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Each year the Federal Government spends between $73 million and $117 million on human nutrition research. This represents about 3% of the $3 billion it spends annually on all research in agriculture and health. Several Federal departments and agencies support human nutrition research although no department or agency has human nutrition as its primary mission. Findings/Conclusions: Major knowledge gaps and related research needs have been classified into four broad and interrelated areas that are important for sound nutrition planning whether a nutrition program's target is an entire population, a population subgroup, or an individual. The areas include: human nutritional requirements; food composition and nutrient availability; diet, disease causation, and food safety; and food consumption and nutritional status. Research needs for responding to these knowledge gaps include: long-term studies of human subjects across the full range of both health and disease; comparative studies in populations of different geographic, cultural, and genetic backgrounds; basic investigation of the functions and interactions of dietary components; updated and expanded food composition data; and improved techniques for assessing long-term toxicological risks. The following barriers to nutrition research persist: lack of central focus and coordination, shortage of nutrition scientists, and uncertainty of Federal funds for extramural research. Recommendations: The Director, Office of Science and Technology Policy, should work with Federal agencies to further define areas of human nutrition research and make recommendations to the Director, Office of Management and Budget to: assign, where practicable, each area to a lead agency; eliminate unnecessary research that may exist among Federal agencies; and promote Government-wide human nutrition research planning, coordination, and reporting. (RRS)

5847

BY THE COMPTROLLER GENERAL

Report To The Congress

OF THE UNITED STATES

Federal Human Nutrition Research Needs A Coordinated Approach To Advance Nutrition Knowledge

The Federal Government spends from $73 to $117 million annually on human nutrition research--about 3 percent of the $3 billion it spends annually on all agriculture and health research.

Several Federal departments and agencies support human nutrition research. However, comprehensive, consolidated information on Federal human nutrition research activities is limited, and some barriers to human nutrition research persist. GAO recommends steps for the executive branch to help overcome these barriers.

Information needs to be developed concerning

--human nutrition requirements;

--food composition and nutrient biological availability;

--diet, disease causation, and food safety; and

--food consumption and nutritional status.

UNITED STATES GENERAL ACCOUNTING OFFICE

Volume I

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MARCH 28, 1978

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

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To the President of the Senate and the
Speaker of the House of Representatives

This report identifies major human nutrition research gaps and describes Federal nutrition research activities. We are issuing a second volume with it containing statements of experts that were used as part of the review.

We made our review pursuant to a March 11, 1976, request by the Chairman of the Senate Select Committee on Nutrition and Human Needs.

We are sending copies of this report to the Acting Director, Office of Management and Budget; the Director, Office of Science and Technology Policy; the Secretaries of Health, Education, and Welfare and Agriculture; and the heads of the other departments and agencies mentioned in the report.

Elmer B. Staats
Comptroller General
of the United States

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

FEDERAL HUMAN NUTRITION RESEARCH NEEDS A COORDINATED APPROACH TO ADVANCE NUTRITION KNOWLEDGE

D I G E S T

Information in this two-volume report should aid the Congress in evaluating the direction and emphasis of Federal human nutrition research.

The Congress should determine whether the recent initiatives of the Office of Science and Technology Policy and the Office of Management and Budget and the implementation of the Food and Agriculture Act of 1977 will result in the focus, direction, and coordination needed for this important work.

The U.S. Government spends between $73 and $117 million annually on human nutrition research--about 3 percent of the $3 billion it spends annually on all agriculture and health research. Comprehensive, consolidated information on Federal human nutrition research activities is lacking; no department or agency has human nutrition as its primary mission.

Hearings of the Senate Select Committee on Nutrition and Human Needs demonstrated the importance of nutrition in public health and diet potential in health care and showed that substantial knowledge remains to be developed before the full benefits of human nutrition can be realized. (See p. 1.)

Noting that advancement in nutrition research is fundamental to improving human health, the Senate Select Committee on Nutrition and Human Needs asked GAO to examine and report on human nutrition research gaps and needs and on changes needed to facilitate progress. (See p. 121.)

RESEARCH GAPS AND NEEDS

On the basis of opinions and observations of 32 persons in the nutrition field (See vol. II), Federal officials and researchers, and studies on nutrition research and manpower needs, GAO found the following gaps in human nutrition research:

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--Knowledge of dietary nutrients required to promote or maintain growth, development, or well-being under various stages and conditions of life. (See pp. 7 to 17.)

--Information on the composition of the current U.S. food supply and the extent that nutrients are biologically available. (See pp. 18 to 20.)

--Evaluation of long-term health consequences of the modern diet. (See pp. 21 to 29.)

--Assessment of the Nation's current nutritional status in terms of dietary excesses, imbalances, as well as deficiencies. (See pp. 30 to 35.)

Among the research needs GAO cites for responding to the knowledge gaps are:

--Long-term studies of human subjects across the full range of both health and disease. (See pp. 14 to 15.)

--Comparative studies in populations of different geographic, cultural, and genetic backgrounds. (See pp. 14 to 15.)

--Basic investigation of the functions and interactions of dietary components. (See pp. 15 to 17.)

--Updated and expanded food composition data (See pp. 18 to 20.)

--Improved techniques for assessing long-term toxicological risks. (See pp. 27 to 29.)

ORGANIZATION AND COORDINATION OF HUMAN NUTRITION RESEARCH

The two principal Federal agencies that support human nutrition research are the Agricultural Research Service (Department of Agriculture) and the National Institutes of Health (Department of Health, Education, and Welfare). The Agricultural Research Service is concerned primarily with food and nutrient needs of normal, healthy people. The National Insti-

tutes of Health focuses on nutritional needs of specific age groups and the prevention and treatment of disease through diet.

Although these and other Federal agencies are supporting research addressing critical gaps in nutrition knowledge (see ch. 3), the following barriers to human nutrition research persist:

--Lack of central focus and coordination.

--Shortage of nutrition scientists.

--Uncertainty of Federal funds for extramural research.

Several persons perceived fragmentation of human nutrition research among Federal agencies as a likely reason why some areas are not receiving adequate research. They called for greater coordination of human nutrition research programs to avoid overlapping and redundant work. (See p. 60.) For example, the separation of the national food consumption survey (Department of Agriculture) from the nutritional health status surveys (Department of Health, Education, and Welfare) is seen to result in information that is inadequate for sound nutrition planning. (See p. 61.)

The National Institutes of Health supports research on carbohydrates, lipids, vitamins, minerals, and protein, while the Agricultural Research Service has separate laboratories for research on the same nutrients. Other examples include studies of obesity, nutrient availability, food fortification, and dietary fiber.

Many scientists and research administrators believe that there is a shortage of capable scientists working in the nutrition field. (See p. 63.) For instance, clinical nutrition research needs individuals trained in health-related areas of nutrition, and there is a shortage of nutritionists with the background and experience to teach at universities and medical schools.

Several persons expressed concern over the uncertainty of Federal funds for extramural research. (See p. 64.) Some mentioned establishing regional nutrition research centers or laboratories possibly working in conjunction with selected universities and colleges. These centers could serve as vehicles for cooperatively funded projects among Federal agencies and could be used for long-term research programs, including nutritional monitoring of regional population groups. (See pp. 65.)

Action is needed to:

--Establish a central focus for human nutrition research planning and coordinate research programs Government-wide.

--Define areas of human nutrition research and the roles of agencies involved.

--Assess the need for regional research centers working with colleges and universities that have comprehensive nutrition departments and programs.

RECOMMENDATION

The Director, Office of Science and Technology Policy, should work with the Federal agencies to further define areas of human nutrition research and make recommendations to the Director, Office of Management and Budget, to:

--Assign, where practicable, each area to a lead Federal agency.

--Eliminate unnecessary research that may exist among Federal agencies.

--Promote Government-wide human nutrition research planning, coordination, and reporting.

The Secretary of Agriculture, in assessing the need for regional food and nutrition research centers, should consider access by colleges and universities with comprehensive nutrition departments and programs.

AGENCY COMMENTS

The Office of Science and Technology Policy said that implementing GAO's recommendations, together with its own, could make the Federal human nutrition research effort substantially more effective. HEW said the GAO report is a reasonable, accurate reflection of Federal human nutrition research activities.

The Department of Agriculture pointed out that the lack of a clear-cut definition of the scope of ongoing studies on human nutrition research has caused confusion. GAO agrees that until there is some consensus among the Federal agencies on the definition of human nutrition research, doubts will remain about the extent of Federal resources directed to this research effort.

The National Science Foundation, Veterans Administration, and others said that some overlap or duplication of nutrition research areas may be desirable, especially if it (1) results in complementary approaches to gaining knowledge, (2) verifies earlier research, and (3) stresses reliability.

The Office of Science and Technology Policy cautioned against recommending construction of major regional research centers, and the National Science Foundation believed these centers would prove difficult for outside researchers from other colleges and universities to use. The Office of Science and Technology Policy also said that if more funds are available or if funding is certain for long periods of time, more scientists may enter the nutrition research field. (See pp. 72 to 75 and apps. II to VII.)

Tear Sheet

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ABBREVIATIONS

HEW	Health, Education, and Welfare
DOD	Department of Defense
FAO/WHO	Food and Agricultural Organization/World Health Organization
GAO	General Accounting Office
HANES	Health and Nutrition Examination Survey
NIAMDD	National Institute of Arthritis, Metabolism, and Digestive Diseases
NICHD	National Institute of Child Health and Human Development
NIH	National Institutes of Health

OSTP	Office of Science and Technology Policy
RDAs	recommended dietary allowances
USDA	United States Department of Agriculture

GLOSSARY

amines	Chemicals that are breakdown products of proteins found naturally in many foods (wines, tea, fish, etc.) and synthetically in drugs (tranquilizers and analgesics).
anthropometric measurements	Dimensions of the human body (such as, height, weight, skinfold thickness) to determine differences in individuals and groups.
arteriosclerosis	A thickening and loss of elasticity of the artery walls.
atherosclerosis	A condition in which fatty deposits clog primarily the arteries that carry blood to the heart or brain. If this leads to formation of a clot and complete blockage of a vessel, a heart attack or stroke results.
beriberi	A disease caused by lack of vitamin B1 (thiamin) in the diet. It is characterized by nerve disorders, body swelling, etc.
biological availability of nutrients	The degree that a nutrient, once consumed, becomes available to and usable by the body.
carbohydrates	Energy-supplying nutrients. They help the body use fats efficiently and decrease the need for protein by furnishing energy so that protein is used for more important functions. They are provided by such foods as potatoes, bread, cereal grains, rice, fruits, and vegetables.
cholesterol	A lipid or fat-like substance manufactured by the body and also obtained from foods of animal origin. It is used to form hormones and vitamin D and is essential for good health. However, excess cholesterol in the blood may be deposited in the inner layers of the arteries and interfere with circulation.

dietary fiber	Often called roughage, fiber is the part of food that cannot be digested. It is a desirable part of a balanced diet because it stimulates the intestinal muscles for proper evacuation. It also promotes the growth of useful bacteria in the intestines.
enrichment	The addition of specific nutrients to a food as established by a Federal standard of identity and quality (for example, enriched bread).
fabrication	The development or manufacture of synthetic food or food substitutes, such as margarine, textured vegetable proteins, and cholesterol-free egg substitutes.
fats	Nutrients that provide the most concentrated source of energy (twice as much energy as carbohydrates or protein). Fats are also valuable because they carry certain vitamins and essential fatty acids.
fortification	The addition of specific nutrients to foods. The amount added is usually over that normally found in the food because it is important to provide additional amounts of the nutrients to the diet. Certain foods are fortified because they are good carriers for the nutrients; e.g., milk is frequently fortified with vitamin D.
hypertension	A disease signaled by an abnormally high blood pressure.
inborn error of metabolism	A genetically determined biochemical disorder that produces a metabolic block that may have disease consequences at birth or later in life.
kwashiorkor	A nutritional disease caused by a serious deficiency of protein despite an adequate intake of calories. It is characterized by emaciation, stunted growth, and underdeveloped muscles and is found predominantly

among impoverished children in developing countries.

lipids	A broad group of organic substances (fats and fat-like substances) that are easily stored in the body, serve as a fuel source, and are constituents of cell structure.
marasmus	A form of protein-calorie malnutrition, usually occurring in the first year of life, characterized by emaciation and extreme wasting.
metabolism	The entire operation of handling and using food and its nutrients in the body through the processes of digestion, absorption, and assimilation.
nitrosamines	Under certain conditions, nitrite and amines (present in food and drugs) interact to form nitrosamines that are carcinogenic (cancer-causing).
nutrients	Chemical substances in food that nourish the body. Nutrients are classified as carbohydrates, fats, proteins, vitamins, minerals, and water. They furnish energy, provide materials for building and maintaining body tissues, and supply substances that regulate body processes.
parenteral nutrition	The introduction of nutrients into the body by means other than the intestinal tract. One method is intravenous (directly into a vein) feeding by a liquid formula.
pellagra	A disease caused by a dietary deficiency of niacin and characterized by rough and irritated skin, chronic digestive disturbances, and mental disorders.
polyunsaturated fats	Contain fatty acids missing more than one pair of hydrogen atoms that tend to be of vegetable origin

	and liquid (for example, corn and safflower oils).
recommended dietary allowance (RDA)	Daily amounts of protein, vitamins, minerals, and calories judged to be adequate for maintenance of good nutrition for all healthy persons in the United States. These guidelines were established by the Food and Nutrition Board of the National Academy of Sciences--National Research Council in 1943 and have been revised several times since.
U.S. recommended daily allowance (USRDA)	A standard set of daily quantities of specified vitamins, minerals, and protein essential to human nutrition, derived by the Food and Drug Administration from the RDAs developed by the Food and Nutrition Board. USRDAs are a simpler set of values designed in 1973 for nutritional information labeling.
rickets	A disease, chiefly affecting children, characterized by softening and often bending of the bones. It is usually caused by a lack of vitamin D in the diet and insufficient exposure to sunlight.
saturated fats	Contain fatty acids that are saturated or filled with hydrogen atoms. Saturated fats tend to be of animal origin and solid at room temperature (such as, butter, cheeses, and meat fats).
scurvy	A disease caused by a deficiency of vitamin C (ascorbic acid) in the body, characterized by weakness, anemia, spongy gums, bleeding from the mucous membranes, etc.
synthesis	The artificial buildup of a chemical compound by the union of its elements or from other suitable starting material.

CHAPTER 1

INTRODUCTION

Recent estimates show that each year the Federal Government spends between $73 million (estimated for 1975 by the Congressional Research Service) and $117 million (estimated for 1977 by the Office of Science and Technology Policy) on human nutrition research. This represents about 3 percent of the $3 billion it spends annually on all research in agriculture and health. Several Federal departments and agencies support human nutrition research, although no department or agency has human nutrition as its primary mission.

Hearings of the Senate Select Committee on Nutrition and Human Needs 1/ demonstrated the importance of human nutrition in public health and the potential of diet in preventive health care. These hearings have also indicated that much more needs to be known before the benefits of human nutrition can be fully realized. The Committee asked us to examine and report on human nutrition research gaps and needs and on changes needed for progress.

A recent report by the Congressional Research Service 2/ found that the planning and conduct of human nutrition research is scattered throughout complex and diversified Federal organizations, none of which could provide comprehensive nutrition information. Although congressional interest in human nutrition is increasing, comprehensive, consolidated information for determining the focus and direction of Federal human nutrition research is lacking.

Traditionally, human nutrition research has been concerned with identifying essential nutrients, defining the role of nutrients in the human body, and preventing nutritional deficiency diseases. Good nutrition has been taken for granted if the individual gets the minimum recommended nutrients. Little attention has been given to factors

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1/ The Committee was abolished on December 31, 1977. Committee functions were transferred to the Subcommittee on Nutrition, Senate Agriculture, Nutrition, and Forestry Committee.

2/ "The Role of the Federal Government in Human Nutrition Research," Mar. 1976.

influencing an individual's eating patterns, what is eaten aside from particular nutrients, or the long-term health implications of dietary practices.

Today it is recognized that nutrition plays a vital role in health throughout life and that good nutrition is more than simply getting those nutrients considered essential. The major nutritional deficiency diseases have disappeared in the United States, and nutrition research has turned to more elusive pursuits, such as effects of diet on human intellect and lifespan. While identifying and characterizing specific nutrients is an important and incomplete task, the concept of malnutrition now includes food and nutrient excesses as well as deficiencies. As a consequence, human nutrition research has become complex and multidisciplinary, involving dietetics, biochemistry, physiology, medicine, microbiology, genetics, endocrinology, food technology, and agricultural science.

Three factors underscore the broadening scope of human nutrition in the United States. First, it is apparent that the best hope for achieving any significant extension of life expectancy lies in disease prevention. In the long run, the greatest benefits to human health are likely to arise from improving the health habits and environment of all Americans. Diet and nutrition is a major component of that environment. Second, the costs of health care and disease are a large and growing burden on the Nation's resources. Improving the American diet could help ease that burden. Third, an American public sensitive to health and nutrition is vulnerable to unsupported claims promoting various dietary substances and practices. As a matter of public health policy, consumers should be provided authoritative dietary guidance.

NUTRITION, LONGEVITY, AND PREVENTIVE HEALTH CARE

During the 20th century much progress has been made in extending Americans' average life expectancy. In 1900 the life expectancy at birth was 46.2 years for American men and 48.3 years for women. In 1974 those figures were 68.3 years and 75.9 years. This extension of average life expectancy came mainly through control of infectious diseases and, some experts believe, through improved maternal and preschool nutrition. Also, research on vitamins during the early part of this century led to virtual elimination of the classic nutritional deficiency diseases, such as beriberi, rickets, and pellagra. However, a host of other diseases remains, including heart disease, cancer, and stroke--the three leading

causes of death in the United States. Consequently, while the increase in life expectancy at birth has been dramatic since 1900, life expectancy at age 45 has increased less than 5 years for American men and less than 10 years for women.

Research evidence suggests that diet and nutrition may have a role in preventing disease and extending life. Dietary components have been linked to the development of atherosclerosis, the underlying cause of heart disease and stroke, and more than half of all cancers in women and at least one-third in men have been correlated to diet. Moreover, to date nutrition has been the only environmental factor to increase the life span of experimental animals. While the human environment is more complex than the controlled environment of test animals, nutrition nevertheless seems to be a key factor affecting human longevity.

On the basis of a study of health-related behaviors of 7,000 adults, Dr. Lester Breslow, Dean of the School of Public Health, University of California at Los Angeles, estimated that 11 years could be added to men's lives and 7 years to women's lives if they exercised regularly, maintained moderate weight, ate breakfast, did not snack between meals, avoided smoking, limited liquor consumption, and slept at least 7 hours a night. Of the seven health-promoting behaviors, four--maintaining moderate weight, eating breakfast, not snacking between meals, and limiting alcohol consumption--are related to nutrition.

COSTS OF HEALTH CARE AND DISEASE

National health care expenditures in 1976 were estimated to be $139 billion. This represents an average expenditure of $638 per person, a 13-percent increase over the estimated $564 spent in 1975. For the second year, health expenditures rose at a significantly greater rate than the gross national product. While the gross national product increased 18 percent from 1974 to 1976, health spending rose 31 percent.

While gauging potential savings attributable to preventive health measures is a rather subjective exercise, the Department of Health, Education, and Welfare (HEW) and the U.S. Department of Agriculture (USDA) estimated that improving the diet may substantially reduce health costs. HEW estimated that eliminating heart disease, cancer, and stroke in 1970 would have provided a gain of 383 million productive years of life. A 1971 USDA report estimated that more than $12 billion could be saved annually through improved diets.

Potential benefits from reducing heart and vascular disease alone was set at $6.3 billion annually.

PUBLIC AWARENESS OF NUTRITION

The public is concerned about nutrition, as shown by the controversy over dietary fiber. By one estimate, 600 articles and books have been published decrying the lack of fiber in the diet and linking it to a host of diseases from colon cancer to varicose veins. Today fiber-fortified products are being promoted as providing something extra, although no one fully understands what it is or what the long-term consequences of eating fiber might be. Nutrition science has yet to determine whether fiber should be classified as an essential part of diet; one writer suggested that roughage be named "vitamin R."

CHAPTER 2

MAJOR GAPS IN NUTRITION KNOWLEDGE AND RELATED RESEARCH NEEDS

The information presented on each major knowledge gap and research need represents opinions expressed by one or several sources. These sources include written comments received from 32 persons active in research, teaching, and clinical practice of nutrition; interviews with Federal officials responsible for nutrition research programs; and reports (such as the Report of the President's Biomedical Research Panel) that address nutrition knowledge gaps and research needs. Excerpts of the written comments are contained in volume II of this report.

A knowledge gap may be defined in broad or narrow terms. In this report, major gaps and research needs are defined broadly, although we also cite narrower issues in discussing each gap. While we recognize that health care delivery, nutrition education, and world malnutrition are highly important subjects, we have focused on major food and biomedical nutrition problems in the United States.

The major knowledge gaps and related research needs have been classified into four broad and interrelated areas (see table 1) that we believe are important for sound nutrition planning whether the nutrition program's target is an entire population, a population subgroup, or an individual. These areas include (1) human nutritional requirements, (2) food composition and nutrient availability, (3) diet, disease causation, and food safety, and (4) food consumption and nutritional status. The knowledge gaps and research needs within each area are discussed in the this chapter.

TABLE 1

MAJOR GAPS IN NUTRITION KNOWLEDGE AND RELATED RESEARCH NEEDS

Knowledge Gap	Research Need
Human nutritional requirements	
What are the dietary requirements for promoting or maintaining growth, development, or well-being at various stages of the life cycle and under various conditions, including pregnancy, infancy, and lactation; childhood and adolescence; women; the elderly; disease and stress; and drug and vitamin usage?	Conduct long-term studies of human subjects across the full range of both health and disease.
	Conduct comparative studies in populations of differing geographic, cultural, and genetic backgrounds.
	Conduct basic research of the functions and interactions of dietary components, particularly dietary fiber and trace mineral elements.
Food composition and nutrient availability	
What is the nutrient composition of the current U.S. food supply as consumed?	Update and expand available information on food composition.
To what extent are the nutrients in food biologically available for utilization in the body?	Develop improved methods to determine effects of food production, processing, and preparation techniques on food composition and nutrient availability.
	Conduct physiological studies on how the nutrients are used in the body.
Diet, disease causation, and food safety	
What are the long-term health consequences of the modern diet?	Determine the processes by which dietary excesses, deficiencies, and imbalances lead to development of diseases and disorders, especially obesity, heart disease, stroke, and cancer.
	Evaluate clinically the effects of dietary modifications undertaken as a disease prevention measure.
	Develop improved techniques for assessing long-term toxicological risks of dietary components.
Food consumption and nutritional status	
What is the current nutritional status of the Nation in relation to dietary excesses and imbalances as well as deficiencies?	Monitor continuously food consumption, nutritional status, and health states of representative population groups.
What is the effect of nutritional status at one period of life on subsequent periods?	Develop more reliable techniques to measure food intake and faster, readily reproducible methods to assess nutritional status.
	Identify the determinants of nutritional status.
	Determine the role of diet in the aging process.

CHAPTER 2 - PART 1

HUMAN NUTRITIONAL REQUIREMENTS

The human organism lacks the ability to manufacture a variety of chemical compounds needed for forming and maintaining body tissues and for carrying out other life-sustaining functions. These compounds, together with a number of mineral elements, are known as the essential nutrients because humans must obtain them preformed from the environment. At least 45 (possibly as many as 50) nutrients, including amino acids (the building blocks of body protein), vitamins, fatty acids, mineral elements, and water, are now recognized as essential to the human diet. In addition, the body needs a supply of energy, obtained primarily from fats and carbohydrates and measured in calories, to function normally. As long as the overall diet supplies all the essential nutrients, together with adequate calories, the human organism is capable of making the many additional compounds required for life. The essential nutrients are summarized in appendix I.

Although much information is available about the essential nutrients and calories, quantitative standards of human requirements are not well established in several population groups. Additional knowledge is needed on the nutrients required for promoting or maintaining growth, development, or well-being during pregnancy, infancy, and lactation, and during childhood and adolescence. More knowledge is also needed about the needs of women, the elderly, those with disease and stress, and those taking drugs and vitamins.

Filling the gaps in our knowledge of human nutritional requirements is important for developing more complete and specific standards used in planning nutrition programs and prescribing therapeutic diets.

USES AND LIMITATIONS OF CURRENT QUANTITATIVE NUTRITION STANDARDS

Two concepts--"minimum requirements" and "recommended allowances"--have been adopted in developing quantitative nutrition standards. A minimum requirement is defined as the lowest external supply of a nutrient needed to prevent a deficiency, as determined by clinical symptoms or other indicators of nutritional status. The calorie requirement adopted by the Food and Agricultural Organization/World Health Organization (FAO/WHO) is an average minimum requirement.

A recommended allowance is based on the defined minimum requirement adjusted for individual variation and a safety factor to cover the everyday stresses of life. This concept underlies the recommended dietary allowances (RDAs) developed by the National Academy of Sciences/National Research Council. RDAs are the levels of essential nutrients considered, on the basis of current scientific evidence, to be adequate to meet the known nutrient needs of almost every healthy person. RDAs provide for individual variations among most normal persons under usual environmental stress and represent upper intake limits considered appropriate for assuring nutritional adequacy of the U.S. population as a whole.

FAO/WHO standards represent assessments intended to meet the nutritional needs of people in all countries. RDAs serve as a guide for planning food intakes for domestic population groups, including those target groups of certain Federal assistance efforts such as the National School Lunch Program. RDAs also are the basis for the U.S. recommended daily allowances, the standards formulated by the Food and Drug Administration for food and vitamin labeling.

Neither FAO/WHO standards nor RDAs include all essential nutrients. FAO/WHO standards include assessments of needs for protein, 10 other essential nutrients, and calories. RDAs include allowances for protein; 16 other essential nutrients; and calories for infants, children, and males and females ages 11 years and older; as well as additional allowances for pregnant and lactating women.

A major limitation of RDAs and FAO/WHO standards is that they are based on data derived from small and possibly unrepresentative samples that have been extended to populations of all types. Estimated requirements for some nutrients are based on human studies that are usually brief (3 weeks or less), while estimates for other nutrients depend on data obtained in animal studies or judgments of adequate intakes based on the amounts consumed by well-nourished groups.

The appropriateness of quantitative standards has been questioned. For example, some experts believe the RDA for protein may be insufficient for long-term health, while others question whether RDAs may encourage nutrient overconsumption and lead to nutritional imbalances in those persons having requirements below the levels of recommended intakes. Due to the lack of good research data, quantitative standards are not well established for individuals at various stages of life or under certain conditions.

PREGNANCY, INFANCY, AND LACTATION

The United States lags behind most Western European nations in preventing infant deaths. A key factor is the high incidence in this country of low-birth-weight infants--babies born too small or too soon to survive. More than 230,000 babies (7.4 percent of annual U.S. births) are low-birth-weight infants. Low-birth-weight infants account for 70 percent of deaths occurring in the first month of life. The problem is particularly acute with teenage pregnancies.

Research has shown a connection between maternal malnutrition and low birth weight and has indicated the importance of adequate nutrition during fetal growth and development. The pregnancy period is particularly critical for fetal development of organ systems, mental capability, and probably the ability to withstand childhood diseases and disorders. Animal studies have shown that poor nutrition affects brain growth and leads to diminished learning capacity and behavior disorders. Evidence suggests this is also true in humans but that, to some extent, early effects of poor nutrition can be overcome by subsequent environmental enrichment that includes improved nutrition. Evidence also indicates that infant feeding patterns may lay the groundwork for obesity and other disorders later in life.

Issues relating to nutritional requirements in pregnancy and infancy needing investigation include

--severity of malnutrition during pregnancy that will cause fetal damage;

--relative significance during pregnancy of caloric deprivation versus protein deprivation in causing fetal damage;

--mechanisms by which specific nutrients are transported from the mother to the fetus;

--impact of infant feeding patterns on growth, development, health, disease, behavior, and intelligence; and

--effect on the fetus of nonnutrient substances, such as alcohol and other drugs taken by the mother.

An estimated 35 to 40 percent of American women breast feed their babies, yet nutritional requirements in lactation is a relatively new research area, and data are lacking for

nearly all dietary nutrients. Research areas for developing nutritional standards include the

--effect of nutrition on the composition and quantity of milk,

--mechanisms by which milk is produced and secreted and by which disease immunity is imparted to the infant, and

--effect on the infant of nonnutrient substances taken by the mother and passed through the milk.

CHILDHOOD AND ADOLESCENCE

Due to the building and maintaining of new body tissues, high level of physical activity, and emotional adjustments of maturation, children and adolescents have unique nutritional needs. However, according to a study by the Agricultural Research Service, either no data or only fragmentary data exist on requirements in these groups for virtually all essential nutrients.

There is a tendency to consider children as little adults in setting quantitative standards and, with an allowance for growth, extend their requirements proportionately by body weight on the basis of data showing the needs of older individuals. Growth rates vary among individual children and adolescents, and the onset of maturation can occur any time between ages 11 and 16. Adolescents commonly have unorthodox eating habits in meeting their increased caloric needs. These variations in growth, maturation, and eating habits raise doubts about evaluating dietary adequacy on the basis of standards derived from limited data intended for the population as a whole. Current standards reflect dietary protein requirements that are based on rapid growth rates, but it is not known if those requirements are optimal for mental development in preschool childhood or if rapid growth in adolescence is optimal for a full and productive life.

WOMEN

Comparatively little information exists on the nutritional requirements of women at all ages, especially those in the postmenopause period and after age 50. Data on normal nutrient blood levels and other indicators of nutritional status in women that would be useful for defining requirements are not available. This shortfall in knowledge is important since women outnumber men, have different

nutritional needs from men, and are susceptible to different health disorders. Further, at age 50, women have an average one-third of their lives remaining.

THE ELDERLY

The elderly--those persons aged 65 years or older--number 22.7 million and account for 10.6 percent of the U.S. population. On the basis of 1974 census data, the number of elderly persons will reach an estimated 27 million in 1985 and represent 11.4 percent of the population. Despite the large and growing number of elderly, very little is known about their nutritional requirements. Substantive data on requirements are lacking for nearly all essential nutrients and calories. Current quantitative standards are extensions from data on younger adults with a downward adjustment in calories, based on the assumption that elderly persons are more sedentary and thus require less energy.

Few efforts have been made to determine whether changes occur in human requirements when physical growth ceases. The limited information available indicates that age apparently does not influence requirements for vitamins and that, contrary to common belief, vitamin absorption is not impaired in elderly persons. There is also no strong evidence to indicate that age affects protein or amino acids requirements, although the evidence is not in complete agreement. Calorie requirements for the elderly are uncertain, since reduced energy needs result not only from decreases in the basal (basic) rate of nutrient use but also from such changes as the level of physical activity.

DISEASE AND STRESS

Nutritional requirements in disease and stress need further investigation for several reasons. First, modifying normal diet patterns is advisable or even essential for treating some disorders. In certain cases normal ingestive and digestive processes are disrupted, and parenteral nutrition (the introduction of nutrients into the body by means other than the digestive tract) is needed for treatment. Yet the factual basis for prescribing therapeutic diets is inadequate. RDAs are not appropriate since they are intended to meet the needs of healthy persons under usual environmental stress. Second, chronically ill individuals often have poor appetites and eating habits that compound their health problems by leading to chronic nutrient deficiencies. Third, recent revelations of poor nutritional status among hospital patients indicate that too little attention has been given

SOURCE: NICHD

A RESEARCHER ATTACHES A DEVICE TO A PUPPY FOR LONG-TERM PARENTERAL NUTRITION (THE SUPPLYING OF NUTRIENTS BY MEANS OTHER THAN THE INTESTINAL TRACT). THIS RESEARCH PROJECT AT COLUMBIA UNIVERSITY IS SUPPORTED BY THE NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT AND SEEKS HOW BEST TO FEED SMALL-FOR-DATE NEWBORN INFANTS WHO CANNOT BE FED BY MOUTH.

to the secondary effects of illness on nutritional health. Fourth, biological stress, due to environmental pollution or other factors, may cause rapid depletion of nutrient stores in the body and alter nutritional requirements.

Depending on the nature of a disease or disorder, dietary treatment may involve changes in the diet's quantitative requirements or qualitative composition. Protein requirements, for example, may be altered by disease or injury, and entail either increased protein needs or a change in the balance between enough and too much.

Cancer is one of many diseases for which the role of dietary modifications for therapy is not well established. The emaciation and weight loss of cancer patients suggest that tumor tissues compete with normal tissues for available nutrients. Also, the nutritional requirements of many tumors are substantially different from those of normal tissues, which raises the possibility of selectively adjusting available nutrients to feed healthy tissue and starve the tumor. While available information suggests that some therapeutic measures can be successful, additional knowledge is required to meet the array of individual requirements in cancer treatment. Other conditions for which information is limited about requirements in diet therapy include intestinal problems, burns, various forms of stress, and osteoporosis (a bone disease).

Parenteral nutrition is important for recovery of persons suffering trauma, burns, liver or kidney failure, and other severe conditions in which normal ingestive or digestive processes are disrupted. Although parenteral nutrition has received wide clinical applications during the past decade, especially in managing birth defects and various gastrointestinal disorders, little knowledge exists about nutritional requirements without the intestine's modifying effects. Unlike the relatively large tolerances in healthy persons eating normally, tolerances for nutrients in parenterally fed persons are limited, and the factual basis for prescribing parenteral feeding, particularly total intravenous feeding, is inadequate. Much information is needed on the ideal types or mixtures of amino acids, carbohydrates, fats, and minerals.

DRUG AND VITAMIN USE

Evidence is increasing that drugs, including alcohol, interact adversely with nutrients, either interfering with normal nutrient functions or changing the nature of a drug

reaction. Oral contraceptives have been found to reduce certain vitamin levels and may be related to mental depression, while high intake of certain carbohydrates has been shown to increase the duration of barbituate-induced sleep. Similarly, evidence suggests that large doses of vitamins may pose health risks as well as benefits.

Despite the increasing use of drugs in preventing and treating disease, most of the available information on drug-nutrient interrelationships has been derived from experimental laboratory studies rather than epidemiological or clinical data. Only in recent years have well-defined adverse effects on humans been identified. Further knowledge is important to the health of all individuals, especially the elderly, malnourished, long-term care patients, and individuals recovering from acute stress.

Massive doses of vitamin C or vitamin E have generally been discredited as disease cure-alls. However, there is evidence that relatively large doses of vitamin A can depress tumor growth and that vitamin C retards the formation of certain cancer-causing substances. The use of such vitamins needs further evaluation so that vitamin use beyond normal practices is not summarily dismissed as faddism.

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Research needs for filling knowledge gaps of nutritional requirements include (1) long-term studies of human subjects across the full range of both health and disease, (2) comparative studies in groups of differing geographic, cultural, and genetic backgrounds, and (3) basic studies of functions and interactions of dietary components.

LONG-TERM AND COMPARATIVE CULTURE STUDIES ARE NEEDED

Research for developing more complete and specific nutritional standards must take into account a variety of internal and external factors influencing human requirements. Such factors include age, sex, psychological disposition, health status, climate, culture, occupation, level of physical activity, and dietary habits. Accordingly, research is needed involving (1) long-term studies of female and male subjects of various ages representing the full spectrum of health and disease and (2) comparative studies of population groups representing different cultural, geographical, and genetic backgrounds.

The short duration and limited representation of past human studies have cast doubts on the appropriateness of current nutrition standards. For example, recent long-term studies (lasting up to 100 days) tested the effects on human subjects of a diet providing protein at a level recommended by FAO/WHO. During the study, test subjects suffered decreases in lean body and muscle mass unless dietary calories up to 20 percent above recommended levels were also fed. The results not only suggest that the current recommendations of dietary protein for large population groups are inadequate, but also show that short-term studies are insufficient for assessing human requirements. Other studies of how the body uses protein found statistically significant differences between university students in the United States and Taiwan. The causes of these differences and their significance for human protein needs are uncertain, yet the results illustrate the risks of basing quantitative standards on studies using sample groups of limited genetic or environmental diversity.

STUDIES DEFINING DIET COMPONENT FUNCTIONS AND INTERACTIONS ARE NEEDED

Additional knowledge of nutrients and nonnutrients in the diet are needed for further development of nutritional standards. Studies are needed to delineate the functions and interactions of diet components that can affect human requirements. For example, defining the role of dietary fiber is important because it is claimed to be beneficial to health, although human requirements are not known. Also important is further work defining human requirements for trace mineral elements. The functions of virtually all trace minerals are not well established, and it is likely that additional trace elements have yet to be identified as essential. The President's Biomedical Research Panel reported in 1976 that among the vitamins, the metabolism and mechanism of action of all of the fat-soluble vitamins and vitamin C are among the least understood areas. Similarly, the bodily processes regulating protein synthesis are not well understood. At present there is no known minimum requirement or maximum tolerance for either total carbohydrates or any individual carbohydrate, and there is still much to be learned about human energy (calories) requirements.

Numerous instances of nutrient interactions affecting human requirements are known, but their implications are not well understood. For example, when dietary calcium is restricted, production of the active form of vitamin D is increased, which in turn increases the efficiency of calcium absorption in the intestine. This process may have implications in

SOURCE. USDA

HIGH ARSENIC DIET BEING FED TO RATS AS PART OF THE TRACE ELEMENT STUDIES AT THE AGRICULTURAL RESEARCH SERVICE HUMAN NUTRITION LABORATORY, GRAND FORKS, NORTH DAKOTA.

treating bone disease. Similarly, the amount of vitamin B1 required is influenced by whether the energy source is primarily fats or carbohydrates, and a high intake of certain fatty acids may increase the need for vitamin E. Protein-calorie deprivation may impair the body's resistance against microorganisms, but knowledge explaining these interrelationships is sketchy.

CHAPTER 2 - PART 2

FOOD COMPOSITION AND NUTRIENT BIOLOGICAL AVAILABILITY

Thousands of processed food items are available to the American consumer. These foods are subject to considerable variation in nutrient composition due to genetic and climatic factors and are exposed to techniques of modern food processing, storage, and cooking which can affect their composition and nutritional contribution to the diet. If standards for human requirements are to have practical applications, more current knowledge on the nutrient composition of foods as consumed and the extent that nutrients are biologically available for absorption and digestion is essential. Research is needed to update and expand food composition data and to develop improved methods for determining food composition and the biological availability of nutrients.

MORE CURRENT AND COMPREHENSIVE FOOD COMPOSITION DATA ARE NEEDED

Current and comprehensive information on food composition is important for planning diets to meet nutritional requirements. Food composition tables should ideally include information on the biological availability of nutrients in foods 1/ as well as the nutrient composition of foods consumed. Present composition tables, however, are out of date and incomplete and do not include data on several nutrients and foods.

USDA's Agriculture Handbook #8 "Composition of Food--Raw, Processed, Prepared," which includes composition values for some 2,500 foods, was last revised completely in 1963; currently it is being revised. The handbook contains values for only a limited variety of nutrients. The composition values should more closely reflect the nutrients of foods as consumed rather than as purchased.

Additional studies are needed to determine the effect of processing (especially newer methods of processing) on the

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1/ USDA, in comments on a draft of this report, stated that although it is a desirable goal to include biological availability information in tables of food composition, it should be recognized that there is no clear-cut basis for reporting the available portion because many important factors affect utilization.

nutrients of foods so that composition values take into account nutrient losses occurring before consumption. For example, thawing or cooking results in loss of certain nutrients, such as vitamin C. The current revision of Handbook #8 will correct many of the deficiencies. It will provide updated information on many more foods and nutrients, including fatty acids, amino acids, and additional vitamins and minerals. Agricultural Research Service officials said that even with an expanded and revised table of food composition, there will still be areas of incompleteness because of the lack of data for some nutrients in some foods.

Other USDA reference tables have similar limitations. "Home Economics Research Report 4," the reference table on the amino acid content of foods, dates back to 1957, omits 4 of the 22 naturally occurring amino acids, and covers only 316 food items. Report 36, which contains reference values for certain vitamins, was issued in 1969 and covers about 700 foods. The data presented in USDA Handbook #456 (1975), give values in household measures and market units of foods and were derived primarily from Handbook #8.

Only a few essential mineral elements are included in the USDA standard reference tables, and only fragmentary composition data exist on several essential vitamins and certain carbohydrates. In addition, new strains of fruits and vegetables, produced by different methods, are replacing strains for which nutrient composition had been known. High-temperature, short-time canning, new dehydration and freezing techniques, continuous dough techniques for bread, and hydrocooling of produce in the field exemplify innovations in food industry practices that have unknown effects on nutrient composition. Similarly, precooked frozen foods, microwave heating, and boil-in-the-bag cookery are preparation methods whose effect on nutrient composition has not been ascertained.

Apart from being limited in their coverage of nutrients and foods and failing to consider nutrient losses, composition tables do not distinguish between those nutrients that are biologically available for absorption and digestion and those that are not. Present composition tables generally give a total value for a nutrient even though a large portion may be nutritionally useless. In some cases, a nutrient's chemical form can affect its biological availability. One form of vitamin E, for example, is more biologically useful than other forms. In other cases, interactions among nutrients and nonnutrient substances in foods can alter biological availability. Phytate, a component of cereals and plant foods, decreases the availability of dietary zinc for intestinal absorption. Thus, cereals presumably are not good sources of

dietary zinc. Composition tables do not recognize the limiting effects of such interactions nor do they include composition data on nutrient antagonists (like phytate) in foods.

IMPROVED METHODS FOR DETERMINING COMPOSITION AND BIOLOGICAL AVAILABILITY ARE NEEDED

To develop more current and comprehensive food composition tables, research is needed to improve methods of determining the effects of food production, processing, and preparation procedures on food composition and nutrient availability.

Most methodologies used in composition work today are adaptations of analytical procedures devised 30 or 40 years ago. As a result, they are labor-intensive, time-consuming, expensive, and, in some cases, have been found to be unreliable. Good analytical methodology exists for only about half the 75 to 100 known dietary nutrients.

Improved composition analysis methods are urgently needed for several of the amino acids, vitamins, and mineral elements. In the case of dietary fiber (a substance of growing interest to nutritionists) data are needed for computing its various types in the diet.

CHAPTER 2 - PART 3

DIET, DISEASE CAUSATION, AND FOOD SAFETY

Given the present state of nutrition knowledge, it is not possible to say what constitutes an adequate diet. Studies have found great diversity in dietary practices and adaptations to food sources among world cultures. Eskimos, for example, have traditionally consumed large quantities of animal fat and protein, yet experienced little the heart disease normally associated with such a diet. On the other hand, persons in New Guinea have been observed to consume high carbohydrate-low protein diets with no apparent problems. Compared to previous generations, Americans today consume a diet higher in protein, fat, sugar, and salt and lower in fresh fruits and vegetables, whole grains, and cereals. Most of our foods come in cans and boxes, and over half of our diet includes processed foods.

Since the end of World War II, people have been consuming processed, fabricated, and fortified foods in greater amounts. The nutritional impact of this experience has never been adequately evaluated. Evidence is accumulating that, among other consequences of modern dietary practices, several diseases and disorders arise partly from diet excesses and imbalances. Evidence also indicates that despite a plentiful food supply, many Americans apparently suffer from undernutrition of some essential nutrients, particularly iron.

Increased knowledge of the consequences of dietary intakes and practices is important to improving the quality and safety of the food supply. Research is needed to (1) identify and describe the processes by which dietary constituents lead to the onset and development of disease, (2) evaluate the effects of diet modifications proposed as preventive measures, and (3) develop improved techniques for assessing toxicological risks.

DIET AS A FACTOR IN THE CAUSE OF DISEASES AND DISORDERS

Six of the 10 leading causes of death in the United States are thought to be diet related. These six are heart disease, cancer, stroke, diabetes, cirrhosis of the liver, and arteriosclerosis. Also related to diet are obesity and hypertension--two prevalent disorders contributing to death and disability. Other disorders having a dietary component contributing to their cause include dental caries, periodontal disease, and osteoporosis.

The following sections discuss obesity, heart disease, stroke, and cancer to illustrate the complex interrelationships in disease causation and to demonstrate the need for research that defines the role of diet in disease and evaluates diet alternatives.

Diet in obesity

Obesity, defined as 20 percent or more above desirable body weight based on body height and build, is probably the foremost nutrition-related health problem in the United States. An estimated 20 percent of all adults are overweight to a degree that may interfere with optimal health and longevity; after age 40 the figure jumps to 35 percent. An estimated 10 to 40 percent of school children are overweight (those whose weight is 10 percent above the desirable body weight). It is also estimated that 36 percent of the children who are at or above the 90th percentile in weight during the first 6 months of life will be obese as adults.

A number of serious disorders can stem from or be aggravated by obesity. Obesity aggravates cardiovascular disease and bone arthritis and increases the risk of hypertension, atherosclerosis, hernia, and gallbladder disease. Obesity also facilitates emergence of diabetes in certain individuals and adds to surgery risks.

The immediate cause of obesity is the consumption of calories beyond energy needs--the underlying causes are not well understood, however. In perhaps 5 percent of total cases, obesity results from hormonal imbalance, brain damage, certain drug treatments, or other relatively rare circumstances. For the great majority of cases, current scientific opinions hold that obesity is biologically programed or arises from certain kinds of lifestyles and eating behaviors. The gaps in knowledge of diet and obesity relate to the validity of those opinions and to the means employed in combating obesity.

The opinion that obesity is biologically programed rests in part on recently developed knowledge about the "organ" of obesity--adipose (fatty) tissue. It appears that the adult normally has a relatively fixed number of fat cells that will enlarge as they store excess fat and shrink as existing fat in the cells is used up. The total number of fat cells is fixed by mid-to-late teens. During infancy and early adolescence, however, overfeeding with rapid weight gain can produce a substantial increase (two to five times normal) in fat cell numbers in the still-developing adipose tissues. Once the

cells become established, the number will not decrease in later life despite weight reduction efforts.

How this knowledge of adipose tissue can be applied to preventing obesity is not yet established. It is important to identify the preadipose cell. Identification before fat accumulates in the cell will permit accurate description of adipose tissue growth during its proliferation phase. It may then be possible to characterize genetic and environmental factors controlling fat cell proliferation and the time at which proliferation normally ceases.

Evidence, however, indicates that obese persons may not be biologically destined to be overweight. Lack of physical activity, chronic consumption of food for nonnutritive purposes, and a lifestyle vulnerable to overeating are factors believed to underlie obesity in some cases. The importance of "internal" and "external" cues of eating behavior has been emphasized increasingly. Internal cues include contraction and expansion of the stomach, dryness of the mouth, changes in body temperature, and other physiological conditions. External cues include such factors as the sight, appearance, aroma, and taste of food. It has been proposed that lean persons are more responsive to internal than external cues and thus are able to regulate their energy balance and control their weight. Obese persons, by contrast, appear to be more sensitive to food-related external cues than to cues of satiety or hunger.

The appropriate means and effectiveness of dietary modifications for controlling obesity are not well established. About $10 billion is spent annually on weight-reducing treatments (much of it to little or no avail) without understanding the risks and benefits associated with diet modifications. One recent popular regimen involved a diet in which fat may be extremely high and carbohydrate excluded. The adverse effects or implications of such a diet are not well understood. Similarly, starvation for varying lengths of time has been recommended as a remedial technique in cases of gross obesity, yet the effects of recurrent starvation and refeeding are not well understood.

Diet in heart disease and stroke

Coronary heart disease and stroke account for half of all deaths of Americans. In addition, some 27 million Americans suffer from hypertension, a contributory factor in heart disease, stroke, and kidney failure.

Cholesterol has long been suspected in the causation of heart disease, although precise cause and effect relationships have not been determined. Salt has been related to certain types of hypertension but, again, the exact cause is unknown.

Epidemiological and clinical research in diet, heart disease, and stroke has focused on the role of individual dietary components, particularly fat and cholesterol. This research has identified the following relationships that have led to the lipid (fat) hypothesis that lowering blood cholesterol levels can prevent, or at least delay, heart disease and stroke.

--In general, the underlying cause of coronary heart disease and stroke is arteriosclerosis, a chronic and usually progressive disease characterized by thickening, hardening, and loss of elasticity of arterial walls due to accumulating cholesterol deposits (atherosclerosis). These arterial changes may prevent blood from reaching the heart or brain, and thus cause heart attack or stroke.

--The higher the cholesterol level in the blood, the greater the risk of developing coronary heart disease.

--With certain exceptions, populations habitually consuming diets high in saturated fat and cholesterol have high blood lipids and high rates of coronary heart disease. Conversely, no population subsisting on a low-fat, low-cholesterol diet has a high rate of coronary heart disease.

--Cholesterol levels in the blood can be effectively lowered by altering the intake of fats and cholesterol.

Unfortunately, despite considerable research efforts the conclusive link binding these relationships (i.e., that dietary fat leads, through elevated blood lipid and cholesterol levels, to development of atherosclerosis) has not been established. Therefore it is uncertain that lowering blood cholesterol levels will prevent or delay atherosclerosis and thus heart disease or stroke.

In addition to saturated fats and cholesterol, atherosclerosis has been variously attributed to blood disorders, hormone disturbances, smoking, obesity, a sedentary lifestyle, a stress-seeking personality type, and heredity. Moreover, some epidemiologists note the absence of sugar and other

refined carbohydrates in the diets of populations experiencing little atherosclerosis. While it has been demonstrated that dietary fat affects blood lipid levels, evidence also indicates that heredity, age, sex, stress, obesity, hypertension, and physical exercise are influencing factors. Similarly, coronary heart disease has been correlated with 37 different factors, principally blood cholesterol levels, hypertension, and smoking, with the significance of the factors varying among individuals.

Given this mixed and multiple picture of interrelationships, further research directed at single cause and effect linkages will probably not prove fruitful. Instead, since modifying fat content of the diet has been recommended, it would be appropriate to evaluate the effects of dietary modifications implementing the lipid hypothesis. A diet altering the relative amounts of polyunsaturated fat (generally of vegetable origin) and saturated fat (generally of animal origin) may entail unknown risks.

Commercially prepared vegetable fats are unnatural polyunsaturates whose nutritional value has not been scrutinized. Moreover, researchers have reported cases where diets high in polyunsaturated fats led to increased incidence of tumors in laboratory animals. In addition, since atherosclerosis is a chronic, usually progressive disease, dietary modification may have to be instituted during childhood or earlier to be effective. Yet children are among the most nutritionally vulnerable groups, so any modification undertaken to forestall or prevent a single disorder should be assessed in relation to overall nutritional needs.

Diet in cancer

Cancer, the term collectively applied to malignant tumors (neoplasms), is the second leading cause of death in the United States. In 1974 cancer accounted for about 356,000, or 18.5 percent, of all deaths. It is estimated that 80 to 90 percent of human cancer is related to environmental factors. Diet, as one environmental factor, is estimated to be related to 41 percent of all cancer incidences in men and 60 percent in women, including (in decreasing order of incidence) cancer of the colon, rectum, breast, prostate, stomach, liver, and kidney.

The evidence implicating diet as a cause of cancer is based on epidemiological studies contrasting cancer incidences among populations of different diets and on animal studies relating various diet elements to tumor growth.

These studies suggest that long-term diet imbalances, perhaps coupled with other environmental hazards, provide a continuous low level of insult which leads to onset and development of neoplasms. Diet imbalances may entail nutritional deficiencies or excesses. A diet low in milk and raw vegetables has been linked to increased incidence of stomach cancer while a diet high in fat and meat has been related to increased occurrence of colon and breast cancer. Other dietary constituents suggested as influencing development of neoplasms include cholesterol, protein and amino acids certain vitamins, mineral elements, fiber, and a variety of other chemical substances from natural and manmade sources present in foods.

The precise mechanisms or processes by which diet influences cancer onset and development (carcinogenesis) are unknown. Some general modes of influence that have been proposed and await further investigation are that diet:

--Is the major supply of body chemicals, some of which are possible cancer-causing agents (carcinogens).

--May render body tissues susceptible to carcinogenesis by modifying tissue metabolism.

--May facilitate internal generation of carcinogens by changing the composition and metabolic activities of microflora in the gut.

--May alter the profile of metabolic products excreted by gut microflora, thereby affecting the susceptibility of gut cells to carcinogenesis.

Fundamental research is needed on nutrients' role in directing and regulating growth and differentiation of body cells. Also having potential significance is study of the enzyme complex known as the mixed function oxidase system. The activities of this enzyme system (which is present in many body cells and is involved in activating metabolism of ingested chemicals) have been found to be influenced markedly by an individual's nutrient intake and nutritional status.

Dietary fiber in disease prevention

Dietary fiber has been defined as that part of plant material in the human diet that resists digestion in the gastrointestinal tract. It comprises a mixed group of carbohydrate compounds and a noncarbohydrate substance known as lignin.

Epidemiologists have suggested that the lack of fiber in the diets of industrial nations contributes to the high incidence of diseases common in the Western World, including colon and rectum cancer, coronary heart disease, gallstones, appendicitis, varicose veins, hemorrhoids, and diverticular disease. It has been estimated that, compared to consumption in 1900, Americans in 1970 ate about one-third less fresh fruits, fresh vegetables, and whole wheat flour and cereals--the dietary fiber sources.

Fiber is known to affect the composition of bacterial and chemical conditions of the intestine and to speed up bowel transit time. These factors may play a role in preventing colon cancer by binding and eliminating bile acids, substances suspected of interacting with bacteria in the gut to form carcinogens. In addition, since the conversion of cholesterol to bile acids is the primary pathway for body cholesterol, dietary fiber's ability to bind bile acids and prevent their reabsorption may explain how fiber decreases the size of body cholesterol pools and thus may serve as a preventive agent in heart disease.

Today, commercial food products high in fiber are being promoted, although the long-term consequences of consuming a high-fiber diet are unknown and disagreement exists over how much fiber is beneficial. Increased fiber intake is associated with increased consumption of phytate, a substance known to tie up dietary zinc and reduce its availability for absorption. Increased dietary fiber also apparently reduces digestibility of other dietary components, presumably because of less time for digestion and absorption.

Dietary fiber has not received much scientific evaluation, and further study is needed to define the range of fiber intake most favorable for health maintenance.

IMPROVED TECHNIQUES ARE NEEDED FOR ASSESSING TOXIC HAZARDS IN FOODS

Food is a mixture of thousands of chemicals, the great bulk of which occur naturally. The normal components of natural food products constitute more than 99 percent of the weight of the daily diet. Food additives comprise the bulk of the balance, with pesticide residues and contaminants from both natural and manmade sources contributing only trace amounts. Any one of the chemicals in foods is potentially hazardous and perhaps fatal to humans if ingested in sufficient amounts. Thus, food safety is not concerned with the toxicity per se of these chemicals but with their consequences

for human health and their safe levels of ingestion under normal consumption patterns. A major challenge to the science of food toxicology is to develop more sophisticated and faster methods to identify and assess the long-term hazards of food chemicals.

Toxicological assessment of long-term health hazards in foods is important if large scale food fortification or enrichment schemes are to be put on solid footing. While vitamin A has been shown to cause fetal damage in laboratory animals, its natural presence in foods is not considered a toxic risk. When a nutrient is added to foods, however, the additional dosage may create a health hazard, depending on its toxic potency. In the case of some mineral elements, toxicological assessment is especially important since the margin between safe and hazardous levels of ingestion appears to be quite slim.

While public attention has focused on chemicals introduced into foods by man, especially food additives, toxic hazards in natural food components are also believed to be important causative agents in cancer, cardiovascular-kidney disease, mental disorders, and other chronic ills of unknown origin. Relatively few of the chemicals naturally present in foods have been evaluated toxicologically. Instead, most have been accepted because humans have learned by experience that these substances do not seem harmful when consumed in the ordinary diet.

Only in recent times have long-delayed harmful effects come under suspicion. The role of dietary salt in hypertension and dietary sugar in heart disease are subjects of current controversy. Similarly, the presence of the potent carcinogens nitrosamines in natural plant foods has intensified the concern that the incidence of cancer in humans may be partly attributable to natural food sources.

Existing epidemiological evidence indicates that food additives may not have a measurable effect on the incidence of human cancer in the concentrations currently ingested. Cancer incidences differ markedly between Japan and the United States, although the general food contamination in both nations is similar. The epidemiological evidence would be more impressive, however, if it were based on comparisons between populations having similar dietary practices except for the presence of food additives. Unfortunately, among industrial nations it is virtually impossible to find a population not exposed to additives to serve as a control group. Moreover, it is possible that chemicals introduced by man

interact with chemicals naturally present in foods to create potential long-term hazards. Sodium nitrite, a compound commonly added to meats, is known to combine with food amines to form nitrosamines, carcinogens that appear to be most effective in forming tumors in experimental animals when ingested in small, chronic doses.

The exact amounts of additives in use are not known, but many are used for purposes other than to augment nutrient content of foods. A review of the 658 substances characterized in the current "Food Chemicals Codex," which sets standards of identity and purity for chemicals added directly or indirectly to foods, shows that the majority (79 percent) are used principally to color, flavor, cure, shape, texturize, or otherwise enhance the physical appearance or appeal of processed foods. Sodium nitrite in particular is used principally as a color fixer, although its use has been defended as a preservative agent for controlling botulism.

Approval of food additives rests on varying degrees of testing, expert opinion, and experience in use. Animal experimentation for identifying toxic hazards and setting safe dosage levels is the subject of much controversy. It is known that the relative potency of some carcinogens depends on the diet fed to laboratory animals, thus the question arises over what diet to use. Moreover, feeding an animal a fully nutritious diet laced with the chemical under examination may be a questionable model for the human experience. Humans are forced to deal with hundreds of chemicals in their diet, any number of which may interact to create a potential hazard.

CHAPTER 2 - PART 4

FOOD CONSUMPTION AND NUTRITIONAL STATUS

While it is evident that many Americans have developed or are at risk of developing health problems related to dietary imbalances and excesses, knowledge is lacking on the current national nutritional status; the location, prevalence, and magnitude of marginal as well as acute nutritional inadequacies; and the relationship between nutritional status at one period of life to health in later periods.

Knowledge of the relationships among food consumption, nutritional status, and health problems of the general population and population subgroups is important for effective nutrition planning at the Federal, State, and local levels. To establish priorities and utilize limited resources effectively, policymakers need to know the magnitude of nutritional problems, the identity of persons who can best be helped by intervention, and the success of past assistance programs. Although the Federal Government spent $8.4 billion in 1976 on assistance programs having a nutrition component, the long-term effect of such programs on nutritional status has rarely been evaluated.

To provide the required information, research is needed to (1) continuously monitor the food consumption, nutritional status, and health of representative sample populations, (2) develop more reliable techniques to measure food consumption and faster, readily reproducible, and inexpensive methods to assess nutritional status, (3) identify the determinants of nutritional status and their significance for improving health, and (4) identify, through studies of the relationship between diet and the aging process, the effect of nutritional status in one period of life on subsequent periods.

A SURVEILLANCE PROGRAM MONITORING NUTRITIONAL STATUS IS NEEDED

A nutrition surveillance program should monitor changes in the nutritional status of both the general population and specific population groups, and it should identify those persons at risk of developing a nutritional problem over time. The magnitude and prevalence of diet-related disorders and the individuals affected and their locations must be identified, and subsequent intervention efforts should be systematically evaluated. In addition to collecting data on dietary intakes, clinical examinations, biochemical measurements, and anthropometric values (such as height, weight, arm

circumference, and skinfold thickness), the surveillance program should relate nutritional status to disease and stress resistance and assess nutritional status in relation to behavioral adaptation and factors such as intellectual development, sensory and motor functions, and academic performance.

Although several nutritional status studies have been performed, few have been conducted on a regional or national basis. National and regional studies by the Federal Government did not determine diet imbalances and excesses of the average American at risk of developing heart disease, cancer, diabetes, or other diet-related disorders, nor did they identify relationships among nutritional status, behavioral development, and resistance to or prevention of chronic disease. Moreover, the information provided by these surveys is fragmented and out of date.

The last national Household Food Consumption Survey (conducted by USDA) was completed over 10 years ago. Limited to measuring food consumption, this survey did not attempt to clinically assess diets in relation to nutritional status. Between 1968 and 1972 HEW sponsored three major nutrition-related surveys: the Ten State Survey, the Preschool Nutrition Survey, and the initial Health and Nutrition Examination Survey. The first two surveys were limited to identifying nutritional deficiencies among low income and early childhood population groups. The Health and Nutrition Examination Survey collected data on the nutritional status of the population as a whole, but its sample population was probably too small to uncover unique regional problems. Conditions such as the recently identified deficiency of the essential nutrient zinc among Colorado school children are unlikely to be detected under the survey's broad approach.

METHODS OF NUTRITIONAL ASSESSMENT AND IDENTIFYING DETERMINANTS OF NUTRITIONAL STATUS NEED TO BE IMPROVED

Nutritional assessment should include standardized indices that can be combined into an objective profile of nutritional status. A surveillance program, to provide information in a timely fashion, should include fast, inexpensive, and automated measurement methods.

The techniques traditionally used to measure nutritional status--diets, clinical examinations, biochemical analyses, and anthropometric measurements--suffer methodological drawbacks.

SOURCE:NIH

A SKIN CALIPER IS BEING USED TO MEASURE THE THICKNESS OF A SKIN FOLD. THE SKIN FOLD TEST IS A ROUTINE PROCEDURE USED IN NUTRITION RESEARCH TO ASSESS FATNESS OF A PERSON.

Recall, food intake records, diet history, and weighed food intake are methods used to measure individual diets, while the food list and food record methods are used for measuring household food consumption. The recall technique, in which individuals list the kind and quantity of food consumed during the past 24 hours, is subject to large errors and has been found unreliable for identifying persons with low nutrient intakes. The diet history technique is expensive because it must rely on skilled interviewers knowledgeable about diet habits.

The methodology of the current USDA Nationwide Food Consumption Survey is a combination of the 7-day aided recall, the 24-hour recall, and the 48-hour diary. We reported 1/ that the methodology for the current survey has not been fully validated and that there are no assurances that the data obtained will actually measure the amount of food consumed. In commenting on the draft of this report, USDA stated that it had initiated a study to determine approaches that may be used in providing further validation of food consumption measures.

The weighed food intake, while the most accurate, is also the most tedious, requiring participants to weigh food items. As techniques for obtaining household food consumption data, the food list method is subject to recall errors while the food record method is expensive and burdensome, entailing several interviewer trips to weigh food at the survey's beginning and end.

Clinical examinations assessing an individual's nutritional status are limited by the observer's skill and subjectivity and the possibility that a clinical symptom is nonnutritional in origin. Biochemical analyses of blood and urine can indicate levels of several essential nutrients and other dietary components but are expensive, time consuming, and require specialized skill. Anthropometric values of height, weight, arm circumference, and skinfold thickness can identify possible cases of diet deficiency or excess but are subject to measurement and recording errors.

In addition to these limitations, no definitive method is available to combine existing indices into an overall indicator of nutritional status. Most experts agree that

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1/"Nationwide Food Consumption Survey: Need For Improvement and Expansion" (CED-77-56, Mar. 25, 1977).

existing indices represent normal values, but it is not certain that improvement in the indices represents enhanced nutritional status. Similarly, it is not certain that enhancing nutritional status beyond some relatively minimal level will significantly improve an individual's functional abilities and performance.

Research also is needed to identify the determinants of nutritional status and their significance for improving health. Some experts have pointed out health problems, economic factors, food additives, and the general American lifestyle as possible determinants of nutritional status. Findings of the initial Health and Nutrition Examination Survey indicate, for example, that exercise should be considered a nutritional variable in the United States. Yet according to officials at the National Center for Health Statistics, there are less than a dozen well-designed studies investigating relationships among energy intake, obesity, and exercise.

THE ROLE OF DIET IN THE AGING PROCESS NEEDS TO BE DEFINED

A number of experiments on a variety of animals have demonstrated that, when the intake of certain nutrients is lower than the recommended allowances, lifespan increases and the incidence of several diseases found in later life is reduced. Similarly, very high intake of some nutrients has been reported to shorten life. Animal studies have also shown that early nutritional interference with brain growth leads to abnormal behavior and that, to some extent, those detrimental effects can be overcome by subsequent nutrition improvements.

Neither the biological mechanisms underlying the relationship between diet and aging nor the relationship of nutritional status of one period of life to the remaining life periods is well understood. Fuller definitions of these relationships are needed to plan better diets--particularly for early age groups.

It once was believed that diet manipulations that increased lifespan had to be imposed during early growth. Animal studies had found that, while the lifespan of survivors was increased, chronic restriction of food intake begun in the postweaning period was also associated with increased infant mortality, stunted growth, and other impairments. More recently, however, it has been shown that dietary restrictions can be imposed in adulthood so that increased lifespan may occur without the physiological abnormalities associated with diet restriction during growth.

It was also once believed that diet restriction extended lifespan by delaying the transfer of genetic information, thereby altering the rate of occurrence of life events such as the onset of puberty or menopause. The implications seem profound. Puberty could be postponed until the twenties and menopause pushed back toward the seventies. Later studies do not support the concept of delayed genetic transfer, however. Instead, they suggest that diet restriction reduces the use of the genetic code throughout life and thereby minimizes genetic imperfections as they occur late in life.

Animal research clearly indicates that diet restriction that increases lifespan delays the onset of a variety of diseases, including heart muscle degeneration, mammary cancer, and kidney inflammation. At present no explanation has been offered for these relationships. Similarly, firm conclusions are not yet available for the relationships between diets at different life stages and the risks of subsequently developing a disease. Evidence indicates that rapid growth and overfeeding seem to be incompatible with an extended lifespan that is relatively free of diseases of age and, if left to consume at will, laboratory animals will select a diet that boosts the likelihood of developing a disease of age.

CHAPTER 3

FEDERAL AGENCY NUTRITION RESEARCH PROGRAMS AND PLANS

Several Federal agencies support human nutrition research that relates to both food and health issues. No agency has human nutrition as its primary mission, although each supports research addressing major gaps in nutrition knowledge.

The principal agencies supporting human nutrition research are the Agricultural Research Service, U.S. Department of Agriculture (USDA), and the National Institutes of Health, Department of Health, Education, and Welfare (HEW). The Agricultural Research Service is primarily concerned with the food and nutrient needs of the normal, healthy population. The National Institutes of Health focuses on the nutritional needs of certain age groups and disease prevention and treatment through diet.

In addition to those two principal agencies, the Health Resources Administration, HEW, conducts the Health and Nutrition Examination Survey, a major research project intended to measure and monitor the nutritional status of the American people.

The research programs and plans of the Federal agencies supporting nutrition research are described below.

AGRICULTURAL RESEARCH SERVICE

The Agricultural Research Service (the Service) seeks to improve the nutrition and well-being of the American people as part of its overall mission to develop new knowledge and technology to assure an abundant and economical food supply and to provide for the continued improvement in the American standard of living. In fiscal year 1976 the Service budgeted about $9.7 million supporting three principal programs in nutrition research. These programs cover human requirements for nutrients, food composition and improvement, and food consumption and use. Most Service research in 1976 was conducted intramurally at regional laboratories.

The Service has emphasized research on animal and plant production and marketing, use, and effects of agricultural products; it has given nutrition low priority. On the basis of budget data for fiscal years 1975-77, nutrition has

received only about 4 percent of all research funds. Of the 376 research proposals given priority ranking for fiscal year 1977, only 12 were related to nutrition.

Human nutrient requirements

The Service's research goals for nutrition requirements are to (1) develop recommendations of dietary intake for fats, mineral elements, vitamins, protein and amino acids, carbohydrates, and energy and (2) identify forms of those nutrients in foods. Pursuing these goals during 1976, the Service budgeted research totaling about $5.4 million. Several research projects are relevant to filling gaps in knowledge of human nutritional requirements, nutrient functions and interactions, and biological availability of nutrients in foods. These include human, animal model, and molecular studies that

--develop improved methods for determining diet requirements for protein and estimate availability of essential amino acids in foods;

--determine the effects of stress on requirements for vitamin E and selenium;

--identify the nutritional role of the trace elements nickel, vanadium, and arsenic;

--determine the effects of mineral deficiencies;

--determine the effect of dietary fiber on metabolic processes;

--identify the effects of moderately reducing blood lipids by diet;

--determine interrelationships among zinc and copper, lipid metabolism, and cardiovascular disease; and

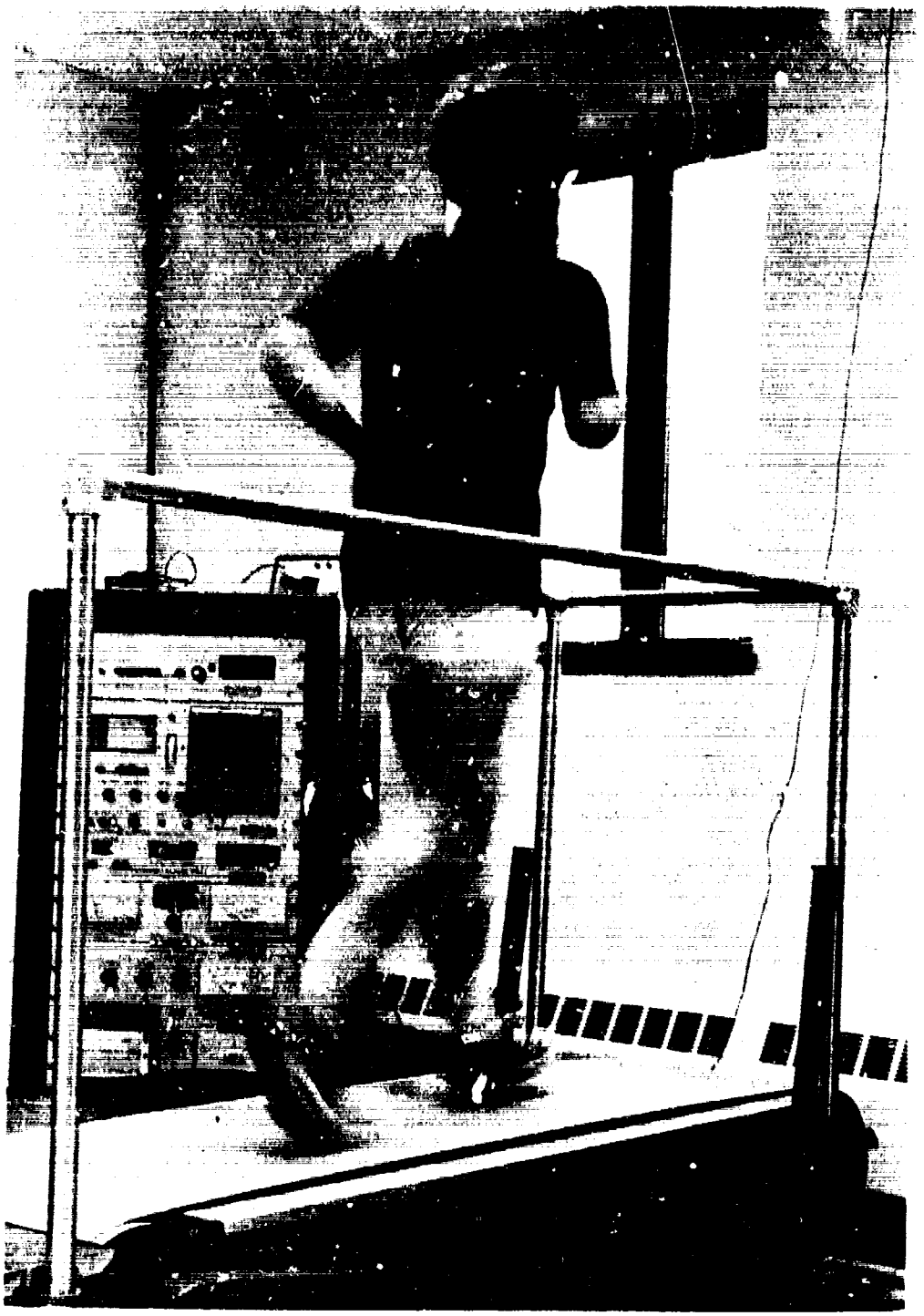
--determine effects of caloric starvation and refeeding.

Current research plans set forth several objectives in human requirements to be achieved by 1985. Among those objectives are to

--determine the importance, biological availability, and human requirements for several trace mineral elements;

USDA PHOTOGRAPH

VOLUNTEERS DINE ON A VARIETY OF FOODS IN A 6-DAY MENU. THEIR "AVERAGE" AMERICAN DIET INCLUDES SCRAMBLED EGGS, FRENCH TOAST, CHICKEN AND MASHED POTATOES, CHICKEN-RICE CASSEROLE, BREAD AND BUTTER, SUGAR COOKIES, AND APPLE PIE. THE FOOD IS PURCHASED WITH ATTENTION TO LOT NUMBER TO ASSURE UNIFORM NUTRIENT COMPOSITION AND IS PREPARED IN A HIGHLY TECHNOLOGICAL DIET KITCHEN. RESEARCH ON THESE VOLUNTEERS AT THE SERVICE'S HUMAN NUTRITION LABORATORY IS DESIGNED TO PROVIDE KNOWLEDGE ON THE ROLES AND REQUIREMENTS OF SPECIFIC NUTRIENTS.



SOURCE: USDA

A VOLUNTEER WALKS A TREAD MILL THAT CAN BE OPERATED AT VARIOUS SPEEDS AND INCLINES. A STAFF OF MEDICAL DOCTORS AND REGISTERED NURSES MONITORS THE VOLUNTEERS' HEALTH THROUGHOUT THE STUDIES AT THE SERVICE'S HUMAN NUTRITION LABORATORY IN GRAND FORKS, NORTH DAKOTA.

SOURCE: USDA

A MEDICAL OFFICER TAKES SWEAT SAMPLES FROM VOLUNTEERS. THE SWEAT WILL BE ANALYZED IN THE SERVICE'S HUMAN NUTRITION LABORATORY'S CLINICAL CHEMISTRY UNIT.

--develop a new technique for measuring protein nutritional status in humans and a scientific basis for establishing upper limits of protein intake for optimal health;

--delineate the fat-producing effects of the dietary carbohydrates starch, sucrose, fructose, and glucose; and

--determine the physiological effects of unsaturated dietary fats to plan improved technology in processing of food fats.

Food composition and improvement

The goals of the Service's research on food composition and improvement are to provide (1) accurate, current, and comprehensive information, in readily usable form, on food composition and (2) technology for improving the nutritional quality of foods to correct possible diet faults. Studies of food composition and analysis were budgeted at about $3.2 million in 1976.

Major work on food composition is carried out by the Service's Nutrient Composition Laboratory, established in 1975 to update USDA's Agriculture Handbook #8 "Composition of Foods." According to the Chief of the Laboratory, the long-term objective is to develop standardized analytical methods for use by industry or other parties performing food composition work. The Laboratory has placed special emphasis on lipid nutrients in foods and methods of lipid analysis. This work is done under a cooperative funding agreement with the National Heart, Lung, and Blood Institute (National Institutes of Health). Additional Laboratory projects, either scheduled or in progress, include developing reliable methods to routinely determine trace elements in foods and to use those methods to analyze representative food samples; investigating alternative methods for analyzing dietary food fiber; improving methodology for assaying vitamins; and developing carbohydrate analysis methods.

Other projects in food composition and improvement are studies of the physical properties of cereal grain fiber, effects of air pollution on nutrient content of certain crops, effects of processing practices on amino acids, and protein fortification of foods.

Current research plans have the following long-range objectives in food composition and improvement:

--Make available a revised Handbook #8 showing revised composition values representing current food practices and covering many new foods.

--Provide composition data on a spectrum of nutrients in over 2,000 new food items not presently tabulated in Handbook #8 or those food items presently tabulated for which new nutrient analyses are clearly needed.

--Provide additional composition data on nutrients for which diet recommendations are being made.

--Develop procedures of nutrient fortification for various cereal and milk products.

Food consumption and use

The Service's goals in food consumption and use are to provide (1) accurate, current, and comprehensive information in readily usable form on food consumption and dietary levels and (2) consultative assistance on diet planning and selection to consumers, educators, and other users of nutrition information. Research projects directed toward achieving those goals were budgeted at about $1.1 million in 1976.

A major Service food consumption project is the Nationwide (formerly Household) Food Consumption Survey, scheduled to be conducted over a 1-year period ending March 1978. The survey includes measurements of household and individual food intakes in the continental United States on a year-round basis. The survey includes, for the first time, supplemental surveys in Alaska, Hawaii, Puerto Rico, and on the elderly. Survey objectives include determining the kind, amount, and monetary value of foods consumed; the food purchase and use practices of families; and the nutritive content of consumed foods. Values will be calculated showing intakes of calories and 14 nutrients on a household and individual basis. It is expected that data derived from the survey will be used to evaluate the diet levels of lower income households and participants in Federal feeding programs. The survey cost is $8.9 million, which includes a $6.9 million contract awarded in September 1976 and a supplemental $2 million awarded in September 1977 to cover a sample of low-income households.

NATIONAL INSTITUTES OF HEALTH

In fiscal year 1975 the National Institutes of Health (NIH) spent nearly $68 million on direct and related research in human nutrition, 1/ or about 4 percent of NIH's total expenditures on health research and development. In contrast to the Agricultural Research Service's reliance on intramural research, NIH's nutrition research is largely extramural.

NIH supports studies on the role of nutrients on normal development, health promotion, disease prevention, and disease treatment. A major focus of NIH nutrition research is on the study of diseases and particular conditions influenced by nutrient insufficiency, imbalance, and excess. The research scope includes the following subject areas:

1. New knowledge of nutrients--studies of nutrient requirements in normal and diseased states, the effects of excesses and deficiencies, nutrient interactions, and the diet's role in the onset and development of disease.

2. Food and nutrient utilization--studies of the consequences of food or nutrient ingestion and other factors related to digestion, absorption, metabolism, and excretion.

3. Diets for maintaining health and treating disease--studies developing diets for optimal health in normal individuals and formulating therapeutic nutritional regimens. Among the diseases studied are obesity, cancer, heart disease, deficiency diseases and anemias, diabetes, dental caries, and inborn errors of metabolism.

4. Nutrition and behavior--studies of diet patterns, the impact of malnutrition or specific nutrients on behavior and intelligence, the behavioral aspects of obesity, and psychological factors that determine nutrient intake and the means by which these factors may be modified.

1/NIH direct research in human nutrition includes studies measuring the consequences of nutrient intake in the intact organism. Related research includes studies involving nutrient variables or studies with results expected to have nutritional health significance through diet.

5. Nutrition and health status--epidemiologic studies or nutrition surveys to assess food and nutrient intake in relation to the evidence that disease states may have an associated nutritional basis and to appraise the nutritional status of individuals and groups.

6. Nature and composition of food--studies of the nutrient composition of foods, the biological availability of nutrients, methods of modifying the nature of foods, and the effects of food processing on availability and composition of nutrients.

Several NIH research programs are pertinent to the major gaps in nutrition knowledge. Particularly relevant is the research supported by the National Institute of Child Health and Human Development; the National Institute on Aging; the National Cancer Institute; the National Heart, Lung, and Blood Institute; and the National Institute of Arthritis, Metabolism, and Digestive Diseases. These institutes accounted for about three-fourths of all NIH nutrition research in 1975.

National Institute of Child Health and Human Development

Nutrition research supported by the National Institute of Child Health and Human Development (NICHD) focuses on meeting nutritional needs in pregnancy, infancy, and lactation to prevent fetal deaths and promote growth and development during early life. Nutrition research expenditures in 1975 totaled $11.6 million.

Major study areas include (1) malnutrition and retarded growth in the uterus (a major cause of fetal death), (2) parenteral nutrition for premature infants, (3) nutrition and mental development, (4) nutrition and abnormal nutrient metabolism, (5) nutrition and immunity mechanisms, and (6) nutrition and the reproductive function. In addition, since research has shown that several adult disorders can be traced to nutrition and diet in infancy and childhood, the NICHD is concerned with identifying early indicators of adult disorders, especially obesity.

Examples of pertinent research projects include studies examining:

--Mechanisms by which maternal malnutrition, nutrient transport across the placenta, and fetal disease influence retarded growth in the uterus.

--Optimal composition of formulas for parenteral feeding of low-birth-weight infants.

--Long-term behavioral effects of early malnutrition and the effects of iron deficiency anemia and other deficiencies of specific nutrients.

--Role of abnormal use of amino acids, trace elements, and other nutrients in damaging the nervous system.

--Effects of retarded growth in the uterus on development of disease immunity and the mechanisms by which immunity is imparted to the infant by breast milk.

--Mechanisms controlling fat cell development in infancy and childhood and the role of genetic factors in obesity.

NICHD's research plans place highest priority on malnutrition as a factor in the outcome of pregnancy, particularly as it may contribute to prematurity and small-for-date infants. Special attention will be given to nutritional needs in teenage pregnancy. Other pertinent subjects to be emphasized include prenatal and early postnatal nutrition in development of disease immunity and the ability to withstand infection; effects of oral contraceptives on nutritional status; incidence and persistence of childhood obesity; the relationship of undernutrition to mental and behavioral development; and nutritional needs in adolescence.

National Institute on Aging

The National Institute on Aging spent $1.3 million in 1975 to support basic and clinical nutrition research on minimizing the debilitating effects of aging in humans. Research projects address the nutritional requirements of the elderly and the effects of diet on the aging process and are primarily concerned with

--identifying factors that may alter the nutritional requirements of the aged;

--determining changes in nutrient intake as they occur with aging;

--determining the impact of nutrition on age-related changes and their reversibility in human populations;

SOURCE: NICHD

THE 10-WEEK-OLD, GENETICALLY OBESE MOUSE AND ITS LEAN LITTERMATE ARE SUBJECTS OF A STUDY ON THE DEVELOPMENT OF OBESITY IN GENETICALLY OBESE RODENTS CONDUCTED AT COLUMBIA UNIVERSITY WITH NICHD SUPPORT. THE PROJECT'S PURPOSES ARE TO (1) IDENTIFY THE MECHANISMS THAT CONTROL FATTY TISSUE MASS AND THE DEFECTS THAT MAY OCCUR WHEN OBESITY IS INHERITED AND (2) DEVELOP A BIOCHEMICAL PROFILE FOR IDENTIFYING THE "PRE-OBESE" CHILD.

--evaluating the feasibility of changing eating habits at all ages to assure optimal nutrition during aging; and

--determining the nutritional manipulations that affect the biological mechanisms of aging.

Specific studies included:

--determining whether the increased longevity in dietary-restricted adult animals results primarily from protein or caloric restriction;

--comparing the rates of age changes in enzyme activities and immune-system responsiveness in normal animals and those whose lifespan has been extended by low-protein diets; and

--establishing whether vitamin supplementation in adult animals results in delay of age-related changes and/or increased lifespan.

Among the research areas to be emphasized by the Institute are determining whether age-related changes of nutrient intakes in women are comparable to those thus far obtained in men and determining the interrelationships among the intervention point, dietary restriction, lifespan, and age-related changes.

National Cancer Institute

The focal point for research on the role of diet and nutrition in preventing and treating cancer is the Diet, Cancer, and Nutrition Program of the National Cancer Institute. This program, developed in response to a mandate in the 1974 amendments to the National Cancer Act (P.L. 93-352), develops and disseminates information on cancer causation, therapy, and rehabilitation. Direct and related Institute nutrition research expenditures totaled $9.5 million in 1975. About 41 percent of intramural and direct extramural expenditures supported research on cancer causation, 55 percent supported research on therapy and rehabilitation, and 4 percent supported miscellaneous research services.

Research on cancer causation is oriented toward ascertaining the underlying causes and interrelationships among dietary and nutritional factors leading to the onset and development of cancer in humans. Research projects include:

--Evolution studies on diet adaptation and animal models to determine whether changes in man's diet

habits are accompanied by changes in his cancer experience.

--Studies of acute and chronic diet alterations in man and animals to assess carcinogenesis in relation to various dietary components, including under- or over-nutrition, protein, fat, carbohydrates, fiber, vitamins, and mineral elements.

--Epidemiologic surveys to develop leads on dietary causes of cancer.

Cancer therapy research is oriented toward the role of metabolic and dietary processes in cancer development and toward the use of nutritional supplementation in supporting surgical, chemical, and radiation therapy. Research projects include:

--Human and animal studies focusing on changes in metabolic processes produced by cancer, including changes in protein, lipid, energy metabolism, and toxic substances produced by a tumor.

--Studies on the alteration of taste and smell perception in the cancer patient to overcome appetite loss.

--Studies to develop improved methods of nutritional support to bring the cancer patient into a normal state of nutrient metabolism.

Research on rehabilitation seeks to reassimilate the cancer patient into the family unit and community.

Future research in cancer causation will continue to stress studies of dietary evolution and adaptation, dietary excesses and deficiencies, and cancer incidences among population groups, with emphasis on defining desirable diets Children will be a primary target for investigation, since cancer has a relatively long latent period and dietary habits are formed early in life. To identify the mechanisms of carcinogenesis and improve toxicological assessment, studies will be undertaken to evaluate

--the role of diet and nutrition in carcinogen degradation systems;

--nutrient interactions in carcinogenesis;

--animal models for investigating dietary, nutritional, and cancer interactions;

--the nutritional adequacy of existing animal diets for carcinogenicity testing; and

--existing animal diets in relation to spontaneous and chemically induced cancer.

Future cancer treatment research will include studies of the effects of nutritional status on the immunity response of the cancer patient, nutritional control of tumor growth, diet and behavior modifications to improve appetite, and parenteral nutrition in cancer therapy.

National Heart, Lung, and Blood Institute

The objectives of the nutrition research supported by the National Heart, Lung, and Blood Institute include (1) defining diet's effect on blood lipids and coronary heart disease and death, (2) increasing the accuracy of measuring diet intake, (3) developing more comprehensive tables of food composition, and (4) achieving diet change to reduce blood serum cholesterol. Nutrition research expenditures in 1975 totaled $16.5 million.

In pursuing its objectives, the Institute:

--Conducts studies and clinical trials to (1) determine the prevalence of lipid abnormalities and associations with coronary heart disease among different populations, (2) determine whether reduction of cholesterol by itself or together with reduction of other risk factors will significantly reduce death from coronary heart disease, and (3) bring about changes in eating habits.

--Funds research grants that use both animal models and human participants to determine the role of specific nutrients in the metabolic processes related to heart disease.

--Codes all diet recall data collected in clinical trials and maintains a complex food table for calculating nutrients.

--Collaborates with USDA and the Food and Drug Administration in food analysis projects.

Future nutrition research will include continuing clinical trials on diet and heart disease with increased emphasis on modifying eating behaviors and greater support of food composition studies and analysis.

National Institute of Arthritis, Metabolism, and Digestive Diseases

The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) spent $15.2 million in 1975 on studies of nutrient functions and requirements and relationships of diet and nutrients to health and disease--obesity is an area of emphasis. NIAMDD has established an obesity center at St. Luke's Hospital, New York City, to conduct multidisciplinary investigations exploring various approaches to achieving weight loss such as starvation, intestinal-bypass surgery, and behavior modification. Other areas receiving substantial support include nutritional anemia studies; parenteral nutrition; and nutrient functions and interactions, including protein and amino acids, fat-soluble vitamins, and trace mineral elements.

Nutrition plans call for obesity to continue to receive high research priority. Other areas to receive emphasis include studies of parenteral nutrition, iron deficiency anemia, and trace elements.

HEALTH RESOURCES ADMINISTRATION

The Health Resources Administration conducts the Health and Nutrition Examination Surveys to determine the Nation's nutritional status. This is done by collecting and analyzing data on dietary intake, clinical examinations, and biochemical and anthropometric measurements. The initial survey, conducted from 1971 to 1974, collected data on a national sample of about 30,000 persons from age 1 through 74 years. A follow-on survey (begun in 1976 and to be completed in 1979) collects data on a sample of 25,000 to 30,000 persons from age 6 months to 74 years.

Some laboratory tests that were used in the initial survey have been dropped or curtailed in the current survey, including those for thiamine, riboflavin, iodine, and creatinine. Other biochemical and laboratory tests, including those for anemias and levels of copper, zinc, and lead, have been added or are receiving greater emphasis. In addition to data on nutritional status, the current survey collects data to measure the prevalence of several diseases and disorders, including heart disease, hypertension, diabetes, osteoarthritis, and spinal disc

SOURCE: NIAMDD

A RESEARCHER AT THE NIAMDD LABORATORY OF NUTRITION AND ENDOCRINOLOGY CHECKS THE WEIGHT OF A VITAMIN A-DEFICIENT RAT. THIS STUDY AND OTHERS AT NIAMDD HAVE CONTRIBUTED TO A BETTER UNDERSTANDING OF THE ROLES OF VITAMINS A AND E IN HUMAN NUTRITION.

degeneration. Survey costs totaled about $4.8 million in fiscal year 1976. Expenditures on the nutrition component of the survey were approximately $2.4 million.

According to HEW officials, data collected during the surveys should provide improved bases for estimating human nutritional requirements. They expect that data collected during the initial survey on blood levels of specific nutrients in women will be published shortly and that the follow-on survey will provide additional information.

OTHER FEDERAL AGENCIES SUPPORTING NUTRITION RESEARCH

Other HEW agencies supporting research addressing nutrition knowledge gaps include the Food and Drug Administration; the Center for Disease Control; the Health Services Administration; and the Alcohol, Drug Abuse, and Mental Health Administration.

Nutrition research is also supported by the Department of Defense; the Agency for International Development, Department of State; the National Science Foundation; the Cooperative State Research Service, USDA; the National Aeronautics and Space Administration; and the Veterans Administration.

Nutrition research of these Federal departments and agencies bearing on major knowledge gaps is described below.

Food and Drug Administration

The Food and Drug Administration, the Federal agency responsible for protecting Americans from foods that are not pure, wholesome, and safe to eat, supported intramural and extramural research in nutrition totaling about $2.9 million in 1976. Projects relating to major gaps in nutrition knowledge included human, animal-model, and fundamental studies to:

--Determine cardiac toxicity by examining the effects of dietary components on lipid metabolism and development of atherosclerosis.

--Determine requirements for protein, carbohydrate, and trace mineral elements.

--Determine the effects of dietary fiber on the absorption and metabolism of essential nutrients and develop and assess methods of determining fiber in the diet.

--Identify possible toxic effects of megadoses of vitamin B6 and vitamin C.

--Measure the biological availability of iron, determine its use and toxicity in combination with vitamins and protein, and assess food sources as vehicles for iron fortification.

--Survey and evaluate protein quality of new foods and develop rapid, reliable methods of measuring availability of amino acids in foods.

--Develop new and improved methods of food composition analysis for amino acids, fatty acids, and vitamins.

--Determine the levels of several mineral elements in food commodities and consumer diets.

--Increase nutrient retention in foods during cooking.

--Assess the antinutritional effects of modified carbohydrates in foods.

--Examine nitrosamines in foods.

Center for Disease Control

The Center for Disease Control has been instrumental in improving standards and techniques of nutritional assessment. It presently provides data collection, analytical, and dissemination services to 14 States and 3 municipalities conducting nutritional surveillance programs and provides laboratory support for the HEW Health and Nutrition Examination Survey. In addition, the Center has accepted the long-term responsibility for developing standardized laboratory methods used in assessing nutritional status.

The surveillance programs conducted by the various States entail assessing children who have been identified as "at risk" nutritionally and who are receiving clinical attention. In support of these programs, the Center has helped develop anthropometric standards for identifying retarded growth and obesity. About $250,000 was to be spent in fiscal year 1976 to support the Center's efforts.

The Center intends to help develop improved methods of determining anemia and more reliable and reproducible procedures for measuring body height and weight. In addition, the Center is developing reference methods and product class standards for nutritional analyses of commercial products.

Health Services Administration

Nutrition research supported by the Health Services Administration focuses on the nutritional needs of infants and children to provide a basis for nutrition counseling services and evaluation. Six extramural projects totaling $448,000 were funded in fiscal year 1976. The largest project addressed iron deficiency among infants and children to provide new knowledge for preventive health programs. Other projects concerned with nutritional problems of early life included studies of factors associated with food preferences, obesity, elevated cholesterol levels, milk sugar intolerance, and changes in nutritional status following institution of health and socioeconomic services.

Alcohol, Drug Abuse, and Mental Health Administration

In 1976 the Alcohol, Drug Abuse, and Mental Health Administration supported 22 intramural and extramural nutrition-related projects costing about $1.1 million. The bulk of those projects addressed the nutritional aspects of alcohol, such as the effects of alcohol consumption on nutrient metabolism or deficiency. Two extramural projects totaling $172,000 were supported to examine flavor, taste, and other appetite cues in normal and obese persons and to study the effects of food additives on hyperactive children.

Department of Defense

The Department of Defense (DOD) supports nutrition research aimed at (1) establishing nutrition standards for military personnel under normal environmental conditions and various environmental extremes, (2) determining the nutritional status of military personnel, and (3) determining the nutritional adequacy of foods. Although this research is concerned primarily with meeting military personnel needs, it may produce results applicable to the general population for defining human requirements, measuring nutritional status, and improving food quality.

DOD spent about $2.3 million in fiscal year 1976 on direct nutrition research, nearly all of which was conducted intramurally. This research included human, animal-model, and molecular studies to determine nutritional requirements and develop nutritional standards considering various environmental activities and conditions, such as combat and other stress circumstances and recovery from wounds, bone injuries, and gastrointestinal disorders.

Other DOD direct nutrition research addressed the nutritional status of military personnel and food composition and safety. This research included studies to develop analytical procedures applicable to nutrition surveys and assess nutritional status in terms of physical performance as well as the traditional parameters of clinical, biochemical, and food-intake measurements. Composition and safety research included studies determining nutrient composition and availability in foods and identifying toxic substances produced by microorganisms and insects.

In addition to its direct nutrition research, DOD estimates that it spent about $1.8 million on nutrition-related research projects. These projects included studies of the (1) nutritional adequacy of rations and food systems, (2) wholesomeness of current and future food and feeding systems, and (3) nutritional support of the medical or surgical patient.

Future DOD nutrition research will seek to learn the nutritional effect of disease and injury and nutritional manipulations that may speed recovery. Also planned or in progress is research emphasizing clinical nutrition problems that may affect military performance. Specific research areas include

--the effects of diet on acclimation;

--protein requirements under various conditions;

--laboratory and field studies to establish diet requirements for health-related problems of military personnel;

--the effects of stress, disease, and injury on nutrient requirements;

--human and animal-model nutrition studies of prevention and repair of bone fractures;

--fundamental research followed by applied human field studies on nutrition and metabolism, particularly energy metabolism; and

--the development of new methods for assessing nutritional status and evaluating special rations.

Agency for International Development

The Agency for International Development (AID) supports human nutrition research as part of its nutrition program and mandate to assist less developed countries. The program focus is on societies where undernutrition rather than overnutrition is the major nutritional concern. AID nutrition research concentrates on improving the delivery of more and better food to impoverished populations. Research is directed at identifying nutritional deficiencies and devising cost-effective methods for alleviating these deficiencies.

During fiscal year 1977, the Agency supported human nutrition research studies costing approximately $3 million. All projects were funded by contracts. Currently, AID has contracts of $1 million with other Federal agencies.

The nutrition research program is centered on the following activities:

--Developing methods for (1) assessing the effects on nutrition of other development activities, (2) diagnosing the causes of malnutrition, and (3) selecting appropriate interventions for addressing the problems identified.

--Developing low-cost, rapid methods for determining nutritional status and dietary intake.

--Developing appropriate nutrition inputs for integration into low-cost nutrition/health systems.

--Determining the bioavailability of iron compounds in typical less developed countries' diets and for assessing the prevalence of iron deficiency anemia.

--Developing procedures for assessing the prevalence of vitamin A deficiency and the efficacy of vitamin A fortification/supplementation programs.

--Determining the relative significance of protein versus calorie deprivation in relation to fetal and postnatal physical growth and morbidity and mortality rates during the the first 2 years of life.

--Developing appropriate technologies for fortifying foods with amino acids, protein concentrates, minerals and vitamins, and preparing low-cost, nutritious blended foods.

--Developing methods for utilizing nonformal techniques, including mass media, in nutrition education and evaluating the effectiveness of nutrition education programs.

The AID and the nutrition research programs of other Federal agencies have common interests in human nutrient requirements, nutrient bioavailability, and determination of nutritional status and dietary intake.

National Science Foundation

The National Science Foundation does not have a distinct program in nutrition, but it does support extramural studies on nutrition in carrying out its mission of initiating and supporting basic scientific research. Foundation officials identified 77 nutrition-related projects for which about $4.3 million was obligated during fiscal year 1976 or the transition quarter. The scope of these projects is wide ranging and relates to aspects of applied medicine as well as agriculture. A substantial number of projects address processes by which food components are synthesized and broken down; other projects study mechanisms by which food is located, ingested, or processed within the organism; and a few projects focus on land use and food production, fabrication, and distribution. In terms of major knowledge gaps, the research activities below, totaling about $315,000, appear most relevant:

--Six studies on obesity, appetite control, and eating behavior.

--One study on nutritional and environmental effects on aging and behavior.

--One study on the effects of malnutrition on behavior.

Cooperative State Research Service

The Cooperative State Research Service (CSRS) functions primarily to administer congressional acts that authorize appropriations for agricultural research conducted by non-Federal parties. CSRS's estimate of its research expenditures

in fiscal year 1976 was about $8 million for human nutrition and well being, food safety, and improved food products.

The research projects administered by the Cooperative State Research Service cover a broad range of nutrition areas. About two-thirds of the funds devoted to nutrition research in 1975 were used to support studies of either nutritional status or food composition safety and nutrient biological availability. The remaining funds supported studies of human requirements, nutrient function and metabolism, diet in disease, and nutrition education.

National Aeronautics and Space Administration

Although the National Aeronautics and Space Administration does not have a formal nutrition mission, it does support extramural and intramural research to define nutritional requirements for maintaining human health in space flight and to develop novel food forms and delivery systems for meeting those requirements. About $185,000 will be spent in fiscal year 1977 on the nutrition component of current studies.

While the agency's research deals with a healthy adult population in space flight, some of its research could have consequences for human nutrition requirements on earth. For example, on the basis of earlier findings of significant calcium, nitrogen, and phosphorus losses from the bones and muscle of Skylab astronauts, a current project is seeking to prevent bone demineralization through dietary mineral supplements. While the research results would be applicable principally to long-term space flight, they also may be applicable to dietary treatment of long-term bedridden patients. Other projects are examining the effects of diet variations of proteins, calcium, and vitamin D on the muscles and bones and studying nutrient retention of freeze-dried foods.

Veterans Administration

One Veterans Administration mission is to provide quality medical care to eligible veterans. The agency does not have a distinct nutrition program but does conduct nutrition-related studies to support medical and surgical research. Nutrition research expenditures in fiscal years 1975 and 1976 were estimated at $450,000 for each year.

Research projects included studies of obesity using human subjects and animal models to

--characterize the physiological processes of obesity,

--assess the metabolic effects of intestinal-bypass surgery in producing weight loss, and

--evaluate behavioral techniques for motivating weight reduction (such as monetary rewards and participation in structured group activities).

VA also supports studies in nutritional requirements for trace metals, vitamin B12 utilization, regions of the brain responsible for appetite control, and physiological effects of artificial food additives.

CHAPTER 4

BARRIERS TO PROGRESS IN HUMAN NUTRITION RESEARCH AND POTENTIAL SOLUTIONS

On the basis of written comments of persons active in the nutrition field, nutrition manpower studies, and discussions with nutrition researchers, university nutrition department heads, representatives of nutrition professional societies, and Federal officials, we identified three principal barriers to progress in human nutrition research. These barriers are the (1) lack of central focus and coordination, (2) shortage of nutrition scientists, and (3) instability of federally funded extramural research.

Various proposals have been made to overcome these barriers. The Congress enacted legislation in September 1977 that addresses these barriers.

LACK OF CENTRAL FOCUS AND COORDINATION

Human nutrition research is not a well-defined discipline. Instead, it is a multidisciplinary field related to both food and health that has broadened substantially as the importance of diet in disease has gained recognition.

While NIH and the Agricultural Research Service provide the bulk of research funds, neither of these agencies has human nutrition research as its primary mission.

NIH is concerned with biomedical nutrition research as part of its overall mission of fostering, supporting, and conducting laboratory and clinical research to increase the understanding of the life processes and the cause, treatment, and prevention of disease. Nutrition research programs are disseminated throughout individual institutes that are categorically organized by diseases. Only NICHD and the National Institute on Aging have a lifecycle perspective on research.

In seeking to assure an abundant and economical food supply, the Agricultural Research Service is concerned with human nutrition apart from disease entities. However, the Service has not given human nutrition research high priority.

Several persons cited fragmented research among Federal agencies as a barrier to progress and called for greater focus on human nutrition and improved coordination of research programs. Fragmentation and lack of focus and coordination

are perceived to cause (1) the likelihood that important nutrition areas are not receiving adequate emphasis and (2) the support of overlapping and possibly redundant research projects.

Inadequate or possibly redundant research

The division between USDA and HEW of national food consumption and nutrition status surveys is seen to result in information that is inadequate for sound nutrition planning. Neither Department provides the comprehensive national nutritional surveillance system relating diet to health on a continuous, long-term basis.

The USDA Nationwide Food Consumption Survey permits some conclusions about the nutritional adequacy of diets. However, since the Survey does not include collection of clinical and biochemical measurements, its data cannot be used to assess nutritional status. The HEW Health and Nutrition Examination Survey may permit some generalizations about the Nation's nutritional status and changes in that status over time. The Survey is concerned with identifying possible nutritional deficiencies and the prevalence of certain diseases. HANES is a periodic survey which does not continuously assess all aspects of nutritional status. The surveillance programs involving the Center for Disease Control do entail continuous nutrition assessments but are limited to children already identified as "at risk."

There are several instances of overlapping and possibly redundant research. For example, a nutrition researcher with a major university noted that both NIH and USDA support studies of various nutrients. NIH supports research on carbohydrates, lipids, vitamins, mineral elements, and protein, while the Agricultural Research Service maintains separate laboratories for research on the same nutrients.

USDA officials told us the Service and NIH approach the same research areas from different perspectives. The Service is oriented toward the nutrition requirements of healthy individuals, while NIH is concerned about nutrition and disease treatment and its prevention. They said there is some overlap and confusion in the roles of the Service and NIH, especially in maintaining a healthy individual and preventing disease. USDA officials told us that a bridge needs to be made between agriculture and medicine to overcome any existing obstacles.

Other examples of overlapping research include studies of obesity, nutrient availability, food fortification, and dietary fiber. Obesity research is supported by NIH; the National Science Foundation; and the Alcohol, Drug Abuse, and Mental Health Administration. Research on nutrient biological availability is supported by USDA and the Food and Drug Administration. Research on food fortification is supported by USDA, the Food and Drug Administration, and the Agency for International Development. Research on dietary fiber analysis is supported by USDA and the Food and Drug Administration.

Coordination efforts by Federal agencies

Nutrition coordinating groups do exist within certain Federal departments and agencies. These groups differ in their authority to set research priorities and direct research resources. Agencies have also collaborated on nutrition research projects of mutual interest.

USDA nutrition research is coordinated through the Assistant Secretary for Conservation, Research and Education and the Committee on Food and Nutrition Research. Established in 1972, the Committee includes representatives from seven USDA agencies and coordinates and appraises food and nutrition programs, identifies research needs, recommends research programs, and maintains liaison with other groups or agencies concerned with human nutrition research.

The Secretary, HEW, adopted a formal policy statement in 1975 that provides that nutrition shall permeate all HEW health-related activities. No group coordinates nutrition research among the various HEW agencies, however. An HEW committee that was established in 1973 to provide a focus for nutrition and promote research, policy, and program coordination was subsequently terminated. According to the chairman, the committee was terminated due to differing priorities among agencies; lack of authority, expertise, and interest among committee members; and insufficient financial support.

NIH established a Nutrition Coordinating Committee in 1975 composed of representatives with expertise and common interests in nutrition. While it does not set research priorities or direct research resources, the Committee serves as a forum for exchanging nutrition information among the Institutes, discussing other HEW agencies' programs, and disseminating nutrition information to the scientific community. The Committee also has been developing a nutrition plan and has established subcommittees for improving and standardizing the reporting of nutrition research and for organizing workshops to identify nutrition knowledge gaps.

Among Federal departments and agencies with nutrition coordinating groups, the Joint Nutrition Research Planning Board, DOD, exercises the most authority. Composed of representatives from the military services and the Office of the Surgeon General, the Board is responsible for formulating research goals; assigning research priorities and identifying duplicate, unnecessary, or overlapping research efforts within DOD.

In some cases Federal agencies collaborate on research projects of mutual interest. For example, agencies outside USDA are contributing $1.1 million to the Nationwide Food Consumption Survey. The National Heart, Lung, and Blood Institute collaborates with the Food and Drug Administration and USDA on food analysis projects. In addition, agencies contribute funds to the National Academy of Sciences to support development of the recommended dietary allowances and the "Food Chemicals Codex."

SHORTAGE OF NUTRITION SCIENTISTS

Many members of the scientific community believe that there is a shortage of scientists capable of operating effectively in nutrition. Thus, insufficient manpower could be a barrier to substantial progress in human nutrition research. Existing information is inadequate for delineating nutrition manpower shortages by specialty areas. Forecasting manpower needs is extremely difficult because little accurate information exists on the number of nutrition researchers, nutritionists, food technologists, and dietitians employed in the United States, the jobs held, their degree of training, and their scientific specialty. However, during this review we noted that certain manpower areas are perceived as being of particular concern.

One shortage area is clinical nutrition research, in which individuals trained in health-related nutrition areas are needed. More clinical researchers are believed to be needed in defining the roles of various nutrients, investigating the nutritional causes of and contributions to disease, and exploring appropriate nutrition treatment methods.

Nutritionists with the background and experience in nutrition to teach at universities and medical schools are also cited as being in short supply. In the broad medical area, the demand for clinical faculty in medical schools has been increasing and is expected to increase at an annual rate of between 5 and 8 percent to 1980. There are presently far more openings for academic nutritionists than candidates

to fill them, and several university department heads and professors said they are having difficulty finding qualified candidates.

Another concern to some nutrition administrators is that the number of graduate students enrolled in nutrition programs is low compared to need. As an academic discipline, nutrition may be found among departments of biological science, animal science, home economics, public health, medical science, and food science. Only during the past 10 or 15 years have universities consolidated nutrition-related areas in comprehensive departments and programs.

The Federal Government, through the National Academy of Sciences/National Research Council, has begun to focus on determining manpower in specialty areas and on improving abilities to forecast manpower requirements. These efforts could be important to determining the personnel shortages affecting the Nation's nutrition research capabilities and the types of Federal manpower development actions that may be needed.

INSTABILITY OF FEDERALLY FUNDED EXTRAMURAL RESEARCH

Several persons providing comments on nutrition knowledge gaps expressed concern over the instability of federally funded extramural research. This issue is not unique to nutrition. The President's Biomedical Research Panel reported that the necessity of achieving funding stability was a recurring theme among the 160 witnesses it consulted. The Panel noted that stable funding involved stability within any given year, stability from year to year, and sufficient program content stability to permit effective planning and performance.

Funding stability appears especially pertinent to nutrition, however, since filling gaps in knowledge may require long-term research. For example, epidemiological studies and clinical trials often require several years. Similarly, development and use of animal models for long-term studies may involve substantial space requirements, environmental controls, and measures to protect against infectious disease.

POTENTIAL SOLUTIONS TO RESEARCH BARRIERS

Several potential solutions exist for overcoming the barriers to progress in human nutrition research. A national nutrition institute has been proposed by some, under which

all Government nutrition-related activities would be centralized and research grants would be provided. An alternative would be to create a central planning and coordinating office that would oversee all Federal agency nutrition-related activities and guide research funding.

Several persons contacted commented on establishing regional nutrition research centers or research laboratories, possibly in conjunction with selected universities and colleges. Such centers or laboratories can offer several advantages for human nutrition research. They could more readily identify food and nutrition problems unique to regions and evaluate the effectiveness of diet modifications for preventing or treating those problems. Similarly, they could help increase participation by the extramural research community, enable investigators trained in various disciplines to collaborate on research projects, and provide advanced nutrition research training. The centers or laboratories could serve as vehicles for cooperatively funded projects among Federal agencies and could be used for long-term research programs, including nutritional monitoring of regional populations.

The executive branch and the Congress recently considered solutions to the problems of human nutrition research focus, direction, emphasis, and organization.

Study by the Office of Science and Technology Policy

Under the National Science and Technology Policy, Organization, and Priorities Act of 1976 (P.L. 94-282), the Congress established the Federal Coordinating Council for Science, Engineering, and Technology. Composed of the Director, Office of Science and Technology Policy (who serves as chairman), and representatives of Federal departments and agencies, the Council was established to consider problems and developments in science, engineering, and technology and related activities affecting more than one Federal agency. Council functions include recommending policies and other measures to (1) identify research needs (including areas requiring additional emphasis), (2) achieve more effective use of scientific resources and facilities of Federal agencies, including eliminating unwarranted duplication, and (3) provide more effective planning and administration of Federal scientific programs.

The Office of Science and Technology Policy began an analysis in May 1977 for the Office of Management and Budget on Federal human nutrition research activities. OSTP's

draft report, dated September 16, 1977 (revised December 1977), recommended that actions need to be taken to improve coordination of research in the many areas of overlapping responsibilities among the agencies. Also, HEW and USDA need to establish clear and, wherever possible, distinct missions for human nutrition research. OSTP identified high-priority research in (1) effects of nutrition on human health and performance, (2) food sciences, (3) nutrition education research, and (4) diet and nutritional status surveillance. (See p. 72 for additional comments on the OSTP draft report.)

White House initiative

The President directed on August 25, 1977, his Reorganization Project staff (at OMB) to conduct a review of the organization and structure of Federal food and nutrition programs. The objective of this review is to improve the Government's capability to address the Nation's needs for adequate supplies of reasonably priced, safe, and nutritious foods. The review will focus on seven major areas including a section on food research and education.

Legislation

At the time our report was with the Federal agencies for comment, the Congress enacted the Food and Agriculture Act of 1977 (P.L. 95-113, approved Sept. 29, 1977). The act provides for (1) creating within USDA a national food and human nutrition research and extension program, (2) mechanisms for USDA and Government-wide research planning and coordination, (3) periodic reporting of research efforts and accomplishments, and (4) a competitive research grants program in USDA that emphasizes research on high-priority areas. In addition, the act requires USDA and HEW to formulate a plan for a comprehensive nutritional status monitoring system for consideration by the Congress.

The act provides that food and human nutrition research be established as a separate and distinct mission of USDA. It also provides that the Secretary of Agriculture study the potential value and cost of establishing regional food and human nutrition research centers. The study would be required to assess the feasibility of using existing Federal facilities in establishing such centers.

Subject areas defined in the act to be part of USDA's food and human nutrition research and extension program include (1) human nutritional requirements, (2) nutrient composition of foods and the effects of agricultural practices,

handling, food processing, and cooking on food nutrient content, (3) factors affecting food preferences and habits, (4) development of techniques and equipment to assist consumers in selecting a nutritionally adequate diet, and (5) surveillance of the nutritional benefits provided to participants in food programs administered by USDA.

The planning and coordinating of research and extension would be facilitated under the legislation through a:

--Subcommittee on Food and Renewable Resources under the Federal Coordinating Council for Science, Engineering, and Technology. The Subcommittee would be composed of representatives from 10 Federal departments and agencies and would be chaired by the principal representative of USDA.

--Joint Council on Food and Agricultural Sciences within USDA composed of members from USDA, CSTP, other Federal departments and agencies, and members from other organizations involved in food and agriculture issues.

--National Agricultural Research and Extention Users Advisory Board within USDA; composed of members representing various organizations and interest groups.

The latter two groups would be responsible for annually (1) examining federally supported agricultural research and extension programs, (2) identifying the priority needs of programs, and (3) making recommendations to the Secretary, USDA, on allocations of responsibilities and levels of funding among those programs.

CHAPTER 5

CONCLUSIONS, RECOMMENDATIONS, AND AGENCY COMMENTS

CONCLUSIONS

Human nutrition research has entered a new era, marked by growing evidence implicating diet as a major cause of disease and by increasing public concern about nutrition. To determine diet's potential for helping reduce disease and related health care costs, nutrition research faces complex challenges needing long-term and interdisciplinary investigation. These challenges are to:

--Define human nutrition requirements for promoting or maintaining growth, development, or well-being during pregnancy, infancy, lactation, childhood, and adolescence, and for women, the elderly, those with disease and stress, and those taking drugs and vitamins.

--Determine the nutrient composition of the current food supply and the biological availability of the nutrients in foods.

--Evaluate the health consequences of the modern diet.

--Monitor the Nation's nutritional status continually and determine the relationships among nutritional status at one period of life on health in later periods.

To help meet these challenges, there is a need for (1) a central focus for human nutrition research and Government-wide coordination of research programs, (2) definition of subject areas comprising human nutrition research and the responsibilities of Federal agencies, and (3) assessment of the need for establishing regional nutrition research centers in conjunction with colleges and universities that have comprehensive nutrition departments and programs.

Central focus and improved coordination are needed

Federal support of varied aspects of human nutrition research is a reflection of our decentralized (pluralistic) system that encourages each agency to support research

essential to its primary mission without direction from a central authority. While the pluralistic system is generally believed to have enabled the United States to maintain strong scientific leadership, it can cause unwarranted overlap or duplication in some areas and insufficient coverage in others.

Some agencies support overlapping and possibly redundant research, while no one agency conducts the comprehensive national nutritional surveillance system relating diet to health on a continuous, long-term basis. The overlapping interests of the various agencies involved in human nutrition make a central focus and coordination essential to assuring mutually compatible and coherent research programs.

The Food and Agriculture Act of 1977 designates USDA as the lead agency for agricultural research (excluding the biomedical aspects of human nutrition concerned with diagnosis or treatment of disease), extension, and teaching in the food and agricultural sciences. The act requires the Secretary, USDA, to jointly establish with the Secretary, HEW, procedures for coordinating of nutrition research in areas of mutual interest and to formulate a plan for a comprehensive nutritional monitoring system.

The act also

--provides mechanisms for coordinating agricultural research within USDA and on a Government-wide basis and

--establishes food and human nutrition research as a separate, distinct mission of USDA.

Research areas and responsibilities need to be defined

One complicating aspect of human nutrition research is that it is not a well-defined discipline. Instead, it is a multidisciplinary field related to both food and health that involves the missions of several agencies. Under the pluralistic system, some research overlap among agencies is inevitable. For example, the Agricultural Research Service promotes health through diet and NIH prevents disease through diet; thus, human nutrition requirements will continue to be an area of mutual interest. This is not necessarily an inefficient arrangement, provided that the programs are coordinated so that unnecessary research is eliminated and areas needing greater emphasis are identified and supported. To facilitate effective coordination, the subject

areas comprising human nutrition research and the roles of various Federal agencies involved in food and health research should be clearly defined.

To assure that unnecessary research is eliminated and areas identified as needing additional emphasis will be addressed, we believe the subject areas comprising human nutrition research should be defined and, where practicable, each area should be assigned to a lead Federal agency. We also believe that identifying key subject areas of human nutrition research enhances the potential for meaningful analysis of the Nation's nutrition manpower shortages and needs.

The Food and Agriculture Act of 1977 defines some of the key areas of human nutrition research. It requires the Secretary of USDA to develop and implement a national food and human nutrition research and extension program that shall include (but not be limited to)

--research on human nutrition requirements;

--research on the nutrient composition of foods and the nutritional effects of agricultural practices, handling, food processing, and cooking;

--surveillance of the nutritional benefits provided to USDA food program participants;

--research on the factors affecting food preference and habits; and

--the development of techniques and equipment to assist consumers in the home or in institutions in selecting food that supplies a nutritionally adequate diet.

While the act defines some of the areas, there is still a need to continue the process of defining and refining the subject areas of human nutrition (such as, human nutritional requirements involving biomedical research other than that directly related to disease). The roles of the Federal agencies in planning and implementing such research should also be clearly delineated.

Regional research centers working in conjunction with universities and colleges need to be considered

The Food and Agriculture Act of 1977 requires the Secretary, USDA, to assess the potential value and costs of establishing regional food and nutrition research centers in the United States. In this assessment the Secretary is to examine the feasibility of using existing Federal facilities in establishing such centers.

If established in conjunction with universities and colleges that have comprehensive nutrition departments and programs, regional food and nutrition research centers may offer several advantages. First, such centers could help increase participation by the extramural research community, enable investigators trained in various disciplines to collaborate on research projects, and provide research training and development to help meet the Nation's nutrition manpower needs. Second, the centers could be used to promote long-term research, including comprehensive nutrition surveillance of representative populations.

Research centers could also help identify unique regional food and nutrition problems and evaluate the effectiveness of diet modifications for preventing and treating those problems. In addition, the centers could be vehicles for cooperatively funded projects among Federal agencies that have common nutrition interests.

We believe that any assessment of the feasibility of establishing regional food and nutrition research centers should consider access by colleges and universities with comprehensive nutrition departments and programs.

RECOMMENDATIONS

We recommend that the Director, Office of Science and Technology Policy, work with the Federal agencies to further define the subject areas comprising human nutrition research and make recommendations to the Director, Office of Management and Budget, to:

--Assign, where practicable, each area to a lead Federal agency.

--Eliminate unnecessary research that may exist among Federal agencies.

--Promote Government-wide human nutrition research planning, coordination, and reporting.

We recommend the Secretary, USDA, in assessing the need for regional food and nutrition research centers, consider access by colleges and universities with comprehensive nutrition departments and programs.

AGENCY COMMENTS AND OUR EVALUATION

OMB, OSTP, USDA, HEW, DOD, AID, NSF, NASA, and VA reviewed and commented on our report. (See apps. II through VI.) GAO notes to some of the agency comments are in appendix VII.

OSTP said that a great deal of support now exists from the Congress and the Administration for making changes to enhance the effectiveness of federally supported human nutrition research. It said that the our recommendations, together with its own, could make the Federal human nutrition research effort substantially more effective. OSTP agreed that lead agency responsibilities have to be established and that a central focus is necessary for planning and coordination. It said that actions should be taken such as joint agency participation in conducting research, developing research plans, and monitoring ongoing research.

OSTP issued a draft report in September 1977 (revised December 1977) on federally supported human nutrition research. The report was based on the work of a group of representatives from five Federal agencies. The OSTP report

--defined the scope of human nutrition research;

--described and assessed existing Federal nutrition research programs;

--identified research areas requiring increased attention; and

--suggested mechanisms for enhancing coordination and improving the scientific quality of Federal research activities.

We believe OSTP's work is a positive step toward more effective Federal human nutrition research.

HEW said our report is a reasonable, accurate reflection of Federal human nutrition research activities. It said the identified research needs, the conclusions, and recommendations are generally consistent with thinking within the scientific community, both within and outside the Federal Government. HEW recently instituted a review of its nutrition efforts to formulate a long-range departmental nutritional policy. As a result of that review, HEW determined that nutrition activities have been inadequately coordinated within the Department and have not received the emphasis they deserve.

USDA pointed out that the lack of a clear-cut definition of the scope of the ongoing studies and reports on human nutrition research has created some confusion. It said that we and OSTP reported different estimates of the Federal funds for human nutrition research. In our August 1977 report draft, we showed that about $80 million was spent in fiscal year 1975 for human nutrition research. OSTP's report in September 1977 reported that about $93 million was spent in fiscal year 1975. The difference between our and OSTP's reported amounts is based on revised estimates provided by NIH. An NIH official told us that NIH's revision in estimated expenditures was due to an improvement in its research reporting system, which identified the nutrition component of biomedical research projects.

It should be recognized that a major obstacle for any review of Federal human nutrition research is the lack of good data on the amount the Federal Government spends and the research projects pursued. Any estimate of human nutrition research will depend on how human nutrition research is defined. Estimates used in our report are based on data supplied by the departments and agencies and are dependent on the agencies' concepts or definitions of nutrition. In some cases, the agencies included projects in which nutrition is only one aspect of a research project.

Until there is some concensus among the Federal agencies on the definition of human nutrition research, the exact level of Federal resources devoted to this research cannot be determined. Development of meaningful reporting systems for human nutrition research will, likewise, depend on resolution of the definition problem.

OSTP, USDA, NSF, and VA said that some overlap or duplication of nutrition research areas may be desirable and not necessarily inappropriate or unwarranted. They said that overlap or duplication is appropriate especially

if it results in complementary approaches to gaining knowledge, verifies earlier research, and stresses reliability. We agree that some overlap and duplication can be desirable; however, with limited resources (research funds and nutrition scientists), we believe mechanisms should be in place to assure that needed areas of nutrition research are not being neglected because of unnecessary duplication in other areas and to help assure that the duplication is justified.

OSTP and NSF commented on the need to consider establishing regional research centers in conjunction with universities and colleges. OSTP cautioned against recommending construction of major regional facilities. NSF said that, if past experience is any indication, these centers will prove difficult for outside researchers from other colleges and universities to use. While our draft report was with the agencies for comment, the Food and Agriculture Act of 1977 was approved by the President. It requires the Secretary, USDA, to assess the potential value and cost of establishing regional food and nutrition research centers. USDA said that our proposal to explore potential value and costs of establishing them in conjunction with universities and colleges is a very important one. We believe the Secretary's study should cover all cost and benefit issues of regional food and nutrition centers.

OSTP said it did not find much concern about the shortage of nutrition scientists and doubts that it is a major barrier. We believe a nutrition manpower shortage could be a barrier to substantial progress in human nutrition research especially if there is an expanded Federal nutrition research effort in the short term. As noted in our report, there is not sufficient information delineating the nature, extent, and specialty areas of nutrition manpower shortages. We agree with OSTP's conclusion that if more funds are available or if funding is certain for long periods of time, then more scientists may enter the nutrition research field.

DOD said it supports the conclusions and the general recommendations made in the report. NASA said it agrees fully with the purposes and objectives of the report and that there is clearly a need for increased emphasis on nutrition research.

The President directed his Reorganization Project staff (at OMB) on August 25, 1977, to conduct a review of the

organization and structure of Federal food and nutrition programs. This review will focus on seven major areas including a section on food research and education. OMB said that it will be looking at many of the nutrition research issues identified in our report. We believe the Administration's initiative could help develop and implement a coherent Federal food and nutrition policy.

MATTERS FOR ATTENTION OF THE CONGRESS

The information developed in this report should be useful to the Congress in evaluating the direction and emphasis of Federal agencies' human nutrition research.

In its monitoring and oversight of the Federal human nutrition research, the Congress should determine whether the recent initiatives of OSTP, OMB, and the implementation of the Food and Agriculture Act of 1977 result in the needed focus, direction, and coordination for this important research effort.

CHAPTER 6

SCOPE OF REVIEW

In identifying (1) major gaps in nutrition knowledge, (2) nutrition research needs, and (3) barriers to research progress, we:

1. Obtained written observations and views from 32 individuals active in research, teaching, or clinical practice of human nutrition.

2. Examined major studies of nutrition research and manpower needs, including

   a. the Report of the President's Biomedical Research Panel (1976);

   b. interim and final reports of the National Academy of Sciences/National Research Council's Study on World Food and Nutrition (1975, 1976, 1977);

   c. the report of the 1975 Working Conference to Meet U.S. and World Food Needs, Agricultural Research Policy Advisory Committee;

   d. the report of the Agricultural Research Council/Medical Research Council, United Kingdom, on Food and Nutrition Research (1974);

   e. a report of the National Institute of General Medical Sciences (1971);

   f. the final report of the 1969 White House Conference on Food, Nutrition and Health; and

   g. the draft report by the Office of Science and Technology Policy on human nutrition research (Sept. 1977 and Dec. 1977 revision).

3. Reviewed information obtained by the Office of Technology Assessment on human nutrition research.

4. Interviewed officials from the National Institutes of Health, Food and Drug Administration, Agricultural Research Service, and Cooperative State Research Service.

5. Interviewed university nutrition department heads, nutrition researchers at universities, representatives of nutrition professional societies, and a public interest group.

While we recognize that health care delivery, nutrition education, and global malnutrition are important issues, our primary concern in identifying nutrition knowledge gaps was food and biomedical research for meeting nutritional needs in the United States.

To identify and determine (1) human nutrition research supported by the Federal Government and (2) the Federal agencies' research missions and activities, we:

--Analyzed information on research projects, programs, and plans provided by USDA and HEW agencies, DOD, the Agency for International Development, the National Science Foundation, the National Aeronautics and Space Administration, and the Veteran's Administration.

--Reviewed reports on Federal human nutrition research prepared by the Senate Select Committee on Nutrition and Human Needs and the Congressional Research Service.

THE ESSENTIAL NUTRIENTS

Amino acids (Protein)

Eight to 11 amino acids are essential; that is, required in the human diet, depending on the stage of physical development. Other amino acids are also needed, but the body is capable of manufacturing them.

Amino acids are the building blocks of body proteins. As such, they are needed for protein synthesis in body cell growth, maintenance, and repair. If one or more of the essential amino acids is not present in sufficient quantity when body protein is synthesized, the synthesis is limited quantitatively by the availability of the essential amino acid in lowest supply. Protein synthesized in excess of body needs serves only as an energy source and, in cases of caloric insufficiency, much of the protein is used for energy rather than bodybuilding.

Deficient amino acid intake (and, thus, deficient body protein) leads to kwashiorkor and, coupled with low caloric intake, marasmus (emaciating diseases found predominately among impoverished children in developing countries). Protein deficiency during pregnancy can inhibit fetal growth and development. Excess amino acid intake possibly aggravates or potentiates chronic disease states. For example, some evidence suggests that high levels of dietary protein hasten calcium loss and thus may be a factor in osteoporosis, a degeneration of the bone found especially in women after menopause.

Vitamins

Fourteen vitamins classified as water soluble (the B-complex of vitamins and vitamin C) or fat soluble (vitamins A, D, E, and K) are required in the diet in very small amounts.

Most water-soluble vitamins facilitate metabolic reactions of other substances. Fat-soluble vitamins have more diverse functions, such as maintaining skin and skin-like tissues (vitamin A), promoting mineralization of bones (vitamin D), preventing damage to cell membranes (vitamin E), and regulating blood clotting (vitamin K).

Fatty acids

Three fatty acids have been identified as essential. They are involved in the maintenance of cell membrane structure and function, and their deficiency in the diet can cause poor growth and skin lesions.

In recent years, fatty acids have been recognized as precursors of prostaglandins, a family of hormone-like compounds having diverse body functions. The interrelationship of prostaglandins with the essential fatty acids and the significance of prostaglandins to human health have yet to be fully established. Prostaglandins provide a basis for the body's natural defenses, and they may have a role in the body's response to aspirin.

Mineral elements and water

Seven major and 10 trace mineral elements are essential to humans. The major elements include calcium, cholorine, magnesium, phosphorus, potassium, sodium, and sulfur. The trace elements (so called because they are present in the body in only trace amounts) include chromium, cobalt, copper, fluorine, iodine, iron, manganese, molybdenum, selenium, and zinc. In addition, the trace minerals nickel, silicon, tin, and vanadium, which were previously considered to be health hazards, are now known to be essential to experimental animals, and may be so in humans.

The essential mineral elements are interrelated and balanced against each other in the body. In general, they are involved in nerve and muscle functions, bone and tooth formation, enzyme activation and, in the case of iron, oxygen transport. However, the specific functions of few, if any, of the mineral elements are completely understood, and it is likely that some essential trace minerals have yet to be identified.

Water is an essential nutrient by virtue of its transport, temperature-regulating, and reactive functions.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

OCT 13 1977

Honorable Victor L. Lowe
Director, General Accounting Office
Washington, D.C. 20548

Dear Mr. Lowe:

Thank you for giving the Office of Management and Budget the opportunity to review your draft report to the Congress on "Federal Human Nutrition Research--Need for a Coordinated Approach to Advance Our Knowledge" (Volumes I and II). This report is especially interesting to us in view of the major reorganization study in the food and nutrition area that the President announced on August 25, 1977. As part of our study, we will be looking at many of the nutrition research issues that your report identifies, and we are grateful to you for having covered this ground so well.

I have asked Lester M. Salamon, whose Division is responsible for the Food and Nutrition Reorganization Project, to contact you soon to discuss this report and its implications for our work. If you have any questions about our project, please do not hesitate to call Mr. Salamon directly at 395-5017.

Sincerely,

Jim McIntyre

James T. McIntyre, Jr.
Acting Director

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20500

September 22, 1977

Dear Mr. Gutmann:

Thank you for giving us the opportunity to comment on your draft report on "Federal Human Nutrition Research--Need for a Coordinated Approach to Advance Our Knowledge." As you may know, this topic is of particular interest to the Office of Science and Technology Policy.

I am pleased that the Congress shares the Administration's concern about nutrition research. We believe that a great deal of support now exists for making changes to enhance the effectiveness of Federally supported human nutrition research. The recommendations you have made, coupled with those from our own study, could, if implemented, make the Federal human nutrition research effort substantially more effective.

Enclosed are comments prepared by Louis Blair, a senior policy analyst for Human Resources, on Volume 1 of your draft. I would also like comments from your staff on our draft report "Findings and Recommendations on Federally Supported Human Nutrition Research."

Yours sincerely,

Frank Press

Frank Press
Director

Enclosure

Mr. R. W. Gutmann
Director
Procurement and Systems Acquisition
Division
U. S. General Accounting Office
Washington, D. C. 20548

Comments by

Louis H. Blair
Senior Policy Analyst for Human Resources
Office of Science and Technology Policy

Overall, the report identifies a number of important problem areas and recommends activities which, if undertaken by the appropriate Federal agencies, could lead to substantial improvements in the scope of Federal Nutrition Research efforts. The report is clearly written and is developed in a logical manner. Findings from the survey of 32 persons are very informative.

Specific suggestions are:

p. i Provide a definition for Human Nutrition Research.
[See GAO note 1, p. 113.]

p. i Check the total expenditure figures for nutrition research. Our estimate is $112 million for FY 1977 and $93 million for FY 75. The differences are in estimates of spending by NIH which provided OSTP with an estimate for 1975 of $70 million.

p. iii We did not find much concern about the shortage of nutrition scientists and doubt that it is a major barrier. If more funds are available or if funding is certain for long periods of time, there should be enough scientists.

p. iv Some overlap may be desirable if it results in complementary approaches to gaining knowledge.

p. v Regional centers could be useful, but they should be subject to very critical external review and each probably should have a special research area (e.g., obesity, aging, maternal problems) as well as a role of monitoring populations in that region. The report should be careful not to recommend construction of major regional facilities.

p. vi We agree that lead agency responsibilities have to be established. This might require assistance from the Congress as well as Administration agreement.

p. vi We agree that a central focus is necessary for planning and coordination. There are other means which should also be implemented such as joint agency participation in conducting research, in developing research plans, and in monitoring ongoing research.

p. vii Responsibility for reporting probably should be vested in DHEW for Human Nutrition Needs and in USDA for Food Sciences and Monitoring and Surveillance.

p. 13 NIH provided OSTP with an estimate that 10% of the annual births are low-birth-weight infants.
[See GAO note 2, p. 113.]

p. 22 Potential issues of Vitamins C & E toxicity might be mentioned here.

p. 22 Long-term studies are expensive and difficult. Rather than recommending them for the full-spectrum (sex/age/health status/etc.), I suggest concentrating on only a few groups most likely to suffer from nutrition-related problems (pregnant women, infant, culturally or economically disadvantaged).

p. 27-30 We strongly agree on the need to examine the biological availability of nutrients in foods when they are consumed.

p. 35-40 Are you recommending increased funding for research on diet, heart disease, hypertension, and cancer? We felt that research should continue but that since immediate research breakthroughs do not appear likely, no increases in funding are appropriate. We believe the "researchability" of these areas is relatively low.
[See GAO note 3, p. 113.]

p. 49 Surveying and monitoring is needed not only as a regional basis, but also among particular subgroups with high-risk factors or with special needs, dietary consumption patterns, or with unusual nutrition/health status.

p. 52 We wonder if the Role of Diet in the Aging Process is researchable at this time.

p. 68

p. 97

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

AGRICULTURAL RESEARCH SERVICE
OFFICE OF ADMINISTRATOR
OF UNITED STATES DEPARTMENT OF AGRICULTURE
WASHINGTON, D.C. 20250

September 27, 1977

Honorable Henry Eschwege
Director, United States General
Accounting Office
Washington, D. C. 20548

Dear Mr. Eschwege:

Thank you for the opportunity to review the draft report on "Federal Human Nutrition Research—Need for a Coordinated Approach to Advance our Knowledge."

The many recent studies and reports on human nutrition research have certainly been helpful in focusing attention on the critical needs associated with it, but the lack of a clear-cut definition of the scope of these various reviews has created some problems. Human nutrition research involves dietetics, genetics, endocrinology, food technology, and agricultural science as indicated on page 2 of the report. However, to arbitrarily label all or, at times, only part of such activities under the heading of nutrition leads to confusion in accountancy. For example, the draft GAO report states that $80 million of Federal funds are spent annually to support human nutrition research. The OSTP will shortly report that $112 million is being spent annually for the same activity. These differences in estimates are significant and should be reconciled before public release. Neither report contains a satisfactory accounting of how funds spent by the bio-medical groups relate to nutrition research regardless of how it may be defined.

We are surprised that throughout the report concern is expressed that no Federal research agency has a primary mission in human nutrition research. While the level of funding has not always been provided to carry out the clearly mandated needs, this Department has never questioned its lead role in human nutrition research specifically defined in the Agricultural Marketing Act of 1946 (7 U.S.C. 427) and in Title 14 of S. 275 (the Farm Bill) which is presently on the President's desk for signature.

[See GAO note 4, p. 113.]

Attached is a consolidation of the more specific comments from individual reviewers within the Department.

Sincerely,

T. W. Edminster
Administrator

Enclosure

Individual Reviewer's Comments on
GAO REPORT: FEDERAL HUMAN NUTRITION
RESEARCH -- NEED FOR A COORDINATED APPROACH
TO ADVANCE OUR KNOWLEDGE

VOLUME 1

A. General Comments:

1. This is an excellent review of the "health" of human nutrition research in the U.S. at this time. Very important gaps in knowledge have been highlighted repeatedly. Some barriers have been described but the reasons for the situations are not entirely clear. For example, the image of Human Nutrition research is not particularly good among biological scientists. Reasons for this are rather nebulous. If they were understood, it might be easier to increase manpower. However, making more money available may also motivate more scientists to get involved in nutrition research.

2. The critical need for research on effective transmission of the findings of human nutrition research to the general public has not been addressed to any extent. Much of the interest in nutrition in U.S. has been stimulated by nutrition misinformation. Even with the gaps in knowledge the known nutrition facts are certainly not being transmitted effectively to John Q. Public.

[See GAO note 5, p. 113.]

3. If an imprecise classification of nutrition research such as that used to account for bio-medical research is used in USDA, practically all ARS research outside that devoted to cotton and wool can be considered nutrition research. This merely highlights the difficulties posed by the lack of a definition of nutrition research (page 56).

4. The report is unnecessarily redundant in exposition of hypothetical connections between nutrition and disease. Nobody will gain by overemphasis of ill-proven claims of benefits to be derived from nutrition research. It may be more factual to relate increased costs of Federal health programs to increases in the price of unnecessary medical attention to the indigent than to lack of proper nutrition. This is not to be construed as derogatory to the concept of increasing support for nutrition research but merely reflects a desire to have the case made on more rational grounds. It is somewhat surprising that the lengthy sections of the report that treat the relationships between diet and disease (considered as dis-ease) fail to mention what further nutrition research would do to alleviate indigestion, "heart burn", "gas", and constipation - issues of high importance and most closely associated in the public minds with the consumption of food.

5. The vital role of food processing is ill considered in Chapter 2, Parts 2 and 3 of the report. The readers are left with the general impression that "since the end of World War II have people been systematically exposed to diets of processed, fabricated, and fortified foods." This is not true. Since man has learned to control fire and leave the "hunter-gatherer" stage, his foods have been increasingly processed to improve their digestibility, safety, storage stability and acceptability. The heating, drying, pickling, fermenting, and blending of foods with flavoring, coloring, and preservatives has been practiced throughout all of historical times. The desirability of these practices was determined empirically. Now, it can best be said that a scientific basis for the improvement of these practices may be developed. The need for them has not changed.

[See GAO note 6, p. 114.]

6. The GAO report contains the recommendation that OSTP study human nutrition research and assign "lead agency" status to the various Departments and Agencies conducting research related to nutrition. This has already been done by the Congress in the Agricultural Marketing Act of 1946 and just recently in S. 275 (the Farm bill).

[See GAO note 4, p. 113.]

7. The GAO has obviously become aware of the fact that the methodology available to determine food composition, bioavailability of nutrients, and assessment of nutritional status of large population groups has not been developed to the point that meaningfully work can be done without the incurrence of great expense. It is surprising that intensification of research in this area is not recommended for increased support.

8. The GAO is properly concerned about unnecessary overlap in human nutrition research activities supported by Federal funds. Not considered is the fact that the community of scientists engaged in these activities automatically concerns itself with overlap since duplicate results obtained beyond verification of initial published observations have no peer group status. Therefore, the GAO may wish to recognize the built-in controls that scientists have already established in their professional organizations to eliminate unnecessary overlap of research activities.

9. The report recommends consolidation of the programming of human nutrition research supported by Federal funds. This may be unwarranted and, as the GAO recognizes in its report, counter to the spirit of many operations typical of this country. We believe that the Departments and Agencies authorized to conduct specific activities should maintain their flexibility of operation. Exchange of information on common problems is highly desirable but its attainment by investing authority in joint committees is questionable. A novel approach, that Congress may wish to consider, is strengthening the professional societies

representing scientists engaged in activities in and related to human nutrition research. This may be effected by direct support of their abstracting activities and making more funds available for the travel of scientists to meetings designed to promote the exchange of research information available.

10.

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

11. Conclusions about Recommendations - These are strong and well documented. Although Regional Research Centers may not be the answer to the knowledge needed in human nutrition, the proposal to explore potential value and costs of establishing them in conjunction with universities and colleges is a very important one.

B. Additions:

1. There is no mention of investigating the nutritional requirements of developmentally disabled individuals (mentally retarded). The condition is one of stress and is a completely untouched one in human nutrition. It concerns an unusually large portion of the population. In 1976 there were 176,000 developmentally disabled residents in 235 public residential facilities in 50 States. In addition, many more are living at home. The current basis for dietary planning for institutions is the RDA which is a standard for healthy people. The age groupings are inappropriate for people with entirely different growth patterns. Undoubtedly, the absorption and metabolism of nutrients are different for individuals with these many developmental abnormalities. Recent suggestions for treatment with megavitamins has led to confusion and at times, exploitation. The cost of providing care for the developmentally disabled population is great. Food is one of these costs and more accurate information about nutritional requirements might reduce waste as well as improve the welfare of the residents in institutions.

   This addition could be made on page 15 and 16 under "Childhood and Adolescence" or in page 18 under "Disease and Stress."

2. The CSRS contributions to human nutrition research are broader than described. There is concern about the effects of marketing practices, processing methods, and genetic varieties on nutritional value of foods in this organization as well as in ARS.

The Regional Research program, supported in part by Hatch funds, is a means of pursuing research on problems which are regional in nature and/or are too large for one research group to attack. The regional research approach has proven to be an exceptionally useful one for human nutrition. CSRS, State Agricultural Experiment Station directors, the human nutrition scientists, and scientists in other Federal agencies work together to develop and carry out the research; the CSRS role is one of facilitator, consultant, and evaluator, as well as administrator of funds.

C. Corrections:

1.

2.

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

3.

4. Pages 29-30 - The statement concerning availability is correct, but vitamin B would be a better example than vitamin E.

The very complex nature of factors affecting availability emphasizes the need for information. The statement tends to over-simplify the problem. The phytate in cereals, for example, is dydrolyzed by yeast enzymes when food products are prepared from cereals by yeast fermentation, thus allowing the zinc to be utilized. It might be more persuasive to allude to such complications than to imply that antagonists could simply be listed in a table.

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

5.

6. Page 49 - Relationships between the USDA and DHEW surveys are unclear. Also, information on the time frames should facilitate public understanding of the problem. The following statement is offered for consideration for use by GAO.

Prior to 1965, national nutritional surveillance was limited primarily to results from periodic USDA surveys of household food consumption which measured levels and shifts in the nutritional adequacy of household diets. During April-June 1965, the first national study of food intakes of individuals was undertaken as an adjunct of the 1965-66 Nationwide Household Food Consumption Survey. The food intake survey was limited to measuring the food and nutritional content of individual diets and provided new methodology in this field which was utilized subsequently.

Shortly thereafter, DHEW initiated surveys to measure nutritional status of individuals. A 24-hour recall of food intake, together with health-related examinations, provided the basis for clinical assessments regarding dietary adequacy of individuals. Between 1965 and 1972, DHEW sponsored three major nutrition-related surveys.

7. Page 50 - Paragraph 2 - suggest adding: Further studies should be carried out which will focus on remediable shortcomings in methodologies presently applied and indicators of levels of limitations not subject to remedy.

8. Page 50 - Paragraph 3 and page 51, paragraph 1. Statisticians and others will find statements confusing. The apparent goal is to point out limitations in alternative procedures for measuring food consumption. If so, the following approach might be used.

Information on individual food intakes is difficult to obtain. Recalls, food intake records, dietary histories, and weig food intake methods have been used in various surveys. Each h limitations in terms of time frames, reporting ability, b den, and nonresponse. The 24-hour recalls of food intakes used in the USDA and DHEW surveys, for example, are within the memorary span of most respondents and have high response rates. Food measurements and descriptions are subject to reporting error. Day-to-day fluctuations in food intake limit the reliability of the approach to identification of persons having low (or high) levels of nutrient intakes. Food intake diaries provide a means for expanding the period under study. Many respondents, however, are unable to prepare diaries. Others refuse to undertake the effort or underreport food intakes over time. The dietary history technique is expensive due to its reliance on skilled interviewers knowledgeable about dietary food habits.

9. Page 50 - Last paragraph - The following wording is offered in clarification:

The methodology used in prior USDA studies has been revised in the 1977-78 Nationwide Food Consumption Survey as a result of exploratory studies and review by outside experts. The food intake phase utilizes a 1-day recall followed by 2-day diaries which are examined by interviewers at time of pickup rather than a 1-day recall. In the household sector, respondents are asked to keep food notes which will aid in a 7-day recall of household food consumption. Previously, recalls were obtained without advance notice.

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

10.

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

Suggest that food improvement should be discussed apart from food composition in a separate section.

11.

12.

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

13.

VOLUME II

General Comments:

1. Page 27, last paragraph, stresses an important point related to research - emphatic opposition to research contracts. Dr. Campbell expresses the problems with contracts very effectively and consideration should be given to his recommendations. Dr. Harper, page 55 (top of page) emphasizes grants rather than "rigid contracts" also.

2. Dr. Harper's letter, pages 52 and 63, is comprehensive and detailed, and his introduction and statements of problems are well summarized.

APPENDIX V

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

DEC 7 1977

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Federal Human Nutrition Research--Need for a Coordinated Approach to Advance our Knowledge." 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,

Thomas D. Morris

Thomas D. Morris
Inspector General

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE ON THE COMPTROLLER GENERAL'S DRAFT REPORT TO THE CONGRESS OF THE UNITED STATES ENTITLED "FEDERAL HUMAN NUTRITION RESEARCH--NEED FOR A COORDINATED APPROACH TO ADVANCE OUR KNOWLEDGE"

General Comments

The report is a reasonable and accurate reflection of research activities concerned with human nutrition conducted or supported by various segments of the Federal Government. The identified research needs and the conclusions and recommendations are generally consistent with current thinking within the human nutrition scientific community, both within and outside the Federal Government.

We believe significant contributions have been made by this GAO report, coupled with recent studies undertaken by the Office of Science and Technology within the Executive Branch and the Congressional Office of Technology Assessment. These studies have provided the Department with the opportunity to assess the progress of current Department efforts to improve the health status of the American people through improved nutrition.

Secretary Califano has instituted an interagency review of nutrition efforts in order to formulate a long-range Departmental nutritional policy. As a result of that review, he has determined that nutrition activities have been inadequately coordinated within the Department and have failed to receive the emphasis they deserve. The specific recommendations resulting from that review are being carefully considered and are consistent with the GAO's draft report.

Specific Comments

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

Chapter 2, Part 3--The discussion of food may be subject to misinterpretation since it goes beyond nutrients that are food additives and the interactions between nutrients and food additives. The discussion includes the area of the safety and hazards of food additives in general, which is a broad subject that is separate from nutrition science except as noted above. Discussion of food additives beyond the nutritional aspects does not appear to be an appropriate part of this report.

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

Pages 47 and 49--It is true that "National and regional studies by the Federal Government (they include Health and Nutrition Examination Surveys (HANES)1) did not seek to determine dietary imbalances and excesses of the average American at risk of developing heart disease, cancer, diabetes, or other diet-related disorders, nor did they identify relationships between nutritional status, behavioral development, and resistance to or prevention of chronic disease." (Parenthetical element added.) HANES did, however, collect data on dietary intake, heart disease and nutritional status. These data have not been interrelated to date but, if additional funds should become available, this will be done.

Page 49, paragraph two--Regarding the question of uncovering "unique regional problems" HANES' data will be looked at by four major regions.

Page 50, paragraph three--Although it is correct that the 24-hour recall of food intake is subject to large errors and has been found unreliable for identifying persons with low nutrient intakes it has value in comparing dietary intake between different groups by age, sex, ethnicity, and income. This is the only way it is being used in HANES.

Page 51, last paragraph--It is true that no definitive method exists for combining existing indices into an overall indicator of nutritional status. HANES data, however, lend themselves to such a methodological study using a factorial method of analysis which could develop indices and probably also an overall indicator of nutritional status.

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

Pages 73 and 74--The section on the National Heart, Lung, and Blood Institute should be replaced with the following material. The new write-up describes specifically the Institute's program and sets the 1975 nutrition research expenditures for the Institute at $16.5 million instead of $6.8 million.

National Heart, Lung, and Blood Institute

The objectives of the nutrition research supported by the National Heart, Lung, and Blood Institute include (1) defining the effect of diet on blood lipids and on coronary heart disease (CHD) and death, (2) increasing the accuracy of quantification of dietary intake, (3) developing more comprehensive tables of food composition, and (4) achieving dietary change to reduce blood serum cholesterol. Nutrition research expenditures in 1975 totaled $16.5 million.

Current Institute Programs Are:

Definition of the Effects of Diet on Blood Lipids and Lipoproteins.

a) The Lipid Research Clinics Prevalence Study is an internationally based study of the prevalence of dyslipidemias (lipid diseases) in defined populations using comparable methodology. It is hoped that, with large numbers and more defined methodology, dietary influences on lipid transport diseases will be detected.

b) The Arteriosclerosis Specialized Centers of Research Program is concerned with particular components of human and animal diet in relationship to hyperlipidemia and to the etiology of arteriosclerosis heart disease. Several centers are studying the extent to which dietary manipulations can prevent or modify the course of the risk factor in the development of disease in humans.

c) The Cardiovascular National Research and Demonstration Center at the Baylor Medical Center pursues several nutrition education projects including the designing of nutritious, low cholesterol meals for restaurant use. Another project tested the ability of three plans to lower blood cholesterol in the community.

d) Regular Research Grants primarily consist of basic research into the role of specific nutrients in metabolic processes related to heart disease.

Definition of the Effect of Diet on CHD Morbidity and Mortality.

Clinical Trials: This program consists of two major clinical trials designed to investigate the role of dietary change on coronary artery disease. The focus is on the reduction of dietary saturated fats and cholesterol and its effect on plasma cholesterol and coronary disease. It is hoped that in the next decade these studies will provide definite evidence to support positive findings from animal studies and suggestive epidemiological data that lowering blood cholesterol is beneficial.

Mortality Surveillance and Follow-up. The Lipid Research Clinic Prevalence Study follow-up phase will provide prospective information on the effects of dietary intake on cardiovascular mortality.

Pilot Epidemiological Studies in Thrombosis.

Under this joint NHLBI and United States Department of Agriculture (USDA) project rural areas were selected in the United States, Finland, and Italy on the basis of their ingestion of widely differing dietary fats. Dietary differences were correlated with differences in platelet function and plasma, red blood cells, and platelet lipids.

Development of Comprehensive Tables of Food Composition.

The NHLBI has entered into a collaborative program with the USDA to underwrite the acquisition of certain nutrient data that not only serves the needs of the Institute but also benefits the nutrition community. The Institute supports literature research by the Consumer and Food Economics Institute at USDA, as well as basic food analyses for fatty acids and cholesterol. This activity has accelerated the updating of the USDA Handbook No. 8 entitled "Composition of Foods."

An up-to-date and comprehensive food table has been developed and is in use for calculating nutrient intakes. The Institute supplies funds to the Nutrient Composition Laboratory of the USDA to pursue development of automated analytic techniques for direct analyses of food and improved methods for collecting, recording, and evaluating dietary data.

Nutrition Education Pilot Study. This study aims to reveal factors that influence food selection in cafeterias so that the populace will select low calorie, heart-healthy diets. This project demonstrated new means of data collection through identification of food types recorded on cash register tapes and illustrates cooperative effort between private enterprise, consumers, and NIH.

Dissemination of Information. The Research and Demonstration Center for Arteriosclerosis has an extensive community-based nutrition component. The Institute also has developed handbooks for the dietary management of hyperlipoproteinemia to provide information to physicians and their patients in the high risk group; that is, those who have high cholesterol or other blood lipids.

Achieving Dietary Change. This is a current primary objective of Institute clinical studies. When there is a clear understanding of the role of diet in heart disease, a goal will be established to achieve massive scale change to heart-healthy diets. In FY 1976, the Institute sponsored a national workshop on nutrition and behavioral modification; another is planned for this year.

These workshops, as well as other Institute-sponsored conferences have brought biomedical and behavioral scientists together to

attack the problems of altering dietary patterns. Currently, techniques and materials in education and behavior modification are being developed, tested, and evaluated with the clinical trials and community-based programs. One project is to determine what factors are necessary to achieve and maintain dietary compliance. Another is evaluate the use of mass communications media to change health behaviors. We hope that these programs and those planned for the future will point the way to effective community action.

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

Pages 77 and 78--The description of FDA's nutrition research program and plans is generally incomplete and does not appear to be based on GAO's interviews with FDA officials. **[See GAO note 7, p. 114.]**

Pages 88 and 89, paragraph one--A statement in this paragraph is not correct. The Division of Health Examination (DHES)/NCHS does provide ". . . the comprehensive nutritional surveillance of the Nation relating diet to health on a continuous, long-term basis." A more correct terminology is "nutritional assessment and monitoring" instead of surveillance. **[See GAO note 8, p. 115.]**

Page 89, paragraph two--The statement is not correct that ". . . the Survey is concerned with identifying possible nutritional deficiencies and the prevalence of certain diseases rather than assessing nutritional status on a continuous basis." HANES does both. The identification of possible or probable nutritional deficiencies (using the risk terminology) is an important part of the assessment of the nutritional status. The HANES program is set up on a continuous basis. **[See GAO note 8, p. 115.]**

Page 92, last paragraph--Another example of collaboration between agencies is the HANES DHES/NCHS collaboration with the Center for Disease Control in the areas of nutrition and growth.

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

Page 101--The monitoring on a continuous basis of the nation's nutritional status is listed among the challenges to nutrition research. The HANES program has been set up to meet this challenge.

Page 102, last paragraph--It is not true that ". . . no agency conducts the comprehensive nutritional surveillance of the nation relating diet to health on a continuous, long-term basis." DHES/NCHS does exactly this.

[See GAO note 8, p. 115.]

In addition to the above comments on specific points, several statements in the report may be subject to misinterpretation, particularly hypotheses that are stated in a manner that implies that they are established fact. Following are examples of this.

The inadequacies of current knowledge of normal human nutrient requirements are overstated. More is known than the report implies. The USDA stresses the knowledge gaps relative to normal requirements to a degree felt by some in the HEW biomedical community to be excessive. This USDA emphasis is clearly reflected in the GAO report. Most HEW scientists feel the greatest gaps in the knowledge of nutrient requirements are in the disease-related areas, not in areas involving normal individuals, with exceptions such as those relating to some trace minerals.

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

Page 24--". . . the functions or underlying mechanisms of action are not well known for all of the fat-soluble vitamins, vitamin C, and some of the major mineral elements." We feel that this is an overstatement.

[See GAO note 9, p. 117.]

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

Page 31--We believe that this epidemiologic discussion is loose and should be rewritten. For example, the statements concerning Eskimos and New Guineans are open to question.

[See GAO note 10, p. 117.]

THE UNDER SECRETARY OF DEFENSE
WASHINGTON, D.C. 20301

RESEARCH AND
ENGINEERING

4 NOV 1977

Mr. R. W. Gutmann
Director, Procurement and
Systems Acquisition Division
U. S. General Accounting Office
Washington, D. C. 20548

Dear Mr. Gutmann:

This is in reply to your letter to the Secretary of Defense regarding your draft report, dated 25 August 1977, on "Federal Human Nutrition Research--Need for a Coordinated Approach to Advance Our Knowledge" (OSD Case 4704, GAO Assignment Code 952140).

The Department of Defense supports the conclusions made in the report identifying research gaps and focusing on the status of organization and coordination of human nutrition research in the national perspective. Although the Department of Defense (DoD) food and nutrition research program is small compared to the total effort, it is specifically tailored to satisfy military requirements. The programs have to some degree suffered along with the national effort from the shortage of technical personnel dedicated to nutrition studies and from uncertainties in funding. Since the military environment, particularly regarding readiness and actual combat, imposes unique requirements, little if any of the DoD effort can normally be conducted extramurally. However, as noted in the report, science and technology transfer into the civilian sector from military programs has been and will continue to be effective.

The Department of Defense also supports the general recommendations concerning definition of each Federal Agency's role in human nutrition research, the assignment, where practicable, of a lead Federal Agency, the elimination of duplicative or unnecessary research and the promoting of Government-wide human nutrition research planning, coordination, and reporting. DoD will provide managerial and technical representation to the appropriate subcommittees of the Federal Coordinating Council for Science, Engineering, and Technology (FCCSET),

APPENDIX VI

Office of Science and Technology Policy (OSTP), to facilitate program coordination, peer review, planning, and reporting of research in progress. Such activity should assure the desired cooperation between all Federal Agencies while supporting military readiness in the context of the optimum dedication of available national resources.

Sincerely,

Gerald P. Dinneen

Gerald P. Dinneen
Principal Deputy

DEPARTMENT OF STATE
AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

Auditor General

OCT 5 1977

Mr. Richard W. Gutmann, Director
Procurement and Systems Acquisition Division
U. S. General Accounting Office, Room 6915
441 G Street, N. W.
Washington, D. C. 20548

Dear Mr. Gutmann:

Thank you for providing the draft General Accounting Office report, "Federal Human Nutrition Research--Need For A Coordinated Approach To Advance Our Knowledge," for comment. The report has been reviewed with interest by the responsible offices. Provided herewith is the Agency comment provided by the Assistant Administrator for Technical Assistance, whose bureau has primary responsibility for research.

We would appreciate your consideration of these comments in preparing your final report, but do not consider it necessary to include them as an attachment as mentioned in Mr. Fasick's letter of August 25 transmitting the draft.

Sincerely yours,

Herbert L. Beckington

Enclosure

APPENDIX VI

MEMORANDUM

SEP 29 1977

TO: AG, Mr. Herbert Beckington

FROM: Acting AA/TA, Marjorie Belcher

SUBJECT: Review of GAO Draft Report "Federal Human Nutrition Research - Need for a Coordinated Approach to Advance Our Knowledge" dated August 25, 1977

In response to a request for comment concerning this report the following suggestions are offered:

A.

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

B. Definition of Human Nutrition Research

Human nutrition research is defined too narrowly. The end product of the Federal Government research program should result in improved well-being of its citizens. Nutrition education and an evaluation of the U. S. nutrition intervention program are, therefore, needed steps in carrying out a comprehensive nutrition improvement program. The research is required to determine how best to: (a) influence people to modify detrimental food behaviour patterns and (b) evaluate the effectiveness of existing nutrition programs (food stamps, school lunch, etc.). It is suggested that nutrition education and evaluation of ongoing nutrition programs be added to the list of critically needed research.

NATIONAL SCIENCE FOUNDATION
WASHINGTON, D.C. 20550

OCT 3 1977

Mr. Richard W. Gutmann, Director
Procurement and Systems Acquisition Division
U. S. General Accounting Office
441 G Street, NW
Washington, D. C. 20548

Dear Sir:

Reference is made to Mr. Ahart's letter of August 25, 1977, which transmitted copies of the GAO draft report on "Federal Human Nutrition Research--Need For A Coordinated Approach To Advance Our Knowledge" (Volumes I and II) for our review and comment.

The draft report has been reviewed carefully by program officials in the various Directorates and Offices of the Foundation most intimately concerned with the subject matter. The resulting comments are transmitted as attachments I, II and III to this letter, and constitute the Foundation's response to GAO.

We appreciate the opportunity to comment on the draft report and trust that our comments will be helpful to you in finalizing a report to the Congress.

Sincerely yours,

M. Kent Wilson
Acting Director
Office of Planning and
Resources Management

Enclosures

The staff of the GAO has done a generally fine job of bringing together data from diverse Federal agencies and coordinating it into a report describing both current research and plans for undertaking future research that is needed.

It is critical that the material supporting Table 1, page 9, be as complete as possible. If the research gaps are not identified fully, there will be a built-in lack of support for areas that "fall between the cracks." If the research identified to fill the specified gaps will not in fact provide the necessary knowledge, then the gaps will remain unfilled. Some examples follow of gaps that were not given enough attention in the report, and of "research needs" that may not be adequate to fill specific gaps:

> There are no plans to deal with different carbohydrates except for the USDA/ARS study mentioned on page 61. Even that plan (to determine the fat-producing effects of starch and of three sugars) does not differentiate among starches. I think it is significant that the Glossary defines "carbohydrates" as "a nutrient" (emphasis added), because it shows that there is no recognition of the fact that there are many carbohydrates and that they differ in their properties. We in fact know virtually nothing of the effects of these differences for human nutrition and disease, even though there are indications that the differences are important; for example, on page 21 it states that "high intake of certain carbohydrates has been shown to increase the duration of barbiturate-induced sleep."
>
> [See GAO note 11, p. 117.]
>
> We need to investigate the role of substances in the diet other than the monolithic groups covered in Appendix 1, page 111. For example, recent evidence shows that ingesting the tannins in grapes and grape products increases resistance to viruses. Tyramine is another example; it is found in a number of foods, but it, along with the amino acids

putrescine and cadaverine, is produced by decomposition and decay organisms as a protein breakdown product. In many victims of migraine headaches Tyramine produces symptoms of poisoning (headache, nausea, vomiting) and considerable economic loss results from job absenteeism. Because Tyramine is not one of the standard nutrients, its presence in foods is not labeled; indeed, I do not know if a quick, cheap assay for it exists. Surely there are many such substances whose role in nutrition and disease is not known, yet this topic is not mentioned as a "knowledge gap" in the report.

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

Research needs identified to fill the gap entitled "Human Nutritional Requirements" would supply needed background information, but it is obvious from the discussion on pages 11-13 that we need also to establish meaningful new standards of dietary requirements.

The following comments about specific statements in the reports may be helpful:

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

(page 42) Another question about the new emphasis on dietary fiber that should be considered is how increasing fiber intake affects total nutrient intake, especially if one takes in large quantities of high-fiber food that is not very nutritious.

[Deleted agency comments pertained to matters no longer in final report or suggestions by the agency that were incorporated in the report.]

(page 49) It is important to avoid placing too much emphasis on family units when assessing nutritional needs. Some of the most poorly nourished people may be those living alone. It is a step in the right direction that the USDA has changed the title of its "Household Food Consumption Survey" to "Nationwide . . . Survey."

(page 113) It should not be considered too technical in a report of this nature to name the three essential fatty acids.

A word of caution should be added about the heavy emphasis in the report on regional centers for nutrition research. If past experience is any indication, these centers will prove difficult for researchers from other colleges and universities to use, particularly for long-term research. Such centers would undoubtedly bolster research at the selected institutions, but we should not expect that outside researchers, especially those constrained by academic time schedules, will put them to much use.

The insights of the 32 nutritionists on the barriers to an effective federal program in human nutrition have not been adequately synthesized in the GAO draft report. Volume I of the draft now sights three barriers: (1) disparate and duplicative efforts in many agencies; (2) not enough nutritionists; (3) no sustained research funding for needed long term studies. While these three barriers are mentioned by the nutrition experts, they are neither the overriding barriers or most sited obstacles to improved human nutrition. By restricting chapter IV to these three obstacles, the subsequent recommendations made in Chapter V of the report appear rather bureaucratic: (1) coordinate and centralize; (2) train more nutritionists; (3) spend more money on human nutrition. The experts surveyed did not say nutrition problems in the United States will be solved with more money, nutritionists and centralization, but rather through innovative approaches to the science of nourishment attempted by interdisciplinary research teams.

[See GAO note 12, p. 117]

The barriers to an innovative science of nourishment, given in Volume II of the GAO report, exist within the present disciplinary structure of the university, the stagnated science of nutrition, and the current federal budget attempt to define "bang for the buck" before allocating research funds.

As Dr. D. Mark Hegsted of Harvard University stated: "The curse and the strength of nutrition is that it cuts across all areas" (Vol. II, p. 66). Dr. Alfred E. Harper of the University of Wisconsin agrees. Human nutrition cannot be fitted into narrow disciplinary departments. Philip R. Lee, M.D. of the University of California, San Francisco, sited the herculean effort of the interdisciplinary team at U.C., San Diego which has combined the expertise needed to investigate the jeopardy to brain development of low birth weight babies. Researchers from the fields of neuroscience, nutrition, public health, communication, and child development led by Dr. Robert Livingston, have statistically analyzed existing national nutrition surveys to show that 60% of pregnant women below the poverty level consume too few calories during gestation for normal fetal brain development. This research group has been operating out of the Institute for Information Systems with a great deal of difficulty obtaining funding.

The first recommendation of the GAO draft is to clearly delineate the tasks and responsibility of each agency conducting human nutrition research, and have central coordination. But, innovative approaches to real world problems such as that of Dr. Livingston's sometimes overlap several agencies' functions. If the recommendation to strictly define research responsibilities for each agency remains in the final report, an agency should be named and funded for the cross-cutting studies that cannot receive funding from any one agency. Multidisciplinary, cross mission research will be needed for an effective federal effort in human nutrition research. Only one respondent, Dr. Winich, gave examples of wasteful duplication of agency efforts (AID conducts research on vitamin and mineral deficiencies in developing countries, NIH supports vitamin and mineral studies, and USDA has vitamin and mineral labs doing the same research). The GAO recommendation to centralize and coordinate nutrition efforts appears to be based on the information provided by federal agencies on what they are doing (Chapter III). The agencies' descriptions of their on-going and planned work appear so thorough that it may have prompted the GAO recommendation to avoid duplication through centralization and coordination. The major problem of human nutrition research is not duplication, however, but neglect.

Dr. Harold H. Sanstead, Director of the Agricultural Research Service Human Nutrition Laboratory in North Dakota, stated that the USDA has not studied human nutrition requirements. Rather, considerable time and energy has been expended on the nutritional requirements of plants and animal species (Vol. II, p. 102). Other barriers to effectiveness of these federal agencies were sited by nutritionists in Volume II.

Ross Hume Hall, a biochemist from McMaster University, laments that the science of nutrition has isolated itself from the reality of the U.S. food system. Nutrition text books describe the fat,carbohydrates and proteins of meat, vegetables and other whole foods, while 75% of all food consumed in the U.S. and Canada is processed, boxed, and canned. Only 5.9% of daily intake consists of fresh food. Since World War II, the food industry has embraced chemical technology, and broken foods into known component parts for refabrication. Thirty-five hundred chemicals are eaten every day in a conventional diet. "What are the effects of the chemical combinations? No one knows, and there is no point hiring more toxicologists to find out because they do not know how to study such a problem" (Vol. II, p. 49). The second recommendation of the GAO draft, to train more nutritionists, should be augmented to include these considerations.

Dr. Draper, a Canadian nutritionist, also stressed these methodological barriers to improved human nutrition research and the need for rapid assay of nutritional quality and safety in processed foods.

The Research Applied to National Needs (RANN) program of the National Science Foundation has been funding exploratory methodologies for rapid assay of nutritional quality for several years. For example, research at the University of Nebraska by Professors Kendrick and Satterlee, has resulted in a rapid assay technique which can evaluate the nutritional and functional properties of protein isolates as well as whole foods.

This rapid assay technique will obviate the lengthy and costly animal feeding trials for nutritional evaluation.

A further obstacle to an effective federal effort in human nutrition cited by the respondents was the federal budget process of attempting to quantify the payoff from human nutrition research to justify public funding. Dr. Doris Calloway of the University of California, Berkeley, states that "somehow we must provide for the very real possibility that we cannot easily identify areas of high return for investment, that we may be missing the target, or even that we are aiming for the wrong target entirely" (Vol. II, p. 23).

What was cited repeatedly was the need for applied research to know whether programs are effective and useful to people (American Dietetic Association).

Dr. Beverly Winikoff of the Rockefeller Foundation stated that applied research will have the greatest leverage on nutrition, rather than scientific breakthroughs. Dr. Ann Burroughs of Extension Service stated that the USDA feeding programs have not developed nutritional evaluation criteria.

The GAO draft does not distinguish that NSF supports research related to nutrition through its Directorate of Biological Sciences and its Research Applied to National Needs (RANN) program. An NSF/RANN grant to a small business research firm has just completed a study of alternative food delivery systems with nutrition as a criterion of performance. The Marketing Analysis Division of USDA has requested RANN to fund research to develop nutrition evaluation criteria for a demonstration project on improved food delivery service for the inner city.

Summary

The Federal Human Nutrition Research draft does provide a good summary of major gaps in nutrition knowledge based on the responses of the 32 nutritionists to a GAO questionnaire (questions 1 through 4) Vol. II, Appendix I. Volume I of the report would be greatly strengthened, however, by synthesizing the responses of the nutritionists to question five of the GAO survey: what problems -- organization, methodological, financial or other -- could prevent or inhibit federal support of the research needed. The insights of leading nutritionists, given verbatim in Volume II have not been adequately reflected in Chapter IV of Volume I on the barriers to progress in human nutrition research. It is essential to augment chapter IV to reflect the real extent of the problems to mounting a federal effort so that the GAO can provide a more comprehensive set of conclusions and recommendations (Chapter V) to improve human nutrition research in the United States.

The most critical comment I have is that the entire report — except for certain mild qualifying statements made on pages 103-104 — seems to rest on the premise that since there is "overlap", "duplication", and "redundancy" in Federal human nutrition research, centralizing tendencies should necessarily be injected into such research. This may be an erroneous conclusion. Overlap, duplication and redundancy are most often used to express a negative (and normative) judgment, as though they were always synonymous with waste and inefficiency. But reliability, the probability that a given function will be performed, depends on a certain amount of redundancy. If there is only one existing mechanism, the first breakdown will result in failure to finish the job.

The report fails to consider that in terms of budgeting, the redundancy enjoyed by this nation is crucial. Particularly in a multidisciplinary field — and the GAO report frankly admits that "one complicating aspect of human nutrition research is that it is not a well-defined discipline" — redundancy compensates for uncertainty. In place of economy and rationalization, the funding system for such research incorporates duplication, competition, and back-up systems. It stresses reliability instead of, and sometimes at the cost of, efficiency. The built-in feature of redundancy allows experimentation and failure on the way. Risks are spread so that should one line of policy turn out to be wrong, not only is the financial loss within acceptable limits but other alternatives have not been sacrificed in the process.

I feel, then, that much of the claimed strength of the conclusions and recommendations in the report rests on a non-sequitur. I recommend that this bias be eliminated and that the investigation at least cite some of the benefits of "overlap", "duplication" and "redundancy." Under such analysis, the conclusions and recommendations of the report would have more balance.

A second comment concerns the use and manner of presentation of statistical data in the report. More specifically, on page 1 of the report it is noted that the "Federal Government spends about $80 million annually on human nutrition research, a sum representing less than 3 percent of the $3 billion it spends on all research in agriculture and health." However, no notation is made as to what year these amounts are for, whether they constitute increases or decreases from previous years, or whether they represent outlays or obligations. Proper citations are needed if the figures are to be placed in context of past and/or planned funding by Congress in this area. Again, on page 5, the report cites the increase in national health care expenditures over the last several years, especially as a relationship to growth in GNP. However, the figures used are in current dollars, and may actually be misleading since, as we know, health care costs have risen faster than the general price level (or GNP price deflator). It is suggested that the figures used be in constant dollars with, if possible, some adjustment (by index of health costs) to determine the real increase (or decrease) in such expenditures. Certainly this would be important to Congress in its assessment of the real direction in such expenditures.

[See GAO note 13, p. 117.]

Finally, the report fails to address anywhere what level of funding the field could realistically support, considering the current state-of-the-art of research. Such data would certainly be needed if Congress is to gauge the urgency of the report's recommendations.

[See GAO note 14, p. 118.]

APPENDIX VI

NASA

National Aeronautics and
Space Administration

Washington, D.C.
20546

Reply to Attn of: W

OCT 14 1977

Mr. R. W. Gutmann
Director
Procurement and Systems
Acquisition Division
U.S. General Accounting Office
Washington, DC 20548

Dear Mr. Gutmann:

Thank you for the opportunity to review the draft of GAO's report entitled "Federal Human Nutrition Research--Need For A Coordinated Approach To Advance Our Knowledge, Volumes I and II", which was requested by the Chairman, Senate Select Committee on Nutrition and Human Needs.

We agree fully with the purposes and objectives of the report. There is clearly a need for increased emphasis on nutritional research, and in the problem areas so well identified. In our view, this would in no way interfere with our work but rather would serve to enhance our effort and future capabilities.

Sincerely,

Kenneth R. Chapman
Assistant Administrator for
DOD and Interagency Affairs

VETERANS ADMINISTRATION
OFFICE OF THE ADMINISTRATOR OF VETERANS AFFAIRS
WASHINGTON, D.C. 20420

OCTOBER 19 1977

Mr. Gregory J. Ahart
Director, Human Resources Division
U. S. General Accounting Office
441 G Street, N. W.
Washington, DC 20420

Dear Mr. Ahart:

The Veterans Administration (VA) appreciates the opportunity to comment on your recent draft report, "Federal Human Nutrition Research -- Need for Coordinated Approach to Advance Our Knowledge."

The report asserts that very little is known about human nutritional requirements. Although several Federal departments and agencies are supporting research, some barriers to human nutrition research persist. GAO is recommending steps to be taken by the Congress and Executive Branch to help overcome these barriers. We are commenting on recommendations affecting this agency and selected narrative portions of the report.

Our expenditures on nutrition research, estimated at $450,000 in Fiscal Year 1975, continued at the same level for Fiscal Year 1976. In addition to the VA research projects on obesity listed in Chapter 3, we are also sponsoring studies in nutritional requirement for trace metals, vitamin B12 utilization, regions of the brain responsible for appetite control, and the physiological effects of artificial food additives.

The VA is in a unique position to address nutritional problems of the elderly, disease and stress, and drug and vitamin usage. The VA Cooperative Studies approach is an excellent medium for studying a male population of geographic, cultural, and genetic diversity.

We agree that a lead agency needs to be established for all nutrition research. The lead agency should be defined as that receiving the major (funded) research appropriation of all funded agencies. The lead agency would report annually to Congress and Executive Office of the President on the nature and status of federally supported nutrition research; areas of gap, overlap and duplication; and status of needs for human, material and financial resources. The definition of subject areas comprising human nutrition research and the responsibilities of federal agencies involved should be accomplished. However, the necessity of establishing a lead agency for each subject area might be bureaucratically unwieldly and preclude optimal operational efficiency.

The report's reference to "unwarranted overlap" needs to be clarified. Investigator initiated research obviously can duplicate that of other investigators in whole or part. These occurrences are not necessarily inappropriate or unwarranted.

We agree that an assessment should be made of the potential value in establishing regional nutrition research centers in conjunction with colleges and universities having comprehensive nutrition departments and programs.

An interagency committee on nutrition research should be established. This group, rather than the Office of Science and Technology Policy or Office of Management and Budget, should have primary responsibility for the selection of a lead agency for subject areas, as well as recommend action in the other areas cited.

We are in agreement in the matters for attention of the Congress.

Thank you for the opportunity to review this draft report.

Sincerely,

MAX CLELAND
Administrator

GAO notes:

Page references in the agency comments in appendixes II through VI refer to the draft report and may not correspond to the pages of the report.

1. A good definition of human nutrition research is needed. There is no universally accepted definition. For the purposes of our review, we broadly grouped human nutrition research into the following areas: human nutritional requirements; food composition and nutrient biological availability; diet, disease causation, and food safety; and food consumption and nutritional status. The definition is broad and includes both direct (primary) and nutrition-related (secondary) research.

2. The percent of low-birth-weight infants to total births is 7.4 percent on the basis of 1975 statistics from the National Center for Health Statistics. This is the figure used in our report. An NIH official told us that the 10-percent figure used by OSTP is a rough estimate, suitable for the purposes of the OSTP report.

3. We are not recommending a change in funding for research on diet and heart disease, hypertension, and cancer. We point out the need for continued research in this area.

4. At the time our draft report was sent to the agencies for comment, S.275 (the Farm Bill) was being debated in the Congress. On September 29, 1977, the bill became law--the Food and Agriculture Act of 1977 (P.L. 95-113). The act designates USDA the lead Government agency for agricultural research (except with respect to the biomedical aspects of human nutrition concerned with diagnosis or treatment of disease), extension, and teaching in the food and agricultural sciences. The act also requires the Secretary of Agriculture to develop and implement a national food and human nutrition research and extension program. The Secretary is also required to establish food and human nutrition research as a separate and distinct mission of USDA. The Agricultural Marketing Act of 1946 (7 U.S.C. 427) authorizes and directs the Secretary, USDA, to conduct agricultural research including research into the problems of human nutrition. However, this act did not clearly establish USDA as the lead agency in the Federal Government for human nutrition research.

5. We agree that there is a critical need for effective nutrition education. This report does not include the important

area of nutrition education. We are currently doing an in-depth review of the Federal nutrition education efforts.

6. The Chief, Nutrient Composition Laboratory, ARS, testified on September 30, 1977, before the Senate Select Committee on Nutrition and Human Needs that:

> "We are consuming processed foods in greater amounts now than in the 1950's and in forms that did not exist then. Data on the effects of processing on the nutrient contents are particularly needed * * *"

We do not deny the desirability and need for food processing to improve the digestibility, safety, storage stability, and acceptability of food, but we believe that more emphasis needs to be directed at the nutritional and health consequences of food processing.

7. Our coverage of FDA's nutrition research activities is brief and it is based on material provided by FDA. Recently, the FDA Commissioner identified some of the agency's major nutritional concerns before the Senate Select Committee on Nutrition and Human Needs. He identified the following:

--Keeping an extremely careful eye on changes in nutritional quality of the food supply as an ever-increasing proportion of the food supply is processed (about 55 percent) and consumed away from home (about $1 of every $3 expended for food).

--Creating a regulatory climate in which we foster research and application of modern nutrition principles to management of critically ill and chronically ill patients.

--Studying the adverse effects of long-term intakes of excess amounts of individual nutrients, because the practice has become very widespread through the advocacy of the so-called "health food" movement.

--Collaborating with all agencies involved in nutrition education to improve public understanding of the relationships between diet and health.

--Collaborating with our sister agencies to improve nutrition methodologies, including food consumption

methods, clinical methods for measuring nutritional status, and nutrient analytical methods.

8. Our use of the term "surveillance" is in the broad sense. It is a broad system which includes HANES, the Nationwide Food Consumption Survey, CDC Surveillance Program, and other surveys. No one agency conducts the comprehensive national nutritional surveillance system relating diet to health on a continuous, long-term basis. Instead, there are various diet and health surveys and nutrition and health delivery programs throughout various agencies which theoretically could be coordinated and supplemented to make up a comprehensive national nutritional surveillance system. The HANES survey conducted by NCHS could be a major component of a broad surveillance system, but by itself it is not the comprehensive, long-term surveillance system as called for in our report, as defined in the Joint FAO/UNICEF/WHO Expert Committee Report on the Methodology of Nutritional Surveillance and as suggested by several nutrition experts.

A NCHS official told us that although HANES is a nutritional surveillance in a limited, technical sense, there is still no comprehensive national surveillance system in the broad sense. The official said that there are gaps in HANES which will be addressed in a proposal to the Congress for a comprehensive nutritional status monitoring system. (See p. 66.)

Surveillance, as contrasted to a survey, implies continuity--a frequent and continuous watching over of nutritional status and changes in status over time. A good example is the CDC system, which continuously evaluates the status of children known to be at risk nutritionally. By contrast, HANES is periodic, having been conducted in 1971-74 on certain population sample groups and now being conducted during 1976-79 on other sample groups. In the HANES plan of repeated surveys, the time between the surveys is protracted. A periodic system like HANES would appear inadequate for searching out long-term effects. Moreover, HANES and its predecessor, the Ten State Survey, have suffered erratic funding that hardly is characteristic of a long-term and continuous commitment and effort.

In addition to being a continuous and long-term effort, a comprehensive national nutrition surveillance system should include the dietary and health surveys of USDA, FDA, CDC, and NCHS and be linked to the nutrition intervention and health delivery programs.

The Congress also expressed a need for a comprehensive nutritional status monitoring system by the recent passage of the Food and Agriculture Act of 1977. The act requires HEW and USDA to submit to the Congress a proposal for a comprehensive nutritional status monitoring system. The proposal should include

--an assessment system consisting of periodic surveys and continuous monitoring to determine the extent of risk of nutrition-related health problems, which population groups or areas are affected, and the causes;

--a surveillance system to identify remedial nutrition-related health risks to individuals or for local areas and to allow direct intervention and treatment; and

--program evaluations of nutrition-related programs in reducing health risks to individuals and populations.

As a result of the act's requirement, a working group of 11 representatives from USDA and HEW agencies are formulating a proposal for a comprehensive monitoring system.

In November 1977, HEW submitted to OMB a paper entitled "The Role in HEW in Human Nutrition: Future Directions," as a supplement to the Department's fiscal year 1979 budget submission. The paper presents several nutrition program objectives and proposals. HEW noted that there was a need to:

--Expand the nutrition surveillance and monitoring network to provide adequate information for public policy decisionmaking. (Specifically, the NCHS system, HANES, needs to be expanded in time, scope, and demographic coverage.)

--Use nutrition surveillance and monitoring data more directly in setting public policy at the Federal, state, and local levels.

--Develop a better process for deciding what nutritional indexes to monitor.

--Analyze the existing data collected in the HANES programs and CDC surveillance activities on an accelerated basis.

--Provide wide dissemination of nutrition surveillance information.

OSTP's draft report identified the need to improve the surveillance of dietary intake and nutritional status of the population and of high-risk subgroups as a priority area of human nutrition research. OSTP said there are serious limitations in the methods and timing of USDA's Nationwide Food Consumption Survey (NFCS) and HEW's HANES survey. There is also a need to correlate the data already collected in the HANES and NFCS surveys. Tabulations are yet to be completed on nutritional biochemistry and food consumption information collected under HANES in past years.

9. In April 1976, the President's Biomedical Research Panel reported on research conducted and supported by NIH and the Alcohol, Drug Abuse, and Mental Health Administration. In its review of nutrition research, the Nutrition Cluster of the Panel reported that among the vitamins, the metabolism and mechanism of action of all the fat-soluble vitamins and vitamin C are among the least understood and therefore are promising areas of needed research.

10. The Eskimo and New Guinea experiences were cited to show the lack of simple and clear-cut explanations of the relationship between diverse eating habits and varying disease experience.

11. There are many carbohydrates and they differ in their properties. The glossary of our report has been changed to reflect this.

12. NSF attributes the information in chapter 4 of our report solely to the 32 experts. As noted in chapter 6, "Scope of Review," the identification of nutrition gaps, needs, and barriers were based on several sources. In addition to the 32 nutrition experts, we also interviewed many Federal officials and researchers, university administrators and researchers, and representatives of nutrition professional societies. We also examined the major studies of nutrition research.

13. The use of the gross national product (GNP) and health care expenditures in current dollars is appropriate because we are concerned with total costs, including that due to price inflation. The proportion of our resources devoted to health care is substantial and growing, regardless of whether current or constant (deflated) dollars are used.

14. NSF said that our report fails to address the level of funding that the nutrition field could realistically support considering the state of the art. We agree. Our report points out the areas needing further research and the barriers needing attention by the Federal agencies.

PRINCIPAL OFFICIALS RESPONSIBLE FOR ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of Office From		Tenure of Office To	
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE				
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:				
Joseph A. Califano, Jr.	Jan.	1977	Present	
David Mathews	Aug.	1975	Jan.	1977
Caspar W. Weinberger	Feb.	1973	Aug.	1975
DEPARTMENT OF AGRICULTURE				
SECRETARY OF AGRICULTURE:				
Bob Bergland	Jan.	1977	Present	
John A. Knebel	Oct.	1976	Jan.	1977
Earl L. Butz	Dec.	1971	Oct.	1976
DEPARTMENT OF DEFENSE				
SECRETARY OF DEFENSE:				
Harold Brown	Jan.	1977	Present	
Donald H. Rumsfeld	Nov.	1975	Jan.	1977
William P. Clements, Jr. (Acting)	Nov.	1975	Nov.	1975
James R. Schlesinger	July	1973	Nov.	1975
DEPARTMENT OF STATE				
SECRETARY OF STATE:				
Cyrus R. Vance	Jan.	1977	Present	
Henry A. Kissinger	Sept.	1973	Jan.	1977
NATIONAL SCIENCE FOUNDATION				
DIRECTOR:				
Richard C. Atkinson	May	1977	Present	
Richard C. Atkinson (Acting)	Aug.	1976	May	1977
H. Guyford Stever	Feb.	1972	Aug.	1976

	Tenure of Office	
	From	To
VETERANS ADMINISTRATION		
ADMINISTRATOR OF VETERANS AFFAIRS:		
Max Cleland	Mar. 1977	Present
Richard L. Roudebush	Oct. 1974	Mar. 1977
Richard L. Roudebush (acting)	Sept. 1974	Oct. 1974
Donald E. Johnson	June 1969	Sept. 1974
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION		
ADMINISTRATOR:		
Robert A. Frosch	June 1977	Present
Alan M. Lovelace (acting)	May 1977	June 1977
James C. Fletcher	Apr. 1971	May 1977
OFFICE OF SCIENCE AND TECHNOLOGY POLICY		
DIRECTOR:		
Frank Press	Apr. 1977	Present
Frank Press (acting)	Feb. 1977	Apr. 1977
Vacant	Jan. 1977	Feb. 1977
H. Guyford Stever	Aug. 1976	Jan. 1977
OFFICE OF MANAGEMENT AND BUDGET		
DIRECTOR:		
James T. McIntyre, Jr. (acting)	Sept. 1977	Present
Bert Lance	Jan. 1977	Sept. 1977
James T. Lynn	Feb. 1975	Jan. 1977

(952140)

APPENDIX IX

GEORGE McGOVERN, S. DAK., CHAIRMAN
HERMAN E. TALMADGE, GA.
PHILIP A. HART, MICH.
WALTER F. MONDALE, MINN.
EDWARD M. KENNEDY, MASS.
GAYLORD NELSON, WIS.
ALAN CRANSTON, CALIF.
HUBERT H. HUMPHREY, MINN.
CHARLES H. PERCY, ILL.
ROBERT DOLE, KANS.
HENRY BELLMON, OKLA.
RICHARD SCHWEIKER, PA.
ROBERT TAFT, JR., OHIO
MARK O. HATFIELD, OREG.
ROBERT M. SHRUM, STAFF DIRECTOR
ALAN STONE, GENERAL COUNSEL

United States Senate

SELECT COMMITTEE ON NUTRITION AND HUMAN NEEDS
(CREATED PURSUANT TO S. RES. 281, 94TH CONGRESS)
WASHINGTON, D.C. 20510

March 11, 1976

B-164031(3)

The Honorable Elmer B. Staats
Comptroller
United States
General Accounting Office
Washington, D.C.

Dear Mr. Staats:

The Congressional Research Service has prepared the enclosed report, "The Role of the Federal Government in Human Nutrition Research," disclosing inadequate federal funding for human nutrition research and uncoordinated federal activity in this area.

Advancement in human nutrition research is fundamental to improving the health of United States citizens and all mankind. Consequently, I request that the General Accounting Office examine all federal activity in human nutrition research and report on the major gaps in our nutrition knowledge, what federal agencies are doing to fill them and what areas of inquiry may be receiving insufficient attention and funding. In addition, we request recommendations on organizational, legislative or other changes needed to facilitate progress.

Our purpose is to provide Congress with an outline of the most pressing needs in human nutrition research and a plan for action.

We recognize this as a complex task, but we feel it is of utmost importance, and we hope it might be completed as quickly as possible.

Sincerely,

George McGovern

George McGovern
Chairman

BY THE COMPTROLLER GENERAL

Report To The Congress

OF THE UNITED STATES

Federal Human Nutrition Research Needs A Coordinated Approach To Advance Nutrition Knowledge

This second volume of a two-volume report contains the observations and views of 32 individuals active in research, training, or clinical practice of human nutrition. The topics addressed were human nutrition research gaps and needs.

UNITED STATES GENERAL ACCOUNTING OFFICE

Volume II

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MARCH 28, 1978

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

FEDERAL HUMAN NUTRITION
RESEARCH NEEDS A COORDINATED
APPROACH TO ADVANCE NUTRITION
KNOWLEDGE

D I G E S T

This is the second volume of GAO's two-volume report "Federal Human Nutrition Research Needs A Coordinated Approach To Advance Nutrition Knowledge" and contains responses solicited from 32 individuals working in nutrition as teachers, administrators, medical specialists, and public health nutritionists.

GAO asked (see app. I):

--What issues should be identified as major human nutrition knowledge gaps? Please explain why they represent major gaps.

--Please list and rank your priorities and explain the reasons underlying your rankings.

--Based on your knowledge of the nutrition research supported by the Federal Government, which of the gaps listed under question 2 are not receiving adequate attention by Federal agencies? Please cite reasons why you believe Federal support has not been adequate.

--Based on your identification and prioritization of the knowledge gaps, what types of research activity are needed?

--What problems--organizational, methodological, financial, or other--could prevent or inhibit Federal support of needed research? Please explain the particular problems you cite.

The responses center around a number of recurring issues and concerns broadly categorized as:

--Human nutrition requirements. The quantitative requirements for many nutrients are either not fully defined or not defined at all. Information is needed to identify the

differences in nutrient requirements according to an individual's sex, age, level of activity, and physical or mental stress condition. The interrelationships of nutrients and other food components affecting nutrient availability need to be determined.

--Food composition and nutrient biological availability. Current and comprehensive information on food composition is needed for planning diets to meet nutritional requirements. Food composition tables should include information on the biological availability of nutrients in foods as well as nutrient composition of foods as consumed. Research is needed to improve methods of determining the effects of food production, processing, and preparation procedures on food composition and nutrient availability.

--Diet, disease, causation, and food safety. The most frequently stated concern was the role of nutrition in maintaining good health and preventing chronic and degenerative diseases. Research is needed on diet as one of several factors in the cause of disease and disorders such as obesity, heart and vascular disease, cancer, diabetes, and hypertension. Research also is needed to determine the long-term health effects of chemical food additives.

--Food consumption and nutritional status. Little is known about the Nation's current nutritional status. Research is needed to continuously monitor the population's food consumption and nutritional status. Special target groups must be identified before effective intervention programs, such as medical and preventive health care, nutrition education, and food assistance, can be designed and implemented. Better methods to determine nutritional status are needed. Information is needed on more segments of the population and more areas of the country.

The nutrition research gaps are interrelated, calling for a research effort on a broad front. A multidisciplinary approach must be used because of the complexity of nutrition problems

and their relationship to both food and health issues. Many respondents cited a need for better coordination among the Federal departments and agencies performing and supporting nutrition research.

The comments and observations by the experts do not necessarily represent positions of the organizations with which they are affiliated, the former Senate Select Committee on Nutrition and Human Needs, or GAO.

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Roslyn B. Alfin-Slater, Ph.D.
Professor and Division Head
Environmental and Nutritional Sciences
School of Public Health
University of California, Los Angeles

Re your letter of October 14, having just completed writing a chapter on "Nutrition and Aging", I was appalled by how little information is available in this area. Therefore, I am suggesting the following:

1) Nutritional requirements of an over 65 year old population. Although there are now 22.7 million persons (10.6% of the total population) over the age of 65, we know little of their nutritional requirements. The RDA is an extrapolation from those of younger adults with a downward adjustment for energy (calories), since it is assumed that the older segment of the population is more sedentary. There are insufficient nutritional evaluations on older people to determine whether there are nutrient inadequacies in this population, and if this is so, the cause needs to be determined. Is this due to an inadequate intake of specific nutrients? poor nutritional absorption? drug-nutrient interactions? increased requirements resulting from chronic disease conditions? etc.

In my opinion, what is needed are the following:

1) Basic research on aging.

2) Nutritional evaluations and nutrition histories.

3) Clinical evaluations.

4) Laboratory tests on aging populations.

5) Research on nutrient-drug interactions.

6) Research on the relationship of nutrition to chronic diseases, e.g. atherosclerosis, cancer, arthritis, hypertension, etc.

Unfortunately, nutrition and gerontology have been low-priority items as far as the funding of research applications is concerned. I think it is time for a change.

October 29, 1976

American Dietetic Association
Chicago, Illinois

1. ISSUES IDENTIFIED AS MAJOR HUMAN NUTRITION KNOWLEDGE GAPS

A. Nutritional status of the total population as determined by systematic nutritional assessment programs.

This information is available for only certain segments of the population and certain areas of the country. The results from the most comprehensive HANES survey of USPHS are not available in entirety and apparently no plans exist for extending and continuing this study. Dietary studies such as HANES and the USDA Household Consumption do not provide information readily useful to the local community. Such data should be available in terms of census tracks, prospective data on dietary patterns and development of chronic disease as related to the dietary patterns surveyed.

B. Nutrition and health related issues.

The individuality of the utilization of nutrients in both health and disease requires considerable attention. e.g., What is the availability of iron to the human body as related to its source? In general, what is the availability to the human body of nutrients as related to their source? Such information could be significant in developing a public policy useful in food supplement programs such as WIC. It would also be useful in developing and updating standards for nutritional requirements such as the Recommended Daily Allowances.

What is the relationship between disease, especially the degenerative diseases, cancer, and diabetes, and nutrition practices? What are the effects of specific dietary components on health? Examples of the latter are fiber, lactose, trace minerals, and the expanding use of vegetable proteins. What is the duration of recovery from illness as related to human nutritional status?

What are the interrelationships of nutrients in mixtures of foods such as in meals? How does the body utilize nutrients in mixed diets in common usage versus isolated nutrients? e.g., milk containing calcium vs. calcium?

B. Nutrition and health related issues (continued)

More research is needed into the protein requirements of humans in both health and disease, as well as protein supplements and their effectiveness. Such information is needed not only for individuals but to determine both national and international protein needs and policies thereto. What is the effect of prolonged adoption of food fads? What is the long-term effect of the use of vegetarian diets?

The health related issues are important because of the high incidence of factors among the U. S. population leading to high mortality rates. Because complex and mutliple causative factors are no doubt involved the public is confused and unsure of available nutrition information.

C. Identification of nutritional at-risk groups in the population and the factors involved.

There is a need for specific nutrition standards for the rapidly growing numbers of aging in the population. At what age should we be concerned about nutritional rehabilitation? What is the effect both physically and mentally on the aging when we initiate aggressive nutritional rehabilitative measures? We believe it to be positive but we really do not know.

Nutritional standards are not presently available for the "non-healthy" individual, such as the person under stress, the hypermetabolic, the handicapped, and other individuals. The Recommended Daily Allowances are designed for the healthy person.

This is closely related to item 1-A., but such study would further identify underlying causes for all at-risk categories. These causes would include factors such as: economics, educational gaps, social, age-related, medical, eating patterns and the food delivery system.

D. Study, development and coordinations of standards for nutritional care.

Federally supported nutritional care programs vary in the standards and kinds of care provided. Research into the cost-

effectiveness of all such programs would assist in arriving at answers to the question: Does a variety of standards lead to prevention of illness and rehabilitation, prime goals of nutritional care? There appears to be a need to develop a standard to be adopted in all federally assisted facilities in regard to nutritional care., e.g., acute care, intermediate care and long term care. There is a need to evaluate the nutrition assessment and nutrition education components of all Federally assisted food programs. Presently WIC is the one program having such a requirement. The determinations of the cost-benefit ratio of all programs is necessary if we are to determine their contribution to health.

E. Food quality and safety.

It is important to narrow the gap between nutrition knowledge, food technology and industry so that products offered for public consumption are in adequate supply and are consistently representative of the best in current applied nutrition information. e.g., convenience foods, enriched and fortified foods.

There should be a program to monitor the food supply for planned and "accidental" additives and for "manufactured" and highly processed foods. This is considered an area of need for further research in the regulatory agencies are not always coordinated in their efforts. There is some controversy regarding the practices of the agencies in monitoring procedures employed; there is much public and Congressional influence in regulations and controls.

F. Revision/updating of current information/publications.

The Recommended Daily Allowances (RDA's) are directed toward those enjoying good health. They need to be assessed as they relate to disease.

Rewrite Handbook #8 "Composition of Foods" with a complete analysis of all foods including values for amino acids, vitamins, minerals, triglycerides and fatty acids.

2. RANKING BY PRIORITY

A. Nutritional status assessment

Medical and preventive health care, food supplement programs, nutrition education programs must be targeted to those groups who are most needy and most likely to benefit from such assistance. They must be identified before the most effective programs can be designed and implemented.

B. Nutrition and health.

Illness and mortality rates in the degenerative diseases are high. It would be possible to develop more effective educational and preventive health programs if there were more complete knowledge of the factors involved.

C. Nutritional at-risk groups in the population and causative factors.

This is closely related to "A" - Nutritional status assessment. All of the nutritional assessment surveys to date indicate segments of the population with consistently low intakes of certain nutrients. The relationship of these findings to recommended levels of intake and reasons for low intake needs further investigation in order to alleviate the problems and as a basis for remedial programs.

D. Study, development and coordination of standards for nutritional care.

Various standards and criteria for care in Federally assisted programs are currently being used. Research as suggested in the first four "priorities" can help to identify those areas of nutritional care where standardization can lead to more and better cost-effectiveness.

E. Food quality and safety.

Optimal nutrition is possible only when safe, nutritious food is available at all times to all persons.

3. INADEQUATE FEDERAL ATTENTION IS BEING GIVEN IN THE FOLLOWING:

A. Nutritional assessment of the population.

Such surveys are expensive both in time and money. They must have local support and cooperation. It is only recently in this country that we have begun to recognize the importance of an adequate diet to optimal health and that both overnutrition and undernutrition are problems. There has not been Congressional support for the continuation and expansion of the HANES Survey nor the Ten State Nutrition Survey.

B. Nutrition and health related issues.

The studies which we have suggested are long term ones which require money and time and frequently provide less recognition for those conducting the research. The recognition of the importance of nutrition in health and disease is a comparatively recent occurence.

C. Identification of nutritional at-risk groups.

A growing awareness of some of the needs accounts for some programs in which nutrition is identified as an important factor. e.g., WIC, Nutrition Programs for the Aging, School Foodservice. The treatment of causative factors, evaluation of program outcomes and the coordination of food, money and educational aspects of programs is still needed.

D. Study, development, coordination of standards for nutritional care.

Federally assisted programs have not all originated at the same time nor have they all been based in the same agencies, hence guidelines and regulations determining the quantity and kinds of nutritional services to be provided have not been "standardized". With the advent of the concept of professional standards review and "quality assurance", programs for health care delivery may begin to develop standards for nutritional care that can be applied to all health care delivery situations.

E. Food quality and safety.

Activities in monitoring the food supply for quality and safety are diversified and not always coordinated; legislation and regulations frequently do not keep pace with the rapidly changing food supply available to the public; precise methodology is still not completely adequate.

4. TYPES OF RESEARCH ACTIVITY NEEDED

A. Nutritional assessment programs, possibly directed by USPHS and conducted with the cooperation of state and/or district Public Health Departments. This should include study of present nutritional standards to determine validity.

B. Studies of long duration on given levels of nutrients and the relationship of sources of nutrients to utilization in the human body; nutrition and its role in degenerative diseases; the long term effect of nutrient deficiencies created by "fad" diets; development of nutritional standards which will be flexible, to provide for the "non-healthy" or "at-risk" individual.

C. Identification of foods which can and should be fortified with nutrients; amounts of fortification, etc.

D. Coordination of research in food production, food processing, delivery systems and the like that influence nutrient content as it reaches the consumer.

5. PROBLEMS PREVENTING OR INHIBITING FEDERAL SUPPORT

Organizational - USDA, DHEW, Food and Drug, the Federal Trade Commission traditionally fund and support different types of research. Health related research projects done on a cooperative basis have not usually been accomplished under the present delineation of administrative responsibilities.

Financial - The administration of programs such as the child nutrition programs, nutrition programs for the aging, supplemental food programs such as WIC and Food Stamps is spread

through several departments and agencies. Large sums of money have been allotted to these programs and in most cases we have little or no nutritional assessment data before and after the programs have been implemented. If funds are not so earmarked before programs are started they rarely are available at a later time. The goal of each of the programs mentioned is to improve the nutritional status of the recipient but we have little or no data to support progress in this direction. Sometimes there is duplication of effort; at other times certain factors are completely ignored, or certain population groups excluded.

Population surveys are expensive. Failure to conduct them is probably attributable to this fact.

Adoption of a national nutrition policy with the responsibility for its administration located in the executive branch of government would provide a focal point for the coordination of all programs in nutrition research.

December 7, 1976

C.L. Brumback, M.D., M.P.H.
Director, Palm Beach County
Health Department, Florida

Thank you for your letter of October 5 inviting me to respond to your questions regarding Federal activity in human nutrition research.

Because Mrs. Ruth Baker, our senior nutritionist, and I felt that we needed additional information, Mrs. Baker spoke with your associate, Mr. John Miller. Mr. Miller was good enough to send us a copy of the National Nutrition Plan which we have reviewed carefully. (See GAO note.) Mr. Joel Elias, another nutritionist, has participated in the review and in the drafting of our response.

We find the Plan to be very comprehensive. It is quite exciting in describing the broad range of concerns to which research is being addressed. We note with interest and approval that both pure and applied research are included and that there seems to be a commitment to the sharing and coordination of results, even to the extent of defining procedures for communicating information. It is encouraging to note the emphasis on activities which have potential for prevention, and we are pleased that the entire age range receives consideration.

Among our most urgent concerns are nutrition and cancer, and nutrition and cardiovascular disease. It was good to note substantial funding for both areas.

Essentially, we endorse the National Nutrition Plan. There are certain areas, however, which seem to us to merit exploration and we enumerate them below. We have listed them in order of priority.

1. Overnutrition:

It is our impression that the NIH nutrition plan has generally equated overnutrition with obesity. As a result, other consequences of overnutrition may receive less attention than they deserve. For an example, with little or no restriction on the availability of over-the-counter nutritional supplements, we feel some concern for questions relating to the excessive intake of such supplements. What are the long-term and short-term

GAO note: Plan refers to draft copy of the National Institutes of Health Plan which contains a description of past, present, and proposed nutrition activities at NIH.

physiological responses to the nutritional imbalances created? What potential exists for subclinical problems such as hypervitaminosis D in children who consume supplements in addition to a wide variety of fortified food substances?

We are also concerned with the potential for overnutrition inherent in the Recommended Dietary Allowances. Since the RDA's refer to upper limits of intake to insure nutritional adequacy for the population as a whole, the application of these standards to meal programs, food packages and nutrition labeling may result in overnutrition for those consuming foods to meet RDA standards which are in excess of their individual nutritional needs. We would therefore encourage investigations to determine whether the RDA is the most reasonable or desirable guide to nutrition possible.

2. Substance Interactions and Toxicological Controls:

In recent years we have witnessed the progressive accumulation of evidence for nutrient interactions in foods both prior to and following ingestion. Nutrients not only act upon other nutrients, but also interact with other biologically active substances such as drugs, hormones and a wide variety of food additives. For this reason, we should like to see the development of more sophisticated techniques of toxicological testing which assess such interactions. We should also urge the development of uniform standards for testing substances prior to their approval for commercial use. Such standards should define acceptable outcomes of testing and specify the methodology to be used for testing. This would help to avoid later controversies over the validity of test results and would give the public greater confidence in the safety of their food supply.

3. Nutrition, Stress and Environment:

Until recently, nutritional requirements were established without regard for the quality of the social and physical environment in which an individual might be living. It is now apparent that pollution and other factors which contribute to biological stress alter normal bodily functions and can lead to accelerated depletion of specific nutrient stores. Clearly, the nutritional status of the individual must suffer unless his nutrient intake can be altered to accommodate the effects of such stress.

We would like to see more research to clarify how physiological and biochemical functions are altered by stress and what specific changes in nutritional requirements are likely to result. We would also like to know more about how the resulting changes in nutritional status contribute to the etiology of diseases (such as cancer, CHD), and what nutritional interventions, if any, may help to protect the body from the effects of particular environmental insults.

4. Infant Nutrition:

It would seem that within both the lay and professional communities there often exist contradictory and confusing opinions regarding the normal nutritional requirements of the infant, the foods most appropriate for satisfying those needs, and the ideal age at which the various foods ought to be introduced. As a consequence, few persons are able to state with confidence what is best for the infant, and many often resort to equivocal statements reflecting the ambivalence with which they entertain questions from concerned parents and other professionals.

We would like to see research leading to the dissemination of some practical guidelines on infant feeding which take into account the infant's actual nutritional needs, level of physiological development and capabilities with respect to physical coordination.

5. Anthropological Nutrition Studies:

Cross-cultural studies suggest a great variety of food practices among the world's peoples, yet we possess relatively little information relating to the degree of physiological adaptation that may accompany so diverse a set of practices.

The Masai of Africa depend in large measure on the blood and milk of their cattle, while the Eskimo traditionally consume large quantities of animal protein and fat. On the other hand, horticulturists in New Guinea have been observed to consume high carbohydrate-low protein diets with no apparent problems. In our own culture the consumption of dairy products results in what some consider to be an excessively high intake of calcium as compared to other societies in which the consumption of calcium-containing foods is remarkably low.

We believe that, in order to achieve a fuller understanding of what constitutes "normal" nutrition, one must understand both the evolution of human diet through time, and the range of genetic potential of the human organism for adaptation to diets of widely varying nutrient content. We should therefore, look forward to additional government support of such projects.

6. Food Composition Tables:

At present, food composition tables are at best rough approximations of the nutritional content of foods. This is due, in part, to the fact that not all of the nutrients present in a food are necessarily available for digestion and absorption by the body. Current techniques for food analysis do not differentiate between available and unavailable nutrients. We should welcome research toward the development of techniques for food analysis which would more nearly duplicate the capabilities of human digestive and absorptive processes. This would give us a better guide to the nutritional value of foods, as opposed to the mere quantitative analyses of present composition tables.

Furthermore, since both nutrient content and availability often change during the preparation of foods, we believe it would be desirable to develop tables which report on foods as consumed, rather than the more traditional practice of reporting on foods as purchased.

7. Agricultural Research and Alternative Food Sources:

Emphasis in agricultural research has been largely restricted to increasing the yield of those cultigens traditionally consumed by Western peoples. As a result, agricultural success has become dependent upon increasingly costly expenditures of energy and labor to obtain maximum yields from relatively few genera. Furthermore, varieties have been developed requiring a degree of environmental control that may prove to be unattainable, with potentially disastrous consequences for the world's food supply. Aggravating this situation is the fact that world livestock production has been brought to hinge upon human food production, instead of the reverse, by placing animals in competition with humans for the same foods.

To help alleviate some of these pressures on present food resources, we would look forward to research into the following areas:

a. The development of energy sparing, labor intensive agricultural techniques including complex systems of mixed cropping to maximize nutrient production per hectare.

b. The development of secondary cultivated species with specialized adaptation to agriculturally marginal regions.

c. The development of nutrient-rich livestock feeds derived from agricultural and forest crops and their by-products-foods that require the ruminant digestive tract will thus provide animal protein without decreasing the human food supply.

d. Increased research into the development of protein alternates for meals to decrease dependence on animal protein sources.

8. Drugs and Nutritional Status

There are many factors affecting the manner in which drugs are metabolized, not the least important of which is the nutritional status of the individual.

We would like to see greater awareness of a test subject's nutritional status reflected in the testing methodology. We are interested in the effects a drug may have on nutritional status, as well as in the effects that nutritional status may have on the metabolism and effectiveness of the drug. We are particularly interested in these relationships as they occur in elderly, malnourished, and long-term care patients suffering from chronic illness. We are similarly concerned about individuals who are recovering from acute episodes of sudden onset which may have resulted in depressed nutritional status.

In regard to questions 3, 4, and 5, page 2, of your letter, we do not feel sufficiently familiar with research activities and Federal support to write a useful and meaningful reply. We have listed research gaps as we have perceived them from the viewpoint of practitioners in the field of public health. Mrs. Baker and I have responded from the perspective of many years. Mr. Elias has responded as a recent graduate (1975) of the Human Nutrition Program, University of Michigan School of Public Health.

Although we understand that other agencies will deal with consumer issues, we wish to stress the need for support of studies of methods to translate available knowledge to consumers in an effective manner. We need to know much more about motivation, effecting behavioral change,and helping individuals to develop and maintain patterns appropriate to their particular lifestyles and health

conditions. These problems require concerted efforts on the part of physicians, nutritionists, health educators, social scientists, economists, communications specialists, and others. We hope that these matters of application will receive adequate attention.

November 19, 1976

Ann L. Burroughs, Ph.D.
Assistant Director
Cooperative Extension
University of California, Berkeley

Major Human Nutrition Knowledge Gaps:

a. More information is needed on behavioral modification relative to the amounts and types of foods people eat.

   Obesity is the United States' number one nutrition problem and is associated with diseases which increase mortality and morbidity. Information is available on how to control obesity, but many individuals find it difficult to reduce and stay at ideal weight. We need more information on the forces which drive an individual to select particular foods and to select the amounts of those foods.

b. We need a surveillance system so that we have information on the types and quantities of foods people use on a regular basis. An attempt could be made with the use of a computer to identify basic food patterns. It is my guess that there are probably 15 to 30 such "basic patterns". Marketing Research Corporation of America does have information on the types of foods people eat. While this is proprietary information it probably would be available for research purposes if appropriate confidentiality were assured. To the best of my knowledge MRCA has not attempted to quantitate their diary system of collecting information. The "Ten Year USDA Surveys" are not frequent enough and the information from these surveys has a very large time lag to its availability for practical use. Possibly, with computers the study presently being undertaken will be completed more rapidly.

c. More information is needed about the specific relationships between dietary intake and health in humans. Further elucidation of the appestat control mechanism is desperately needed. This presupposes information which could be used in modification of the mechanism.

   Further information on the basic mechanism relative to cardiovascular disease, diabetes, aging, osteoporosis, and dental diseases in humans is also needed.

   Initial research on the potential relationship of nutritional deficiencies/imbalances and mental diseases/disorders is needed. Specifically, further research on megavitamin therapy, and on the possibility of a relationship between lithium deficiency and schizophrenia.

d. Better information is needed on the nutritional value of foods, including information on the bioavailability of nutrients in humans and interactions between nutrients both in humans and in foods. Assays for the various lipid components in foods are dependent on more accurate and more rapid assay methodology. Better methodology is also needed in order to identify the complexes in which minerals exist in foods, which may be related to the bioavailability. I've already indicated that the bioavailability of minerals in particular does need further study. Assays of vitamins in foods also suffer from laborious methodology techniques which are frequently of dubious accuracy, thus further research monies for chemists need to be made available.

e. Improved evaluation and continual surveillance of nutritional status of people is needed. The present methodology used for nutritional assessment seems to be particularly effective where there are severe deficiency diseases and is most ineffective where there are "subclinical" nutritional conditions. While a search for improved methods of nutritional surveillance is being undertaken, present methods should be used on appropriate subsamples of the population so that effective means could be devised for necessary intervention.

f. Information is needed on effective methods of intervention or effective methods of improving dietary situations where problems are known. This has been alluded to specifically relative to obesity under portion "a" but is also needed in many other situations. For example, has school lunch improved nutritional status of the youngsters participating in the program? Are food stamps helpful in improving nutrition of people who have food stamps? Is enrichment/ fortification of cereals/flours truly effective?

Some study should be given relative to the reward system for "basic" versus "applied" research. While there is no question that further "basic" research is desperately needed, it is also true that such research is of little use as long as it stays in the ivy tower. We do need to be doing a great deal of "applied" research so that we can be confident that our programs are effective and useful to people.

It appears that the bottom line on present funding is altogether too low to insure that adequate research both basic and applied is being undertaken. A specific policy that makes study of human subjects difficult are the policies relative to the restrictions that are placed on such research for very good human reasons. However, they frequently seem to inhibit perfectly safe research on humans.

I have tried to list the nutritional gaps in our knowledge and the needs in what I consider priority order.

Nothing in your letter indicates that any comments relative to funding for training needs or education for students should be mentioned; however, I do see this as a very real need.

March 7, 1977

Doris Howes Calloway, Ph.D., Professor and Chairman
George Chang, Ph.D., Associate Professor
Janet King, Ph.D., Assistant Professor
Rosemarie Ostwald, Ph.D., Professor
Department of Nutritional Sciences
University of California, Berkeley

I circulated to the staff your inquiry concerning nutrition research programs. What follows is an amalgamation of comments from Professors Rosemarie Ostwald, Janet King, George Chang and myself (Doris H. Calloway).

Team 9 of the NAS World Food and Nutrition Study had different terms of reference from yours but identified research areas that we believe to be particularly relevant to tackling the more immediate and pressing problems of world-wide malnutrition. As I was a major architect of profiles I and II, I feel free to provide you with draft copies as submitted to the NAS. Profile I is addressed to the problem of scaling; it describes research required to define malnutrition in functional terms, that is the effects of different nutritional states (from deficiency to excess) on various biological, social, cultural and economic performances (GAO note). Profile II speaks to the question of total diets as the source of nutrients and other biologically active substances; it subsumes within it issues of food quality, carcinogenesis and the like (GAO note).

Profile I as written does not emphasize the major methodologic problems that would have to be overcome if we wished clearly to identify nutritional effects within the total spectrum of environmental (health, social, etc.) factors present in deprived and disadvantaged populations. It may not be seen to be pragmatic to do so, because it is almost impossible to achieve sustained nutritional improvement without simultaneous improvement in levels of living. However, not to do so is, in the end, unsatisfactory because it leaves us with no sound basis from which to predict or to prevent undersirable outcomes from continuous processes of societal change. Some of the functions about which we need to know have never been studied in terms of socially relevant--in contrast to solely economic--values. Thus attempts to answer the questions raised or implied in Profile I will lead inevitably to research of a more fundamental nature than is first indicated, and this is entirely proper. Knowing this, if I could have only one topic of research to sponsor, Profile I would be it.

GAO note - See p.24 for brief summaries of Profile I and II of the National Academy of Sciences World Food and Nutrition Study.

Several of our staff have commented on the need to know more precisely the human requirement for the micro-nutrients. This topic was ruled out in Profile I but should not be eliminated from an overall research program plan. We set these issues aside only because the lack of this knowledge need not hinder significantly the development of intervention schemes. We also assumed that ongoing basic research would continue to receive support. In examining the issue of requirements, early attention should be given to those age-sex groups about which least is known: pregnant and lactating women, the aged, healthy women of all ages and prepubertal children. Among the nutrients, information about the trace elements is least adequate. We are not certain that all have been identified and we do not know the most biologically active forms. The balance among the elements may prove to be critical and the range between required and toxic levels appears to be uncomfortably close. It will not be possible to take the view, as is often done with respect to the vitamins, that allowances should be made generous to cover uncertainty of our estimates as to actual need. Here again, methodologic problems are severe and research programs must deal with their development.

Another important area for study is the interaction of host and internal and external environmental factors. A chief internal environmental agent is the intestinal microflora and needs to be investigated. The gut microflora obviously play a major role in the etiology and course of diseases of the bowel itself (colon cancer, malabsorption syndromes...) but also exert systemic effects by production of physiologically and pharmacologically active compounds (amines, hydrogen sulfide, serotonin, vitamins) and by degradation of body metabolites (steroids, porphyrins).

Past research on the gut microflora has focused mainly on the enumeration of various arbitrary classes of bacteria in the intestines and stools of patients and control subjects. This research suffers from the following drawbacks:

1) It is a retrospective approach. It is impossible to determine if an altered flora is the cause or the effect of a disease or state.

2) Since so little is known about the physiology of the various classes of microbes, it is difficult to interpret the meaning of the results of enumeration experiments.

3) There is a great deal of variation in the populations of various bacteria from subject to subject and from time to time. This variation makes it difficult to interpret point-specific results.

A more meaningful approach would be the direct measurement of the metabolic activities of the gut microflora in situ or in a simulation system. This would be technically very difficult and other less direct approaches should be explored, such as measurement of the activities of the various metabolic enzymes of the gut microflora.

Diet is perhaps the most important external environmental factor affecting health and disease processes. For example, it has become increasingly evident that the food and specific nutrients which we eat have a direct, as well as an indirect, relationship to one or more of the various types of tumor and cancer growth in man and experimental animals. Common foodstuffs such as meat, oils, fat, and coffee have been reported to be active in either increasing or decreasing various cancers--especially cancer of the bowel. In addition, a number of dietary constituents (when present naturally or added inadvertently) such as flavones, sterols, certain vitamins, mycotoxins, nitrosamines, antioxidants, artificial sweeteners and dyes, and benzpyrene (in smoked foods) have been implicated in this disease, either negatively or positively.

Among the reasons for examining the relationship between diet and cancer are:

1) The diet is the major supply of chemicals for the body. It is also a potential source of carcinogenic chemicals.

2) The diet may modify the metabolism of the host, rendering it more susceptible to carcinogenesis.

3) The diet may modify the composition and metabolic activity of the gut microflora, permitting the endogenous generation of carcinogens.

4) The diet may change the profile of metabolites excreted by the microflora. These metabolites may change the susceptibility of gut cells to carcinogenesis.

The research just described is clearly directed toward recognized, well-defined problems. Underpinning this must be fundamental research on the role of nutrients in directing and regulating cell growth and differentiation. This work had to await development of instrumentation and techniques for the study of cells and subcellular components but rapid progress now should be possible. Similarly advanced approaches

are needed for the study of nutritional control of regulatory processes: How do organisms adapt to changes in nutritional inputs? What constitutes the biological memory of, for example, starvation? When these sorts of questions can be answered it may then be possible to intervene to promote or prevent adaptive/maladaptive responses.

Past nutritional history is reflected in development of the endocrine system and in brain weight and the numbers of neurons and supporting cells; we do not yet know but suspect that nutritional state may also affect the orchestration of events involved in further organization of the adult brain. Research with animals has proved that early nutritional interference with brain growth leads to diminished learning capacity and to aberrant behavior. There is strongly suggestive evidence that this is also true in man, but evidence also exists that early nutritional effects can be compensated to some extent by later environmental enrichment that includes improved nutrition.

Recent nutritional and dietary history determines the composition of the fluids surrounding the neural and endocrine tissue, and thus in major part, the signals and components needed for their integrative action. Some of the nutrients and non-nutritive substances presented from the diet are themselves pharmacologically active. Research in the neurosciences has led to the discovery of brain peptides that have diverse effects including the sensation of pleasure or well-being, and the ability to learn by punishment or negative reinforcement. We also know that contrary to earlier belief, the balance of neurotransmitter substances in the brain can be altered by diet. We do not know if this is also true of the peptides.

The implication of these findings is that both early and ongoing nutritional state might have a profound impact on such socially significant behaviors as learning, aggression and recidivism. The ultimate resolution of pathophysiological deficits that may result from nutritional deprivations, excesses and imbalances depends upon the advancement of nutritional science along a broad frontier of study.

Institutional arrangements for the support of nutrition research (and its application!) need to be strengthened. I am not sure how this can best be done but my own involvements over the years (as advisor, grantor and grantee) suggest some particular problems. A key issue, I think, is that nutrition does not have an identified home among the agencies, standing with one foot in agriculture and the other in health. Agriculture has been the backbone of nutrition research, consistently

supporting something even in the lean years and when nutrition was out of vogue. Left to the ministrations of the health sector, we would have made little progress over the years. Health, no matter what is said, looks more upon disease than upon positive states of well-being. Agriculture has been dominated by producer concerns rather than having a consumer orientation; hence, more is spent on knowing what to feed animals than people. Perhaps these attitudes reflect reality: perhaps legislators appropriate funds only if they themselves and their constituents are sufficiently frightened by the spectre of disease; perhaps agriculture responds to the power and influence of producers because that is the legislators' basis for assessment of their budgetary needs. Perhaps these views are possible because of the nature of the nutrition process--the effects of nutritional errors can take years to develop and may go unrecognized and food serves multiple purposes, most of which are non-nutritional. It is a topic that cannot be squeezed into the usual cost-benefit mold.

There is also the problem that the body most able to render advice, the National Academy of Sciences, Nutrition Research Council, has no formal ties to either the legislative or executive branches of government. Thus it has no systematic way to raise issues. There is no provision for input from people who are qualified to speak without their words being funnelled through agencies that have a vested interest in the distribution of money.

How can research best be fostered? Probably by means of training and research grants. Funds for research should be awarded as competitively within as outside the governmental establishment. Throughout my years of federal service, I never saw anything like the quality of project review that is automatic in consideration of research grant awards from the NIH and NSF. No doubt the NIH review system is costly and cumbersome, but it is the best I have encountered so far. One of my colleagues here has, however, commented that the conditions imposed by Federal granting agencies on Universities and individual researchers are becoming more and more unfavorable for the conduct of productive research. Methods for awarding research grants, their administration and accounting are so cumbersome and so at odds with the inherent capabilities and competency of scientists that an enormous amount of time and effort that could be used for the pursuit of science is wasted. Included here are the rules governing spending the money once it has been awarded, the need for hypocrisy in justifying why the project should be done (instant applicability) and the enormous amount of paper work.

A particularly undesirable feature of the research and training grants system is lack of continuity. Some projects simply cannot be expected to show orderly year-to-year progress but rather will creep along until some threshold is crossed. It is difficult to attract and hold top students when training support is indefinite and Universities cannot themselves insure against the vicissitudes of governmental allocations. The ability to pay should not be a criterion for advanced study, nor should it limit severely the set of disciplinary options open to people with creative minds and talents.

No matter how orderly one might like to make the research support process, there must also be room for some organized chaos. There must be enough latitude in the system to permit small and wildly improbable ventures. Somehow we must provide for the very real possibility that we cannot easily identify areas of high return for investment, that we may be missing the target, or even that we are aiming for the wrong target entirely.

December 29, 1976

SUMMARIES OF PROFILES I AND II FROM NATIONAL ACADEMY OF SCIENCES WORLD FOOD AND NUTRITION STUDY

Profile I - The Functional Significance of Nutritional Status

What are the effects of what levels of malnutrition (both under- and overnutrition) on the function of the individual--work performance, school performance, behavioral adaptation, fertility, lactation, resistance to infections, and so on--and the consequences of these effects for society? To decide which nutritional problems should receive priority and how resources may best be allocated among various target groups, it is essential to know the relative seriousness of different states of nutrition and the degree of benefit derived from specific increments of nutritional improvement. The purpose of the research is to define malnutrition in terms of the degree of impairment of biological, social and economic functions associated with different degrees of nutritional deficiencies.

Profile II - Ensuring the Quality, Safety, and Adequacy of Diets

What foods in what quantities and in what combinations are required to meet the needs that will be established in Profile I? Little is known about the nutritional adequacy, quality and safety of diets as consumed and opportunities for beneficial change that would result from alternative food procurement, handling and distribution practices in the household. Research in such areas will provide decision-making guidance on agricultural production issues (e.g., goals for plant breeding) incentives to and regulations of food industries, and evaluation of policies affecting the availability of particular classes of foods to target populations. It would facilitate identification of intervention points and techniques to influence food habits and thus nutritional status.

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Rather than try to identify all human nutrition knowledge gaps, I shall enumerate and explain only those that I am most familiar with. The following corresponds numerically to your questions.

1. Major human nutrition knowledge gaps

a. Relationship between nutrition and cancer prevention

Cancer incidence has been shown to have important and highly significant correlations with dietary practices. Although there has been increasing focus on this relationship in the last one to two years, most of this focus is directed at nutritional management of cancer chemotherapy strategies, identification of long-term diet composition-cancer incidence relationships, and more epidemiological and anthropological survey work. Without judging the merit and priorities of these areas, almost no effort has been addressed to the effect of nutrition on cancer prevention.

There is general agreement among researchers in the field that the greatest future progress in cancer research will be in the area of cancer prevention. It is now recognized that 80-90% of all human cancers are caused by chemicals and these chemicals, when ingested, almost always require metabolic activation by an important enzyme system called the mixed function oxidase (MFO). The MFO enzyme system is present in many cells of the body. Moreover, nutrient intakes or nutritional status can markedly affect the activity of this enzyme system. There is recent but limited information that nutritional status may alter susceptibility to these chemical carcinogens.

Within the current Diet [illegible]trition Cancer Program at NCI, there is almost no mention made of th[illegible]mportant new area. In my opinion, there may be more importan[illegible]ividends returned from such studies than all other areas of this program combined.

I do not know why there is this deficiency unless those in the heretofore separate areas of cancer research, MFO biochemistry, and nutrition were not sufficiently aware of the other areas to recognize this important overlap. Having written several reviews on this topic in the last 12-18 months, I am inclined towards this view.

b. Methodology for extrapolation of *in vitro* experimental research to clinical practice

This has long been recognized as an important task; we simply haven't come very far.

My complaint is that far too often researchers study nutrient or chemical activities at unphysiologic levels for sound experimental reasons, perhaps, but then either they or others attempt to extrapolate their data to practical situations without due regard for the accompanying caveats and limitations.

This problem needs to be addressed and understood both within and without the research community. Perhaps more research on appropriate methodologies and strategies which interrelate in vitro and in vivo data are in order.

This criticism is particularly relevant to data on the potential toxicity of various environmental chemicals. One needs to simply view the confusion attendant to the Mirex, DDT, cyclamate and saccharin-type problems to realize that a clearer understanding of in vitro *vs.* in vivo principles is badly needed. There are some new and exciting technologies just now emerging that should be studied in much greater depth, because of their potential for addressing this problem.

c. Elaboration of nutritional conditions which affect drug response

This area is quite similar to that suggested in part a, since metabolism of drugs is catalyzed by the same MFO enzyme system as that for chemical carcinogens. Moreover, drug response may be affected by one's nutrition through an effect on the MFO enzyme activity. Therefore, a large proportion of the variability in drug response may be traced to that individual's nutritional status.

This area is receiving increasing recognition - particularly by the group at the Hoffmann LaRoche Foundation - in the last one to two years. Previous to that there were scattered reports off and on for 15-20 years, but with very little attention. The first review of the subject was only written in 1975.

Still today, however, very few researchers have the required expertise to evaluate or even appreciate the significance of these findings. Worse, there is no study section at NIH which can adequately

review this type of research proposal. Nutritionists are poorly trained in the mechanisms and principles of enzyme biochemistry, as well as in the principles of pharmacology; pharmacologists have apparently had little or no training in nutrition. These inadequacies are clearly seen in the lack of competent review of research proposals, poor review of manuscripts, and research papers better left unpublished.

2. Priority rankings

I cannot justifiably rank the three research recommendations given above.

3. Federal agency efforts

I have made the above suggestions, in part, because of inadequate recognition by federal agencies of these areas. There is a program in "diet-nutrition-cancer' but it does not yet cover fundamental studies involved in nutrition and carcinogen metabolism, which is so important to cancer prevention programs.

As I mentioned above, factors which foster this problem are a) absence of a study section with appropriate focus or expertise at NIH, b) inadequate interdisciplinary training and recognition of principles of companion disciplines, and c) relative lack of critical data and technology which only now is emerging and which indicates the importance of these areas.

4. Research activity needed

This has been covered in questions 1 and 2.

5. Changes needed

I do not believe that legislative changes need be made. There are existing mechanisms available to fund these areas. I would wish to emphasize, however, that the peer review system employed by either NIH and/or NSF in their grants review process be maintained and employed for any new emphasis in these areas.

I am emphatically opposed to any new use of the research contracts approach for this kind of research. Having had rather extensive experience with both grants and contracts approaches, I am unalterably opposed to the latter for fundamental type studies such as those suggested above. They are relatively unproductive and demeaning because of the arbitrary direction dictated by individual project

officers who cannot possibly be competent enought to 'direct' such research. Research of this type must be generated collectively by the scientific community by individual, independent research groups who freely interact at workshops, conferences, seminars, etc., to exchange and defend their views.

The latter comment is also meant for most areas of basic biological research and not only for the three areas recommended. I am chagrined to see the movement away from the grants process to the contracts process of funding. No matter what guidelines are employed to insure fairness in the contract bidding process, it doesn't work; the 'buddy system' still operates. Using this system, I've won some and lost some; others do the same.

October 27, 1976

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1. Regarding the gaps in nutrition knowledge I would cite the following:

1) The role of simple sugars in contributing to coronary heart disease.
2) The mechanisms by which serun cholesterol is lowered by dietary means.
3) The role of trace minerals in human nutrition.
4) The nutritional determinants of cancer, with special emphasis on the effect of various food fibers on colon carcinoma.
5) The need for more accurate and reproducible biochemical methods for the assessment of nutritional status.
6) What biologic and psychosocial determinants affect eating behavior.
7) How both frank malnutritional and suboptimal nutritional deficiencies can be defined in Americans and how that may influence growth and development; particularly central nervous system development, learning, cognition,perception and behavior.
8) Determination of the prevalence and magnitude of various degrees of malnutrition in the United States; establishment of regional centers where such malnutrition may be both monitored and corrected.

2. Efforts of Federal agencies to fill the gaps

1) Establishment of a National Nutrition Program, perhaps as previously established at the CDC in Atlanta, or the creation of a new office in Washington.
2) Ongoing adequate funding for the Food and Nutrition Board of the National Academy of Science.
3) Establishment of a National Nutrition Library, making literature searches available.
4) Establishment of a National Nutrition Research Program, perhaps as a component of the NIH which focuses on public health nutrition research rather than concentrate on the basic science aspects only.

3. Research areas receiving insufficient funding

1) How to apply nutrition knowledge already on hand to the public via local public health agencies, medical schools, etc.

2) How nutrition can be most effectively taught from preschool levels all the way to medical schools and other graduate institutions.

3) The discovery of new, more effective, relatively simple biochemical or laboratory indices of nutritional status.

4) Development of Nutrition Training Program to more effectively support graduate students, and especially physicians who wish to make nutrition their career (establishment of fellowships, etc.).

4. Organizational and legislative changes needed to facilitate research

1) Creation of permanent Senate Nutrition Committee, as is presently active.

2) Establishment of office of the National Nutrition Program (as cited above) which will have representation in all major governmental committees related to nutrition problems, i.e., Advisory Committee of the Diet, Nutrition and Cancer Program, the NHLBI Programs related to nutrition (such as the MRFIT Program), etc.

3) Closer organizational link between Congressional, Governmental (Food and Nutrition Branch of the NAS, CDC, NIH) and professional nutrition agencies such as the American Institute of Nutrition, Food and Nutrition Committee of the AMA.

4) It is crucial that the American Branch of Nutrition be recognized as a bona fide subspecialty of medicine by the AMA. Governmental agencies should be concerned with this problem.

5) Development of a National Food and Nutrition Policy with a close liaison between the USDA and the National Nutrition Program cited above and the Senate Nutrition Committee.

6) Development of closer liaison with the food industry so that they may develop policies and products based on guidelines consistent with the National Nutrition and Food Policy.

7) The USDA should also develop national agricultural policies based more on the nutritional needs of the entire population.

January 12, 1977

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1. What issues should be identified as major human nutrition knowledge gaps.

1a. In my opinion, the two major nutritional questions still awaiting a satisfactory answer are:

A. How many calories do human beings need under a variety of conditions.

B. How much protein do human beings need under a variety of conditions.

The two questions are intimately connected and are to be answered as a pair.

As you know, Recommended Daily Allowances have been issued by the WHO and by the Food and Nutrition Board. Unfortunately, the methodology employed to arrive at such recommendations is highly questionable and has recently been challenged. [Hegsted, Mark: J. Nutr 106; 307 1976], (Costa and Young: in preparation. A preliminary manuscript is attached.) In this context, a recent article by Garza et al from MIT [AM J. Clin Nutr 28; 280-287; 1976] is of interest. The authors have studied for 59 to 77 days young, healthy subjects fed "safe" levels of egg protein [a protein of very high biological values] as recommended by the FAO/WHO 1973 guidelines. They found that at these levels of protein intake, significant potassium loss [indicating a wastage of lean body mass] occurred unless excess dietary calories [as much as 20% above the estimated requirements] were fed. It might be almost shocking to think that this is the only study in which the FAO/WHO recommendations have been tested in human beings for more than a few days.

Very little solid data is available concerning the requirement for protein and calories by patients. A flurry of letters to the Editor appearing in the 14 October issue of the New England Journal of Medicine illustrates this point [Protein Sparing Therapy N. England Journal of Medicine 295 [16]; 903-905; 1976].

The fundamental importance of the problem is made particularly cogent by considerations of the worldwide availability of food in general and protein in particular.

1b. Another problem of primary importance is to determine accurately, food consumption by the average american.

A number of surveys have been conducted. Most of them focus on underpriviledged americans. How much the average american - the one who develops Diabetes, Heart Disease, and Cancer - eats is not known. Methodology in this field is still rudimentary and should be refined. Another survey is being planned by USDA. It might or might not answer this question.

2. I would rate 1a ahead of 1b because of its worldwide implications. Both questions (how much humans need and how much they eat) are fundamental.

3. My knowledge of nutrition research support by the Federal Government is not deep. Some areas are being supported through NHLI, some through NCI, some through USDA, and a minimal amount through NSF. With particular emphasis on question 1a and 1b, I believe that Federal support has not been adequate because the questions are too general to fall into the specific scope of any one of the existing agencies which are aimed primarily to targets other than nutrition per se.

4. I believe that we need an agency or an additional NIH institute who deals primarily with nutritional problems, and not with the nutritional aspects of other biological questions.

5. Nutrition Research support is fragmented between a number of institutes and agencies who do not have nutrition as their main objective of study.

1 November 1976

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This is in response to your letter of October 14 in which you asked that I discuss four particular points with respect to nutrition and human needs.

As a general statement let me enclose a copy of report No. 57 of the Council for Agricultural Science and Technology which was prepared to answer at least part of the questions which you proposed.

We still do not know with any great accuracy the effect which many disease conditions exert upon the requirements for the various nutrients known to be needed by the human. I anticipate that in the years immediately ahead the greatest need for research will be in the area of interactions of various nutrients whether mineral elements, vitamins or amino acids. There is also a great lack of information about the effect of long term marginal deficits of our required nutrients. For example, it has been estimated that 75 to 80% of our population over 60 years of age suffer from periodontal disease. It seems likely that this is the result of a complex, perhaps very slight, distortion of dietary intake over a very considerable number of years.

The various government agencies concerned with nutrition have been unable to mount long term studies because of the vagaries of funding. The pressures which are put on these agencies for practical returns within a matter of a few years have prevented the development of studies which may be very critical to the long term health of our population.

The areas of research which require additional attention and funding are listed in the CAST report and also in that report you will find some implied changes in organization although it is a policy of the CAST organization to avoid any appearance of dictating what should be done. One of the major problems facing nutrition in this country is the very diversity of governmental agencies which have some responsibility. There is therefore a need for coordination at the level of the President's Cabinet which would have reasonable authority to insist on a limitation of duplication or at least coordination and joint projects. Furthermore this coordination should extend to the agencies whose activities impinge upon good nutrition for our people. This of course includes such widely divergent

activities as those of the Federal Trade Commission, the Food and Drug Administration, the U.S. Department of Agriculture, the Department of Commerce, the Environmental Protection Agency, and the Department of Defense to mention some whose activities in the past have had a major impact upon the supply of food and its quality as received by the consumer or general public.

November 4, 1976

"Significant Issues in Nutrition"
(Report No. 57 of the Council for Agricultural Science and Technology, July 19, 1976)

SUMMARY

In meeting the objectives of health, avoidance of disease, and maintenance of a satisfying quality of life for U.S. citizens, the following nutrition-related issues are considered to have high priority for the nation:

1. Nutrition and health. The health and well-being of the population are partly a function of nutritional status of the people. Of special importance in this regard are: (a) Degenerative and related diseases, cancer, and diabetes. (b) Dietary deficiencies including protein-calorie malnutrition, vitamins, and trace elements. The role of fiber needs clarification. (c) Special needs of specific population groups including infants, teen-agers, and pregnant women. (d) Subtle effects of inadequate nutrition such as infant mortality, impact on adaptive behavior of school children, and impaired productivity and work-time loss of adults. To provide a sound basis for programs to alleviate these problems, however, will require a more precise understanding than we now have of the real contribution of nutrition to each of the issues mentioned.

2. Food Safety. Matters of greatest importance in this area are thought to be: (a) Coordination of government actions affecting health-related aspects of food production and nutrition. (b) A critical examination of concepts such as zero-tolerance relative to regulation of food safety. (c) Risk/benefit interest. (d) Continuing evaluation of food quality and safety. (e) Development of methods for rapid determination of long-term safety of food additives and food components.

3. Nutrition Education. Since freedom of choice in the selection of foods is a part of our way of life, nutrition education is a high-priority issue because the public must be provided the information that will encourage good nutrition practices and will combat the spread of misinformation.

4. Food Enrichment. Food enrichment programs can solve specific nutritional problems because they build upon food preferences already in existence. Food enrichment programs are of high priority in solving short-term problems because they can be implemented relatively quickly and easily. They complement educational programs that are long-term solutions to nutrition problems.

5. Assistance programs. Coordination of the food-stamp program with other food and non-food transfer programs that have been developed to alleviate malnutrition in vulnerable and low-income groups is deserving of high priority apart from any impact on personal economic status.

6. Nutrition monitoring. Continuous monitoring of food consumption, dietary patterns, and the nutritional status of all segments of the population is a priority matter because the data thus obtained are essential in establishing appropriate criteria for programs of nutrition for health, food safety, nutrition, education, and food enrichment.

7. Further Research. A sound research program is implicit in several of the previous items. In addition, research on the aspects of nutrition related to food safety assurance, education, food enrichment, and assistance programs deserves early priority because the results are needed to implement the programs.

INTRODUCTION

To define the national nutritional issues of greatest significance requires first a decision on the goals of our national nutrition policy. If our objectives are adequacy of the quantity, quality, and variety of foods for health, avoidance of disease, and maintenance of a satisfying quality of life for U.S. citizens, certain nutritional issues deserving of high priority may then be identified. In this report, seven broad nutrition issues or classes of issues are identified as being of primary significance for the United States.

NUTRITION AND HEALTH

The health and well-being of the population are integrally related to nutrition. The following four areas are considered of greatest importance for policy attention:

1. Long-term effects of diet on degenerative and related diseases. Cardiovascular disease, cancer, diabetes, dental caries, obesity, and diseases of the gastro-intestinal tract are examples of diet-related disorders.

2. Dietary deficiencies. These include protein-calorie malnutrition and deficiencies of vitamins and trace elements. The role of fiber needs clarification.

3. Special needs of specific population groups. Population groups of particular concern are infants, teen-agers, and pregnant women, especially teen-age girls.

4. Subtle effects. Effects of malnutrition that are more subtle but nevertheless significant include infant mortality, impact on adaptive behavior of school children, and impaired productivity and work-time loss of adults.

To provide the sound background needed to develop appropriate food and nutrition policies leading to action programs, however, will require research to define the current status of these questions more clearly than is possible with existing information.

FOOD SAFETY

Coordination of government actions affecting health-related aspects of food production and nutrition deserves top priority. The current dispersion of authority among several government agencies can lead to contradiction and confusion.

A critical examination of concepts relevant to regulation of food safety is in order. Deserving of particular attention are zero tolerance, "no-effect" levels, response to different levels of intake of food components, and use of a dual standard for naturally occurring substances and for additives that have, or are suspected to have, deleterious effects.

Risk/benefit evaluations of safety regulations as standard practice would provide a sound basis for decisions in the public interest.

Continuing examination of food delivery practices is to be encouraged since the practices affect the maintenance of certain essential nutrients in foods and are therefore a part of food safety.

Deserving of priority is a continuing evaluation of the quality and safety of food supplies accompanied by dissemination of the information to the public with reference data from the past for comparison.

Research is needed on rapid methods to determine the long-term safety of food components and food additives.

NUTRITION EDUCATION

The ultimate value of food is realized only when it is consumed. Nutrition education is thus of high priority because the public must be provided the information that will promote the interest in nutrition required to encourage good nutrition practices. Such education

would combat the spread of misinformation. Integration of sound nutrition practices into health-delivery systems will require continuing education of health professionals, including trained nutritionists, and a general concern for preventive medicine as a part of U.S. health programs.

In a concerted effort, health professionals, physicians, dentists, nurses, physical therapists, and others should be provided with extensive nutrition education as part of their professional education. Educators of all categories should receive training in nutrition, and nutrition should be included as an explicit curriculum item in primary and secondary schools. This intensive approach would ensure that most members of the public would in time become moderately well informed on the elements of good nutrition. Basic research on factors stimulating personal motivation to make good use of nutrition knowledge will be a continuing need.

FOOD ENRICHMENT

Established food habits are not readily changed in a short time even with education. Hence, education is a long-term approach to good nutrition practices.

To improve the nutrition of the public on a short-term basis, while providing for a variety of personal choices, food-enrichment programs merit high priority. Where nutrient deficits are identified, special effort could be made to eliminate the deficiencies. Health problems including rickets, goiter, and pellagra have already been solved in this manner.

ASSISTANCE PROGRAMS

Poor diets are found at all economic levels. Those occurring among persons at high economic levels may be improved through education and enrichment programs. Poor diets occurring among persons at low economic levels may be improved in these same ways; but, in addition, food assistance programs are needed to provide the opportunity for purchase of nutritionally adequate diets.

The nutritional needs of low-income groups are of high priority. The food-stamp program aimed at this group is of great potential benefit to the nutrition of recipients because it enables broad segments of the low income population to purchase adequate diets if they choose to do so. Several other programs have been developed to alleviate malnutrition in vulnerable and low-income groups. The coordination and integration of these additional programs deserves high priority to limit overlapping of benefits and to ensure the most equitable allocation of national resources. Determination of the actual nutritional impact of these programs is considered an essential component of the programs.

NUTRITION MONITORING

Continuous monitoring of food consumption, dietary patterns, and the nutritional status of all segments of the population is a priority matter. The data obtained in such monitoring activities are essential for justifying the need for food assistance programs; for establishing appropriate criteria for programs of nutrition for health, food safety, nutrition education, and food enrichment; for tailoring the benefits; and for measuring the effectiveness of the programs. Improved monitoring techniques and models are to be desired as well as central coordination to provide for transfer of the knowledge gained to legislators, program administrators, and directors of educational programs.

Basic to the interpretation of the findings are the standards on which the judgments of the adequacy or inadequacy of the nutrition are based. Research is required to develop these standards.

FURTHER RESEARCH

In addition to the special areas requiring research which have been mentioned in previous sections, research on the aspects of nutrition related to food safety assurance, education, food enrichment, and assistance programs deserves early priority because the results are needed to implement the programs. Further recognition is needed for fundamental research in evaluation and development of methods, nutrition education, standards for nutritional assessment, and techniques for motivation stimulation.

A number of the National Institutes of Health and other DHEW components as well as the USDA and DOD support nutrition research. Coordination of these programs at a high level in the Executive branch of the government is deserving of high priority.

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This is in response to your letter requesting information on nutrition and human needs re Senator George McGovern's concern for Federal activity in this area. It took us some time to collect our thoughts on the five difficult questions cited on page 2 of the letter. The following, however, is an attempt to respond to them in the same order they were posed:

1. Major human nutrition knowledge gaps in a decreased order of priority are:

   a. Updating our knowledge on nutritional deficiences based on comprehensive epidemiological data and documented with modern biochemical markers.

   b. Need for scientifically documented enrichment guidelines to ensure rational nutrient profile for selected classes of products such as:

      1. Cereals
      2. Meat analogs
      3. Formulated foods and beverages, etc.

   c. Nutrition and health related problems, e.g.

      1. Overweight and obesity
      2. Degenerative bone and joint disorders
      3. Diabetes
      4. Dental health
      5. Cardiovascular
      6. Renal
      7. Congenital malformation and infant mortality

   d. Clinical nutrition

      1. postoperative nutritional requirement
      2. nutritional requirement in severely catabolic diseases (cancer) or condition (burn or multiple fracture patients)
      3. nutritional requirements for premature and light-for-date infants (ICN babies)

e. Nutritional requirement under prolonged physical and mental stress.

f. Food allergy in pediatrics and prophylactic means of dealing with it.

g. Drug interactions and nutritional requirements (immuno-suppressives, broad spectrum antibiotics, etc.)

2. The order of priority in dealing with various human nutrition issues follows the same order presented under #1.

<u>REASONS</u>:

a. Modern research in nutrition is far more sophisticated nowadays than when classical syndromes of deficiencies were reported in the literature for various nutrients. The ability to recognize "SUBCLINICAL" symptoms of deficiency with modern techniques and biochemical markers will be of great value in preventing "CLASSICAL" symptoms from showing in the population. The need to update our knowledge in this vital area is seriously lacking.

b. The enrichment guidelines come second to ensure proper and well balanced profile of nutrients in processed foods.

c. The relation between nutrition and certain diseases needs to be examined closely to ensure proper prophylactic application of modern nutritional knowledge and in the management of the disease categories listed above.

d. Serious gap exists in our knowledge of the requirement of postoperative and ICN babies. Proper nutrition can shorten the period of stay in the hospital and reduce the soaring cost of hospitalization.

e. Stress (physical and mental) was described as the major disease of modern societies. Changes in the body biochemistry and physiology under stress is a well recognized medical fact. Chronic exposure to stress may result in a significant change in nutritional requirements that need to be closely examined and evaluated.

f. There is some evidence that the human body in a modern industrialized society is exposed to an increasing number of environmental insults that trigger the immune system to react to neutralize their effects. A better understanding of the nature and extent of this problem, as well as knowledge of how the food we eat might relate to the problem, is badly needed.

g. Modern drugs that shut off normal metabolic or biochemical pathways (immunosuppressives) or destroy the symbiotic relation that exists between the body and intestinal flora may have a profound effect on the nutritional requirement.

3 & 4 Federal agencies must recognize the prophylactic value of nutrition in eliminating serious environmental and health problems of modern societies. The transformation that nutrition research went through during the past twenty years emphasizes the fact that nutritional tables should no longer present the average requirements of the population, but rather be far more specific with regard to age, sex, health condition, occupation, etc. We believe that more aggressive federal support to research institutions in these two areas is needed in order to stimulate original research and proper application.

5. Failure to recognize the important role of building proper human nutritional knowledge in improving the quality of life in modern societies may result in placing it at a low priority to compete for federal funding. It should be emphasized at this point that a long range program to fill out the gaps in our human nutrition knowledge will be both expensive and time consuming. However, a task team of scientists in nutrition and other related areas of research should be formed to size up the program and give its recommendation on the planning and organization on the way to fill out the gaps in knowledge of nutritional knowledge of modern man.

January 6, 1977

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In responding to your request for suggestions as to priorities in nutrition research, I will attempt to identify what I think are some general problems pertaining to the current food supply and some specific areas in which new information is needed.

It is worthwhile to consider the nutritional problems of the United States and other industrialized countries in two categories: those of overnutrition and those of undernutrition. Overall, the former (with their correlates of obesity, heart disease, hypertension, diabetes, etc.) are of greater significance to public health than the latter and they are less susceptible to a solution. While they can, to some extent, be modified by specific changes in food composition (such as an increase in the proportion of polyunsaturated fatty acids) the basic problem is one of adaptation to the lifestyle of affluent populations. Successful adaptation will require not only a modification of eating habits to accomodate reduced caloric needs, but at least a partial reversal of the trend toward a more and more sedentary existence. It is now apparent that physical inactivity has a degenerative effect on heart and skeletal muscle, bone and probably other tissues which cannot be offset simply by reducing food intake to forestall obesity. As technology reduces the need for manpower and creates more leisure time, this problem will become correspondingly more serious.

Despite the current abundance of food there is in our society pervasive undernutrition with respect to certain vitamins and minerals. In considering possible solutions to this problem, it is instructive to consider how it came about. From what I have been able to learn about the nutrition of various aboriginal populations, it seems to me that it is only in recent times that human societies have experienced undernutrition in the presence of adequate food. This means that the average quality of the food supply has declined. This has happened not because there is any paucity of nutritious items in our food chain (in fact, there is a greater number than ever before) but because there is an unprecedented proportion of low quality foods. The deteriorative effect of substituting low quality processed foods for native foods is clearly evident, for example, in the declining nutritional status of Alaskan Eskimos Erosion of the three-meals-a-day eating pattern characteristic of an agricultural society has accentuated the problem of low quality foods in the food supply, since foods eaten at other times are generally below the quality of foods eaten at regular meal times. I don't think it is of any use to resist the trend toward snacking, but it is essential to respond

to it by making sure that snack foods are capable of providing adequate nutrition. There is no technological reason why such foods cannot be improved in nutritional quality. While I am not opposed to programs of nutrition education, I doubt that any substantial progress in eliminating nutritional deficiences in the population can be made without setting higher standards for convenience foods.

The main requirement in this context is for formulation and enforcement of stricter legislature regarding the nutritional quality of processed foods. There may be reluctance to do this, but I see no satisfactory alternative. For some reason food quality is seen as a less important environmental problem than air quality or water quality.

There is increasing evidence of the importance of adequate nutrition during uterine growth and early childhood in the physical and mental health of adults. I refer to such aspects as immunocompetence, brain development and obesity. There is also an increasing awareness of previously unsuspected trace mineral deficiencies in the population (copper, zinc, possibly magnesium and chromium) which deserve a strong research effort, especially as they apply to children. Some of these problems suggest a metabolic disorder rather than a simple dietary deficiency, but in either event it is important to determine how many people are at risk and how they can be identified.

Nutrition of the aged and the chronically ill is in need of additional investigation. These groups commonly have either a poor appetite or eating habits that lead to chronic deficiencies of certain nutrients. Recent revelations concerning the poor nutritional status of many hospital patients indicate that too little attention has been given to the secondary effects of illness on nutritional health. The effect of cancer on nutritional status is an example. Also, the role of nutrition in the etiology of diseases of aging, including cancer and osteoporosis, needs further elucidation.

The United States has long been pre-eminent in basic research in nutrition and support of meritorious research projects should be given a high priority. Basic discoveries in nutrition are rapidly translated into health benefits. Recent developments with respect to vitamin D and various trace elements show that there are still important basic principles to be discovered.

November 15, 1976

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It seems important to emphasize at the outset that although my own research is highly focused on human subjects, I do not believe that all important questions in human nutrition can be best answered by studies of humans. Study of animal models and certain in vitro studies are not only useful but essential and I hope that planning for closing the gaps in human nutrition knowledge will not focus exclusively on clinical investigation.

I shall restrict my comments to gaps in nutrition knowledge in the area with which I am most familiar--pediatrics. Three topics seem important to mention: (1) nutrient requirements of low-birth-weight infants, (2) later consequences of nutritional management during infancy and childhood, (3) short-term consequences of changes in the American diet that might be of long-term benefit in prevention of atherosclerosis.

Nutrient Requirements of Low-Birth-Weight Infants

In recent years an increasing number of infants of very low birth weight (less than 1500 g) have survived the immediate neonatal period. These infants present great problems in nutritional management. Excessive intakes of essential nutrients may be as hazardous as inadequate intakes. The need for establishing the requirements is therefore obvious. The magnitude of the problem from a public health point of view is greater by far than that presented by all inborn errors combined. Yet, the effort in nutritional study is far less in the premature area.

Later Consequences of Nutritional Management During Infancy and Childhood

Although the evidence is not strong, bits of information suggest that nutritional management during early infancy may influence health in the adult. Does overfeeding during infancy or early childhood increase the risk of obesity in the adult? Does intake of cholesterol and saturated fatty acids during infancy and/or childhood influence the development of atherosclerosis in the adult? Does intake of sodium chloride during infancy and childhood influence the development of hypertension in the adult?

If we are to combat the problems of obesity, atherosclerosis and hypertension in the adult, we need to know whether preventive

measures should be emphasized in early adult life or later, or whether they need to be initiated during infancy or childhood.

Short-term Consequences of Possible Changes in the American Diet

At some future time it may be decided that a change in the American diet should be broadly promoted with decreased intake of cholesterol, saturated fats and foods of animal origin and increased intake of vegetable products. Such a change would almost surely result in a decreased intake of protein and, possibly, a decreased intake of various vitamins and minerals. The short-term (1 to 2 year) nutritional consequences of such dietary modification have not been well studied even in adults, and there has been almost no study of children - probably the most vulnerable age group.

November 2, 1976

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In addressing myself to the questions you pose I would like to start off by trying to define the issues then I will make some specific suggestions.

Definition of the Issues

There appears to be two worlds of nutrition, one is that of the professional nutritionists, outlined in nutrition texts and in official pamphlets extolling the four basic food groups. The other is the world of nutrition as it is practiced - the food people actually eat. Text books of nutrition show photographs of fresh produce, red meat, they talk of protein balance and carbohydrate intake. That is not the real world of nutrition. The majority of food eaten in the United States comes in cans and boxes, over 75 percent of it factory processed. Fresh fruit and vegatables account for only 5.9 percent of the daily calorie intake and that percentage is sinking. A great gap has opened between the theoretical problems with which text book nutrition concerns itself and the real nutritional problems the average American family faces.

The science of nutrition has essentially stagnated since the early 1950's when the last vitamin to be discovered was announced. To be sure, nutrition science continues to publish research, mostly on the nuances of animal nutrition. What lacks are new ideas, new departures. The technology of nutrition, on the other hand, has not lagged. It is moving rapidly and skilfully towards its announced goals of feeding the American public a complete diet of fabricated food. The science of nutrition which should be examining the effects of this new style of nourishment is outmatched. It is decades behind on developing the necessary techniques and conceptual approaches to examine this new technology and, moreover, has little hope of catching up.

Why should the technology of nourishment be moving so rapidly? Food processing has been around for generations. Up until the time of World War II, factory processing of food used the same techniques used in home cooking, only on a grander scale. After World War II, the industry embraced chemical technology which sparked development of an entirely new concept of human nourishment. The new concept is that nourishment can be fabricated out of a few basic raw materials to produce an endless cornucopia of edibles. This concept may work for production of motor cars but not necessarily for the intimate biological process of human nourishment. A variety of genuine foods seems to be required for optimum nourishment. Not only has chemical

technology reduced the biological base of nourishment of the average American, it has taken the natural foods used as raw materials and restructured their very molecular architecture.

No awareness of the sophisticated chemical production of food appears on the pages of nutrition texts. The texts discuss protein, fats, carbohydrates, as if chemical processing of foods did not exist or if it does, its effect on nutritional quality is negligible. This assumption is made without carrying out any experiments.

In 1946, Oxford University was offered a large sum of money to found an institute of human nutrition. The Board of Governor turned it down because they felt that within 10 years all problems in human nutrition would be solved. In 1976, reflective biological scientists realize that we know practically nothing of human nutrition except in the most general terms. This ignorance was not so critical at the practical level in the past because people still ate most of their food in natural forms. At least, if scientists didn't know what was good for you, nature did. This ignorance formerly benign begins to menace because it permits the technology of nourishment to race ahead unscrutinized. We just do not know what will be the effects of an entire population deriving most of its calories from chemically fabricated food.

The generation grown up since World War II is the first fabricated food generation. They are not being poisoned (at least acutely) and they seem reasonably robust, or are they? You experience nourishment over a lifetime, what happens in one part of life can affect the rest. Dentists tell us there is a certain period during early life when tooth enamel is laid down. If nutrition is inadequate during that period, no matter how superb the nutrition, the rest of one's life the tooth remains weakened. How many other human development processes are similarly vulnerable? Nourishment lasts more than one lifetime. Experiments with animals show that the nutritional sins of parents are visited on the next and the next generation. If the food technologists have made a serious miscalculation, and in my view they have, what is in store for future generations of Americans?

Major Knowledge Gaps

The major problem is understanding the effects of food as it is actually eaten. This problem subdivides into two parts.

a) Effects of chemical additives: ice cream, according to a release from the FDA contains over 1500 chemical additives. The GRAS system provides for evaluation of chemical additives, one at a time. Much argument ensues over whether a particular additive is dangerous or not. But that argument concerns only laboratory rats who eat a nutritious diet laced with only the one chemical. The body of the person eating

ice cream and other fabricated foods is faced with the herculean task of coping with some 3500 different chemicals every day. That is reality. What are the effects of the chemical combinations? No one knows and there is no point hiring more toxicologists to find out because they do not know how to study such a problem.

b) Nutritional deficiency: Fabricated food looses much in the course of manufacture. Because we don't know all what it is in natural food that makes it nourishing, there is no way you can consciously restore lost nutrition to the food products. Vitamin fortification is not the answer.

Parts A and B compound each other. We don't know how the chemical additives intervene in normal nutritional processes. But we do know that inadequate nutrition can potentiate the toxicity of chemicals.

Types of research activity needed

To understand the effects of eating modern food requires both nutritional and toxicological studies. Neither science, at their present stage of evolution, is capable of addressing the problem. For this reason offering resources to the existing sciences may not produce the desired results. What is needed is a whole new scientific approach to these problems. How to create the new science will not be easy because it depends on ideas and ideas cannot be bought with money. However, there is an avenue that I might suggest.

In the early 1950's the science of biology and biochemistry were completely revitalized by the infusion of large numbers of experts from other areas, engineers, physicists, mathematicians. The vigorous meld of ideas created the field of molecular biology. Of course, there were some good basic ideas to begin with, but the lesson of this experience is that somehow the sciences of nutrition and food safety have to be opened up and open-minded experts from other disciplines attracted to work in the area. They will not be attracted if the problems in human nutrition continue to be defined in the style of the 1950's.

To illustrate, allow me to give an example. The RDA's have become the foundation of the current approach to defining human nutrition. The exact values are contested and all experts in the area agree more research is necessary in order to put the RDA's on a firmer scientific footing. That is the wrong goal. If you look at nourishment as a total life experience, the concept of the RDA's has no meaning. The assumptions on which the RDA's are based dissolve away. What is needed in place of the RDA's is a new concept of total nourishment that takes into account the actual practice of nutrition.

Human nourishment is a mix of science, practice, cultural values and social experience. A new concept of nourishment should integrate all these areas of human expression. One of the defects of the science of nutrition is that it has isolated itself from the reality of the other areas.

Agriculture

I have not mentioned agriculture yet, we cannot discuss human nourishment without considering where it all begins - in the soil. A number of the issues I have touched on start on the farm. In fact one of the failings of the classic science of nutrition is to isolate itself from how crops are produced and farm animals raised. Any new concept of nourishment must integrate agriculture practice into the concept. At the practical level American agriculture has geared itself to produce the raw materials for the fabricated food industry, which means limiting itself to producing a few basic food stuffs. The decisions to switch to this style of agriculture were taken without considering any nutritional effects. The USDA has been notably remiss in taking any leadership in improving the quality of nourishment. They seem to believe that producing more satisfies nourishment.

Legislation and Policies

Nutrition science and food safety are two underdeveloped areas. The priorities of the scientific community lie elsewhere. I suppose everyone would acknowledge that sound nutrition is essential for good health. In practice this truism is ignored. The National Institutes of Health have a budget for research of the order of two billion per annum. A large percentage of that budget supports basic biological research and the study of the effects of poor nutrition - degenerative disease. Very little of that budget supports basic research in nutrition and toxicology and the research supported is the dull classical type. The decision makers of the National Institutes of Health are scientists who do not consider these two sciences interesting and important, and they seem totally unaware of what people eat and the potential effects of eating a fabricated diet.

One cannot legislate ideas, but one can legislate the intellectual environment for fresh approaches. I would suggest setting up interdisciplinary groups (not too large) about the country to study these problems. The fewer classical nutritionists and toxicologists in these groups the more innovative and effective they will be. Bring in young people of varied backgrounds, including the social sciences and the humanities.

Summary and Conclusion

I have deliberately avoided suggesting specific problems in this discussion because I am pleading for a new intellectual approach and

from this new approach will come new problem definitions. It would be easy for me to suggest more research on the RDA's or on new protein sources but perhaps when we study the issues in more depth these particular issues will turn out to be non-problems. This represents a longer term but necessary approach. More immediately, I can suggest six nutritional issues that are not now receiving any attention but on the basis of my own studies are critical to the health and well-being of the public.

1) The health effects of eating fabricated food over a lifetime.

2) The effect of drugs fed to meat animals, on their physiology and biochemistry as it affects the ultimate eater.

3) The ultimate effects on humans of excessive plant and animal in-breeding.

4) The health effects of reducing the varieties of food crop, i.e. Sixty varieties of apples were once freely available now only a few remain on the market.

5) The effects on health of consuming combinations of chemicals.

6) The effects of intensive mono culture on the quality of nourishment.

These six areas represent a study of the technology of nutrition as presently practiced. The goal would be to modulate these activities so that they could become compatible with principles of sound nourishment. Finally, I would recommend that an equal amount of resources go to support search for a new style of nourishment compatible with the basic laws of ecology and human biology. This would probably mean a revolution in the style of agriculture, food processing and distribution.

October 21, 1976

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In my view, the basic problem in human nutrition research and education is not one of identifying gaps in our knowledge and providing funds for research on these. The problem is much deeper and more serious than that: 1) there is a scarcity of "centers of excellence" in nutrition; 2) there are too few qualified investigators doing research in human nutrition; 3) support for accumulating nutrition information that is needed but the collection of which presents no challenge to competent investigators is inadequate; 4) nutrition is not clearly identified as a profession distinct from dietetics and medicine; 5) the efforts of the limited number of people in the field are diverted by the wide variety of demands made upon them by a large number of organizations; 6) there has been a failure to recognize nutrition as a discipline distinct from biochemistry, medicine, food science, dietetics and various others; 7) there has been a failure to distinguish between nutrition as a branch of basic biological science and nutrition as a branch of medicine--the practice of nutrition; 8) medical schools have failed to recognize nutrition as an important health science; 9) at the Federal level nutrition programs are not clearly distinguished from income support programs; 10) no procedures have been established for coordination of nutrition activities in various Federal agencies. Overall, this probably can be summed up by saying that there has been no national policy on nutrition.

As you will note, nearly all of these problems have to do with Item 5 on page 2 of your letter of October 14. I shall include below comments on items 1 to 4 but feel that such comments are very much secondary to those relating to organization and basic support.

5. PROBLEMS RELATING TO ORGANIZATION AND FEDERAL SUPPORT

A. The major need, as I see it, is for development grants for nutrition departments. During the early 1950's there were relatively few first-rate biochemistry departments in the U.S. Beginning in the late 1950's the biological sciences related to health received massive support from NIH in the form of research grants, training grants, career development grants and construction grants. As a result, during the 1960's the number of excellent biological science departments that had first-rate research programs increased substantially. Nutrition benefited from the research grant program, with many competent investigators obtaining support. However, much of the support for nutrition research went to those who were not primarily in nutrition but who were working on nutritional

subjects in medical research units and biological science departments and who were working, in large measure, on biochemical problems. Training grants were few and limited, as were career development awards. Little investment was made in construction of facilities for nutrition departments.

This situation was not specifically the fault of federal programs nor of those who administered them. Nutrition was, and still is, a fragmented discipline. It was dispersed among biological science departments, nutrition units in the animal sciences in agricultural colleges, in schools of home economics, in schools of public health, in a variety of medical departments and in some food science departments. It was, therefore, difficult both for outside agencies to identify cohesive nutrition units and for universities to consolidate nutrition programs. Among the difficulties were that many biological scientists who were working on nutritional problems did not identify with those working on practical aspects of human nutrition; that nutrition, as such, was not part of many medical programs and what nutrition was included was identified as pediatrics, hematology, gastroenterology or endocrinology; that those in nutrition in schools of home economics were often completely isolated from both medical and biological research groups.

It has now become evident that comprehensive nutrition programs cannot be fitted into narrow disciplinary departments. A program in human nutrition is rarely compatible with the interest and objectives of a biochemistry department oriented toward molecular biology and enzymology. A nutrition education program does not fit with the interests and objectives of a biological science department. Human nutrition is fragmented among medical departments and can rarely be identified as such. There is conflict when food science and nutrition are combined, for the objectives of food science programs are largely producer-oriented whereas those of nutrition are largely consumer-oriented. As a result, development of integrated nutrition programs has been slow and success has been limited. However, over the past 15 years, primarily during the past 10 years, efforts have been made in many universities to consolidate nutrition programs, so that the variety of types of nutrition interests can be consolidated in a single comprehensive program. Unfortunately, this occurred just when federal funding was undergoing retrenchment.

For these reasons I am convinced that <u>the most effective way to stimulate nutrition research and education is through a program of development grants for universities that are willing to consolidate comprehensive nutrition programs in unified, integrated departments</u>. It is essential, in my view, that such departments have a strong component of basic biological research, a component concerned

with human and clinical nutrition, and a component concerned with education and public service and, if possible, an international program linked with the latter two. Such organizations can provide a focus for the entire range of nutrition activities. Basic biological underpinning is essential for all of the other activities of such a department and the other activities are essential in order to prevent those in the biological science of nutrition from losing touch with practical nutrition problems.

Development grants, as I see them, would include support for faculty development, program development and facility development Awarding of them would depend upon evidence that nutrition activities would be consolidated in an effective and meaningful way. Priority would be given to programs that included a clinical unit attached to a medical school. My experience so far indicates that there is little interest in medical schools in development of nutrition units, although some pediatric departments do have effective nutrition groups. The potential for establishing nutrition in medical schools through programs in departments of preventive medicine may be greater than in the more classical medical departments but evidence for this is lacking.

B. Training grants and career development awards would be my second priority. There is a dearth of highly qualified people in human nutrition and there are few centers where adequate programs in human nutrition are available. I would not limit the training support to human nutrition but would make it an important emphasis. If applied nutrition programs as components of health care and welfare programs expand, as it seems they will, it will be difficult to find enough well-qualified people to fill the positions that will open up. It will be difficult even to provide educational opportunities on a large enough scale.

C. Organizational problems at the Federal level also represent an obstacle to the development of nutrition research and education. These are of several types. At the outset there is a need for a greater degree of coordination in Federal nutrition activities. There is a need to distinguish between food problems and nutrition problems although the two are linked. There is a need to establish clearly that nutrition is a profession distinct from dietetics and from medicine. There is a need for clear identification of nutrition as a component of preventive medicine.

The National Institutes of Health (NIH) have been the major source of grant support for nutrition research. The NIH is a disease-oriented organization but has served as a funding agency for basic biological research. The Department of Agriculture (USDA) has been the major center for human nutrition research but, as the USDA is largely product and production oriented, human nutrition research there has had only limited support compared to

disease-oriented research in NIH. With the exceptions of the 10-State Survey and more recently the health surveys of the Bureau of Health Statistics, USDA has been the main agency concerned with collection of information on nutritional status. USDA has also had responsibility for nutrition education programs and public health programs in nutrition. USDA has not had a research grant program but has depended largely upon rather rigid contracts to provide extramural research support. As USDA is the only Federal agency concerned primarily with nutritional status unrelated to disease entities, a research grant program in nutrition through USDA would be a major contribution to nutrition research generally.

D. Many of the gaps in nutrition research can be filled only by the accumulation of information of a type that does not attract the attention of faculty members in universities because it is routine, offers limited challenge, produces publishable results only slowly and is not in the mainstream of biological or medical research. Some of the USDA regional laboratories have active programs on some of these subjects, such as methods for estimating the availability of nutrients in foods. These are comparable to programs of the NIH for investigating the carcinogenicity of chemical compounds which are often done through commercial contracts. Assessment of nutritional status falls into this category as does assessment of nutrient intake and much of the investigation and reinvestigation of human nutrient requirements.

The USDA Division of Human Nutrition has a grasp of the significance of these problems which is not evident in the program projections of NIH. The Human Nutrition Laboratory in Fargo, North Dakota and some of the Regional Laboratories are investigating several such problems. How best to expand research on such subjects is difficult to decide. A proposal has been made by Senator McGovern for an Institute of Preventive Medicine. In my view, such an institute would be overwhelmed in the disease-oriented NIH. It would probably be inappropriate to assign it to the USDA. Much as I hesitate to suggest yet another unit involved with nutrtion programs, it seems to me that a new and novel unit that would incorporate many of the activities of the USDA Division of Human Nutrition and those of the National Institute of Child Health and Human Development is required so that responsibility for public health nutrition programs and programs in preventive medicine could be separated from those concerned with food production and those concerned with the cure of diseases. This might be a center for nutrition and preventive medicine that consolidated programs of both HEW and USDA in this area, including the USDA extension and education programs in nutrition. It might be of value to look at the Army Nutrition Laboratory in San Francisco as a small scale model for this.

To stimulate the collection of information on food composition, on the biological availability of nutrients and on nutritional status, the USDA or such another unit should establish, in academic institutions where there are both nutrition departments and medical schools, analytical laboratories for food, blood, urine and tissue analysis for nutrients with research programs on methods for the analysis of nutrients and metabolities of nutrients. Such laboratories are essential for much basic nutrition research. Rarely can hospital clinical laboratories provide the services needed for analyses for nutrients.

E. Another need for the development of nutrition is the establishment within the civil service of classifications for nutrition scientists and nutritionists of other types independent of the classifications for dietitians, physicians and biochemists. This is essential for the development of professional recognition and such positions with appropriate qualifications should be identified when Federal nutrition programs are instituted.

F. For extramural research support, I am convinced that there is no model as sound as that of the NIH. The NIH should continue to support research in nutrition that relates to disease and research in basic aspects of the biological and medical sciences. Research on nutrition as a means of understanding, diagnosing and treating non-nutritional diseases should fall within the scope of the NIH as it does now. However, with an extramural research program that dealt with the more practical aspects of nutrition, with nutritional requirements and preventive medicine in the USDA (or in a new center), NIH would be relieved of general responsibility for such programs. The same would apply to intramural programs.

I realize that the distinction between nutrition in health and nutrition in disease is not so clear-cut that overlap will be eliminated. I do not see that as a problem. When information obtained through nutrition investigations of healthy people provides leads as to factors that contribute to or influence the development of disease, it would be logical for certain aspects of such projects to be supported by NIH while others are supported by USDA (or an alternate Preventive Medicine Center).

The need for division of responsibility for various types of nutrition programs emphasizes the need for a national nutrition policy and for a coordinating organization for nutrition programs.

1. MAJOR GAPS IN HUMAN NUTRITION KNOWLEDGE

Gaps in human nutrition knowledge are boundless. The greater the accumulation of knowledge, the greater the number of gaps so this is essentially a limitless exercise.

The needs for additional knowledge can be categorized in a variety of ways, e.g.,

A. The need for practical knowledge, basic to the planning of public health and preventive medicine programs.

B. The need for knowledge to improve the understanding and treatment of non-nutritional diseases with a nutritional component.

C. The need for general knowledge of nutrient deficiencies, balances, and interrelationships that may affect health.

D. The need for fundamental knowledge of function and metabolism of nutrients, information that may bear on any one or all of the other categories.

Another approach would be to list the various nutrients and indicate the gaps in our knowledge about each of these.

Still another would be to identify various aspects of metabolism and identify gaps in our knowledge of how these are influenced by nutrition.

None of these are entirely satisfactory but any one is probably better than a random listing of problems. Whatever scheme of organization is used there will be overlap. Perhaps the first type of categorization is most satisfactory for my approach.

A. The Need for Knowledge for Planning Practical Programs

1. The continuing need for evaluation of nutritional status.

2. The continuing need for monitoring quantity and composition of food supply.

3. The need for information about food consumption and nutrient intake.

4. The need for accurate information about nutrient requirements.

5. The need for appropriate and reliable standards for assessment of nutritional status.

6. The need for knowledge of the reasons for nutritional inadequacy occurring in a population with an excellent food supply.

7. The need for assessment of the accuracy of the nutrition knowledge of the public.

These may or may not be research needs but they are certainly information needs. Intervention programs and public policy should be based on sound knowledge of present nutritional status of the population and the state of the food supply. Continuing health surveys of the type being conducted presently by the Bureau of Health Statistics provide information of a general nature about the population as a whole but would probably fail to identify unique health problems. It is, therefore, important to support, as well, special surveys of unique groups who are at risk, e.g. native Indians, migrant workers. As an example, researchers in Denver identified problems relating to zinc deficiency in children in Colorado that would not have been found in standard nutrition surveys.

The USDA has a program now for updating food composition tables. This is a crucial activity that has not been adequately supported. The same is true of food consumption studies, which were in danger of being eliminated by Congress. Both of these activities represent continuing needs as they provide important bases for assessment of nutrient consumption and of the nutritional adequacy of the food supply. The third component of this is knowledge of human requirements for nutrients. Research needs in connection with this will be discussed under C, below. In my personal view this would best be accomplished by a highly specialized research unit located near a population, such as a religious sect, that was highly motivated to serve as subjects for such studies. The probability of obtaining the needed information on a methodical basis through sporadic studies by individual investigators is limited. Enough information might accrue from such an approach over a prolonged period of time but the number of investigators prepared to undertake such studies and the facilities for doing them are extremely limited.

Above all, in this connection, there is a need for careful investigation and analysis of the reasons for the occurrence of nutritional inadequacy. Poverty is an obvious reason but this, too, needs to be analyzed carefully. Poverty does not necessarily mean insufficient money to purchase food--and food programs do not necessarily have nutritional impact. Money saved on food purchases can be used to reduce other forms of deprivation. There is no evidence that the food supply is inadequate in nutrients with the possible exception of iron. Problems that lead to severe nutritional deficiency include alcoholism, neglect through social disintegration of families, psychological or mental problems, among others. There is a serious need to get all of this into proper perspective in the planning of any public nutrition policy.

B. The Need for Knowledge to Improve the Treatment of Diseases that are Not Exclusively Nutritional

The major diseases and clinical conditions in which nutrition may be part of the method of treatment or may be a contributing cause are heart disease, cancer, osteoporosis, dental caries, diabetes, kidney disease, alcoholism and trauma. Many of these are currently receiving attention either through congressional action or as parts of on-going programs of NIH. They all deserve active attention and an immense number of topics could be listed under each.

Continuing studies are needed of the influence of nutrients, especially of carbohydrates and lipids and their constituents, on the concentrations of blood lipids including cholesterol, on the development of plaques in blood vessels and of the interrelationships among nutrition factors and other factors involved in heart disease. Such studies should have a strong metabolic emphasis. Until the significance of nutrition in heart disease is clearly established, this subject deserves strong but selective support.

Studies of diet in relation to cancer have been funded by Congress, probably beyond an amount that can be used effectively. It seems logical to emphasize primarily studies of food contaminants, additives and non-nutrient components of foods in relation to cancer.

The role of fiber in the development of cancer, particularly of the lower bowel, should have high priority in view of the claims made for this substance as a preventive agent. Fiber should also be examined carefully for possible adverse effects and for a role in other diseases such as heart disease.

Osteoporosis is a seriously debilitating disease. Knowledge of the role of vitamin D and hormones in the process of calcification of bone has been well supported by NIH and continued support is merited. The interactions among minerals in the diet, vitamin D and hormonal state provide the potential for understanding and treating this disease.

Kidney disease is not known to be caused by nutrient imbalances but investigation of the effect of excessive intakes of protein, such as are common in the U.S., deserves study. Emphasis, however, should be mainly on nutritional management of this disease in order to provide greater knowledge of the role of vitamin D, trace minerals, protein and amino acids in prolonging life and reducing the need for dialysis in severe kidney failure. Again, support for such studies through NIH has been strong.

Dental caries is a major public health problem. The role of nutrients in its development is still only incompletely understood. Investigation not only of the influence of carbohydrates but also of trace minerals and other nutrients deserves continuing support. The National Institute of Dental Health supports such investigations well.

Trauma, while not a disease state, occurs as the result of surgical treatment of many diseases, as the result of fractures and accidents of many types. Hormonal changes, metabolic disturbances and nutrient losses occur. Understanding of the role of nutrition in the management of trauma could provide valuable information for management of this condition. It is a logical subject for NIH support and has received considerable attention.

Diabetes and alcoholism are diseases that lead to nutritional problems and require nutritional treatment. Many facets of both of these in relation to nutrition have been and continue to need study. Such investigations are commonly supported by NIH.

Although studies of the role of nutrition in all of these diseases deserve high priority, all receive considerable support through NIH.

C. The Need for General Knowledge of Nutrient Deficiencies, Imbalances and Interrelationships that May Affect Health

Obesity is considered a major public health problem and the incidence in the U.S. population is high. It is considered to predispose people to many other diseases. It can be considered as a chronic disease resulting from nutritional imbalance owing to defective regulation of food intake. Research on this problem is a major need and should have high priority.

Many facets of obesity deserve attention. These range from studies of efficiency of energy utilization, studies of the regulation of food intake, studies of the influence of diet on neurotransmitter concentrations and functions and the role of behavior in the development and prevention of the problem.

Studies of individual variability in nutritional needs should have special attention in relation to studies of nutrient requirements. Establishment of public policy requires establishment of estimates of maximum requirements among individuals for nutrients. Preventive medicine requires knowledge of conditions that lead to uniquely high needs, e.g., genetic defects of metabolism. This subject receives casual attention as a component of other studies but deserves specific attention.

Quantitative estimates of nutritional requirements were mentioned under A. Emphasis here should be on human requirements for trace minerals and on new approaches involving metabolic measurements for the reassessment of requirements for vitamins. The USDA, Armed Services, NASA and AID have supported a number of such studies but

only limited support has been provided through NIH. These, for the most part, are not the type of investigations that lead to the frontiers of knowledge, they are expensive and time-consuming. They, therefore, attract a limited number of investigators and limited support. As indicated in A, they would probably be best done in a unique government-supported laboratory where advancement of investigators did not depend upon publication at short intervals.

The need for investigation of factors that influence requirements for nutrients is greater than the need for routine investigation of requirements. The influence of energy (calorie) intake on protein utilization is the center for some controversy currently. The influence of energy expenditure (exercise and work) on nutritional needs, other than for energy and thiamin, has received little attention. The problem of meeting nutritional needs during periods of low food consumption is important in relation to weight reduction regimens. Interactions among nutrients, such as the influence of protein intake on calcium and other mineral needs is currently a pertinent subject. The relationship between copper intake and zinc requirement is another such area.

The need for knowledge of the relationship between malnutrition and mental development is great. This should not be restricted to protein malnutrition. In fact, the influences of energy deprivation and deficiencies of other nutrients should have equally high, if not higher priority--and investigations on animals should be placed on a sound quantitative basis so that extrapolation from animal studies to human problems can be placed on a sounder basis.

The role of nutrition in resistance to infections remains an area with need for much attention. Highly suggestive interactions have been reported but the surface is barely scratched.

Many nutritional interrelationships require continuing study. Calcium utilization is influenced by protein intake--this could be of public health significance in relation to the development of osteoporosis. Many trace mineral interrelationships may influence requirements and utilization of these nutrients but more knowledge is needed to provide information that can be applied practically.

The list of gaps in relation to the knowledge of nutrient functions, interrelationships and roles in health and disease could be continued almost indefinitely. A few additional topics that require attention are listed without comment:

--studies of availability of nutrients in foods

--knowledge of essential fatty acid requirements

--interactions of drugs and nutrients

a) how nutrients influence drug action
b) how drugs influence nutrient utilization

--knowledge of changing nutritional needs with age.

D. Need for Fundamental Knowledge of the Function and Metabolism of Nutrients

Understanding the role of nutrients in health and disease depends, in the long run, on an understanding of how the body uses nutrients and how nutrients function in the metabolic reactions involved in energy production and tissue formation.

Among the topics that require investigation are:

--influence of diet on hormone action

--influence of endocrine state on nutrient utilization

--specific functions of many essential minerals such as chromium, manganese, zinc

--specific functions of vitamins E and C

--the relationships between metabolic functions of water soluble vitamins and the signs and symptoms that occur in deficiency states

--the role of fatty acids in the diet on the production of prostaglandins

--the relationship between protein intake and the concentrations of neurotransmitters in brain and nerve

--the adaptive responses of metabolic processes to changes in nutrient intake especially the effects of excessive and deficient intakes of nutrients.

Research in this category, in particular, requires imagination and insight. The extramural grant procedure for identifying projects that are likely to advance knowledge is probably the best way to approach such problems. To set priorities on these is a wasted effort if imaginative research proposals are not forthcoming from individual investigators.

Finally, in trying to set research priorities, it is important to recognize that "optimal" health is a meaningless term. The most satisfactory diet will not be the same for all individuals and a variety of types of diets will be equally satisfactory for large numbers of individuals. The only practical approach is to identify what is unsatisfactory so that we can approach as closely as possible to what is most satisfactory. In order to accomplish this it would be well to focus initially on clearly identifiable problems. A specific sequence in the listing of priorities is probably not very meaningful but, at risk of being considered arrogant, I shall list my own research priorities below.

Obesity--investigation of food intake regulation, efficiency of utilization of energy sources, behavioral research on the obese.

Interactions of drugs and nutrients--investigations of how drugs influence nutrient utilization and how nutrient intake influences drug action.

Nutritional management of heart disease--investigation of influence of nutritional changes on blood lipids and lipoproteins and on the metabolism of carbohydrate and fat.

Investigation of naturally occurring non-nutrient compounds in natural and processed foods for toxic and carcinogenic effects.

Investigation of methods for assessing nutritional status with respect to specific nutrients, especially vitamin B-6, folic acid, zinc, and chromium.

Investigation of the biological availability of nutrients in foods with special reference to iron.

While it may not be research, high priority in establishing public policy must be given to continuous assessment of nutritional status of the population and the nutritional adequacy of the food supply.

November 24, 1976

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I should like to begin with a few general comments about the support of research today. These comments are, of course, not specific to nutrition.

The call from Congress and others for more evidence of utility and application from research is understandable. It must be appreciated, however, that by its very nature research appears to be wasteful. We cannot necessarily recognize a good idea until it is proven to be good. The call for better evaluation or accountability of the research dollar has had several undesirable effects. One is more direction from Washington, often by contract rather than research grant. There simply is no evidence that this produces a better yield and most people believe it is more wasteful.

Some consideration needs to be given to the maintenance of some stability in research operations. As money has become tighter, it has become much more difficult to maintain productive research. One simply cannot conduct most research on an "off and on" basis depending upon whether a research grant is approved.

It should be clear that the only source of people to do research is the university. The only way to learn how to do research is by doing research. Thus, research support in the university fills three functions--provides faculty for teaching, does research, and trains future researchers. These functions should be adequately considered when decisions are made about the mode of support or who should do it. Government or other agencies that only do research do not fulfill these functions.

Finally, I feel it is time for someone to reconsider the role of overhead funds. We all recognize the validity of this expense yet it seems likely that something between a third and a half of total research funds now go to overhead. Since additional funds have not been provided, the growth of overhead costs have competed directly for research funds. All of us have seen the growth of the administrative staff in universities and other institutions which appears to be Parkinson's Law in action. Obviously how well these funds are justified is a mute point, but it is galling to investigators to struggle with the granting agency over every dollar in the direct budget and then have the total bill automatically raised by 50, 60 or more percent.

With regard to the nature of the areas where I believe there is an important gap in research effort, I would place the highest priority on the important causes of death and disability in the United States, other than heart disease. This would include cancer, diabetes, hypertension, obesity, gallstones, osteoporosis, diverticulosis and perhaps others. There appears to be a strong etiologic role of nutrition in all of these and they are obviously significant in our population. The discussion of dietary fiber has focused some attention in this area, but there are other competing hypotheses of equal validity. The nutritional role would obviously be largely in the prevention of these diseases which should be an ultimate and primary objective of medical research.

In all of these diseases the collection of good epidemiologic data is important. It is usually necessary to collect data worldwide. The United States population is too mobile and there may not be sufficient variance in nutritional intakes to identify nutritional factors (as is true in ischemic heart disease). The epidemiologic data can rarely prove causation but the correct hypotheses must be consistent with epidemiologic evidence.

The utility and kind of clinical research will obviously depend upon the hypotheses generated in each case. Yet it is clear that human populations can rarely be manipulated for very long periods of time. We must assume that many or most of these diseases are the result of many years of dietary insult. Thus, I feel that a great deal more effort will have to be put into the development of appropriate animal models. Here there are several obstacles. Most animal facilities are simply not equipped for very long-term, lifetime, studies. One cannot afford these kinds of studies unless proper protection against infectious disease and good environmental control is assured. The space requirements are also substantial and, finally, one cannot expect investigators to enter such a field unless support over a reasonable period is assured. The usual three year grant is simply not reasonable.

I feel that there should also be a definite effort to improve and expand our search for animal models. Many of those currently available--the susceptibility of the guinea pig to scurvy, diabetes in the sand rat, the folic acid requirement of the chick, etc.--are serendipitous discoveries. Nutritionists are usually rat feeders, geneticists use mice, surgeons use dogs, etc. The reasons why are usually clear but they may or may not represent the most efficient approach. Much effort has recently been put into the expansion of primate facilities (few of which have emphasized nutrition) for obvious reasons but I suspect we are missing many opportunities.

Similarly, the utility of the genetic studies on mice is clear. Yet rats, which are a much better species for nutrition studies, have had practically no genetic investigation. The potential in the area is exemplified by the chance availability of the Zucker obese rat and the

strain with spontaneous hypertension. There should be a deliberate effort to develop genetic models in various common laboratory species.

The reason why nutrition in the many chronic diseases has been relatively neglected is, no doubt, multiple. I believe the main one is that we are now only entering the new era of nutrition. Major emphasis up to now has been aimed at the discovery of essential nutrients, definition of requirements, assurance of adequate intakes, etc. This job is not yet completed. Nevertheless, the new era appears to have little to do with essential nutrients but rather with overnutrition of various kinds or imbalance in nutrition, excessive fat, protein, sugar, lack of fiber, etc. This kind of research requires new approaches--long-term studies, better animal facilities, etc. It is simply harder to do and requires a different strategy.

Another reason is that the disease-oriented approach to medical research means that the dominant people in each area set research aims and priorities. Nutrition and nutrition research has not had a priority position in most of these. We cannot expect researchers in every area to have this expertise. The curse and the strength of nutrition is that it cuts across all areas. Probably the only way to bring emphasis to nutrition in some of these areas which do not have enough funds now to do what they want to do will be to earmark funds as has been done for cancer and nutrition.

I have not included coronary heart disease as a priority area because of the funds currently available. Yet I am not satisfied with the emphasis in this area of research. There is a certain sophistry in biomedical research. If there is a Nobel Prize in the area which seems possible, it will most likely go to the individuals who demonstrate the mechanisms by which diet controls serum lipids. The finding that nutrition <u>does</u> control serum lipid levels--probably the most significant applied aspect--is simply not sophisticated enough to win any prizes. Thus, one finds that many of the major research operations in this area have scant interest in nutrition and few or no nutritionists on the staff.

The next priority area that I would list would be nutrition--toxicology-carcinogenesis. This is related to the first but needs additional emphasis. There is clearly a great deal of public interest in food additives, toxicology of all kinds, and carcinogens. There are large efforts underway. Yet we know that for many toxins and carcinogens the relative toxicity or potency is dependent upon the diet fed the animals. It is somewhat frightening to think that much of this testing may be relatively inappropriate because we do not know what kind of diet to use. Current data on the prevalent cancers in the United States do not suggest that these are the result of carcinogens in the food supply, but it is at least possible that the diet eaten might greatly increase susceptibility to dietary carcinogens.

The requirements in this area are similar to those listed above--better animal facilities and long-term support.

The next priority I would list would be in a more mundane area--the development of an effective system for monitoring nutritional status of the population. Both dietary and biochemical methodology in current use are relatively cumbersome and have not advanced greatly in recent years. It is not a popular area of research. New and more sensitive biochemical methods are needed and many of these must be automated so that the turn around time is short enough to make them useful in program management and a whole system to coordinate various kinds of information is needed. Up-to-date food composition data are needed. We are told that the USDA is doing this. I am uncertain about the magnitude or quality of this effort.

As fourth priority I think I would place the important question of how much food does man require? This is probably the most important question relative to world food problems and it is amazing how little is known about it. Basic studies in enzyme energetics which are extremely voluminous have, so far, yielded little in application. I suspect much of the information in the textbooks which go back to about 1900 is erroneous. A great deal of work on obesity, control of food intake, etc., has so far been disappointing. Yet obesity remains a major problem and lack of food presumably the major world problem. I see no alternative other than more and better research even though I am disappointed with progress.

I have not listed many current exciting areas such as the rather large advances in nutritional management of patients, the studies on trace minerals, the effect of the "pill" on nutritional needs, nutrition and immunological response, nutrition of genetic abnormalities, etc. I have no way of knowing the level of current support nor the quality of applications now being received.

My guess would be that the field is relatively inadequately supported now and not much slack will be found. I would point out that many of the attempts to classify nutrition research or the amount of it have been quite misleading. Many research projects get included in such classifications because diet may be a variable (all patients have to be fed) but scarcely qualify as nutrition research.

Finally, I think I should emphasize that the number of well qualified researchers in nutrition is small. By definition nutrition research has not been as exciting as many areas of biochemistry. There is a very large biochemical group competing with a small nutrition group for the best students. Although we find a lot more interest in nutrition among students, we rarely have the financial ability or the scientific stature

to really compete. With the loss of training funds, the limited ability available to train students will be further diminished. We need a plan to gradually increase research support, training, and facilities in nutrition as they can be absorbed effectively. Too much money at one time will undoubtedly attract poor biochemists or physicians into nutrition.

October 13, 1976

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I have procrastinated in responding to your request of October 14 regarding the pressing needs for human nutrition research in this country. My reluctance stems from the difficulty of evaluating these complex questions. We can see clearly how to solve basic problems in science which have no obvious relationship to human health, but when we seek to relate a given problem to public health, the situation becomes less clear. Experimentation with human nutrition, always difficult and tedious, has become next to impossible in recent years.

Nonetheless there are some human diseases which are generally conceded to have dietary implications which should receive attention. As with any phase of preventive medicine, the evaluation of public health measures may be very difficult in spite of the clear logic of instituting that measure. For example the effect of enriching flour with B-vitamins and iron in the 1940s has been assumed beneficial, but I know of no hard evidence that the nutritional welfare of our population was influenced. This brings me to my first gap in knowledge of human nutrition.

(1) Better methods of evaluating nutritional status. We need objective, reliable and simple methods for evaluating the nutritional status of individuals with regard to every nutrient. A glimpse of what such methods might entail is provided in the recently reported methods for estimating thiamine, riboflavin and vitamin B_6-dependent enzymes in erythrocytes with and without the added coenzymes involved. Such evaluation of individuals when applied to a properly selected population might be highly indicative of the nutritional status of the entire population.

(2) More fundamental knowledge regarding the physiological processes by which nutrients are handled. These would include absorption, transport, renal excretion, and the specific binding proteins involved in these processes. It has become clear that each mineral, amino acid and vitamin must be understood so that its overall economy can be considered in evaluating nutritional status. How and where they are absorbed, how and in what form they are transported between organs, where their essential reactions occur and the factors influencing their incorporation into enzymes, coenzymes, etc. are all important questions.

(3) Better understanding of the trace element requirements of the human. There is some evidence that mineral elements, not previously recognized as essential nutrients for experimental animals, are required under special conditions of feeding and housing. If these findings are also applicable to humans it is possible that heretofore unknown nutritional diseases may exist as we use more refined foods.

(4) Ascertain the effect of diet on coronary heart disease. In spite of much attention over a long period of time the role of diet in atherosclerosis and other circulatory disorders remains obscure. Recent results would suggest that genetic factors might outweigh nutritional factors. More information is needed in all areas, particularly as related to fiber, cholesterol, and fatty acid content of human diets.

These gaps are arranged in the priority I would give them from 1 to 4. The first item is considered top priority because of the need to have objective means of evaluating the nutritional state of individuals then populations. Certain people are attributing many health problems directly to poor nutrition without ample evidence. Such speculation can best be refuted by proper objective evaluation of the nutrient intake and nutritional status of a proper sample of our population.

The second area is given high priority because such data are needed to implement the first. Disease might result from deficiency secondary to impaired handling of a nutrient by the individual.

The third and fourth areas are ongoing research areas whose importance to human health remain somewhat in doubt. Trace elements have been important in preventing human ailments e.g. (iodine, iron and zinc). The newer trace elements may be very important, but no obvious applications to human disease states are evident. It seems safe, however, to assume that elements required by other organisms are required by man. Until we know about requirements, and intake, etc. we cannot draw conclusions about their current concern in public health.

The substantial support of diet and heart disease research over a long period of time has not yielded clear answers. Because it is such an important problem, it deserves yet more attention. Research in this area is receiving good support presently. What is needed are new ideas which may originate in some seemingly unrelated project. Current levels of support may be adequate until some new approach emerges.

Attempts are being made to remove these gaps now. Work with item 1 depends upon basic biochemical knowledge and cannot arise from clinical type observations. When methods prove reliable on experimental animals they can and should be applied promptly in human studies.

The present level of funding of NIH in these "gap areas" is not sufficient to fund all applications of merit, though the better ones are funded, usually at considerably lower levels than requested. Some of these gaps can only be removed by experimenting with humans, which is costly and frequently the types of studies which may be done are restricted by the constrictions inherent in such human dietary studies.

Finally, it should be recognized that the nature of research is such that new basic developments may make a previously promising area of applied research no longer promising or even feasible. This means that we should not neglect basic research in any science. When this happens the foundation upon which applied science is supported may crumble leaving the applied of doubtful significance.

December 6, 1976

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I would consider the following issues as major gaps in our knowledge of human nutrition: (1) The relationship of nutrition/food to good health and to the development of disease. (2) The relationship of nutrition/food to the effect of drugs (in this case, I'm referring to drugs used to treat or prevent disease). (3) The nutritional requirements of individuals under "stress" conditions. (4) Nutritional requirements of individuals in relation to performance (performance being described as not only physical performance, but also physiological performance in relation to reproduction, maintaining body temperature, etc. and also psychological performance). (5) The relationship of nutritional status to overall health status.

In several instances, I have made reference to both nutrition and food. I think it is essential to put nutrition and food in a correct relationship since our major source of nutrients is food and those components of food which may result in some adverse effect in man becomes part of the "nutritional" problems. In terms of ranking, I would list the relationship of nutrition/food to health as a key and probably first priority to other items I've listed. Number 2, I would list performance and Number 3, nutrition/food in relation to drugs as I defined them above.

I think we must start with the development of a better understanding of how the nutritional status of an individual will influence his overall health status and how these in turn relate to his "performance". This information will be basic to our understanding of how one can improve the nutritional status and also what one can expect in terms of the individual when the nutritional status is improved. There has been considerable information published proposing great benefits on the basis of improved nutritional status. There is relatively little information that supports that in the real world individuals will perform significantly better if the nutritional status is improved above some relatively minimal level. While there is no question that severely malnourished individuals do not perform well in any of the categories suggested above, the point at which improved nutritional status results in no benefits has not been well defined.

My concern in relation to the question of drugs relates to the rather broad and increasing use of drug treatment for various diseases as well as prevention of diseases with relatively little evaluation

of the interrelationship between nutritional status and those drugs. Only in recent years were well defined adverse effects identified as the nutritionist has been called in to work with the physician and drug research expert to determine what problems might develop. A better data base in this area could be beneficial both to the nutritionist who might acquire a better understanding of nutritional requirements of man and to those developing drugs who can better define potential problems and possibly synergistic effects that would be beneficial.

Based on my observation of nutrition research supported by the Federal Government, I think that in all categories there is inadequate support for those items that I've listed both in terms of the broad issues and the specific priorities. Though there is considerable funding available in areas that appear to relate to some of these priorities, the problem is frequently the lack of coordination of activities and the failure to develop a long term, well defined program which will result in reaching the kinds of conclusions that are needed. This in part is the result of the failure of many involved in the funding of research in these areas both in the Federal Government and in private organizations that ten one-year granting periods will not produce the results of longer term support such as five to ten year grants that provide for the continuity of effort and do not require that senior scientists and their staffs worry on a regular basis that unless something is achieved in a current year, they may not get another chance. Much of the basic research in nutrition must be carried out over an extended period of time and cannot be made up of intermittent short term projects tied together by assumptions and unrelated studies.

Additional reasons which I think have had a negative influence on the Federal support of nutrition related research deals with the fundamental failure to appreciate that research on food alone is not nutrition research, thus, considerable sums of money are spent on food research identified as nutrition research without clearly recognizing that unless food and nutrition work is developed in close coordination that individual food projects do not provide nutrition information. In addition, nutrition and food gets caught up in the whole policy question dealing with science, medicine, and welfare both at the state and Federal level. It is often proposed that research work in nutrition is essential to welfare programs and while this sounds good on paper, it leads to projects that do not speak to the type of issues mentioned earlier, but seek to justify programs where in some cases demonstrate that they are not needed in terms of a welfare or medical aid activity.

The types of work required are essentially those that are defined by the lists under the first two items dealing with key issues and priorities. In this area, I think that there are some general types

of research that need to be considered which involve the development of methods to determine "good" and "bad" nutrition as it relates to health and performance. This in turn should be tied to epidemiological evaluations which can provide keys to the influence of other factors. Nutrition cannot be looked at alone, but must be considered in terms of the environment of the individual and the basic genetic and metabolic factors that are at play in each person. In relation to long term, a program that strongly supports work at each level from the very fundamental biochemical work at the cellular level through clinical work involving both treatment and prevention must be carried out. More innovative approaches to nutrition research in man are required particularly in the face of the more restrictive rules dealing with the use of man in experimental situations.

From a problem standpoint, your Item 5 probably speaks to one of the key restraints on the nutritional research programs. There are simply too many groups that are involved, too many open grants which are "nutrition" only because they deal with some nutrient, etc. and tend to provide the various factions within the nutrition and health communities monies to support their own personal types of projects. An example is the incredible amount of money that is spent over the last two decades on the relationship of fat to coronary artery disease. I seriously question that we can better define the relationship today than we could in 1948. What we have developed are several schools of thought seeking to prove a position and then get funds to build stronger walls against the attacks of others on that particular idea. Nutrition lends itself to the sensationalism of the media and to the exploitation of the food manufacturer. There has been in recent years an eagerness on the part of the food industry to pick on specific reports and to exploit these both in advertising and in some cases, new products. Currently fiber is the issue and a host of new products are being pushed into the marketplace with claims as simple as increase the bulk in your diet to implications that the prevention of cancer, reduction of the possibility of coronary artery disease, and the reduction in the possibility of environmental contamination from pesticides in the diet all can be related to a high fiber diet. This in turn leads to the demand on the part of scientists to get funds for this type of research and since everyone realizes the half-life of the new idea is relatively short, no one wishes to carry out the kind of long term systematic work that must be done. I think that those who are funding projects have to fight this type of development and that the kind of long term proof of efficacy that is required of drugs even though this may delay to some degree the movement into the marketplace of effective drugs needs to be practiced by funding agencies. This assumes, of course, that adequate funding will be made available.

Perhaps my rambling comments do not speak to some of the questions that you would hope to address in your program, however, I think that there are many who can list the very specific items in terms of specific research projects, but my view at this time after observing both from within and without is that our failures in the area of nutrition, and I have been party to many of them, are associated with our unwillingness to do the basic types of work.

In the early days of nutrition when vitamins were first discovered and the role of vitamins in terms of preventing deficiency diseases and the role as part of the metabolic process was being worked out, the type of long and tedious work that is still required was being supported and carried out. Today, it would appear that no one has the time to work out details and to develop the data base necessary to be sure that statements being published can be supported and that we are not moving down a path that may provide many publications, but will not anwer key questions.

November 9, 1976

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1. Major gaps in human nutrition knowledge

a. Role of nutrient interactions in the development of coronary disease.

This particular approach has received little attention with most activity being centered on research pertaining to specific nutrients, i.e., fats, carbohydrates, proteins, trace elements and fiber. Data are being developed which suggest that the "right" type of fiber (alfalfa) may overcome deleterious effects of the "wrong" protein (casein) in certain experiments. This is a gap because of oversight due to pre-occupation with single factors.

b. Nutrition in cancer

Epidemiological data suggest that high fat diets (unsaturated) may promote breast cancer; animal fat and protein are positively correlated with colon cancer, etc. These epidemiological suggestions can be tested in animal feeding experiments. This gap exists because until recently there has been little interest in diet and cancer. Tannenbaum and others did some work in the 1950s. Since then we have learned so much about the biology of cancer that we might now be able to explain the findings at the molecular level and thus gain a general insight into tumor growth and, possibly, control.

c. Nutrition and the immune response

This is a relatively new area of research but is of great importance.

d. Nutrition of patients with cancer

Can better nutrition permit patients to withstand the disease and to respond to therapy. There is a lot of activity in this field but we need to know more.

e. Nutrition in aging

With an increasing number of aged in our population we need to learn more about their likes and dislikes (this may sound trivial but its basic to promoting good diet); foods which can increase level of health, immunity to illness. To date most work has centered on adequate

nutritional support but not on nutrients which may play a specific role in health. (This may be a social problem as well, i.e., eating alone, etc. and thus may be beyond the purview of this questionnaire.)

f. The role of vitamins such as A, C, and E in coronary disease and cancer

There are some data which suggest that relatively large doses of A and C (which render them pharmaceutical agents and not vitamins) can affect growth of some types of tumors. This area has been impugned because of the stigma of "fadism". The best way to settle the question is to obtain unequivocal data.

2. List of priorities (letters refer to answers to question 1)

1.a. Since some form of vascular disease is the cause of over 50 percent of all deaths in the U.S., this problem must receive first priortity. Heart disease is a multifaceted disease and diet appears to be one important factor. Because of the correlation between blood cholesterol and heart disease most effort has been experded on studies of cholesterol and lipids. It now becomes evident that all factors in the diet may affect lipoproteinemia, even in cholesterol-free diets. It is most important that we understand the effects of all aspects of diet.

2.c. The immune response appears to underlie susceptibility to tumor formation; it may play a role in artherosclerosis; and it is important in some infectious diseases. We have very little information on the influence of nutritional status and of specific nutrients on antibody formation. This information would broaden the research base in cancer and heart disease.

3.b. The influence of diet on susceptibility to cancer and on proliferation of cancer must be delineated in order to get a complete picture of the establishment and course of this disease (at least some types of tumor, i.e., colon, breast, stomach). If we can understand all the factors contributing to tumorigenesis we can increase our avenues of approach to its cure.

4.e. There is work in this area but more is needed.

5.d. As above.

6.f.

3. There is considerable support for work on nutrition and heart disease but most of it is channeled towards the more orthodox studies relating to lipids.

There was an attempt to do something about nutrition and cancer with establishment of the CREGS program. The guidelines were all wrong, however. They sounded like RFP's rather than grant suggestions. More flexibility in preparing proposals would be needed. The work on nutrition of the aged (or research on nutrition and aging) doesn't seem to attract many imaginative proposals.

4. First, more support of basic research. There are still too many unknowns for directed proposals to provide successful answers.

There should also be encouragement of program-project proposals. This is especially true for the cancer field where the combined efforts of nutritionists, immunologists and molecular biologists are needed.

5. It might be unreasonable to expect support for survey programs without a well-organized effort for canvassing and treatment. I am not clear on the meaning of this question. An idea without a place to put it into practice (i.e., inadequate laboratories) would not be deemed supportable. In general, the major bar to more investigation is lack of research monies. In the heart field the expenditure of funds on large clinical studies - which have to be supported once begun - cuts deeply into the available grant money.

January 7, 1977

Philip R. Lee, M.D.
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I am responding to your letter of October 15 regarding the GAO report on human nutrition research for the Senate Select Committee on Nutrition and Human Needs. I regret that it is not possible for me to supply you with a detailed response to the five questions that you pose in your letter.

A number of the questions you ask are answered in a statement I delivered to the committee on July 27, 1976. I am sending you a copy in hopes that it will be of use to you.

October 28, 1976

STATEMENT BY
Philip R. Lee, M.D.*
Jenny Johnson, M.P.H.**
ON NUTRITION AND HEALTH
BEFORE THE
SENATE SELECT COMMITTEE ON NUTRITION AND HUMAN NEEDS
July 27, 1976

Mr. Chairman, members of the Select Committee on Nutrition and Human Needs, I am pleased to have the opportunity to discuss with you a number of problems related to nutrition and health. Increasingly, it is becoming apparent that nutritional diseases are still among the most important health problems in the United States.

As a physician I am concerned about the number of people who suffer from cardiovascular diseases, particularly hypertension and arteriosclerotic heart disease.

--I am concerned about the growing number of patients who consult physicians because of diabetes mellitus;

--I am concerned with the large number of men and women who continue to develop cancer of the colon year after year;

--I am concerned about the millions who have difficulty dealing with the problem of obesity;

--I am concerned about the individuals who are suffering lifelong disabilities because of malnutrition during gestation and early infancy;

--I am concerned about the many old people whose lives are limited because of osteoporosis; and,

--I am concerned because of the growing problem of alcoholism in our society.

The prevalence of nutrition related diseases such as atherosclerosis, diabetes mellitus, obesity, osteoporosis, colon cancer and alcoholism, as well as the existence of malnutrition among pregnant women, the aged, and poor children particularly, clearly underline the need for the Select Committee on Nutrition and Human Needs to extend its area of concern.

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I know that too many people in this country, particularly the poor and the aged, don't have enough money to purchase an adequate diet. I know that the aged and the poor who need nutrition counseling to better manage their health problems are often denied these services because nutrition services are not reimbursed by their private health insurance or by Medicare or Medicaid. I know also that all of us get most of our information about food and nutrition from food advertising, which promotes food for profit - food which is high in fat and refined sugars; food that has too much salt, provides too few nutrients for the calories consumed, and contains untold amounts of food additives whose effects we know too little about.

Nutrition and the Decline in Infectious Diseases

We know that good nutrition means more than just preventing a deficiency disease. Improvement in human nutrition was the single most important factor in the decline of infectious diseases as the major killers in Europe and the United States in the 19th and 20th Centuries. This change represented the most significant and dramatic change in man's health in the past 10,000 years.

It is widely assumed that improvements in medical care, particularly immunization and antibiotic therapy, accounted for much of this improvement. Not so. Except for smallpox, diphtheria and tetanus immunization, these measures did not become important until the mid-1930s. Today they are vitally important for the prevention of half a dozen diseases and the treatment of individual patients with infectious diseases, but most of the decline in mortality from infectious diseases preceded their discovery and use.

Professor Thomas McKeown of the University of Birmingham, England, has provided substantial evidence to support this view. He summarized the reasons for the marked improvement of human health in England and Wales since the 18th Century:

> This interpretation of the modern advance in health and rise and eventual control of population puts the emphasis on the following: increased food supplies from the early eighteenth century; limitation of numbers and removal of adverse influences in the environment by improved hygiene from the late nineteenth century; and specific medical measures (immunization and therapy) from the second quarter of the twentieth century. The contribution of the last influence to the total decline of mortality was relatively small and the improvement in human health therefore was due predominantly to a change in reproductive behavior and to modification of the environment by provision of food and protection from physical hazards. It should also be noted that only two

of the four major influences were introduced in order to improve health; the reasons for increasing food supplies and limiting numbers were only indirectly related to this objective.

In the United States it is likely that the same forces have been at work. The age-adjusted death rate declined steadily after the turn of the twentieth century until it was briefly interrupted by the flu epidemic in 1918-19. In the mid-1930s the impact of modern medical care began to be seen, and for about twenty years the age-adjusted death rate declined at two percent per year, instead of the previous one percent. Between 1955-68 there was little if any decline, but since 1970 the age-adjusted death rate seems to be falling again at about two percent per year.

U.S. Disease Burden

The decline in mortality from infectious disease has had an enormous impact on the health status of Americans. The most dramatic changes in this century have been the sharp decline in infant mortality and a large gain in life expectancy from birth. However, life expectancy from the age of 27 has increased little for males and only modestly for females. Life expectancy at 45 has increased less than 5 years for U.S. males and less than 10 years for females since the turn of the century.

Why has life expectancy increased so little for adults, particularly adult males in the United States? The answer may be found in personal behavior or life style. Some of our behaviors are health promoting, others disease producing.

In California, Nedra Belloc of the California Department of Health and Dr. Lester Breslow, Dean of the UCLA School of Public Health, have found seven health-related behaviors in a study of 7,000 adults in Alameda County. The behaviors related to good health were.

--moderate drinking, not more than one or two alcoholic drinks per day;

--no cigarette smoking;

--seven to eight hours of sleep per night;

--eating regularly and not between meals;

--eating breakfast;

--keeping a normal weight, neither being overweight or underweight; and,

--moderate regular exercise.

At every age from 20 up to 75 years, the health of persons with seven good habits was better than that of persons with six; health of the latter better than those with five, and so on consistently with four, three and two or fewer good habits.

Life expectancy (average number of years of life remaining) at age 45 for men in the zero to three good health behavior group was 21.6 years compared with 33.1 years for those in the six to seven good health practices group. The magnitude of this 11.5 years difference is better understood if we consider that life expectancy for white men aged 45 in the United States increased by only 3.6 years from 1900 to 1973. It should be noted that four of the seven health promoting behaviors are related to nutrition.

Quite another pattern of behavior is evident when we look at arteriosclerosis, the most important cause of death of Americans. Coronary artery disease, the most important killer in the United States, is associated with a number of risk factors related to life style. Coronary artery disease is commonly associated with a sedentary life style, a high fat diet, cigarette smoking, high blood pressure and emotional stress. The recent Framingham studies demonstrated that relative or absolute hypercholesterolemia is the single most important risk factor for the development of myocardial infarction in man. A plasma cholesterol concentration of 250 and 350 milligram percent, for example, was found to carry a two-fold to five-fold greater risk of coronary disease than did a cholesterol level of below 220 milligrams percent.

The factors in our modern industrial society that contribute to the high morbidity and mortality from coronary artery disease have been vividly described by Backburn:

> Modern man in industrial society is an animal which, shortly after maturation, is confined to a system of special cages, in one of which, a mobile steel and plastic cage, he is exposed for one or two hours daily to complex decisions, frustration and danger, in an atmosphere high in carbon monoxide, while transported to and from other cages. In other cages, under constant temperature environments, the animal's physical activity is strictly constrained to many hours of sitting and a few moments daily of standing, with short, level walks, all of very low energy expenditure. The industrialized species of man is habitually overfed with animal and grain chow which usually include 20 percent of all calories from saturated fats, 20 percent from refined carbohydrates, and 10 percent from fermented spirits, plus varying concentrations of herbicides, pesticides, hormones, antibiotics, oxidizing agents, and radioactive isotopes. Man is systematically conditioned to self-administer 20 potent doses of nicotine, and five of caffeine alkaloids

daily. He is also trained to lie motionless in a darkened cage for three hours and watch a cathode ray tube which continuously presents ambiguous information and repeated suggestions for unhygienic, purposeless activity. He is rewarded to the degree that he pursues this goal-less activity during the day.

Exposed to such an environment for half his life span, nearly all the animals develop largely irreparable lesions in the vascular system, and about half of the male animals experience severe damage to cardiac muscle. If the animal survives the dramatic onset of acute arterial insufficiency to the heart, it is returned as soon as possible to the same cages and systems.

Physicians and patients are generally aware of the risk factors in heart disease and particularly the importance of life style and stress in relation to coronary artery disease. Insufficient attention, however, has been paid to nutritional factors, particularly the role of saturated fats. Americans consume about 40 percent of their calories as fat. Diets containing this much fat in animals impair the capacity of tissues to convert saturated to unsaturated fatty acids because the desaturating enzymes are repressed under these conditions.

Recent studies have demonstrated the role of polyunsaturated fats in lowering and of saturated fats in raising serum cholesterol. In contrast to the marked effect of saturated and unsaturated fatty acids on serum cholesterol levels, numerous studies have now demonstrated that dietary cholesterol alone has a relatively small effect on the concentration of cholesterol in the blood.

What does this have to do with myocardial infarction? Studies in Finland have demonstrated that patients who were transferred from saturated fat to polyunsaturated fat diets had less than half the incidence of myocardial infarctions as did those on saturated fats. The Diet Heart Study of the National Heart and Lung Institute indicates that polyunsaturated fat diets are practical and effective in lowering cholesterol in man.

Coronary artery disease and myocardial infarction are not the only problems associated with overnutrition. Current estimates indicate that one-fourth to one-third of the American adult population and ten percent of American children are obese. Nutrition is only one of the factors in the etiology of obesity; others include genetic factors, socioeconomic status, cultural patterns, stress and physical activity.

Recent studies have demonstrated the importance of obesity in infancy and childhood as a determinant of adult obesity. Both the number of fat cells (adipocytes) and the size of these cells determine the fat content of the body. The number of adipocytes stabilizes relatively early in life, certainly before adulthood. The number of adipocytes increases in obese infants compared to those of normal weight. It is too early to determine how effectively this knowledge can be applied in the prevention of obesity.

Undernutrition, as well as overnutrition, causes serious health problems. Early protein-calorie undernutrition in children can result in a decreased number of brain cells, reduced myelination and other biochemical changes which may be permanent. Mental function and behavior may be modified as a result of these changes. Nutritional deficiencies during pregnancy and lactation can also permanently affect the development of the brain. How widespread this problem is in the United States is currently a matter of dispute. The consequences are so serious, however, that we should have as a matter of the highest priority the prevention of malnutrition in pregnancy, infancy and childhood.

A number of diseases that are not the direct cause of death but contribute significantly to mortality, morbidity and disability, such as hypertension, alcoholism, and diabetes mellitus are related to what we eat. Intestinal cancer is also related to what we eat. Cancer of the colon and rectum will strike about 100,000 Americans this year and almost 50,000 will die from the disease. More people in the United States will develop cancer of the colon and rectum than any other cancer except non-melanoma skin cancers. Possible dietary factors include the role of highly processed foods in relation to slower transit time and increased exposure of the intestinal tract to carcinogens, the relationship between the amount of meat eaten and cancer of the colon and the relation to lack of fiber in the diets of countries where colon cancer is prevalent and the high fiber content of diets where it is uncommon.

Gastric cancer, like cancer of the colon, varies widely from one country to another. In Japan the mortality rate is considerably higher than in the United States. Japanese who move to the United States experience a slight decline and their children a very significant decline in gastric cancer. Gastric cancer appears to be more common in people who consume a good deal of smoked fish, pickled vegetables and dry salted fish.

We have much to learn about the relationship of diet and gastrointestinal cancer, but the evidence is sufficient to warrant careful and detailed epidemiological studies.

The role of nutrition as a determinant of health status is broad and complex and inadequately researched. To stay alive, man requires food as a source of energy and essential nutrients. If a person lacks sufficient calories, he is hungry. If he lacks one or more of the essential nutrients, he is malnourished. Carried to an extreme, either hunger or deficiency of essential nutrients is fatal. In milder, chronic forms, both of these conditions are common in the United States.

The era of narrow interpretation of the role of nutrition solely in terms of meeting essential nutrient requirements is past. The science of nutrition is concerned with the effects of food intake on the internal ecology of the organism and the external manifestation of well-being. Deficiencies, excesses, or imbalances of nutrients affect the system adversely at many points with far reaching consequences. When the classical definition of nutrition is expanded to include vulnerability to malnutrition of all kinds - excesses, imbalances, and deficiences - as well as vulnerability of individuals and groups for whom physiological and social factors predispose to nutritional problems, then a framework for identifying groups in greatest need for assistance has been established:

> We are concerned about overnourished and malnourished adult Americans who eat a diet high in fats, refined carbohydrates, salt, and calories. We know that too much fat leads to diseases of the heart, our number one killer. We know that too much salt is related to hypertension, a precursor of cerebrovascular accidents, which kills 10% of all Americans. We know that refined carbohydrates, particularly sugar, are implicated in dental caries, the most prevalent chronic disease, and one which produces profound dietary difficulties in later life with the loss of teeth. We know that a high calorie diet causes obesity, a problem suffered by many adult Americans, and one that carries life threatening consequences.
>
> We are concerned about undernourished and malnourished poor Americans because they lack sufficient funds to purchase foods supplying a consistently adequate diet and suffer highly disproportionate rates of malnourishment and disease.
>
> We are concerned about malnourished pregnant women who suffer from anemia, toxemia, have a greater rate of fetal accidents, and produce a disproportionate number of low birth weight babies. "It has been fairly well established that the nutritional status of the mother at the time of conception is as important for the outcome of pregnancy as is the diet during the period of gestation." Maternal

nutrition programs must emphasize interconceptual nutrition and develop long term food habits that result in adequate nutrition before, during and in between pregnancies.

We are concerned about low birth weight babies. The causal relationship between poor maternal nutrition and high infant mortality is unclear but the relationship of high infant mortality with low income and minority status suggests an association. More clearcut is the relationship between low birth weight babies and maternal nutrition.

The United States is trailing behind fourteen other nations in the prevention of infant mortality. Analysts at the National Institute of Child Health and Human Development are convinced that a key reason for our dismal showing in this area is our high incidence of low birth weight infants--babies who are born too soon, or too small, to cope with the demands of life outside the womb. Of the more than 3 million children born in the United States each year, 7.6 per cent, or about 240 thousand, will weigh less than 5 and a half pounds at birth. More than 40 thousand of these low birth weight infants will die in their first month of life, thereby contributing 70 per cent of the 53 thousand infant deaths which occur annually. And the 200 thousand low birth weight babies who survive beyond infancy will suffer a disproportionate incidence of handicaps in later life.

Not surprisingly, the women who are most at risk of giving birth to small babies are the very young, the poor, and the black--the same women who have always had the greatest difficulty in obtaining adequate medical, emotional, and economic support during their pregnancies. Of the more than 600 thousand infants born to teenage mothers each year, about 61 thousand or 10 percent, will be of low birth weight. Of the more than 500 thousand infants born to black mothers each year, about 75 thousand, or 13 percent, will be of low birth weight. And of the 171 thousand infants born to black teenage mothers, about 25 thousand, or <u>15 percent</u>, will be of low birth weight!

Obviously, the infants born in these categories are likely to have more than enough disadvantages imposed on them by the larger society; they do not need the additional handicap of low birth weight threatening them at the very outset of their lives. If we are to reduce the incidence of low birth weight, nutritional intervention programs aimed at

high-risk mothers must become part of our system of prenatal care. Research funded by the National Institute of Child Health and Human Development indicates that there is a definite connection between maternal malnutrition and low birth weight.

Several studies have shown that careful nutritional guidance and supplementation can improve the outcome of pregnancy for women who are most at risk of delivering low birth weight infants. One study sponsored by the NICHD showed that daily food supplements had a favorable effect on the birth weight of infants born to two categories of high-risk mothers in Harlem--women who smoked and women of less than 110 pounds prepregnant weight. A Canadian study showed that when nutritional counseling and food supplements were given to pregnant out-patients at a public hospital, their odds of delivering low birth weight babies dropped to equal those of more affluent women attending private hospitals. Similarly, a recent study involving pregnant teenagers in the United States showed that a careful program of prenatal care and nutritional guidance, aimed at ensuring that each patient continued gaining weight at an appropriate rate throughout her pregnancy, was sufficient to reduce the incidence of low birth weight from 18 per cent to 0 per cent.

Given the present rate of death and disability among infants born in this country, it seems that we can hardly afford to ignore any reasonable opportunity for prevention. And nutritional programs aimed at pregnant women represent more than an opportunity; they represent a national obligation to the youngest and most vulnerable members of our society.

Livingston, Calloway, et. al. in their study U.S. Poverty Impact on Brain Development developed estimates of a "level of nutritional intake at which human brain development is in unambiguous jeopardy." Applying this conservative criteria to data from the earlier nutrition surveys, the authors state that "nearly sixty percent of all women living below poverty in the United States are evidently consuming calories at such a low level that brain development in their unborn children will likely be deficient. ...Of children between the ages of one and four years, the surveys show that from 18 to 24 percent are in jeopardy for brain development..." The fraction of undernourished children in both surveys decreases significantly when the group below poverty is compared with either of the other two income levels.

We are concerned about poorly nourished children because they fail to learn in school, fail to develop to their

potential, suffer from anemia and dental caries, resist infection poorly, and lay the pattern for later adult chronic disease.

We are concerned about malnourished elderly Americans because they are more vulnerable to acute and chronic disease, suffer from debilitation, chronic brain syndrome, anemia, obesity, osteoporosis, and ematiation.

We are concerned about other Americans who suffer from alcoholism, a disease that may begin and end in malnourishment.

The chronic conditions that afflict and eventually kill most Americans have profound relationships to nutritional status. Our individual nutritional status has a direct relationship to how well our brains and bodies develop, our ability to cope with infection, our physical and mental stamina and performance, and our success in preventing or limiting chronic disease.

U.S. Nutritional Status--What We Have Learned From Surveys

Since the recognition of widespread hunger and malnutrition in this country in the mid-1960s, several national studies have documented the seriousness and extent of the problem. I speak specifically of the Ten State Nutrition Survey, the Study of Nutritional Status of Pre-School Children, and the Health and Nutrition Examination Survey. The more noteworthy findings include:

(1) Malnutrition is directly related to low-income and minority status.

(2) Adolescents and the elderly show markedly high rates of nutritional deficiencies.

(3) Among the poor, the problem is more one of lack of sufficient quantity of food than of nutritional quality.

(4) Low hemoglobin and substandard iron intakes are widespread and correlate strongly with low socio-economic and minority status. The HANES states that about 95 percent of the preschool children and childbearing women studied exhibited substandard iron intakes.

(5) A large proportion of Americans have calcium intakes below standards. Particularly vulnerable groups include the poor, minority peoples, women of childbearing age, and the elderly.

(6) A substantial proportion of Americans have substandard intakes of vitamin A, vitamin C, riboflavin and calories.

(7) Obesity is most prevalent among adult women in lower socio-economic groups, particularly black women. In some groups more than 50 percent of the adult women are obese.

What Americans Eat

A clue to the etiology of the chronic disease burden of the United States lies in what we eat. The USDA Household Consumption Survey found that half of the households studied had diets that failed to meet the Recommended Dietary Allowance for one or more nutrients. Calcium, vitamin A, and vitamin C were the nutrients most often below the allowances.

Even more important is the dramatic change in the average intake patterns for Americans during this century. We eat fewer fresh vegetables and fruits, fewer whole grains, cereals, and dried legumes than did our ancestors. We eat more protein, fat (43% of our total calories), sugar and sweeteners (125 pounds per American annually), and salt (about 10 times what the body requires daily). Over 50 percent of our total intake is in processed foods. Over one-third of our meals are eaten outside of the home, based on convenience foods or on automated methods of quantity cooking. Manufacturers added over 1 billion pounds of additives to our food last year. Per capita consumption of meat totaled approximately 180 pounds in 1975; chicken was about 40.5 pounds, milk about 543 pounds (252 quarts). We ate 276 eggs per person last year. What this all adds up to is a diet high in meat, fat, refined sugar, additives and calories. It is low in several essential nutrients and low in fiber.

Recommendations for the Select Committee

What should be the concerns of the Select Committee on Nutrition and Human Needs in relation to the evidence indicating the importance of proper nutrition in human health and of under-nutrition, over-nutrition and malnutrition in relation to the present burden of disease in America?

As a matter of first priority I believe the committee should thoroughly explore the relationship of nutrition during pregnancy and early life to the later health and performance of the individual. This inquiry should consider the impact of undernutrition on brain development and behavior as well as the relationship of overnutrition in infancy and childhood to the subsequent development of obesity.

The relationship of diet to cancers of the gastro-intestinal tract needs to be thoroughly explored and the American people fully informed of your findings. Is the suggestive evidence about the high meat content of our diet and cancer of the colon significant? Is the problem too much meat and fat or not enough fiber? What about the role of diet in other intestinal cancers?

The relationship of nutritional status in coronary artery disease, diabetes mellitus, osteoporosis, and hypertension needs to be explored fully.

The problems of obesity, its importance in relation to health and its role as a factor in many chronic diseases should be explored.

This committee has played a vital role in informing the American public about the problems of undernutrition and malnutrition, particularly among the poor. It has also played the key role in affecting the policies of the U.S. Government in dealing with other problems. That job is not done, but we have made substantial progress in the past decade. The task ahead, however, will be even more difficult because it affects all Americans and the way they eat.

While these studies are underway by the Committee there are other actions that should also be considered.

Recommendations Related to Federal Programs

(1) The Federal government should adopt a continuing surveillance of the nutritional status of Americans. Monitoring should include identification and assessment of nutritional problems, their extent and location. Trends of American eating habits should be monitored and researched for their long term health consequences. The American public must be more fully informed about the health hazards of chronic malnourishment. Congress and State legislatures must be informed about effective points of intervention to formulate appropriate legislation. State and local health departments should be provided the information in a form that is useful at the State and local level.

(2) A hard look at the Federal government's food assistance programs is in order. Some observers suggest that only half of the Americans eligible for food stamps actually receive them. Other critics state that various administrative policies--hours of operation, inconvenient location, payment-for value-received formula--act as disincentives for participation by those people in greatest reed. The bulk of the evidence suggests that poor Americans are wise consumers, purchasing a high nutrient per calorie diet. But they require financial assistance in supplying a consistently adequate diet to their families.

(3) Higher priority must be given to nutrition services in health care. Nutrition education and dietary counseling by nutritionists and dietitians should be reimbursable under Medicaid, Medicare, and private health insurance. Nutritionists and dietitians must participate in community health programs, in health planning through the Health System Agencies and in health care in group practices, Health Maintenance Organizations, hospitals and other health care institutions.

(4) Research should be supported in the behavioral or lifestyle components of diet selection, and how to influence these important health determinants. Biomedical research on the relationship of nutrition to optimal health status, as well as the prevention and treatment of dietary related disease, must be expanded. Of particular concern is the relationship of dietary fat to elevated blood lipids and cardiovascular disease and the relationship of diet to intestinal cancer.

(5) Activities in researching and monitoring food additives should be upgraded. We have doubts about the safety and wholesomeness of our food. What happends to the nutrient value of food when agricultural practices change, when food is processed, packaged, transported, and stored? What are the long term health consequences of eating food altered by preservatives, coloring agents, emulsifiers, fortifiers, stabilizers, flavors, hormones, pesticides, ripeners, and other additives?

Finally, the Federal government must begin an active national campaign of nutrition education in cooperation with state and local health departments, voluntary agencies, health care institutions and the health professions. The work of the Select Committee can trigger such a sustained national effort.

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A. Major gaps in human nutrition

1. Requirements of man for many of the 40 - some odd nutrients for which he has a dietary need are not well defined at any age group. Determination of requirements are sorely needed, particularly, for the infant, the young child, the young adolescent, the elderly and the pregnant female.

2. Almost untouched is the area of nutrient interrelationships. For example, only recently has it been recognized that level of protein intake has a profound effect on calcium requirement. That is, the higher the protein intake, the higher the calcium requirement. There must be many other nutrient interrelationships that need to be uncovered.

3. I think some effort must be given to trying to find the best proportion of calories from carbohydrate protein and fat. The average person strongly believes [illegible]rtly because of "information" from the media of television and radio and the newspaper, that man consumes too many of his calories in the form of carbohydrate and of fat. I am convinced he often consumes too many in the form of protein! And since most of calories must come from these three sources, someone has to be wrong. Along the same line more attention must be given to the real deficiency in protein-calorie malnutrition. Calories are often deficient, and this may be because of the very low fat intake! For example it has often been observed that fat supplies only 10 percent of the calories of children in developing countries. Perhaps it might be well to remember that fat furnishes over 50 percent of the calories of human milk; protein accounts for only 7 percent of the calories! Has too much emphasis been placed on the belief that the world has a short supply of protein?

4. Nutrient requirements of man for trace elements are largely unknown.

5. Fiber is being indiscriminately added to foods by food companies. We must know if large amounts of dietary fiber are good or bad. What is the long term effect of what may be a chronic excess?

B. Efforts of Federal agencies to fill these gaps have been varied. In general, efforts have been only fair.

C. All of the research areas mentioned in A above have not received sufficient funding. Research in human nutrition is expensive. This fact must be properly recognized. Answers to these problems must come from studies done on human subjects under controlled dietary and experimental conditions. It is commonly believed by many scientists , many of whom review and evaluate research proposals concerning human nutrition, that strict dietary studies cannot be carried out on human subjects unless they are confined, like animals, to a strict location because they will not adhere to the dietary and other experimental conditions. This belief is utter nonsense.

Subjects can be free to live in their ordinary places of residence and to follow their ordinary schedules if they are properly instructed and motivated by investigators skilled in working with human subjects. It should also be realized that any competent investigator has a number of ways to check whether or not the diet has been followed by the individual subjects.

1 & 2. It is difficult for me to rank the gaps given in the first part of this letter; all are important and all need attention.

3. Perhaps the real answer is that there are too few people who are willing and capable of working with human subjects. Also as I explained earlier many good research proposals concerning human research have been turned down because the review board, composed mainly of men, did not believe the work could be done.

4. This has been covered.

5. Studies in human nutrition research are more expensive than studies using animal models.

January 10, 1977

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Thank you for your letter of October 5. I will attempt to provide you with the information you have requested. This is based on some of my own convictions and does not represent a collective response from faculty at Cornell. I will first try to respond to the questions on page 2 of your letter.

1. Major human nutrition research gaps.

a. There is a major need for increased research effort relative to human nutrition requirements. The data on which estimates are based for human needs for many nutrients are limited and greater emphasis must be given to a study of human nutrition requirements. Such studies must also address the potential functional significance of sub-optimal nutrient intake. We must become more aware of the consequences to individual health and to society in general of sub-optimal nutrient intake. Does a low intake of iron affect resistance to infection, work performance or learning ability? What are short and long term effects of energy and protein deficiency for children or pregnant mothers in terms of behavioral or educational outcomes? At what stage does a sub-optimal nutrient intake become a significant problem that must be considered in national nutrition and food policy decisions?

Many approaches are necessary to address these questions. Controlled experiments are required with human subjects that can be used to assess nutrient requirements. Epidemiological studies of populations are also required to assess potential relationships between population nutrient intake and human health.

b. The role of nutrition in the etiology of chronic illnesses of our population must be better defined. The dietary recommendations that can be made to minimize the incidence of heart disease, stroke, gastrointestinal disorders, diabetes, and cancer are not known. There is considerable evidence that suggests that dietary factors are involved in the genesis of these diseases but the data required to make intelligent recommendations for dietary modification need to be obtained.

c. Coupled with a better understanding of nutrient requirements, there is a need for better methods of assessing both nutrient intake and nutritional status. Assessment of food and nutrition needs of population groups requires that appropriate methods are available to carry out that assessment.

d. Variations in food composition and nutrient availability that occur in various food delivery systems should be investigated. The changes in the nutritional quality of the food supply must be assessed from farm to the consumer in an effort to assess the consequences of various food distribution systems that have developed in the U.S. over the past 25 years. Food is the vehicle for nutrients and the nutritional quality must be assured and should be considered as agronomic practices are developed.

e. Methodology for testing food additives and food contaminents for safety must be improved. The use of various additives to food is important to maintaining quality and attractiveness of food as it is delivered to the consumer in its various forms. Food contaminents are more readily detectible today and may pose threats to the food supply. Methods for assuring safety must be developed that will protect consumers and yet not stifle developments that may improve the quality and availability of foods.

2. Research priorities.

I would rank priorities in human nutrition research in essentially the (a) through (e) listing that I have discussed under 1. These are:

(a) Research on human nutrient requirements, particularly for protein, energy, vitamins, calcium, iron, magnesium and trace elements.

(b) Research on the role of nutrition in chronic disease - cardiovascular disease, gastrointestinal disorder, obesity, cancer.

(c) Methods for monitoring and assessing population nutritional status.

(d) Factors influencing food composition and nutrient availability.

(e) Food safety testing.

Associated with these categories of research needed, support for basic research in all these areas is essential. The assessment of protein requirements needs a thorough understanding of basic aspects of protein digestion, absorption, body protein synthesis, turnover, amino acid metabolism and nitrogen excretion. A basic understanding of these factors provides information on which to base criteria for optimal protein nutrition. Similar examples could be given for other areas.

3. Areas of priority needs not receiving sufficient Federal support.

The research under 2(a), (c) and (d) are probably receiving the least emphasis in research funding by the Federal Government. The USDA has been the major source of funds for research in these categories. The amount of nutrition research funds available through USDA has been extremely small. NIH spent nearly $45 million on nutrition or nutrition related research through its extramural program in FY 75. The USDA made available about $750,000 for competitive grants for the same fiscal year for food and nutrition research. The cost of determining human requirements is great and USDA has not had resources to support this area of research nearly at the level required.

Health or specific disease related research has received greater emphasis through NIH but only recently has NIH become aware of the potential relationships between nutrition and health. The research in 2(b) above is supported primarily by NIH and is receiving proportionally more emphasis than items that have normally been the responsibility of USDA.

4. As indicated in 2 above, the priority research areas need to have a component of both basic and applied research. Human nutrient requirements have a very practical application but a basic research approach is needed to determine methods for estimating human nutrient requirements and to determine appropriate criteria for nutritional adequacy.

5. I believe there must be Federal coordination of nutrition research activities among agencies of the Federal Government. The assignment of various components of nutrition research support to different agencies makes it likely that certain important areas of nutrition research may not receive the emphasis that is required. This is due to varying commitments of the agencies involved to the problem as well as different levels of Federal funding available to the agencies involved.

Some methods for coordinating the role of the Federal Government in food and nutrition research should be found. The examples cited above as to different levels of funding in USDA and NIH are illustrations of the problem encountered.

Although your letter indicated that aspects of nutrition education were not being considered in your study, I believe that research of nutritional needs of human beings must be translated into dietary practices. I believe that support for research in methodology of nutrition education is also important.

I am sure you are aware of numerous other studies that have been underway during the past year that have dealt with nutrition research priorities and issues. Study Team 9 of the National Academy of Sciences has discussed issues in an international context that are in many cases equally applicable to domestic problems. A group of nutritionists under sponsorship of CAST (Council for Agricultural Science and Technology) sent a report to Max Milner in OTA that dealt with some of the issues you raise. I have also reviewed an NIH nutrition plan which speaks to some of these issues. I hope, after all of this activity some viable unified Federal nutrition research policy is forthcoming.

October 28, 1976

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Nutrition is the sum of the processes by which an animal procures, ingests, digests, absorbs, utilizes and excretes food substances. Basic research in nutrition, therefore, is an interdisciplinary area of research since it may take physiologists, biochemists, microbiologists, pathologists, etc. to solve a nutritional problem. Some of the major nutritional problems are not only nutritional but include as part of the problem components such as exercise, learned behavior, and other environmental components affecting nutritional status. For these reasons I think the best approach to solving nutritional problems would be to establish Regional Nutrition Research Centers where "core" support is provided by the Federal Government. These centers should include both basic and applied research; both human and animal nutrition research.

Research in the United States has solved many problems and yet there are problems that have been researched for many years that have not yet been solved. It is fallacious to believe that all research should be applied--or that all research should be directed toward solving problems in human nutrition. The life sciences are coming closer together and now more than ever before the elucidation of nutritional problems in animals will result in its application to humans. Therefore, there will be a double pay-off for nutrition research done in companion animals (dog, cat, horse); zoo animals (more exotic animals like carnivorous snakes, Kawala bear, etc.) as well as farm animals. Experience has shown that the next knowledge to be applied to the human situation may come from what may seem the most exotic research.

Since I believe the above I think that research needs to be carried out on all aspects of the components of the definition of nutrition (procure, ingest, etc.). I think the very first step has been grossly neglected. The nutrients cannot be utilized unless they are ingested. What factors are involved in the voluntary ingestion of an adequate diet? If we knew <u>how</u> the animal (including humans) selects his food, we could devise regulations for fortification, processing, etc. that would take this information into account. For example, if it were known that all animals exhibited a specific hunger for each essential amino acid, then we would not have to worry about every protein being well balanced--only that the choices available were sufficiently broad and feasibly purchasable (economically) so that the population as a whole whould have an adequate choice and thereby receive an adequate supply of all essential amino acids (via proteins.) On the other hand,

it is probable that there are several trace minerals which provide no signal for a specific hunger, and therefore provide no drive for their ingestion. If this information were known then certain processing (which removes the nutrients from our food) and/or fortification procedures could be instituted such that adequate intake of all nutrients for our population is assured. Therefore, vigorous research programs should be supported to elucidate the mechanism involved in the control of food intake and dietary choice. A second problem this would have an impact upon would be the problem of obesity. The reason should be self evident.

Below I will give a few comments directly to the five questions asked:

1. Human Nutrition Knowledge Gaps

   a. Effect of Nutritional Adequacy on Food Selection and Amount of Food Eaten.

   b. Nutritional Component and Effect on Such Diseases as:

      --Cancer
      --Atherosclerosis (CHD)
      --Hyperkinesis
      --Arthritis

   c. Quantitative Requirements for Many Nutrients (especially certain trace minerals). (For Man, but also for cats, dogs and other animals.)

2. Priorities.

   a. The highest priorities should go to basic research that can be identified as being important in providing information relating to the above nutritional problems but especially toward understanding the voluntary choices people make for food that are adequate and inadequate nutritionally.

   b. Atherosclerosis

   c. Arthritis, cancer and other diseases

3. a. The problem described in 2a is receiving very little support.

   b. Atherosclerosis may be currently supported at an adequate level.

   c. Other diseases and interactions have received very little support.

4. See above in introduction.

5. The biggest problem in nutrition research is that it always plays second class to other problems because of the organizational structure. I think there should be a separate Nutrition Institute in the National Institutes of Health--then if it were adequately funded nutrition research could be monitored, encouraged, etc. in a positive way. This would also provide visibility needed for the gathering of public support for the needed program.

Food faddism is a continual threat to the nutrition and health of the American people. It permeates all levels of our society. Much of it is harmless and yet some food faddism has resulted in inadequate nutrition for certain segments of our population. There should be an active part of the nutrition support directed toward education of the American people for their protection and for the protection of the research nutritionist.

There have been problems during the past two or three decades getting enough research funds to do first-class research. For example, molecular biology has been in the limelight and has been very successful. If success is expected in the future for nutritional research, then adequate support will be required for more automation in food intake systems, clinical laboratory analyses, computer modeling, etc.

October 27, 1976

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It is difficult to identify the most important areas where knowledge of human nutrition is lacking. This is because the field is extremely broad, and our understanding of many aspects of human nutrition is limited.

In the past, there has been a considerable expenditure of time and energy on the identification of nutritional requirements of plants and animal species other than man. The effort to identify human nutrient requirements, and the relationship of nutritional status to human health, has been less. There appear to be a number of reasons for this emphasis. They included the very practical matter of assuring an adequate food supply in the present and future. A second reason is the breadth of the subject and difficulties which have been encountered by those who have attempted to define where the emphasis should be placed in studies of human nutrition. A third reason has been the difficulty encountered by those who have attempted to define the cost/benefit of research on human nutrition. A fourth reason has been the limited number of trained investigators. A fifth reason appears to be a relative lack of interest in human nutrition as a subject area for clinical investigation and basic research among policy makers at the NIH and USDA. Funds have been channeled into other "more attractive" and possibly less controversial areas. A sixth reason has been a lack of understanding on the part of the Congress of the impact of malnutrition on the community and society; the apparent disbelief that we have important nutrition problems in the United States; and a belief that any problems we might have can be solved simply by food stamps or giving out food. There seems to be a naive opinion that it is not necessary to understand the causes and effects of malnutrition on individuals in order to prevent it.

Knowledge of the role of nutrition in achievement of the human genetic potential is limited. This includes the role of nutrition in mental development, growth, reproduction, and resistance to disease, including both infectious and degenerative diseases. Our understanding of the optimal levels of nutrients in the diet and the effects of deficiencies or excess in humans is distressingly limited. Even more limited is knowledge of the interactions among nutrients and nonnutrients in the diet, and among nutrients and drugs. Thus, you can see it is difficult to pinpoint a specific area where we have a major lack of knowledge.

I am inclined to believe that major emphasis should be placed on the identification of human nutrient requirements under various physiological and disease conditions. As more is learned regarding requirements under various conditions, knowledge will be derived which pertains to the role of nutrition in the achievement of genetic potential. An understanding will also be gained of the interactions among nutrients and nutrients with non-nutrients, such as dietary fiber, as well as drugs.

With regard to Federal funding of nutrition, I believe funding has not been adequate in the past. The hearings of the McGovern Committee tend to support my impression. Possible reasons for the lack of support have been indicated above. It is my understanding that the U.S. Department of Agriculture, Agricultural Research Service has asked for substantial increases in funding for human nutrition research, beginning in 1978. If you need more specific information regarding plans and proposals of the Agricultural Research Service, I suggest that you contact Dr. Jack Iacono of the National Program Staff of the Agricultural Research Service in Washington. I have no knowledge of the plans of FDA and NIH.

With regard to the types of research which are needed, I believe there should be a considerably increased effort placed on studies utilizing human volunteers to more precisely define human requirements. In addition, there should be an increased expenditure of effort utilizing experimental animal models, particularly primates. Such experiments would be extremely useful in the definition of interactions among nutrients, nutrients and drugs, and nutrients and non-nutrients. Studies of interactions should also be done on humans, where appropriate. To carry out research on human volunteers, available clinical research facilities and new clinical research units might have a portion of their activity dedicated to studies relating to nutritional topics. This could be accomplished, both within the Federal establishment and through program project grants to medical schools.

I support the statement of the McGovern Committee regarding a national nutrition policy. I believe suggestions are made in that statement which, if implemented, would significantly improve nutrition research in the United States. At present, there is a lack of focus. Research is underway in a variety of institutions, but there is relatively little coordination or communication among the research groups. Some have proposed that a National Nutrition Institute be established, under which all nutritionally related activities of the government would be centered, and from which grants would be provided to investigators at universities. An alternative is a central planning and coordinating office which would oversee the nutrition related activities of various government agencies and would provide guidance regarding

funding of research proposals. It seems to me that without some sort of focal point, dissemination of necessary research funds and a coordination of research will continue to be difficult. I believe the experiences of the National Cancer Institute and National Heart Lung Institute illustrate the benefits of having a strong focal point for attack on a particular subject area. I would support such an approach for human nutrition.

December 13, 1976

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MAJOR NUTRITION KNOWLEDGE GAPS: LISTED ON BASIS OF NEED AND PRIORITY

1. Anemia - borderline to severe in the U.S. population raises numerous issues

   (1) Why the high prevalence of suboptimal hemoglobins and serum Iron values in adolescent males and females, pregnant and lactating females? (2) What is the health implication and cost in hematinics as well as possible lowered productivity? (3) What is the most effective and economical method of prevention? Could this be accomplished by improved cereal enrichment? (4) Should cereal enrichment also include (besides a biological available iron) folic acid, Vitamin B_{12}, Vitamin B_6 and trace minerals, i.e., copper, zinc, chromium? (5) Food sources of the above nutrients in foods and meal dishes as served (this will be discussed under Food Analysis). (6) Elucidation and definition of iron needs and the prevalence and seriousness of iron toxicity.

2. What is the health cost of our ignoring the obesity problem until it becomes "after the fact"?

   (1) Assess the health benefit-cost effectiveness of optimizing physical fitness - non-obesity in early life. Need a long-term Framingham type of study early with teenagers or even younger to assess health benefits - reduced medical care costs possibly resulting from a greatly reduced incidence of obesity related diseases - diabetes, cardiovascular disease, renal, liver, etc.

3. GAPS IN OUR KNOWLEDGE ON TRACE MINERALS

   essertial vs. toxic minerals

   essential vs. toxic levels of trace minerals

   Gaps in the fact there is a lack of knowledge reference interrelationships of the many trace minerals (example: Se, As, Hg, or Co, Cu, Mo).

4. Nutritional requirements of aging. This is an unknown field. Gap exists as to the reduced - (how low) - caloric requirement and the possible need of a greatly improved nutritional quality of the diet.

5. Simple nutrition assessment tests to signal nutritional health risk at early stages.

6. Serious gaps exist in the nutrient composition of foods, and meal dishes after processing and at time of consumption. Analysis needs great expansion over the current archaic simple list of 7 to 9 food nutrients. Such analysis data needs continued up-dating as new products are marketed. List should contain the following besides the usual analysis: Vitamin B_6, Folic Acid, Vitamin B_{12}, Vitamin E, Pantothenic Acid, minerals - sodium, chloride, potassium, iodine, zinc, magnesium, manganese, chromium, selenium, as well as levels of non essential lead, mercury, etc.

7. Interrelationships to Cancer

   (1) Role of fiber

   (2) Role of saturated fat $\pm$ cancer production.

   (3) Can trace minerals be involved

   (4) Are aflatoxin - or type products in our food supply? What is the risk level?

   (5) Are there foods that provide protection or inducement of gastrointestinal cancer?

8. Diet and Heart Disease

   (1) Is there validity to the cholesterol theory? This is serious.

   (2) Is hyperlipidemia a precipitating cause of heart disease?

   (3) Do drastic diet changes result in increased risk of other chronic diseases?

9. In-Born Errors of Metabolism and Nutrients

   (1) Investigation of and levels of special diets for treatment.

10. Interrelationship of Pharmacological Agents - Drugs on Nutrient Requirements

11. Influence of Oral Contraceptives on Nutritional Requirements

AREAS NOT RECEIVING FEDERAL RESEARCH SUPPORT

(A general statement in essence covers nearly all of the priority items):

Anemia Problem

There has not been a focal point in our Federal Government - neither in HEW nor in Agriculture nor in the President's Science Advisory Groups. Nutrition has had no champion. Everyone is apparently a self-made specilist. The Bureaucracy has creamed even well intended legislative mandates and funds for disease prevention--interpreted as "infectious disease" and NOT nutritional disease. The Bureau of the Budget and, in recent years, Manpower and Budget, have historically decided that Nutrition was food and food belonged to Agriculture and they did not need research funds for this area.

In NIH, for example, nearly every Institute lays claim to support of Nutrition. In all honesty, they do admit it is indeed a hap-hazard, come-as-may - if we have excess money approach.

Reference: See "Report to the Surgeon General on the Mission and Functions of the Public Health Service related to Food Hazards" May 1966 - Chairman: John D. Faulkner.

Since I served on this committee from inception to end - April 16, 1965 - May 23, 1966, I recommend its frankness and critical review of the field. I have enclosed the letter of transmittal and a copy of the recommendations (pages 18-28). (See GAO note.)

The people have changed, the problems still exist and basically these recommendations are still valid. Further, I urge you to consider Chapter 1 of the White House Conference on Food, Nutrition and Health, December 1969.

November 16, 1976

GAO note: Material not included in this report.

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This will acknowledge your letter of October 14 which presents an important opportunity. I wish I could answer in the detail and length that the questions deserve but as I am about to leave on another foreign trip I simply cannot.

I would, however, like to stress again the importance of support of clinical research both to determine normal nutritional needs and the acute and chronic effects of dietary deficiencies and excesses, as well as nutritional disorders secondary to other disease.

This implies not only the need for greatly increased support of such research in human subjects and patients but also support for the training of physicians in nutrition metabolism so that they are qualified to do such research as well as teach clinical nutrition to physicians. As you well know, physicians currently receive little or no training in nutrition and are often as woefully ignorant or misinformed as laymen on nutritional matters. Most of the persons doing nutrition research in the country today, including most of the physicians so engaged, are working with experimental animals. This is cheaper, quicker to produce publishable results, and far easier, but increasingly less relevant to problems of human nutrition as the same ground is being ploughed over and over with minor variations. Yet for a variety of reasons support for this type of nutrition research predominates within NIH and there is no other major funding source, governmental or non-governmental, for work of the type required in human subjects.

At one time the Hartford Foundation was venturing into this area but its greatly reduced financial resources have largely ended their involvement.

You ask 1) Major gaps in nutrition knowledge: here there is a desperate need for better knowledge of human nutritional requirements in health and disease, the relationship of diet to chronic degenerative diseases, and the effect of diet during the early years on subsequent patterns of morbidity, mortality, and performance. 2) Efforts of Federal agencies to fill these gaps: USDA which claims responsibility for research in normal human nutrition should either be given the funds to support extramural research in this area on a scale comparable to that of NIH for nutritional disease or the responsibility for such research should be assigned to NIH

or some other designated agency with adequate provision for funding. The same can be said for research on the nutritional value of foods, the effect of food toxicology, and the effects of food processing on nutritional value and safety. Responsibility for extramural support of research in these areas should either be clearly assigned to USDA with line budget provisions or to FDA or to some other specifically designated Federal agency. In addition the role of NSF in supporting innovative research to develop new sources of food along the lines suggested in the M.I.T. Protein Resources Study should be clearly designated and supported (NSF-RA-T-75-037). Food development efforts sharply competitive with conventional agriculture are unlikely ever to be appropriately supported by USDA and this is an appropriate role for NSF. 3) Research areas which may receive insufficient attention and funding: this is covered by the above comments. 4) Organizational, legislative or other changes needed to facilitate research to fill the major gaps: a) a line budget item for institutional training grants and/or fellowships for the training of physicians in clinical nutrition and metabolism, b) a line item in the budget of USDA or other appropriate agency for extramural research on normal human nutritional requirements and the nutritional value and safety of the foods available in the United States today, c) identification of the appropriate role for NSF in supporting research on protein and other food resources and technology and specific budgetary provision to enable them to fulfill this role, d) recognize that NASA, ERDA, FDA, DOD and other Federal departments and agencies have limited and specialized but important contributions to make to the support of research concerned with human diets and nutritional problems.

I hope this grossly incomplete response will be of some help to you.

October 27, 1976

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1) What issues should be identified as major human nutrition knowledge gaps? Explain

a) For many of the essential nutrients the mechanisms of biologic activity have not been ascertained or fully elaborated. The extension of such basic scientific knowledge is needed to afford more direct and precise measures of deficiency or excess. Moreover, it is through this information that we come to more complete understanding of why a given vitamin or mineral is required or essential in the diet.

b) There is very limited specific information concerning the nutrient requirements of humans and of the many factors which influence these requirements. As a result, the Recommended Dietary Allowances must be derived from experimentally determined requirements of laboratory animals and the observed nutrient intakes of humans under a variety of conditions of diet and of living. Although presently available food or nutrient standards for human diets are not likely to be limiting, they for most nutrients include built-in excesses or margins of safety. As growing world populations call for expansion of food supplies and as obesity increases in prevalence, it might be desirable to reduce the margin of safety, so long as there is a scientific basis for assurance concerning requirement.

Such information is needed also for more ready recognition and evaluation of the effects of other factors on human requirements. I refer to such factors as environment, coexisting disease and medications and their effects on nutrient needs.

c) It would be very helpful to have additional information concerning the many factors which influence and control human appetite and consumption of food. The largest problem of malnutrition in the U.S. today is obesity. For the persons involved, as well as their physicians and nutritionists, there is frustration and discouragement in the search for control of appetite and moderation of food intake.

d) A very large gap in the effectiveness of evaluation of nutrient intake and in modification of diet relates to the incompleteness of tables of food composition. The problems relate to outmoded data derived decades ago, the consumption of an ever increasing number of new food products for which there is little or no information concerning nutrient content, and the relatively limited number of nutrients for which analyses may be readily done and recorded. In addition to the development of expanded tables of food composition, I believe that other research projects concerned with nutrient intake should utilize the analysis of homogenates of mixed foods consumed during 24 hours by subjects or participants. By such means there may be more immediate assessment of nutrient factors such as fiber, vitamin E, etc. which would not be included in food tables.

e) There is need for added effort in evaluating the possible role of nutrient excesses or deficits in the etiology of a variety of commonly occurring and dreaded diseases of mankind, i.e. coronary artery disease, cancer and osteoporosis. A large body of evidence indicates that excesses of dietary fat and cholesterol add greatly to the risk of hypercholesterolemia and myocardial infarction, but totally conclusive evidence is not yet in hand. For this disease and others the effectiveness of the physician in affording advice and prescription for prevention and treatment could be facilitated if remaining questions were removed.

f) New attention has been given to diet and weight gain in pregnancy during the past decade. Concurrently, there has been significant reduction in infant mortality. Yet these rates continue to be higher in the U.S. than in most countries of western Europe. Moreover, low birth rates remain relatively high (i.e. greater than 8 percent) and the proportion of births to teen-aged girls has increased. A gap remains, therefore, in procedures influencing nutritional status and pregnancy outcome in youngest mothers. New knowledge and techniques directed to this problem would have an important influence for further reduction in infant mortality rates.

2) <u>List and rank the foregoing by priority</u>

a) Support of basic research developing further knowledge of mechanisms of nutrient action.

b) Updating tables of food composition and extension of the numbers of foods and nutrients included.

c) Nutritional research pertinent to the etiology, prevention and treatment of certain diseases, especially heart disease, cancer and osteoporosis.

d) Extension of scientific knowledge concerning maternal nutrition and pregnancy outcome, particularly in youngest mothers.

e) Research concerning the physiologic and other determinants of appetite and/or food intake.

f) Studies to enhance our knowledge of the nutrient requirements of humans.

These priorities are derived with the following reasoning. The basic scientific information concerning physiologic roles of nutrients is necessary to and of top priority for maintaining a viable science of nutrition and its use for promotion of human health and treatment of disease. Secondly, assessment of the nutrient content and quality of the human diet is dependent on more extensive and appropriate tables of food composition or the use of other means of determining nutrient intake (i.e. food aliquot analysis).

Following the first two listings are three others which are of great importance to health and disease experience in the U.S. today. The final listing relates to the need for on-going reassessment of the nutrient requirements of mankind.

3) Which of the above are not receiving adequate attention by Federal agencies? Cite possible reasons

The support of basic research dealing with the essential nutrients and their physiologic functions, as well as the role of diet in the etiology and treatment of disease, is the responsibility of the National Institutes of Health. Most of the Institutes have some involvement, but there is little visibility of nutrition research as an area of program emphasis. Some current attention is being given to recognition of the needs for planning and coordination of research support between Institutes through an intramural or staff Nutrition Program Committee. This appears to be a positive action and a first step. But I believe much more could and should be done. One suggestion might be to propose a National Nutrition Commission comparable to the National Diabetes Commission. This would seem to me to offer opportunity for broad recognition of the need for expanded efforts in nutrition research throughout the NIH and permit effectual planning. A new Institute of Nutrition would not be the answer in my view.

Any review of the requirements for expanded programs in nutrition research will demonstrate a shortage of qualified investigators in the field. New programs of post-doctoral research training and research career development awards are needed and could be effectively promulgated by a National Nutrition Commission.

A major problem confronting assessment of human [illegible]utritional status is the division of responsibility between [illegible]partment of Agriculture and the National Institutes of Health. [illegible]s should be carefully reevaluated and new and more definitive program responsibilities be assigned to each group. My own preference would be to give a larger share of these responsibilities to the NIH or the Public Health Service.

Questions 4 and 5 in your list would bring repetition of statements recorded in answering the earlier questions.

November 12, 1976

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1. What issues should be identified as major human nutrition knowledge gaps?

A. Obesity

In spite of exciting new advances in our understanding of energy balance in man and animals we really know remarkably little about human obesity. We suspect that it has a genetic component but no genetic markers have been identified. We suspect that it is a sign, like hypertension or anemia, which signals a variety of underlying disturbances. Yet, classification is very unsatisfactory. We have only crude, but slowly improving, methods of identifying people at greatest risk of developing obesity. We understand little about many mechanisms which predispose obese individuals to a variety of diseases, accidents and anesthetic deaths. The obvious association between obesity and adult-onset diabetes mellitus is still incompletely understood.

B. Atherosclerosis

In spite of the accumulation of a vast literature there are few hard facts which connect nutrition with susceptibility to atherosclerosis. Much of the literature, some of it polemic in nature, is inferential, circumstantial, or merely suggestive. Sucrose, saturated animal fat, cholesterol, have been implicated as contributory factors to atherosclerosis but in no case is there a clear dissociation of the substance under study from the activity patterns of the population under study, or, in some cases, from each other.

C. Cancer

There are studies which indicate that certain kinds of cancer particularly of the breast and womb, occur more frequently in obese than in thin women. Experimental animals which are genetically susceptible to cancer show earlier and faster-growing cancers when they are fed a high fat, low carbohydrate diet. There is a strong suspicion that some of the differences in the incidence of certain cancers which are observed by epidemiologists may be related not only to genetics but also to food habits of large populations.

2. List and rank priorities

See 1.

I rank obesity and atherosclerosis ahead of cancer because the morbidity and premature death associated with these diseases generally occur in younger people than many who develop cancer. Therefore, a calculation would reveal that, together, obesity, atherosclerosis and diabetes involve more lost "person-years" than does cancer.

3. Which . . . are not receiving adequate attention?
I can only answer this question on the basis of the small sample of literature in these fields that I can follow. As an individual investigator, I do not know much about the amounts of money and encouragement the various agencies allot to these problems. There is no way of estimating how many qualified investigators there are who might make useful contributions to the solution of some of these problems. I am not even sure that the bottle neck of progress is lack of money, although, statistically, if there were enough extra money to induce more people to address themselves to these problems, there would be a greater probability of success.

4. What types of research activity are needed?

In spite of the recent scientific information explosion, I believe that we are only at the beginning of our understanding of biologic mechanisms. We really know very little about obesity, atherosclerosis, and the nutritional aspects of cancer. Work should proceed in these areas at all levels from molecular to epidemiologic. Animal models (i.e. of obesity, diabetes, atherosclerosis and cancer) have been useful as vehicles for the conceptualization of problems in man. With the development of new methods, the quality of clinical investigation is improving. I don't think it is feasible at this time to do "targeted" research in the areas I have described because I do not think enough is known to define any but the most remote targets. Generally I consider the sequestration of research support (cancer, heart disease, etc.) a retrogressive step because the more basic the study, the more likely it is that an illuminating idea or method will come from some completely unsuspected source. The NIH peer review system that I have participated in seems to me to be the best way we now have of sorting out ideas and evaluating them. We now have several study sections which deal extensively with applications in the areas I have outlined. Allowing some small margin for error these committees are eminently fair and their collective judgements are sound.

Recent allocation of funds for the establishment of obesity centers and diabetes centers at selected medical schools seems to me to be a good maneuver. Those of us who have been on review committees for such center grants have been impressed by the fact that even the composition of a center grant proposal has resulted in collaborative research among people who discovered that they had interests in common although they had been working in the same medical center for some time.

In summary, I believe that it is impossible to segregate nutritional problems from major problems in pathobiology which are being attacked by investigators who are using non-nutritional approaches. If one accepts this analysis, the best way of encouraging potentially valuable research in nutrition is to support legislation which encourages both intramural and extramural NIH research programs with full utilization of the remarkable peer review system that has evolved over the past 25 years.

November 4, 1976

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I am pleased to be able to respond to your recent request for attitudes and information concerning nutritional research. I have taken the opportunity of obtaining information from Carolyn D. Berdanier, PhD., who is my research associate and who is a nutritionist with graduate training and degree from Rutgers. Carolyn Berdanier is a former research nutritionist from the Agricultural Research Service, Department of Agriculture and is now a faculty member of the Departments of Medicine and Biochemistry at the University of Nebraska Medical Center. The comments which I shall make are the synthesis of information coming from both Dr. Berdanier and myself. First, I should like to present a list of the areas or issues which we feel deserving of attention in relation to human nutrition.

1. There is a very important need for additional study of parenteral nutrition. There is very little knowledge of the requirements for nutrients in the absence of modifying effects of the gut. The tolerances of nutrition taken orally in the normal individual are very great, however, the tolerances for nutritional elements in patient dependent upon parenteral nutrition are very limited and the factual basis for prescribing hyperalimentation or parenteral nutrition is inadequate. Parenteral nutrition is particularly important to the stressed patient whose recovery from severe illness, trauma, or burns may depend in large part upon intravenous alimentation.

2. There is a very definite need for study of the specific nutritional needs of patients with different types of diseases. For example, the role of nutrition in the treatment of patients with cancer, regional ileitis, granulomatosis disease of the bowel, bowel resection--partial or total, burns, stress of many different forms, and osteoporosis is based upon rather limited information. These different disease states have differing nutritional requirements and a much more precise definition of the role of the gastrointestinal tract in absorption of specific food elements plus increased information about the need of specific and combined food elements in different disease states are topics that deserve attention. Long-term studies with human subjects are needed to define the role of calcium intake, vitamin intake, plus the intake of phosphate, total calories and other food elements in the development of senile osteoporosis. The response of patients to increased caloric intake and the effect of nutrition upon

the rate of growth of cancers is deserving of much more attention. We have very little knowledge of the effect of trauma and burns upon nutrient requirements. Some early studies by Cuthbertson have shown that protein catabolism is greatly enhanced but we can only infer that other nutrients are similarly affected. This list is very incomplete and is given only to illustrate some areas of potential study of the relation of nutrition to a specific disease processes.

3. Very little research has been conducted upon genetic variation in nutrient utilization and requirements. We need to know the extent of the variation and the long range consequences to the individual of either malnourishment or over-nourishment as a result of not properly meeting the nutritional requirements. A more precise definition of the role of nutrition in our major problem of atherosclerosis is needed and the genetic response of different nutritional states in relation to atherosclerosis is an area that deserves major attention.

4. The nutritional needs and changes of our aging population are worthy of attention. The changes in taste perception and hence changes in nutrient intake that develops with age and with the onset of certain diseases leads to a lack of interest in eating. The role of nutrition in longevity is probably greatly influenced by the changing eating patterns with aging. The effect of different levels and types of nutrition upon the aging process are areas that are well worth investigating. We need to learn what really controls appetite and satiety and why the normal clues for satiety go awry with the process of aging.

5. Study of the minimal nutritional requirements for vitamins and minerals needs continued investigation. The minimal requirements that are recommended in this country are greatly different from those recommended in developing nations as well as other highly developed civilizations of the world. We need to know if our nutritional recommendations are realistic.

6. A major area of study that has received very little attention concerns the control of gastrointestinal hormones by specific food elements. We have learned recently that the gastrointestinal tract produces a great variety of polypeptides which have major influences upon metabolism and function of the entire body. The role of nutrition in the elaboration of such polypeptide hormones and the effect of such hormones on growth development, aging, and degenerative processes in the body is an area for major basic research.

7. We need more information on nutrient-drug interactions. Of particular need is the study of the effect of commonly used drugs such as antibiotics, barbiturates, aspirin, and antihistaminics and tranquilizers upon body nutrient stores and hence on the requirements for these nutrients by patients whose chronic conditions require long-term drug treatments. In this line we need information on the effect of oral contraceptives on nutrient requirements. We have at present some information on the effect of oral contraceptives on folic acid requirements but other hormone-nutrient interactions may also be important.

8. In today's world of interest in weight control, a good deal of study needs to be undertaken of the metabolic consequences of starvation and refeeding. The metabolic consequences of short-term starvation are known but less well defined are the consequences of partial starvation. The effects of refeeding upon the vascular system and the long-term effects of recurrent starvation-refeeding programs upon the development of atherosclerotic-degenerative diseases is a field that could well receive a great deal of attention.

9. One of the major nutritional needs of our country is not so much a need resulting from gaps in nutritional knowledge but rather a need to improve our ability to teach nutrition to patients and to the general population. In order to do this, I feel that there is a need for improved teaching of nutrition to the personnel who will become the educators, namely, physicians, nurses, and other allied health personnel. There are poorly developed formal programs for nutrition education in most of the medical and nursing schools of this country. Very few schools have really well formalized, well-developed programs. Probably individuals have more nutrition education presented to them by the American Dairy Industry and other commercial interests than they do by those who are probably more impartial and could be knowledgeable, effective teachers of nutritional needs.

It would be difficult to rank the above topics in a more meaningful sequence than presented. All of these areas are important and deserving of attention. Some of the problems mentioned are currently of more interest but in the long run all are probably equally important.

Based on my understanding of the current support of Nutrition Research by the Federal Government which is in large part administered by the National Institutes of Health there is a poorly defined field of nutrition which is receiving direct support. I feel that there are nutritional implications of many of the research programs of the various Institutes of Health. I would say that all of the above suggested areas are inadequately funded and deserving of additional attention and support. I think that one of the major reasons why Federal support may be lacking for these programs is that the nature

of funding has not identified nutrition as a major discipline requiring support. The various institutes tend to be disease oriented and the nutritional implications of such diseases are of secondary consideration. Improved study of the role of nutrition in the development of diseases may well indicate that study of nutrition in the long run is as important as study of the disease process. The role of nutrition in prevention of disease may have much greater impact on our health and health economy than does the nutritional treatment of an established disease process.

In response to question #4, I would suggest that increased emphasis on and support of nutritional research programs by both the National Institutes of Health and the Agricultural Research Service are desirable.

Concerning question #5, I do not think that there are methodological problems which would prevent study of the gaps in information which we have tried to identify. There are well developed techniques for studying nutritional requirements which could be applied to solve most of the points that we have listed. The biomedical research community of the country is quite well prepared to undertake st[illegible] of these problems. Perhaps the major impediment is the [illegible] identification of support for nutritional research or a l[illegible] of interest in nutritional research that could lead to better understanding. I believe that such support and encouragement for nutritional research could very readily come through already established organizations such as the National Institutes of Health to develop greater research in the area of nutrition.

Both Dr. Berdanier and I feel that nutrition is of major importance to the well-being and health of our country and that there are clearly definable areas in which the understanding of nutrition could be improved.

November 18, 1976

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Enclosed is a statement of what I consider some major problems in nutrition today, and for which scientific answer must be provided if we are to be effective in meeting the needs of people of U.S.A.

These are the areas in which my own work, and presumably that of other nutritionists, is severely impeded because of lack of scientific information.

MAJOR PROBLEMS IN HUMAN NUTRITION TODAY

1. The nutritional requirements of women, especially those in the postmenopausal period and after age 50 years.

Comparatively few data are available on the quantitative nutrient requirements of women at all ages, and especially at the menopausal period when women begin to encounter an increasing number of health problems we do not even have "normal" indicators, such as blood levels of nutrients and other nutritional status data for women which might serve as a base line to calculate the possible nutrient requirements of this group.

Nutrient requirements of women, and their susceptibility to various health disorders are different from those of males. In the past, because of greater accessibility to groups of males for research studies, data have been collected on males. The population of females exceeds that of males, and women after 50 years of age have approximately one-third of their lives yet to live.

2. Nutrition in relation to the aging process and the quantitative nutrient requirements of the elderly.

There is beginning to be more investigation of the effects of nutrition on the aging process but much more work is needed. Greater knowledge in this area should make it possible to plan better diets for the population, especially in the early age groups, and thus to forestall the onset of many of the nutrition-related diseases and so called degenerative diseases which occur in later life.

The elderly are a group which make up an increasingly greater proportion of the population. There are minimal quantitative data regarding the nutrient requirements of the elderly; most of the nutritional information provided for the elderly today is from estimation or calculation from data of earlier age groups. It is assumed

that there is no significant change in the quantitative nutrient needs of the elderly, but this may not be so.

Independent, or non-institutionalized living is the desirable goal for the elderly; lower health-care costs and improvement of the enjoyment of living could be an anticipated outcome of such research on nutritional needs of the aging population.

3. Significance of trace elements in human nutrition, their effects on health at different ages and stages in the life cycle, and the quantitative requirements for these trace elements.

Investigation of the trace elements in human nutrition is comparatively new. We now have the sophisticated laboratory equipment and techniques to make quantitative studies on these trace elements and their function in the human organism. Their relation to health and prevention of disease needs to be more clearly identified. Indications are that these trace elements could have as great an impact on nutritional knowledge and practice as the vitamins have had since their identification in the 1920s and 1930s.

4. Knowledge of the nutrient composition of all foods on the market today; the effect of processing, preparation, cooking procedures, holding, storage, and other treatment is essential for planning of normal and therapeutic diets.

Nutrient needs and the maintenance of normal nutrition, as well as the treatment of all clinical conditions of an individual, is dependent on food. Foods normally differ widely in their nutrient content, many of the nutrients are lost in modern processing and other treatment that food undergoes in preparation for marketing, and for home consumption.

Since 1896 with the publication of Atwaters bulletin 28 on the composition of foods, the U.S. Department of Agriculture has had the responsibility for providing and compiling information on nutrition values of foods. New work on several of the vitamins, and the discoveries regarding the trace elements demand new research to provide information on food sources of these nutrients. Information is also needed on the nutritive value of the effect of home and institutional preparation on nutrient losses. Such data are essential for all who work in applied nutrition and diet planning, and thus ultimately for the consumer.

5. The relation of nutrition to cancer incidence and treatment, including the effects of fiber in the diet need to be investigated.

Research papers are beginning to appear on the interrelationship of nutrition and cancer indicating that some nutrients, and also non-nutritive material such as fiber, may influence the development of certain types of cancer. NIH has active programs of cancer research but the nutritional aspects need greater emphasis, and broader investigation.

6. Interaction of drugs and nutrients.

There is increasing evidence that drugs (alcohol, hard drugs, and physician-prescribed drugs) interact with nutrients. Some drugs interfere with the utilization of nutrients, and in other cases the drug reaction is changed by nutrients. Studies should be extended in this area. This information is essential for the physician in health care of all individuals, especially the elderly, and for the consumer to have a better understanding of what he is doing to his own health status when he uses drugs of any kind.

All of these areas of nutrition information are significant ones today and it is difficult to give priority ratings. If priorities must be established then they should be in the order in which the issues are presented here.

November 1, 1976

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GAPS IN OUR KNOWLEDGE

1. The effect of nutritional deficiencies and excesses on early growth and development.

We already have evidence that this is an important area from work involving the central nervous system and the fat cell depot. However, there is still a great deal to be learned about specific nutrient deficiencies and excesses and how they can affect development. In order to accelerate research in this area, newer and better methods to measure "development" need to be developed.

2. Obesity.

This is an area of major health concern in the United States. Yet comparatively little imaginative research is being carried out in this field. Within this general field there are a number of specific questions which should be addressed.

a. Are there forms of obesity which are genetic? If so, which types? Can they be diagnosed early enough to do something about them?

b. Are there critical periods, especially during early life, when the organism is vulnerable to particular types of obesity?

c. Are there particular weight reduction regimens which produce physiological effects which might be either beneficial or harmful? If so, can we define these effects?

d. Is the control of appetite different in obese and nonobese individuals?

e. Is taste perception the same in obese and nonobese individuals? If different--how and do these differences disappear with weight reduction?

f. Can eating behavior be modified in obese individuals or in individuals destined to become obese? If so, what are the best methods for behavior modification?

3. Nutrition in the elderly

As the number of people reaching senior citizen status increases it becomes more and more important that we understand problems in nutrition which have a high incidence in this age group. The available information in the general nutrition area is extremely limited. We do not even know whether requirements for basic nutrients such as calories, and carbohydrate are different for older people. We know that they are more apt to have certain nutritional deficiencies, but we don't know why. We also know that certain "diseases" of old age may be in part due to nutritional considerations. These include osteoporosis and periodontal disease. More research in these areas are needed.

4. Nutrition of the adolescent

This is an age group undergoing rapid physiologic changes. At the same time this is a group which has unorthodox eating habits. We know little about the requirements for adolescents, their special nutritional inadequacies, and their nutritional status in this country.

5. Nutrition and pregnancy

A great deal of interest has recently focused on the effects of nutrient deprivation or excesses during pregnancy on the developing fetus. Critical questions not yet answered are:

a. How severe does general malnutrition have to be before damage is done to the fetus?

b. Is caloric deprivation or protein deprivation more important?

c. What is the role of specific nutrients (i.e., iron, zinc, vitamin A) in fetal development?

d. How are individual nutrients transported across the placenta?

6. Nutrition and lactation

This is a relatively new area in terms of research and an extremely important one. More women in the U.S. are breast feeding. The number is now around 35-40 percent. Breast feeding is very important in developing countries. We need to know more about:

a. The effect of nutrition on the composition and quantity of milk as well as on the mechanisms by which milk is produced and secreted.

b. The excretion of substances (nonnutrient) ingested by the mothers (i.e., alcohol, drugs, toxins, etc.).

c. The mechanism of immunity imparted by breast milk.

7. Trace minerals

This is a fast growing and important area asking the questions--What are the trace mineral requirements of man? What occurs with either deficiency or excess? There is a lot already going on in this field with large amounts of Federal (U.S.D.A.) support.

8. Vitamins

This area has been studied a great deal. The major health concerns at present involve the use of very large doses for the prevention or cure of diseases.

9. Nutrition and drugs

As more people are taking more and more drugs, this is an important area. For example, the pill causes certain nutritional deficiencies. This is now under investigation. We know little about other drugs and their relation to nutrition.

10. Nutrition and cancer

An extremely important area in which there is nowhere near enough research going on. Evidence suggests a relationship between certain human cancers and long-term eating patterns. The nature of these relationships and what they mean is still unknown. Animal experimentation in this area is weak. In addition, the emaciation of patients with cancer, their weight loss, and ultimate death suggests that the normal tissues are being "starved" at the expense of the tumor tissues. This also has not been adequately explored. Finally, the nutritional management of patients with cancer and with patients undergoing radio- or chemotherapy is not well worked out.

11. Nutrition and cardiovascular disease

More studies to define the relation of long-term eating patterns to the development of cardiovascular disease are needed. The importance of fat, sugar, and protein as well as certain vitamins and minerals need further investigations.

12. Nutrition and gastroenterology

An important area, since all diseases of the G.I. tract have nutritional implications.

13. Nutrition and genetics

The interaction of environmental factors and genetic factors in causation of various diseases has become an important issue. Nutrition is one of the most important long-term environmental factors. Such diseases as obesity, diabetes, hypertension, and perhaps even cancer fall into this category. The interaction of nutrition and genetics in these diseases has not been adequately studied. In addition, certain genetic diseases directly affect nutrition. For example, phenylketonuria, galactosemia, cystic fibrosis, etc. all have major nutritional considerations in their management.

14. Delivery of nutritional services

Although this is a service area, much research is necessary to establish the best way to deliver certain services and to integrate the delivery system into the health care system and the delivery systems for other essential services.

15. Nutrition education

Again while strictly speaking not research, we need studies to establish the best means of education to employ for various groups.

I would list in order of priority the following:

High Priority

1. The effect of early nutrition on future development.

   This is a crucial issue affecting our future populations and may impart permanent changes.

2. Nutrition and pregnancy.

   For the same reason as above and because there are large numbers of women at risk.

3. Nutrition and cancer.

   Because of the importance of cancer as a health problem and the obvious importance of nutrition in that context.

4. Nutrition in the elderly.

The susceptibility of this population and their increasing numbers make this an important problem.

5. Obesity.

Because it is so clearly a nutritional disease and so important in contributing to increased morbidity and mortality.

6. Nutrition and gastroenterology.

All diseases of the G.I. tract have nutritional implications and many are caused by nutritional practices.

Middle Priority

1. Nutrition and genetics.

A new area which promises to be more important in the future.

2. Nutrition and lactation.

An area which is becoming more important as more women breast-feed.

3. Nutrition and drugs.

Again a new area but one of obvious importance.

4. Trace minerals.

Although much is going on, the area is so vast that it will remain important for some time.

Lower Priority

1. Nutrition of the adolescent

2. Vitamins

3. Cardiovascular disease

4. Delivery of nutrition services

5. Nutrition education

The major problem at the Federal level is that there is no clear-cut responsibility for nutrition research. At N.I.H. it is scattered among several institutes. It is also handled by various other subdivisions of H.E.W. and U.S.D.A. has a large nutrition research component. In addition, the Department of State through A.I.D. is involved in a good deal of nutrition research. This leads to duplication of efforts, funding of similar projects by different agencies. For example, N.I.H. funded an important intervention study in the U.S. and Guatemala. A.I.D. funded similar studies in Formosa. U.S.D.A. operates the W.I.C. program which has presumably evolved from the findings of the two other studies (as well as others). They have just completed an evaluation of the results of the program. Many of the problems in this evaluation could have been anticipated had the groups involved in the other studies been adequately consulted.

This is only one example of what happens over and over. N.I.H. funds studies on vitamins and minerals. U.S.D.A. has special vitamin and mineral labs doing the same kind of studies while A.I.D. spends funds investigating vitamin deficiencies in developing countries. Thus the organization is inefficient and wasteful. In addition, the total dollars for nutrition related research is inadequate.

For example, N.I.H. in 1975 spent around $30 million on nutrition related research. This is very small in view of the importance of the problem and the total N.I.H. budget. The N.C.I. has $6 million in 1976 for research in the area of nutrition and cancer. This is the first money so earmarked. Previously, they spent very little in this area and are only doing it now because it has been mandated by Congress.

Finally, I think there is a fundamental reluctance on the part of medical researchers in general to accept the importance of nutrition in human health. This is in part due to lack of support for nutrition research but more to lack of nutrition education and training in medical school and subsequently.

October 21, 1976

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New York, New York

It seems to me that two essential levels of knowledge remain in need of further expansion in order to structure the most logical Federal efforts in nutrition. The first level relates to the scientific underpinnings of knowledge in human nutrition: what you have identified, I suppose, as "knowledge gaps." The second level of necessary information emphasizes a greater understanding of optimum policy choices. Clearly, policy must run parallel to what is scientifically known about individual human nutrition, but what one would prescribe for the individual is not necessarily what one would prescribe as policy.

For an obvious example, one might desire an individual serum cholesterol lower than 200 mg percent, but one would not advocate as policy the screening of every individual and reduction of every cholesterol level to below 200mg percent. Nor, indeed, would one advocate as policy rationing the amount of cholesterol permitted in any individual's diet, although one might well prescribe such a regimen to an individual patient.

As another example, the issue of caloric requirements might be instructive. On the whole, we have a fairly good idea of human caloric requirements at different stages of life, and under different conditions of stress and activity. On the other hand, we do not know how to translate available food supply into patterns of consumption so that, given free access to food, Americans do not consume more than the required number of calories. I consider this a major and fundamental gap in our knowledge of <u>human nutrition policy</u>. I am not sure whether this qualifies as a major human nutrition knowledge gap in the terms of your study. I do think, however, that this issue of the translation of scientific knowledge into <u>appropriate</u> policy stances is central and perhaps the missing link in constructing <u>appropriate</u> public nutrition behavior in the United States.

In connection with this thought we should note that there is a vast fund of nutritional knowledge already at the fingertips of scientists and policymakers. Much of this nutritional knowledge is not currently used optimally in public policymaking. The search

for more complex, more interesting, and more detailed knowledge is endless, and one can always identify the lack of such knowledge as a major "gap." In the meanwhile, however, we should be quite willing to acknowledge that fundamental nutrition questions have been well explored and some very responsible "best guesses" can be made from what is currently known.

After the lengthy digression, I will attempt to stick to the questions as you have asked them in your letter:

Number 1: Issues in human nutrition needing further study

1. Nutritional epidemiology:
   a) the assessment of nutritional patterns as risk factors for disease states,
   b) the nutritional contribution to biochemical and physiological risk factors for disease, and
   c) the relationship of nutritional patterns to behavioral deviation and mood change.
2. The relationship of nutrition and diseases, especially
   a) chronic degenerative diseases,
   b) the process of aging, and
   c) cancers, with nutrition as a potential internal environmental "cause."
3. Implications of early patterns of nutrition (including infant feeding patterns) for later patterns of growth, development, health, disease, behavior and intelligence.
4. Genesis of obesity; in particular, the genetics of eating and weight disorders, the influence of weight disorders on morbidity, mortality, and the question of fat-cell size and number in relation to eating habits, weight disorders, and genetics.
5. The interactions of various constituents of the diet.
6. The physiological implications of anemia and how best to define the importance of iron deficiency in relationship to its clinical and public health importance.

Number 2: The ranking of these issues is based on the relative importance of each of these problems vis a vis the entire population of the United States, and the extent to which knowledge gained could potentially improve the quality of life of the American population.

Number 3: Areas of nutrition research which seem particularly under-funded are those which use an epidemiological approach, especially with relationship to chronic diseases, aging, behavioral change, cancer, and infant feeding practices. This is because the epidemiological approach to research has been relatively under-emphasized in training institutions for the basic sciences, and because laboratory-based research has received priority within scientific institutions and in the glamorizing attention of the national press and other public forums.

Number 4: As per above, population-based research is most urgently needed in order to understand what is happening to our population as it lives - and eats - in the real world.

Number 5: Organizational problems result from the division of authority in areas related to nutrition research, especially epidemiological research where responsibility for health has been allocated to HEW and food has been the province of the USDA. The artificial separation of activities has resulted in a dividing line squarely down the middle of nutritional concerns. Human nutrition and the diet problems of the American public thus have never been the real responsibility of any one agency. Programs in nutrition, therefore, are not likely to enhance the stature of one particular Department, and nutrition has, therefore, never been a particularly attractive field for a bureaucrat or a division or an agency to make its name as a leader in national policy.

In addition, leadership in the studies outlined above would normally and logically fall within the province of the health research system which tends to undervalue this type of research. Nutrition certainly has not been the fashion of the day in medical schools or in graduate science programs within universities. As a result, relatively few scientists are drawn into epidemiological work, and young talent is not added to the research pool as readily as in the highly glamorous laboratory fields of research.

A further constraint is the fact that large-scale epidemiological studies, especially when designed as prospective studies, can be enormously expensive. Innovative planning and assiduous use of already existing data bases should form a large part of any new Federal effort in these fields.

It is clear to me that this list is by no means exhaustive, and I will probably think of more issues as time passes. I would be happy to add to your list of important topics for research as new ideas occur. I would still emphasize, however, that the key to rational Federal action towards the goal of improving nutritional health will more likely be found in the structuring of policy in information dissemination, consumer education, behavioral change, and health care delivery, than in breakthroughs in specific scientific and technological research. Of course, both basic research and clinical research are necessary to maintain national standards of nutrition as well as excellence in this field of science. But breakthroughs in science, as we have learned in other fields of health, can never substitute for concerned government policy which aims at identifying and modifying the large and fairly easily identifiable problems of its citizens.

November 10, 1976

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Cambridge, Massachusetts

In my opinion, research areas that would fill important gaps in knowledge of human nutrition and which merit support with the highest priority include the following:

1. Research relating to complex interactions among diet, nutritional status and environmental factors (chemical and physical) in the causation of disease.

   Considerable epidemiological evidence demonstrates a clear association between diet and the incidence of many forms of cancer. Because the majority of cancers are caused by environmental chemicals and physical agents, diet is thought to act as a modifying influence, determining the responsiveness of individuals to environmental carcinogens to which entire populations are exposed; or as a vector for food-borne carcinogens. Very little information exists to demonstrate the mechanisms operative in creating this etiological association. While, in principle, this situation is amenable to control by intervention, a strategy for intervention cannot be developed without a base of information not now in existence.

2. Research concerning the influence of diet and nutrition on response to therapeutic agents.

   It is clear that adequate nutritional support and optimal nutritional status will improve the capacity of cancer patients to receive and tolerate therapy, increase survival, and have a beneficial impact on the quality of their life. Many cancer patients literally die of malnutrition and not of their neoplasia. While some interventive measures can be successfully derived from existing information, a great deal of new data will be required to meet the array of individual problems presented by different chemotherapeutic requirements.

   Beyond this specific instance which is dramatically evident, the potential modifying effects of nutritional status on response to other therapeutic drugs, prescriptional and proprietary, are also becoming increasingly apparent. Efficacy and side effects of drugs are heavily influenced by metabolic processes which are in turn dependent upon nutritional status in many instances. Nonetheless, all forms of drugs are prescribed and used with little or no regard to the nutritional status of individuals exposed to them.

3. Research aimed at improving capabilities for determining and quantifying dietary intake and nutritional status of individuals at various stages of development, age and physiological status.

It is accurate to say that methodology does not exist to assess dietary intake of an individual in American society. Consequently, estimates of nutritional status are both inaccurate and insensitive. Conventional dietary survey techniques and questionnaires yield unreliable information. Such information is essential to the problems outlined in 1 and 2 above. Consequently, a central need for the entire area is the evolution of objective, quantitative techniques that can be applied to individuals, not populations, to assess dietary intakes and nutritional status.

With respect to problems impeding Federal support for research needed in these and other related areas, in my judgement the problem of overriding importance is lack of a central organizational structure dealing with human nutrition in all of its aspects. Consequently, no mechanism exists for formation and implementation of an organized and coordinated program in this area. Responsibilities are currently fragmented among Federal agencies (e.g., USDA, NIH, FDA, etc.), and even within a given agency such as NIH, no cohesive program seems to exist.

This situation often thwarts the implementation of programs for which support has been allocated. Resolution of this situation would greatly improve the probability of success of future research programs in the human nutrition field.

January 11, 1977

GAO LETTER REQUESTING COMMENTS ON FEDERAL HUMAN NUTRITION RESEARCH

Dear Dr. :

As discussed with you on the phone recently, Senator George McGovern, Chairman of the Senate Select Committee on Nutrition and Human Needs, has requested that the U.S. General Accounting Office review Federal activity in human nutrition research and report on:

1. Major gaps in nutrition knowledge.

2. Efforts of Federal agencies to fill those gaps.

3. Research areas which may be receiving insufficient attention and funding.

4. Organizational, legislative, or other changes needed to facilitate research to fill the major gaps.

Following receipt of this report, the Committee intends to provide the Congress with an outline of the most pressing needs in human nutrition research and recommend a plan of action.

As part of our review, we are seeking the counsel of informed individuals. Our approach is open-ended. Rather than eliciting responses to a highly structured list of questions, we are seeking opinions and ideas concerning major knowledge gaps, relative priorities, research needs, and problems which may inhibit Federal support of needed research activities.

We are aware that other agencies have been or are addressing nutrition issues, including the on-going study by

the Office of Technology Assessment to develop a plan for national food policy. In our review, we are focusing on the relationship between research activity and public nutrition policy; i.e., the information required for prescribing dietary practices which promote optimal health and for targeting intervention programs at those individuals in the nation who are at risk nutritionally. Within this context, however, we are not including information dissemination, consumer education, behavioral change, or other issues of health-care delivery.

We would appreciate your responding to the questions listed below as well as commenting on any other matters you believe are pertinent.

1. What issues should be identified as major human nutrition knowledge gaps? Please explain why they represent major gaps?

2. Please list and rank your priorities and explain the reasons underlying your rankings.

3. Based on your knowledge of the nutrition research supported by the Federal Government, which of the gaps prioritized under question 2 are not receiving adequate attention by Federal agencies? Please cite reasons why you believe Federal support has not been adequate.

4. Based on your identification and prioritization of the knowledge gaps, what types of research activity are needed?

5. What problems--organizational, methodological, financial, or other--could prevent or inhibit Federal support of the research needed? Please explain the particular problems you cite.

We realize this request is an imposition on your time. However, recognizing your expertise in nutrition and the Senate Committee's desire for imaginative ideas, we believe your input will be a major contribution to our review. Should you have any questions, contact

John Miller on (301) 496-2107 or Ed Morahan on (703) 557-2151. An addressed return envelope is enclosed for your convenience.

Your participation is greatly appreciated.

Very sincerely,

Murray Grant, M.D., D.P.H.
Medical Consultant

Enclosure