test Method, [P944509]"

Federal Trade Commission
Office of the Secretary
Room H-135 (Annex L)
600 Pennsylvania Ave, N.W.
Washington, D.C. 20580

To Commissioners of the Federal Trade Commission,

The American Cancer Society Cancer Action Network (ACS CAN) is the nonprofit, nonpartisan partner advocacy organization of the American Cancer Society dedicated to eliminating cancer as a major health problem. ACS CAN supports legislative, regulatory, and policy efforts that will make cancer a top national priority.

Lung cancer is the leading cause of cancer deaths in the United States today, and tobacco use is responsible for 87 percent of all lung cancer deaths[1]. ACS CAN has established aggressive goals to reduce cancer – including lung cancer incidence and mortality – that we are pursuing with the cooperation and collaboration of the public, private, and nonprofit sectors. ACS CAN strongly supports the Federal Trade Commission's (FTC) proposal to rescind its 1966 guidance regarding the FTC Test Method of machine-measured tar and nicotine yields as an important step toward reducing the tobacco industry's ability to deceive current smokers and addict new, young smokers.

While the tobacco industry has spent the last 50 years vehemently denying and misleading smokers about the dangers of tobacco use, the American Cancer Society and more recently ACS CAN have helped document the lethal consequences of smoking and its detrimental effects on almost every organ of the body[2]. Currently, tobacco use is the number one preventable cause of death in the United States, responsible for more than 438,000 deaths each year[3]. Tobacco use accounts for at least 30 percent of all cancer deaths and an increased risk of at least 15 different types of cancer, as well as heart

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[1] American Cancer Society. *Cancer Facts & Figures 2008.* Atlanta: American Cancer Society; 2008. Doll R, Peto R. *The Causes of Cancer.* New York, NJ: Oxford Press; 1981. US Department of Health and Human Services. *Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General*. Rockville, MD: US Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 1989.

[2] US Department of Health and Human Services. *Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General*. Rockville, MD: US Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 1989.

[3] Centers for Disease Control and Prevention. Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses – United States, 2000. *MMWR*. 2005; 54(25): 625-628.

disease, stroke, and other lung diseases[4]. In addition, the risk of developing lung cancer is approximately 23 times higher in male smokers and 13 times higher in female smokers than it is in lifelong nonsmokers[5].

The tobacco industry responded to the public's growing concern about the health risks associated with smoking by introducing filters beginning in the 1950s and by producing cigarettes with progressively lower machine tar yield during the 1960s and 1970s. However, despite the decrease in machine-measured tar yields between the 1950s and 1980s, lung cancer death rates increased during this period. By the mid-1990s it became clear that the lung cancer risk in current smokers had nearly doubled in men and had increased more than five-fold in women in the time between the first American Cancer Society Cancer Prevention Study (CPS-I, 1959-1965) and the second Cancer Prevention Study (CPS-II, 1982-1988)[6]. It has now been proven that these so-called "low-tar" cigarettes can provide the smoker with the same levels of tar and nicotine as regular cigarettes (while still producing low machine-measured tar yields) because of the cigarette's redesign and because of compensatory behavior by smokers. Therefore, the use of the current FTC Test Method for tar and nicotine yields has become meaningless; in fact, it can serve to mislead smokers into underestimating their health risk.

The FTC officially adopted the machine-measured method for determining tar and nicotine yields – first developed by the tobacco industry in the 1930s – and renamed it the FTC Test Method in 1966. The FTC acknowledged that the machine-measured yields were not an accurate reflection of human behavior. At that time, the public health community supported the use of the FTC Test Method of measuring tar and nicotine yield because it appeared to be a standardized, uniform approach for informing smokers about the relative toxicity of different brands. Based on the science known at that time, many believed that reducing a smoker's exposure to tar would reduce his or her health risk. However, the public health community greatly underestimated the tobacco industry's ability to manipulate FTC Test Method yields, the powerful addictive properties of nicotine, and the compensatory behavior of smokers.

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[4] US Department of Health and Human Services. *The Health Consequences of Smoking - A Report of the Surgeon General*. Rockville, MD: US Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2004.

[5] US Department of Health and Human Services. *The Health Consequences of Smoking - A Report of the Surgeon General*. Rockville, MD: US Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2004.

[6] Thun MJ, Burns DM. Health impact of "reduced yield" cigarettes: a critical assessment of the epidemiological evidence. *Tobacco Control.* 2001; 10: i4-i11. National Cancer Institute. *Changes in Cigarette-Related Disease Risk and Their Implication for Prevention and Control* (Thun et al, Chapter 4). Smoking and Tobacco Control Monograph No. 8. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 97-4213, February 1997.

The tobacco industry redesigned cigarettes in such a way as to ensure low machine-measured tar yields of cigarettes that would still provide adequate nicotine intake to maintain the smoker's addiction. These changes included the use of more porous paper, expanded tobacco, and air ventilation holes that diluted the smoke. Small holes were inserted into the filter tip of a cigarette, which allowed external air in during each puff and thereby reduced the proportion of cigarette smoke inhaled. Because of the placement of the holes, a smoker can, knowingly or otherwise, cover these holes with his or her lips or fingers and actually increase the amount of cigarette smoke inhaled, which raises the smoker's tar and nicotine exposure above the machine-measured yield[7].

The tobacco industry aggressively marketed cigarette filters and "low-tar" yields to the public as implied health claims rather than as technical descriptors[8]. The FTC Test Method became a promotional value for the tobacco industry; it allowed cigarette makers to alleviate smokers' health concerns by marketing their product as "low-tar" and "low-nicotine" despite the lack of evidence of reduced health risk.

Another problem is that smokers compensate when smoking "low-tar" cigarettes in order to maintain the same level of nicotine intake, which eliminates any potential health benefit of the product. Such compensatory behaviors can include taking more puffs per cigarette, inhaling larger puff volume more deeply into the lungs, covering the holes in the ventilation filter, and increasing the number of cigarettes smoked per day.

CPS-I concluded that smokers who switched to "low-tar" cigarettes increased the number of cigarettes they smoked per day[9]. Evidence now shows that when accounting for nicotine yield, smokers of "low-tar" cigarettes are actually exposed to the same levels of tar and carbon monoxide as smokers of "regular" cigarettes. "Low-tar" or "very-low-tar" cigarettes were found to be just as hazardous with respect to lung cancer as those cigarettes labeled as "regular" or "full" tar[10]. It also became clear that the type of lung cancer caused by smoking had changed from squamous cell or small-cell lung cancer to lung adenocarcinoma. This change was attributable to changes in smoking behavior and to cigarette redesign in response to the virtual market takeover of "low-tar" cigarettes[11].

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[7] Stephens WE. Dependence of tar, nicotine and carbon monoxide yields on physical parameters: implications for exposure, emissions control and monitoring. *Tobacco Control.* 2007; 16: 170-176.
[8] WHO. SACTob Recommendation on Health Claims Derived from ISO/FTC Method to Measure Cigarette Yield. (January 2003). Tobacco Control. WHO Tobacco Control Papers. Paper ISO200. Lozlowski LT, Pillitteri, JL. Beliefs about "Light" and "Ultra Light" cigarettes and efforts to change those beliefs: an overview of early efforts and published research. *Tobacco Control.* 2001; 10: i12-i16. Shiffman S, et al. Smokers' beliefs about "Light" and "Ultra Light" cigarettes. *Tobacco Control.* 2001; 10: i17-i23.
[9] Thun MJ, Burns DM. Health impact of "reduced yield" cigarettes: a critical assessment of the epidemiological evidence. *Tobacco Control.* 2001; 10: i4-i11.
[10] Harris JE, Thun MJ, Mondul AM, Calle EE. Cigarette tar yields in relation to mortality from lung cancer in the Cancer Prevention Study II prospective cohort, 1982-8. *BMJ.* 2004; 328(7431): 72-76.
[11] Thun MJ, et al. Cigarette Smoking and Changes in the Histopathology of Lung Cancer. *Journal of the National Cancer Institute.* November 6, 1997; 89(21): 1580-1586.

Lung adenocarcinoma is typically found in the peripheral lung tissue suggesting that smokers are inhaling tobacco smoke more deeply, a behavior seen in "low-tar" cigarette smokers.

It is now clear that the original intent of the FTC Test Method – to provide smokers with standardized, uniform measures of tar and nicotine yields – is no longer valid. The FTC Test Method provides no public health benefit and, in fact, could be contributing to smokers continuing to smoke instead of quitting.

The National Cancer Institute concluded the following in its 2001 Monograph, *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yield of Tar and Nicotine*[12]: "Measurements of tar and nicotine yields using the FTC method do not offer smokers meaningful information on the amount of tar and nicotine they will receive from a cigarette. The measurements also do not offer meaningful information on the relative amounts of tar and nicotine exposure likely to be received from smoking different brands of cigarettes." In addition, the report concluded, "Epidemiological and other scientific evidence, including patterns of mortality from smoking-caused diseases, does not indicate a benefit to the public from changes in cigarette design and manufacturing over the last fifty years."

The tobacco industry has capitalized on its ability to use certification of the FTC Test Method to imply reduced heath risk claims despite evidence to the contrary. Removing the industry's ability to rely on the uninformative and misleading FTC Test Method will, in part, prevent cigarette companies from making deceptive health claims targeting smokers, particularly those concerned about their health risk associated with smoking. In addition, elimination of the FTC Test Method does not change the FTC's responsibility as it relates to all of the tobacco industry's marketing practices.

ACS CAN will continue its work to ensure the public has accurate, scientifically-based information regarding the health risks associated with smoking and believes that rescinding the FTC's 1996 guidance is critical to this effort.

Respectfully,

Daniel E. Smith
President

[12] National Cancer Institute. *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine.* Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02-5074, October 2001.