III. <u>RECOMMENDATION REGARDING THE FTC CIGARETTE TEST METHOD</u>

Cigarette smoke is a highly complex mixture of gases and particulate matter, containing

thousands of chemical compounds. Despite the complex and hazardous nature of cigarette

smoke, the only information that is currently widely available to smokers concerning smoke

constituents is the tar, nicotine, and carbon monoxide ratings produced by voluntary industry

testing, using an FTC approved testing protocol. Since 1967, the five largest cigarette

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manufacturers have used this voluntary testing protocol to produce ratings for their cigarettes.

A. Limitations of the Current System

Cigarette ratings for tar, nicotine and carbon monoxide are currently determined by machine testing conducted in accordance with a methodology adopted by the Commission in 1967. The tar and nicotine testing program was intended to provide smokers seeking to switch to lower tar cigarettes with a single, standardized measurement with which to choose among the then-existing brands.³

The five largest domestic cigarette manufacturers voluntarily include tar and nicotine ratings in their advertising. Less than 6% of cigarette packs sold in 1997 disclosed those ratings, however, and the major manufacturers do not disclose carbon monoxide yields either in advertising or on labeling. Smaller domestic manufacturers and cigarette importers are under no obligation either to test their cigarettes for tar, nicotine and carbon monoxide yields or to disclose those yields to their customers.

Over the past 30 years that the current system has been in place, there have been dramatic decreases in the machine-measured tar and nicotine yields of cigarettes. Since 1968, the average sales-weighted machine-measured tar yield has fallen from 21.6 mg. to 12.0 mg. Today, 70% of all cigarettes sold have machine-measured tar yields of 15 mg. or less.

Despite these substantial decreases in machine-measured yields, the Commission has been

³ When the test method was adopted, the public health community believed that "[t]he preponderance of scientific evidence strongly suggests that the lower the tar and nicotine content of cigarette smoke, the less harmful would be the effect." U.S. Dep't of Health and Human Services, *The Health Consequences of Smoking: The Changing Cigarette* 1 (1981) (quoting 1966 Public Health Service statement).

concerned for some time that the current test method may be misleading to individual consumers who rely on the ratings it produces as indicators of how much tar and nicotine they actually get from their cigarettes. In fact, the current ratings tend to be relatively poor predictors of tar and nicotine exposure. This appears to be due primarily to compensation -- the tendency of smokers of lower rated cigarettes to take bigger or more frequent puffs, or otherwise alter their smoking behavior to get the amount of nicotine they need. Such variations in the way people smoke can have significant effects on the amount of tar, nicotine, and carbon monoxide they get from any particular cigarette. The Commission is concerned that smokers may incorrectly believe, for example, that they will get three times as much tar from a 15 mg. tar cigarette as from a 5 mg. tar cigarette. In fact, if compensation is sufficiently great, it is possible for smokers to get as much tar and nicotine from relatively low rated cigarettes as from higher rated ones. Although these limitations have been present in the system since its initiation in 1967, they have become of substantial concern more recently because of changes in modern cigarette design and a better understanding of the effects of compensatory smoking behavior.

Some public health agencies have also expressed concerns that new studies may question the basic assumption underlying cigarette testing -- that cigarettes with lower machine-measured tar and nicotine ratings are less harmful than ones with higher ratings. For example, in 1997, the National Cancer Institute issued a monograph noting that the apparent mortality risk among current smokers has risen in the last forty to fifty years, even though machine-measured tar and nicotine yields have fallen during the same period.⁴ In attempting to understand this fact, the

⁴ Smoking and Tobacco Control Monograph 8: Changes in Cigarette-Related Disease Risk and Their Implications for Prevention and Control, National Institutes of Health, National Cancer Institute (1997).

monograph suggested that the increased mortality risk might be due to increases in current smokers' lifetime exposure to cigarette smoke or that the reduced tar levels of modern cigarettes may have less benefit than previously believed. In addition, a number of studies have also found that changes in smoking behavior and cigarette design appear to have resulted in an increase in a type of cancer that occurs deeper in the lung than the lung cancer traditionally associated with smoking.⁵

B. <u>HHS Review and Recommendation</u>

In light of these concerns, in 1998 the Commission requested that the Department of Health and Human Services ("HHS") conduct a complete review of the FTC's cigarette testing methodology.⁶ This review will be completed in September 2000.

The Commission believes it is vital that there be a mechanism for implementing the recommendations once the review is completed. Although the Commission brings a strong, market-based expertise to its scrutiny of consumer protection matters, it does not have the specialized scientific expertise needed to design scientific test procedures. Indeed, when

⁵ See Thun, M.J., et al., "Cigarette Smoking and Changes in the Histopathology of Lung Cancer," 89 J. of the Nat'l Cancer Inst. 1580 (1997); Ernster, V.L., "The Epidemiology of Lung Cancer in Women," 4 Annals of Epidemiology 102 (1994); Levi, F.S., et al., "Lung Carcinoma Trends by Histologic Type in Vaud and Neuchatel, Switzerland, 1974-1994," 79 Cancer 906 (1997).

⁶ Among other things, HHS's review is designed to reconcile the findings of recent studies suggesting that cigarettes with lower tar ratings may not be less harmful with the findings of other studies suggesting that there may be some risk reduction from the use of lower tar cigarettes. *See* Parish, H. et al., "Cigarette smoking, tar yields, and non-fatal myocardial infarction: 14,000 cases and 32,000 controls in the UK," 311 *Brit. Med. J.*, 471 (1995); Tang, J. et al., "Mortality in relation to tar yield of cigarettes: a prospective study of four cohorts," 311 *Brit. Med. J.* 1530 (1995).

evaluating medical or other scientific issues, the Commission often relies on other government agencies and outside experts with more knowledge in the relevant areas. Therefore, the Commission recommends that Congress consider giving authority over cigarette testing to one of the Federal government's science-based, public health agencies. Furthermore, because the limitations of the current system have such substantial implications for public health, the Commission believes it is essential that procedures for implementing the HHS recommendations

be established to facilitate swift and broad implementation by the appropriate Federal agency.