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Laboratory Research Related to the FTC Method

Statement of

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For Release on Delivery Expected at 2:30 p.m. Tuesday, November 13, 2007 Mr. Chairman and Members of the Committee, I am Dr. David Ashley, Chief of the Emergency Response and Air Toxicants Branch and Chief of the Tobacco Laboratory in the National Center for Environmental Health of the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services. I am also the Chair of the World Health Organization's Tobacco Laboratory Network. I am pleased to be here today to discuss research findings from the CDC Tobacco Laboratory that provide a better understanding of the Federal Trade Commission (FTC) method and how results from the FTC method should be interpreted.

Our laboratory has five research priorities: 1) to characterize the chemical constituents and chemical additives of tobacco products; 2) to characterize the chemical and physical properties of tobacco products that influence delivery of nicotine and other harmful substances; 3) to identify the causative agents of disease in tobacco and tobacco smoke; 4) to assess the exposure of the U.S. population (including children, women of childbearing age, and other susceptible groups) to the harmful chemical constituents of tobacco smoke; and 5) to collaborate in health studies examining the relationship of secondhand smoke exposure to health outcomes, such as cancer. We work closely with CDC's Office on Smoking and Health.

Smoking causes diseases of the lungs and coronary arteries of the heart, the latter being the leading cause of death in the United States. Cigarette smokers are 2 to 4 times more likely to develop coronary heart disease than nonsmokers. While attempting to decrease the risk of cancer associated with smoking by reducing exposures to suspected or known carcinogens is worthwhile, it is equally important to recognize that the amount of small

particles, called particulate matter, is inhaled from cigarettes by smokers at many times the levels found to be associated with significant risk for diseases of the lung and heart among persons breathing air containing these particles from other sources such as industrial pollution or fires.

Our laboratory has developed a broad set of capabilities to measure addictive and toxic substances in the tobacco product, in cigarette smoke, and in people who smoke and are exposed to the smoke of others. We use multiple machine smoking regimens (i.e., specified puff volumes, puff rates, total smoking time), including the FTC smoking regimen, in our research.

For the past 20 years, our lab at CDC has conducted research on assessing exposure to cigarette smoke. We developed new methods to measure cotinine, a metabolite of nicotine, in serum and saliva as a marker of tobacco smoke exposure. We have applied this measurement to national surveys to track over time the exposure of the U.S. population to tobacco smoke, both for smokers and persons exposed to secondhand smoke. We have documented substantial decreases in exposure to secondhand smoke in the U.S. population and identified differences in exposure between age, sex, and race/ethnic groups.

CDC has also developed and applied measurements to better understand the amount of addictive and toxic substances in cigarettes and factors that affect the delivery of these substances to smokers and persons exposed to secondhand smoke. Our smoking machines enable us to assess the influence of various smoking conditions on the delivery

of addictive and toxic substances to smokers. In tobacco and tobacco smoke, we currently measure nicotine, "tar" (i.e., nicotine-free dry total particulate matter), tobacco-specific nitrosamines, volatile organics, aldehydes, polycyclic aromatic hydrocarbons, and heavy metals. Our lab has performed studies that assess the smoke intake of individual smokers. In addition, we have measured components of cigarette smoke in the urine and blood of smokers and people exposed to secondhand smoke.

The FTC method originated in observations made by J.A. Bradford and Colleagues (1) in 1936 on how people smoked and was described again by C.L Ogg in 1964 (2). The smoking parameters they proposed (i.e., 35 milliliter puffs of 2 seconds duration with a puff each 60 seconds to a butt length of 23 millimeters or to the length of the overwrap plus 3 millimeters, whichever is longer) were based on how the cigarettes which were sold at that time were smoked. Since then, cigarette designs have changed, through, for example, changes in the tobacco blend composition, ventilated filters, porous paper, reconstituted tobacco, and expanded tobacco (3).

In carrying out a measurement using the FTC regimen, the tips of up to 20 cigarettes at a time are placed into holders that are attached to the smoking machine, which contains syringes or other devices for drawing air through the cigarettes. The holders include a glass filter commonly known as a Cambridge filter pad for collecting particulate matter. Special bags collect the gas phase which is drawn through the Cambridge filter pads. To measure nicotine and "tar", the particulate matter collected on the pad is extracted and analyzed by a separate analytical instrument known as a gas chromatograph. The carbon

monoxide generated during smoking is measured by an infrared spectrometer that samples from the collection bags.

Cigarette manufacturers have added ventilation holes to the modern cigarette, punched in the paper surrounding the filter. These holes are far enough from the tip of the cigarette that they are exposed to room air when the cigarette is placed in the smoking machine to be tested using the FTC method. As a result, room air is pulled into the cigarette and dilutes the smoke that is collected on the filter pad and in the collection bag. This dilution using ventilation holes results in lower measured levels of nicotine, "tar", and carbon monoxide (3). Other factors can also influence the delivery of nicotine, "tar", and carbon monoxide including the length of the filter, the design of the filter, and the porosity of the paper; but, of these, filter ventilation is the major factor.

The way that people smoke cigarettes varies between people and there are also variations in the way an individual smokes at different times. Factors that influence smoking patterns include nicotine level of the cigarette, the smoker's level of stress, mood and the time since they smoked their last cigarette. One of the more important factors in determining how people smoke is their need for nicotine. Persons smoking cigarettes with a range of nicotine levels adjust the way they smoke to obtain a relatively steady amount of nicotine per cigarette (4). Unlike the machine, smokers are able to adjust the way they smoke by taking larger puffs, more frequent puffs, or blocking ventilation holes so that they can increase their nicotine uptake, when smoking cigarettes with lower machine-measured "tar" and nicotine (5).

When a larger puff is taken, puffs are taken more frequently, or ventilation holes are blocked, cigarettes deliver much higher levels of the toxic and addictive components of tobacco smoke than is characterized using the FTC method. When individual smokers smoke cigarettes of different designs, compensation techniques result in exposure of smokers to levels of smoke that vary much less than would be expected based upon results from machine smoking using the FTC method (4).

Studies of biomarkers in smokers (chemical measurements in blood and urine) have also shown that exposure to the toxic and addictive components of tobacco smoke are fairly consistent, whether a smoker uses a light, medium, or full-flavored cigarette (4,6). These findings are largely explained by compensation techniques used by the smokers.

Machine smoking regimens that are more intense than the FTC method are currently in use. Health Canada requires tobacco companies to report levels of chemicals in tobacco smoke using a modified method with 55 milliliter puffs taken every 30 seconds and all ventilation holes blocked. The State of Massachusetts has required reports of tobacco emissions using a regimen of 45 milliliter puffs taken every 30 seconds with half of the ventilation holes blocked. These more intense smoking regimens are aimed at better approximating how the average smoker actually smokes the cigarette.

In summary, our laboratory has developed a broad set of capabilities to measure addictive and toxic substances in the tobacco product, in cigarette smoke and in people. We have investigated different machine smoking regimens, including the FTC method and how cigarette design factors can influence the delivery of toxic and addictive substances. We

have found that using multiple smoking regimens improves our understanding of the variation in actual delivery of nicotine, "tar", and carbon monoxide to the smoker compared to using the FTC method alone.

Thank you for this opportunity to present this information to you. I would be happy to answer any questions you may have.

References

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