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Attachment S

Foreword from

National Cancer Institute Monograph 7

***The FTC Cigarette Test Method for Determining Tar, Nicotine, and
Carbon Monoxide Yields of U.S. Cigarettes***

NIH Publication 96-4028, August 1996

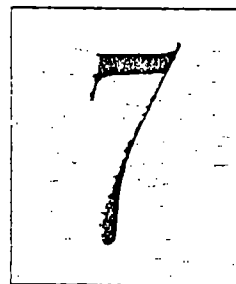
SMOKING

AND

TOBACCO

CONTROL

MONOGRAPH



The FTC
Cigarette Test
Method for
Determining
Tar, Nicotine,
and Carbon
Monoxide Yields
of U.S. Cigarettes

Report of the NCI Expert Committee

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES
Public Health Service
National Institutes of Health

Foreword

In response to the emerging scientific evidence that cigarette smoking posed a significant health risk to the user, in the early 1950's the major cigarette manufacturers began widespread promotion of filtered cigarettes to reassure smokers that, regardless of whatever unhealthy constituents were in cigarette smoke, filters were a "scientific" breakthrough.

Advertisements for Viceroy's "health guard filter" stated, "DENTISTS ADVISE—Smoke VICEROYS—The Nicotine and Tars Trapped by The Viceroy Filter CAN NEVER STAIN YOUR TEETH!" and "Leading N.Y. Doctor Tells His Patients What to Smoke—Filtered Cigarette Smoke Is Better For Health. The Nicotine and Tars Trapped . . . Cannot Reach Mouth, Throat Or Lungs." Chesterfield was "Best for you—low in nicotine, highest in quality," while L&M's were "Just What the Doctor Ordered." Lorillard Tobacco Company stressed its science-based Kent micronite filter (the original micronite filter was made of asbestos) and claimed it removed seven times more tar and nicotine than any other cigarette, which "put Kent in a class all by itself where health protection is concerned." Of course, we know today that not only were these claims patently false, but the cigarette companies knew it.

In the early 1950's the Federal Trade Commission (FTC) challenged a variety of health claims made for cigarettes in their advertising, including claims about tar and nicotine. In 1955 FTC published advertising guidelines that, among other things, prohibited claims by cigarette manufacturers that a particular brand of cigarettes was low in tar and nicotine or lower than other brands, when it had not been established by competent scientific proof that the claim was true and the difference was significant. Cigarette manufactures, however, continued to advertise tar numbers. In the absence of a standardized test methodology, this resulted in what is referred to as a "tar derby"—a multitude of inconsistent, noncomparable claims that did not give consumers a meaningful opportunity to assess the relative tar delivery of competing brands. The tar derby ended in 1960 when discussions with FTC culminated in an industry agreement to refrain from tar and nicotine advertising.

In 1966, however, the U.S. Public Health Service (PHS) prepared a technical report on "tar" and nicotine that concluded, "The preponderance of scientific evidence strongly suggests that the lower the 'tar' and nicotine content of cigarette smoke, the less harmful would be the effect." In reaching this conclusion, the report noted the clear relationship between dose of cigarette smoke received by the smoker and disease risk. Regardless of how dose was calculated—by number of cigarettes smoked per day, age of initiation, total number of years one smoked, or depth of inhalation, mortality rates among smokers increased. When smokers quit smoking, their risk was reduced in proportion to the length of time off cigarettes.

Subsequent to the PHS statement, FTC reversed its decision banning tar and nicotine claims in advertising and established a standardized testing protocol for assessing tar and nicotine yields. Today that protocol is widely known as the FTC test method. In 1980 the protocol was broadened to include measurement of the carbon monoxide yields of cigarettes as well.

The initial protocol adopted by FTC was largely based on the work of U.S. Department of Agriculture chemist C.L. Ogg, as published in the *Journal of the Association of Official Agricultural Chemists* in 1964. It appears, however, that this protocol was based on one person's observations about how people smoked.

Much the same protocol had been proposed by American Tobacco Company researchers in 1936. Writing in the July issue of *Industrial and Engineering Chemistry*, J.A. Bradford and colleagues noted, "The present writer's arbitrarily selected rate is a 35-cc puff of 2-second duration taken once a minute."

However, cigarettes consumed at that time were vastly different from those manufactured and marketed later. In fact, tar and nicotine levels began to decline during the 1950's, concurrent with the mass marketing of filter cigarettes. Market share of filter cigarettes increased from almost zero in 1950 (0.6 percent of the market) to 50 percent by decade's end. Total cigarette sales, which had begun to decline after the first public statements about the hazards of smoking in the early 1950's, rebounded to new highs.

Although filter efficiency may have contributed to some of the reduction in tar/nicotine yields in the 1950's, the decline resulted mostly from less tobacco being used to make filtered as opposed to unfiltered cigarettes. However, during the 1960's and 1970's major cigarette design changes resulted in significantly lower machine-measured cigarette yields. The changes included increased use of ventilated tobacco rods and filters, use of more porous cigarette papers, and increased use of expanded and reconstituted tobacco. Concurrent with these modifications in cigarette design, cigarette manufacturers increasingly made use of additives in manufacturing. Today about 600 different compounds are routinely added to domestic cigarette brands, yet no routine testing is performed to determine whether these compounds pose any additional health risk to the smoker when they are burned in a cigarette.

U.S. market share of cigarettes yielding 15 mg tar or less went from 3.6 percent in 1970 to 44.8 percent by 1980. The sales-weighted average tar and nicotine yields of all U.S. cigarettes are now approximately 12 mg tar and 0.9 mg nicotine. By comparison, sales-weighted yields in the early 1950's were 35 mg tar and 2.5 mg nicotine.

As consumption of low-yield cigarettes began to proliferate, the public health community became concerned that these products were not what they seemed. Increasingly, scientific studies documented that smokers who switched to these low-yield products smoked them differently, thus negating

the reason many of them changed in the first place—to lower their health risk.

The U.S. Congress also voiced its concern in 1978 when it enacted the Health Services and Centers Act. Section 403 of that legislation directed the U.S. Department of Health and Human Services (DHHS) to conduct a "study or studies of (1) the relative health risks associated with smoking cigarettes of varying levels of tar, nicotine, and carbon monoxide; and (2) the health risks associated with smoking cigarettes containing any substances commonly added to commercially manufactured cigarettes." The Secretary of the Department of Health and Human Services addressed this issue as part of the 1981 Surgeon General's report, *The Health Consequences of Smoking: The Changing Cigarette*. The overall conclusion of that report was clear: "There is no safe cigarette and no safe level of consumption." Although the report did note that smoking cigarettes with lower yields of tar and nicotine reduces the risk of lung cancer to some extent, the benefits are minimal in comparison with giving up cigarettes entirely. Evidence relating to heart disease, other cancers, or chronic obstructive lung disease was not sufficient to permit conclusions to be drawn. As to the accuracy of the FTC test method, the report stated: "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."

Growing numbers of questions were raised about the accuracy of the FTC test protocol to measure tar, nicotine, and carbon monoxide levels from low-yield cigarettes—questions raised not just by the public health community but also within the tobacco industry. Competitors complained to FTC that Brown and Williamson's (B&W) Barclay brand cigarette did not test accurately with the FTC test method. They argued that the brand was designed with unique air ventilation channels that caused it to test low on the FTC method. The ventilation channels, which remained open when Barclays were smoked on the FTC machine, were rendered inoperable when a human being smoked the cigarettes. In April 1983 FTC announced that its testing method understated values for constituents in Barclay cigarettes, and as a result, until new testing methods were developed, FTC would no longer report an official rating for Barclay cigarettes. Later, FTC took similar steps with respect to other B&W cigarette varieties that used a filter design similar to Barclay's.

Eventually FTC closed its cigarette testing laboratory, in part because of insufficient expertise within the agency to carry out an increasingly complex and costly testing program. Since 1987, constituent levels for domestic cigarette brands have been determined for the manufacturers by the Tobacco Institute Testing Laboratory with oversight by FTC. The Tobacco Institute serves as a trade organization as well as the information and lobbying arm of the tobacco industry.

In June 1994 the Chairman of the House Subcommittee on Health and the Environment wrote the Director of the National Cancer Institute (NCI), asking him to convene a meeting of experts to "... review and make

recommendations on the accuracy and appropriateness of the Federal Trade Commission's method for determining the relative 'tar' and nicotine content of cigarettes." A similar request was received from the FTC Chairman asking that NCI convene a consensus conference on the topic and outlining several areas it wished to be considered.

On December 5 and 6, 1994, a meeting of the NCI ad hoc expert committee was convened under the aegis of the President's Cancer Panel to examine this issue. The committee consisted of 11 individuals from diverse scientific backgrounds and experience. The committee had the benefit of excellent presentations from 14 experts whose professional careers were not only involved in research on smoking, but who have been active contributors to this field of scientific inquiry. Two of the individual participants were cigarette industry scientists, who participated in all discussions.

From the outset of the committee's deliberations, it was clear that the intent of the meeting was not to redesign the FTC testing protocol but, rather, to examine the protocol and make suggestions for improvement, if warranted. To provide a framework for discussion, the committee was asked to consider three basic questions:

1. **Does the evidence presented clearly demonstrate that changes are needed in the current FTC protocol for measuring tar, nicotine, and carbon monoxide? If yes, what changes are required?**
2. **Should constituents other than tar, nicotine, and carbon monoxide be added to the protocol?**
3. **Does the FTC protocol provide information useful to smokers in making decisions about their health?**

I. The committee reached the following conclusions with respect to the first question.

- A. The smoking of cigarettes with lower *machine-measured* yields has a small effect in reducing the risk of cancer caused by smoking, no effect on the risk of cardiovascular diseases, and an uncertain effect on the risk of pulmonary disease. A reduction in *machine-measured* tar yield from 15 mg tar to 1 mg tar does not reduce relative risk from 15 to 1.
- B. The FTC test protocol was based on cursory observations of human smoking behavior. 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.
- C. Accordingly, the committee recommends the following changes to the FTC protocol:

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1. This system should also measure and publish information on the range of tar, nicotine, and carbon monoxide yields that most smokers should expect from each cigarette sold in the United States.
 2. This information should be clearly communicated to smokers.
 3. A simple graphic representation should be provided with each pack of cigarettes sold in the United States and in all advertisements. The representation should not imply a one-to-one relationship between measurements and disease risk.
 4. The system must be accompanied by public education to make smokers aware that individual exposure depends on how the cigarette is smoked and that the benefits of switching to lower yield cigarettes are small compared with quitting.
- D. There should be Federal oversight of cigarette testing, but such testing should continue to be performed by the tobacco industry and at industry expense.
- E. The questions involved in the purpose, methodology, and utility of the FTC protocol are complex medical and scientific issues that require ongoing involvement of Federal health agencies, including the National Institutes of Health, the Food and Drug Administration, and the Centers for Disease Control and Prevention.
- F. The system should be reexamined at least every 5 years to evaluate whether the protocol is maintaining its utility to the smoker.
- G. When a cigarette manufacturer makes significant changes in cigarette design that affect yields, it should notify the appropriate Federal agency.
- II. With regard to the second question, the committee recommends that to avoid confusing smokers, no smoke constituents other than tar, nicotine, and carbon monoxide be measured and published at the present time. Smokers should be informed of the presence of other hazardous smoke constituents with each package and with all advertisements. These constituents should be classified by toxic effects.
- III. In considering the third question, the committee reached the following conclusions:
- A. Information from the testing system is useless to smokers unless they have ready access to it. The information from the testing system should be made available to all smokers, including those who smoke generic brands and other brands not widely advertised.
 - B. 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.

- C. The available data suggest that smokers misunderstand the FTC test data. This underscores the need for an extensive public education effort.

As Chairman of the President's Cancer Panel under whose aegis this meeting was convened, I would like to express here my admiration and deep appreciation to the members of the NCI ad hoc committee and its expert consultants for a job well done. In transmitting this report to both the U.S. Congress and the Federal Trade Commission, it is my sincere hope that the recommendations contained herein will receive the serious and thoughtful consideration they deserve.

Harold P. Freeman, M.D.
Chairman, President's Cancer Panel

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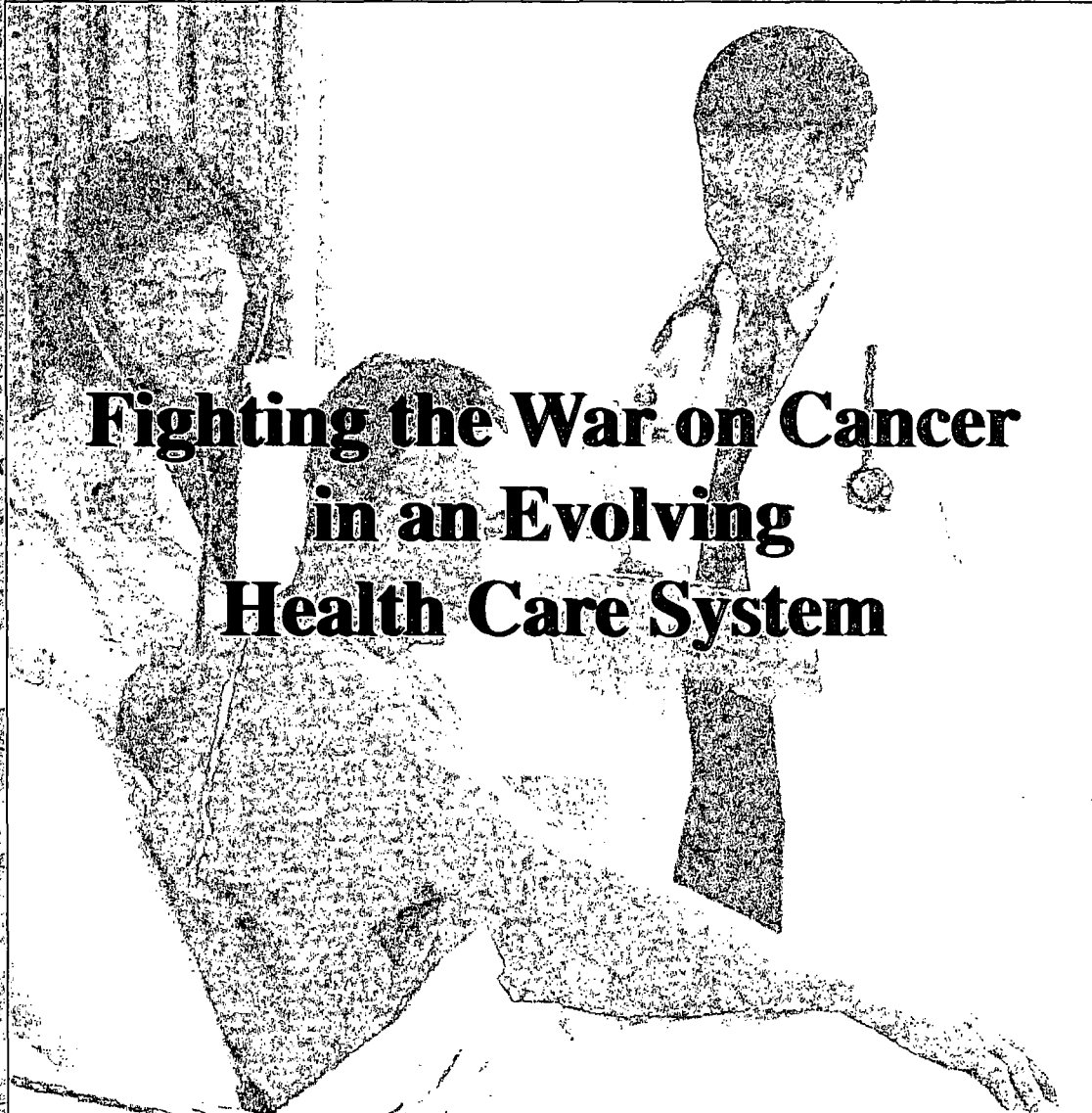
Report of the President's Cancer Panel

January 1, 1996 to December 31, 1996

Fighting the War on Cancer in an Evolving Health Care System

PRESIDENT'S CANCER PANEL

JANUARY 1, 1996 TO DECEMBER 31, 1996



Fighting the War on Cancer in an Evolving Health Care System

NATIONAL CANCER PROGRAM

NATIONAL CANCER INSTITUTE