Public Health Implications of Changes in Cigarette Design and Marketing

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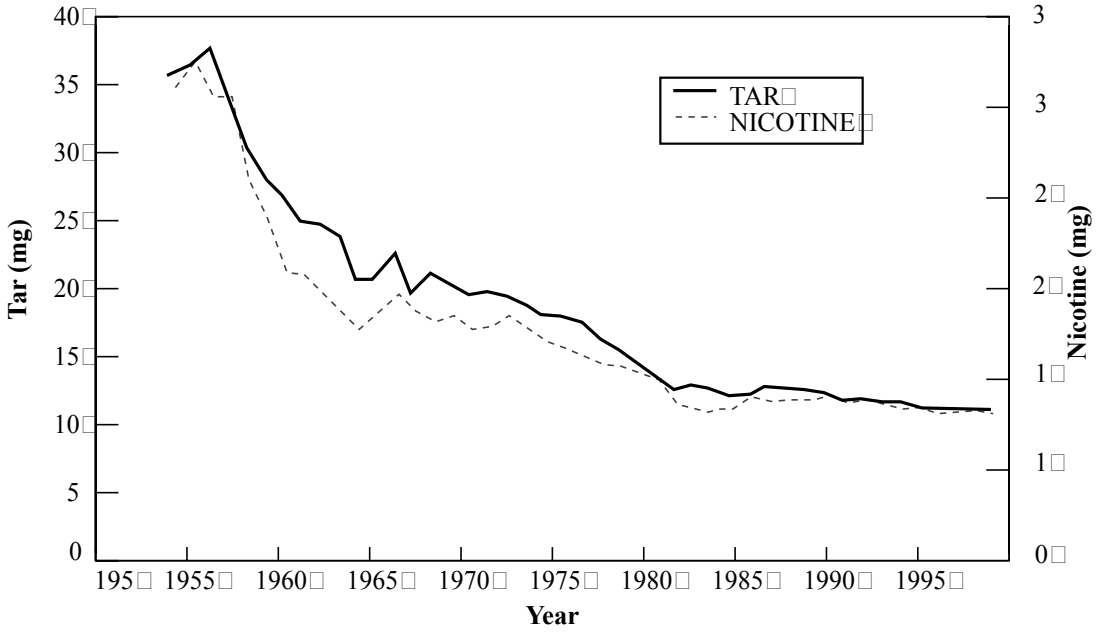
INTRODUCTION Cigarettes have changed dramatically over the last 50 years, but the data contained in this volume make it clear that the disease risks associated with smoking have not. Following the demonstration that cigarettes could cause cancer in the 1950s (Wynder and Graham, 1950; Doll and Hill, 1952, 1954; Hammond and Horn, 1958), cigarette manufacturers added filters to their products. They also embarked on an effort to lower the machine-measured tar and nicotine yields produced by their cigarettes when tested under a protocol specified by the Federal Trade Commission (FTC) (Pillsbury, 1996). These changes led to more than a 60-percent reduction in machine-measured tar yields of U.S. cigarettes over the last 50 years (see Figure 1-1).

However, it appears that many of the same changes in cigarette design that reduced machine-measured tar yields also led to a disassociation between the machine-measured yield of the cigarette and the amount of tar and nicotine actually received by the smoker (see Chapters 2 and 3). As a result, tar and nicotine measurements made by the FTC method for current cigarettes have little meaning for the smoker, either for how much he or she will receive from a given cigarette or for differences in the amount of tar and nicotine received when he or she smokes different brands of cigarettes.

The absence of meaningful differences in smoke exposure when different brands of cigarettes are smoked (see Chapter 3) and the resultant absence of meaningful differences in risk (see Chapter 4) make the marketing of these cigarettes as lower-delivery and lower-risk products deceptive for the smoker (see Chapters 6 and 7). The reality that many smokers chose these products as an alternative to cessation—a change that would produce real reductions in disease risks—makes this deception an urgent public health issue.

HOW DID IT HAPPEN? Epidemiological studies established an increased risk of lung cancer among cigarette smokers in the 1950s (Wynder and Graham, 1950; Doll and Hill, 1952, 1954; Hammond and Horn, 1958). At the same time, it was discovered that painting tobacco tar on the backs of mice could produce cancers (Wynder *et al.*, 1953). Widespread public dissemination of the results of these studies led many smokers to quit (Burns *et al.*, 1997), but the majority of smokers were addicted and were unable to quit or unwilling to try. Faced with the continuing exposure of large numbers of smokers to the cancer-causing substances in tobacco smoke, public health authorities made the valid conclusion that cigarettes that delivered less tar

Figure 1-1
Sales-Weighted Tar and Nicotine Values for U.S. Cigarettes as Measured Using the FTC Method 1954*-1998



**Values before 1968 are estimated from available data, D. Hoffmann personal communication.*

to smokers would be likely to produce less cancer as well (U.S. Congress, 1967), and the effort to produce and market low-tar cigarettes began to gather momentum.

The recommendations by public health authorities to produce low-tar cigarettes failed to appreciate two important realities. First, smokers were powerfully addicted to the nicotine in cigarettes. They actively changed the way they smoked individual cigarettes (see Chapters 2 and 3)—and some smokers increased the number of cigarettes they smoked per day (see Chapter 4)—in order to preserve their moment-to-moment and daily intake of nicotine. Because cigarettes deliver smoke with a relatively fixed ratio of tar to nicotine, smokers also preserved their dose of tar when they preserved their dose of nicotine.

Second, public health authorities dramatically underestimated the ability of cigarette manufacturers to engineer cigarettes that would yield very low tar and nicotine values when machine smoked, but yielded much higher levels of tar and nicotine when smoked by the smoker. Cigarettes were designed with an elasticity of delivery that allowed smokers to get much higher yields of tar and nicotine by altering their pattern of puffing. Smokers may also obtain higher yields of tar and nicotine by blocking ven-

tilation holes in the filters with their fingers or lips (see Chapter 2). Low-yield cigarettes were designed in such a way that the same alterations in puff profile (*e.g.*, larger, faster puffs) that resulted from a smoker's effort to compensate for a reduced nicotine delivery also generated much higher deliveries of tar and nicotine from the cigarette. In addition, the ventilation holes in cigarette filters were placed in locations where they could easily be blocked by smokers' lips or fingers. The combination of these two phenomena—compensation on the part of the smoker and elasticity of delivery in the cigarette—meant that most, perhaps nearly all, smokers who switched to these low-yield brands did not substantially alter their exposure to tar and nicotine and, correspondingly, did not lower their risk.

COMPENSATION IN SMOKERS Nicotine intake is a principal reason why most smokers smoke (U.S. DHHS, 1988). In the absence of nicotine, smokers do not continue the compulsive use of cigarettes that characterizes addiction. Tobacco companies recognized early in the process of developing lower yield cigarettes that smokers would attempt to preserve the amount of nicotine derived from smoking (Wakeham, 1961). Compensation for reduced delivery of nicotine takes many forms and develops over time after shifting to lower yield cigarettes (see Chapter 3). Smokers may take larger puffs, inhale more deeply, take more rapid or more frequent puffs, block ventilation holes in the filters with their fingers or lips, or increase the number of cigarettes they smoke per day.

The most important question on compensatory smoking is the extent to which it occurs when smokers actually switch brands of cigarettes through their own choice. Unfortunately, this is also the most difficult circumstance under which to obtain detailed measurements of large numbers of smokers. Many studies have examined smokers when smoking in a laboratory setting or when asked to switch at specific points in time or to specific brands of cigarettes. These studies offer some insight into how smokers compensate, but may not reflect smokers' behavior when they are switching of their own volition to a brand of their choice.

Some compensatory smoking changes are evident immediately upon switching to lower yield cigarettes, but it is common for smokers to require some time to learn how to smoke lower yield cigarettes in ways that increase the delivery of nicotine to the smoker. Even under laboratory conditions, when smokers are rapidly switched to lower yield cigarettes, considerable compensation is evident. The extent of compensation increases in smokers who are allowed longer periods to adapt to smoking the new cigarettes or who are switched under conditions that more closely mimic the voluntary switching of smokers to lower yield cigarettes. When smokers of cigarettes with different machine-measured nicotine yields from the general population are examined, there is little or no relationship between the nominal nicotine yield of the cigarette smoked and measures of nicotine intake by the smoker, such as blood cotinine levels (Benowitz *et al.*, 1983: Benowitz, 1996; Jarvis *et al.*, 2001). These observations suggest that, at least when considering modern cigarettes, switching from higher to lower yield cigarettes per se is not likely to reduce tar intake and resultant disease risks.

ELASTICITY OF DEMAND IN THE CIGARETTE

Early in the 1950s, cigarette manufacturers began to place filters on the end of the cigarette rod. Many different filters were developed, but the most common type used in the United States was made of cellulose acetate. A variety of other approaches to tar reduction was also utilized, including "puffing" the tobacco to reduce the weight of tobacco in a cigarette, altering the blends of tobacco and porosity of the paper wrapper, changing the density of the tobacco rod, using tobacco stems and reconstituted tobacco sheet, and using a wide variety of filter materials (see Chapter 5).

In exploring these approaches, cigarette manufacturers recognized that approaches to reduction of tar yields that actually reduced the nicotine (and tar) delivery to smokers resulted in smokers discontinuing the use of those brands of cigarettes. This led to an effort to design into the cigarette an elasticity of delivery so that smokers could extract from the cigarette as much nicotine as they needed by changing the pattern of puffing on the cigarette (see Chapter 2). The goal of this effort was to develop cigarettes that would produce very low yields of tar when tested by machine smoking using the FTC protocol, but would deliver a much higher dose of nicotine when these cigarettes were smoked by actual smokers with the puffing profiles the companies knew they would use.

An important cigarette design feature allowing a low machine-measured yield with a higher actual yield is the use of ventilated filters. Holes are cut into the paper wrapping the filter in locations where they are not covered when the cigarettes are placed into the smoking machine. However, the lips or fingers of the smoker can easily cover the holes. When the holes are uncovered and the low draw rates specified by the FTC protocol are used, air is drawn into the smoking machine, diluting the smoke coming through the rod of tobacco and lowering the machine-measured tar values. When the holes are covered or when the smoker draws more rapidly on the cigarette, much more of the puff volume is composed of smoke drawn through the rod of tobacco and much less is composed of air drawn from the ventilation holes. The result is a dramatic rise in the tar and nicotine delivered to the smoker by the cigarette.

A given cigarette can be made to deliver any lower level of tar in machine measurements by increasing the size or number of the ventilation holes in the filter. The amount of nicotine in the unburned tobacco is similar for cigarettes with a wide range of machine-measured nicotine yields, as is the tar-to-nicotine ratios of the smoke from these cigarettes when they are smoked under conditions that mimic those of actual smokers (see Chapter 3). This combination of factors, plus the learned compensatory behaviors of the smoker, allows most cigarettes to deliver similar amounts of tar and nicotine to cigarette smokers without regard to the amount of tar and nicotine reported using the FTC method.

This effort by cigarette manufacturers to design cigarettes that could yield very low levels of tar when smoked by the machine while delivering full doses of tar and nicotine to smokers was not the only option available to the cigarette manufacturers. Internal tobacco company documents are

replete with descriptions of filters that could selectively remove toxic smoke constituents, of treatments of tobacco with catalysts like palladium that reduced levels of carcinogens in the smoke, and of other promising modifications of cigarette toxicity. Many of the changes in cigarette design developed by cigarette manufacturers lowered levels of the toxic constituents in cigarette smoke, at least as the cigarettes were smoked using the FTC protocol. However, these paths were not pursued to the point of bringing products to market with scientifically established reductions in toxicity or carcinogenicity for smokers. The principal marketing advantage of a cigarette design scientifically established to cause less harm would be the reduced toxicity of the product. Because cigarette manufacturers persistently maintained that cigarette smoking did not cause any disease, they could not advertise a product as safer since it would be necessary to acknowledge the risks of their existing products.

One unfortunate outcome of the tobacco companies' position that cigarettes had not been established to cause any disease is the lost opportunity to develop cigarettes that have actual reductions in biological toxicity rather than simply the ability to reassure smokers concerned about the risk of smoking. The more unfortunate outcome of this position was the marketing of cigarettes with no real difference in disease risks as "safer" products.

MARKETING OF LOW-YIELD CIGARETTES

The link between tar and cancer risk also led to marketing of cigarettes with lower machine-measured tar yields as reduced-risk cigarettes. Terms such as 'Light' and 'Ultra-Light' were added to brand names, and substantial numbers of smokers switched to these brands in an effort to reduce their disease risks (see Chapter 6). Marketing this illusion of risk reduction would have been of concern even if the target for these brands had been confined to continuing smokers. Instead, these brands were targeted at those smokers who were thinking of quitting in an effort to intercept the smokers and keep them smoking cigarettes (see Chapter 7). The switch to low machine-measured-yield cigarettes with the illusion of risk reduction was, therefore, substituted for a real risk reduction that would have occurred had the smoker quit smoking altogether.

Beginning in the 1950s, filter cigarettes were advertised using claims of scientific discoveries, modern pure materials, and implied endorsements from medical and scientific organizations. These claims were not supported by testing that demonstrated lower deliveries of tar and nicotine to smokers or by studies of actual disease risks. However, the clear message delivered to smokers by the advertising was that these cigarettes were safer.

With the endorsement of lower tar cigarettes by public health authorities in the 1960s (U.S. Congress, 1967), cigarette marketing began to focus on machine-measured tar deliveries. Tobacco industry research and engineering efforts recognized that at least two directions were possible with the development of either a health-image (health reassurance) cigarette or a cigarette with minimal biological activity (one that would actually produce less disease) (Green, 1968). Unfortunately, the dominant direction taken was the production of health reassurance cigarettes engineered so that they

Figure 1-2
Low Tar is Important to Me

would deliver low yields of tar under FTC machine-smoking conditions. These low machine yields were touted in the advertisements and incorporated into cigarette brand names with terms such as 'Light' and 'Ultra-Light'. However, the promise of low tar delivery was only valid for the smoking machine. Smokers received a much higher dose of tar and enough nicotine to satisfy their addiction.

This dichotomy of delivery between smokers and machines was the intended result of the engineering effort to design elasticity of delivery into cigarettes. Testing of these design concepts on actual smokers revealed that Light and Regular cigarettes delivered the same levels of tar and nicotine when smoked by smokers (Goodman, 1975) and that advertising these cigarettes as low-tar-yield cigarettes was deceptive (Peeples, 1976). But these cigarettes satisfied the demand for cigarettes that could be marketed as low-tar cigarettes with full flavor or taste (See Figure 1-2). The low-tar claim presented in the ad only existed for machine smoking and the full flavor received by the smoker was accompanied by full yields of tar and full disease risks.

DISEASE RISKS Having demonstrated that smokers derive similar amounts of nicotine from cigarettes with a wide variety of machine-measured nicotine yields because those cigarettes were designed to deliver a full dose of nicotine (and tar) to the smoker, one might expect that there would be little or no difference in disease risks among groups of smokers who smoke cigarettes with different machine-measured tar and nicotine yields. However, epidemiological studies have demonstrated that smokers of lower tar or filtered cigarettes had lower lung cancer risks (see Chapter 4). These findings, made in the late 1960s and 1970s, were particularly exciting since smokers had been smoking these reduced-yield cigarettes for only short periods of time. As more individuals used these products for longer periods of time, the reduction in disease risk would be expected to increase and national lung cancer death rates would fall.

Use of lower yield cigarettes grew until they were the dominant type of cigarette on the U.S. market, with 97 percent of the cigarettes currently sold in the United States being filtered cigarettes, but lung cancer rates continued to rise. Lung cancer death rates finally peaked in 1990 among White males; they continue to rise among women in spite of a higher prevalence of low-yield cigarette use among females. Examination of these trends show that they are explained by changes in smoking prevalence without postulating reductions in disease risks due to changes in cigarette design (Mannino *et al.*, 2001; see Chapter 4).

In addition, prospective mortality studies examining smokers in the United States (Thun and Heath, 1997; Thun *et al.*, 1997) and the United Kingdom (Doll *et al.*, 1994) revealed an increase—rather than a decrease—in the risk of smoking over a period when tar and nicotine yields of cigarettes were declining. Data from two large prospective mortality studies conducted by the American Cancer Society (ACS) more than 20 years apart are particularly compelling (Thun and Heath, 1997). Machine-measured tar and nicotine yields of U.S. cigarettes declined dramatically in the interval between these two studies (see Figure 1-1), and the machine-measured yields of the cigarettes actually smoked by the participants in these two studies were dramatically different as a result (see Figure 1-3). Despite the substantive reduction in tar yield of the cigarettes smoked in CPS (Cancer Prevention Study)-II, lung cancer disease risks increased, rather than decreased, compared to CPS-I, even when controlled for differences between the two studies in number of cigarettes smoked per day and duration of smoking.

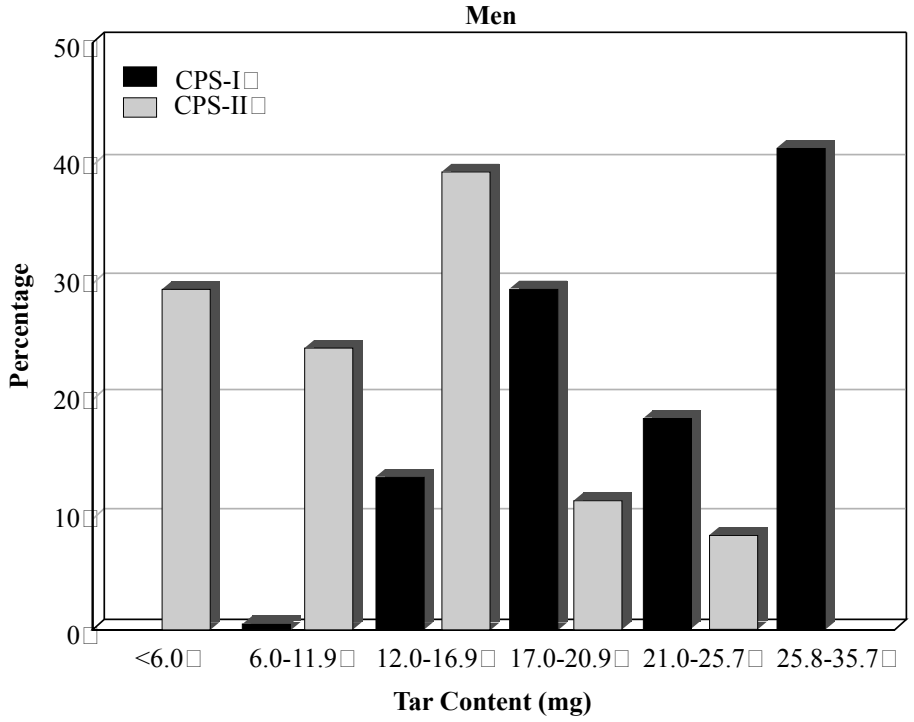
The risk reduction with use of lower yield cigarettes demonstrated in epidemiological studies and the absence of a risk reduction in U.S. lung cancer mortality trends or in the two ACS studies with changing cigarette design are observations that offer apparently conflicting interpretations of the likely disease consequences of smoking lower yield cigarettes. The epidemiological observation of lower risks with use of filtered and lower tar cigarettes has been reproduced in multiple populations and cannot be dismissed as an artifact of a single analysis or a single population. Similarly, national death rate trends are real observations not easily dismissed.

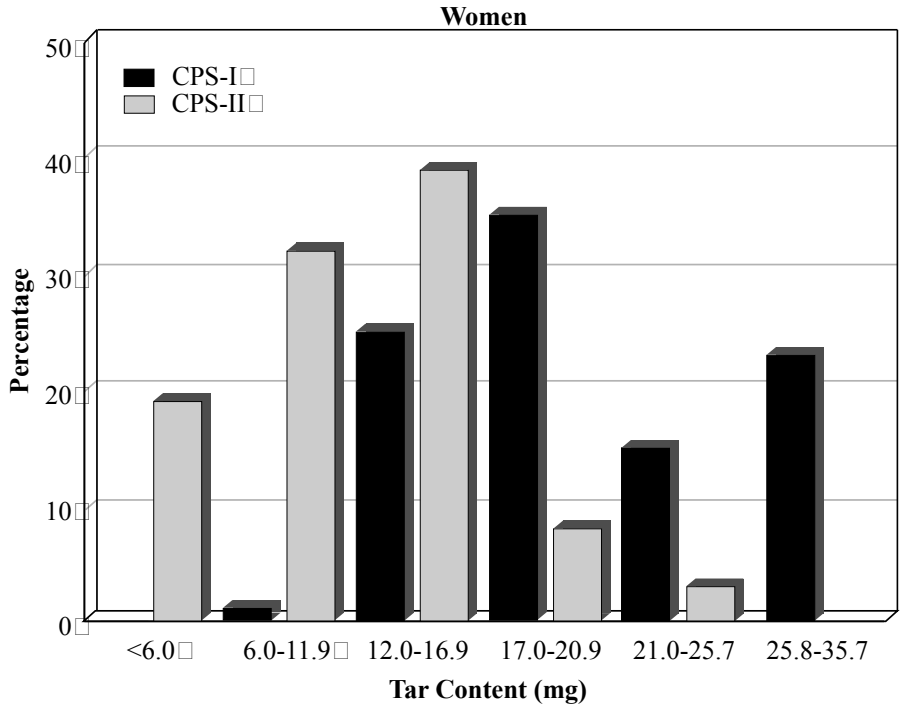
Epidemiological studies and national death rates both measure the impact of low-yield cigarettes in somewhat different ways. Epidemiological studies of disease risks compare disease rates among populations of smokers who use cigarettes with different characteristics. These studies can define whether the disease experiences of smokers of different types of cigarettes are different. However, attributing differences in disease experience to the type of cigarette smoked requires careful consideration of, and adjustment for, characteristics of the two groups that may influence disease risks other than the type of cigarette smoked.

National mortality rate trends are the cumulative result of all of the changes in smoking behavior over time, changes in cigarette design, demographic changes, and changes in smoking behavior. However, smokers of different types of cigarettes cannot be examined directly for their contribution to these trends.

The marketing of low-yield cigarettes as less risky (see Chapters 6 and 7) results in smokers switching from higher to lower yield cigarettes in an effort to reduce their disease risks (Cohen, 1996a & b; see Chapters 6 and 7), in an effort to quit, or in an effort to substantially reduce their smoking (Giovino *et al.*, 1996). Because of these health concerns and an ongoing interest in cessation, these same low-yield cigarette smokers may also have higher rates of successful long-term smoking cessation or may voluntarily reduce the amount that they smoke for health reasons. Risk reductions that

Figure 1-3
Percentage Distribution of Tar Content, as Measured by Machine Smoking, of the Cigarette Brand Smoked at Enrollment





accompany cessation or lowered smoking intensity may appear to be related to the tar level of the cigarette smoked when a population is followed longitudinally for assessment of disease risk without repeated follow-up assessment of smoking status. This effect and other differences in health-related behaviors linked to low-yield cigarette use may confound the analysis of disease risk in prospective studies of low yield cigarettes.

Many published epidemiological studies of low-yield cigarettes have adjusted for the number of cigarettes smoked per day because it is the most readily available quantitative measure of smoking intensity. The potential for smokers to increase the number of cigarettes they smoke per day when they switch to lower yield cigarettes can confound analyses of disease risks among smokers of different types of cigarettes in both case-control and prospective epidemiological evaluations (see Chapter 4). Data presented in Chapter 4 show that smokers who switched to low-yield cigarettes in the ACS CPS-I increased the number of cigarettes that they smoked per day, and that smokers of ultralow-nicotine-yield cigarettes smoked more cigarettes per day in recent California tobacco surveys.

The differences between self-selected populations of smokers of different types of cigarettes and the potential for confounding between type of cigarette smoked and the number of cigarettes smoked per day may explain why epidemiological studies have demonstrated a risk difference when one has not appeared in national death rates.

However, it is clear that the expected lung cancer risk reduction offered by the reduction in lung cancer rates in epidemiological studies has not been realized in national lung cancer death rate trends. When all of the epidemiological evidence is considered in the context of what is currently known about cigarette design and compensation, it does not support the conclusion that a reduction in disease risks has occurred in the population of smokers due to the design changes that occurred in cigarettes over the last 50 years.

This report reviews evidence on the FTC method for measuring tar and nicotine yields and the disease risks of machine-measured low-tar cigarettes. The evidence is derived from research on human behavior and exposures, cigarette design and yields, smoke chemistry, epidemiological other and population-based data on human disease risk. In conducting this review, the objective was to determine whether the evidence taken as a whole shows that the cumulative effect of engineering changes in cigarette design over the last 50 years has reduced disease risks in smokers. Traditional scientific judgment requires compelling evidence of a difference before concluding that use of lower yield products reduces disease risk. These judgments are especially important for harm reduction claims, as they may deter smokers from cessation of tobacco use. Moreover, there have been previous public policy statements on the likely benefits of lower yield products. These prior statements may lead to confusion by creating an implication that the appropriate standard for judgment would require proof of the absence of an effect before the policy recommendations should be withdrawn. Given the consequences of being wrong on the advice given to

smokers, the burden of proof should not be shifted from proving the presence of an effect. The perspective of this report is whether the existing evidence is sufficient to support claims that disease risks are reduced when smokers switch to lower yield cigarettes and policy recommendations that smokers who cannot quit should switch to these products. The answers to these questions are that current evidence does not support either claims of reduced harm or policy recommendations to switch to these products.

Many questions remain unanswered. For example, the disease risks of recently introduced cigarettes or cigarette-like products are not known. Similarly, the cancer risks for individuals who have only used low and ultra-low cigarettes, and who may have different intensities of smoking as a result, have yet to be fully described. Changes in age-specific lung cancer death rates at younger ages in the United Kingdom suggest that the future lung cancer experiences of these young smokers may differ from that of prior generations of smokers. In addition, the possibility exists that individual product design changes, or future changes in tobacco industry produced nicotine delivery devices, may reduce disease risks in the future. However, the burden of proof for these benefits must remain with those who would make the claims. The proof must integrate both measurements of dose and measures of actual biological effect. The very real probability that addicted smokers will seek out and rely upon the promised potential of reduced risk for products that allow continued smoking creates an obligation to require clear scientific proof of harm reduction claims before they are communicated to potential product users.

CONCLUSIONS

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.

2. For spontaneous brand switchers, there appears to be complete compensation for nicotine delivery, reflecting more intensive smoking of lower-yield cigarettes.

3. Widespread adoption of lower yield cigarettes in the United States has not prevented the sustained increase in lung cancer among older smokers.

4. 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.

5. 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.

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