Testimony
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United States Senate

Research Findings Concerning So-Called Low-Tar or "Light" Cigarettes

Statement of

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Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to testify today on the research findings of the National Cancer Institute (NCI), part of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS), regarding the disease risk of so called low-tar or "light" cigarettes, and the challenges of conveying accurate information to smokers about the levels of tar, nicotine, and other hazardous chemicals in cigarette smoke. I am Dr. Cathy Backinger, Acting Chief of the National Cancer Institute's Tobacco Control Research Branch. The Branch's mission is to lead and collaborate on tobacco control and prevention research, and to disseminate evidence-based findings to prevent, treat, and control tobacco use. We envision a world free of tobacco use and tobacco-related cancers.

I would like to begin by stating the NCI's goals regarding cigarette smoking, the cause of an estimated 438,000 U.S. deaths annually and about one-third of all deaths from cancer. NCI supports, conducts, and disseminates research to prevent youth from ever starting to use tobacco products, to assist youth and adults who smoke in quitting, and to protect nonsmokers from exposure to secondhand smoke, a serious cause of disease and death in its own right.

As I will describe, there is a substantial, longstanding body of evidence demonstrating that "light" and low-tar cigarettes do not reduce smokers' exposure to hazardous compounds or their risk for disease. Moreover, descriptors such as "light," low-tar, "ultra-light," and others, are aimed at conveying to consumers what NCI Monograph 13

termed "the illusion of risk reduction."[1] Not surprisingly, research has demonstrated that these terms are interpreted by many smokers to mean reduced risk. Finally, measurements of tar and nicotine yields using the Federal Trade Commission (FTC) test method do not offer smokers meaningful information on the amount of tar and nicotine they will receive from a cigarette, or on the relative amounts of tar and nicotine exposure they are likely to receive from smoking different brands of cigarettes.[2]

Cigarette manufacturers have made changes to cigarettes over the last 50 years, largely in response to concerns that the growing body of evidence that smoking causes disease would motivate smokers to quit. In the 1950s, the major manufacturers began widespread promotion of filtered cigarettes; advertisements for these cigarettes depicted filters as a technology to remove the harmful elements of smoke.[3] By 1960, filtered cigarettes had become the dominant product on the market. In the early 1970s, manufacturers introduced new low-tar cigarette brands; by 1997, half of all cigarette advertising dollars were dedicated to low-tar products. Many of the advertisements made health claims, most implicitly, so as to reassure smokers who were concerned about their health risks. Over time, the market share for these brands increased dramatically. In 1967, low-tar cigarettes[4] constituted 2.0% of the market. By 2005, these products held 83.5% of market share.[5]

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[1] National Cancer Institute, Smoking and Tobacco Control Monograph 13, *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*, October 2001, page 5
[2] Monograph 13, page 10.
[3] U.S. Department of Health and Human Services, *Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General*, 1989, page 664.
[4] Low-tar cigarettes contain less than or equal to 15 mg of tar per cigarette.
[5] *Federal Trade Commission Cigarette Report for 2004 and 2005*, issued 2007 (http://www.ftc.gov/reports/tobacco/2007cigarette2004-2005.pdf)

By the early 1980s, however, scientific studies had begun to show that when smokers switched to low-tar cigarettes, they changed the way they smoked, by smoking greater numbers of cigarettes, increasing their depth of inhalation, taking more frequent and/or larger puffs, as well as holding smoke in their lungs longer. Additionally, cigarette design features allowed smokers to vary the amount of smoke they inhaled, such as by covering ventilation holes on the filter with their fingers or lips. Based on this emerging evidence, the 1981 Surgeon General's report, *The Changing Cigarette*, concluded that, "the benefits [of smoking low-tar cigarettes] are minimal in comparison with giving up cigarettes entirely," and, "the tar and nicotine yields obtained by present testing methods do not correspond to the dosages that the individual smokers receive: in some cases they may seriously underestimate these dosages."[6] In short, more than 25 years ago, the Surgeon General warned that smoking low-tar cigarettes was no substitute for quitting, and raised serious questions about the FTC test method.

Our understanding of why smokers compensate when smoking "light" cigarettes was enhanced significantly by the 1988 Surgeon General's report, *The Health Consequences of Smoking: Nicotine Addiction*. The major conclusions of this volume were that: 1) cigarettes and other forms of tobacco are addicting; 2) nicotine is the drug in tobacco that causes addiction; and 3) the pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine. In retrospect, public health authorities did not fully understand that when

[6] U.S. Department of Health and Human Services, *The Health Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon General*, 1981, page vi.

smokers switched to a cigarette with lower machine measured tar and nicotine content they would change the way they smoked in order to preserve their daily intake of nicotine. This was understood much earlier however, by some cigarette manufacturers, as demonstrated by their internal documents.

Tar and nicotine yields have historically been measured by a standardized machine testing regimen - the FTC test method - also known internationally as the ISO (for International Organization for Standardisation) machine-smoking method. This method, adopted in 1967, determines the yield of a cigarette by smoking it on a machine, in a standardized fashion, according to a predetermined protocol. The smoking machine is calibrated to take one puff of 2-second duration and 35-ml volume every minute; cigarettes are smoked to a butt length of 23 mm or to the length of the overwrap plus 3 mm, whichever is longer. These parameters were determined by a U.S. Department of Agriculture tobacco chemist so as to constitute an average of his observations of human smoking behavior. The FTC test method provided a uniform analytical procedure that could be replicated in different laboratories simultaneously and in the same laboratory over time.

The FTC long recognized that the machine testing did not replicate human smoking because, "No two human smokers smoke in the same way," and "No individual smoker always smokes in the same fashion."[7] Instead, the test was seen as a way for consumers

[7] National Cancer Institute, Smoking and Tobacco Control Monograph 7, *The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes: Report of the NCI Expert Committee,* August 1996, page 2.

to make valid comparisons between different brands of cigarettes. "Thus, if the consumer smoked each different cigarette [brand] the same way, he would inhale 'tar' and nicotine in amounts proportional to the relative values of the FTC figures."[8] However, the standardized machine measurements assumed that smokers would not engage in "compensatory behaviors" to control their intake of nicotine.

In 1996, NCI's Smoking and Tobacco Control Monograph Number 7, *The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes: Report of the NCI Expert Committee*, compiled evidence available at the time on the FTC test method, its relation to actual human smoking behavior, and consumer perceptions of tar and nicotine ratings. Among the major conclusions of the monograph were: 1) Actual human smoking behavior is characterized by wide variations in smoking patterns, which result in wide variations in tar and nicotine exposure. Smokers who switch to lower tar and nicotine cigarettes frequently change their smoking behavior, which may negate potential health benefits; 2) Brand names and brand classifications such as "light" and "ultralight" represent health claims and should be regulated and accompanied, in fair balance, with an appropriate disclaimer; and 3) The available data suggest that smokers misunderstand the FTC test data. This underscores the need for ongoing and extensive public education efforts.

[8] Monograph 7, page 4, quoting 1978 Federal Register, p. 11856

Lastly, in 2001, NCI's Smoking and Tobacco Control Monograph Number 13, *Risks Associated with Smoking Cigarettes with Low Tar Machine-Measured Yields of Tar and Nicotine*, reviewed and synthesized what was by that time a vast amount of data from epidemiology, chemistry, toxicology, laboratory studies of smoking behavior, studies of risk perception and advertising, studies of product design, as well as previously confidential tobacco industry documents. The Monograph's most important finding is that "there is no convincing evidence that changes in cigarette design…have resulted in an important decrease in the disease burden caused by cigarette use."[9] That is, smokers who switch to low-tar cigarettes do not reduce their risk of disease; the only proven way to reduce the disease risks of smoking is to quit. The report also found that cigarette marketing and advertising for "filtered and low tar cigarettes were intended to reassure smokers (who were worried about the health risks of smoking) and were meant to prevent smokers from quitting based on those concerns," and that, "internal tobacco company documents demonstrate that the cigarette manufacturers recognized the inherent deception of advertising that offered cigarettes as "Light" or "Ultra-Light," or as having the lowest tar and nicotine yields."[10] The major conclusions of Monograph 13 are the following:

1. Epidemiological and other scientific evidence, including patterns of mortality from smoking-caused diseases, does not indicate a benefit to public health from changes in cigarette design and manufacturing over the last fifty years.

[9] Monograph 13, page 146.
[10] Monograph 13, page 233.

2. Widespread adoption of lower yield cigarettes in the United States has not prevented the sustained increase in lung cancer among older smokers.
3. Many smokers switch to lower yield cigarettes out of concern for their health, believing these cigarettes to be less risky or to be a step toward quitting. Advertising and marketing of lower yield cigarettes may promote initiation and impede cessation, more important determinants of smoking-related diseases.
4. 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.

The conclusion of Monograph 13 with regard to low tar cigarettes was reiterated by the 2004 Surgeon General's report, *The Health Consequences of Smoking*, the most comprehensive review of the evidence on smoking and health since the 1964 Surgeon General's report. This report stated as one of its four major conclusions that, "Smoking cigarettes with lower machine-measured yields of tar and nicotine provides no clear benefit to health."[11]

In summary, while cigarettes have changed over the last 50 years, the disease risks have not. Cigarette manufacturers have long understood that consumers would respond to the widespread dissemination of the grave health risks of smoking by quitting.

[11] U.S. Department of Health and Human Services, *The Health Consequences of Smoking: A Report of the Surgeon General*, 2004, page 25.

Manufacturers worked to reassure "health conscious" smokers by marketing filtered and low-tar cigarettes, and heavily advertising these products as ways to reduce the risk of smoking. Smokers erroneously saw these products as viable alternatives to quitting, and as a result, many more smokers continued to smoke who might otherwise have quit. The marketing and advertising of low-tar cigarettes and manufacturers' use of the FTC test method data continues today.

A new generation of products is now being marketed by the tobacco industry with advertisements suggesting that they deliver lower amounts of toxic or addictive agents. For example, one such advertisement says, "all of the taste … less of the toxins." These products – sometimes referred to as potential reduced-exposure tobacco products, or "PREPs" – are highly engineered products which utilize new technologies to try to reduce certain harmful constituents, such as carcinogens (cancer causing agents) from tobacco smoke. To date, however, the scientific evidence is insufficient to evaluate whether these new products actually reduce the users' exposure or risk for tobacco-related diseases. The 2001 Institute of Medicine report *Clearing the Smoke* concluded that currently-available data does not allow for drawing meaningful differences in toxicity or harm between tobacco products and that a structure for regulatory oversight would be essential to any scientific assessment of claims for reduced harm.

There is a need for independent, objective, scientific research to provide guidance to the public about the health effects of different tobacco products. In order to address this research gap, NCI has introduced several new initiatives, including:

- A Program Announcement titled, "Testing Tobacco Products Promoted to Reduce Harm," which aims to stimulate multidisciplinary research on the characteristics of different tobacco products, methods for measuring users' exposure to toxic constituents, and the impact of manufacturers' claims on smokers' perceptions of risk. Currently funded grants under this Program Announcement include projects studying:
  - The impact of low ignition propensity ("fire-safe") cigarettes (Roswell Park Cancer Institute)
  - Mutagenicity of tobacco smoke in human cell co-cultures (New York University)
  - Clinical models for evaluating PREPs for tobacco users (Virginia Commonwealth University)
  - Laboratory based evaluation of potential reduced exposure products (Georgetown University)
  - Smoking topography and harm exposure in a new PREP (University of Pennsylvania)
- A 5-year Research and Development contract with the Lombardi Cancer Center at Georgetown University to support the advancement of laboratory methods for tobacco product testing, taking into account human behavior. Once developed, these methods could be utilized to assess the potential for new products to reduce exposure in the laboratory and in human clinical trials and to assist in evaluating the potential impact of product design changes on individuals and the population as a whole.

- Support of the University of Minnesota Transdisciplinary Tobacco Use Research Center (TTURC), which is conducting research on ways to reduce smokers' exposure to tobacco smoke and its constituents.
- Support of the Roswell Park Cancer Institute TTURC, which is studying how changes in cigarette design alter smokers' actual exposures and their perceptions of the health risks of smoking. Their ongoing multi-country survey also collects information on smokers' perceptions of "light" and "ultra light" cigarettes.
- NCI is utilizing two of its ongoing national surveys – the Health Information National Trends Survey and the Tobacco Use Supplement to the Current Population Survey – to collect data on tobacco use and health risk perceptions related to new PREPs and other tobacco products.
- Collaboration with research partners, including other NIH Institutes and Centers, HHS's Centers for Disease Control and Prevention (CDC), and the World Health Organization (WHO), to identify research priorities and develop expertise related to tobacco products. NCI scientists are currently active members of the WHO Study Group on Tobacco Product Regulation and the Tobacco Laboratory Network, which aim to develop guidance on tobacco product testing.

Research also suggests that there is substantial risk that smokers over-interpret reduced risk claims made for modified tobacco products. Exposure reduction messages associated with these products appeal to smokers who are contemplating quitting.[12] Therefore, marketing of these products with messages that imply reduced exposure or harm may

[12] Shiffman, S, Pillitteri, JL, Burton, SL, and Di Marino, ME. Smoker and ex-smoker reactions to cigarettes claiming reduced risk. *Tobacco Control* 2004; 13:78–84.

undermine youth prevention and adult cessation, which could result in an overall increase in harm to the population.

There is an ongoing need to ensure that consumers receive accurate information about the health risks of smoking. The use of misleading descriptors like “light” and “mild” and similar terms have been banned in 43 countries, including Canada, Brazil, and the 27 countries of the European Union.

Tobacco smoke is extremely complex, containing thousands (over 4,800) of constituents including at least 69 known carcinogens. Because of the complexity of tobacco smoke and variations in smoking patterns, it is unlikely that any single machine test will be able to provide meaningful estimates of actual human exposure to harmful constituents. Instead, it is likely that a battery of tests will be needed to make meaningful comparisons across products. Currently, standardized machine measurements of tobacco smoke emissions continue to be useful in laboratory settings to understand the properties of different cigarettes. However, these measurements do not provide meaningful information about the actual exposure or risk for the individual smoker. A WHO expert advisory group has stated that numerical ratings for tar, nicotine, and carbon monoxide from the FTC/ISO test method are misleading and recommended that they should not be displayed in advertising or on the cigarette packaging.[13]

[13] World Health Organization, "SACTob Recommendation on Health Claims Derived form ISO/FTC Method to Measure Cigarette Yield" (January 1, 2003). *Tobacco Control. WHO Tobacco Control Papers*. Paper ISO200. http://repositories.cdlib.org/tc/whotcp/ISO200

Since the 1964 publication of the landmark Surgeon General's Report on Smoking and Health provided conclusive evidence of the health risks of smoking to the nation, education to better inform the public on smoking and health issues has been a crucial component of tobacco control and prevention efforts. For decades, the public has been misled by advertising implying, directly or indirectly, that low-tar cigarettes are less hazardous than other cigarettes. It is vital that the public understand that the only proven way to reduce the enormous burden of disease and death due to tobacco use is to prevent youth from beginning to smoke, and to help smokers, both youth and adults, to quit.

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