PART I

Introduction, Summaries, and Conclusions

Chapter 1

Introduction

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Realizing that for the convenience of all types of serious readers it would he desirable to simplify language, condense chapters and bring opinions to the forefront. the Committee offers Part I as such a presentation. This Part includes: (a) an introduction comprising, among other items, a chronology especially pertinent to the subject of this study and to the establishment and activities of the Committee, (b) a short account of how the study was conducted, (c) the chief criteria used in making judgments, and (d) a brief overview of the entire Report.

HISTORICAL NOTES AND CHRONOLOGY

In the early part of the 16th century, soon after the introduction of tobacco into Spain and England by explorers returning from the New World, controversy developed from differing opinions as to the effects of the human use of the leaf and products derived from it by combustion or other means. Pipe-smoking, chewing. and snuffing of tobacco were praised for pleasurable and reputed medicinal actions. At the same time, smoking was condemned as a foul-smelling, loath some custom, harmful to the brain and lungs. The chief question was then as it is now: is the use of tobacco bad or good for health, or devoid of effects on health? Parallel with the increasing production and use of tobacco, especially with the constantly increasing smoking of cigarettes, the controversy has become more and more intense. Scientific attack upon the problems has increased proportionately. The design, scope and penetration of studies have improved, and the yield of significant results has been abundant.

The modern period of investigation of smoking and health is included within the past sixty-three years. In 1900 an increase in cancer of the lung was noted particularly by vital statisticians, and their data are usually taken as the starting point for studies on the possible relationship of smoking and other uses of tobacco to cancer of the lung and of certain other organs, to diseases of the heart and blood vessels (cardiovascular diseases in general; coronary artery disease in particular), and to the non-cancerous (non-neoplastic) diseases of the lower respiratory tract (especially chronic bronchitis and emphysema). The next important basic date for starting comparisons is 1930, when the definite trends in mortality and disease-incidence considered in this Report became more conspicuous. Since then a great variety of investigations have been carried out. Many of the chemical compounds in tobacco and in tobacco smoke have been isolated and tested. Numerous experimental studies in lower animals have been made by exposing them to smoke and to tars, gases and various constituents in tobacco and tobacco smoke. It is not feasible to submit human beings to

experiments that might produce cancers or other serious damage, or to expose them to possibly noxious agents over the prolonged periods under strictly controlled conditions that would be necessary for a valid test. Therefore, the main evidence of the effects of smoking and other uses of tobacco upon the health of human beings has been secured through clinical and pathological observations of conditions occurring in men, women and children in the course of their lives, and by the application of epidemiological and statistical methods by which a vast array of information has been assembled and analyzed.

Among the epidemiological methods which have been used in attempts to determine whether smoking and other uses of tobacco affect the health of man, two types have been particularly useful and have furnished information of the greatest value for the work of this Committee. These are (1) *retrospective studies* which deal with data from the personal histories and medical and mortality records of human individuals in groups; and (2) *prospective studies*, in which men and women are chosen randomly or from some special group, such as a profession, and are followed from the time of their entry into the study for an indefinite period, or until they die or are lost on account of other events.

Since 1939 there have been 29 retrospective studies of lung cancer alone which have varying degrees of completeness and validity. Following the publication of several notable retrospective studies in the years 1952-1956, the medical evidence tending to link cigarette smoking to cancer of the lung received particularly widespread attention. At this time, also, the critical counterattack upon retrospective studies and upon conclusions drawn from them was launched by unconvinced individuals and groups. The same types of criticism and skepticism have been, and are, marshalled against the methods, findings, and conclusions of the later prospective studies. They will be discussed further in Chapter 3, Criteria for Judgment, and in other chapters, especially Chapter 8, Mortality, and Chapter 9, Cancer.

During the decade 1950-1960, at various dates, statements based upon the accumulated evidence were issued by a number of organizations. These included the British Medical Research Council; the cancer societies of Denmark, Norway, Sweden, Finland, and the Netherlands; the American Cancer Society; the American Heart Association; the Joint Tuberculosis Council of Great Britain; and the Canadian National Department of Health and Welfare. The consensus, publicly declared, was that smoking is an important health hazard, particularly with respect to lung cancer and cardiovascular disease.

Early in 1954, the Tobacco Industry Research Committee (T.I.R.C.) was established by representatives of tobacco manufacturers, growers, and warehousemen to sponsor a program of research into questions of tobacco use and health. Since then, under a Scientific Director and a Scientific Advisory Board composed of nine scientists who maintain their respective institutional affiliations, the Tobacco Industry Research Committee has conducted a grants-in-aid program, collected information, and issued reports.

The U.S. Public Health Service first became officially engaged in an appraisal of the available data on smoking and health in June, 1956, when, under the instigation of the Surgeon General, a scientific Study Group on

the subject was established jointly by the National Cancer Institute, the National Heart Institute, the American Cancer Society, and the American Heart Association. After appraising 16 independent studies carried on in five countries over a period of 18 years, this group concluded that there is a causal relationship between excessive smoking of cigarettes and lung cancer.

Impressed by the report of the Study Committee and by other new evidence, Surgeon General Leroy E. Burney issued a statement on July 12, 1957, reviewing the matter and declaring that: "The Public Health Service feels the weight of the evidence is increasingly pointing in one direction; that excessive smoking is one of the causative factors in lung cancer." Again, in a special article entitled "Smoking and Lung Cancer--A Statement of the Public Health Service," published in the Journal of the American Medical Association on November 28, 1959, Surgeon General Burney referred to his statement issued in 1957 and reiterated the belief of the Public Health Service that: "The weight of evidence at present implicates smoking as the principal factor in the increased incidence of lung cancer," and that: "Cigarette smoking particularly is associated with an increased chance of developing lung cancer." These quotations state the position of the Public Health Service taken in 1957 and 1959 on the question of smoking and health. That position has not changed in the succeeding years, during which several units of the Service conducted extensive investigations on smoking and air pollution, and the Service maintained a constant scrutiny of reports and publications in this field.

ESTABLISHMENT OF THE COMMITTEE

The immediate antecedents of the establishment of the Surgeon General's Advisory Committee on Smoking and Health began in mid-1961. On June 1 of that year, a letter was sent to the President of the United States, signed by the presidents of the American Cancer Society, the American Public Health Association, the American Heart Association, and the National Tuberculosis Association. It urged the formation of a Presidential commission to study the "widespread implications of the tobacco problem."

On January 4, 1962, representatives of the various organizations met with Surgeon General Luther L. Terry, who shortly thereafter proposed to the Secretary of Health, Education, and Welfare the formation of an advisory committee composed of "outstanding experts who would assess available knowledge in this area [smoking vs. health] and make appropriate recommendations . . ."

On April 16. the Surgeon General sent a more detailed proposal to the Secretary for the formation of the advisory group, calling for re-evaluation of the Public Health Service position taken by Dr. Burney in the Journal of the American Medical Association. Dr. Terry felt the need for a new look at the Service's position in the light of a number of significant developments since 1959 which emphasized the need for further action. He listed these as:

1. New studies indicating that smoking has major adverse health effects.

2. Representations from national voluntary health agencies for action on the part of the Service,

3. The recent study and report of the Royal College of Physicians of London.

4. Action of the Italian Government to forbid cigarette and tobacco advertising: curtailed advertising of cigarettes by Britain's major tobacco companies on TV: and a similar decision on the part of the Danish tobacco industry.

5. A proposal by Senator Maurine Neuberger that Congress create a commission to investigate the health effects of smoking.

6. A request for technical guidance by the Service from the Federal Trade Commission on labeling and advertising of tobacco products.

7. Evidence that medical opinion has shifted significantly against smoking.

The recent study and report cited by Surgeon General Terry was the highly important volume: "Smoking and Health–Summary and Report of the Royal College of Physicians of London on Smoking in Relation to Cancer of the Lung and Other Diseases." The Committee of the Royal College of Physicians dealing with these matters had been at its work of appraisal of data since April 1959. Its main conclusions. issued early in 1962, were: "Cigarette smoking is a cause of lung cancer and bronchitis, and prohably contributes to the development of coronary heart disease and various other less common diseases. It delays healing of gastric and duodenal ulcers."

On June 7, 1962, the Surgeon General announced that he was establishing an expert committee to undertake a comprehensive review of all data on smoking and health. The President later in the same day at his press conference acknowledged the Surgeon General's action and approved it.

On July 24, 1962, the Surgeon General met with representatives of the American Cancer Society, the American College of Chest Physicians, the American Heart Association, the American Medical Association, the Tobacco Institute, Inc., the Food and Drug Administration, the National Tuberculosis Association, the Federal Trade Commission, and the President's Office of Science and Technology. At this meeting, it was agreed that the proposed work should be undertaken in two consecutive phases, as follows:

Phase I–An objective assessment of the nature and magnitude of the health hazard, to be made by an expert scientific advisory committee which would review critically all available data but would not conduct new researrh. This committee would produce and submit to the Surgeon General a technical report containing evaluations and conclusions.

Phase II–Recommendations for actions were not to be a part of the Phase I committee's responsibility. No decisions on how Phase II would be conducted were to be made until the Phase I report was available. It was recognized that different competencies would be needed in the second phase and that many possible recommendations for action would extend beyond the health field and into the purview and competence of other Federal agencies.

The participants in the meeting of July 27 compiled a list of more than 150 scientists and physicians working in the fields of biologv and medicine,

with interests and competence in the broad range of medical sciences and with capacity to evaluate the elements and factors in the complex relationship between tobacco smoking and health. During the next month, these lists were screened by the representatives of organizations present at the July 27 meeting. Any organization could veto any of the names on the list, no reasons being required. Particular care was taken to eliminate the names of any persons who had taken a public position on the questions at issue. From the final list of names the Surgeon General selected ten men who agreed to serve on the Phase I committee, which was named *The Surgeon General's Advisory Committee on Smoking and Health.* The committee members, their positions, and their fields of competence are:

Stanhope Bayne-Jones, M.D., LL.d., (Retired), Former Dean, Yale School of Medicine (1935-40), former President, Joint Administrative Board, Cornell University, New York Hospital. Medical Center (1947-52) ; former President, Society of American Bacteriologists (1929)) and American Society of Pathology and Bacteriology (1940). Field: Nature and Causation of Disease in Human Populations.

Dr. Bayne-Jones served also as a special consultant to the Committee staff.

Walter J. Burdette, M.D., Ph. D., Head of Department of Surgery, University of Utah School of Medicine, Salt Lake City. Fields: Clinical & Experimental Surgery; Genetics.

William G. Cochran, M.A., Professor of Statistics, Harvard University. Field: Mathematical Statistics, with Special Application to Biological Problems.

Emmanuel Farber, M.D., Ph. D., Chairman, Department of Pathology, University of Pittsburgh. Field: E xperimental and Clinical Pathology.

Louis F. Fieser, Ph. D., Sheldon Emory, Professor of Organic Chemistry, Harvard University. Field: Chemistry of Carcinogenic Hydrocarbons.

Jacob Furth, M.D., Professor of Pathology, Columbia University, and Director of Pathology Laboratories, Francis Delafield Hospital, New York, N.Y. Field: Cancer Biology.

John B. Hickam, M.D., Chairman, Department of Internal Medicine, University of Indiana, Indianapolis. Fields : Internal Medicine, Physiology of Cardiopulmonary Disease.

Charles LeMaistre, M.D., Professor of Internal Medicine, The University of Texas Southwestern Medical School, and Medical Director, Woodlawn Hospital, Dallas, Texas. Fields: Internal Medicine, Pulmonary Diseases, Preventive Medicine.

Leonard M. Schuman, M.D., Professor of Epidemiology, University of Minnesota School of Public Health, Minneapolis. Field: Health and Its Relationship to the Total Environment.

Maurice H. Seevers, M.D., Ph. D., Chairman, Department of Pharmacology. University of Michigan, Ann Arbor. Field : Pharmacology of Anesthesia and Habit-Forming Drugs.

Chairman: Luther L. Terry, M.D., Surgeon General of the United States Public Health Service.

Vice-Chairman: James M. Hundley, M.D., Assistant Surgeon General for Operations, United States Public Health Service.

Staff Director

Eugene H. Guthrie, M.D., M.P.H.
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