

Chapter 3

Producing the Surgeon General’s Report From 1964–2014: Process and Purpose

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Introduction

In 1964, U.S. Surgeon General Luther L. Terry appointed an expert committee to submit a report to review and evaluate the current data on smoking and health. The publication of the committee's report, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the United States* (U.S. Department of Health, Education, and Welfare [USDHEW] 1964), marked the first of a long series of reports issued by the Office of the Surgeon General to the American people on smoking and health (Table 3.1). This series of reports, released over a 50-year period, comprises a remarkable set of scientific documents that have provided internationally accepted consensus judgments on the scientific evidence implicating smoking in disease causation. In addition, the reports have built a scientific foundation to support tobacco control programs and interventions intended to control the epidemic of tobacco-caused disease (see Chapter 2, "Fifty Years of Change—1964–2014"). The reports have also been invaluable to the scientific community by highlighting what is known in this area and identifying the critical evidence gaps to be addressed with further research. Finally, the methods for reviewing evidence and causal inference have been widely applied in other contexts (Rothman and Greenland 1998).

The reports of the Surgeon General have developed a formal framework for assessing evidence on disease causation, and the formats of the reports have provided detailed presentations of the scientific evidence underlying each of their conclusions (USDHEW 1964; U.S. Department of Health and Human Services [USDHHS] 2004). The reports have been produced using a balanced and comprehensive review and editorial process to ensure that the evidence, rather than the authors' opinions, defines the conclusions. Across the five decades of reports, the emphasis has been on the evidence base and the scientific validity of the conclusions, and scientific conclusions have been clearly separated from any policy decisions that may result from the findings.

The result of the work undertaken over this 50-year period has been a series of reports that have maintained their utility and credibility despite marked shifts in governmental policies toward tobacco, powerful opposition from tobacco industry interests, and the sometimes heated debates on science and policy that have taken place within the tobacco control community. This chapter covers the production and evolution of the reports during the past 50 years, emphasizing the processes that have sustained their utility.

Development of a Scientific Consensus

Often considered the first report of the Surgeon General on the health consequences of smoking, the 1964 report on smoking and health was actually (as noted in the introduction above) a report of an expert Advisory Committee to the Surgeon General (USDHEW 1964). Although this report is widely viewed as pivotal in establishing with certainty that cigarette smoking causes lung cancer, a similar conclusion with regard to causation had been reached earlier by several scientific reviews and by Surgeon General Leroy E. Burney (see Chapter 2).

Given the rising evidence and to once again critically review the cumulative evidence, the Surgeon General in 1962 convened an independent group of scientists who had not up to that time publicly expressed an opinion on whether smoking caused lung cancer. This group of

scientists was asked to review all of the available evidence on possible links between cigarette smoking and disease and to form a scientific judgment on this issue. In addition, the scientists were expected to report back to the Surgeon General with a solid evidence-based foundation for appropriate remedial action by the U.S. Public Health Service (PHS) responding to the emerging epidemic of lung cancer being caused by a highly profitable consumer product, the cigarette.

To ensure transparency, the committee codified the criteria used to reach the conclusion that smoking causes lung cancer. Both the resulting systematic, transparent review and the synthesis of evidence using those criteria were pioneering for the time.

Table 3.1 Surgeon General's reports on smoking and health, 1964–2012

Year	Title	Surgeon General	Subject/highlights	Number of pages
1964	<i>Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service</i>	Luther L. Terry, M.D.	First official report of the federal government on smoking and health. Concluded that “Cigarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action” (p. 33). Also concluded that cigarette smoking is a cause of lung cancer in men and a suspected cause of lung cancer in women. The report was also responsible for the passage of the <i>Cigarette Labeling and Advertising Act of 1965</i> , which among other things, mandated the familiar Surgeon General's health warnings on cigarette packages (USDHEW 1964).	387
1967	<i>The Health Consequences of Smoking: A Public Health Service Review</i>	William H. Stewart, M.D.	Confirmed and strengthened conclusions of the 1964 report. Stated that “the case for cigarette smoking as the principal cause of lung cancer is overwhelming” (p. 16). Found that evidence “strongly suggests that cigarette smoking can cause death from coronary heart disease” (p. 26), which was upgraded from the 1964 conclusion of an “association.” Also concluded that “Cigarette smoking is the most important of the causes of chronic non-neoplastic bronchopulmonary diseases in the United States” (p. 31) (USDHEW 1967).	199
1968	<i>The Health Consequences of Smoking: 1968 Supplement to the 1967 Public Health Service Review</i>	William H. Stewart, M.D.	Updated information that was presented in the 1967 report. Estimated that smoking-related loss of life expectancy among young men as 8 years for “heavy” smokers (more than 2 packs/day) and 4 years for “light” smokers (less than ½ pack/day) (USDHEW 1968).	117
1969	<i>The Health Consequences of Smoking: 1969 Supplement to the 1967 Public Health Service Review</i>	William H. Stewart, M.D.	Also supplemented 1967 report. Confirmed association between maternal smoking and infant low birthweight. Identified evidence of increased incidence of prematurity, spontaneous abortion, stillbirth, and neonatal death (USDHEW 1969).	98
1971	<i>The Health Consequences of Smoking</i>	Jesse L. Steinfeld, M.D.	Reviewed entire field of smoking and health with emphasis on most recent literature. Discussed new data indicating associations between smoking and peripheral vascular disease, atherosclerosis of the aorta and coronary arteries, increased incidence and severity of respiratory infections, and increased mortality from cerebrovascular disease and nonsyphilitic aortic aneurysm. Concluded that smoking is associated with cancers of the oral cavity and esophagus. Found that “Maternal smoking during pregnancy exerts a retarding influence on fetal growth” (p. 13) (USDHEW 1971).	458

Table 3.1 Continued

Year	Title	Surgeon General	Subject/highlights	Number of pages
1972	<i>The Health Consequences of Smoking</i>	Jesse L. Steinfeld, M.D.	Examined evidence on immunologic effects of tobacco and tobacco smoke, harmful constituents of tobacco smoke, and “public exposure to air pollution from tobacco smoke” (p. 121). Found tobacco and tobacco smoke antigenic in humans and animals; tobacco may impair protective mechanisms of immune system; nonsmokers’ exposure to tobacco smoke may exacerbate allergic symptoms; carbon monoxide in smoke-filled rooms may harm health of persons with chronic lung or heart disease; tobacco smoke contains hundreds of compounds, several of which have been shown to act as carcinogens, tumor initiators, and tumor promoters. Identified carbon monoxide, nicotine, and tar as smoke constituents most likely to produce health hazards of smoking (USDHEW 1972).	158
1973	<i>The Health Consequences of Smoking</i>	Merlin K. DuVal, M.D. ^a	Presented evidence on health effects of smoking pipes, cigars, and “little cigars.” Found mortality rates of pipe and cigar smokers higher than those of nonsmokers but lower than those of cigarette smokers. Found that cigarette smoking impairs exercise performance in healthy young men. Presented additional evidence on smoking as a risk factor in peripheral vascular disease and problems of pregnancy (USDHEW 1973).	249
1974	<i>The Health Consequences of Smoking</i>	Charles C. Edwards ^a	Tenth anniversary report. Reviewed and strengthened evidence on major hazards of smoking. Reviewed evidence on association between smoking and atherosclerotic brain infarction and on synergistic effect of smoking and asbestos exposure in causing lung cancer (USDHEW 1974).	124
1975	<i>The Health Consequences of Smoking</i>	Theodore Cooper, M.D. ^a	Updated information on health effects of involuntary (passive) smoking. Noted evidence linking parental smoking to bronchitis and pneumonia in children during the first year of life (USDHEW 1975).	235
1976	<i>The Health Consequences of Smoking: Selected Chapters from 1971 through 1975</i>	Theodore Cooper, M.D. ^a	Compiled selected chapters from 1971–1975 reports (USDHEW 1976).	657
1979	<i>The Health Consequences of Smoking, 1977–1978</i>	Julius B. Richmond, M.D.	Combined 2-year report focused on smoking-related health problems unique to women. Cited studies showing that use of oral contraceptives potentiates harmful effects of smoking on the cardiovascular system (USDHEW 1979b).	60

Table 3.1 Continued

Year	Title	Surgeon General	Subject/highlights	Number of pages
1979	<i>Smoking and Health</i>	Julius B. Richmond, M.D.	Fifteenth anniversary report. Presented most comprehensive review of health effects of smoking ever published, and first Surgeon General's report to carefully examine behavioral, pharmacologic, and social factors influencing smoking; to consider role of adult and youth education in promoting nonsmoking; and to review health consequences of smokeless tobacco. Many new sections, including one identifying smoking as "one of the primary sources of drug interactions in man" (p. 12-22) (USDHEW 1979a).	1,194
1980	<i>The Health Consequences of Smoking for Women</i>	Julius B. Richmond, M.D.	Devoted to health consequences of smoking for women. Reviewed evidence that strengthened previous findings and permitted new ones. Noted projections that lung cancer would surpass breast cancer as leading cause of cancer mortality in women. Identified trend toward increased smoking by adolescent females (USDHHS 1980).	359
1981	<i>The Health Consequences of Smoking—The Changing Cigarette</i>	Julius B. Richmond, M.D.	Examined health consequences of "the changing cigarette" (i.e., lower tar and nicotine cigarettes). Concluded that lower yield cigarettes reduced risk of lung cancer, but found no conclusive evidence that they reduced risk of cardiovascular disease, COPD, and fetal damage. Noted possible risks from additives and their products of combustion. Discussed compensatory smoking behaviors that might reduce potential risk of lower yield cigarettes. Emphasized that there is no safe cigarette and that any risk reduction associated with lower yield cigarettes would be small compared with benefits of quitting smoking (USDHHS 1981).	252
1982	<i>The Health Consequences of Smoking—Cancer</i>	C. Everett Koop, M.D.	Reviewed and extended understanding of the health consequences of smoking as a cause or contributory factor of numerous cancers. Included first Surgeon General's report consideration of emerging epidemiologic evidence of increased lung cancer risk in nonsmoking wives of smoking husbands. Did not find evidence at that time sufficient to conclude that relationship was causal, but labeled it "a possible serious public health problem" (p. 9). Discussed potential for low-cost smoking cessation interventions (USDHHS 1982).	322
1983	<i>The Health Consequences of Smoking—Cardiovascular Disease</i>	C. Everett Koop, M.D.	Examined health consequences of smoking for cardiovascular disease. Concluded that cigarette smoking is 1 of 3 major independent causes of CHD and, given its prevalence, "should be considered the most important of the known modifiable risk factors for CHD" (p. 6). Discussed relationships between smoking and other forms of cardiovascular disease (USDHHS 1983).	384

Table 3.1 Continued

Year	Title	Surgeon General	Subject/highlights	Number of pages
1984	<i>The Health Consequences of Smoking—Chronic Obstructive Lung Disease</i>	C. Everett Koop, M.D.	Reviewed evidence on smoking and COLD. Concluded that smoking is the major cause of COLD, accounting for 80–90% of COLD deaths in the United States. Noted that COLD morbidity has greater social impact than COLD mortality because of extended disability periods of COLD victims (USDHHS 1984).	545
1985	<i>The Health Consequences of Smoking—Cancer and Chronic Lung Disease in the Workplace</i>	C. Everett Koop, M.D.	Examined relationship between smoking and hazardous substances in the workplace. Found that for the majority of smokers, smoking is a greater cause of death and disability than their workplace environment. Risk of lung cancer from asbestos exposure characterized as multiplicative with smoking exposure. Observed special importance of smoking prevention among blue-collar workers because of their greater exposure to workplace hazards and their higher prevalence of smoking (USDHHS 1985).	542
1986	<i>The Health Consequences of Involuntary Smoking</i>	C. Everett Koop, M.D.	Focused on involuntary smoking, concluding that “Involuntary smoking is a cause of disease, including lung cancer, in healthy nonsmokers” (p. 7). Also found that, compared with children of nonsmokers, children of smokers have higher incidence of respiratory symptoms and infections and reduced rates of increase in lung function. Presented detailed examination of growth in restrictions on smoking in public places and workplaces. Concluded that simple separation of smokers and nonsmokers within same airspace reduces but does not eliminate exposure to environmental tobacco smoke (USDHHS 1986a).	359
1986	<i>The Health Consequences of Using Smokeless Tobacco</i>	C. Everett Koop, M.D.	Special report of advisory committee appointed by the Surgeon General to study the health consequences of smokeless tobacco. Concluded that use of smokeless tobacco can cause cancer in humans and can lead to nicotine addiction (USDHHS 1986b).	195
1988	<i>The Health Consequences of Smoking—Nicotine Addiction</i>	C. Everett Koop, M.D.	Established nicotine as a highly addictive substance, comparable in its physiological and psychological properties to other addictive substances of abuse (USDHHS 1988).	639
1989	<i>Reducing the Health Consequences of Smoking—25 Years of Progress</i>	C. Everett Koop, M.D.	Twenty-fifth anniversary report highlighted the dramatic progress that was achieved since the first report was issued in 1964. Highlighted important gains in preventing smoking and smoking-related disease, reviewed changes in programs and policies designed to reduce smoking, and emphasized remaining challenges (USDHHS 1989).	703

Table 3.1 Continued

Year	Title	Surgeon General	Subject/highlights	Number of pages
1990	<i>The Health Benefits of Smoking Cessation</i>	Antonia C. Novello, M.D., M.P.H.	Examined how an individual's risk of smoking-related diseases declines after quitting smoking (USDHHS 1990).	628
1992	<i>Smoking and Health in the Americas</i>	Antonia C. Novello, M.D., M.P.H.	Reviewed broad issues surrounding production and consumption of tobacco in the Americas (USDHHS 1992).	213
1994	<i>Preventing Tobacco Use Among Young People</i>	M. Joycelyn Elders, M.D.	Addressed the crucial problems of adolescent tobacco use by providing a detailed look at adolescence, the time of life when most tobacco users begin, develop, and establish their smoking behavior (USDHHS 1994).	314
1998	<i>Tobacco Use Among U.S. Racial/Ethnic Minority Groups</i>	David Satcher, M.D., Ph.D.	Described the 4 major U.S. racial/ethnic minority groups—African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, and Hispanics—patterns of tobacco use, adverse health effects, and the effectiveness of interventions in terms of tobacco's cultural and socioeconomic effects on the members of these groups. This report described the complex factors that play a part in the growing epidemic of diseases caused by tobacco use in these 4 groups (USDHHS 1998).	332
2000	<i>Reducing Tobacco Use</i>	David Satcher, M.D., Ph.D.	First report to offer a composite review of the various methods used to reduce and prevent tobacco use. This report evaluated each of the 5 major approaches to reducing tobacco use: educational, clinical, regulatory, economic, and comprehensive (USDHHS 2000).	462
2001	<i>Women and Smoking</i>	David Satcher, M.D., Ph.D.	Concluded that the increased likelihood of lung cancer, cardiovascular disease, and reproductive health problems among female smokers make tobacco use a serious women's health issue (USDHHS 2001).	675
2004	<i>The Health Consequences of Smoking</i>	Richard Carmona, M.D., M.P.H.	Concluded that smoking causes diseases in nearly every organ of the body. Also concluded that cigarette smoking is causally linked to leukemia, cataracts, pneumonia, and cancers of the cervix, kidney, pancreas, and stomach (USDHHS 2004).	941
2006	<i>The Health Consequences of Involuntary Exposure to Tobacco Smoke</i>	Richard Carmona, M.D., M.P.H.	Concluded that there is no risk-free level of exposure to secondhand smoke. Found that even brief secondhand smoke exposure can cause immediate harm. The report said the only way to protect nonsmokers from the dangerous chemicals in secondhand smoke is to eliminate smoking indoors (USDHHS 2006).	709
2010	<i>How Tobacco Smoke Causes Disease—The Biologic and Behavioral Basis for Smoking-Attributable Disease</i>	Regina Benjamin, M.D., M.B.A.	Described in detail the specific pathways by which tobacco smoke damages the human body (USDHHS 2010).	704

Table 3.1 Continued

Year	Title	Surgeon General	Subject/highlights	Number of pages
2012	Preventing Tobacco Use Among Youth and Young Adults	Regina Benjamin, M.D., M.B.A.	Updated the 1994 report on youth and described the epidemic of tobacco use among youth 12–17 years of age and young adults 18–25 years of age, including the epidemiology, causes, and health effects of this tobacco use and interventions proven to prevent it (USDHHS 2012).	899

Note: **CHD** = coronary heart disease; **COLD** = chronic obstructive lung disease; **COPD** = chronic obstructive pulmonary disease; **USDHEW** = U.S. Department of Health, Education and Welfare; **USDHHS** = U.S. Department Health and Human Services.

^aAssistant Secretary for Health issued the report.

Development of the Criteria for Causation Used in the 1964 Report

The meaning of the word “cause” has a long and rich philosophical history; the term has been applied variably in different scientific contexts. Among these contexts have been the demonstration of causation experimentally in the laboratory, the causal attribution of a specific infectious disease to a specific microbiologic agent, and the understanding of the mechanism(s) leading to a disease. In the years before the creation of the Advisory Committee, the groups which considered the question of cigarette smoking as a cause of lung cancer recognized that these scientific contexts, and the resulting context-specific constructs of causation, could not be readily applied to the question of whether cigarette smoking caused human disease (Blackburn and Labarthe 2012; Glass et al. 2013). Obtaining direct experimental evidence in humans is an ethical impossibility and understanding the mechanisms of disease occurrence involves considering an ongoing, open-ended set of scientific questions. Furthermore, neither of these scientific contexts for defining causation is well suited to examining the effects of human behaviors and exposures on subsequent disease occurrence in populations.

The early scientific reviews that examined whether smoking causes human disease used the common, generally understood meaning of the term “cause”: that the disease occurs as a result of exposure to the agent. This meaning was expressed in the 1964 report of the Surgeon General as follows: “The word *cause* is the one in general usage in connection with matters considered in this study, and it is capable of conveying the notion of a significant, effectual, relationship between an agent and an associated disorder or disease in the host” (USDHEW 1964, p. 21).

The 2004 Surgeon General’s report, *The Health Consequences of Smoking*, described the subsequent refinement of the 1964 language for application in public health and epidemiologic considerations as “The qualitative judgment that an exposure causes a particular disease signifies that in the absence of exposure some fraction of cases or deaths would not occur or would occur at a later age” (USDHHS 2004, p. 10).

The 1964 report of the Advisory Committee clearly stated that the decision that cigarette smoking was a cause of lung cancer in men resulted from a judgment based on a synthesis of all of the available evidence, rather than the outcome of a single scientific study or a single line of evidence. Specifically, the report (USDHEW 1964, p. 20) noted:

Statistical methods cannot establish proof of a causal relationship in an association. The causal significance of an association is a matter of judgment which goes beyond any statement of statistical probability. To judge or evaluate the causal significance of the association between the attribute or agent and the disease, or effect upon health, a number of criteria must be utilized, no one of which is an all-sufficient basis for judgment.

Included in the evidence base for the 1964 report were observational data from epidemiologic studies of human populations. During the 1940s and 1950s, epidemiology was rapidly developing as a scientific discipline, but the observational, as opposed to experimental,

nature of epidemiologic approaches led some scientists to question whether such approaches could be used to determine causation scientifically. Others confused epidemiologic analyses with the statistical methods used to describe the data (Shimkin 1979). Cigarette manufacturers and their spokespersons capitalized on this confusion by claiming that only experimental approaches could lead to evidence establishing causation: the evidence used by public health authorities to conclude that smoking caused lung cancer was only “statistical” and therefore not scientific (Brandt 2007; Proctor 2011).

Given the ethical impossibility of conducting human experiments to establish causation and recognizing the validity of epidemiologic methods, the various groups (before the Advisory Committee's report) that examined the question of whether cigarette smoking caused lung cancer had relied heavily on epidemiologic studies as a key part of the evidence base establishing causation. Each review described how the epidemiologic data were examined and considered. The reviews acknowledged that epidemiologic studies lacked the methodologic reassurance and needed careful attention to identify potential methodologic flaws, various biases, and both measured and unrecognized confounding (e.g., lifestyle differences between never smokers and smokers) that might have resulted in the demonstrated association. Each of these reports explained how these factors were considered in assessing the evidence, but the Advisory Committee went further and defined the criteria by which epidemiologic evidence could be examined and synthesized to reach a causal judgment.

The Committee's process for using epidemiologic data in assessing causation included multiple steps. The process involved: (1) establishing that cigarette smoking was associated with lung cancer; (2) examining whether the association could be explained by other factors such as methodologic flaws, bias, or confounding; (3) examining whether there were plausible alternative explanations for the observed association; (4) considering the main points of criticisms raised about the association and its potential causal nature; and (5) ensuring all of the lines of evidence were generally consistent with a causal hypothesis (USDHEW 1964). A similar careful and extensive process for considering evidence of causality had been implemented earlier by Cornfield and colleagues (1959) in their review of smoking and lung cancer: their considerations provided guidance for the methodologic approach adopted by the Advisory Committee in 1964. Subsequent reports of the Surgeon General have used the same approach for examining questions of causality for smoking and specific diseases.

In its report, the Advisory Committee formally presented a set of criteria by which epidemiologic data could

be used to define the causation of human disease: (1) the consistency of the association (replication of findings across different studies and populations), (2) the strength of the association (magnitude of the increased risk associated with exposure), (3) the specificity of the association (presence of a unique exposure-disease association), (4) the temporal relationship of the association (exposure comes before effect), and (5) the coherence of the association (support for the association from other lines of evidence) (USDHEW 1964).

These criteria were included in the widely recognized criteria for interpreting epidemiologic evidence in public health presented by Sir Austin Bradford Hill in 1965 (Hill 1965). The Bradford Hill criteria added four additional criteria, most notably the presence of a biologic gradient (dose-response relationship) in the evidence. The other three included plausibility (subsumed under coherence in the Surgeon General's criteria), experiment, and analogy.

Detailed discussions of these criteria, how they evolved, and how they are applied in reviewing epidemiologic evidence are presented in the 1964 report (USDHEW 1964) and the 2004 report (USDHHS 2004); that discussion will not be repeated here. Rather, the public health significance of formally expressed criteria for the use of epidemiologic evidence in defining causality is the focus of the present discussion. Historically, the articulation of these criteria marked a turning point in the utilization and acceptance of epidemiologic evidence. It laid the foundation for the current widespread use of epidemiologic evidence to define disease causation and identify methods for disease prevention and education of the public. These criteria, and their use by the Advisory Committee in reaching a judgment that smoking caused lung cancer in men, established an approach that remains in use for causal inference based around epidemiological and other evidence.

Evolution of the Application of the Criteria for Disease Causation in Subsequent Reports

As the evidence on smoking as a cause of disease expanded to include numerous disorders or problems (various cancers, multiple manifestations of atherosclerotic vascular disease, chronic obstructive pulmonary disease [COPD], complications of pregnancy, and a myriad of other diseases and conditions [USDHHS 2004]), a variety of terms were used to describe the established causal associations, including “cause,” “causal factor,” “risk factor,” “contributing factor,” and “causal association.” Some of

these descriptor choices were stylistic, reflecting the preferences of authors and editors; others reflected differences in how causal associations were described for different disease processes, notably the use of risk factor in the literature on cardiovascular disease, where there are multiple causal factors. However, some uses of these terms were intended to convey different levels of certainty about the strength of the evidence establishing causation.

This use of multiple terms led to some ambiguity and confusion as to what was actually being said. Eventually, terms modifying the descriptors of causality were also introduced. These terms described the impact of smoking on the population in relation to either other causes of disease or the contribution of smoking for a specific disease. For example, the 1989 Surgeon General's report on smoking and health stated that "Smoking remains the single most important preventable cause of death in our society" (USDHHS 1989, p. 11). This modifier was intended to describe the magnitude of the effect of smoking on the population in contrast to other causes of premature death. Similarly, the relationship of cigarette smoking and lung cancer was described as "Cigarette smoking is the major cause of lung cancer in the United States" (USDHHS 1982, p. 5), which qualitatively characterized the fraction of lung cancer deaths in the population caused by smoking. This mixing of terms, which quantified the population disease burden with terms describing the strength of the evidence establishing disease causation, had the potential to create ambiguity about what was being concluded, particularly when the modifier was used for some diseases but not others, in the same report.

Importantly, the 2004 Surgeon General's report on smoking and health (USDHHS 2004) standardized the forms in which judgments on disease causation and statements about the population consequences of diseases caused by smoking were presented. For causation, the language, which defined the strength of the evidence establishing that smoking caused a specific disease, was

made uniform to ensure clarity across the divergent disease processes, as illustrated by the following statement from the report:

The first step in introducing this revised approach is to outline the language that will be used for summary conclusions regarding causality, which follows hierarchical language used by Institute of Medicine committees (Institute of Medicine 1999) to couch causal conclusions, and by IARC [International Agency for Research on Cancer] to classify carcinogenic substances (IARC 1986). These entities use a four-level hierarchy for classifying the strength of causal inferences based on available evidence as follows: (a) Evidence is **sufficient** to infer a causal relationship; (b) Evidence is **suggestive but not sufficient** to infer a causal relationship; (c) Evidence is **inadequate** to infer the presence or absence of a causal relationship (which encompasses evidence that is sparse, of poor quality, or conflicting); and (d) Evidence is **suggestive of no causal relationship** (USDHHS 2004, pp. 17–18).

The evidence on disease causation for each specific disease is synthesized, and a judgment on causation is made and expressed using the standardized language presented above. This format clearly defines both the evidence on which the judgment is based and the strength with which that conclusion can be expressed. As for the public health impact of smoking-caused disease for the population and the fraction of the disease caused by smoking, both are presented in these reports under a separate heading named "Implications" following the Conclusions section. It is in that section that the population-level impact of smoking and the fraction of the disease caused by smoking are examined.

Methods for Reviewing the Evidence and Developing Conclusions

The reports of the Surgeon General have continued to play a role in defining the science that underlies efforts in tobacco control by certifying the causation of various diseases and expressing the state of the science on the effectiveness of tobacco control interventions, approaches, and policies. The success of the series of reports reflects the

processes used for reviewing and presenting the evidence and for the development of the conclusions. The processes used for subsequent reports evolved from the process used in the 1964 report of the Advisory Committee.

The 1964 report, at 387 pages, was substantively longer than the independent reviews that had preceded it. As

a consequence, it was able to offer a much more detailed presentation of the evidence in the text rather than simply providing references to the individual studies in support of the conclusions.

The depth of the evidence presentation in the Advisory Committee's report in 1964 can be seen readily in subsequent reports, and this comprehensive approach has been one reason for the reports' continuing credibility. An editorial standard evolved that required the conclusions of individual sections of the report to be based on discussions of the literature presented in the text that were coupled with relevant study results presented in the text, tables, and figures of those sections. This approach, of presenting the totality of evidence in sufficient detail to allow the reader to evaluate it, contrasted with the general approach of the time for written reviews, which relied heavily on syntheses of evidence by authors with literature citations for the publications reviewed. In the Surgeon General's reports, presentation of the critical findings from the relevant studies, coupled with discussion of the methods used to generate the evidence in the text of the report, has allowed readers to assess the validity of the conclusions directly rather than requiring them to conduct a time-consuming search of the cited publications. This transparency has strengthened the reports' findings in the face of the inevitable criticisms.

In synthesizing the evidence on exposure to secondhand smoke and disease, meta-analysis has been used, both in the Surgeon General's reports and in other evaluations. Generally, the term "meta-analysis" refers to the systematic analysis and quantitative summarization of the findings of multiple studies containing evidence to address the same question (Greenland 1987; Egger and Davey Smith 1997; Institute of Medicine 2011). In a meta-analysis, the data are the summary findings of the studies identified through a systematic review and not the data at the individual level. Meta-analysis has been used to summarize the evidence on exposure to secondhand smoke, primarily because the associations are generally much weaker than they are for active smoking. Meta-analysis was not used in the 1986 report, but it was applied to multiple outcomes in the 2006 report, *The Health Consequences of Involuntary Exposure to Tobacco Smoke*, and is used in this report.

Although meta-analysis has proven useful for summarizing the evidence and quantifying the risks of exposure to secondhand smoke as precisely as possible, the findings of meta-analyses and, particularly, information on whether an association found in the meta-analysis was statistically significant, have not figured directly in the causal inferences presented in the reports of the Surgeon General. The results are most useful for providing a single,

combined estimate of the risk for calculating the associated burden of disease and, potentially, for exploring why results vary from study to study.

The practice of presenting the relevant evidence needed to support the conclusions also has helped to ensure the validity of the conclusions as has the tiered approach and peer review process of the chapters. In the Surgeon General's reports, the initial author of an individual section is tasked with reviewing and assembling all of the relevant evidence available and presenting it in the text and related tables and figures with a level of detail sufficient to support the conclusions. Based on that presentation, the author then considers and discusses what conclusions the evidence supports. This comprehensive review process helps reduce inaccuracies that may occur when authors synthesize the evidence and reach conclusions based on their recall of what the literature shows, rather than on the evidence actually contained in that literature.

Passing the section on to the editors allows a different group of people to consider the evidence presented to evaluate the basis for the conclusions and to revise them, if appropriate. Similarly, as the chapters and reports proceed through the various review stages, the reviewers can independently consider the evidence presented as they consider the accuracy, completeness, balance, tone, and language of the conclusions. In providing their comments, the reviewers can focus on the evidence presented, consider whether the review of that evidence is complete, and judge whether the conclusions are supported by the evidence.

The intense criticisms of the reports by the cigarette manufacturers and their representatives prior to the late 1990s (see Chapter 2) helped to strengthen the process of developing conclusions for the reports. The anticipation of criticism motivated the development of conclusions that were firmly based on evidence without speculation. Before its elimination as a result of the 1998 Master Settlement Agreement, the Tobacco Institute (a representative of cigarette manufacturers) conducted a well-funded and highly visible public relations campaign to denigrate the quality of the science in each Surgeon General's report and question the validity of their conclusions (Kluger 1996; Brandt 2007; Proctor 2011). Based on the historical pattern of challenges to the Surgeon General's reports (see Chapter 14, "Current Status of Tobacco Control") the authors, editors, and reviewers of the reports assumed that every conclusion might be challenged and, therefore, each had to be solidly and fully supported by sufficient evidence. The result was that, as conclusions were drafted and reviewed, there was an intense focus on the quality and robustness of the evidence. Conclusions were structured to be unas-

sailably grounded in a foundation of evidence and the language of the conclusions was “conservative” such that the strength of evidence was not overstated. As the evidence foundation advanced, conclusions were strengthened.

This effort to achieve scientific transparency by laying out the evidence foundation for the conclusions has defined with clarity the state of the scientific evidence on

disease causation, the effectiveness of efforts in tobacco control, and the consequences of changes in public policy. In addition, it has provided solid support for evidence-based public policy decisions on tobacco issues, has identified the areas where scientific certainty exists as separate from those areas where uncertainty remains, and has been a principal reason for the enduring credibility of this series of reports.

Process of Ensuring Consensus and Strength of the Peer Review

In a series of governmental reports, such as those of the Surgeon General which have both great visibility and a substantial impact on public policy, protections are needed to resist influences that could distort the process of forming a consensus and affect the conclusions.

As a report is in development, a myriad of factors may come into play: political pressures; pressures from a variety of individuals and groups to have the conclusions conform to their preexisting policy positions; the recognition that some conclusions can influence decisions on research funding; and even the well-intentioned belief of authors of sections of the report that the final conclusions should substantiate positions they have adopted based on their own research. Without a process to insulate the report’s conclusions from such influences, the conclusions might be perceived as based on the politics and pressures of the moment rather than on a consensus of scientific opinion.

The National Clearinghouse for Smoking and Health prepared the initial series of reports (1967–1976) which followed the 1964 Surgeon General’s report. The scientific and technical staff of the clearinghouse, a forerunner of the current Centers for Disease Control and Prevention’s Office on Smoking and Health, was responsible for both drafting and editing the volume. The 1971 report, *The Health Consequences of Smoking*, was a comprehensive review of all of the available evidence, but the other reports in the 1967–1976 period were intended to review the evidence on the relationship of smoking to cancer, cardiovascular disease, and COPD that had been published since the previous report, with additional chapters focusing in more depth on specific topics. The “in-house” preparation of the volume was counterbalanced by a multilevel review process. Each draft chapter was reviewed by experts, external to the clearinghouse, from the academic community and select PHS agencies who were asked to evaluate the accuracy and completeness of the chapter. After the reviewers’ comments were incorporated into the draft chapters,

the chapters were assembled into a draft report. That version of the report was sent to a larger group of experts, broadly knowledgeable in smoking and health, who were asked to comment on the balance, tone, and accuracy of the volume and its conclusions. The draft report was also submitted for review to those agencies within PHS that were involved with tobacco issues. Revisions were made in response to these comments, and the volume was then submitted for formal clearance and release as the official position of PHS on the science of tobacco and health. As required by law, it was also transmitted to the U.S. Congress. This complex, multilayered peer review helped to ensure not only that the science in the volume was accurate but also that the positions expressed on the science were the prevailing view of the scientific community at the time and represented concurrence without being unduly influenced by any one individual or group.

Beginning with the 1979 Surgeon General’s report on smoking and health and continuing to the present, an additional layer of insulation was added by selecting a set of editors for each volume who were drawn from the academic and scientific communities and, when selected, were not employees of the federal government. These editors have been tasked with ensuring the accuracy of the scientific content of the reports and providing additional independent oversight for the process of incorporating reviewers’ comments. These independent editors, rather than the authors, have been responsible for making the final decisions on incorporating reviewers’ comments into the text, thereby creating a layer of objectivity regarding reviewers’ comments as they are considered and preventing the views of any single author from controlling the conclusions.

The evolution of this production process demonstrates that it is possible for a governmental review of a scientific topic of high societal interest and relevance to be conducted in a way that ensures independence and scientific accuracy for the resulting scientific conclusions.

Separation of Scientific Conclusions and the Formation of Policy

The findings of the reports of the Surgeons General have been the basis for a wide-ranging set of policy decisions and consequently some may consider the reports as offering policy recommendations. The overall intent of the reports, however, has been to provide a clear evidence foundation for scientific judgments on the diseases caused by smoking, the factors influencing smoking initiation and cessation, the effectiveness of smoking and tobacco control interventions, and the results of tobacco control programs and changes in public policy. The characterization of the state of the science on these issues remains the mission of the reports of the Surgeon General and is their principal enduring value. Although it is hoped that these scientific judgments will be used in the formation of public policy, and the reports have often examined the evidence on the effects of public policy decisions, the content of the reports has been limited to the state of the science on these issues. The reports have avoided defining or recommending specific public policies, leaving those decisions to the entities responsible for policy formation, including the Secretary of HHS and the various components of that department. The conclusions of the report have been intentionally framed to state what could be

concluded scientifically from the evidence and to lay out the implications of those conclusions for the population.

The separation of scientific conclusions from policy recommendations, initially adopted because policy decisions and implementation occurred at organizational levels well above that of the National Clearinghouse for Smoking and Health, has helped to ensure the ongoing credibility of this series of reports. Public policy decisions are, and often must be, made before the evidence supporting them is complete. These reports have been the benchmark on the status of the evidence for decision-making.

By preserving its exclusive focus on the scientific foundation and avoiding the inclusion of policy recommendations by the scientists involved with the report, the reports of the Surgeon General have preserved their credibility and somewhat insulated the report development process from the need for scientific certainty among those responsible for forming public policy. Correspondingly, the recognized independence of the reports' conclusions has resulted in a solid and enduring foundation that supports those who are tasked with defining and implementing public policy.

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