Chapter 3

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In making critical appraisals of data and interpretations and in formulating its own conclusions, the Surgeon General's Advisory Committee on Smoking and Health--its individual members and its subcommittees and the Committee as a whole--made decisions or judgments at three levels. These levels were:

I. Judgment as to the validity of a publication or report. Entering into the making of this judgment were such elements as estimates of the competence and training of the investigator, the degree of freedom from bias, design and scope of the investigation, adequacy of facilities and resources, adequacy of controls.

II. Judgment as to the validity of the interpretations placed by investigators upon their observations and data, and as to the logic and justification of their conclusions.

III. Judgments necessary for the formulation of conclusions within the Committee.

The primary reviews, analyses and evaluations of publications and unpublished reports containing data, interpretations and conclusions of authors were made by individual members of the Committee and, in some instances, by consultants. Their statements were next reviewed and evaluated by a subcommittee. This was followed at an appropriate time by the Committee's critical consideration of a subcommittee's report, and by decisions as to the selection of material for inclusion in the drafts of the Report, together with drafts of the conclusions submitted by subcommittees. Finally, after repeated critical reviews of drafts of chapters, conclusions were formulated and adopted by the whole Committee, setting forth the considered judgment of the Committee.

It is not the intention of this section to present an essay on decision-making. Nor does it seem necessary to describe in detail the criteria used for making scientific judgments at each of the three levels mentioned above. All members of the Committee were schooled in the high standards and criteria implicit in making scientific assessments; if any member lacked even a small part of such schooling he received it in good measure from the strenuous debates that took place at consultations and at meetings of the subcommittees and the whole Committee.

CRITERIA OF THE EPIDEMIOLOGIC METHOD

It is advisable, however, to discuss briefly certain criteria which, although applicable to all judgments involved in this Report, were especially significant for judgments based upon the epidemiologic method. In this inquiry the

epidemiologic method was used extensively in the assessment of causal factors in the relationship of smoking to health among human beings upon whom direct experimentation could not be imposed. Clinical, pathological and experimental evidence was thoroughly considered and often served to suggest an hypothesis or confirm or contradict other findings. When coupled with the other data, results from the epidemiologic studies can provide the basis upon which judgments of causality may be made.

In carrying out studies through the use of this epidemiologic method, many factors, variables, and results of investigations must be considered to determine first whether an association actually exists between an attribute or agent and a disease. Judgment on this point is based upon indirect and direct measures of the suggested association. If it be shown that an association exists, then the question is asked: "Does the association have a causal significance?"

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. These criteria include :

a) The consistency of the association
b) The strength of the association
c) The specificity of the association
d) The temporal relationship of the association
e) The coherence of the association

These criteria were utilized in various sections of this Report. The most extensive and illuminating account of their utilization is to be found in Chapter 9 in the section entitled "Evaluation of the Association Between Smoking and Lung Cancer".

CAUSALITY

Various meanings and conceptions of the term *cause* were discussed vigorously at a number of meetings of the Committee and its subcommittees. These debates took place usually after data and reports had been studied and evaluated, and at the times when critical scrutiny was being given to conclusions and to the wording of conclusive statements. In addition, thoughts about causality in the realm of this inquiry were constantly and inevitably aroused in the minds of the members because they were preoccupied with the subject of their investigation--"Smoking and Health."

Without summarizing the more important concepts of causality that have determined human attitudes and actions from the days even before Aristotle, through the continuing era of observation and experiment, to the statistical certainties of the present atomic age, the point of view of the Committee with regard to causality and to the language used in this respect in this report may be stated briefly as follows:

1. The situation of smoking in relation to the health of mankind includes a host (variable man) and a complex agent (tobacco and its products, partic-

ularly those formed by combustion in smoking). The probe of this inquiry is into the effect, or non-effect, of components of the agent upon the tissues, organs, and various qualities of the host which might: a) improve his well-being, b) let him proceed normally, or c) injure his health in one way or another. To obtain information on these points the Committee did its best, with extensive aid, to examine all available sources of information in publications and reports and through consultation with well informed persons.

2. When a relationship or an association between smoking, or other uses of tobacco, and some condition in the host was noted, the significance of the association was assessed.

3. The characterization of the assessment called for a specific term. The chief terms considered were "factor," "determinant," and "cause." The Committee agreed that while a factor could be a source of variation, not all sources of variation are causes. It is recognized that often the coexistence of several factors is required for the occurrence of a disease, and that one of the factors may play a determinant role, i.e., without it the other factors (as genetic susceptibility) are impotent. Hormones in breast cancer can play such a determinant role. 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.

4. It should be said at once, however, that no member of this Committee used the word "cause" in an absolute sense in the area of this study. Although various disciplines and fields of scientific knowledge were represented among the membership, all members shared a common conception of the multiple etiology of biological processes. No member was so naive as to insist upon mono-etiology in pathological processes or in vital phenomena. All were thoroughly aware of the fact that there are series of events in occurrences and developments in these fields, and that the end results are the net effect of many actions and counteractions.

5. Granted that these complexities were recognized, it is to be noted clearly that the Committee's considered decision to use the words "a cause," or "a major cause," or "a significant cause," or "a causal association" in certain conclusions about smoking and health affirms their conviction.