AD-A145 760 NATIONAL ACADEMY OF SCIENCES' REPORTS ON DIET AND HEALTH--ARE THEY CREDIBLE AND CONSISTENT?(U) GENERAL ACCOUNTING OFFICE WASHINGTON DC RESOURCES COMMUNITY A.. 1/2

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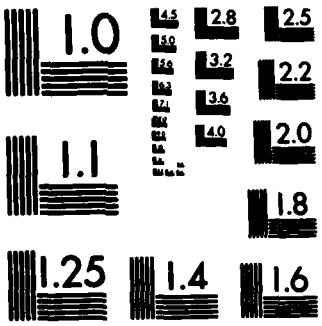

MICROCOPY RESOLUTION TEST CHART

REPORT BY THE U.S.

General Accounting Office

AD-A145 760

National Academy Of Sciences' Reports On Diet And Health-- Are They Credible And Consistent?

Two National Academy of Sciences' reports sparked public controversy because they differed about whether the public should modify its diet to reduce cancer risk. *Toward Healthful Diets* (1980) concluded that no sound scientific basis existed for recommending dietary changes to reduce cancer risk, while *Diet, Nutrition, and Cancer* (1982) concluded that the evidence indicated a link between some dietary components and cancer, and suggested interim dietary guidelines which it stated were likely to reduce cancer risk.

GAO found that different scientists' philosophies about what scientific evidence is necessary as a basis for providing the public with dietary advice to reduce the risk of cancer are a major factor in the reports' different conclusions and recommendations. Also, the reports are different because they were done for different purposes, on different topics, at different points in time by different groups.

The Academy has report development processes which are designed to ensure that all its reports are supported by scientific evidence and free from conflicts of interest which might make them less credible to the public. GAO found, however, that the Academy has no formal means to clarify scientists' disagreements for the public. For this reason, the Academy should consider making reporting changes to aid public understanding.

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AUGUST 21, 1984

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UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION

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The Honorable J. James Exon
The Honorable Charles E. Grassley
The Honorable Roger W. Jepsen
The Honorable John Melcher
United States Senate

The Honorable Cooper Evans
The Honorable William F. Goodling
The Honorable Arlan Stangeland
The Honorable Charles W. Stenholm
The Honorable Tom Tauke
The Honorable Charles Whitley
House of Representatives

In response to your September 30, 1982, October 1, 1982, and December 20, 1982, requests, we have examined the National Academy of Sciences' reports Toward Healthful Diets and Diet, Nutrition, and Cancer. This report outlines the controversies on the relationship of diet to cancer, explains the issues, and provides background information on the various points of view involved. It also discusses the Academy's processes of preparing reports, which are designed to provide objectivity in assessing controversial areas such as diet's relationship to health.

As agreed with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this report. At that time, we will send copies of this report to the Chairmen, House and Senate Committees on Appropriations; Senate Committee on Agriculture, Nutrition, and Forestry; House Committee on Agriculture; House Committee on Government Operations; Senate Committee on Governmental Affairs; House Committee on Energy and Commerce; House Committee on Science and Technology; and Senate Committee on Labor and Human Resources; and the Director, Office of Management and Budget.

Copies will be available to other interested parties who request them.

Sincerely yours,

J. Dexter Peach
Director

REPORT BY THE U.S. GENERAL ACCOUNTING OFFICE

NATIONAL ACADEMY OF SCIENCES' REPORTS ON DIET AND HEALTH--ARE THEY CREDIBLE AND CONSISTENT?

D I G E S T

In the fall of 1982, 11 Members of Congress, expressing their belief that recommendations to the public in the area of diet and health must be consistent and credible, requested GAO to study the processes used by the National Academy of Sciences[1] to produce two reports on the relationship of diet to health: Toward Healthful Diets (1980) and Diet, Nutrition, and Cancer (1982). Because the reports differed about whether the U.S. public could reduce its chronic disease risk through dietary changes, GAO was asked to (1) obtain information on the Academy's processes of providing reports in controversial areas and (2) present the agenda of issues and the range of scientific fact and judgment on the relationship of diet to cancer, outlining the controversies, explaining the issues, and giving background on the various points of view involved. GAO did not evaluate the two reports' scientific methodology or assess the validity of the reports' recommendations.

ACADEMY REPORTS PROVED CONTROVERSIAL

Both reports sparked controversy among scientists, public officials, and special interest groups holding different views on the issues. Toward Healthful Diets was criticized by some for suggesting that dietary modification was not generally of proven benefit for the U.S.

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[1]The National Academy of Sciences, chartered by Congress in 1863 as an official U.S. Government advisor, is a quasi-public honorary organization to which scientists are elected annually by vote of the membership. The Academy provides most of its advice through the National Research Council, which can call upon respected scientists and engineers, who are not necessarily Academy members, to serve on volunteer committees.

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AUGUST 21,1984

Tear Sheet

public in reducing the incidence of chronic diseases such as heart disease and cancer. Diet, Nutrition, and Cancer was criticized by others for suggesting, allegedly without sufficient scientific evidence, that dietary modifications could reduce the risk of cancer (see p. 31). Both reports' authors were criticized as allegedly having one-sided views of the scientific issues involved. (See p. 14.)

Academy officials are concerned that Academy reports are credible to the public and to public policymakers, but the Academy's primary objective is developing reports that are credible to scientists. Scientific and public credibility are different issues. According to Academy officials, scientifically credible reports must be scientifically sound evaluations of all relevant scientific evidence. Credibility does not mean that all scientists agree with a report's conclusions. In their request letters, the Members of Congress expressed their belief that for Academy reports to be credible to the public, authors should be free from conflicts of interest, reports should be consistent with other studies by the Academy, and scientific fact and judgment should be clearly differentiated.

Academy officials do not expect its reports necessarily to come to the same conclusions because scientific evidence is constantly changing. Also, where complex scientific questions remain to be answered, two groups of scientists could review the same scientific data and come to different but supportable conclusions. According to Academy officials, this is hard to communicate clearly to the public which expects clear and absolute answers to questions about issues such as diet and health.

ACADEMY PROCESSES FOR CREDIBLE REPORTS

According to the Chairman of the Academy Report Review Committee, when a report is approved for publication the Committee is certifying that it is scientifically credible--that the group which authored the report was competent to address the issues, unbiased in evaluating and responsible in interpreting the scientific data, and fair in presenting study results. To ensure that its reports are scientifically sound, the Academy has standard processes for phases of report development including: (1) review of study proposals, (2) appointment

of scientists to study groups, and (3) review of reports. The Academy also has a standard process for notifying the news media about reports of interest to the public. (See pp. 8, 12, 20, and 24.)

GAO believes that the Academy's standard processes were followed by the groups which authored both Toward Healthful Diets and Diet, Nutrition, and Cancer. However, GAO notes that both reports' press releases contained examples of specific foods which were not mentioned in the reports. Controversy about Diet, Nutrition, and Cancer resulted when this difference was called to the public's attention by agricultural interest groups who disagreed with the report's conclusions and guidelines and believed that their products were being unfairly singled out.

To better present information in Academy press releases and to aid public understanding, the Academy President may want to consider indicating in press releases that specific food examples which are not contained in the report are given for illustrative purposes. (See p. 28.)

CONSISTENCY BETWEEN REPORTS

Toward Healthful Diets and Diet, Nutrition, and Cancer differed on the issue of whether diet changes could reduce chronic disease risk. However, according to the reports' authors, the fundamental dietary advice about variety and moderation provided by both reports is similar. The dietary advice in the Academy reports is also consistent with dietary advice offered by other groups. (See p. 36.)

GAO noted the following factors that help explain why the two reports, while providing fundamentally similar dietary advice, differed about the potential for diet changes to reduce chronic disease risk.

Comparability of the two reports

Academy officials told GAO that the two reports are substantially different because they were written for different purposes, for different audiences, on different topics, at different points in time, and by different groups.

Tear Sheet

Toward Healthful Diets, authored by a task force of the Academy's Food and Nutrition Board using Board funds, is a 24-page position statement which (1) considers diet's relationship to five diseases including cancer and (2) makes recommendations about what healthy adult Americans should eat to remain healthy. In a 1-1/2 page discussion, it concludes that no sound scientific basis exists for general recommendations to modify the U.S. diet to reduce cancer risk. The more recent report, Diet, Nutrition, and Cancer, drew upon reference material that was not available to the earlier study group. About one-fifth of the bibliographic references in it were dated 1980 or later, after Toward Healthful Diets was drafted. Authored by an ad hoc committee funded by a National Cancer Institute contract, it is a 460-page scientific literature review of diet's relationship to cancer that suggests interim dietary guidelines which it states are likely to reduce the public's cancer risk. (See p. 32.)

Two schools of thought about dietary advice

The reports represent two schools of thought on what scientific evidence is sufficient for providing public advice about dietary changes to reduce chronic disease risk. According to scientists and Academy officials, because nutrition science is not developed sufficiently to provide all the answers to questions about diet, and no universal standard of scientific evidence has been agreed on for making public recommendations about diet's relationship to health, legitimate disagreements will continue to exist. (See p. 43.)

The authors of Toward Healthful Diets believe that the U.S. public is generally long-lived and healthy, due in part to its good diet, and that, as the report states, any dietary changes recommended to reduce chronic disease risks should be proven safe and effective before they are pronounced. These scientists and physicians stated that the evidence supporting dietary recommendations as a chronic disease prevention measure is incomplete, and that some risk may be involved when individuals alter their diets without medical supervision in an effort to prevent specific diseases.

Although the scientists and physicians who subscribe to Diet, Nutrition, and Cancer's approach agree that the evidence is incomplete,

they believe that chronic diseases are a public health problem of such magnitude that some action is needed. They stated that if evidence from many sources converges to point toward a course of preventive action, no risk of taking the action has been identified, and the potential benefits are great, then recommendations to the public ought to be made. They also stated that people are making changes based on past recommendations and living longer.

GAO observations

GAO noted that the 1980 report did not fully document the methodology used to arrive at the conclusions about diet's relationship to chronic diseases, nor are the reasons for the two Academy reports' different conclusions about diet's relationship to cancer discussed in the 1982 report. GAO believes both omissions contributed to public controversy.

The Academy has no formal means to require assessment of whether reports by its study groups are consistent or to explain the significance of scientists' disagreements for public policy. To ensure freedom of thought, authors of Academy reports are given the discretion to determine how to best present their findings. (See p. 33.)

To aid public understanding and to provide a better context for policymakers as they assess the issues, GAO believes the Academy President could consider emphasizing to its study groups the importance of clearly setting forth how and on what basis they arrive at conclusions and recommendations. The Academy President also could consider including a statement in future public reports on topics of major public interest that sets out scientists' disagreements about what scientific evidence is sufficient to provide public advice on topics such as diet's relationship to health. (See p. 46.)

COMMENTS FROM THE ACADEMY AND OTHERS

GAO obtained comments on this report from the National Academy of Sciences, the Departments of Health and Human Services and Agriculture, the Food and Drug Administration, and from individual scientists responsible for, or involved in the debate about, each Academy report.

The National Academy of Sciences, the Departments, and the Food and Drug Administration agreed that GAO's report provides a balanced discussion on the controversies and issues raised by the two reports. The Academy also stated that GAO's suggestions to facilitate providing advice and information to the government and to the American public are especially useful and will be given careful study. (See pp. 28 and 48 and apps. IV, V, VI, and VII.)

GAO made a number of changes suggested by the Academy, by the Departments, and by individual scientists (see app. VIII) to improve the report's clarity and technical accuracy.

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ABBREVIATIONS

ALS	Assembly of Life Sciences, National Research Council, National Academy of Sciences
FNB	Food and Nutrition Board, National Research Council, National Academy of Sciences
GAO	General Accounting Office
HHS	Department of Health and Human Services
NAS	National Academy of Sciences
NCI	National Cancer Institute, National Institutes of Health, Department of Health and Human Services
NIH	National Institutes of Health
NRC	National Research Council
RDA	recommended dietary allowances
RRC	Report Review Committee, National Research Council, National Academy of Sciences
USDA	U.S. Department of Agriculture

GLOSSARY

Cholesterol	a fat found in all body cells which is a necessary building block for cell walls, is a precursor of hormones such as sex hormones and which shares in other essential processes. Cholesterol is carried in the bloodstream. It is synthesized by the body and also is derived from the diet. Cholesterol is found only in food of animal origin. The amount of cholesterol that is found in the blood is not directly proportional to the amount eaten
Chronic disease	disease which persists for months or years in contrast to acute disease which leads quickly to recovery or death
Clinical intervention trials	a method of scientific testing using human subjects which is used to determine the safety and effectiveness of new drugs and other treatments and to provide scientists with basic research information. In such studies the free-living subjects are divided into groups and one or more groups are provided treatment and other groups are not. At the end of the study the groups are compared to determine whether the treatment had any effect. Clinical intervention trials are considered part of experimental epidemiology
Diet	the total composition of ingested food, including nutrients and non-nutritive substances
Dose-response	a gradient response where exposure to successively stronger doses of a substance produces a successively stronger response
Epidemiology	the branch of medical science which uses statistical and experimental techniques to measure and analyze the incidence, distribution, and determinates of disease in human populations
Laboratory tests	experiments conducted by scientists on non-human subjects, or on materials removed from humans such as blood. These tests include analysis of chemical reactions in test tubes (*in vitro* studies) as well as analysis of living organisms such as animals (*in vivo* studies). Clinical investigations of humans, for example, in hospital metabolic wards, are also considered laboratory tests

Macronutrient	an element that is essential for the life of an organism, is required in relatively large amounts, and is usually measured in grams. Carbohydrates and calcium are examples of macronutrients
Nutrient	a component of food that provides nourishment for growth, reproduction, and maintenance of the organism
Nutrition	the science of food and its relationship to health, which includes the processes by which an organism uses food nutrients to maintain the structural and biochemical integrity of its cells, thereby ensuring the organism's viability and reproduction potential
Recommended dietary allowances	recommended levels of intake of a number of essential nutrients that are considered to be adequate to meet the known nutritional needs of practically all healthy people
Risk	as used in this report, risk refers to the probability of occurrence of a disease in a given population group. This does not refer to the probability of any individual's contracting a disease

CHAPTER 1

INTRODUCTION

In the fall of 1982, 11 Members of Congress, expressing their belief that public recommendations in the area of diet and health must be consistent and credible, requested us to study the processes used by the National Academy of Sciences (NAS)[1] to produce two reports on the relationship of diet and health: Toward Healthful Diets (May 1980) and Diet, Nutrition, and Cancer (June 1982). We were asked to (1) present the agenda of issues and the range of scientific fact and judgment on the relationship of diet to cancer, outlining the controversies, explaining the issues, and giving background on the various points of view involved and (2) obtain information on NAS' process of producing reports in controversial areas such as diet's relationship to health. (See app. I.)

Scientific and public credibility are different issues. Scientific credibility means, according to NAS' Report Review Committee (RRC) Chairman, that NAS reports must be scientifically sound evaluations of all relevant data, performed by competent scientists. In their request letters, the Members of Congress expressed their belief that for NAS reports to be credible to the public, NAS authors should be free from conflicts of interest, reports generally should be consistent with other NAS reports, and scientific fact and judgment should be clearly differentiated.

The two NAS reports, Toward Healthful Diets and Diet, Nutrition, and Cancer, appeared to be contradictory because although they provided fundamentally similar dietary advice, they disagreed about the potential for reducing the public's chronic disease risk by dietary means. The first report, which made recommendations on what healthy people should eat to remain healthy, found no sound scientific basis for recommending modifications to the U.S. diet to reduce the risk of cancer. The second suggested guidelines for diet which the report stated were likely to reduce cancer risk.

The question of what one should eat to become healthy and remain healthy is important because diet and nutrition are factors in disease as well as health. Diet and nutrition are different concepts. Diet is defined as the total composition of food eaten including nutrients--a component of food such as protein or fat that provides nourishment for growth, reproduction, and maintenance--and non-nutrients, such as naturally occurring contaminants such as aflatoxin (a plant mold) and additives such as

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[1]The National Research Council, under the oversight of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine (see p. 3), was responsible for the two studies discussed in this report. For simplicity in this report, we refer to this complex of organizations as NAS.

food preservatives. Nutrition is defined as the science of food and its relationship to health, which includes the processes by which a person uses food nutrients.

Much is known about what people generally should eat to remain healthy. However, some scientists believe that developing public dietary guidelines is difficult because not all nutritional needs are known, and individuals differ in their need for food due to factors like heredity, age, and activity level. The dietary guidelines offered by a variety of public and private organizations sometimes seem to conflict with one another. Because all the needed scientific facts are not known and scientists differ in their interpretation of scientific data, the field of diet and health will remain controversial.

Toward Healthful Diets was produced by the NAS Food and Nutrition Board (FNB). FNB, currently located within the Commission on Life Sciences,[2] has been a standing NAS committee since 1940 and in 1943 produced the first U.S. dietary guidance, the Recommended Dietary Allowances (RDAs),[3] which it periodically revises. FNB produces studies in the area of food and nutrition. It has a rotating membership of eminent scientists and physicians appointed for 3-year terms.

Toward Healthful Diets is a 24-page position statement which makes recommendations on what healthy people should eat to remain healthy. It was written by FNB on its own initiative to reduce the confusion in the minds of the public which FNB believed had resulted from the many sources of advice available on diet and health. It is not an exhaustively documented scientific report. It deals, among other issues, with the relationship between diet and five diseases: obesity, cardiovascular disease, hypertension, cancer, and diabetes. The report makes five dietary recommendations for healthy adult Americans to follow (except for pregnant and nursing mothers) to improve general nutritional status and perhaps prevent or delay the onset of some chronic diseases. The report states that the authors believe following the dietary recommendations would incur no appreciable risk. Its authors

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[2]The Commission on Life Sciences, formerly the Assembly of Life Sciences, has as its goals to (1) contribute to the advancement of life science disciplines such as biochemistry as well as their effective intercommunication, (2) make available the knowledge, analytic tools, and methods of life sciences for analyses of the nation's major problems and to assist in their alleviation, and (3) relate to professional societies in the life sciences. The Commission's chairman is, ex officio, a member of all its boards and committees.

[3]RDAs are recommended levels of intake of a number of essential nutrients and are considered to be adequate to meet the needs of practically all healthy people.

stated that the report advocates moderate diets, in accordance with traditional sound dietary practices.

Diet, Nutrition, and Cancer is a 460-page survey of the state of scientific knowledge on diet and cancer with interim guidelines which if followed, the study states, are consistent with good nutritional practices and likely to reduce the risk of cancer. It was prepared under contract to the National Cancer Institute (NCI), National Institutes of Health (NIH), Department of Health and Human Services (HHS). NCI initiated the study at a time when public and congressional interest in the relationship of diet to cancer was high. The contract required NAS to (1) perform a comprehensive review of the scientific literature pertaining to the relationship between diet, nutrition, and cancer, (2) develop recommendations related to dietary components and nutritional factors which could be communicated to the public, and (3) propose recommended areas for needed further research. Diet, Nutrition, and Cancer was written by an ad hoc committee of expert scientists and physicians, working under the Assembly of Life Sciences (ALS)[4] to fulfill the first two objectives of the NCI contract. A second volume, Diet, Nutrition, and Cancer: Directions for Research (1983, 74 pp.), was written to meet the third objective.

THE NATIONAL ACADEMY OF SCIENCES

NAS is a quasi-public "society of distinguished scholars in scientific and engineering research dedicated to the furtherance of science and its use for the general welfare." It was chartered by the Congress in 1863 to serve as an official adviser to the government on science and technology issues.

By authority of its congressional charter, NAS is ultimately responsible for the affairs of the overall organization, which also includes the National Academy of Engineering and the Institute of Medicine. In 1916, NAS established the National Research Council (NRC) which performs most of NAS' work. NRC's duties are to stimulate scientific research to increase knowledge, strengthen national defense, and contribute to public welfare. It also is to formulate research projects and develop means of using the country's scientific and technical resources to fulfill them; promote cooperation in national and international research; gather and collate scientific and technical information and provide it to duly accredited people; and bring scientists into active cooperation with federal departments and agencies.

A 13-member Governing Board oversees NRC, composed of six members of the Council of the NAS, five members of the Council of the National Academy of Engineering, and two members of the Council of the Institute of Medicine. The NAS President is the

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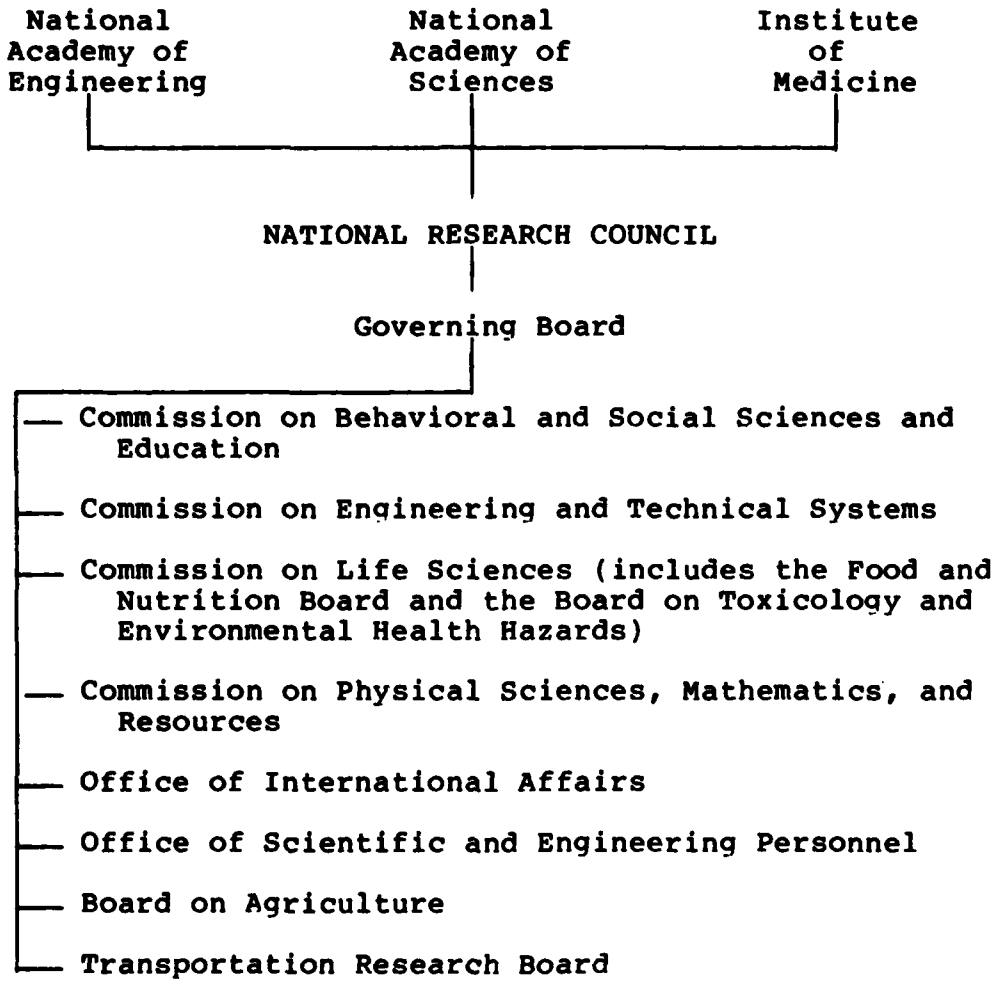
[4]The Assembly of Life Sciences was reorganized on July 1, 1982. It is now the Commission on Life Sciences.

Governing Board's chairman as well as NRC chairman, and the National Academy of Engineering President is the vice-chairman of both the Governing Board and NRC. Each year the Governing Board reviews and approves program activities for subordinate NRC units.

Most of NAS' work is done through NRC's commissions, offices, and boards. Each of these organizations is further subdivided into working groups as necessary. These working groups are either permanently or temporarily established to report on specific matters. As many as 800 temporary working groups may be in existence at any one time. Each year about 20 percent complete their tasks and disband while an equal number are initiated.

The following chart depicts NAS' structure.



In 1975, the Public Interest Campaign, a nonprofit educational and charitable association, sued NAS to compel it to comply

with statutes[5] designed to "open the door" on government advisory organization deliberations. In its decision, the U.S. District Court for the District of Columbia held that NAS was not a government agency and that a committee established by NAS was not a government advisory committee covered by those statutes.[6]

Academy membership

NAS members are drawn from the entire scientific community. New members are elected annually by the membership based on original research contributions to scientific knowledge and professional achievement in their scientific disciplines. Membership is a highly prestigious honor bestowed to recognize sustained exceptional achievement rather than single accomplishments.

Staffing

NRC commissions, offices, and boards for the most part are composed of volunteer experts from the scientific community. The NRC Chairman approves the appointment of the members of commissions, offices, boards, and working groups. Membership in these organizations is not restricted to NAS members and is drawn from academia, industry, and government. Nominations are based on distinguished contributions to the field involved, demonstrated ability, knowledge, interest, and willingness to devote time to the work. The chairman also approves high-level, full-time NRC staff appointments.

The NRC Chairman, the Vice-Chairman, and the President of the Institute of Medicine are the only elected officials who are paid on a full-time basis. The NRC commission chairmen spend 25 to 33 percent of their time on NRC matters, and the organizations they are affiliated with are usually reimbursed for their time. As a general rule, each commission, office, board, or working group member is a volunteer and receives no compensation for his or her services except for reimbursement of travel or certain other expenses.

As of June 30, 1983, NAS also had a full-time staff consisting of 419 professionals and 475 others. The professional staff supports the commissions, offices, boards, and working groups by performing administrative and other tasks as assigned.

Funding

NAS' fiscal year 1983 budget was about $84 million. It receives funds from (1) study contracts and grants from federal

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[5]The Federal Advisory Committee Act, 5 U.S.C. App. I (1982), and the Freedom of Information Act, 5 U.S.C. 552 (1982).

[6]Lombardo v. Handler, 397 F. Supp. 792 (D.D.C. 1975).

agencies, state governments, local governments, and private foundations, (2) donations from private organizations and industry, and (3) endowment income. About 80 percent of NAS revenues comes from its contracts and grants with the federal government. NAS receives no direct appropriations from Congress although it is required annually to report to Congress about its activities.

Contract funding supports specific projects designed to meet the contracting agencies' needs. Industry contributes unrestricted funds to support self-initiated studies of national problems by NAS.

OBJECTIVES, SCOPE, AND METHODOLOGY

The objective of this study is to examine issues raised by Toward Healthful Diets and Diet, Nutrition, and Cancer. We were requested by 11 Members of Congress to (1) present the agenda of issues and the range of scientific fact and judgment on the relationship of diet to cancer, outlining the controversies, explaining the issues, and giving background on the various points of view involved, and (2) obtain information on NAS' process of providing reports in controversial areas such as diet's relationship to health.

The 11 Members of Congress were Senators J. James Exon, Charles E. Grassley, Roger W. Jepsen, and John Melcher and Representatives Cooper Evans, Tom Hagedorn, Clint Roberts, Arlan Stangeland, Charles W. Stenholm, Tom Tauke, and Charles Whitley. Representative William F. Goodling also endorsed the request.

We visited NAS to obtain information on (1) whether it has standard processes for appointing balanced committees that could preclude undue influence from any direction and for reviewing reports and related publications such as press releases to assure accurate and fair presentation of committee findings and (2) whether the processes were followed in producing both Toward Healthful Diets and Diet, Nutrition, and Cancer.

We obtained information about how the reports were initiated and funded, the study groups were selected, the reports were prepared, the reports were reviewed, and the reports were publicized. We compared the way the reports were prepared to NAS' usual processes. We also determined the reports' objectives, scopes, and methodologies.

To present the agenda of issues and the range of opinion surrounding the issue of diet's relationship to health, we read the two NAS reports, interviewed NAS officials, scientists who authored both reports, government and other scientists, and government officials. We also reviewed literature on the issue of diet and health.

Our primary source of information was interviews with individuals responsible for or involved in the debate about each NAS report. We selected 20 scientists and medical doctors to

interview because they represented a range of scientific perspectives, and we were concerned with obtaining a balanced look at the scientific viewpoints involved. We asked these individuals whether they believed (1) the reports were comparable, (2) the reports' recommendations conflicted, (3) the two study groups were balanced, (4) the two reports were consistent with other diet and health reports, and (5) opportunities existed to improve the process or alleviate public controversy. We asked the scientists to discuss the issue of cause and effect in diet's relationship to health. We also interviewed individuals at HHS and the U.S. Department of Agriculture (USDA) to determine the results of those departments' reviews of Diet, Nutrition, and Cancer (see app. II). We reviewed documents provided by NAS and individuals, as well as documents gathered in our search of the literature.

We examined the similarities and differences between the dietary advice provided by each NAS report and compared the advice to dietary recommendations provided to the public by other organizations. Appendix III contains a chart comparing the two NAS reports' dietary advice with recommendations from Healthy People: the Surgeon General's Report on Health Promotion and Disease Prevention (1979); the USDA/HHS report, Nutrition and Your Health--Dietary Guidelines for Americans (1980); the Senate Select Committee on Nutrition and Human Needs' report, Dietary Goals for the United States (second edition, 1977); and the American Heart Association's Committee on Nutrition, Diet, and Coronary Heart Disease's 1978 recommendations. The three governmental reports were selected because they frequently are referred to in the literature. The American Heart Association's report was selected because it is frequently referred to in the literature and also because it was prepared by a prestigious private group.

Our work was conducted from January to October 1983. Because NAS is essentially a private enterprise, our statutory audit authority is limited to NAS records that relate to costs incurred under contracts and grants with federal agencies, such as those between NCI and NAS. NAS declined to permit us to review confidential internal documents concerning committee members' potential sources of bias and report reviewer comments, as noted on pages 13 and 21. Although this did affect our ability to independently assess whether NAS' procedures for identifying potential sources of bias and for report review were implemented, we were told by the appropriate NAS officials responsible for these tasks that they were carried out in accordance with NAS procedures. Except as noted above, our work was conducted in accordance with generally accepted government auditing standards.

We did not evaluate the two studies' scientific methodology, nor did we assess the validity of the reports' recommendations. Because NCI's contracting procedures for Diet, Nutrition, and Cancer were peripheral to the issues, we did not review the adequacy of its contracting procedures. We did not employ outside expert consultants to advise and assist us because we believed consultants with sufficient expertise would have necessarily preformed opinions about the issues.

CHAPTER 2

HOW AND WHY THE TWO REPORTS WERE DEVELOPED

NAS issues about 350 reports per year. NAS has standard processes for report development including study proposal reviews, committee selection, report review, and publicity. The process of collecting and evaluating the data and writing the report is not standardized although scientists we interviewed stated that it follows generally accepted scientific practices. Report writers have the discretion to determine the most appropriate process and format for each report.

Members of Congress, in letters requesting this study, asked us to obtain information on the NAS report development process because NAS is an important government advisor, and deficiencies in NAS' institutional operation could become deficiencies in the public policy process. Both Toward Healthful Diets and Diet, Nutrition, and Cancer became the subject of public controversy when they were issued because interest groups on different sides of the diet and health question and scientists with opposing viewpoints criticized them in the news media. The controversies raised questions about whether NAS report development processes had broken down because the two reports were perceived to be contradictory.

The groups involved in producing both Toward Healthful Diets and Diet, Nutrition, and Cancer were judged by NAS and other scientists as competent to examine the issues, diligent in carrying out their tasks, and as interpreting the data reasonably. NAS certifies its reports' credibility in approving them for public release.

The NAS processes of appointing individuals to perform the work and of reviewing reports are key to NAS' assurance that its reports result in good science but cannot assure that NAS reports will not be contradictory, that is, that they will be consistent. The issue of the NAS reports' credibility is addressed below. The issue of consistency is addressed in chapter 3.

PROJECT INITIATION

NAS develops reports to fulfill contracts with requesting organizations and on its own initiative pursues topics it believes need to be studied. About two-thirds of NAS' reports are requested by federal agencies. The reports' scopes are defined by NAS/agency contracts covering the topics, products, methodologies, costs, and other issues. Reports usually are written by NAS ad hoc committees established solely for the projects and funded by contracts. At times, one of the NAS commissions, boards, or offices will examine a topic and draft a report on its own initiative, sometimes using its own funds.

NAS' constitution and bylaws provide that, on government requests, proposals for investigations or reports shall be submitted to the NAS Council, a 17-member executive body, for

approval. The NAS Council has delegated that responsibility to the NRC Governing Board. The Governing Board or its Executive Committee also reviews and approves NRC program activities.

Both NAS reports originated as study proposals from within NAS. Toward Healthful Diets was internally funded by FNB and Diet, Nutrition, and Cancer was externally funded by NCI.

Toward Healthful Diets' initiation

FNB was established to recommend means of improving the nutrition of the military and civilian populations as the United States prepared for World War II. FNB traditionally has exercised continuing surveillance over nutrition science developments, initiating studies, making recommendations, and alerting appropriate groups or agencies to needed actions as it deemed appropriate.

On May 21, 1977, ALS submitted a proposal to the Governing Board for FNB to evaluate the Senate Select Committee on Nutrition and Human Needs' Dietary Goals for the United States (Jan. 1977) for NIH.[1] The Governing Board did not approve the project. Rather than comment on the Senate report, it instead suggested that FNB delineate dietary goals for the public. FNB was interested in such a project because many questions were raised about the adequacy of the scientific knowledge used in establishing public dietary guidelines while it was preparing a report for NIH entitled Research Needs for Establishing Dietary Guidelines for the U.S. Population (1979).

In addition, FNB members told us that they were concerned about the many groups which were making public recommendations suggesting dietary changes to prevent chronic diseases, such as heart disease or cancer, and to lead to weight reduction, among other things, which some members believed did not have a sound scientific basis. FNB was concerned that the public was confused by contradictory diet recommendations.

The former NAS President stated that he also was concerned with the numerous contradictory recommendations which were being provided to the public. FNB's Committee on Dietary Allowances had had prior success in analyzing the scientific literature to recommend the quantities of a number of essential nutrients which should be eaten (the RDAs); thus, he suggested to FNB that it address the question of the desirable pattern of consumption of major nutrients, analyze all available evidence, and offer the public authoritative advice.

In late 1977, USDA and FNB began negotiations for a contract requesting FNB to review the research base underlying Dietary

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[1]The Dietary Goals were perceived as the first national government dietary guidelines for the public and were controversial. The committee revised and reissued the Dietary Goals in Dec. 1977.

Goals and identify those areas in which (1) firm guidelines can be established, (2) provisional guidelines can be recommended, and (3) alternative guidelines for different subgroups (such as infants and pregnant women) should be considered. The guidelines were to include acceptable, though provisional, ranges and levels of consumption of substances such as fatty acids, carbohydrates, protein, and several other nutrients. These guidelines were to be designed for healthy people. Further, USDA asked FNB to identify the diet-related public health issues which most urgently needed attention in developing public dietary guidance. The revised proposal was approved by the Governing Board as part of FNB's 1979 annual program plan.

The proposed USDA/NAS contract offer was withdrawn on February 23, 1978. USDA, responding to questions on the matter stemming from a special hearing before a subcommittee of the Senate Committee on Appropriations on July 16, 1980, stated that the contract was cancelled because USDA was reorganizing. When the USDA contract offer was withdrawn, leaving FNB with no outside funds with which to conduct the study, FNB decided that producing such a report was important, and at a June 1978 meeting it decided to do so using FNB funds.

Diet, Nutrition, and Cancer's initiation

Diet, Nutrition, and Cancer was funded by an NCI contract awarded in June 1980. The initial concept for the study originated in the Board on Toxicology and Environmental Health Hazards, ALS, from the individual who eventually would become project director for the study. Finding that the idea had merit, the Toxicology Board suggested development of a formal proposal to NCI, representatives of which had also expressed interest. In February 1979, NAS submitted for NCI consideration the first of three formal study proposals which had been prepared by ALS staff with the assistance of both FNB and Toxicology Board members. The proposal subsequently would be approved by the Governing Board. The FNB member responsible for evaluating the literature on nutrition and cancer for Toward Healthful Diets assisted in preparing the study proposal. The NAS study was funded under NCI's Diet, Nutrition, and Cancer Program, which in 1982 was the responsibility of the Division of Resources, Centers, and Community Activities.

According to the Division of Resources, Centers, and Community Activities' 1982 Annual Report, nutrition and nutrition-related research have been an important part of NCI's activities for many years. In response to 1974 amendments to the National

Cancer Act,[2] the Diet, Nutrition, and Cancer Program was established within NCI to develop and disseminate information related to the role of diet and nutrition in the cause and prevention of cancer.

There has been continuing congressional interest in this topic. On October 2, 1979, the NCI Director testified before the Senate Committee on Agriculture, Nutrition, and Forestry, Subcommittee on Nutrition's hearing on diet and cancer research at NCI. At the Subcommittee's request, the Director provided preliminary information on the relationship between diet and cancer and interim dietary principles. The Director stated that a rigorous examination of the diet and cancer relationship needed to be undertaken and that NCI expected to contract for such a study.

According to the Director, Division of Resources, Centers and Community Activities, NCI, in the late 1970's there was a general consensus in the scientific community that the scientific information on diet and cancer had evolved to the point where it was appropriate for a high-level scientific group to review the studies and assess the state of knowledge on the relationship between diet and cancer. To achieve this goal, NCI awarded NAS a contract to develop the report Diet, Nutrition, and Cancer.

According to NCI officials, the Diet, Nutrition, and Cancer study will help NCI to set research priorities and guide planning for multi-million-dollar research contracts. The study has pinpointed other areas where HHS needs to make improvements, such as obtaining better information about what the U.S. public eats.

The NCI contract was a noncompetitive procurement. However, before awarding the contract, NCI published a "sources sought" synopsis in the NIH Guide Supplement on October 16, 1979, and in the Commerce Business Daily on October 23, 1979, to determine whether other qualified organizations could perform the study. Three organizations besides NAS responded. NCI found them to be unqualified after evaluation.

In April 1980, NAS submitted its final study proposal. The proposal underwent review by the NCI Technical Review Committee.

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[2]NCI was required by the National Cancer Act Amendments of 1974 (Title I of Public Law 93-352, July 23, 1974) to provide and contract for a program to disseminate and interpret, on a current basis, for practitioners and other health professionals, scientists, and the general public, scientific and other information respecting the cause, prevention, diagnosis, and treatment of cancer. NCI was required by the Biomedical Research and Training Amendments of 1978 (Title II of Public Law 95-622, Nov. 9, 1978) to collect, analyze, and disseminate information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer) useful in the prevention, diagnosis, and treatment of cancer.

The contract was let in June 1980. The project was to cover the period from June 10, 1980, to June 9, 1983, and funds required were estimated at about $1 million. The contract required NAS to (1) review the state of knowledge and information pertinent to diet/nutrition and the incidence of cancer, (2) develop a series of recommendations related to dietary components (nutrients and toxic contaminants) and nutritional factors which could be communicated to the public, and (3) develop a series of research recommendations related to dietary components and nutritional factors and the incidence of cancer.

Although both FNB and the Toxicology Board were involved in developing the study proposal, the Governing Board placed the ad hoc study committee directly under ALS for oversight.

Two individuals serving on FNB during the time the Diet, Nutrition, and Cancer proposal was being developed told us that they refused to conduct the study within FNB because it required public dietary recommendations. They did not believe such public health recommendations were an appropriate objective for a contractual agreement because the scientific evidence should determine whether or not recommendations could be made. They stated that they did not believe that NCI viewed recommendations as optional. However, NCI acted within its authority as the contracting agency in setting this contract objective.

COMMITTEE SELECTION

Almost all NAS studies are performed by ad hoc committees. The committees are composed of scientists from academia, industry, and the government who are selected for their professional qualifications and knowledge. Observers have stated that the members of NAS committees are among the best minds in science.

NAS uses committees to prepare reports because it believes that when the proper mix of viewpoints and scientific disciplines is selected, a committee can provide a better, more extensive, and more thorough study than any one or two scientists can accomplish.

The initial search for committee members begins with the cognizant NAS commission, board, or office deciding what scientific disciplines need to be represented, depending upon the study's scope and objectives. Names of potential committee members are sought from NAS professional staff members who follow the scientific literature, from other knowledgeable individuals in the subject area, and from professional scientific organizations. NAS staff asks potential members for any public statements they have made which might indicate a bias on the subject to be studied.

From this list, potential committee members are selected by the cognizant staff based on the staff members' knowledge in the specific scientific fields necessary to develop the report. The staff prepares a list of first choices and alternates which is reviewed within the commission. The chairman of the commission sends the final list to the NRC Chairman for his approval. After

the final selections have been made, each candidate is contacted to determine whether he or she is willing to participate.

If the study will fulfill a government contract, the agency may suggest names of committee members, but NAS does not allow the agency to specify what scientific disciplines are needed or to approve membership. This insulates NAS from undue agency influence on appointments.

Procedures to protect against bias

NAS has conflict of interest procedures which must be followed by all NAS working groups. NAS requires that the question of bias will be raised formally for discussion at the first meeting of every new working group, and not less frequently than once annually thereafter. According to the Manual on Nominations and Appointments to Units of the National Research Council, this discussion includes matters such as sources of research support provided to members which could be construed as biasing their judgments, and prior public statements on the topic to be studied.

In addition, working group members are required to fill out "Potential Sources of Bias" forms. The form asks for such information as sources of research support other than employer for 5 years immediately preceding the form's filing; companies in which the committee member or his/her spouse or minor children have financial interest; organizations in which the member is a director or corporate officer or paid consultant; and sources of public statements on the topic to be studied. At the time of the two NAS studies discussed in this report, the forms were reviewed by the executive director of the commission and the NRC Chairman. Potential members may be included or excluded based in part on the responses on these forms. The forms are confidential and we were not permitted to review them.

According to its manual, NAS believes that the question of possible bias is of particular concern in committees that deal with matters bearing on public policy issues such as diet and health. Frequently in these cases, findings must rest upon professional value judgments and social concerns as well as upon conclusions based on strict scientific or technical grounds. For some studies, nearly all the identifiable individuals with the necessary competence have a background consisting of experience and connections that constitute, or can be construed by others to constitute, potential bias. Under these circumstances, NAS seeks out views on all sides of the question in order to obtain balanced committees.

The authors of Diet, Nutrition, and Cancer were appointed under the NAS process described above. Toward Healthful Diets' authors, as FNB members, had already submitted bias statements upon FNB appointment. However, they were not specifically appointed by NAS to perform the Toward Healthful Diets study as NAS working groups usually are. Both groups' composition was criticized as being biased. It is doubtful that any means exists

to completely preclude criticism of NAS committees' composition when conclusions resulting from the work are controversial.

Selection of the groups which prepared the two reports

FNB established a six-member task force of FNB members to prepare Toward Healthful Diets. According to NAS officials, establishing task forces for a specific purpose under a standing board was uncommon but not unheard of. The task force's composition changed over time. The task force also had one NAS professional staff member whose responsibilities were to support task force members, for example, by editing the report.

After Toward Healthful Diets was published, FNB's composition was criticized by consumer interest representatives and in the news media. Several of FNB's members had received research grants or were consultants with food industry companies. According to NAS officials, receipt of such funds does not necessarily bias scientists' opinions. NAS knew of these industry ties when FNB members were appointed. NAS appointed them because of their excellent research records.

The authors of Toward Healthful Diets also were criticized by consumer interest representatives[3] for bias toward the agricultural industry because of the committee's composition and the manner in which it addressed the issue of dietary fat and heart disease. Although they did not believe the criticism was justified because FNB members are eminent and respected, NAS officials wanted to alleviate even the appearance that a work group might be "one-sided" in its views of the scientific issues. In September 1980, NAS revised its Manual on Appointments and Nominations to require that standing boards' memberships be reviewed to determine that members are "suitable in every way" to undertake a study not included in the board's prescribed task when the board was originally selected.

According to NAS officials, the controversy engendered by Toward Healthful Diets made NAS especially sensitive to the issue of balanced group memberships on studies about diet and health. For Diet, Nutrition, and Cancer, committee member affiliations and interests are included as an appendix to that report.

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[3]FNB's Consumer Liaison Panel was a group of individuals who worked with FNB from 1974 to 1980 to represent consumers' viewpoints to FNB. In a 1980 letter to the NAS President, the Consumer Liaison Panel Chairman stated that the panel was resigning because of differences over Toward Healthful Diets. The panel objected to some FNB members' food industry affiliations; the way in which the report was publicized; the lack of epidemiologists on FNB; and the report's recommendations that contradicted the recommendations of other organizations.

The Diet, Nutrition, and Cancer Committee was a 13-member ad hoc committee selected specifically to prepare the report. According to the NAS project director, nominations were sought from FNB, the Board on Toxicology and Environmental Health Hazards, and other NAS groups. A literature search was also made to see who was working in the area and what disciplines would be appropriate. The tentative membership was discussed with the Executive Director and the Chairman, ALS, and then because of the study's importance, the list was reviewed by the former NAS President. According to the project director, because the former president was himself a nutritional biochemist, many changes were made to the final nominations. An FNB member served on the final committee.

Although we were not permitted to review the files, the NAS project director stated that the committee complied with the NAS appointment procedures regarding bias described above. The forms were filed and reviewed, and annual discussions were held as required. The first committee meeting was devoted partly to a discussion of committee members' views on the issue of diet and cancer. According to the project director, if the committee had appeared one-sided after the first meeting, members might have been added to provide balance, although the committee was already large. This was not believed to be necessary.

The ad hoc committee which produced Diet, Nutrition, and Cancer was criticized by agricultural interest representatives and USDA as allegedly being one-sided because the group did not include a food scientist or food technologist familiar with how food is processed in the United States, nor did it include, according to critics, a nutrition expert familiar with providing public dietary guidance. The NAS project director said that she does not believe such criticism is justified because several committee members were familiar with providing public guidance, including one expert in nutrition education and two other nutritionists, one of whom was from USDA. Several food scientists made presentations or gave papers to the committee as needed.

The committee also had a staff of three NAS professionals. According to the study proposal, the role of the NAS staff members on Diet, Nutrition, and Cancer was an important one.

REPORT PREPARATION

Each committee determines the way in which it wishes to address the literature and prepare its report, although scientists whom we interviewed stated that generally accepted scientific practice is followed. To ensure free thought, NAS avoids directing scientists about how to study an issue and write a report. NAS report preparation activities vary according to the study topic. Two activities are common: information gathering and evaluation, and report drafting. The information gathering stage usually includes reviewing the scientific literature and discussing the information during committee meetings. Sometimes public meetings and workshops are held to allow the committee members to

obtain information from researchers which has not yet been published and to learn of views held by other interested parties such as consumer or industry groups.

After the committee develops the report outline, the report may be written by one member, members may divide up into subcommittees to write report segments, or individual members may each write segments depending upon where their expertise and interest lie. Once a draft is prepared it may be mailed to all members for comment and debated at committee meetings. Often segments are rewritten during committee meetings.

How committees evaluate the data before them and arrive at judgments is a crucial point in NAS report preparation. The methodology agreed upon to review studies, the criteria agreed upon to weigh the evidence, and the consensus about what conclusions can be based on available data and what will be based on the committee's judgment are activities which form the basis for resulting reports. We discuss these issues on pages 38-46.

All committees seek consensus about what the scientific data mean and what conclusions can be drawn, but dissent is allowed when the scientists cannot all agree. When a minority of the committee holds views that differ substantially from those of the majority, and consensus cannot be reached, the minority is given the option to prepare a minority statement. A minority opinion can be denoted by adding a footnote to the text stating that not all committee members agree on a specific point, or by including a statement of the dissenting members' views. Neither Toward Healthful Diets nor Diet, Nutrition, and Cancer includes a minority statement.

Preparation of Toward Healthful Diets

The former NAS President estimated that Toward Healthful Diets cost $10,000 to prepare. Due to its limited funds, FNB could not prepare an in-depth study of all diet/health relationships as it had originally envisioned. During a June 1978 meeting, FNB established the initial six-person task force on guidelines for a healthful diet and agreed on an initial outline for the report.

The task force was responsible for reviewing the scientific literature and preparing sections of the draft report. Each member was to research and draft a paper on one of the topics from the outline that fitted his or her expertise and interest. The initial topics were: a general introduction to the subject of diet and health; energy, obesity, and weight control; the RDAs expressed in terms consumers could understand; heart disease, hypertension, atherosclerosis and diet; and cancer and diet.

A computerized literature search was done to provide the task force with a list of current studies. The task force chairman estimated that 400 scientific papers were reviewed. As report section drafts were prepared they were circulated to the other

task force members and discussed and debated during FNB's regularly scheduled meetings. Task force members were not able to get together to discuss the report other than at regular FNB meetings because funds were limited. Between June 1978 and September 1979, FNB met six times. In September 1979, the first report draft was finished. According to the task force chairman, the report went through 10 revisions before it was approved by the entire 15-member FNB and entered the NAS report review process.

According to the FNB executive secretary and the task force chairman, the audience for Toward Healthful Diets was scientists, health care personnel, dietitians, USDA extension agents, and academicians teaching undergraduates about nutrition. It was designed for professionals involved in dietary counseling, particularly those who deal with the public. It was not written for the general reading public.

The report's audience influenced its style. The text was written using language which FNB thought the intended audience would understand. FNB also decided to include an abbreviated list of 52 references because an exhaustively documented scientific report was not considered appropriate for such an audience.

Although task force members wrote initial draft report segments, the task force chairman pulled the segments together and gave the report a consistent style. He also coordinated initial reviews and made revisions as he considered necessary.

Preparation of Diet, Nutrition, and Cancer

The Committee on Diet, Nutrition, and Cancer was to prepare two reports: the first to advise NCI whether scientific evidence indicated that certain dietary habits may affect the risk of developing cancer, and the second to inform NCI and the scientific community about useful directions research might take to increase knowledge in this area. Diet, Nutrition, and Cancer: Directions for Research was published in 1983 to fulfill the second requirement.

In a letter responding to NCI comments on its proposal for the work, NAS stated that

> ". . . The preliminary nature of the available information [on diet and cancer] in many areas . . . does not diminish the size of the data base or preclude the necessity to review and assess it, but rather only makes it more difficult to reach firm conclusions . . . The controversial and contradictory nature of reports in this literature mandates a critical assessment and substantial discussion--both of which require time."

For this reason, among others, the first report took 2 years.

According to the Chairman, Diet, Nutrition, and Cancer Committee members devoted approximately 10-30 days annually to the

project. The committee met 10 times between August 1980 and June 1982 when the first report was published. According to the NAS study proposal, while the committee of volunteers would deliberate, make all decisions, and write the final report, all the administrative work and the background work on scientific matters were the responsibility of NAS staff. The administrative work included (1) organizing and managing the study, (2) organizing meetings and reports of meetings, (3) preparing progress reports, (4) supplying scientific papers, reports, and information, (5) managing finances, (6) procuring documents, (7) editing, preparing, and publishing all documents, and (8) searching the literature, collecting data, preparing preliminary analyses of reports and data from research studies, and preparing background papers on scientific issues.

The committee held its first meeting on August 20-21, 1980. During this meeting the members discussed the committee's charge (as designated by the contract), a rough outline of the report, means of obtaining literature, and plans for a public meeting to be held in November 1980. It also determined which members were interested in working on subgroups to examine selected topics.

According to NAS progress reports to NCI, the committee reviewed the literature on the subject of diet, nutrition, and cancer from 1940 to 1982, focusing especially on the period from 1960 onward. NAS staff periodically provided computerized lists of scientific papers which had been published within this time frame. Scientists serving on the committee also provided research studies they believed were relevant. The committee members reviewed several thousand papers and selected those studies that would form the basis of committee conclusions. Of these, 1,738 citations were listed in the report.[4] The committee divided into subgroups to work on report sections.

The committee sought varying viewpoints on the diet and cancer issue and on the issue of public recommendations. It held a public meeting in November 1980 to obtain information from

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[4]A private consulting firm was hired by the American Meat Institute and the National Livestock and Meat Board to independently review the dietary recommendations of Diet, Nutrition, and Cancer. They concluded that the committee had conducted a thorough review of the epidemiological studies published between 1960 to 1981. The group concluded that (1) the data currently available would not support any recommendation for a reduction in meat consumption, but that it seems prudent to reduce meat's fat content, (2) the results of studies associating frequent consumption of salt-cured or smoked foods with increased risk of certain cancers in some parts of the world do not appear applicable in the U.S. where typical processed meats, with few exceptions, are not salt-cured, and (3) the NAS' recommendation to reduce fat consumption is prudent. (See app. II.)

scientists, public interest group representatives, government and food industry officials, the media, and private citizens.

In addition to the public meeting, the committee sponsored two scientific conferences in March and May 1981. At the Mini-Conference on Diet, Nutrition, and Cancer on March 9, 1981, one topic addressed by those attending was the issue of how complete the data must be before recommendations can be made to the public. Attendees were invited to the conference, according to a committee progress report, because they held different points of view about diet, nutrition, and cancer.

At the fourth meeting of the committee, a scientist from Rockefeller University was invited to discuss the issue of when scientific data support conclusions about diet's relationship to health, based on past controversies engendered by relating diet to heart disease. At this time, a Workshop on the Methodology of Dietary Studies in Cancer Epidemiology was also held. The committee sponsored the workshop because it had recognized a need for special attention to interpreting the results of epidemiological studies.

According to the project director, committee subgroups wrote draft sections and chapters which were circulated by mail to the committee members. According to the chairman, in early meetings the committee discussed possible conclusions to help them focus their research efforts. Much of the time during mid-point and later committee meetings was spent debating the meaning of data they had uncovered and discussing the drafts that had been written. According to the committee chairman, the committee spent the last meeting on the report's executive summary.

The committee debated and reached consensus on each interim guideline. The committee chairman and members we interviewed stated that if the scientific evidence had not warranted making interim guidelines, they would not have done so despite the NCI contract requirement. One member noted that there were several nutrients for which guidelines were debated, but for which the committee concluded that the scientific evidence was insufficient. This report was approved unanimously by the committee members before entering report review.

According to the project director and the committee chairman, Diet, Nutrition, and Cancer's audience was the scientific community. The committee intended to write for researchers in the field, and the report's structure and level of language were determined by the needs of that audience.

The report's executive summary (a 16-page abbreviated version of the report presented as chapter 1 which summarizes the committee's judgment about all the evidence it reviewed) was directed to a slightly different audience but also was not intended to be written for the general public. According to its authors, the executive summary was directed to nutrition professionals, government policymakers (including legislative officials) in the nutrition area, and the scientific media. The committee believed that

these groups would translate it for the public as they saw fit because one of the reasons NCI contracted for the report was to provide it with information which it could then provide to the public.

Executive summaries have been in use for some time by some NAS groups, according to the Assistant to the NAS President. The official told us that in the late 1970's NAS began a conscious effort to encourage the use of executive summaries so that busy readers could have a document that is easy to read that makes study findings and recommendations easy to find. NAS does not employ a standard report format, however.

Scientists and agricultural interest group representatives who disagreed with Diet, Nutrition, and Cancer about the strength of the scientific evidence supporting its conclusions and interim guidelines alleged that its executive summary is misleading because it does not accurately portray statements made in the technical section. We found that the executive summary's statements about committee conclusions almost exactly repeat the language found in other sections of the report. The report's authors told us that the summary is not intended to stand apart from the rest of the report. In the executive summary the Diet, Nutrition and Cancer Committee discusses its judgments about what the scientific data mean for the U.S. public's dietary habits and formulates interim dietary guidelines. As we discuss in chapter 3, significant disagreement exists about whether or not current scientific evidence supports dietary guidelines to reduce chronic disease risks.

REPORT REVIEW

Report review, or peer review, is a process used in both the natural and social sciences to obtain a critical review of scientific work. Different types of reviews are used for different purposes, but they generally follow the same basic principles, according to the former NAS RRC Vice-Chairman: (1) scientists prepare detailed critiques of the product, (2) the critiques are provided to the project's author, and (3) reviewers' comments are anonymous.

Review is commonly used by agencies which give out research grants, such as the National Science Foundation or NIH, to determine which researchers' proposals should be funded. Review also is used by scientific journals to judge articles submitted for publication to determine whether they are factual, logical, and supported by the evidence.

Report review is a crucial element in the publication of NAS reports. Review is performed so that final reports not only represent the considered opinion of the authoring committee but also carry the authority of the institution as a whole. Since 1970, NAS has had a standing RRC charged with assuring "the highest scientific and expository standards" in NAS reports. Each report is reviewed by the cognizant NAS commission before publication. Before 1981, RRC at times appointed its own review

committee to perform a second review for reports dealing with particularly sensitive or complex topics. The two reviews now are combined, but RRC appoints one of its members to monitor the report review process and may add members to the review panel. If RRC is not satisfied with a review, it may also appoint its own panel. According to the RRC Executive Director, RRC works with commissions to oversee review procedures. It may become closely involved with between 50 and 60 particularly sensitive reports in a year.

According to the RRC Chairman, each NAS committee has a unique approach to the issues before it. Each committee may be more or less comfortable with scientific uncertainty. RRC's goal is to ensure that despite the differences, the resulting reports are scientifically sound.

NAS report review follows the standard scientific review practice by (1) selecting knowledgable reviewers who have not been involved in the report's preparation and who are "perceptive critics with expert general knowledge in the field," although not necessarily specialists in the report's subject matter, (2) providing resulting critiques to report authors for their consideration, and (3) protecting reviewers' anonymity to ensure their candid opinion.

NAS report reviewers are selected by the commission which sponsored the study, subject to RRC oversight and approval. Reviewers with divergent viewpoints are sought out. Reviewers are provided Guidelines for Review of Reports which directs them to consider (1) whether a report's conclusions and recommendations derive from adequate data, (2) whether there is evidence of bias, (3) whether the report appears to be complete, fair, and responsive to the charge given to the committee, and (4) whether the presentation is clear and concise.

According to the RRC Chairman, these considerations are directed to the report's credibility--i.e., is it good science, does it provide a reasonable interpretation of the data which can stand until better information is obtained, and is it credible to scientists in the field. The report is not reviewed for consistency with other NAS reports. Science is always changing, and new scientific problems cannot always be addressed in the same way as earlier problems were addressed. Also, scientists may find the report credible, even though they may disagree with its interpretation of the data.

RRC works to resolve disputes between reviewers and authors. According to the RRC Chairman, on argued points, authors have the benefit of the doubt. If differences between the reviewers and authors cannot be reconciled with RRC assistance, the NAS President has ultimate decision authority. According to the RRC Executive Director, such interventions are rare.

Because the NAS report review process is confidential to protect the reviewers' anonymity, we were not permitted to review the report review files on Toward Healthful Diets or Diet, Nutrition,

and Cancer to ascertain whether or not reviewers held viewpoints different from report authors'. The RRC Executive Director prepared a chronology of the two reports' reviews so that we could determine that both reports followed the NAS report review process. We did not assess independently the adequacy of the report authors' responses to review criticisms.

The review of both Toward Healthful Diets and Diet, Nutrition, and Cancer followed the usual NAS report review process. Both were reviewed by reviewers selected by ALS with RRC oversight. Toward Healthful Diets was reviewed by four scientists and four individuals from FNB liaison panels, and Diet, Nutrition, and Cancer was reviewed by nine scientists, as well as by FNB.

According to the former RRC Vice-Chairman, who was involved in both reports' reviews, the reports' conclusions and recommendations or interim guidelines are supported by the evidence, both reports address the objectives they were designed to meet, and both are balanced.

Toward Healthful Diets' review

On November 16, 1979, the NAS Division of Biological Sciences, an ALS subunit of which FNB was a part, sent draft copies of Toward Healthful Diets to RRC. Because the review process is handled for authoring committees by a person not directly involved in the work, the Director of the Division of Biological Sciences coordinated the review of Toward Healthful Diets. The coordinator acts as the review panel chairman. According to the RRC Executive Director, the former RRC Chairman and Vice-Chairman read the report and decided not to conduct a formal, separate RRC review. The former RRC Chairman indicated that he wished to see reviewer comments, however.

The responsibility for selecting report reviewers was assigned by RRC to ALS because, according to the RRC Executive Director, RRC believed that group would be in a good position to find reviewers. According to the Executive Director, the eight reviewers consisted of four outside scientists, two people representing the FNB Industry Liaison Panel, and two people representing the FNB Consumer Liaison Panel.

According to the RRC Executive Director, reviews were received from six individuals. The FNB task force chairman stated that the consumer panel also provided both oral and written report comments to FNB which were considered but which were not significant to the scientific issues. However, the comments from the Consumer Liaison Panel are not part of RRC records.

According to the former RRC Vice-Chairman, Toward Healthful Diets was reviewed by clinical nutritionists who would have understood that the position statement was presenting the views of clinical nutritionists, who prescribe diets for people, about the need for common sense and flexibility in designing diets to fit people's differing needs. He also stated that nothing in the document was scientifically controversial.

According to the FNB task force chairman and the FNB Executive Secretary, the task force did not hold a meeting to respond to reviewer comments; revisions were handled by telephone and mail. The chairman said the reviewer comments were not critical of the report, except for those by the Consumer Liaison Panel.

Although we did not have access to RRC files of comments, Toward Healthful Diets was publicly criticized after its release, including criticism from a former Consumer Liaison Panel Member, as discussed on pp. 31 and 40 and in app. II.

The Director of the Division of Biological Sciences sent review comments to the RRC Chairman who examined them and, in February 1980, decided that RRC need take no further action. Also, according to the RRC Executive Director, the former NAS President closely followed the report's development because of his interest in the work and his expertise in the area.

Diet, Nutrition, and Cancer's review process

Because Toward Healthful Diets sparked public controversy about NAS reports on diet's relationship to health, according to the RRC Executive Director, RRC members were aware from Diet, Nutrition, and Cancer's initiation that the report would require close attention. The draft report, including the executive summary, was sent to reviewers on February 1, 1982. RRC appointed its monitor[5] to represent RRC and supervise the review process. The RRC monitor reviewed the panel selected by the ALS chairman and did not appoint additional reviewers. FNB was also asked to comment.

Because Diet, Nutrition, and Cancer was an important project, the Chairman, ALS, acted as the review coordinator to work with the authoring committee.

Nine reviewers and FNB responded with comments. FNB comments were critical of the report, according to two FNB members whom we interviewed. The RRC monitor forwarded a memo to the ALS review coordinator with his analysis of major review points and also informed the RRC Chairman. The ALS review coordinator assessed the review points, and through the Diet, Nutrition, and Cancer project director, the committee chairman received both the coordinator's assessment and review points (including FNB's), organized by chapter.

The committee met in March 1982 to discuss review points and to revise the report. The project director then provided the RRC monitor with a point-by-point written discussion of how review comments were incorporated into the report. On March 30, 1982,

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[5]Only NAS members may be appointed as RRC monitors, according to the RRC Executive Director, because RRC is the guardian of NAS standards.

the RRC monitor recommended to the RRC Chairman that the report was ready to be prepared for publication.

Although we did not have access to RRC comment files, Diet, Nutrition, and Cancer was publicly criticized after its release, including some FNB members' criticisms, as discussed on p. 32 and in app. II.

REPORT PUBLICITY

The NAS Office of Information prepares press releases and informs the news media when NAS reports are published. The Office was involved in publicizing both Toward Healthful Diets and Diet, Nutrition, and Cancer. NAS as a matter of policy reserves the right in its contractual agreements with the government to publish reports which result from studies it performs. According to NAS officials, government departments and agencies generally do not provide contract funds to support report publication and distribution.

The Office arranges for news media coverage of reports it considers newsworthy and answers inquiries from the public and the news media. The Office follows ongoing studies through a report-status reporting system. After the Office decides that a report will be of interest to the general reading public, it works with NAS scientific staffs to decide jointly what kind of publicity the report should be given.

According to the Director, Office of Information, the Office's function is not to promote NAS reports as a public relations office might do but "to offer newspaper-like language to national news media, which accurately portrays the scientific content of reports." According to the Director, approximately 60 to 90 press releases are prepared annually while perhaps 10 reports, because of their high public interest, will be accorded a press conference or dinner symposium where individuals, such as Members of Congress and interested government officials, are invited to hear a report discussed prior to release.

Working with a draft report, Office of Information staff draft press releases, working either alone or with the assistance of the authoring committee staff. Press releases are written to emphasize what the general reading public will find interesting about the report. Thus, they do not always exactly repeat the report's language. At times, notes are prepared for the Office of Information writer by the technical/scientific staff to emphasize what they think is important.

Press releases do not go through the processes administered by NAS to ensure that reports are scientifically credible. However, a week or so before a NAS report is scheduled for release, the draft press release is sent to the NAS staff of the ad hoc committee which authored the report for technical review to ensure its accuracy. The committee staff officer and, at times, the committee chairman review the press release for technical accuracy

and content. The executive director of the sponsoring NAS commission also reviews releases from the standpoint of technical accuracy and institutional policy concerns. The full authoring committee does not review the press release, according to the Office Director, because the chairman has the authority to speak for the committee. If the press release concerns a major national policy issue or if he has taken personal interest in the project, the NAS President may review the press release also.

According to the Office Director, NAS press conferences are managed so that the news media are assured of receiving accurate information about NAS reports. Press conferences are by invitation only. Journalists who are invited must be accredited, i.e., working full time as a journalist for an open circulation publication, although sometimes free-lance journalists attend also. The Office may invite representatives of special interest groups to attend the press conference as observers. Observers who are not accredited journalists are not allowed to participate in questions. The Director stated that this policy is intended to preclude use of the press conference as a forum for making a statement.

Before the press conference, according to the Director, Office of Information staff sit down with members of the report committee to prepare the scientists to answer questions from the press. Information Office staff make an effort to ask questions, however critical, which the press could be expected to ask.

After a report is released, the Office follows up resulting stories to track what the media are saying. According to the Director, if NAS studies are being misrepresented, NAS will write letters to the editor or, at times, the Director may phone the reporter to clarify the issue.

The NAS press activities for both Toward Healthful Diets and Diet, Nutrition, and Cancer were controversial. A consumer group critic stated, in the case of Toward Healthful Diets, that the press release was not an appropriate NAS activity because it was directed "to a lay audience ill-equipped to evaluate" the report. Diet, Nutrition, and Cancer's press release's wording was criticized by agricultural industry groups for, among other things, listing examples of specific foods to be eaten in moderation which were not in the report itself. The NAS project director stated that the examples were taken from the NAS report The Health Effects of Nitrate, Nitrite, and N-Nitroso Compounds (1981) and incorporated by reference.

The NAS Administrative Guide on the Office of Information, dated April 20, 1981, states that ". . . the success of the Academy in meeting its overall objectives depends, to an increasing degree, on its relationship with its several publics . . . ." The NAS Executive Officer stated that NAS believes it is not possible in an open society such as that in the United States to "close" scientific discussions to all but scientists. Media science writers follow NAS projects and can obtain copies of reports. According to the NAS President, when NAS reports on a

controversial area where scientific knowledge is incomplete, such as diet's relationship to health, and the report correctly alerts the reader about what is and is not known about the subject, the press may disregard the qualifications. Resulting news stories thus, intentionally or not, misrepresent the report's contents. According to officials, NAS tries to manage the public dissemination process through activities such as press releases to preclude misunderstanding. According to the NAS President, public controversy is inevitable in areas of high public interest.

Toward Healthful Diets' publicity

According to the Director, Office of Information, the decision to have a press release for Toward Healthful Diets was made by the Office staff when the report was in final draft. In commenting on this report, the former FNB Chairman noted that the former NAS President emphasized the importance of a press release after he had reviewed the publication. The Office staff worked with the FNB Executive Secretary and staff officer to write the release. The FNB task force chairman and the FNB chairman did not review the release until immediately before the press conference.

According to the Director, Office of Information, stories caused the report to be publicly controversial by criticizing it because (1) the recommendations it made allegedly contradicted the USDA/HHS dietary guidelines and were interpreted by the press to mean that FNB believed the U.S. public did not have to be concerned about reducing dietary fat and cholesterol and (2) conflicts of interest were believed to exist on FNB which made its advice biased. Neither allegation was correct, according to the report's authors whom we interviewed and to testimony given before two congressional hearings. (The hearings are discussed further in app. II.)

Consumer interest representatives criticized NAS for the Toward Healthful Diets press release, stating that it was inappropriate because it was directed to a lay audience "ill-equipped" to evaluate the report's merits.

Diet, Nutrition, and Cancer publicity

According to the Director of the Office of Information, the Office was aware from Diet, Nutrition, and Cancer's initiation that a press release would be required because of the controversial subject of the study.

The Office staff drafted the release. The Director told us that because the staff believed specific examples of foods to be eaten in moderation were needed, examples were selected by the Office staff and reviewed and approved by the Diet, Nutrition, and Cancer Committee project director. The Director, Office of Information, said that she believed examples were needed because the first question the public asks is "What foods are you talking about?" The Diet, Nutrition, and Cancer Committee chairman reviewed the press release. According to the Office Director, the

press release was approved by the ALS Executive Director, as required.

The current NAS President has instituted a policy of holding dinner symposia when a report of special public interest is published so that interested officials can question the scientists who wrote the report. The night before the Diet, Nutrition, and Cancer press conference, NAS held a dinner symposium for government, congressional, and scientific officials and individuals representing special interest groups. The Diet, Nutrition, and Cancer project director stated that it was important to brief these officials to clarify the report's message and allow them to question the report's authors because even though a report is clearly written, misinterpretation still occurs.

Agricultural industry groups who disagreed with Diet, Nutrition, and Cancer publicly criticized its press release's wording because it contained examples of specific foods to be eaten in moderation which were not in the report, among other criticisms. (Toward Healthful Diets' press release also contained a single specific food example, potatoes, which was not in the report, but that did not become an issue.) The press release was criticized for listing examples of smoked, pickled, and cured meats to be eaten in moderation which were not in the report, when, according to industry critics (1) the foods discussed in the report, such as smoked mutton and salted fish, which may have been linked to increased cancer rates were produced and consumed in other countries, (2) the press release inaccurately cites U.S. foods which are not produced in the same manner as foods in other countries and which are not discussed in the report as having possibly been linked to increased U.S. cancer rates, and (3) the press release misleads the public about what the report says about U.S. foods.

The project director for the Diet, Nutrition, and Cancer Committee stated that the foods mentioned in the press release are listed in the NAS report entitled The Health Effects of Nitrate, Nitrite, and N-Nitroso Compounds (1981) on which the committee relied. She added that the U.S. foods mentioned in the press release and the foods (largely from other countries) discussed in Diet, Nutrition, and Cancer are similar in that they contain substances, to a greater or lesser extent, which may be associated with high cancer risk.

According to its authors, Diet, Nutrition, and Cancer was distorted by media coverage. Some women's specialty magazines and newspapers reprinted the report's interim guidelines and prepared their own "anti-cancer diets" which they claimed were prepared in accordance with Diet, Nutrition, and Cancer's interim guidelines. One company used the report in advertisements promoting its product. NAS has cooperated with the Federal Trade Commission in the Commission's actions against the company for false advertising.

According to the Director, Office of Information, the stories in the women's specialty magazines resulted from national news media coverage, not from Office of Information efforts.

CONCLUSIONS

The two NAS reports on diet and health were prepared following NAS' standard processes. Both reports became publicly controversial when interest groups and scientists criticized the study groups' composition, the Diet, Nutrition, and Cancer executive summary, and the press releases. NAS officials told us that they believe controversy is inevitable when NAS reports have high public interest.

Both groups were appointed following NAS processes which are designed to ensure competent and unbiased membership, although Toward Healthful Diets' authors were not specifically appointed by NAS to perform the study as working groups usually are. The Diet, Nutrition, and Cancer executive summary was approved after undergoing the usual NAS report review process, which is designed to ensure that a document presents a reasonable interpretation of scientific data. The executive summary's statements about the committee's conclusions are worded almost exactly like the conclusions in the technical sections. Both press releases were prepared with the assistance of NAS professional technical staff, but press releases do not undergo the processes administered by NAS to ensure that reports are scientifically credible.

NAS is interested in improving its procedures and has made improvements. For example, NAS strengthened its committee selection procedures after Toward Healthful Diets was written to further ensure that when a standing NAS committee decides to write a report itself, the composition of the committee will be reexamined for balance and potential bias.

We noted one area where NAS could make an improvement which may reduce the potential for public controversy about its press releases.

Both reports' press releases contained specific food examples not mentioned in the reports. With regard to Diet, Nutrition, and Cancer, this situation was called to public attention by agricultural interest groups who disagreed with the report. The resulting controversy concerning Diet, Nutrition, and Cancer might have been minimized if readers had been alerted that specific food examples were not contained in the report but were given for illustrative purposes. NAS officials may want to consider indicating in future press releases that examples which are not contained in the report are given for illustrative purposes.

COMMENTS BY NAS AND OTHERS AND OUR EVALUATION

In commenting on a draft of this report, NAS said that the report provides an objective commentary on the Academy's processes that govern the provision of advice to the government (see app. IV). NAS stated that it has found that it is often appropriate in a news release to provide specific examples for illustrative purposes and that, if an example is not directly derived from the study, our suggestion that it might be useful to make that point

clearer is well taken. NAS stated that it recognizes that there is room for improvement in the process of preparing news releases in order that a clear summary of the report's findings and recommendations reaches the public. NAS commented that it has and will continue to address these issues in discussions among Academy officials. NAS also commented that coupled with the uses of the news release is the equally important need to ensure that from the beginning of a study, committee members recognize and understand how their report will be used and who will be the report's ultimate audience.

HHS stated that this report documented that the Diet, Nutrition, and Cancer review was more thorough in terms of amount of literature reviewed, time committed by the review committee, size of the review committee, and the depth of the final document and thus was more credible and that this conclusion should be reflected in the report's digest (see app. V). As discussed on page 7, we did not evaluate the two NAS reports' scientific methodology so that a conclusion about report credibility on that basis is not appropriate. Whether or not a report is credible can be a subjective judgment. For that reason, as discussed in this chapter, we discuss NAS processes for assuring that reports are credible to scientists and also discuss how both NAS reports followed the NAS processes.

USDA commented that if NAS is to issue press releases giving illustrative examples, we should recommend to NAS that the chairman of the study group should review the press release to assure that it is truthful and not misleading (see app. VII). As discussed on page 24, chairmen of NAS study committees may review the press releases, and NAS has review procedures in place to ensure that press releases are technically accurate.

USDA also commented that the Diet, Nutrition, and Cancer executive summary loses much of the tentativeness in which the main report's findings are couched, and recommends that the flavor of the main report, as well as its findings, should be clear from the executive summary. As discussed on page 23, the Diet, Nutrition, and Cancer executive summary along with the rest of the report was reviewed under the standard NAS process, which includes a review to assess whether a report's conclusions and recommendations derive from adequate data and whether the report appears to be complete and fair.

Other comments from the Food and Drug Administration and from individual scientists which pertained to this chapter's clarity and technical accuracy are contained in appendixes VI and VIII. The comments were considered and the chapter was revised where appropriate to improve its clarity and accuracy.

CHAPTER 3

HOW AND WHY THE REPORTS ARE BOTH SIMILAR AND DIFFERENT

Public comparison of diet and health studies is inevitable because of high public interest in the subject. Diet, Nutrition, and Cancer caused public controversy by reporting conclusions that were different from those in Toward Healthful Diets about suggesting dietary changes to reduce cancer risk. Critics of NAS perceived the reports as inconsistent and, therefore, not credible. However, NAS officials told us that they do not view the reports as either contradictory or inconsistent. The officials pointed out that the reports were not really comparable in scope or objectives. NAS officials and scientists stated that the fundamental dietary advice offered by both report groups is similar to and consistent with past advice from other groups.

The difference in the two reports partly stems from disagreements among scientists about what conclusions and public recommendations can be drawn from the available scientific evidence on the relationship between diet and chronic diseases such as cancer and heart disease. NAS officials told us that it is not uncommon for two groups of scientists to review the same scientific data and come to different but supportable conclusions. No standard has been agreed upon among scientists or government policymakers about what scientific data are needed to support suggesting public health measures, such as dietary changes, to reduce the public's risk of developing long-term diseases such as cancer. Scientists whom we interviewed stated that they do not believe a standard of evidence is feasible because scientists could never all agree on a single set of standards and because each public health problem is unique. Because no standard exists, scientists make personal value judgments on the basis of scientific evidence which can result in legitimately different conclusions.

The controversy involves the public, which expects clear and absolute answers to questions about issues such as diet and health. NAS officials told us that the basis for legitimate disagreements among scientists is hard to communicate clearly to the public. The officials also said that public controversy concerns NAS because it damages scientists' public credibility.

This chapter addresses (1) why both reports were controversial, (2) why NAS does not view the reports as contradictory, (3) how the reports' dietary advice is fundamentally similar, (4) how NAS study groups decide what dietary advice to offer, and (5) the differing philosophies held by scientists about what scientific evidence supports suggesting dietary changes to reduce the public's risk of long-term diseases.

BOTH REPORTS WERE CONTROVERSIAL

Both Toward Healthful Diets and Diet, Nutrition, and Cancer sparked controversy among scientists, public officials, and special interest groups holding different views on the issues.

When Toward Healthful Diets was issued in 1980, various groups were advising the public to reduce its intake of dietary fat and cholesterol because high levels of these substances might be linked to increased risk of heart disease.[1] The report stated that it had not been proven that lowering dietary cholesterol through dietary intervention would consistently affect heart disease rates, and, thus, FNB did not believe that a recommendation should be made to the general public to reduce dietary cholesterol to decrease the risk of heart disease.

Several medical and dietary groups and government officials who had advocated decreasing dietary fat, and particularly cholesterol, disagreed with Toward Healthful Diets. Some stated that the report's message was that people could now eat as much fat and cholesterol as they wanted without worrying about heart disease. These groups believed that (1) such dietary practices would increase the risk of heart disease and (2) Toward Healthful Diets' authors were too conservative because they wanted dietary changes proven beneficial and therefore would wait too long to advise changes. They criticized the report on these points. According to Toward Healthful Diets' authors, the report did not advocate unlimited consumption of fat and cholesterol. The report advocated (1) that people eat moderate, well-balanced diets and (2) that people at high risk of certain diseases should be under a doctor's care and follow his/her dietary instructions.

The report also was criticized for differing from the Senate Select Committee on Nutrition and Human Needs' report, Dietary Goals for the United States (1977), and from the USDA/HHS report, Nutrition and Your Health--Dietary Guidelines for Americans (1980). (See app. III for a comparison of all three reports' recommendations.) Both of these reports recommended decreasing the amount of dietary fat and cholesterol.

Further, Toward Healthful Diets also was criticized by medical and dietary groups and government officials for its recommendation that the average person should reduce his/her intake of salt. They stated that the scientific data which FNB used to develop its salt recommendation were not as strong as the data linking dietary cholesterol and fat to heart disease. According to one of the report's authors whom we interviewed, the salt reduction recommendation was made because people generally consume far more salt than they need, which serves no purpose. In

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[1]Most scientists agree that a high blood cholesterol level presents an increased risk of heart disease. One reason is that it is one element contributing to the buildup of deposits on the inner walls of major arteries. Scientists do not all agree that dietary changes can reduce or prevent this buildup.

commenting on this report, the former FNB chairman noted that the recommendation was made to conform with safe and adequate intakes of nutrients recommended by the Committee on Dietary Allowances in the 1980 RDAs.

Diet, Nutrition, and Cancer was criticized by agricultural interest groups and scientists for differing with Toward Healthful Diets. Toward Healthful Diets devoted 1-1/2 pages to the relationship between diet and cancer and concluded that, in the absence of evidence of a causal relationship between the macronutrients[2] in the diet and cancer, there was no basis at the time for making recommendations to modify the American diet to reduce cancer risk.

Agricultural interest groups stated that Diet, Nutrition, and Cancer had drastic dietary recommendations which would decrease the amount of meat and dairy products in the diet although those products contribute to the U.S. public's current good health. The report's authors stated that they believed that the guidelines could be followed by making moderate diet changes.

Some scientists criticized Diet, Nutrition, and Cancer for making recommendations before studies have been undertaken to prove that dietary changes could reduce the risk of developing cancer, i.e., proof of the recommendations' benefits. According to a Diet, Nutrition, and Cancer Committee member, the committee concluded that cancer was related to diet and believed that following the guidelines could lower cancer incidence in the population. According to the committee chairman, the committee set forth interim guidelines to recognize that knowledge in the field is moving so fast that the study should be repeated at 5-year intervals.

NAS DOES NOT VIEW THE REPORTS AS CONTRADICTORY

Although they are concerned about the public controversy caused by Diet, Nutrition, and Cancer, NAS officials told us that they do not believe the two reports are contradictory or inconsistent. As discussed below, NAS officials stated that the two reports are so different that they should not be compared to one another. Neither report represents an NAS position on the question of whether the U.S. public can reduce its chronic disease risk by changing its diet. Each represents only the considered opinion of the authors at a given point in time. Because each NAS report is solely the opinion of its authors, NAS has no formal means of determining whether NAS reports are consistent with one another. Also, science evolves, so that the answers scientists provide to society's questions change over time.

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[2]A macronutrient is an element of the diet that is essential for the life of an organism, is required in relatively large amounts, and is usually measured in grams. Carbohydrates or calcium are examples of macronutrients.

NAS officials view the reports as not comparable

NAS officials said that the two reports are so different that comparison is not justified, although agricultural interest groups compared them and found them to be contradictory. NAS officials pointed to the following differences between the two reports:

--The reports were written for different purposes. Toward Healthful Diets was a position statement written to reduce public confusion by identifying diet guidelines that could be supported on the basis of reliable scientific knowledge. It devoted 1-1/2 pages to cancer. Diet, Nutrition, and Cancer was a 460-page comprehensive evaluation of the diet and cancer scientific literature for NCI.

--The reports were written for different audiences. Toward Healthful Diets was written for scientists and people who deal with the public in providing nutrition advice such as health care personnel, USDA extension agents, and academicians teaching undergraduates. Diet, Nutrition, and Cancer's intended audience was researchers; the exception was its executive summary, which was directed to nutritional professionals, government policymakers, and science writers.

--The two study groups' resources were very different. Toward Healthful Diets was prepared by FNB using about $10,000 of its own funds so that resources for task force meetings and literature searches were constrained. The Diet, Nutrition, and Cancer Committee was funded by NCI at about $1 million, allowing more meetings and an in-depth literature search.

NAS does not assess its reports for consistency

Unlike a government agency where management processes serve as controls to ensure that products are consistent, NAS administers processes such as committee appointments and report review to ensure that its study groups' work results in good science, that is, that reports offer a reasonable interpretation of the data until scientists learn more. According to NAS officials, other ends such as consistency are not seen as appropriate criteria for judging whether or not reports meet NAS standards and it sometimes is difficult to know before a report is issued what points will be publicly controversial.

NAS reports also do not necessarily represent NAS positions on the issues under study. According to the Assistant to the NAS President, NAS positions on science issues are adopted in two ways: (1) the NAS membership by vote may adopt a position on a scientific question or (2) the NAS Council may by resolution endorse a report or take a position on an issue. Neither Toward Healthful Diets nor Diet, Nutrition, and Cancer were adopted or endorsed as NAS positions. Both reports represent the opinions of

their respective authoring groups, although NAS stands behind the manner in which both were prepared.

For these reasons, NAS has no formal means of requiring assessment of whether the two reports' conclusions about diet and cancer were inconsistent or to outline the significance of scientists' disagreements for public policy. Such matters are left to the discretion of the NAS President and the authors.

The NAS President may at times indicate personal disagreement with a report's conclusions and recommendations by including his concerns in a letter bound into the report. The NAS President, according to his assistant, is the individual within the Academy who would be most concerned with NAS reports from the public policy perspective. For example, in a 1982 NAS report, An Analysis of Marijuana Policy, the NAS President disagreed with the authoring committee's conclusions, stating, "My own view is that the data available to the committee were insufficient to justify . . . changes in current policies . . . ." Neither Toward Healthful Diets nor Diet, Nutrition, and Cancer contained a prefatory letter from the NAS President.

According to NAS' Administrative Guide section on "Report Review Process: Guidelines," RRC's decision to participate in a review is based on its perception of the impact the report may have, directly or indirectly, on public policy issues. The RRC monitor is expected to pay special attention to any policy or publicly sensitive issues raised by a study. However, the Guidelines are advisory, as is the RRC monitor's role, to an authoring committee. The Guidelines do not require that reports discuss or acknowledge public policy issues raised by different NAS reports.

NAS' report preparation policy, contained in a May 18, 1978, memorandum, "Notes on the Preparation of NRC Reports," also is advisory. The memorandum states:

> "Questions of policy often extend beyond the institutional purview of the Academy, which in its advisory role, has no authority except that of pertinent knowledge. Social, political, or organizational conclusions and recommendations suggesting national or agency decisions should be avoided except when they can be solidly based on demonstrable evidence, or except in special circumstances which should then be clearly set forth in both the text and the summary portions of the report."

This memorandum suggests that authoring committees consider including material in a report foreword or introduction to assist readers in understanding special considerations relating to a report, but the memorandum does not require committees to discuss or acknowledge public policy issues involved.

For example, the preface to a 1983 NAS report entitled Acid Deposition: Atmospheric Processes in Eastern North America

discussed how a 1981 NAS report which included a chapter on the subject was misinterpreted by the press and others. The discussion was included because public misunderstanding led to the 1983 report.

Further suggestions to study committees and report reviewers are set out in a NAS memorandum entitled "Suggested Guidelines on Risk Assessment and Other Matters of Report Preparation and Presentation" (Oct. 31, 1981). These guidelines, prepared as a result of an internal NAS study, suggest that

> "Related NRC reports should be carefully cited and, if necessary, the report should describe why and how the study committee came to conclusions that differ from those of other NRC reports."

The Diet, Nutrition, and Cancer Committee briefly indicated where it disagreed with Toward Healthful Diets. In chapter 5 the committee included a footnote to its conclusions that

> "The Committee on Diet, Nutrition, and Cancer judged the evidence associating high fat intake with increased cancer risk to be sufficient to recommend that consumption of fat be reduced . . . . Two years ago, the Food and Nutrition Board stated in its report Toward Healthful Diets . . . that 'there is no basis for making recommendations to modify the proportions of these macronutrients, [e.g., fat] in the American diet at this time.'"

The committee did not explain the reasons for the different judgment because it did not believe the two reports were comparable.

NAS officials told us that study groups may arrive at different conclusions because science evolves and much scientific information changes. Science is dynamic, so that scientists are used to uncertainty. The answers that science provides to questions are not final answers but tentative ones usually prefaced with the caveat that they are interpretations based on available information. NAS officials pointed out that the scientific literature considered by the two diet and health study groups was different. The Diet, Nutrition, and Cancer Committee performed a comprehensive literature search on the relationship of diet to one disease, cancer. We determined that 19 percent of the published literature referred to in Diet, Nutrition, and Cancer was dated 1980 or later, after Toward Healthful Diets was drafted. The Diet, Nutrition, and Cancer Committee project director and the Executive Director, Commission on Life Sciences, stated that they believed that the amount of new data was significant. Two former FNB members who commented on the report disagreed that the new data were significant.

NAS officials stated that they do not view Toward Healthful Diets and Diet, Nutrition, and Cancer as contradictory partly because theories are always subject to re-evaluation. One scientist told us that one never has enough data to draw absolutely

firm conclusions, so one always makes judgments based on incomplete data. Scientists' interpretations of the same data often differ. Scientists accept these differences as part of the process of science, although the public may find the differences confusing.

NAS officials and scientists told us that differing interpretations of data usually occur in areas where questions remain to be answered, such as questions about diet's relationship to health. Such differences do not mean that one scientist's interpretation is right and another's is wrong, but that the data from one experiment or from a series of experiments are subject to differences in interpretation.

THE TWO REPORTS OFFER FUNDAMENTALLY SIMILAR DIETARY ADVICE

Although Toward Healthful Diets and Diet, Nutrition, and Cancer were controversial because they were perceived to be inconsistent, scientists involved with both reports whom we interviewed stated that the fundamental dietary advice about about variety and moderation offered by both reports is similar and is consistent with dietary guidance offered by other organizations.

Authors of both Toward Healthful Diets and Diet, Nutrition, and Cancer stated that the major focus of the dietary advice each offered was to advocate dietary moderation. A scientist who served on both the FNB task force and the Diet, Nutrition, and Cancer Committee told us that both reports stressed that moderation was the key to a healthful diet.

According to their authors, both reports emphasized the importance of consuming a balanced diet composed of appropriate servings of basic foods. USDA currently categorizes basic foods as comprising five basic food groups: (1) milk and dairy products, (2) meat, fish, poultry, dry beans, and other high-protein foods, (3) vegetables and fruits, (4) cereals and breads, and (5) fats, oils, sugars, and alcoholic beverages.[3]

The recommendations/interim guidelines from Toward Healthful Diets and Diet, Nutrition, and Cancer are reproduced on the following page.

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[3]Commenting on this report, the Food and Drug Administration noted that the fifth basic food group was added to encourage moderation in consumption.

NAS REPORTS' DIETARY ADVICE

Toward Healthful Diets Recommendations[a]

These guidelines will improve general nutritional status, may be beneficial in preventing or delaying the onset of some chronic degenerative diseases, and incur no appreciable risk:

Select a nutritionally adequate diet from the foods available, by consuming each day appropriate servings of dairy products, meats or legumes, vegetables and fruits, and cereal and breads.

Select as wide a variety of foods in each of the major food groups as is practicable in order to ensure a high probability of consuming adequate quantities of all essential nutrients.

Adjust dietary energy [calorie] intake and energy expenditure so as to maintain appropriate weight for height; if overweight, achieve appropriate weight reduction by decreasing total food and fat intake and by increasing physical activity.

If the requirement for energy is low (e.g., reducing diet), reduce consumption of foods such as alcohol, sugars, fats, and oils, which provide calories but few other essential nutrients.

Use salt in moderation; adequate but safe intakes are considered to range between 3 and 8 grams of sodium chloride daily.

Diet, Nutrition, and Cancer Interim Guidelines

It is possible on the basis of current evidence to formulate interim dietary guidelines that are both consistent with good nutritional practices and likely to reduce the risk of cancer. These guidelines are meant to be applied in their entirety to obtain maximal benefit.

The consumption of both saturated and unsaturated fats [should] be reduced in the average U.S. diet. An appropriate and practical target is to reduce the intake of fat from its present level (approximately 40 percent) to 30 percent of total calories in the diet.

The committee emphasizes the importance of including fruits, vegetables, and whole grain cereal products in the daily diet.

The consumption of food preserved by salt-curing (including salt-pickling) or smoking [should] be minimized.

Efforts [should] continue to be made to minimize contamination of foods with carcinogens from any source.[b]

Further efforts [should] be made to identify mutagens[c] in food and to expedite testing for their carcinogenicity. Where feasible and prudent, mutagens should be removed or their concentration minimized.[d]

If alcoholic beverages are consumed, it [should] be done in moderation.

[a]The guidelines were addressed to adult Americans, but not to infants, children, or pregnant or nursing mothers.

[b]This interim guideline does not address dietary modification.

[c]Mutagen: a chemical or physical agent that interacts with genetic material to cause a permanent, transmissable change in the genetic material of a cell.

[d]This interim guideline does not address dietary modification.

Appendix III is a chart showing dietary advice given by both public and private organizations. Scientists whom we interviewed stated that the recommendations in Toward Healthful Diets and Diet, Nutrition, and Cancer are similar to those made by other groups. The Diet, Nutrition, and Cancer Committee chairman stated that the guideline his group posed regarding fat consumption was buttressed by the fact that it was generally in accordance with those made by other authoritative groups.

We compared the NAS reports with Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention (1979); the USDA/HHS report Nutrition and Your Health--Dietary Guidelines for Americans (1980); the Senate Select Committee on Nutrition and Human Needs' report Dietary Goals for the United States (second edition, 1977); and the American Heart Association's Committee on Nutrition, Diet, and Coronary Heart Disease's 1978 recommendations.

The reports Toward Healthful Diets, Healthy People, Dietary Goals for the United States, and Nutrition and Your Health--Dietary Guidelines for Americans are reports dealing with diet and health in general. The American Heart Association's recommendations deal with the relationship between diet and heart disease. Diet, Nutrition, and Cancer's interim guidelines address the relationship between diet and cancer.

The four reports providing general dietary advice agree that people should maintain their appropriate weight, avoid excessive salt use, and reduce dietary sugar and fat. Toward Healthful Diets limits its advice by stating that fat, alcohol, oil, and sugar consumption should be reduced by those who are overweight (approximately 30 percent of middle-aged women and 15 percent of middle-aged men) and by those who are sedentary, i.e., those whose requirement for energy is low. Also, Toward Healthful Diets directed its advice to adult Americans, but not to infants or children or pregnant or nursing mothers.

The other two reports are more narrowly focused because their purpose is to deal with the reduction of the risk of specific diseases--heart disease and cancer. There are some differences in these reports' advice compared to the general reports. For example, neither deals with sugar because sugar has not been linked to cancer or heart disease. However, as shown in app. III, the dietary advice these two reports offer is fundamentally similar to and consistent with the dietary guidance offered by the other four reports.

HOW NAS GROUPS DECIDED WHAT DIETARY ADVICE TO OFFER

Toward Healthful Diets and Diet, Nutrition, and Cancer were prepared by scientists and physicians following generally accepted scientific practices of gathering scientific information on the topic of diet's relationship to health, reviewing the data to determine their merit, and evaluating the data to arrive at conclusions and recommendations.

Although the two study groups looked critically at the same kinds of scientific evidence, they came to different conclusions about diet's relationship to cancer. FNB concluded that

> ". . . in the absence of evidence of a causal relationship between the macronutrients of the diet and cancer, there is no basis for making recommendations to modify the proportions of these macronutrients in the American diet at this time."

The Diet, Nutrition, and Cancer Committee concluded that

> ". . . it is possible on the basis of current evidence to formulate interim dietary guidelines that are both consistent with good nutritional practices and likely to reduce the risk of cancer."

Toward Healthful Diets' authors were more convinced by clinical intervention trials investigating the effect of diet changes on individuals, while the Diet, Nutrition, and Cancer Committee was more convinced by a convergence of laboratory studies and epidemiological evidence investigating dietary factors associated with changes in disease rates.

The following section discusses (1) the methodology used by the groups which authored the two reports and (2) the viewpoints held by those groups about providing public dietary advice.

The study groups' methodology

The groups which authored Toward Healthful Diets and Diet, Nutrition, and Cancer evaluated studies according to standards common throughout the sciences. Scientists have written that, generally, scientific papers should be evaluated for the (1) competence of the investigator, (2) adequacy of study design, (3) freedom from bias, (4) adequacy of resources, (5) adequacy of study controls, and (6) the logic and justifiability of the conclusions.

To determine what is known about a topic, scientists use the above criteria to decide which papers provide high-quality information and then determine how the papers relate to each other. They see how some papers fill in information that others do not address; whether the findings in one paper contradict those in another; whether reported results are consistent with accepted scientific principles; and where unanswered questions remain.

Authors of both reports said that these principles were followed in evaluating the literature which they used in their studies. However, Toward Healthful Diets' authors did not document the methodology used--that is, how and on what basis they arrived at conclusions and recommendations--at the same level of detail as the authors of Diet, Nutrition, and Cancer because (1) the report was intended to be a position statement for a different audience and (2) FNB did not have the resources to produce an extensively documented scientific report.

Toward Healthful Diets stated that its purpose was "to reduce the confusion in the minds of the public that has resulted from many conflicting [dietary] recommendations." According to scientists and physicians whom we interviewed and documents we reviewed, because FNB did not fully document its methodology, it opened itself up to charges of inconsistency and bias. For example, scientists who authored Toward Healthful Diets were criticized by other scientists for bias on the issue of epidemiological evidence which critics said FNB had ignored.[4] The former FNB Chairman and the task force chairman said that the task force reviewed epidemiological evidence. The FNB task force chairman stated that, to preclude such bias charges in the future, FNB could issue a follow-up report explicitly showing the scientific evidence used as a basis for recommendations.

In general, two types of evidence are used to provide information to scientists on diet and health issues: laboratory tests and epidemiology. Laboratory tests include in vitro studies and in vivo studies. In vitro studies are carried out in test tubes and involve, among other things, determining whether chemical reactions occur. For example, in vitro tests have been used to determine whether substances cause bacteria to mutate. In vivo tests involve testing using living organisms, such as animals or in some cases human subjects. Epidemiological studies examine the incidence and distribution of disease in a population. Both NAS groups used both types of evidence in preparing their reports.

According to scientific literature, epidemiological and laboratory studies have both advantages and disadvantages. The major strength of epidemiological studies is that they are a good way to obtain human population data. Such studies allow scientists to study substances which people are actually exposed to. Epidemiological studies also eliminate the need to make interpretations of the data by extrapolating from the results in animals exposed to doses of a substance to the expected effects in humans. However, epidemiological studies are not as carefully controlled as experiments with laboratory animals because researchers cannot control people's behavior to eliminate all factors which could confound the test results.

In vitro laboratory tests are inexpensive and quick, but they alone do not provide definitive evidence of carcinogenicity in humans. Animal experiments allow the researchers to carefully control the animals' lives and ensure that they are not exposed to things that could distort the results of the experiment and produce inaccurate information. However, animals are not human and the causes of disease manifestation in animals may not always duplicate the causes in humans.

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[4]Epidemiological evidence is studies using statistical and experimental techniques to measure and analyze the incidence, distribution, and determinates of disease in human populations.

Methodology used in Toward Healthful Diets

The FNB task force chairman stated that the task force used the criteria established in the Surgeon General's 1964 report on Smoking and Health in evaluating the evidence used to prepare Toward Healthful Diets. These include criteria for (1) judging the value of each reviewed paper, (2) assessing the force of epidemiologic data using criteria of consistency, strength, specificity, temporality, and coherence of the associations, and (3) determining when an agent has been shown to have such a significant effectual relationship to the associated disease as to denote it as causal.

Toward Healthful Diets' authors stated that they reviewed laboratory[5] and epidemiological evidence. They said that they evaluated each study and then evaluated groups of related studies to determine general conclusions on the relationship between diet and each of the five diseases encompassed by their scope.

The report stated that the task force examined the data to determine whether there was a causal connection between diet and heart disease and cancer. Epidemiological evidence (except for clinical intervention trials), according to Toward Healthful Diets' authors, can show association between diet and health, but not cause and effect. In the absence of such a causal connection FNB declined to make recommendations suggesting dietary changes to avoid heart disease and cancer.

The report also stated that the recommendations' potential effectiveness must be evaluated when determining whether dietary recommendations are appropriate. In addition, there must be clear evidence that recommendations will not be harmful before they can be made. According to the report's authors, such evidence is best provided by clinical intervention trials.

Clinical intervention trials are studies on free-living humans where the study's subjects are divided into groups. One or more of the groups is provided the treatment and others are not. The groups are compared to determine whether the treatment had any effect. This method is used to determine the effectiveness and safety of new drugs or vaccines.

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[5]According to the FNB task force chairman, laboratory research evidence includes clinical investigations which, in contrast to epidemiology, involve a small number of human subjects who are intensively studied by the experimental method, for example, in a hospital metabolic ward. Baseline observations are taken, an experimental variable is interposed, changes are studied, and the individual is returned to the baseline status. This can involve drugs, diets, exercise, or other experimental variables.

Methodology used in Diet, Nutrition, and Cancer

The Diet, Nutrition, and Cancer Committee used both epidemiological and laboratory studies as the basis for its report. According to the project director, in performing its analysis the committee evaluated each paper separately and then evaluated groups of papers on specific topics to draw general conclusions about each topic. In a statement about the criteria used to weigh the evidence, the report stated that the committee had more confidence (1) in data derived from case-controlled and cohort epidemiological studies and in the results of laboratory experiments conducted in more than one animal species or test system, (2) in results that had been produced in different laboratories, and (3) in data that showed a dose-response effect.[6]

Epidemiological studies use statistical and experimental techniques to measure and analyze the incidence and distribution of disease in the population of interest. The report stated that several types of epidemiological studies were used: descriptive studies, correlation studies, case-control studies, cohort studies, and clinical intervention trials. Descriptive studies are observational studies which describe the patterns of disease occurrence in one or more populations, in components of the same population, or in a single population over time. Correlation studies are based on aggregate exposure data and are used to determine correlations between factors which may be linked to diseases and to understand the relationships between them. Case-control studies select individuals who have a disease and match them with controls who do not have the disease. The groups are compared for a variable such as smoking or high fat diets, and differences in exposure are analyzed statistically for strength of association with the disease.

Cohort studies select individuals with desired characteristics, divide them into two groups, and follow them over time to determine the incidence of disease in the two sets of individuals. One set is exposed to the variable being studied and the other set, the control group, is not. Differences between the groups are measured and statistically analyzed to provide researchers with information. Clinical intervention trials are similar to cohort studies, except that investigators randomly assign participants into groups, have groups change their behavior in a certain way (for example, change their dietary patterns), and then measure the differences between the groups over time.

The report stated that the preponderence of the data and the degree of concordance between the epidemiological and the laboratory evidence determined the strength of the report's conclusions. The committee found that the evidence suggested a link between some dietary components and cancer but that the

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[6]A dose-response effect is a gradient response, i.e., one where exposure to successively stronger doses of a substance produces a successively stronger response.

evidence was not strong enough to draw conclusions about the link between other dietary components and cancer.

Different viewpoints about providing public dietary advice

Toward Healthful Diets and Diet, Nutrition, and Cancer are examples of reports whose authors have different philosophies about making public dietary recommendations to reduce chronic disease risk. Both groups say that when the scientific evidence converges from laboratory tests and epidemiological studies, then the evidence is sufficient to make recommendations. In Toward Healthful Diets FNB stated that it believed that

> ". . . advice should be given to the public when the strength, extent, consistency, coherence, and plausibility of the evidence from lines of investigation ranging from epidemiology to molecular biology converge to indicate that certain dietary practices or other aspects of lifestyle promote health benefits without incurring undue risks."

The Diet, Nutrition, and Cancer Committee also agreed with these principles, but because of differences in the authors' scientific judgment, this committee came to a different conclusion than FNB about the feasibility of public dietary advice to decrease cancer risk.

The outlines of the debate on diet's relationship to chronic diseases which the two NAS reports exemplify were drawn after the Senate Select Committee on Nutrition and Human Needs' Dietary Goals for the United States was published in January 1977. Because Dietary Goals was the first government publication to set national diet guidelines, it was controversial. The committee invited comments from 50 experts which were published in an 869-page Dietary Goals for the United States--Supplemental Views (Nov. 1977). Subsequently, the committee revised and reissued the Dietary Goals in December 1977. The following issues were raised by the Dietary Goals debate:

--Scientists are divided over the question of at what point in the development of scientific evidence they should offer public opinions about diet's relationship to health.

--Scientists have substantial disagreements about the benefit of dietary changes by the general population in reducing chronic disease risk.

--Information on what the U.S. public actually eats is incomplete and difficult to improve.

The revised Dietary Goals stated that honest professional disagreement would continue to exist concerning the basic dietary path to good health.

How much evidence is needed?

Scientists whom we interviewed stated that nutrition is a field of inquiry which traditionally has been concerned with the role of diet in preventing nutritional deficiencies such as scurvy, which results from a deficiency of vitamin C. Scientists also have been increasingly interested in how diet may affect complex diseases such as heart disease or cancer. These complex diseases result from many causes--family history of the disease, sex, age, or smoking, for example--and diet may be one factor involved in whether any individual's risk is greater, although scientists disagree about how important a factor it is.

The type and amount of scientific evidence required before providing advice to the public is a controversial matter in the scientific community. In general, the two NAS reports represent two schools of thought concerning the type and amount of evidence needed for providing dietary advice to the public. For explanatory purposes, we term these schools the "possibility of preventive benefit" school and the "proof of preventive benefit" school. While both groups of scientists are concerned about disease prevention, one group focuses more on the benefits which may result from undertaking preventive dietary changes while the other group focuses more on the need for proof that such changes will be reliably effective before advocating action. The scientists whom we interviewed may not agree with our categorization because groups of scientists decide each issue after evaluating the scientific evidence and may not fall consistently into any school of thought.

The "possibility of preventive benefit" school

Scientists have stated that the conclusions drawn by scientists from different schools of thought may differ partly because they begin with different assumptions and look at problems from different perspectives. Conclusions and recommendations reached by some scientists, such as those agreed to by the Diet, Nutrition, and Cancer Committee members, reflect a public-wide approach to problems by focusing on the incidence of disease in a population and searching for methods of reducing disease incidence in populations as a whole. These scientists see cancer as a major public health problem and look for causes, methods of prevention, and cures. Cancer is a very serious disease which is difficult to treat successfully, in part because it may be diagnosed late in the course of the disease. It is the second highest cause of death in the United States.

Many scientists agree that diet is a factor, along with many others, in people's risk of getting cancer. According to such scientists, diet is a risk factor which people can control. Scientists from the possibility of preventive benefit school seek information on how diet is linked to cancer to see what, if any, dietary changes people can make to decrease their cancer risk. Diet, Nutrition, and Cancer stated that although the data are neither clear-cut nor complete, when the laboratory and epidemiological evidence converges to indicate that some dietary changes

may decrease cancer risk and these changes have no known risk, dietary advice may be provided.

These scientists state that dietary changes have not been proven to reduce people's cancer risk. However, rather than wait until all the experiments providing such proof have been performed, these scientists, physicians, and public health officials state their belief that the public should be provided with their best judgment and told that evidence points to dietary changes that may lessen the public's disease risk. They state that the public wants and has a right to know the best information science can provide at a given point in time and that people are making changes based on past recommendations and living longer.

Public health recommendations are designed to decrease the rate of diseases in a given population, which is different from the problem of treating an individual patient with a disease. The potential benefit from just a small decrease in the incidence of disease, in a population is great. Diet, Nutrition, and Cancer's authors stated to us that they were not prescribing therapy for treating disease, nor were they making mandatory recommendations which must be followed. By decreasing the public's chronic disease risk factors, the report's authors state that they hope to reduce the incidence of disease in a population, although a given individual may not be helped. Public health guidelines such as those made by Diet, Nutrition, and Cancer also do not promise benefits to individuals who follow them. Instead they are optional advice and may be beneficial.

The "proof of preventive benefit" school

Some scientists, such as Toward Healthful Diets' authors, also are concerned with preventing chronic diseases and believe the public has a right to know the best information science can provide. However, such scientists have stated that the scientific evidence supporting dietary recommendations as a disease prevention measure is incomplete. They have written that when dietary recommendations are provided to the public, as with treatment of disease they are being prescribed with the promise of benefit. These scientists believe, therefore, that the standard which should be used for making dietary recommendations to the public should be the same as that which is used in approving drugs or vaccines--proven safe and effective.

The proven safe and effective standard is the standard which is used by the Food and Drug Administration (FDA) to determine whether new drugs may be marketed. FDA requires companies which want to market these items to conduct extensive testing on animals and humans to determine that they are safe and will provide the beneficial effects which manufacturers claim they will provide. No new drug is allowed to be marketed unless test results prove it is both safe and effective.

Toward Healthful Diets' authors stated that if the public is advised to change its diet to reduce its disease risk, the recommendations imply that if they are followed beneficial results will

occur. These scientists say that they believe that recommendations should not be made to the public unless scientific evidence has demonstrated that promised benefits will reliably occur. People will decide that science is not credible, according to these scientists, if promised benefits do not occur.

According to the former FNB chairman, this does not mean necessarily that science has to have demonstrated how a phenomenon works. For example, aspirin works reliably to relieve headaches although science does not yet completely understand how, and insulin was prescribed for diabetics because it worked before scientists understood how it worked.

According to the former FNB chairman, nutrition science has been used successfully in the past to treat and prevent nutritional deficiency diseases, sometimes through public programs. Iodized salt to prevent goiter and vitamin D-fortified milk to prevent rickets are examples of successful preventive nutrition measures which, according to the former chairman, were based on established scientific knowledge of effectiveness.

According to the former FNB chairman and the task force chairman, science has not yet demonstrated that dietary changes will reliably reduce cancer risk or help people live longer. People who live in developed countries who have different diets live to about the same ages. If dietary changes have not been proven to extend life, they offer no benefit because the U.S. public is healthy and long-lived consuming its current diet.

Toward Healthful Diets stated that FNB believed it unwise to make single, all-inclusive dietary recommendations to the public because the nutritional needs of population subgroups (such as pregnant women, teenagers, and the elderly) differ. Because people's needs differ, not all people may safely follow general guidelines. One FNB member provided as an example a case where a vegetarian eliminated milk and eggs from his diet, following public advice about cholesterol, and developed a vitamin deficiency as a result.

The FNB task force chairman stated that public dietary recommendations can be misinterpreted. For example, individuals who read that cholesterol is bad might assume that all fatty foods are bad for health. That is not the case because cholesterol is needed in humans and is present in every human cell. According to the scientists, inappropriate reductions of foods can interfere with normal, healthy development.

CONCLUSIONS

The two NAS reports on diet and health came to different conclusions about diet's relationship to cancer although the fundamental dietary advice about variety and moderation offered by both reports is similar and is consistent with past advice from other groups.

The scientific evidence required before providing public dietary advice to reduce chronic disease risk is a controversial matter in the scientific community. The two NAS reports represent two schools of thought on the issue, and the two study groups gave different weight to different types of evidence in reaching conclusions. This is a major factor in why the two groups came to different conclusions about diet's relationship to cancer. Toward Healthful Diets' authors were more convinced by clinical intervention trials investigating the effect of diet changes on individuals, while the Diet, Nutrition, and Cancer Committee was more convinced by a convergence of laboratory and epidemiological evidence investigating dietary factors associated with changes in disease rates.

No standard of scientific evidence has been universally agreed upon for making public recommendations about diet's relationship to chronic disease risk. Both NAS groups agree that in a field such as the relationship between diet and health, the scientific evidence is not yet clear or complete. Scientists say that at some point judgments must be made about what the evidence means for people's health practices.

The authors--scientists and physicians--of Toward Healthful Diets say that they believe that the U.S. public is generally long-lived and healthy, due in part to good diet, and that any dietary changes recommended to prevent chronic diseases should have to meet the same standards as other therapies or preventive measures, such as drugs or vaccines. That is, dietary changes recommended to prevent disease should be proven safe and effective before they are pronounced. According to them, general dietary recommendations should not be made to the public because individuals vary considerably in their need for food. They say that they believe that the evidence supporting dietary recommendations as a disease prevention measure is incomplete and that some risk may be involved when people alter their diets without medical supervision in an effort to prevent specific diseases.

While the scientists and physicians who subscribe to Diet, Nutrition, and Cancer's approach agree that the evidence is incomplete, they say that they believe that chronic diseases are a public health problem of such magnitude that action is needed. Means of preventing chronic diseases such as cancer are of great interest. These individuals state that if scientific evidence from many sources converges to point toward a course of preventive action, no risk of taking the action has been identified, and the potential benefits are great, then recommendations to the general public ought to be made. They state that people are making changes based on past recommendations and are living longer.

Such differences of opinion are common in science and are legitimate differences, although they may lead to public controversy. NAS officials are concerned that public controversy can result in a loss of scientific credibility. However, NAS is concerned about producing reports that are good science, not about producing reports that will seem consistent from the public's viewpoint. Although it advises its study groups to do so, NAS has

no formal means in its report production process to require assessment of whether its reports on diet and health will appear consistent or to outline the significance of scientific disagreements so that the public and policymakers understand why groups arrived at different conclusions. Such matters are left to the discretion of the NAS President or the study group.

NAS report preparation guidelines suggest that study groups should avoid making social conclusions and recommendations except in special circumstances which should be clearly set forth in the report. Guidelines also suggest that study groups should cite related NAS reports and describe how and why the study committee came to conclusions that differ from those of other NAS reports.

Neither Toward Healthful Diets' nor Diet, Nutrition, and Cancer's authors chose to follow the suggestions entirely. Toward Healthful Diets was a brief position statement. Thus, it did not fully document the methodology the FNB task force used to arrive at conclusions and recommendations. Public controversy resulted which might have been alleviated had NAS report preparation suggestions been followed. The NAS President could in the future consider emphasizing the importance of study groups' clearly setting forth how and on what basis they arrive at conclusions and recommendations.

The authors of Diet, Nutrition, and Cancer noted in a footnote to the report that their conclusions about dietary fat's relationship to cancer were different from Toward Healthful Diets' conclusions without discussing the reasons for the difference. If the issue of why the two NAS reports came to different conclusions had been addressed, either in a letter from the NAS President bound into the front of the report or in a foreword, the public controversy might have been precluded or minimized. A letter from the President or a foreword is likely to be read by the general public and by policymakers who have limited reading time. A discussion of the different schools of thought about public dietary advice would have provided a better context for policymakers as they assess the issues involved. The NAS President could consider including a background statement in public reports that sets out differences of scientific judgment on the issue of when scientific evidence is sufficient to provide public advice on such issues as diet's relationship to health.

COMMENTS BY NAS AND OTHERS AND OUR EVALUATION

NAS commented that it welcomed the recognition in the report that legitimate and valid differences in judgment may exist among scientists in their interpretation of scientific evidence, and that such disagreements are often hard to communicate clearly to the public (see app. IV). NAS stated that it appreciated the report's reiteration of the need for study committees to clearly set forth how and on what basis they reached their conclusions and recommendations, and that this objective has been a central theme of the RRC.

Commenting on our suggestion that apparent discrepancies between studies on related topics might be discussed in the NAS President's transmittal letter, NAS stated that it has found that contextual differences between reports and their covering transmittal letters can be confusing to the public reader. NAS stated hat perhaps where differences in studies are sufficiently pronounced as to require explanation, this point could be noted in the transmittal letter. NAS said that while each committee is accountable for the substantive content of its report, the institution also has a responsibility for assuring that reports are as accurate as possible and that each committee has taken account of differences in judgment within the scientific community.

HHS commented that, because our report makes frequent reference to the lack of standards upon which scientific evidence can be evaluated, we might want to refer to the Report of the Task Force on the Evidence Relating Six Dietary Factors to the Nation's Health published in The American Journal of Clinical Nutrition in December 1979 (see app. V). However, as discussed beginning on page 38, consensus about criteria for evaluating scientific evidence does exist. There is no consensus in the scientific community, however, about what and how much scientific evidence supports public recommendations for dietary changes to reduce chronic disease risk. The American Society for Clinical Nutrition study group report referred to by HHS expressly avoided deriving dietary recommendations.

USDA commented that differences in scientific judgment can be better understood in reports that set forth procedures used in arriving at conclusions and clearly differentiate between scientific fact and judgment (see app. VII). USDA said that reports on topics of great public interest such as those on diet and health might discuss disagreements on the conclusiveness of the evidence among committee members, if such disagreements exist. As we discuss on page 16, NAS provides its study group members the option of indicating dissenting opinions in study reports but neither Toward Healthful Diets nor Diet, Nutrition, and Cancer contains a minority statement.

USDA also commented that differences such as that between Toward Healthful Diets and Diet, Nutrition, and Cancer might be expected, and that one approach to minimize misinterpretation in the future might be for agencies to ask NAS to describe and summarize the extent and boundaries of scientific knowledge which relate to a specific problem, but reserve the task of developing national policy to the appropriate responsible government agency. We believe it should be noted that NAS advises on, but does not set, national policy.

Commenting on this report, the former FNB Chairman stated that although the report discusses the major issue responsible for the controversy over reports on diet and health--what type of evidence should be required before advice on the relationship between diet and health/disease is offered to the public--the report does not directly confront the issue (see app. VIII). He stated that he believes that the issue should be brought to the fore and

faced, and recommends that the report include a recommendation to NAS that it convene a broadly based committee to consider the question of developing guidelines for determining when scientific evidence is adequate to serve as the basis for establishing public policy. He stated that such a committee should be asked to deal specifically with the question of the importance of being able to predict accurately the outcome of a public policy recommendation.

As discussed on pages 30, 33, and 47, we were told by scientists whom we interviewed, and discerned from reviewing the literature, that standards of evidence which could be agreed to by scientists were not feasible because scientists could never all agree on a single set of standards and because each public health problem is unique. Also, NAS study groups, which are convened specifically to address problems not only by evaluating the evidence but also by making expert judgments, are given the freedom to address the issues in the manner in which the group decides is best. We do not believe our evidence supports a recommendation such as that suggested by the former FNB Chairman, and it is not clear whether such guidelines would unduly restrict NAS study groups in pursuing the objectives which they and NAS are established to pursue. NAS reports are one of the elements which enter into the making of public policy, but the responsible departments and agencies and the Congress also consider other elements such as economic and political concerns.

Other comments from the Food and Drug Administration and from individual scientists which pertained to this chapter's clarity and technical accuracy are contained in appendixes VI and VII. The comments were considered and the chapter was revised where appropriate to improve its clarity and accuracy.

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COMMITTEES:
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IMMIGRATION AND REFUGEE POLICY;
CHAIRMAN, AGENCY ADMINISTRATION
SPECIAL COMMITTEE ON AGING

September 30, 1982

The Honorable Charles A. Bowsher
Comptroller General of the United States
General Accounting Office
Washington, D.C. 20548

Dear Mr. Bowsher:

Few areas of public health policy have engendered more controversy in recent years than the issues arising from the relationships between diet and health.

The prestigious National Academy of Sciences has been thrust into the center of the controversy over diet and cancer as a result of recent sharply contradictory studies conducted under its auspices.

The existence of these two divergent points of view coming within months of each other from what is widely regarded as the most prestigious and influential scientific body in the nation raises some basic questions as to the role of the National Academy of Sciences in the development of public policy.

The Academy has been termed "the honorary apex of the U.S. scientific community". Established in 1863, as an official advisor to the federal government on scientific and technical questions, it is widely perceived to be a source of independent, objective advice -- an organization that will speak the truth on controversial issues without yielding to the pressures of political leaders or powerful special interest groups. Because of this reputation, the studies, reports and recommendations carried out and issued under its name have a substantial impact on the deliberations of the Congress and the federal government, and on the opinions and decisions of the public as a whole.

The credibility of the Academy's contributions to the public policy process is tied closely to how well, institutionally, the Academy is able to provide for the expression of divergent scientific views, opinion, and judgments in a context that is meaningful to the scientific community, to government decision-makers and to the public as a whole. To what degree does the Academy cope with the "politics" of science, and is it able in its work, to consistently maintain adequate and visible differentiation between scientific fact and scientific judgment

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and opinion? Because the Academy is not an obscure, ivory tower group, but an agency of considerable prestige and influence, deficiencies in the institutional operation of the Academy become, in effect, deficiencies in the public policy process.

It appears that in the area of diet and cancer, at least, the Academy has contributed to the confusion already surrounding the issue.

The two divergent studies dealing with diet and cancer are "Toward Healthful Diets", conducted by the Academy's Food and Nutrition Board and made public in 1980, and the study released this summer, conducted by an ad hoc Committee of the Academy, "Diet, Nutrition and Cancer".

Both studies reflect the considered judgment of the scientists who carried them out -- eminent authorities and experts in the field of nutrition and health. Each study has a different message -- in fact, the messages are just about 180 degrees apart.

The studies are similar in that they both agree that no cause-effect relationships have been established betweeen diet and cancer. This is scientific fact in which they both concur. Beyond that, however, the opinions and judgments of the authors are poles apart.

The authors of "Toward Healthful Diets", for example, take this view:

> The Board considers it scientifically unsound to make single, all-inclusive recommendations to the public regarding intakes of energy, protein, fat, cholesterol, carbohydrate, fiber and sodium"
>
> * * *
>
> "The Board believes that in the absence of evidence of a causal relationship between the macronutrients of the diet and cancer, there is no basis for making recommendations to modify the proportions of these macronutrients in the American diet at this time".

The authors of "Diet, Nutrition and Cancer", on the other hand, take an opposite view, as described by the Academy's President, Dr. Frank Press, in a letter dated July 12, 1982, responding to a Congressional inquiry on the study:

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> "...However, as you are well aware, decisions involving scientific information often are needed before all the evidence is at hand. This is especially true in matters concerning diet and chronic diseases, the complex nature of which makes it unlikely that a precise cause-effect relationship can ever be demonstrated. In such matters, authoritative judgment is a necessary complement to the data base in reaching conclusions. Our committee on diet and cancer, after careful consideration of the evidence and recognition of all the uncertainties, concluded that scientific evidence was available to suggest a course of action, and that not to make dietary recommendations at this time would be a dereliction of its responsibility".

It is evident from this that the difference between the conclusions of the two studies lie in the respective opinions of the authors and not in the scientific facts, on which there is agreement. To the public, however, the studies appear contradictory and confusing -- in 1980 the Academy said one thing and in 1982 its says another. It is not made clear at all that there are some fundamental and very valid differences between the two in terms of basic approach, as can be seen in the following from the 1980 study:

> "...In the case of diseases with multiple and poorly understood etiology, such as cancer and cardiovascular disease, the assumption that dietary change will be effective as a preventive measure is controversial. These diseases are not primarily nutritional, although they have nutritional determinants that vary in importance from individual to individual. ...Those experts who advocate a more aggressive approach and seek to change the national diet in the hope of preventing these degenerative diseases assume that the risk of change is minimal and rely heavily on epidemiological evidence for support of their belief in the probability of benefit. Neither the degree of risk nor the extent of benefit can be assumed in the absence of suitable evidence. ...(The Board) believes that an extensive and critical evaluation of assumptions underlying any recommendations for dietary change should be carried out, including risk-benefit analyses".

Dr. Press, in his July 12 letter, discusses the problem of apparent contradictions in the reports, and points out that:

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Mr. Bowshers
September 30, 1982

> "A further observation in your letter on the substantive aspects of the report on diet and cancer states that American consumers and those who produce food for them cannot afford contradictory advice which unduly raises concerns about dietary patterns. It seems evident from both Congressional and other correspondence that the major concerns over the diet and cancer report are those related to the consumption of both saturated and unsaturated fats be reduced in the average American diet, and that the consumption of meat and dairy products, namely, its recommendations to the consumption of salt cured or smoked foods be minimized. Since many institutions concerned with diet and health have for a number of years urged similar reductions, it seems improbable that the consuming public would be confused by this consistent message."

While it is true that some similar recommendations have been made in the past, the overall effect has been to compound the confusion, rather than lessen it. It is ironic that the 1980 report was a special effort to reduce some of the confusion and controversy over dietary recommendations that had been made up to that time. In its introduction to that study, the Food and Nutrition Board of the Academy said this:

> "The Food and Nutrition Board is concerned about the flood of dietary recommendations currently being made to the American public in the hope that a variety of chronic degenerative diseases may be prevented in some persons. These recommendations, which have come from various agencies in government, voluntary health groups, consumer advocates, and health-food interests, often lack a sound scientific foundation, and some are contradictory to one another. In an effort to reduce the confusion in the mind of the public that has resulted from these many conflicting recommendations, the Board has prepared the following statement".

It is apparent to us that, on this question of the relationship of diet to cancer, even the efforts of the National Academy of Science have left the issues clouded and murky, not only without resolution, but also lacking in any substantive clarification.

In view of this, we ask the assistance of the General Accounting Office in two areas. First, the Academy's efforts have resulted in a clear need for presentation in a useful way of the agenda of issues and the full range of scientific fact and judgment

Page 5
Mr. Bowshers
September 30, 1982

on the relationship of diet to cancer. We request that your agency undertake this task in a manner similar to what you have done in the past on other questions -- that is, provide us with an outline of the controversies, explanation of the issues, and background on the biases that may color the various points of view involved.

Of equal importance is the need to explore the Academy's institutional vulnerabilities and limitations in an effort to determine how the functions of the Academy can be better utilized to provide objective input into the public policy process -- especially in the area of diet and health. Since federal contracts with the Academy provide most of its operating budget, it is important that the contracting process be analyzed in terms of the influence of federal agencies on the Academy in determining the ways in which they are to be addressed. The question on influence on the Academy from private interests must also be explored.

Primarily, however, we believe that the focus of your effort should be on how the Academy can do a better job of clearly differentiating between fact and judgment, of accurately reflecting all points of view within the scientific community -- the range of varied and often divergent opinions and judgments of scientific experts in the field on a particular issue -- and of presenting this information in ways that are clear, meaningful and useful to the Congress, federal agencies, and the public as a whole.

You may be assured of our full cooperation in this effort, and we are hopeful that you will be able to assign staff and resources adequate to accomplish this study in an expeditious manner.

Sincerely,

John Melcher Charles Grassley

Jim Exon Roger W. Jepsen

COOPER EVANS
THIRD DISTRICT
IOWA

Congress of the United States
House of Representatives
Washington, D.C. 20515

COMMITTEES AND SUBCOMMITTEES:
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HOUSING AND CONSUMER INTERESTS
TECHNOLOGY ASSESSMENT BOARD

October 1, 1982

The Honorable Charles A. Bowsher
Comptroller General of the
United States
General Accounting Office
Washington, D.C. 20548

Dear Mr. Bowsher:

The issue of diet and health is an important concern of the American public, and statements linking particular elements of the diet and health can result in great impact, especially if these statements come from respected sources. Consequently, it is imperative that reports from government-related sources be consistent and credible.

In 1980 the Food and Nutrition Board of the National Academy of Sciences issued a study entitled "Towards Healthful Diets." In this report the Board concluded there was no basis for making recommendations to modify the proportions of macronutrients in the American diet. Subsequently, on June 16, 1982, the National Research Council of the National Academy of Sciences released a study conducted by an ad hoc committee of the Academy under contract with the National Cancer Institute. Although this study did not find a cause-effect relationship between diet and cancer, the committee saw fit to make several specific dietary recommendations. The contradictions between these two studies have caused confusion and controversy and raise some basic questions as to the role of the National Academy of Sciences in the development of public policy. Because of its impressive reputation, the studies, reports and recommendations carried out and issued under the name of the Academy have a substantial impact on the deliberations of the Congress and the Federal government, and on the opinions and decisions of the public as a whole.

Consequently, we urge that the General Accounting Office initiate an effort to assist us in addressing some of these questions and resolv-

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☐ 13 WEST MAIN STREET
MARSHALLTOWN, IOWA 50158
(515) 753-3172

ing some of the controversies. We will be pleased to meet with you and members of your staff regarding our concerns in this matter.

Sincerely,

Cooper Evans
Member of Congress

Tom Hagedorn
Member of Congress

Tom Tauke
Member of Congress

ARLAN STANGELAND
7TH DISTRICT, MINNESOTA

COMMITTEES:
AGRICULTURE
PUBLIC WORKS AND TRANSPORTATION

Congress of the United States
House of Representatives
Washington, D.C. 20515

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October 1, 1982

The Honorable Charles A. Bowsher
Comptroller General of the United States
General Accounting Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Bowsher:

Recently the National Research Council of the National Academy of Sciences released a study conducted by an ad hoc committee of the Academy under contract with the National Cancer Institute. Although this study did not find a cause-effect relationship between diet and cancer, the committee saw fit to make several specific dietary recommendations. These recommendations are contrary to conclusions of a report in 1980 of the Food and Nutrition Board, the standing committee in the Academy, which related then that there was no basis for making recommendations to modify the proportion of the macronutrients in the American diet.

The contradictions between these two studies have resulted in confusion and controversy and raise some basic questions as to the role of the National Academy of Sciences in the development of public policy. Because of its impressive reputation, the studies, reports and recommendations carried out and issued under the name of the Academy have a substantial impact on the deliberations of the Congress and the federal government, and on the opinions and decisions of the public as a whole.

We feel strongly that recommendations in the area of diet and health must be consistent and credible. The credibility of the Academy's input in the public policy process is tied closely to how well the Academy is able to provide for the expression of a full range of scientific thought in a context that is meaningful to governmental decision-makers and the public. It is apparent that this latest report of the Academy in the area of diet and cancer is confusing and leaves a basic question in our minds as to the role of the Academy in the development of public policy in this area. We urge that the General Accounting Office promptly initiate an effort to resolve these serious questions and contradictions resulting from the NAS report. Hopefully you could undertake this project as you have done in the past on other similar questions by explaining the issues, outlining the controversies and providing any background on any biases which might affect the points of view involved. Additionally, there is a need to consider the Academy's institutional vulnerabilities and limitations in an effort to determine how the functions of the Academy can be better utilized to provide objective input into the public policy process in this area.

The Honorable Charles A. Bowsher
October 1, 1982
Page 2

We urge a prompt and favorable response to our request, and we will be pleased to meet with you and your staff to outline in more detail our specific concerns.

Sincerely,

ARLAN STANGELAND, M.C.

CHARLES W. STENHOLM, M.C.

CLINT ROBERTS, M.C.

CHARLES WHITLEY, M.C.

BILL GOODLING
19TH DISTRICT, PENNSYLVANIA

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Congress of the United States
House of Representatives
Washington, D.C. 20515

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HANOVER, PENNSYLVANIA
TOLL FREE DISTRICT NUMBER:
800-632-1811

December 20, 1982

The Honorable Charles E. Grassley
U. S. Senate
232 Russell Senate Office Building
Washington, D. C. 20510

Dear Senator Grassley:

I recently had an opportunity to review your September 30, 1982 letter to the Comptroller General of the United States, the Honorable Charles A. Bowsher, concerning the National Academy of Sciences and its contradictory reports on the relationship between diet and health.

I want to let you know that I wholeheartedly endorse your request to the General Accounting Office and am letting them know of my support through a copy of this letter.

There are a large number of farmers in my district and to a great extent their livelihood depends on the receipt of factual information by the consuming public. Too much harm has already been done to the agricultural community through the distribution of inaccurate reports on diet and health -- especially the dairy and pork industries.

Again, I commend you on taking the initiative to request this report by the GAO. If I can be of any assistance to you in this matter, please do not hesitate to let me know.

Sincerely,

Bill

BILL GOODLING
Member of Congress

BG:lr

CC: The Honorable Charles A. Bowsher
Comptroller General of the United States
General Accounting Office
Washington, D. C. 20548

HEARINGS HELD AND STUDIES CONCERNING TOWARD HEALTHFUL DIETS AND DIET, NUTRITION, AND CANCER

Both Toward Healthful Diets and Diet, Nutrition, and Cancer sparked public controversy. The Congress responded, in the case of Toward Healthful Diets, by holding hearings on scientific issues involved in providing public dietary advice, and by requesting evaluation of Diet, Nutrition, and Cancer. The American Meat Institute and the National Livestock and Meat Board sponsored a separate study of Diet, Nutrition, and Cancer's epidemiologic evidence to determine whether the NAS committee's science was sound.

TOWARD HEALTHFUL DIETS HEARINGS

Two hearings were held on Toward Healthful Diets. The Senate Committee on Appropriations Subcommittee on Agriculture, Rural Development, and Related Agencies held a special hearing on the report on July 16, 1980.

This hearing was convened to discuss issues involved in the USDA/HHS Dietary Guidelines for Americans. These guidelines, like many others, were controversial because not all scientists were in agreement as to what recommendations should be made. The hearing's purpose was to "clear the air" about the scientific issues involved with providing public dietary advice and to explore the various viewpoints involved.

The major controversial matter considered by the hearing was whether recommendations could be made concerning diet and heart disease. USDA/HHS and several other groups believed that recommendations could be made concerning diet and heart disease, and that a general recommendation to the public to reduce fat and cholesterol was justified. Other groups including FNB disagreed. The hearing also noted that there was some disagreement within FNB about the need to reduce dietary fat as the FNB committee which prepared the Recommended Dietary Allowances (RDAs) suggested dietary fat should be reduced.

The House Agriculture Committee's Subcommittee on Domestic Marketing, Consumer Relations, and Nutrition held a hearing on Toward Healthful Diets on June 18-19, 1980. This hearing was to examine the differences between the USDA/HHS Dietary Guidelines for Americans' and Toward Healthful Diets' recommendations. Both hearings focused attention on the scientific basis for both sets of recommendations and explored the problem of providing guidance to the public when the scientific evidence is amenable to more than one reasonable interpretation.

STUDIES OF DIET, NUTRITION, AND CANCER

Diet, Nutrition, and Cancer has been the subject of five studies. The first was Diet, Nutrition, and Cancer: An Analysis of the National Academy of Sciences Report (CRS, July 1982). This

study was requested by a Member of Congress. It gave background on the NAS report, examined the report's interim guidelines, and compared them with recommendations and guidelines in 12 reports prepared by private and public organizations, including those of Toward Healthful Diets.

Two Members of Congress also requested a private organization, the Council for Agricultural Science and Technology, to prepare a report on Diet, Nutrition, and Cancer to (1) examine its impact on American agriculture and the health of the American consumer and (2) determine whether its conclusions and recommendations were premature or justified. The Council's report, Diet, Nutrition, and Cancer: A Critique (1982), was a collection of analyses of the NAS report prepared by natural and social scientists. Each essay represented only the opinion of its author. A wide range of opinions was covered in the report as some strongly agreed and others strongly disagreed with the interim guidelines in Diet, Nutrition, and Cancer. The study's introduction stated that because of the wide range of scientists' strongly held views, a consensus could not be reached by commentators on Diet, Nutrition, and Cancer's merits.

The American Meat Institute and the National Livestock and Meat Board contracted a private consulting firm to examine the epidemiological evidence the NAS committee used. Both groups were interested in having a review of the epidemiological studies pertinent to the recommendations concerning meat consumption to determine if the science the NAS committee used was sound.

The consulting firm in its report entitled Review of Diet, Nutrition, and Cancer: Assessment of the Epidemiologic Evidence Used to Support the National Academy of Sciences' Recommendations Concerning the Consumption of Meat, Processed Meats, and Fat (Jan. 1984) found that NAS had performed a thorough review of the epidemiological literature published between 1960 and 1981. The firm's key findings were that (1) the available data would not support any recommendation for a reduction in meat consumption; however, to the extent that meat consumption contributes substantially to total fat intake, an increased cancer risk is plausible and that therefore it would seem prudent to minimize the fat content of meat, (2) the NAS recommendation to avoid foods preserved by salt-curing or smoking appears consistent with epidemiologic data from countries in which these processes predominate; however, the NAS report itself did not recommend a reduction in consumption of the typical processed meats currently consumed in the U.S. which in general are not salt-cured, and (3) that the NAS recommendation to reduce fat consumption in the U.S. diet, which derives from the synthesis of the epidemiologic data with metabolic, animal, and laboratory evidence, are prudent.

Two federal agencies also reviewed Diet, Nutrition, and Cancer. In May 1983 HHS issued its Report of the HHS Task Force on Diet, Nutrition, and Cancer. It stated that NAS' report was a carefully documented and thoughtfully considered evaluation and that the interim guidelines included in the NAS/NRC report should

be implemented within the context of the HHS/USDA Dietary Guidelines and as part of the Public Health Service Nutrition Objectives for 1990. It also stated that its guidelines were similar to the governmental dietary guidelines and many of FNB's guidelines in Toward Healthful Diets. The HHS task force concluded that the recommendations in Diet, Nutrition, and Cancer should be implemented within the context of the USDA/HHS Dietary Guidelines. The HHS task force did not consider the NAS report's guideline on minimizing consumption of salt-cured and smoked foods because, according to the HHS Deputy Assistant Secretary for Health, salt-cured and smoked meats are the responsibility of USDA.

USDA (May 1983) also prepared a review which stated that Diet, Nutrition, and Cancer is a thoughtful and carefully considered review of the current scientific literature on the effects of diet on the development of cancer. USDA criticized the report's executive summary, press release, and some of its guidelines. For example, USDA stated that it proposes to develop dietary guidance materials at fat levels up to 35 percent of total calories as opposed to Diet, Nutrition, and Cancer's suggested interim guideline of 30 percent. USDA also disagreed with the report's interim guideline on salt-cured and smoked foods.

COMPARISON OF DIETARY RECOMMENDATIONS IN VARIOUS REPORTS[a]

Dietary component	Toward Healthful Diets	Diet, Nutrition and Cancer	Healthy People	Dietary Guidelines for Americans (USDA - HHS)	Dietary Goals	American Heart Association[b]
Balanced diet	Select a nutritionally adequate diet from the foods available, by consuming each day appropriate servings of dairy products, meat or legumes, vegetables and fruits, and cereal and breads. Select as wide a variety of foods in each of the major food groups as is practicable in order to ensure a high probability of consuming adequate quantities of all essential nutrients.	The committee emphasizes the importance of including fruits, vegetables, and whole grain cereal products in the daily diet.		Eat a variety of foods.		
Weight control	Adjust dietary energy (caloric) intake and energy expenditure so as to maintain appropriate weight for height; if overweight, achieve appropriate weight reduction by decreasing total food and fat intake and by increasing physical activity. If the requirement for energy is low (e.g., reducing diet), reduce consumption of foods such as alcohol, sugars, fats, and oils, which provide calories but few other essential nutrients.		Maintain ideal weight.	Maintain ideal weight.	Avoid overweight, consume only as much energy as is expended.	A caloric intake adjusted to achieve and maintain ideal body weight.
Carbohydrates						
Starch			Consume more complex carbohydrates.[c]	Eat food with adequate starch.	Increase the consumption of complex carbohydrates[c] and naturally occurring sugar[d].	A moderate rise in dietary carbohydrates to compensate for the decrease in calories from dietary fat.
Sugar	If the requirement for energy is low...reduce consumption of foods such as...sugar.		Consume less sugar.	Avoid too much sugar.	Reduce the consumption of refined and processed sugars.	
Fiber			Eat food with adequate fiber.			
Fat	If overweight, achieve appropriate weight reduction by decreasing total food and fat intake and by increasing physical activity.	The consumption of both saturated and unsaturated fats [should] be reduced in the average U.S. diet to 30 percent of total calories in the diet.	Consume less saturated fat.	Avoid too much fat, saturated fat.	Reduce overall fat consumption from approximately 40 percent to about 30 percent of energy intake. Reduce saturated fat consumption to about 10 percent of total energy intake.	A reduction in total fat calories achieved by a substantial reduction in dietary saturated fatty acids. The comments stated that it would be desirable to decrease the current 40 percent of total calories from fat to a level of 30-35 percent.
Cholesterol			Consume less cholesterol.	Avoid too much cholesterol.	Reduce cholesterol consumption to 300 mg/day.	A substantial reduction in dietary cholesterol.
Fish, Poultry and Legumes			Consume more fish, poultry, legumes, and less red meat.			

APPENDIX III

Dietary component	Toward Healthful Diets	Diet, Nutrition and Cancer	Healthy People	Dietary Guidelines for Americans (USDA - HHS)	Dietary Goals	American Heart Association[b]
Salt	Use salt in moderation; adequate but safe intakes are considered to range between 3 to 8 grams of sodium chloride daily.		Consume less salt.	Avoid too much sodium.	Limit the intake of sodium by reducing the intake of salt to about 5 grams a day.	Avoid excessive sodium.
Alcohol	If the requirement for energy is low...reduce consumption of foods such as alcohol...	If alcoholic beverages are consumed, it [should] be done in moderation.		If you drink alcohol, do so in moderation.		
Salt-cured and smoked foods		The consumption of food preserved by salt-curing including salt-pickling or smoking [should] be minimized.				

[a]Blank spaces on this chart indicate the report made no specific recommendation on the dietary component. The report's text may discuss the dietary components and not make recommendations. Not all dietary components are within each report's scope. For example, recommendations on sugar were not made by either Diet, Nutrition, and Cancer or the American Heart Association because sugar has not been linked to cancer or heart disease.

[b]The 1978 guidelines were used because Toward Healthful Diets was compared with the 1978 guidelines.

[c]Complex carbohydrates are primarily starches.

[d]Naturally occurring sugar is sugar which is found in foods such as fruits and vegetables.

Source:

Toward Healthful Diets - prepared by the Food and Nutrition Board of the National Academy of Sciences, 1980.

Diet, Nutrition, and Cancer - prepared by a National Academy of Sciences Committee on Diet, Nutrition, and Cancer, 1982.

Healthy People. The Surgeon General's Report on Health Promotion and Disease Prevention. - prepared by the Department of Health, Education and Welfare, 1979.

Dietary Guidelines for Americans - prepared by the Departments of Agriculture and Health, Education and Welfare, 1980. Full title - Nutrition and Your Health--Dietary Guidelines for Americans.

Dietary Goals - prepared by the Senate Select Committee on Nutrition and Human Needs, 1977. Full title - Dietary Goals for the United States. Information from the second edition (December 1977) was used.

American Heart Association - prepared by the Committee on Nutrition, 1978.

APPENDIX III

NATIONAL ACADEMY OF SCIENCES

2101 CONSTITUTION AVENUE WASHINGTON, D.C. 20418

OFFICE OF THE PRESIDENT

May 10, 1984

Mr. J. Dexter Peach
Director
Resources, Community, and Economic
Development Division
United States General Accounting Office
Washington, D. C. 20548

Dear Mr. Peach:

This is a response to the invitation afforded by your letter of March 14, to review and comment upon the General Accounting Office's draft report entitled, National Academy of Sciences' Reports on Diet and Health -- Are They Credible and Consistent? It is my understanding that similar requests for views have been addressed separately to individual members of the two study committees involved in the preparation of the reports in question, Towards Healthful Diets (1980) and Diet, Nutrition, and Cancer (1982).

Our comments on the wording of the draft report are minor in nature and have been provided separately to your staff. Since this report will come to the attention of officials in both the Congress and the Administration, the Academy's unique role as a quasi-public advisory body and how it assures the validity and credibility of National Research Council reports should be made clear. In this regard, your draft report provides an objective commentary on the Academy's processes that govern the provision of advice to the government under its charter on scientific and technical issues.

The draft provides, in our view, a balanced discussion of the nature of the controversies and issues raised by these two National Research Council studies. I especially welcome the recognition in your review that legitimate and valid differences in judgment may exist among scientists in their interpretation of scientific evidence. As you indicate, these

Mr. J. Dexter Peach
May 10, 1984
Page 2

disagreements are often hard to communicate clearly to the public which feels more comfortable with categoric answers to questions about such issues as diet and health.

The National Research Council, the operating arm of the National Academy of Sciences and the National Academy of Engineering, releases about 300 study reports each year, many involving major public policy issues. We are constantly seeking ways to improve the conveyance of scientific information in these study reports to the public. Thus your observation on changes that we might consider to facilitate the provision of advice and information to the government and the American public are especially useful and will be given careful study.

I should like to comment briefly upon your suggestions on ways in which the public release of our reports are handled. We have found that it is often appropriate, in a news release, to provide specific examples for illustrative purposes. If an example is not directly derived from the study, your suggestion is well taken that it might be useful to make that point clearer in the release. We recognize that there is room for improvement in the process of preparing news releases in order that a clear summary of a report's findings and recommendations reaches the public. We have and will continue to address these issues in discussions among National Research Council officials. Coupled with the uses of the news release is the equally important need for insuring that from the beginning of a study committee members recognize and understand <u>how</u> their report will be used and <u>who</u> will be the report's ultimate audience.

We appreciate your reiteration of the need for National Research Council study committees to clearly set forth how and on what basis they reached their conclusions and recommendations. This objective has been a central theme of the Academies' Report Review Committee.

Mr. J. Dexter Peach
May 10, 1984
Page 3

You also suggest that apparent discrepancies between studies on related topics might for clarification be noted in the letter of transmittal. As a general rule, we have found that use of the transmittal letter as a substantive commentary on the report should be done sparingly and with care. Contextual differences between reports and their covering transmittal letters can be confusing to the public reader. Perhaps where differences in studies are sufficiently pronounced as to require explanation, this point could be noted in the transmittal letter. While each committee is accountable for the substantive content of its report, the institution also has a responsibility for assuring that reports are as accurate as possible and that each committee has taken account of differences in judgment within the scientific community as exhibited in other scientific reports and papers.

As public debate on questions of diet and health continues, and as further public statements are forthcoming from within and outside the government on this subject, it is important that the public have confidence that recommendations on diet are based upon sound underlying scientific evidence and draw upon the judgments of the nation's best scientists. We believe that the National Academy of Sciences has an important role in building such public confidence. From that vantage point, your comparative review of these two National Research Council reports should be helpful in conveying this confidence to the public reader.

In conclusion, I express again appreciation for the opportunity afforded us to comment upon your draft report. We also were pleased to be of assistance to your staff throughout their review.

Yours sincerely,

Frank Press

Frank Press
President

[GAO NOTE: NAS' suggested changes in the report's wording, furnished separately, were incorporated where appropriate in the report.]

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

APR 18 1984

Mr. Richard L. Fogel
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Fogel:

The Secretary asked that I respond to your request for the Department's comments on your draft report "National Academy of Sciences' Reports on Diet and Health--Are They Credible and Consistent?" The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Richard P. Kusserow
Inspector General

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GENERAL ACCOUNTING OFFICE'S DRAFT REPORT "NATIONAL ACADEMY OF SCIENCES' REPORTS ON DIET AND HEALTH--ARE THEY CREDIBLE AND CONSISTENT?"

General Comments

The General Accounting Office (GAO) draft report presents a reasonable review of the issues related to real or perceived differences between the two National Academy of Sciences reports: Toward Healthful Diets and Diet, Nutrition and Cancer.

The following technical comments on the draft report were provided by members of the HHS Nutrition Policy Board and other HHS officials to whom it was distributed.

Technical Comments

[GAO NOTE: The agency's "Technical Comments" have been deleted and suggested changes have been incorporated in the report except as discussed on p. 29 and p. 49.]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date APR 6 1984

From Director
Center for Food Safety
and Applied Nutrition (HFF-1)

Subject GAO Draft of a Proposed Report on the National Academy of Sciences' (NAS) Reports on Diet and Health

To J.M. McGinnis, M.D.
Deputy Assistant Secretary for Health
(Disease Prevention and Health Promotion)

This GAO document accurately describes the processes used by the NAS to produce the two reports, Toward Healthful Diets (1980) and Diet, Nutrition, and Cancer (1982), and objectively explains the reasons for apparent differences in some of their conclusions about the relationship of diet to health and their dietary recommendations for the public. The document concludes that the dietary recommendations of the two NAS documents are more similar than they are different, and that the differences are related primarily to disagreement in scientist's philosophies about what scientific evidence is sufficient for providing dietary advice to the public. The report prudently avoids both the evaluation of the scientific methodologies used in developing the reports and the assessment of the validity of their dietary recommendations.

The draft is generally well prepared, but needs some technical revisions. The following are major points, and other minor technical revisions are listed on the attachment.

On page 2, paragraph 3, the draft indicates that the Food and Nutrition Board wrote Toward Healthful Diets "to combat food fads." However, the Board states very clearly in the introduction to this publication that its concern was related to "the flood of dietary recommendations currently being made to the American public in the hope that a variety of chronic degenerative diseases may be prevented in some persons." Although dietary fads could be a fall-out if dietary guidelines were not prudently presented to the public, food fads are not mentioned as being the purpose of the publication and this statement would be subject to criticism unless reworded.

On page 31, the draft states that the Food and Nutrition Board did not make a recommendation in the fat/cholesterol area because "it had not been proven that lowering dietary cholesterol will reduce the level of cholesterol in the blood." In their publication, the Board acknowledged that dietary

J.M. McGinnis, M.D.
Deputy Assistant Secretary for Health
(Disease Prevention and Health Promotion)

-2

cholesterol can have some effect on lowering cholesterol blood levels; its major concern was that the assumption had not been adequately tested at that time that reducing high serum cholesterol levels will reduce the probability of cardiovascular disease (pc9).

Sanford A. Miller, Ph.D.

Attachment

cc: Lois Adams (HFA-10)

[GAO NOTE: The page numbers in FDA's comments have been changed to reflect those in the final report. On p. 2 of the report, the report's wording has been revised to accurately reflect the FNB's objectives in preparing Toward Healthful Diets, and on p. 31, the report was revised and a footnote was added to make the discussion about FNB's views on dietary cholesterol accurate and clear. The agency's "Additional Technical Comments" have been deleted and suggested changes to the report made where appropriate.]

United States
Department of
Agriculture

Human Nutrition
Information
Service

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APR 1 9 1984

Mr. J. Dexter Peach, Director
Resources, Community and Economic Development Division
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Peach:

Agencies of the U.S. Department of Agriculture (USDA) that are most concerned with diet and health matters have reviewed the proposed draft report entitled, "National Academy of Sciences' Reports on Diet and Health--Are They Credible and Consistent?"

General Comments:

The report appears to provide the information requested and makes useful suggestions for changes in reporting that the National Academy of Sciences (NAS) might implement or continue to aid public understanding.

USDA agrees with the Academy official's statement that "in areas where complex scientific questions remain to be answered, two groups of scientists could review the same scientific data and come to different but supportable conclusions." Such differences can be better understood in reports that set forth procedures used in arriving at conclusions and clearly differentiate between scientific fact and judgement. Reports on topics of great public interest, such as those on diet and health, might discuss disagreements on the conclusiveness of the evidence among committee members, if such disagreements exist. USDA agrees that the Academy should continue to emphasize these reporting needs to its committees.

It does not appear that the two committees of the National Academy of Sciences had differences in summarizing the scientific knowledge relevant to the topic reports. Rather, they differed as they attempted to suggest policy guidelines from an uncertain science base. Such differences might be expected. One approach that might minimize misinterpretation in future instances such as this follows: The National Academy of Sciences might be asked to describe and summarize the extent and boundaries of scientific knowledge which relate to a specific problem, but the task of developing national policy might be left to the appropriate responsible governmental agency.

[GAO NOTE: These comments are discussed on p. 49 of the report.]

Specific comments:

1. Page iii. The GAO report points out that the "press releases contained examples of foods which were not mentioned in the reports." On page iii, GAO recommends that in the future, press releases make clear that the foods are "given for illustrative purposes." It would appear that if such releases are to be issued, a further step should be recommended--that the chairman of the study group should review the press release to assure that it is truthful and not misleading.

[GAO NOTE: The page numbers in USDA's comments have been changed to reflect those in the final report. This comment is discussed on p. 29, where we indicate NAS procedures provide for review of press releases for technical accuracy.]

2. Page 19, paragraph 6. "The committee believed that these individuals (nutrition professionals, government policymakers, etc.) would translate it (the report) for the public as they saw fit..." This seems to be part of the problem; since different groups interpreted the summary in different ways, and chose different foods to use "for illustrative purposes." In this instance, there appeared to be more controversy about the findings than might have occurred if a short statement had been written for the general public by the study group.

[GAO NOTE: The Diet, Nutrition, and Cancer executive summary was intended for public readers, and was prepared by the study group.]

3. Page 20, paragraph 2. The comment that the Executive Summary's statements about committee conclusions almost exactly repeat the language found in other sections of the report may be true. However, the Executive Summary, through what was not picked up from the main body of the report, loses much of the tentativeness in which the main report's findings are couched. While the committee may have intended that the summary not stand alone, unfortunately many busy readers have not and will not read the whole report. USDA recommends that the flavor of the main report, as well as its findings, should be clear from the Executive Summary.

[GAO NOTE: This comment is discussed on p. 29, where we indicate the executive summary underwent standard NAS report review.]

4. Page 24, paragraph 6. Draft press releases are sent to the "ad hoc committee staff for technical review." What is the ad hoc committee staff? Is this the same group that prepared the report, or some other committee?

5. Page 38, paragraph 3. The second report title should be Dietary Goals not Dietary Guidelines. Otherwise, the USDA/DHHS report is listed twice.

6. Page 65, footnote C. Complex carbohydrates include starch, as well as fiber, pectin and oligosaccharides.

7. Page 65, footnote D. Probably should specify "unprocessed" fruits and vegetables. If processed fruits are packed with sugar, added sugar is not "naturally-occurring." Also, milk and some other dairy products contain the sugar lactose.

8. Page 63. The brief statement on USDA's review of Diet, Nutrition and Cancer implies that USDA proposed an alternate interim guideline of 35 percent of calories from fat. This is not correct. USDA cited its difficulty in developing diets at suggested energy levels, made up of commonly used foods that provide recommended levels of vitamins and minerals and 30 percent of calories from fat at suggested total calorie levels. Because of this USDA proposes to develop dietary guidance materials at fat levels up to 35 percent of calories.

Sincerely,

Isabel Wolf

ISABEL D. WOLF
Administrator

[GAO NOTE: Changes and additions to the report were made in response to specific technical comments where appropriate.]

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April 18, 1984

Mr. J. Dexter Peach
Resources, Community, and
Economic Development Division
United States General Accounting Office
Washington, D. C. 20548

Dear Mr. Peach:

I have enclosed my comments on the GAO report on the NRC/NAS reports on diet and health.

Judging from the parts of the report with which I am familiar, it provides a clear and basically accurate picture of the information provided to the GAO about the background and development of the two reports. It raises a number of pertinent questions about controversies over relationships among diet, nutrition and health and disease that deserve consideration by scientific organizations and policy makers.

Despite the care that has been exercised in assembling and presenting the material, there are a number of places, listed below as specific comments, in which some changes in wording or phraseology would, in my judgment, increase accuracy or improve understanding of the report and the issues raised in it.

Some of the issues raised by the report should, I believe, be given greater emphasis. These are the subject of the general comments below. They have implications broadly for public policy that is based on scientific knowledge. There is a tendency in this country toward viewing the scientist as a magician who, in some obscure and little-understood way, provides simple solutions for highly complex problems. This is particularly true in relation to problems of health and disease. It raises unrealistic expectations and, sometimes, leads to irrational public policies. It seems to me incumbent upon scientists in the National Academy and in various professional scientific societies to assume responsibility for providing the public and policy makers with information about the methods of scientific inquiry, the strengths and the limitations of the process, and the problems that must be faced when scientific knowledge is used as the basis for public policy. The controversies raised by the two NRC reports discussed in this GAO report have focused

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attention on these problems. It would not seem to me out of place for the GAO to emphasize forcefully the need for the Academy, in particular, and for scientists, in general, to give these problems the attention they deserve.

Sincerely yours,

A. E. Harper

Enclosure

AEH:ck

[GAO NOTE: The page numbers in the "General Comments" have been changed to reflect those in the final report. Dr. Harper's "Specific Comments" have been deleted but suggested changes or additions to the report have been made where appropriate.]

COMMENTS ON GAO REPORT ON NRC/NAS REPORTS ON DIET AND HEALTH

A. E Harper

General Comments

The major issue that is responsible for controversy over reports on diet and health is raised in paragraph 2 of the cover summary, in the last sentence of paragraph 2 on p. ii, and in the section beginning just below the middle of p. iv and continuing through to p. v. It is "What type of evidence should be required before advice on the relationship between diet and health [or disease] is offered to the public?" The GAO reports seems not to confront this issue directly.

The issue is not strictly a scientific issue; it is a public policy issue. Resolution of such issues depends upon judgement as to the strength of the scientific evidence required before taking an action. There would appear to be little difference in viewpoint between the two committees whose reports serve as examples in the GAO report regarding the strength of the scientific evidence. The Diet, Nutrition and Cancer Committee states on p. 1-1 "...it is not yet possible to make firm scientific pronouncements about the association between diet and cancer." The Food and Nutrition Board declined to make specific recommendations for this reason. It is clear that the issue is one of judgement: to recommend or not to recommend when the evidence is not firm.

I feel that this problem should be brought to the fore and faced squarely. It is essentially the problem that faces any jury. How strong must the evidence be before an action is taken? Must the evidence be incontrovertible? Can it be circumstantial? If it is circumstantial, does a single doubt about its consistency make it inadequate? Some of these points are brought out in the section following p. 38, but I find myself left with the impression that

the viewpoints of the two Committees are considered equally valid because there are no guidelines. Therefore, there is little to be done other than ask committees to explain the basis for their conclusions, or ask the Academy President to state what evidence is sufficient. A judge is expected to explain this to a jury, but he/she does it, not from personal belief, but from knowledge of long-standing legal tradition based on debates, discussions and analyses of the nature of evidence over the years.

I should, therefore, like to see a recommendation included in the GAO report requesting that the Academy be asked to convene a broadly based committee to consider the question of developing guidelines for determining when scientific evidence is adequate to serve as the basis for establishing public policy. Such a committee should be asked to deal specifically with the question of the importance of being able to predict accurately the outcome of a public policy recommendation.

[GAO NOTE: This comment is discussed on p. 49 where we indicate that views exist on both sides of the question about whether guidelines for public recommendations are feasible or needed. NAS may wish to consider Dr. Harper's suggestion in that context.]

The second general comment has to do with the appropriateness of the National Academy accepting contracts that require recommendations for the public on controversial issues. Should the Academy not be asked to review this question? The Academy, the NRC and its Committees are appropriate bodies for doing analyses of questions but the analysis, it seems to me, should determine whether recommendations are appropriate, not the grantor.

[GAO NOTE: As discussed on p. 19, the Diet, Nutrition, and Cancer committee members interviewed by us indicated that they would not have developed guidelines had they not believed the scientific evidence warranted them.]

Thirdly, I am concerned about the procedures used by the Academy in developing reports. It is evident from the description of the procedure in the GAO report that the Diet, Nutrition and Cancer report was in large measure a staff report rather than a Committee report. The literature searches, preliminary analyses of research studies and preparation of background papers on scientific issues were done by staff. The staff "selected 1,874 studies that would form the basis of committee conclusions." There can be little doubt that staff input was substantial. This raises a question about the appropriateness of Academy procedures for contracted reports. The role of staff in the preparation of reports should be examined critically by the Academy and the NRC.

[GAO NOTE: Dr. Harper's comment refers to a discussion on p. 18 which in the draft report contained misleading information about the role of NAS staff in supporting the Diet, Nutrition and Cancer Committee. This section has been revised to reflect accurate information provided by NAS staff and Diet, Nutrition, and Cancer Committee members in their written and oral comments on the draft report.]

Fourthly, it seems to me that the differences between the conclusions of the Diet, Nutrition and Cancer report and the Toward Healthful Diets are not brought out clearly. In more than one place there are statements to the effect that the reports were written for different purposes, etc. (p. iii), but subsequently the similarity of the two reports is emphasized. This is inconsistent. The recommendations of the Diet, Nutrition and Cancer report were directed specifically toward cancer prevention and did not include recommendations for maintenance of health by healthy people. Some parts of the recommendations in this report overlapped inadvertently with some of those in Toward Healthful Diets, but none of the recommendations in Toward Healthful Diets was directed toward disease prevention. There is thus a basic disagreement in the two sets of recommendations. It seems to me that this difference should be emphasized.

[GAO NOTE: We believe the NAS reports' differences are adequately brought out in the report.]

Fifthly, in view of the paragraph at the bottom of p. 3-14 of the Diet, Nutrition and Cancer report, indicating that the Committee did not present critical reviews of the research it cited and did not want to place too much emphasis on the results of the individual studies it reviewed, it is difficult to accept the view that the report represents a critical review, rather than a compilation, of the literature on the subject.

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C. Wayne Callaway, M.D.
Endocrinology
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April 18, 1984

J. Dexter Peach, Director
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Development Division
Food Coordination and Analysis Staff
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441 G Street, NW
Washington, DC 20548

Dear Mr. Peach:

Thank you for sharing with me the draft of the proposed report on the National Academy of Sciences' Reports on Diet and Health -- Are They Credible and Consistent?

I think that the GAO staff has done a commendable job in responding to the charge given GAO by various members of congress. As the draft points out, the two reports in question were prepared by different groups, with different philosophies, for different purposes, at different times, and with vastly different resources. In any scientific area that is "alive and well", one can expect legitimate differences of opinion. One of the tasks in assembling expert panels is to represent such differences appropriately. In general, the National Academy of Sciences has procedures which allow for this to occur. As noted in the GAO draft, several modificatoins in NAS procedures have been instituted, following the reaction to publication of Toward Healthful Diets. I think that these modifications are appropriate. I would, perhaps, go one step further and suggest that it is impossible to choose experts who are free from bias. Anyone sufficiently well informed will undoubtedly have drawn conclusions already as to how existing data should be interpreted. That being the case, it then becomes desirable to assure that the composition of expert panels accurately reflects the range of legitimate scientific opinion on any given subject. This is an ideal that is rarely (if ever) achieved -- but it is one that should be explicit in the selection of expert panels.

Although I can well sympathize with the desire for consistency in dietary advice, I would agree fully with the conclusion that consistency with previous reports should not be one of the criteria for evaluating the future reports from the NAS. The steps that are proposed are constructive ones, namely, review of new reports for obvious inconsistencies and attempting to address such inconsistencies directly when new recommendations appear. This would probably help clarify the significance of any new report and reduce the tendency to present it in an adversarial manner.

Although I respect the reasons why the NAS declined to permit review of internal documents concerning committee members' potential conflicts of interest and reviewers' comments regarding both reports, I think that the absence of direct review represents a major limitation in the GAO draft. It would seem to me that appropriate levels of confidentiality could be maintained by deleting the names of the individual panel members and reviewers, while still allowing GAO access to information needed in order to determine whether or not NAS procedures were followed. As it stands, the GAO draft simply reiterates the assurance provided by NAS that this was the case.

There is one major misrepresentation in the draft, a misrepresentation that was based upon the testimony of the former president of NAS during the congressional hearings referred to. On page 10, paragraph 1, it is stated that withdrawal of the USDA contract left the Food and Nutrition Board with no outside funds to conduct it's review of relationships among dietary factors and health. This statement is probably correct in regard to decisions made at the June 1978 FNB meeting. However, during the development of the draft for Toward Healthful Diets and prior to it's release, the FNB/NAS contracted with the National Institute of Arthritis, Metabolism, and Digestive Diseases to carry out a 3-year study on this very topic. Thus, the assertion that the FNB had no funds to do an adequate study or to publish a fully referenced document would seem to be incorrect. Given the existence of the NIH contract, one must wonder why the FNB proceeded to publish Toward Healthful Diets on it's own when it was already contracted to develop a more comprehensive publication during the next three years. The NIH contract was not mentioned during the two congressional hearings following publication of Toward Healthful Diets, and I do not know that rehashing the subject at this time will be of public benefit. Perhaps the simplest way to deal with this issue would be to delete the discussion of the USDA/NAS contract. As for the NIH/NAS contract, I understand that the NAS subsequently asked to be relieved of it's commitment and that the request was granted.

Again, may I commend you and your staff for the fairness, insight, and thoroughness reflected in this draft. I do hope that it will prove useful.

Respectfully yours,

C. Wayne Callaway

C. Wayne Callaway, M.D.
Director, Nutrition Consulting Services

CWC:rlc

[GAO NOTE: The page number in these comments has been changed to reflect that in the final report. According to the FNB Executive Secretary, the NIH/NAS contract referred to above does not bear the relationship to the Toward Healthful Diets study which Dr. Callaway imputes to it. The report's discussion of the USDA/NAS contract was not changed to respond to this comment.]

University of Pittsburgh

SCHOOL OF MEDICINE
Department of Biochemistry

April 17, 1984

Ms Janet Lowden
Resources, Community, and Economic
Development Division
United States General Accounting Office
Washington, DC 20548

Dear Janet:

I am responding to the letter sent to me by the Director of your Division, Dr. J. Dexter Peach, asking me to review the draft of a proposed report entitled "National Academy of Sciences' Reports on Diet and Health -- Are They Credible and Consistent? and send comments.

I gave you some comments over the telephone last week and I am writing this letter to expand on some of the points that we could not cover adequately by telephone.

[GAO NOTE: The page numbers in the following comments have been changed to reflect those in the final report.]

Page iii ". . . the dietary advice provided by both reports is similar." As I indicated on the telephone I think dietary advice is not similar. It is true that both reports urged variety and moderation but Diet, Nutrition and Cancer recommended avoidance of fat and smoked foods. Furthermore, the basic four food groups are not emphasized in the "Diet, Nutrition and Cancer" report.

[GAO NOTE: The discussions in the report about the NAS reports' dietary advice has been changed to reflect that both urged variety and moderation in diet.]

Page v. It is not fair to say "GAO noted that reasons why the Food and Nutrition Board arrived at its conclusions about diet's relationship to chronic diseases was not fully discussed in the 24-page 1980 report." In fact, it is quite extensively discussed with respect to cancer. The report stated on page 14, "the Board believes that in the absence of evidence of a causal relationship between the macronutrients of the diet and cancer there is no basis for making recommendation to modify the proportions of these macronutrients in the American diet at this time." Again on page 17 of the 1980 report, under "Decision Making and Public Health," the FNB said, "In the case of diseases with multiple and poorly understood etiology, such as cancer and cardiovascular disease, the assumption that dietary change will be effective as a preventive measure is controversial."

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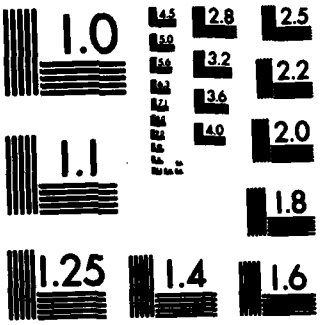

MICROCOPY RESOLUTION TEST CHART

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[GAO NOTE: The report's digest was revised to clarify that FNB did not fully document how and on what basis it arrived at its conclusions and recommendations.]

Glossary. The definition of Epidemiology is a little misleading because it talks about determinants of disease. I think it should read, "Epidemiology is that branch of medical science which uses statistical and experimental techniques to measure and analyze the incidence, prevalence, and the association of host and environmental factors with disease in human population." Epidemiology can not, of itself, prove cause and effect. Please see Hill, A.B., "The Environment and Diseases Association or Causation," Proc. Roy. Soc. Med. 58, 295-300, 1965.

[GAO NOTE: The primary source of our definition of epidemiology is T. Colton and E. R. Greenburg, "Cancer Epidemiology," in Statistics in Medical Research: Methods and Issues, With Applications in Cancer Research (New York: John Wiley and Sons, 1982). Whether or not epidemiology can show cause and effect is a disputed point, and some scientists believe there are conditions under which epidemiology can show cause and effect. In discussions with Dr. Olson, we determined that he was referring in his comment to observational epidemiology, not to experimental epidemiology.]

Under Nutrition I suggest the definition, "Nutrition is a science of food and its relationship to health. It includes a study of the processes by which an organism utilizes the chemical components of food ....."

Recommended Dietary Allowances. Although the 9th Edition of the RDAs gives the definition that you have given, it is misleading and should be changed. The RDAs are not average daily amounts of nutrients, they are amounts that exceed the average requirement and are designed to cover 97% of a healthy population. I suggest it read, "The RDA are daily amounts of nutrients recommended to meet the known nutritional needs of practically all healthy people. The RDA thus exceeds the requirement for most healthy people."

Page 2. Note again the definition of Nutrition as defined above.

Page 2. ". . . differ in their need for food due to factors like age, heredity, and . . . ."

Page 14. "During a June 1978 meeting, FNB established the initial six-person task force ...." As I pointed out to you, the original task force was Garth Hanson of Utah State University, Chairman, with the membership being Alfin-Slater, Harrison, Kritchevsky, Olson, and Rosenberg, which was altered about six months later to elevate me to chairman in place of Hanson and to add Harper to the list. The final task force was Olson, Chairman, Alfin-Slater, Harper, Harrison, Kritchevsky, and Rosenberg.

Page 17. "The FNB was directing its report to scientists as well as health care personnel, dietitians, USDA extension agents, and academicians, but it was using a format similar to the RDAs, which in the 9th Edition in 1980 contained a much smaller bibliography than the total papers reviewed. It was written in a style, furthermore, that was clearly scientific but not pedantic.

Page 18. Did the staff or the Committee select the 1,874 papers for review? I consider it a great weakness of the report if the Committee did not personally, as working scientists, select the papers for review. In the FNB report, all papers for review were selected and critiqued by the task force.

[GAO NOTE: This comment refers to a discussion on p. 18 of the report which in the draft report contained misleading information about the role of NAS staff regarding the Diet, Nutrition, and Cancer Committee. The discussion was revised for accuracy on the basis of written and oral comments from NAS staff and Diet, Nutrition, and Cancer Committee Members.]

Page 33. It is not true that Toward Healthful Diets was written only for people who deal with the public in providing nutrition advice. It was also written for scientists as

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a concise summary of our state of knowledge about the relationship of diet to health.

Page 36. Again let me emphasize the point that the two diets do not offer similar dietary advice. They are similar in terms of basic recommendations about variety and moderation but not in terms of more specific recommendations about fat and smoked foods.

Page 40. The types of evidence cited as being used to provide information are too limited and inaccurate. It should read, "Types of evidence used to provide information to scientists on diet and health issues included clinical medicine, clinical investigation, both observational and experimental epidemiology (clinical trials), and laboratory studies including in vitro and in vivo studies in experimental animals and in bacteria. Clinical investigation, in contrast to epidemiology, involves a small number of human subjects who are intensively studied by the experimental method. Baseline observations are taken, an experimental variable interposed, changes are studied, and the individual returned to the baseline status. This can involve drugs, diets, exercise, and most any other experimental variable." It should also be listed in the next paragraph.

The idea that epidemiology allows scientists to study doses of substances which people are actually exposed to is not entirely accurate because it is very difficult to measure doses that free living Americans are exposed to, including drugs, toxins, pollutants, and dietary components. I think it is important to point out that epidemiologic studies can only determine associations between host and environmental variables and disease but cannot prove cause and effect. To that extent they are "not as carefully controlled as either clinical or animal experiments."

[GAO NOTE: In discussion with Dr. Olson, we agreed to revise the report on p. 41 by adding a footnote, and to include clinical investigations as part of the definition of laboratory tests in the glossary. We also revised the discussion about epidemiology to make it more accurate. However, Dr. Olson's objection about epidemiologic evidence refers to observational epidemiology but not to clinical intervention trials, which are part of experimental epidemiology. For that reason, we did not change our definition of epidemiologic studies.]

Page 41. "laboratory, clinical, and epidemiologic data."

Page 42. "cohort studies are incidence studies." A cohort is actually a group of individuals selected for study, but the Primer of Epidemiology by Gary Friedman (McGraw Hill, 1974) defines a cohort study as an incidence study. In other words you select a cohort of individuals, such as in Framingham, who are healthy at the time that you select them and then you follow them for a period of time in order to determine the appearance of new disease (incidence). Incidence measures the appearance of new disease, where prevalence measures the rate of existing disease.

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case-control studies are different from cohort studies. A case-control study is a study of cases which are selected for the presence of disease, matched to a group of controls similar in age, sex, occupation, and other pertinent characteristics, who do not have the disease. These two groups are then compared for a variable like smoking, coffee-drinking, or high-fat diets. Cohort studies, as indicated, are studies in which a cohort is selected and the appearance of new disease measured over a period of years. These are both so-called observational epidemiology. If you do experimental epidemiology you impose a variable.

If you take a cohort and divide it in two and give one-half of the total group a treatment and the other half not you are doing a clinical trial. For example, the recent Lipid Center Trial with cholestyramine is experimental epidemiology. In this case, 4000 type II heterozygous hyperlipidemics were selected. Half of them were given a placebo and half of them given the drug cholestyramine. After eight years the plasma cholesterol levels and disease incidence were compared in the two groups.

Page 43. "Both groups say that when the scientific evidence converges from laboratory tests, clinical investigations, and epidemiologic studies then the evidence is sufficient to make recommendations."

Page 44. The title should be The "probability of benefit" school or the "possibility of benefit" school as compared on page 45 to the "proof of benefit" school. This is essentially because both schools are looking at preventive medicine and evaluating the likelihood that a given treatment will prevent a disease.

Finally, I refer you to the recent report, "A Prospective on Diet, Nutrition, and Cancer" by Michael Pariza (Journal American Medical Association, 251, 1455-1458, March 16, 1984) which also compares the two reports of the subject of your GAO report. It takes up many of the issues that you have discussed in your report.

It was very nice working with you and talking with you and I look forward to seeing the final report.

Very sincerely yours,

Robert E. Olson, M.D., Ph.D.
Professor of Biochemistry
Professor of Medicine

REO:yh
Enclosure
cc: Dr. J. Dexter Peach

[GAO NOTE: Specific comments regarding the report's clarity and accuracy have been considered and changes made where appropriate to the report.]

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*U.S. GOVERNMENT PRINTING OFFICE : 1984 O-421-043/207

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