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NUTRITION LABELING AND INFORMATION AMENDMENTS OF 1979 TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

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HEARINGS

BEFORE THE

SUBCOMMITTEE ON
TH AND SCIENTIFIC RESEARCH

OF THE

COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

NINETY-SIXTH CONGRESS

SECOND SESSION

ON

S. 1652

ENTITLED THE "NUTRITION LABELING AND INFORMATION AMENDMENTS OF 1979 TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT"

FEBRUARY 20 AND MARCH 19, 1980

Printed for the use of the Committee on Labor and Human Resources

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NUTRITION LABELING AND INFORMATION AMENDMENTS OF 1979 TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

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NUTRITION LABELING AND INFORMATION AMENDMENTS OF 1979 TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

TUESDAY, FEBRUARY 20, 1980

U.S. SENATE,
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH
OF THE COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:05 a.m., in room 4232, Dirksen Senate Office Building, Senator Howard M. Metzenbaum presiding pro tempore.

Present: Senators Metzenbaum, Schweiker, and Pell.

Staff present: Robert M. Wenger, majority counsel, Dr. Rhonda Freedman, legislative assistant, and Cynthia Hilton, professional staff member.

OPENING STATEMENT OF SENATOR METZENBAUM

Senator METZENBAUM. Would those in the aisle be kind enough to take their seats, if there are any seats.

Today, the Subcommittee on Health and Scientific Research is holding the first of 2 days of hearings on diet, nutrition, and health. I want to thank Senator Kennedy for scheduling these hearings and asking me to chair them in his absence.

Over the past few years, it has become increasingly clear that diet plays a large role in the health of Americans. Diet is a risk factor in 6 of 10 leading causes of death. And recently, Dr. Arthur Upton, then Director of the National Cancer Institute, stated that scientists generally agree that diet and nutrition appear to be related to almost 50 percent of all human cancers.

We have now come to realize that malnutrition has two faces. One of them, we have always recognized—the malnutrition suffered by the poor who do not get enough to eat. We have agreed that malnutrition could be eliminated once and for all in America.

It is unfortunate that actions both by the Congress and the administration are not necessarily reflected to this end and we have not achieved the objective.

But there is another kind of malnutrition as well—the kind that comes from overconsumption or from eating the wrong things. And that kind of malnutrition has reached epidemic proportions in this country.

Obesity raises the risk of heart disease, diabetes, hypertension, and some kinds of cancer for millions of Americans.

And to see the effects of bad diet on our people, we need only look at dental health in this country.

By age 11, the average American child has three permanent teeth damaged by decay.

By age 17, eight or nine permanent teeth have decayed, been filled, or are missing.

Tooth decay afflicts 95 percent of Americans and costs the people of this country $2 billion a year in dental bills.

We know that excessive sugar intake is one of the major causes of tooth decay. And yet, as the Senate made amply clear this month, we are not prepared even to allow the FTC to investigate TV advertising directed at the Nation's children that promotes cereals and candies loaded with sugar.

One cereal, Super Orange Crisp, is made up of 71 percent sugar.

We cannot avoid the fact that nutrition has major implications for the Nation's health, for the rising cost of health care and for the future direction of American agriculture.

Three years ago, the Senate Select Committee on Nutrition and Human Needs, chaired by Senator McGovern, issued a landmark report entitled "Dietary Goals for the United States," the first publication in the Federal Government to set guidelines to lower the disease risks associated with our current diet.

In 1978, under the leadership of Senator Kennedy, the Disease Prevention and Health Promotion Act was signed into law. This legislation is a real breakthrough because it supports programs at the State and local level that focus on preventing disease and promoting good health practices. That approach is a real step forward, and one that needs far more emphasis in the future.

During the course of hearings leading to the enactment of that legislation, it became clear that nutrition must be a key component of any prevention program.

And, just 2 weeks ago, the Departments of HEW and Agriculture released their "Dietary Guidelines for Americans," that advises Americans to eat a variety of foods, maintain ideal weight, avoid too much fat, saturated fat and cholesterol, eat foods with adequate starch and fiber, avoid too much sugar, avoid too much sodium, and drink alcohol in moderation.

[The text of S. 1652 follows:]

96TH CONGRESS
1ST SESSION

S. 1652

Entitled the "Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug, and Cosmetic Act".

IN THE SENATE OF THE UNITED STATES

AUGUST 2 (legislative day, JUNE 21), 1979

Mr. MCGOVERN (for himself, Mr. RIEGLE, Mr. KENNEDY, Mr. WILLIAMS, Mr. JAVITS, Mr. METZENBAUM, Mr. LUGAR, and Mr. LEAHY) introduced the following bill; which was read twice and referred jointly, by unanimous consent, to the Committees on Commerce, Science, and Transportation and Labor and Human Resources

---

A BILL

Entitled the "Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug, and Cosmetic Act".

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE: REFERENCE TO ACT

SECTION 1. (a) This Act shall be cited as the "Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug, and Cosmetic Act".

(b) Whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the

reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

DECLARATIONS AND FINDINGS

SEC. 2. The Congress finds that:

(1) Consumers need accurate, objective, and easily understandable nutrition and ingredient information on the foods they eat in order to help them choose healthier diets at reasonable cost.

(2) The ability of consumers to select a more nutritious diet is a critical factor in preventing disease and promoting health because diet is a risk factor in six of the ten leading causes of death, and is a causative factor in obesity and dental caries.

(3) More optimal diet selection can help slow mounting medical care costs because healthier people need less medical attention.

(4) The requirements for nutrition labeling need to be altered to better reflect the significant impact on our health of the consumption of the macro-nutrients—protein, fats, and carbohydrates—as well as such other key dietary components as sodium and cholesterol.

(5) In altering labeling requirements, special attention must be placed on improving labeling formats to convey more effectively needed information in a readily understandable fashion to the average consumer.

(6) In order to achieve maximum benefit from label modifications, consumers must be educated on the use of the nutrition information that is provided.

(7) Nutrition labeling should be approached as an information function that allows for appropriate flexibility on the part of producers, while also protecting and enhancing the consumers' right to know what is in the food they select so that they can make informed choices.

NUTRITION INFORMATION AND OTHER LABELING REQUIREMENTS

SEC. 3. (a)(1) Section 401 is amended by striking out the fourth sentence thereof.

(a) Section 403(g) is amended to read as follows:

"(g) If it purports to be or is represented as food for which a definition and standard of identity have been prescribed as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in such definition and standard.".

(b)(1) Section 403(i) is amended to read as follows:

"(i) Unless its label bears—

"(1) in the case of food that is not subject to paragraph (g) of this section, the common or usual name (if any) of the food; and

"(2) in case it is fabricated from two or more ingredients—

"(A) the common or usual name of each such ingredient in the descending order of its predominance by weight, except that (i) any ingredients that individually comprise 5 per centum or less of a food need not be listed in such order but shall be named at the end of the ingredient list; and (ii) any flavorings that are not sold as such shall be designated as artificial flavorings or natural flavorings, as the case may be, without naming each such flavoring, unless the Secretary requires that the common or usual name of a flavoring be on the label for the purpose of providing health information to consumers,

"(B) a declaration that ingredients are listed in the descending order of predominance by weight, and

"(C) a declaration of the quantity or percentage (as determined by the Secretary) of any specified ingredient (other than a flavoring) or class of ingredients if the Secretary determines that such ingredient or class has a significant bearing on the quality, consumer acceptability, or cost of such food or food of its class.

The Secretary may not require that an ingredient that comprises 5 per centum or less of a food be declared

under subparagraph (2)(C) unless, in addition to the determination under such subparagraph, the Secretary determines that the absence of such declaration is likely to result in deception or confusion. To the extent that compliance with the requirements of subparagraph (2) is impracticable or would result in deception or unfair competition, the Secretary may prescribe exemptions from such requirements.

"(3) The Secretary shall exempt from the provisions of this subsection any food that the Secretary determines is subject to comparable requirements established with respect to such food under any other Federal law.".

(2) The second sentence of section 403(k) is repealed.

(c) Section 403 is amended by adding at the end thereof the following new subsections as follows:

"(q)(1) If it is a food for human consumption and in package form, unless its label bears such nutrition information relating to the food as the Secretary prescribes to provide health information to consumers including at least the following:

"(A) the total number of calories per serving;

"(B) the amount per serving of protein, fats, and carbohydrates in terms of caloric content;

"(C) the amount per serving of sodium unless the Secretary determines that providing such information is not necessary to provide health information to consumers;

"(D) the amount per serving of cholesterol unless the Secretary determines that providing such information is not necessary to provide health information to consumers.

"(2) The Secretary, for purposes of paragraph (1), and after consultation with the Secretary of Agriculture, shall allow, to the maximum extent feasible and appropriate, the use of nutrition data bases that indicate representative (weighted) nutritional value at point of purchase.

"(3) The Secretary shall exempt from the provisions of this subsection any food that the Secretary determines is subject to comparable requirements established with respect to such food under any other Federal law.

"(4) To the extent that compliance with the requirements of paragraph (1) is impracticable or not necessary to provide health information to consumers, the Secretary may prescribe exemptions from such requirements.

"(r) The Secretary may, where appropriate, prescribe a system of symbols, figures, or other devices that will enable consumers to comprehend readily the nutrition information

that is or may be required to be placed on labels by this section.".

(d) The amendments made by this section shall only apply with respect to food that is introduced or delivered for introduction into interstate commerce two years after the date of enactment of this Act.

PREEMPTION

SEC. 4. (a) Chapter IV is amended by adding after section 411 the following new section:

"STATE AND LOCAL FOOD LABELING REQUIREMENTS

"SEC. 412. (a) Except as provided in subsection (b), no State or political subdivison of a State may establish or continue in effect a label or labeling requirement on manufacturers, wholesalers, and packers concerning nutrition and ingredient information applicable to any food that is different from or in addition to any label or labeling requirement applicable to such food under subsections (i) and (q) of section 403.

"(b) Upon application of a State or a political subdivision thereof, the Secretary may, after notice and opportunity for comment, exempt from subsection (a), under such conditions as may be prescribed, a label or labeling requirement of such State or political subdivision if the Secretary determines that the requirement is required by compelling local conditions and compliance with it would not cause a food to be in

violation of a requirement under subsections (i) and (q) of section 403.

"(c) Subsection (a) does not prohibit a State or political subdivision of a State from establishing or continuing in effect a label or labeling requirement respecting the sell or use date of food.

"(d) Within one hundred and eighty days of the date the Secretary receives an application of a State or a political subdivision thereof pursuant to subsection (b), the Secretary shall either approve or deny the application.".

(b) The amendment made by subsection (a) shall only apply with respect to food which is introduced or delivered for introduction into interstate commerce two years after the date of the enactment of this Act.

DEMONSTRATIONS AND EVALUATIONS

SEC. 5. (a) The Secretary of Health, Education, and Welfare may approve demonstrations to ascertain the most effective methods of organizing the food label and of conveying to consumers the information that is or may be required to be placed on labels and labeling under section 403 of the Federal Food, Drug, and Cosmetic Act, as amended by section (3) of this Act,

(1) with particular emphasis on the following methods of conveying such information:

(A) nutrient density;

(B) serving size; and

(C) ingredient function; and

(2) with particular emphasis on conveying information on:

(A) protein, fats, and carbohydrates;

(B) sodium;

(C) cholesterol;

(D) dietary fiber; and

(E) vitamins and minerals.

(b) Upon completion of a demonstration under subsection (a), the persons conducting such demonstration shall submit to the Secretary such information as the Secretary shall require to evaluate the effectiveness of the demonstration. The Secretary shall prepare a written evaluation of any such demonstration within one hundred and eighty days of receipt of such information.

(c) Section 403, as amended by section 3 of this Act, is further amended by adding at the end thereof the following new subsection:

"(s) The Secretary may waive from any requirements of this section, under such terms and conditions and for such periods of time as the Secretary prescribes, any foods that are engaged in demonstrations approved under section 5 of the Nutrition Labeling and Informaton Amendments of 1979 to the Federal Food, Drug, and Cosmetic Act.".

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CONSUMER EDUCATION PROGRAM ON THE USE OF LABELS AND LABELING

SEC. 6. (a) The Secretary of Health, Education, and Welfare, in consultation with the Secretary of Agriculture and other appropriate public and private entities, shall develop, pilot test, and implement a program of consumer education on how to use nutrition labels and labeling effectively.

(b) The Secretary shall submit to the Congress on January 1, 1982, and on January 1, 1983, a report on the program established under subsection (a) including, but not limited to, a detailed description of and an evaluation of the effectiveness of such program.

(c) For the purpose of undertaking such a program, there are authorized to be appropriated $4,000,000 for the fiscal year ending September 30, 1981, $6,000,000 for the fiscal year ending September 30, 1982, and $8,000,000 for the fiscal year ending September 30, 1983.

NOTIFICATION TO AND REPORT BY THE FEDERAL TRADE COMMISSION

SEC. 7. (a) The Secretary of Health, Education, and Welfare shall notify the Federal Trade Commission of the nutrition information that is to be used on labels or in labeling pursuant to subsections (i) and (q) of section 403 of this Act and recommend to the Commission which (if any) of such information should be required by the Commission under the

Federal Trade Commission Act to be included in the advertising of such food.

(b) The Chairman of the Commission shall report two years after date of enactment of this Act and biennially thereafter to Congress on (1) any recommendations made to the Commission by the Secretary under subsection (a) of this section, (2) in those situations where the Commission accepted a recommendation, a description of any action taken to implement such recommendations, and (3) in those situations where the Commission failed to accept, in whole or in part, a recommendation, a description of the reasons for such failure.

Senator METZENBAUM. This morning we will have an opportunity to hear from Dr. Julius Richmond of HEW and Carol Tucker Foreman of USDA about these guidelines, their scientific basis, and programs currently underway and that are planned to implement them. We will discuss with them nutrition research and nutrition education, that are essential components of a national nutrition policy. We will then have a panel of advocates of particular diet regimens, Pritikin, Weight Watchers, and Vegetarians. The panel members represent some different approaches to diet regimens, but certainly not all.

Finally, we will have a panel to discuss the most effective ways in which consumers can be educated about nutrition and changing dietary needs.

Senator Schweiker?

STATEMENT OF HON. RICHARD S. SCHWEIKER, A U.S. SENATOR FROM THE STATE OF PENNSYLVANIA

Senator SCHWEIKER. Thank you, Mr. Chairman.

Mr. Chairman, I am pleased that the subcommittee called this hearing on diet and nutrition at my request. As a member of the former Senate Select Committee on Nutrition and Human Needs, I gained considerable insight into potential benefits for health which accrue from a proper diet.

Given the jurisdiction of this subcommittee, I think it appropriate to look more closely at recent developments in nutritional research to ascertain their significance in the ongoing debate about diet and disease and to consider what steps are necessary to transmit that information to the public.

The axiom "You are what you eat" has never been more true than today. Obesity is often considered our most widespread public health problem. Furthermore, our diets have been linked to other diseases, including many of the leading causes of death. No longer are the Nation's nutritional concerns centered simply on getting enough calories to avoid hunger and starvation. Less than 1 percent of the American people are undernourished in the traditional sense. Rather, our concerns are focused on how the amount of and the balance of macronutrients—fats, proteins, carbohydrates—in our diet, and how the supply of micronutrients—vitamins and minerals—affect our health. It clearly takes more than an abundant food supply to satisfy human nutritional needs.

In our society, food supply is rarely a barrier to what we eat. More often than not, consumers limit their intake of food because of lifestyle, cosmetic, medical or monetary considerations. Despite these personal preferences, the consumer is hard put to make good nutritional choices because an atmosphere of confusion and contradiction prevails about what is nutritionally necessary to maintain good health. Too often, nutritional advice about diet and disease does little but feed fears of the layman.

Of all of the good work done by the select committee before it was disbanded, it is probably best known for its statement on national dietary goals. The dietary goals challenge the dietary practices and the beliefs which have governed nutrition for the last 20 years. It was an important achievement. Those goals have stood

as a benchmark against which theories of nutrition have been tested.

I followed the progression of events which have transpired within nutrition research since the dietary goals were released. These events have culminated with the joint Department of Agriculture and Department of Health, Education and Welfare publication of seven dietary guidelines earlier this month. The guidelines represent the executive branch of Government, its first official pronouncement on nutrition and diet. In the past, Federal agencies responsible for public health and safety of the food supply have stayed out of the controversy over the basic structure of the American diet. Bearing marked resemblance to the select committee's dietary goals, the guidelines are intended to be a clear voice in the battle of dietary information.

As we begin this hearing, we must keep in mind that few things are so sensitive to our concept of individuality as to what we choose to eat. We want Government policy to allow the widest possible diversity for personal preference while at the same time reducing the risk of illness and disability. We want Government policy to be in a form to motivate the public to adjust their own eating patterns, and to motivate industry to put these policies into practice.

While it is evident that good nutrition will not eliminate disease, we do want to reform our eating habits to the extent that it can eliminate the causes of preventable disease, and to the extent that our individual health and well-being will be improved. Hopefully, the witnesses we have called today will bring to light the vital issues at stake and the status of our knowledge in this critical area.

Thank you, Mr. Chairman.

Senator METZENBAUM. Thank you, Senator Schweiker. You have been a living example of diet. You lost about 20 pounds?

Senator SCHWEIKER. Jogging had a little bit to do with it.

Senator METZENBAUM. Dr. Richmond, we are very happy to have you and Carol Foreman here with us today. Please proceed.

STATEMENT OF JULIUS B. RICHMOND, M.D., ASSISTANT SECRETARY FOR HEALTH, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE AND CAROL TUCKER FOREMAN, ASSISTANT SECRETARY FOR FOOD AND CONSUMER AFFAIRS, U.S. DEPARTMENT OF AGRICULTURE

Dr. RICHMOND. Thank you very much, Mr. Chairman. I also have with me this morning Dr. Michael McGinnis.

I am very pleased, Mr. Chairman, to have this opportunity to appear before members of this committee to discuss our Department's efforts to improve the health of Americans through better nutrition.

I would like to acknowledge your leadership role and this subcommittee and the Senate Select Committee to which Senator Schweiker has already referred, in helping the Nation move toward improved nutrition for the population.

I think the charge you put before us in your introductory comments are very, very serious.

It is particularly appropriate, in light of the recently released dietary guidelines, which you have already mentioned, to share

this honor with Assistant Secretary Carol Foreman of the Department of Agriculture with whom we collaborate and with whom the Department collaborates.

I would like also at this time to express our deep appreciation to Secretary Bergland in his role in helping us develop resources for the collaborative activities in which we have been engaged.

The dietary guidelines, as you already know, are very significant. They represent the emerging consensus among scientists about eating habits that may be helpful in maintaining the health of Americans. And, they represent our latest effort to provide the public with the best scientific information available, in easily understandable language, about actions individuals can take that may prevent disease and promote health.

With your indulgence, Mr. Chairman, I would like to abbreviate my remarks considerably and, with your permission, submit the text of our statement for the record.

Senator METZENBAUM. The entire statement will be included in the record, as will be that of all witnesses.

Dr. RICHMOND. I would like to emphasize briefly the scientific basis for the recommendations. We believe that they are entirely reliable.

In 1978, the American Society for Clinical Nutrition examined all available scientific evidence relating six dietary factors to disease and analyzed the strength and the quality of the evidence. The six areas are: cholesterol, fat, carbohydrates, alcohol consumption, excessive calories, and sodium.

With your permission, Mr. Chairman, I would like to enter into the record the consensus statements prepared by the American Society for Clinical Nutrition and published as a supplement to the society's journal in December.

In addition to the American Society for Clinical Nutrition, we also relied upon the expertise of the American Academy of Pediatrics and our own scientists at the National Institutes of Health, the Food and Drug Administration, and the Department of Agriculture.

The association of dietary factors and coronary artery disease is treated essentially as is the association between dietary sodium and hypertension, the role of diet of cancer and the issues related to sugar and the role of obesity.

It is important, we think, that we review with you briefly the issues surrounding nutritional research.

Our Department is committed to supporting research to define the role of diet in health promotion and the prevention and treatment of disease.

Much of the research base for our dietary guidelines was derived from work sponsored by the National Institutes of Health, and programs of the Department of Agriculture. And our efforts are being increasingly strengthened.

Through the newly established national program in clinical nutrition at the National Institutes of Health, our objectives are to create or strengthen multidisciplinary biomedical research in order to develop new knowledge about specific nutrients and health, human development and the prevention and treatment of disease and to improve the education of health professionals in nutrition.

Through both intramural and extramural research, including the establishment of 10 to 12 clinical nutrition research units, we will examine such issues as:

The effects of various components of human breast milk on the physiological development of the newborn;

The effects of aging on nutrient utilization, digestion, absorption, and metabolism;

The development of methods for the determination of dietary status; designing a computer analysis of dietary recalls, histories, and food frequency questionnaires, and;

The physiological and psychological factors that affect eating and behavior.

I could continue with the list, though it would seem endless because clinical nutrition research is a broad field with numerous unanswered questions. We have begun the search for knowledge but we must continue to strengthen the science base which we are building.

We also will be improving our knowledge of the national food supply and providing essential food composition information to consumers. For example, the Food and Drug Administration has a major project in progress to improve food labeling so that consumers will have more and better information about the nutrient profiles of their foods and the ingredients these foods contain. I understand that you will be hearing about the FDA's activities in this area when they testify on food labeling policy next week.

It is also part of our mission to support nutrition surveillance and to monitor the nutritional status of the American population as well as provide for nutritional services through the health care delivery system.

The Center for Disease Control, the National Center for Health Statistics, and other agencies of our Department are working with USDA to complete our nutritional status monitoring system plan to submit to Congress very shortly.

Because we are committed to providing the public with the best information about diet and health that is currently available, it is important to address the question of how we plan to deliver this information to the public.

We have worked closely with the Department of Agriculture to develop a joint distribution plan to get the dietary guidelines into the hands of our constituents and consumers. By early next month, we will have about 1 million copies for the public. We have identified State level networks that are willing to distribute the guidelines to the public. These include nutrition directors in State health departments, directors of State agencies for the aging, the consumer affairs officers of the Food and Drug Administration, and others.

We are also planning to promote the booklet through the health care system. I am sending copies of the guidelines to leaders of national health associations and professional organizations. I have asked each of these organizations to disseminate the guidelines to their State affiliates, their executive boards, and their nutrition committees.

We are also interested in doing a better job of integrating nutrition education into the curriculum for health professionals, so

copies of guidelines are in the hands of deans of medical schools and schools of public health.

Publishers and the press are another source for providing people with information on which to base their choices about nutrition. We are circulating the guidelines to textbook publishers as well as popular journals and magazines.

And finally, we are trying to reach the public directly through outlets for the consumer such as the Consumer Information Center in Pueblo, Colo. To encourage people to write for the information, we are developing, with the U.S. Department of Agriculture, public service announcements to be used in March during National Nutrition Month.

The Department is completing the development of the national health promotion media campaign which will consist of materials for radio, television, newspapers, and magazines emphasizing the message that health risks differ among individuals and that people can take steps to reduce their risks.

The self assessment form that the public will be able to obtain from the Office of Health Information and Health Promotion will include a number of questions related to diet and health. Followup information will be available through the National Health Information Clearinghouse.

This is just a sample of the actions we are taking to supply individuals with the most current nutrition information through our health networks. I will leave to the Assistant Secretary Foreman discussion of the U.S. Department of Agriculture's plans for distribution through their food and nutrition community and the description of the followup publications they are planning which will provide the public with recipes and meal plans consistent with the dietary guidelines.

To conclude, Mr. Chairman, I would like to share with you my belief that we have made great strides during the past 3 years in developing a consensus supporting moderate dietary practices for the American people. The challenge we face now are to continue to strengthen our scientific knowledge about the relationship between diet and health and to be ready to transfer any information we gain to the consumer. The activities we will undertake during National Nutrition Month are just the beginning of the effort we must make to help the consumer make informed choices about diet that will maintain and promote health.

Thank you, Mr. Chairman, for this opportunity to share our progress in nutrition research and education with you.

[The prepared statement of Dr. Richmond follows:]

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

Statement

by

Julius B. Richmond, M.D.
Assistant Secretary for Health
and Surgeon General

On

Diet and Health

Before

The Subcommittee on Health and Scientific Research

Committee on Labor and Human Resources

United States Senate

February 20, 1980

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

I am pleased to have the opportunity to meet with you today to discuss the Department's efforts to improve the health of Americans through better nutrition. It is particularly appropriate, in light of the recently released Dietary Guidelines, to share this honor with Assistant Secretary Carol Foreman of the Department of Agriculture, our co-sponsor on the guidelines.

DIETARY GUIDELINES FOR CONSUMERS

These guidelines are significant. They represent the emerging consensus among scientists about eating habits that may be helpful in maintaining the health of Americans. And, they represent our latest effort to provide the public with the best scientific information available—in easily understandable language—about actions individuals can take that may prevent disease and promote health. At the same time, they recognize that modifications will be necessary in the future as further scientific information is obtained. With your permission, Mr. Chairman, I would like to enter the guidelines into the record of this hearing.

As we noted in Healthy People, the recent Surgeon General's Report on Health Promotion and Disease Prevention, the health of the American people has never been better. There has been a remarkable reduction in infectious and communicable diseases during this century—an achievement that can be partially credited to better nutrition, along

with improvements in vaccines, housing, sanitation, and medical treatment. Although the major health problems now facing us are chronic diseases—heart disease, cancer, and stroke—I believe that further progress is possible through a renewed commitment to efforts designed to prevent death and disability.

Our success will depend on changes in approaches to medical care, strategies designed to reduce health hazards in the environment, and the development of healthy lifestyles. The key health-related behaviors people need to take more seriously are: giving up smoking, avoiding misuse of alcohol and drugs, improving nutrition, exercising regularly and reducing stress. As the relationship between diet and health becomes clearer, it is evident that good nutrition is a lifelong concern—from infancy to old age.

Nutrition and Your Health, the dietary guidelines booklet, contains explanations of what is presently known about the relationships between specific dietary components—such as fat, cholesterol, sugar and sodium—and specific diseases and physical conditions. The recommendations emphasize the maintenance of health through good nutrition—eating a variety of foods to ensure an adequate diet, maintaining ideal weight through diet and exercise, encouraging the adequate intake of foods with starch and fiber, and making sure alcohol intake does not exceed a modest level, if consumed.

There are also three areas where the guidelines recommend reductions: less sugar because of its low nutrient

density and its contribution to tooth decay; less sodium because of our concern about its contribution to hypertension in some people; and less fat because of its high caloric content, and in the case of fat of animal origin because of its contribution to increasing blood cholesterol which is a major risk factor for coronary artery disease.

SCIENTIFIC BASE FOR THE GUIDELINES

The scientific base for these recommendations is reliable. In 1978, the American Society for Clinical Nutrition (ASCN) examined all available scientific evidence relating six dietary factors to disease and analyzed the strength and the quality of the evidence. The six areas are: cholesterol, fat, carbohydrates, alcohol consumption, excess calories, and sodium. With your permission, I would like to enter into the record the consensus statements prepared by the ASCN and published as a supplement to the Society's Journal in December. In addition to the American Society for Clinical Nutrition, we also relied upon the expertise of the American Academy of Pediatrics and our own scientists at the National Institutes of Health, the Food and Drug Administration, and the Department of Agriculture.

A great deal of research is in progress to further define the relationship between diet and disease. I would like to review for you briefly our findings in several areas

of particular interest to Americans concerned about diet and health and indicate for you areas where we need to continue our pursuit of knowledge.

Diet and Coronary Artery Disease

In 1977, heart disease was responsible for over 700,000 deaths and was the leading cause of death for men after age 40. Strokes accounted for over 180,000 deaths—almost 10 percent of all deaths. But we have seen impressive improvements over the past decade. The rate of heart attack deaths declined over 22 percent in the United States between 1968 and 1977 and deaths due to strokes dropped over 32 percent. The reasons for these gains are multiple, but we believe that changes in diet may well have contributed.

During this same period, cardiovascular epidemiologists have made a significant contribution by defining a set of risk factors, traits or habits that help identify those individuals who are at increased risk for heart disease. Some of these risk factors cannot be reversed—namely age, sex, and family history. We can, however, influence the level of cholesterol or blood pressure, how much an individual smokes and his weight. There is conclusive evidence from prospective studies that the higher the blood level of cholesterol (more precisely, the level of low-density lipoproteins [LDL]), the higher the level of blood pressure (whether systolic or diastolic), and the more the individual smokes, the more likely

he or she will be to have a heart attack. In addition, the risk associated with the presence of more than one risk factor is greater than the simple combined risk of each factor alone.

With regards to diet it is interesting to note that, according to a USDA Food Consumption Survey, parallel with the reduction in heart disease death rates over the last decade has been a modest drop in the consumption of milk and cream, butter, eggs, fats and oils of animal origin.

It is also of interest to note that population studies conducted by the Lipid Research Clinics (1972-1976, NIH/NHLBI) suggest that a four to eight percent decrease in plasma cholesterol levels has occurred in the U.S. over the past 10 years, with the most striking changes in the most educated and higher socio-economic groups.

The evidence on the association between serum cholesterol level and coronary artery disease is extensive and unequivocal. It is equally clear that LDL-cholesterol can be lowered by diet or drugs in most patients. What is still hypothetical is that lowering LDL-cholesterol in man will reduce the incidence of heart attack. A great deal of suggestive epidemiologic data supports this presumption, but there is no direct clinical trial evidence in man.

To answer more definitively the question of whether lowering serum cholesterol levels will prevent heart disease, the National Heart, Lung, and Blood Institute is supporting two major ongoing clinical trials: the Lipid Research Clinics

Primary Prevention Trial and the Multiple Risk Factor Intervention Trial (MRFIT).

Until the results of these trials are available and until the benefits of lipid-lowering can be conclusively demonstrated, the question we face is—what advice can we give the public? While we complete our research and analyze the findings over the next five years, it appears wise to recommend a moderate diet change to the American public. The Dietary Guidelines include avoidance of weight gain and obesity, a moderate reduction in the intake of fat (especially saturated fat) coupled with a modest decrease in cholesterol intake. If lowering blood cholesterol levels does prove to be beneficial—as we expect it will—the public will be on the way towards dietary changes that will help to reduce mortality, morbidity and suffering associated with premature coronary artery disease.

Dietary Sodium and Hypertension

In addition to smoking and high serum cholesterol, high blood pressure is an important risk factor for coronary heart disease and stroke. Approximately 17 percent of adults in the United States have high blood pressure. The Dietary Guidelines address the issue of sodium intake because excessive sodium is one of the factors known to affect blood pressure in some people.

Epidemiologic studies indicate that in populations with low-sodium intakes, the incidence of high blood pressure is lower. If people with high blood pressure severly restrict their sodium intakes, their blood pressures will usually fall—although not always to normal levels. Although studies suggest that lowering salt intake will usually improve hypertension, it is not known whether low-salt intake earlier in life would have prevented or delayed the onset of hypertension for any given individual. The National Heart, Lung, and Blood Institute is supporting a number of research projects investigating the role of sodium intake in the etiology, maintenance, and treatment of different forms of hypertension for different population groups.

Diet and Cancer

A third area, and perhaps the one that causes the greatest fear among Americans, is the relationship between diet and cancer. Cancer claims nearly 390,000 lives a year, making it the second leading cause of death for Americans. Although no direct cause-effect relationship has been observed between nutrition and cancer in humans, a considerable amount of epidemiological evidence suggests that diet may play a role in the etiology of certain types of cancer. Such evidence is found in correlation between cancer incidence and dietary habits in numerous studies of migrant populations and special population groups.

The epidemiologic evidence is supported by animal studies which have shown components of food to be capable of acting as enhancers or inhibiters of carcinogenesis. For example, both animal and epidemiologic studies in human populations suggest that a high fat intake may be associated with an increased risk of certain cancers. Both saturated and unsaturated fats have been implicated. The relationship is probably an indirect one, with fat acting through as yet undefined pathways. The evidence is strong enough, combined with our knowledge about the relationship between fat consumption and heart disease, to recommend that Americans avoid too much fat in their diets.

Another dietary constituent which may affect cancer incidence is fiber. Epidemiologic evidence showing higher rates of colon cancer in more developed parts of the world, with generally lower levels of fiber intake, leads us to recommend that individuals consume adequate fiber as a protective measure against diseases of the bowel.

With economic development, populations generally increase their consumption of refined foods. Among the numerous dietary changes this entails, are a lower content of fiber and a diet higher in meat or fat. Although these data suggest a role for fat and fiber in the development of cancer, that role has yet to be defined, and how changes in their intake might contribute to prevention of cancer is not certain at this time.

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Diet is also a factor in cancer treatment, since nutrients are used for the synthesis and repair of living tissue. Anorexia (loss of appetite) and cachexia (profound weight loss) are frequent problems in the care of cancer patients. Although not all cancer patients suffer from these problems, those who do so may lose some capacity to withstand the disease and its treatment. Malnourished cancer patients who receive parenteral hyperalimentation (feeding of a complete nutrient solution by vein) tend to have less anorexia, nausea, vomiting and diarrhea during chemotherapy and, consequently, may tolerate larger and more effective doses of drugs. Randomized, controlled trials to determine whether hyperalimentation will increase the cancer patient's ability to respond to treatment and his subsequent clinical course are being carried out both by the intramural and the extramural program of the National Cancer Institute.

Our scientists are continuing their investigation of a number of other dietary factors that may enhance or inhibit carginogenesis. As our research findings become complete, we will translate them into useful recommendations for the public.

Sugars and Tooth Decay

The major health hazard from eating too much sugar is tooth decay (dental caries). The most extensive and convincing research indicates that a type of streptococcus

is the prime cariogenic microorganism, and there is strong evidence that high frequency consumption of sugars (generally sucrose) potentially enhances the development of caries by influencing the metabolism of the microorganism. Sticky candy and dried fruit, such as dates and figs, eaten between meals contribute, along with poor oral hygiene, to the development of cavities. In fact, Hippocrates had recognized that dried figs contribute to tooth decay, and in his aphorisms, he admonished the Greeks about the eating of too many figs. As we noted in the guidelines, it is the frequency with which people eat sugars and sweets, as well as quantity, that increases risk of tooth decay.

Obesity

Obesity is a major public health problem because of the large number of people affected and the increased risk it carries for cardiovascular disease, high blood pressure, gall bladder disease and diabetes. Maintenance of ideal body weight and weight reduction of the overweight may reduce these risks—lowering blood pressure, blood cholesterol levels, and blood glucose—and may be related to a lower risk of developing heart disease and diabetes. The Dietary Guidelines suggest a range of acceptable weight for individuals by height and sex. These acceptable weights should be sought by gradual weight loss of one to two pounds per week through a lower calorie, yet nutritious diet, combined with an increase in physical activity.

FUTURE DIRECTIONS

I have reviewed for you several of the key areas related to nutrition and health and the scientific base for our recommendations. The next logical query is, what next? It is clear that there are many areas which need more conclusive evidence. We need to learn more about the possible relationship between diet and cancer, the relationship between lower cholesterol and reduced heart disease, and the effect of reducing salt consumption on preventing hypertension—these are just a few of the questions that need to be answered among many others.

Nutrition Research

This Department is committed to supporting research to define the role of diet in health promotion and the prevention and treatment of disease.

Much of the research base for our Dietary Guidelines was derived from work sponsored by the National Institutes of Health, and our efforts are being strengthened. Through the newly established National Program in Clinical Nutrition at the National Institutes of Health, our objectives are to create or strengthen multidisciplinary biomedical research in order to develop new knowledge about specific nutrients and health, human development and the prevention and treatment of disease and to improve the education of health professionals

in nutrition. Through both intramural and extramural research (including the establishment of 10-12 Clinical Nutrition Research Units), we will examine such issues as:

- the effects of various components of human breast milk on the physiological development of the newborn;
- the effects of aging on nutrient utilization, digestion, absorption, and metabolism;
- the development of methods for the determination of dietary status—designing a computer analysis of dietary recalls, histories and food frequency questionnaires, and;
- the physiological and psychological factors that affect eating and behavior.

I could continue with the list, though it would seem endless because clinical nutrition research is a broad field with numerous unanswered questions. We have begun the search for knowledge but we must continue to strengthen the science base which we are building.

We also will be improving our knowledge of the national food supply and providing essential food composition information to consumers. For example, the Food and Drug Administration has a major project in progress to improve food labeling so that consumers will have more and better information about the nutrient profiles of their foods and the ingredients these foods contain. I understand that you will be hearing about

the FDA's activities in this area when they testify on food labeling policy next week.

It is also part of our mission to support nutrition surveillance and to monitor the nutritional status of the American population as well as provide for nutritional services through the health care delivery system. The Center for Disease Control, the National Center for Health Statistics, and other agencies of our Department are working with USDA to complete our Nutritional Status Monitoring System plan to submit to Congress very shortly.

Nutrition Information

Because we are committed to providing the public with the best information about diet and health that is currently available, it is important to address the question of how we plan to deliver this information to the public.

We have worked closely with USDA to develop a joint distribution plan to get the Dietary Guidelines into the hands of our constituents and consumers. By early next month, we will have about one million copies for the public. We have identified State level networks that are willing to distribute the guidelines to the public. These include Nutrition Directors in State health departments, directors of State agencies for the aging, the Consumer Affairs Officers of the Food and Drug Administration, and others.

We are also planning to promote the booklet through the health care system—I am sending copies of the guidelines to leaders of national health associations and professional organizations. I have asked each of these organizations to disseminate the guidelines to their State affiliates, their executive boards, and their nutrition committees. We are also interested in doing a better job of integrating nutrition education into the curriculum for health professionals, so copies of the guidelines are in the hands of deans of medical schools and schools of public health.

Publishers and the press are another source for providing people with information on which to base their choices about nutrition. We are circulating the guidelines to textbook publishers as well as popular journals and magazines.

And finally, we are trying to reach the public directly through outlets for the consumer such as the Consumer Information Center in Pueblo, Colorado. To encourage people to write for the information, we are developing, with USDA, public service announcements to be used in March during National Nutrition Month.

The Department is completing the development of the National Health Promotion Media Campaign which will consist of materials for radio, television, newspapers, and magazines emphasizing the message that health risks differ among individuals and that people can take steps to reduce their

risks. The self-assessment form that the public will be able to obtain from the Office of Health Information and Health Promotion will include a number of questions related to diet and health. Follow-up information will be available through the National Health Information Clearinghouse.

This is just a sample of the actions we are taking to supply individuals with the most current nutrition information through our health networks. I will leave to Assistant Secretary Foreman discussion of USDA's plans for distribution through their food and nutrition community and the description of the follow-up publications they are planning which will provide the public with recipes and meal plans consistent with the Dietary Guidelines.

To conclude, I would like to share with you my belief that we have made great strides during the past three years in developing a consensus supporting moderate dietary practices for the American people. The challenges we face now are to continue to strengthen our scientific knowledge about the relationship between diet and health and to be ready to transfer any information we gain to the consumer. The activities we will undertake during National Nutrition Month are just the beginning of the effort we must make to help the consumer make informed choices about diet that will maintain and promote health.

Thank you for this opportunity to share our progress in nutrition research and education with you.

Senator METZENBAUM. Thank you, Dr. Richmond.

Ms. Foreman, we will be very happy to hear from you. The staff has indicated that I request witnesses, Dr. Richmond and Ms. Foreman, to limit their remarks to 10 minutes each. The balance of witnesses are being asked to limit their remarks to 5 minutes each in order that we may have an adequate opportunity for questions.

Ms. FOREMAN. Thank you, sir.

I think we should begin by pointing out that we are here today to discuss these guidelines largely because of the work that was done by the Senate Select Committee on Nutrition. It was the dietary goals set out by that committee in 1976 that really brought nutrition information and guidance to the public's attention, and began the debate that has led to the issuance of dietary guidelines.

The Surgeon General has explained the scientific evidence which supports the dietary guidelines. I would like to talk a little bit about the public policy issues involved and what the Department of Agriculture will do about them.

The Departments of Agriculture and Health, Education, and Welfare pooled our medical and nutritional knowledge to provide American citizens with dietary guidance. Many people have asked why. The simplest answer to that is that I think a Government of the people should respond to the concerns of its people.

The people have made it clear over the past several years that they are concerned about the relationship between diet and health.

It has been a decade since the White House Conference on Food, Nutrition, and Health first focused national attention on food and its relationship to health. In the intervening years, we have made substantial progress in dealing with one side of that relationship; that is, overcoming hunger and malnutrition and diseases related to them. Government food assistance programs, such as food stamps, the supplemental feeding program for women, infants, and children, and school lunch and breakfast, are responsible for a great deal of that progress.

We have been somewhat less successful with the other side of the equation—health problems which may be related to overconsumption or inappropriate food choices. The dietary guidelines address those problems. They are a response to the legitimate concern of many American people about the food they eat and its effects on their health.

Evidence of that concern is all around us. Last year, the American family report, a survey done by Yankelovich, Skelly, and White, revealed that American family members are concerned now about many food related issues, such as cholesterol, fats, and food additives, which did not worry them in the past.

The majority of the families surveyed believed that overweight is a serious health hazard. They were far more concerned with, and conscious of, the need for good nutrition than they had been in the past. And a majority were interested in preventive health care.

Public concern about the safety of food products has risen sharply in recent months. The public hearings held last year by the Department of Agriculture, the Food and Drug Administration, and the Federal Trade Commission, showed increased consumer concern for more information on the nutritional composition of processed and packaged foods.

The Department has been trying to respond to these concerns. In December, we published preliminary labeling proposals in the Federal Register. The guidelines are another response. And this subcommittee's scheduled hearings on the companion nutrition labeling bills, S. 1651 and S. 1652, are still another.

We welcome this congressional initiative and support the general concepts of the proposals in these bills. We believe that all of these actions will ultimately help the American people make their own informed food choices.

It is not new for the Government to advise its citizens in an effort to protect their health. The Department of Health, Education, and Welfare has been doing it for years. The Department of Agriculture has been doing it for years. The recommended dietary allowances are one example. And we provide information about diets. The guidelines are simply a logical step forward in this process. They represent a cooperative effort between the two Departments to provide new information. They grew out of a joint informal coordinating committee which has representatives from both USDA and the Department of Health, Education, and Welfare.

The committee appointed a task force of scientists from the two Departments and instructed it to translate current scientific knowledge, on which there was consensus, into general dietary guidance for the public.

The dietary guidelines are the result. In developing them, the task force, of course, consulted with a large number of other scientists, as Dr. Richmond noted in his testimony.

These guidelines do not tug at the frontiers of nutrition knowledge. They are firmly grounded in that territory of nutrition science which has been surveyed and studied for many years and is now largely undisputed. The guidelines contain fundamental concepts and practical advice. They are neither a medical prescription nor a nutritional insurance policy. They are simple recommendations which people can use, if they choose, without making drastic changes in their life styles or food preferences.

They are neither law nor regulation. They are advice, but they do reflect a very serious concern: The promotion of health and the prevention or reduction of killer diseases, some of which have reached epidemic proportions in this country.

It is true, unfortunately, that right now we lack the technological sophistication to predict or identify those specific individuals who risk developing such diseases. However, there is not one shred of evidence or research that indicates following the recommendations of the guidelines will do harm to anyone. No research indicates that a diet low in salt, sugar, and fat is harmful to human beings. On the other hand, these guidelines may well help those who choose to follow them, regardless of their risk status.

Now, Government can do more than provide advice and information. It can and should follow the most prudent course in its functions as supplier and regulator. And I would like to take just a minute to talk about what the Department of Agriculture is doing in that regard.

We spend about $3 billion a year of Federal tax dollars on the child and elderly nutrition programs. We purchase directly more than $800 million worth of food for these programs annually.

We have been following the recommendations of these guidelines for some time. We have reduced the fat content in our ground beef purchases from 28 to 22 percent. Last year, we purchased fruits packed in light syrup. This year, we will have fruits packed in their own juices. We are testing the acceptability of vegetables that are packed with only 1 percent salt. And, for the first time in the history of the school feeding programs, we bought fresh fruit and provided it to the school children.

We also set certain standards for school food programs. Here again we try to follow good dietary advice. Our new school lunch regulations recommend that schools attempt to reduce salt, sugar, and fat in their meals. And we require schools to offer a low fat milk to students, in addition to whole milk.

We have followed the directive of Congress and issued a final regulation——

Senator SCHWEIKER. I would like to see you require the airlines to do it too. I have trouble getting low fat milk on the airlines.

Ms. FOREMAN. There's no trouble getting artificial coffee cream, though.

Senator METZENBAUM. Would you also take care of a little margarine on the airlines as well?

Ms. FOREMAN. For years we have avoided the thicket of airline meals. Perhaps you should tell them that we should get into that.

Senator METZENBAUM. They do not understand what you are talking about. I think you ought to do a little educating.

Ms. FOREMAN. Perhaps it could be argued that since airline passengers are even more of a captive audience than schoolchildren, the Government has a role to play here.

Senator METZENBAUM. You know the broad jurisdiction the Department of Agriculture has.

Senator SCHWEIKER. A letter from you would have a big impact I think.

Ms. FOREMAN. We followed the directives you gave us in 1977 and issued a final regulation setting a minimum nutritional standard for foods sold in competition with school meals. And we have proposed changes in the food packages that we offer participants in the women, infants, and children's supplemental feeding program.

We will spend more than $100 million this year to transmit nutrition information, both to the general public and to those groups and individuals who receive USDA food assistance.

Our nutrition education and training programs provide nutrition information to school teachers and food service personnel.

USDA's Human Nutrition Center soon will publish a series of suggested menu guides to assist those citizens who wish to put the guidelines into practice. They will suggest eating patterns which will not require that people change the way they cook very substantially, nor will they alter too much the amount of money that is spent on food. But they will help people adjust their eating patterns to the guidelines, if they choose to do so.

Government is not the only actor here. The food industry obviously has a substantial impact on eating patterns and it does most

of the advertising. I think the industry stands on the threshold of a major decision. It can either decide to say, "Oh, no, we won't go", or they can take the guidelines for what I think they are—an opportunity to open up a whole new marketing strategy, to offer people foods and food products that are consistent with concerns about getting less fat, sugar, and salt in their diets. There are really some very encouraging things happening in this regard.

The Food Marketing Institute, the trade association for supermarkets, has endorsed the dietary guidelines. The institute has provided information to their member supermarket chains and encourages them to provide similar information to their customers.

Perhaps during the question period I can tell you about other supermarket initiatives.

Food processors have not been idle, either. Oscar Meyer and Hormel have been test-marketing low fat hot dogs. The development of lower fat processed meats could be very advantageous in helping people follow these guidelines.

Obviously, nutrition science is an evolving field, and these guidelines are not the last word. We will continue to be ready to accept the advice and counsel of scientists and to use that counsel in our food purchasing and nutrition education programs.

[The prepared statement of Ms. Foreman follows:]

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D. C. 20250

Statement

by

CAROL TUCKER FOREMAN
Assistant Secretary for Food and Consumer Services

on

Diet and Health

Before

The Subcommittee on Health and Scientific Research

Committee on Labor and Human Resources

United States Senate

February 20, 1980

Mr. Chairman and Members of the Subcommittee:

The Surgeon General has explained the scientific evidence which supports the Dietary Guidelines. I want to talk about them from the perspective of public policy.

What prompted the two federal departments most concerned with food and health to pool their medical and nutritional knowledge to provide American citizens with dietary guidance? Who said they wanted any? And, even if they did, where is it written that the advice should come from the federal government?

I believe the simplest answer to those questions is that a government of the people -- and that is what we are -- should respond to the concerns of its people.

You won't get much disagreement on that. The debate arises over how government should respond. And when.

It has been a decade since the White House Conference on Food, Nutrition, and Health first focused national attention on food and its relationship to health. In the intervening years, the United States has come a long way in fighting hunger and malnutrition and the diseases related to them. Government food assistance programs, such as Food Stamps, the Supplemental Feeding Program for Women, Infants, and Children (WIC), and School Lunch and Breakfast, are responsible for much of that progress.

We have been less successful with the other side of the equation -- health problems which may be related to overconsumption or inappropriate food choices. The Dietary Guidelines address

those problems. They are a response to the legitimate concern of/many American citizens about the food they eat and its effects on their health.

Evidence of that concern is all around us. Lat year, the American Family Report, a survey done by Yankelovich, Skelly, and White, revealed that American family members are concerned now about many food products such as cholesterol, fats, and food additives, which did not worry them in the past. The majority of the families surveyed believed overweight to be "a serious health hazard." They were far more concerned with, and conscious of, the need for good nutrition than they had been in the past. And a majority were interested in preventive health care.

Public concern about the safety of food products has risen sharply in recent months. According to a national survey by Consumer Research Corporation, the general level of consumer concern about foods climbed 11% between January and September of 1979. In January, only 38% of those questioned were worried about safety hazards associated with food. By June, the percentage had increased to 45%, and by September, it had reached 49%.

In November, tabulations of mail and telephone calls to Consumer Reports Magazine showed that concerns about food products outnumbered those about automobiles, household cleaning agents, and medical products. It was the first time food had attained that dubious first-place distinction.

Public hearings conducted last year by the Department of Agriculture, the Food and Drug Administration, and the Federal

Trade Commission, showed increased consumer demand for more information on the nutritional composition of processed and packaged foods.

Government has been responding to these concerns. In December, we published preliminary labeling proposals in The Federal Register. The Guidelines are another response. This Subcommittee's scheduled hearings on the companion nutrition labeling bills, S. 1651 and S. 1652, are still another.

I am sure I can speak for Dr. Richmond as well as myself when I welcome this Congressional initiative and support the general concepts of these proposals. We believe that all of these actions will ultimately help the American people make their own informed food choices.

It is not new for government to advise its citizens in an effort to protect their health. Government has been doing it for years. The Recommended Dietary Allowances, originally developed by USDA scientists, are a good example. So are the various USDA publications which give advice on the proper ways to handle and store foods. The information provided to farmers about the best way to sow crops, improve animal feed efficiency, and use pesticides, are other examples. USDA's popular Food book, with suggested menus and recipes, is still another.

So the Guidelines are no great departure from past practice. They are simply the latest effort to provide the American public with a summary of the latest scientific consensus, this one on the relationship of dietary patterns to the risk and incidence of specific chronic diseases.

4.

Government did not rush headlong into the nutritional thicket. The White House Conference, in 1969, recommended that the federal government take action to initiate nutrition education programs for the public.

In 1978, USDA and the Department of Health, Education, and Welfare formed a Joint Informal Coordinating Committee to address issues of mutual concern in human nutrition. The Committee is composed of the Surgeon General, the Director of the National Institutes of Health, and the Commissioner of the Food and Drug Administration, representing HEW; and from USDA, the Assistant Secretary for Food and Consumer Services, the Director of Science and Education, and the Director of the Human Nutrition Center. Nutrition policy coordinators from both departments also sit on the Committee.

This committee appointed a task force of scientists from the two departments and instructed it to translate current scientific knowledge, on which there was consensus, into general dietary guidance for the public.

The Dietary Guidelines are the result. In developing them, the task force, of course, consulted other scientific bodies. Among them were the consensus papers of the American Society for Clinical Nutrition, which were issued last May after an exhaustive, four-way study on the strength of association between dietary factors and prevelant chronic disease.

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5.

The association found four correlations to be of considerable strength. The strongest association was the relationship of alcohol consumption to liver disease. The second was between sugar and dental cavities. The third showed a relationship between salt and hypertension. The fourth showed a relationship between cholesterol and saturated fat and coronary artery disease.

Also reviewed were the conclusions of the special scientific committee of the Federation of American Societies for Experimental Biology, commissioned by FDA to study salt in the diet. Statements by the American Academy of Pediatrics and the National Cancer Institute were also used as sources. So was Healthy People, the Surgeon General's Report on Disease Prevention and Health Promotion.

I think it is important to note that these scientists have no product to sell, nor any particular hypothesis to protect or promote. It could even be argued that their own purposes would be better served by not taking a position. At a time when funds for basic research -- or anything else -- are hard to come by, they might well have concluded that it was the better part of wisdom to plead ignorance and say that the diet-disease controversy needs further study.

No doubt it does. But the Guidelines do not tug at the frontiers of knowledge. They are firmly grounded in the largely undisputed territory of nutrition science. They contain fundamental concepts and practical advice. They are neither a medical prescription nor a nutritional insurance policy. They are simple recommendations which people can use, if they choose, without

making drastic changes in their life styles or food preferences.

While the Guidelines are neither law nor regulation, but advice, they do reflect a very serious concern: the promotion of health and the prevention or reduction of killer diseases, some of which have reached epidemic proportions in this country.

It is true, unfortunately, that right now we lack the technological sophistication to predict and/or identify those specific individuals who risk developing such diseases. However, there is not one shred of evidence or research that indicates following the recommendations of the Guidelines will do harm to anyone. No research indicates that a diet low in salt, sugar, and fat is harmful. On the other hand, these Guidelines may well help those who choose to follow them, regardless of their risk status.

Government can do more than provide advice and information. It can and should follow the most prudent course in its functions as supplier and regulator.

We have no intention of telling the American people to "Do as we say, don't do as we do." We are doing. We spend roughly $3 billion of Federal tax dollars on the child and elderly nutrition programs each year. The government purchases directly more than $800 million worth of food for these programs annually.

We have reduced the fat content in our ground beef purchases from 28 to 22%. Last year, we purchased fruits packed in light, father than heavy, syrup. This year, we will make it available packed in its own juice. For the first time, we have purchased fresh fruits for use in the school feeding programs. And we are testing the acceptability of vegetables canned with only 1% salt.

7.

The Department also sets certain standards which must be met in these feeding programs. In this area, too, we are attempting to follow good dietary advice. School lunch and breakfast regulations now in effect recommend that schools attempt to reduce salt, sugar, and fat in these meals. We require that schools offer a low fat milk to students, in addition to whole milk.

We have followed the directive of Congress and issued a final regulation setting minimum nutritional standards for foods sold in competition with school meals. And we have proposed changes in the food packages for participants in the Women, Infants, and Children's Supplemental Feeding Program.

In addition, this year USDA will spend more than $100 million to transmit nutrition information, both to the general public and to specific target groups served by our food assistance programs.

Thousands of American families are offered assistance in improving their diets and getting the most from their food dollar expenditures through the Expanded Food and Nutrition Education Program, and the Cooperative Extension Services in the states.

Our Nutrition Education and Training Programs offer nutrition information to school teachers and food service personnel so that the school feeding programs can be learning experiences in nutrition. We are working with the National Congress of Parents and Teachers to develop pilot programs for increasing parent and student involvement with school feeding programs.

8.

The Department will continue to develop informational materials for use by the general public. The Guidelines themselves will be distributed by the Extension Services, which operate in 3,100 counties across the country. They will also be used by the nutrition education personnel in the Food Stamp, Child Nutrition, and WIC Programs. These nutritionists may adapt the information to fit their specific education programs or, in some cases, distribute copies of the guidelines directly.

HEW will distribute the Guidelines through state, county, and local Public Health Departments. They will be available to individual health professionals and professional organizations in the health field. 100,000 copies will be available directly to the public through the Consumer Information Center in Pueblo, Colorado.

USDA's Human Nutrition Center, created in 1978 and directed by Dr. Mark Hegsted, will soon publish a series of suggested menu guides to assist those citizens who wish to put the Guidelines into practice. The Center is also working on a second edition of the Food book, which will deal with the reduction of fats, sugar, and salt, and an increase of fiber, in the diet.

Few people quarrel with better information, more stringent requirements on federally-funded regulatory and purchasing programs, and requirements for better labels.

But government is not the only actor here. The food industry is on the threshold of a major decision, and it may be the most important decision on this entire issue. That decision is whether to stand pat and greet every new piece of information which comes from the government as another outbreak of national nanny-itis,

or to turn the information into a major marketing strategy. There are encouraging indications that many businesses will choose the latter course.

The Food Marketing Institute has endorsed the Guidelines and has done an outstanding job of disseminating nutritional information throughout the food industry.

Several supermarket chains have seized the initiative by offering nutrition and health information programs, ranging from the provision of nutrition information, to broader activities which address shopping and meal habits, diet, exercise, and life style.

For example, Giant Food, in cooperation with the Heart, Lung, and Blood Institute of the National Institutes of Health, is conducting a pilot nutrition information program which focuses primarily on heart health. The Giant program concentrates on cholesterol, fats, and salt, but it does touch on sugars and general nutrition information.

Also, two New York grocery chains, in cooperation with the Cooperative Extension Service of Cornell University, have a nutrition education pilot project underway to study how consumer food choices are influenced by a variety of nutrition education methods.

Food processors are not ignoring the public concern over diet either. Hormel and Oscar Mayer have test marketed
7 a low-fat frankfurter. I hope others will follow their lead. I believe that as Americans become more and more food conscious, there will be an ever-expanding market for

food products that are low in fat, sugar, and salt. The industry has taken such initiatives in the past. They developed enriched flour, and poly-unsaturated margarines. They reduced the lard weight in pork, and packed fruit in its own juice. An average of 2,000 new products fill the supermarket shelves each year. More than half the products there now didn't exist 30 years ago.

In closing, Mr. Chairman, let me say that in spite of these positive developments, we are aware that there are those who would have preferred that the publication of the Guidelines await absolute, iron-clad scientific unanimity. Well, we could have awaited unanimity, instead of accepting consensus. We could also have waited for the millenium to dawn, for the cows to come home, and for the moon to be made of green cheese.

But we feel that offering dietary guidance to the public is an appropriate and important response hy government to increasing public concern about the relationship between diet and disease. For too long -- certainly since the publication of the Dietary Goals by the Senate Select Committee on Nutrition and Human Needs -- the nutritional wars have been fought on a battleground littered with milligrams, micro-nutrients, decimal points, and biochemical breakdowns.

That's fine for the scientists and nutritionists, but it does precious little for the eaters. People eat every day. They want relatively simple, easy-to-use guidance based on the best available information.

That is what the Guidelines give. I believe they will be helpful to the millions of healthy Americans who have more than a passing interest in staying that way.

Finally, I cannot tell you that scientific consensus on these issues will never change. No one can. Nutrition is an evolving science. But certainly we do not expect to alter the Guidelines tomorrow. We do stand ready to accept the advice and counsel of our scientists; to use that counsel in food purchasing, food regulation, and nutrition education, and to make changes in all those areas when scientific judgement tells us that we should.

Senator METZENBAUM. Thank you very much.

Dr. Richmond, the Departments have spent a long time developing these guidelines. You have said they are significant, and represent an emerging scientific consensus. Would you say these guidelines indicate that we have reached a consensus in our nutritional policy development and that we are now ready to proceed to implement the policy?

Dr. RICHMOND. I think they are, indeed, Mr. Chairman, a significant step in the direction of an evolving food policy for the Nation. I think the scientific consensus that we have translated into, we think, lucid terms, terms that can be readily understood by the consumer, will be extremely important in gaining additional acceptance of a balanced and appropriate title consistent with our best scientific information. And we think that moving in the direction that Secretary Foreman has indicated, trying to enlist food processors, marketing strategies in the private sector, helping people choose guides, will go a long way toward helping us move in the direction of a sound food policy.

Senator METZENBAUM. Doctor, I get the impression from your answer that although you herald this as an emerging scientific consensus and with much banter. With respect to my question to you whether we are ready to proceed to implement a policy, I get the feeling that your answers are very tentative and indicate we are going to try to get the processors and the supermarkets to educate voluntarily.

The real question is, if the guidelines are as important as you claim they are, then the question is what specific actions does HEW plan to take, what kind of funding are you planning to invest, and, overall, how does this fit into your health promotion effort? Is this just another program that comes forth with fanfare but, when it comes to actual implementation, that the rhetoric is better than the action?

Dr. RICHMOND. Mr. Chairman, I think there is a good deal of action that is associated with the release and distribution of these guidelines. Certainly, we do need to gain a greater acceptance by the public of these kinds of dietary practices.

In your introductory comments, you pointed to some of the inappropriate dietary practices which have promoted development of obesity and cardiovascular disease and so forth. This is related to inappropriate dietary practices which is becoming prevalent in the American community.

I think Senator Schweiker pointed out that hunger which a decade ago was a significant problem, I can remember the Senate Select Committee attending to that problem very significantly in the sixties, has become a relatively small problem. More food and more abundance has not necessarily, as he properly pointed out, been associated with improved nutrition. We think that this subcommittee and what our two departments are doing will move us in the direction and the first objective must be to get that information out to people. We do need to extend our information and I dwelled in my remarks on the importance of extending our research so that we can accelerate the trend toward the reduction of cardiovascular morbidity and mortality that is taking place.

Senator METZENBAUM. What programs does HEW have to actually implement the policy? DHEW has a tremendous budget. What will be done, as a practical matter, to implement this program? Ms. Foreman talked about something the Department of Agriculture is doing; what will HEW be doing?

Dr. RICHMOND. One of the things we have begun to do is to develop clinical nutrition centers in various medical centers around the country. I know Senator Schweiker has pushed us on this in the past. These centers will have the responsibility for developing further knowledge in this field, and even more significantly, educating our health professionals so they have a better understanding as they go out into the community to serve their patients and the public.

The Department has a wide variety of activities in a number of critical areas:

NUTRITION EDUCATION

The Department has recently completed a survey of its nutrition education and information programs and publications and is in the process of reviewing those publications. One of the evaluation criterion is to judge the publication as to its consistency with current Department policy, including the dietary guidelines statement.

Several agencies within the Department are currently involved in nutrition education projects where the guidelines will play a significant role. The Food and Drug Administration has devoted $317,000 in fiscal year 1979 and $332,000 in fiscal year 1980 to evaluate alternative formats for food labeling in order to determine the most effective mechanism for reaching consumers with nutrition information. The Center for Disease Control recently let a $300,000 contract to develop a manual to train elderly persons as peer counselors in nutrition education.

The National Institutes of Health has $4.5 million annually budgeted for nutrition education for professionals and for the public in such activities as articles in professional and lay publications, workshops, and conferences, work with retail grocery outlets, public service announcements. Human Resources Administration provides more than $4 million annually in training grants to edu-

cational institutions in the preparation of health manpower personnel. In addition, the Health Services Administration's Bureau of Community Health Services funds several nutrition training projects; $5.4 million was funded during the last fiscal year on these projects.

NUTRITION LABELING/REGULATIONS

Tentative positions on food labeling set by FDA, FTC, and USDA were issued in December 1979 and final public hearings will take place in March 1980. FDA will: (a) Prepare mandatory labeling of total sugar content on all nutrition labeling when contained above a certain level; (b) propose mandatory labeling for sodium and potassium on all nutrition labeling and in addition will define "low sodium", "moderately low sodium" and "sodium reduced"; and (c) propose increased flexibility in use of cholesterol claims in labeling and will define "cholesterol free", "low cholesterol", and "cholesterol reduced".

Labeling statements relating to usefulness in reducing or maintaining calorie intake or body weight were issues in September 1978 and will become effective in July 1980. The food fortification policy issued on January 20, 1980 relates to the first guidelines, "Eat a Variety of Foods". It addresses standards of identity; nutritional quality guidelines; common or usual name regulations—nutritional equivalence or substitutes; restoration of nutrients lost in processing; and fortification in proportion to caloric content.

Finally, our infant formula regulations will stress breast feeding, discussed under the guidelines on "Eat a Variety of Foods".

NUTRITION STATUS MONITORING

The Department of Health, Education, and Welfare is now working cooperatively with the Department of Agriculture to develop a uniform national nutrition status monitoring and surveillance system. This coordinated system, drawing upon the strengths of this Department in gathering health statistics and those of Agriculture in monitoring food use and consumption patterns, will take into account the principles outlined in the dietary guidelines statement.

NUTRITION SERVICES

In our health service delivery programs there will be ample opportunity for the nutritionists and other health care personnel to incorporate the concepts and principles of the guidelines into their nutrition education and counseling activities. Among the health service delivery programs administered by HEW with nutrition components to children, parents/guardians, and sometimes personnel and staff are the Head Start Program, Follow Through, the Congregate Meal Program for Older Americans, and Community Health Programs for Migrants, Indians, plus the maternal and child health clinics and health departments in each State.

NUTRITION RESEARCH

From September 1977 to January 1980 a number of nutrition research and nutrition training grants were published in the NIH

guide for grants and contracts. Among those with a specific relationship to the dietary guidelines were those titled: "Infant Nutrition," "Studies on Overnutrition and Obesity," "Human Milk Bank Research and Distribution Center," "The Role of Nutrition in the Rehabilitation of Cancer Patients," "National Research Service Awards for Institutional Grants in Nutrition," "Developmental Aspects of Behavior and Nutrition," and "Nutrition Individuality and Dietary Patterns."

Our Health Resources Administration is allocating significantly more money for this kind of professional education. We will be undertaking through our National Cancer Institute the expenditure of additional funds in relationship to gaining a better understanding of the role of diet in prevention as well as the management of cancer.

Senator METZENBAUM. How much of DHEW budget will be allocated to the NIH?

Dr. RICHMOND. That will be $29.3 million in 1980.

Senator METZENBAUM. Out of a total NIH budget of——

Dr. RICHMOND. $83.3 million. But I could also point to the National Heart, Lung and Blood Institute, which will in 1980 be expending $24.5 million; the National Institute of Dental Research, $2.3 million; the National Institute of Arthritis, Metabolism and Digestive Diseases, about $30.4 million. And I am submitting a list of the others.

[The following was received for the record:]

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

APR 18 1980

Honorable Howard M. Metzenbaum
U.S. Senate
Washington, D.C. 20510

Dear Senator Metzenbaum:

I appreciated the recent opportunity to appear before the Senate Health Subcommittee to address the topic of diet, nutrition and health.

During the hearing you inquired about the proportion of the DHEW budget which will be allocated to the various Institutes at NIH and the activities HEW will be undertaking with respect to the new dietary guidelines document. Attached please find a statement of NIH's Budget obligations by Institute for five consecutive fiscal years, FY 1977 through 1981 estimates.

In addition to the projects mentioned in my testimony, I am also submitting for the record examples of ways in which we anticipate the dietary guidelines will impact on Departmental and Public Health Service policies and programs in the near future. Again, we thank you for giving us the time to share our programs with your Committee, and will be happy to provide any additional information you feel will be helpful.

Sincerely yours,

Charles Miller

Acting Assistant Secretary for Health

Enclosures

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Biomedical and Behavioral Nutrition Research and Research Training
(Obligations in thousands of dollars)

Public Health Services

National Institutes Of Health:	1977	1978	1979	1980 Revised Estimate	1981 Revised Request
National Cancer Institute	$16,100	$18,198	$25,251	$29,200	$31,800
National Heart, Lung & Blood Institute	21,349	21,934	23,650	24,200	24,700
National Institute of Dental Research	1,258	2,019	2,221	2,321	2,495
National Institute of Arthritis, Metabolism, and Digestive Diseases	19,520	22,175	26,186	30,031	32,396
National Institute of Neurological & Communicative Disorders & Stroke	1,142	1,203	2,306	2,600	2,700
National Institute of Allergy and Infectious Diseases	736	765	1,206	1,210	1,331
National Institute of General Medical Sciences	2,369	2,832	2,971	2,600	2,600
National Institute of Child Health and Human Development	14,667	16,292	20,407	22,250	23,150
National Eye Institute	1,510	2,664	3,402	3,665	3,789
National Institute of Environmental Health Sciences	3,317	3,534	3,740	3,880	4,095
National Institute on Aging	1,318	1,546	2,739	3,970	4,399
Division of Research Resources	10,000	13,136	13,381	14,545	15,384
Total, NIH	93,286	106,298	127,460	140,472	148,639

Senator METZENBAUM. Dr. Upton, the former Director of NCI, stated last October, if my recollection serves me right, 50 percent of the cancer causes may be related to diet. Would you agree with that statement?

Dr. RICHMOND. Well, I think that we would say there is a strong association between some forms of cancer and diet. But one of the problems there is we do not understand those associations as well as we might, and that is why we want to foster more research.

I should have mentioned that there has been an approximately 40-percent increase in the past 2 years of research projects in the area of diet and cancer funded by the National Cancer Institute.

Senator METZENBAUM. I have some more questions, but I would like to give Senator Schweiker the opportunity to ask some others.

Senator SCHWEIKER. Thank you, Mr. Chairman.

First, I would like to compliment you both for having labored so hard in the vineyard to produce a national dietary guidelines statement. I am very pleased. It has taken a while, but I think that both of you deserve some credit for changing the bureaucratic face on this problem in the Department of Agriculture and the Department of Health, Education, and Welfare.

As Senator Metzenbaum said, how do we get the rest of the establishment to move with the policy? I think you both are to be commended for it.

I have a few questions and I think this, by the way, is an excellent summary. I think our first Senate report was a good detailed statement of experts, but this is really in layman's language. It is easily digestible and also directly applicable to what we are saying. I think it is very well done.

Dr. Richmond, one of the areas that this gets into, and I know there is some controversy about it, is the amount of sodium in the diet. We all seem to know we consume too much sodium and that is due to salt, but we also know that there are many, many other sources of sodium that people do not even know they are eating something with sodium. You get it in many things. Even artificial sweeteners usually have sodium. So there is all kinds of sodium sources.

Where is the trigger? How can we tell the average person to be cautious of things that do have sodium in them? Where is the demarcation between a potential for hypertension and, of course, our need for certain amount of sodium to take care of our basic needs? Is there any advice scientifically that we can give our people?

Dr. RICHMOND. Well, I think, Senator Schweiker, you put your finger on a very important problem because hypertension is so prevalent in this country. Your raising this question is very significant. We do know that we are consuming too much, and we think these guidelines are prudent in the sense they suggest that all of us ought to reduce our intakes somewhat, precisely the lower levels of a floor below which none of us should go is not as clearly established, but, certainly, the select committee suggested there ought to be some quantitative assignments to this.

Now, your question I think really leads to the whole matter of helping inform the public and, particularly, how can we engage in

more effective labeling of foods so that people can make more appropriate choices.

I think we can say without a doubt they ought not salt food. Certainly that is one statement on which we have an absolute consensus. So many foods, as you pointed out, naturally contain sodium. But beyond that, I think we do need, in some of the nonsalt situations, where sodium is a content constituent of what is ingested, we should make that information readily available. And Food and Drug Administration is now moving rather quickly, I think in early March, they will be holding their final public hearings on the matter of food labeling of sodium and potassium constituents. I think we then will make the judgments on the appropriate labeling of various foods.

Senator SCHWEIKER. Well, there is a controversy and we will hear later on this issue at our next hearing. We pretty much conclude that too much fat is obviously a bad element of diet. But we get into a scientific dispute between whether unsaturated fats are as serious a factor as saturated fats. You also touched on that. What guidance you can give us about unsaturated fats in terms of contributing to some of the fat problems as opposed to problems associated with fat per se?

Dr. RICHMOND. Well, I think, Senator Schweiker, we, in general, are concerned about saturated fat and it indicates a movement toward fat in the diet coming from predominantly unsaturated sources. And I think the public has been accepting that reasonably well.

Now, when we get into some areas, like the relationship of fat intakes and cancer, there we are not so certain of what that fat composition would be. We do not have clear data on unsaturated fats as well as saturated fats. These are some of the areas where we have more active research. The National Cancer Institute is pursuing that.

Senator SCHWEIKER. One of the things that I think is a sleeper to the average American, and which health biomedical research points out is the relationship between fat or obesity, as we call it, and disease. There is a very clear-cut relationship between fatness or obesity and disease.

As I read your statement and your other reports, there is a clear-cut relationship between obesity and a lot of other things. Obesity is sort of something that everybody takes for granted in our society. Yet, it is a real killer in many respects.

We ought to be putting out more advice about obesity. I know you do on maintaining ideal body weight, which is a very good goal. How can we dramatize the fact that there seems to be a lot we do not know except that obesity triggers off a high risk of different diseases. What can you tell us about obesity as it relates to disease?

Dr. RICHMOND. Senator Schweiker, certainly life insurance companies that study health issues related to morbidity and mortality have known for decades that obesity is a hazard. They themselves have embarked on educational campaigns on this because it is in their interest.

Is is very true that obesity is a risk factor for many disorders—cardiovascular disorders——

Senator SCHWEIKER. Hypertension, as you pointed out.

Dr. RICHMOND. Now, what we need, it seems to me, is to learn more about how to motivate people to do something about their weight. We have made progress in recent years with the adult male who had the greatest susceptibility, according to statistics in recent decades, to heart disease. He seems to have gotten the message. He is the one smoking less, eating more prudent diets, exercising more. And I think we need to learn more about why that segment of the population, certainly they were a greater risk, why did they get the message about following a more prudent dietary course than other segments of the population.

So, when you raise this question, I think you should not underestimate the importance of what we are calling behavioral research. We need to know why people eat too much to begin with; what will motivate them to follow a more appropriate dietary pattern; what will motivate them to engage in an appropriate amount of exercise. And we intend to enhance our investments in that area with our National Institute on Mental Health and National Institute on Drug Abuse. We are looking at the patterns of excessive dietary habits.

Senator SCHWEIKER. Fatness is not illness, but it is something in that area. The order of magnitude is really great.

I still have some more questions but——

Senator METZENBAUM. Let me say I invited Miss Teenager USA to sit at the table with us. She is a living example of what good diet will do.

Senator SCHWEIKER. She has no obesity problem.

Senator METZENBAUM. And, second, she is from my home State of Ohio. We are happy to have you with us this morning. Anytime you have to leave, feel free to.

Ms. Foreman, I have a couple questions for you.

If we accept the premise that many foods promoted through advertising are not necessarily the most nutritious, how can we expect to reach the American people with a message of the dietary guidelines? For example, TV stations are required to schedule public service announcements. What can you do or we do to compete with the very slick, well-prepared Madison Avenue food advertisements that will suggest eating foods regardless of the nutrient quality? What effort is your Department and DHEW making in this area?

Ms. FOREMAN. I think there are really three ways that we can go at this, Senator Metzenbaum. The first is to continue to make available public service announcements, as we have for several years. The Food and Nutrition Service within the Department of Agriculture is working on a pilot study to see how we can best provide good nutrition information that will be as attractive as some commercial advertising. Can broccoli be sexy, so to speak.

Senator METZENBAUM. That will be a difficult task.

Ms. FOREMAN. A lot of people think that, Senator, and it is taking longer than we expected. We are going to be pilot-testing some commercials, starting next fall. But public service announcements clearly cannot command the same kind of prime time that paid commercials do. So one would hope that the food industry, because it sees a public concern about the relationship of diet to

health, will view nutritional advertising as a good marketing strategy. That would be the easiest way to go at this problem.

Incidentally, most of the studies that we have about people's concern with health come out of surveys done for various industry groups, such as General Mills, and Food Marketing Institute. Companies are out there all the time examining public attitudes to see what kind of response there is on these important food issues.

A third mechanism might be for Congress to authorize us to spend money to purchase advertising time to make good nutrition messages available. Neither USDA nor HEW has that kind of authority at the present.

Senator METZENBAUM. What about encouraging some of the present childrens' programs, like Sesame Street, to include, as part of the program itself, some of the issues to which we are addressing ourselves today?

Ms. FOREMAN. I think that would be a very good idea. We have not communicated with them, although 3 or 4 years ago, as I recall, the President's Consumer Advisor, Ms. Virginia Knauer, suggested that the Cookie Monster try promoting something besides cookies. Sesame Street was very quick to take her up on it.

We do have, in addition, some efforts underway right now with the National Parent Teachers Association to involve local PTA's more closely in the development of the school lunch programs and the dissemination of good nutrition information, through the schools, in a more attractive form.

Senator METZENBAUM. I have one last question. A USDA objective is to keep the agricultural sector of our country strong. Does that objective provide a natural kind of conflict of interest in attempting to improve the American diet?

Ms. FOREMAN. Well, that question seems to assume that farmers can only make money by producing food that is bad for you, and I do not accept that at all. In fact, most of the foods that come from the farm are really quite good for you.

The Department has approached it in a number of ways. First of all, it is USDA-funded research over the past several years that has contributed very substantially to the production of leaner hogs, so that pork is no longer the fatty product it was once widely regarded to be. It is a very lean meat today.

I think that surely no one out there who is raising food would suggest that you should eat this or that because it is economically good for them, rather than because it is nutritionally good for you. The Department does not feel there is any conflict. We feel that it is important to begin moving production and processing in a direction that is consistent with good nutritional information.

Senator SCHWEIKER. Ms. Foreman, I mentioned the airlines a moment ago, and I was serious about it because I have yet to fly an airline that you could get low fat milk on. I understand you can call the airlines ahead and ask for some special diet and they are cooperative, but my point is you have to press the alarm button just to have a good nutritional choice. You go into fast food chains and everything is basically deep-fried. It is really a difficult thing to meet the dietary goals and eat that. Some have moved into the salad bar area, which I think is very commendable and a step in

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the right direction, but it would be more effective if you had a health food bar on the side.

My question is: What can you do, as a friendly persuader, to the airlines, where people do not have choices and are forced to eat the old way to fast foods chains; and many good gourmet restaurants which do not give you any choice. It seems that they take pride on how many fat calories they can put in their great gourmet menus. They think they are being great yet, in essence, they are not giving you what is good for you. Can you not, as a general persuader, do something by way of stimulating them to take the lead so that people are not boxed in with no choices with the airlines, restaurants, and fast food chains?

Ms. FOREMAN. Sir, I strongly suspect that your comments here today will get back to the airlines very quickly.

Senator SCHWEIKER. I am not sure they will reach the fast food chains and gourmet restaurants.

Senator METZENBAUM. We will be very grateful if you will assume the responsibility of getting the word back to them.

Senator SCHWEIKER. You are very persuasive.

Ms. FOREMAN. Actually, you are raising the question that those meals may be a safety issue. That means the Federal Aviation Administration would have jurisdiction. [Laughter.]

Let me make one point: We have control over what goes into the school lunch program because of Federal funding. Airline meals are obviously not a federally regulated program, although both FDA and USDA have some jurisdiction with regard to the safety of the food they serve. We have no jurisdiction over its quality. However, those salad bars are not in some fast food restaurants now because the Government forced them to be there. They are there because there were family members who did not want to go to those restaurants because there was no choice available other than a hamburger and french fries.

Senator SCHWEIKER. They did not go to Gino's though.

Ms. FOREMAN. They put in the salad bars in order to attract customers.

I think it is our view, both at HEW and USDA, that when you create a demand for a product in a very competitive field, as fast food certainly is, you begin to see a rapid response to that demand.

With gourmet restaurants, I am not so sure. Those of us without expense accounts eat in them so rarely that I suspect creating a demand would be more difficult.

Senator SCHWEIKER. That is why I mentioned fast food chains first.

Dr. RICHMOND. Senator, I think that one of the projects in the Department of Agriculture that was mentioned in Secretary Foreman's testimony, could potentially be very important in just the direction you are commenting on, and that is the development of sample menus. If you could develop menus for fast food chains as well as for home use, these could move the industry in some significant way.

Senator SCHWEIKER. Dr. Richmond, as you referred in one of your earlier answers, this committee had a meeting with you back in 1977 and asked you to develop a national nutrition and health report as part of a major prevention policy statement, and that in

June you not only complied, but I think you did a very excellent job of putting together a landmark statement in this area.

But my concern is not with your commitment because I think you are committed here. The concern is to move the rest of the establishment along with you. It is just a matter of followthrough, persuasion, and effectiveness.

On January 2, 1980, GAO transmitted to HEW Secretary Harris a report entitled "Greater Federal Efforts are Needed To Improve Nutrition Education in U.S. Medical Schools." One of my prime concerns is to get health professionals that ought to be training and educating us about nutrition in the act. We have a grant program now that does. But the report says the Bureau of Health Manpower has not done any evaluation of the 11 completed grants. This is a matter of getting nutritional education in medical schools where it ought to be and should have been for 20 or 30 years. Is there any plan to evaluate 13 more recent grants? In other words, here are people who applied for money and participated and we have done nothing to move the program along. Again, I am sure this is something that probably has not been directed to your attention, but I would hope that you would look at the GAO report that states nothing has been done by the Bureau of Health Manpower. I hope you will follow through on that.

Dr. RICHMOND. Senator Schweiker, I can remember those hearings in 1977 very well, and you rather pointedly asked what we were doing about teaching applied nutrition. I commented that I thought we were doing a reasonably good job teaching basic science aspects of nutrition. And I think the 12 centers which we are moving toward are very important as clinical centers teaching applied nutrition and/or fostering further research.

We have made in fiscal year 1979 $4 million worth of grants through those institutions. I think GAO's query about evaluation is important. But I think it is going to take a little time for us to see the results of these efforts. I assure you we will make every effort to evaluate those programs.

Senator SCHWEIKER. Thank you.

Senator METZENBAUM. Thank you, Dr. Richmond and Ms. Foreman.

Our next panel consists of: Nathan Pritikin, director, Longevity Center, Santa Monica, Calif.; Alex Hershaft, president, Vegetarian Information Service; Reva T. Frankle, director of nutrition, Weight Watchers International, Inc., Manhasset, N.Y.

We are very happy to welcome Senator Pell. We are glad to have you with us.

As the Chair indicated at an earlier point, I will ask each of the witnesses to confine their oral presentation to 5 minutes. The entire statements will be placed in the record.

Mr. Pritikin, we will be happy to hear from you at this time.

STATEMENT OF NATHAN PRITIKIN, DIRECTOR, LONGEVITY CENTER, SANTA MONICA, CALIF.; ALEX HERSHAFT, PH. D., PRESIDENT, VEGETARIAN INFORMATION SERVICE; REVA T. FRANKLE, PH. D., DIRECTOR OF NUTRITION, WEIGHT WATCHERS INTERNATIONAL, INC., MANHASSET, N.Y.

Mr. PRITIKIN. Before I start my remarks, in regards to the discussion this morning, I thought you ought to know that the largest airline in the world, with headquarters out in Chicago, whose name I cannot mention, will be featuring our entrees in June; so you can ask for them in my name.

I should also mention that we have been contacted by one of the largest fast food chains in the country to put one of our entrees on their fast food menus. And you have gourmet restaurants right in Washington, D.C., one of the largest in town, Duke Zeibert's that features our entrees. So you are not completely without a source of low fat, low cholesterol meals.

Senator SCHWEIKER. We need a little advertising, I guess.

Mr. PRITIKIN. As director of the Longevity Center, a live-in rehabilitation facility that has treated over 4,000 individuals with a low fat, low cholesterol diet, I have observed closely the profound therapeutic effect of this type of diet on reversal of symptoms associated with heart disease and hypertension.

It is my belief that the high fat, high cholesterol diet consumed by the vast majority of Americans is responsible for almost all heart disease, adult-onset diabetes, and hypertension. It is also the cause of many other lethal or debilitating degenerative diseases, including breast cancer and colon cancer.

The National Cancer Institute's statement in October 1979 and the American Diabetic Association's statement in 1979, all of which increased carbohydrates and lowered fats in dietary recommendations, are a small first step in the right direction, but are insufficient to halt the epidemic of degenerative diseases that rages in the United States.

It should be noted that the degenerative diseases are not a matter of concern to our older citizens alone. Artery closure, which is a result of the high fat and high cholesterol diet consumed in our country by young and old alike, begins to appear in children as young as eight years of age.

The dietary recommendations and guidelines to avoid too much fat and cholesterol is far too general. How much is too much? What kinds of fats are to be avoided?

The American Heart Association has done the public a disservice in encouraging the substitution of polyunsaturated fats for some of its saturated fat intake; total fat intake reduction has not been stressed adequately in their guidelines. Polyunsaturated fats have been demonstrated to reduce cholesterol levels in the blood, but it is now known that some of the cholesterol is diverted to other tissues and organs. In the blood, polyunsaturated fats are as harmful as saturated fats in causing cell sludging and blockage of circulation in the small vessels.

The National Cancer Institute in its recent dietary recommendations specifically pointed to the possible relationship of colon cancer and the intake of large amounts of polyunsaturated fats.

I would recommend that the proposed guidelines call for a drop in the American diet to a maximum total intake of 15 percent fat. In diets higher than this in fat content result in real health hazards of cell sludging, oxygen deprivation, tissue edema, and other consequences.

A safe level of cholesterol intake should not exceed 100 milligrams per day. Amounts ingested in excess of this are stored in the tissues, organs, and vessels.

The chief constituent of the plaques that progressively block the arteries in cardiovascular disease is cholesterol. In heart disease, it is blockage by cholesterol plaques of the coronary arteries that brings on the disease symptoms, including angina. When a diet is sufficiently low in cholesterol is ingested, the cholesterol in the plaques may be gradually withdrawn and with the shrinking of the plaques, blocked circulation is restored, reversing cardiovascular disease symptoms.

The guidelines encourage eating more foods with sufficient starch and fiber. Again, how much more is the question. Complex carbohydrate foods which provide maximum starch and fiber should comprise at least 70 percent of total calories.

In underdeveloped countries where the native population eats a diet with 70 to 80 percent of total calories in whole grains or other complex carbohydrate foods, not only heart diseases and hypertension but diseases of the gastrointestinal tract, from constipation to cancer of the bowel, are almost nonexistent.

The balance of the caloric intake—about 15 percent—should come from protein. This amount is adequate to support all normal needs. In fact, high protein diets have been incriminated as leading to osteoporosis.

The American diet, almost unbelievably, has two-thirds of its calories in fat and sugar, which provide no natural vitamins, minerals or dietary fiber. Being concentrated in calories but very low in bulk, they do not produce a sense of satisfaction and the result has to be overeating. High fat foods bring on cell sludging and underoxygenation. Drowsiness and lassitude follow a high fat meal, discouraging activity and exercising. Thus, too many calories are taken in and too few calories are expended. No wonder obesity is such a problem for so many Americans.

The savings in health care costs related to heart disease and other diet-related degenerative diseases would more than offset the cost of any Government program to assist food processors and suppliers in a transition to kinds of food economy activity that would be compatible with the health needs of the Nation.

I have a more extensive statement that I would like to submit for the record.

Senator METZENBAUM. Thank you very much. We will hear from each of the members of the panel before questions.

Dr. Frankle.

Dr. FRANKLE. Thank you, Mr. Chairman, and members of the committee.

It is an honor and a privilege to appear before you to present the Weight Watchers program as it pertains to health and nutrition.

As a public health nutritionist, a nutrition educator and a registered dietician, I am firmly convinced that nutrition is one of the

most important factors in health promotion and disease prevention. And as nutrition is the cornerstone of the Weight Watchers program on weight reduction and weight maintenance programs, how better to meet a number one public health problem, that of obesity, than to bring the Weight Watchers program to population groups.

I would like to abbreviate my statement and submit my statement for the record at this time.

Senator METZENBAUM. It will be received.

Dr. FRANKLE. Thank you.

I would like to make five points though.

Obesity is a hazard to health and a detriment to well-being, as we have been hearing this morning. It is common enough to constitute one of the most important medical and public health problems of our time, whether we judge importance by shorter life expectancy, increased morbidity or cost to the community in terms of money and decreased productivity, as well as related to the suffering of overweight individuals. Weight loss may reduce these risk factors as well as add to the individual's self-esteem.

The second point I would like to make is the Weight Watchers thrust and our approach to weight control.

Weight Watchers International operates in the United States and 26 foreign countries with about 16,000 classes per week reaching about 600,000 people weekly.

There are many approaches to the treatment of obesity and overweight, but based on my 35 years' experience as a practicing dietitian and a nutritionist, the one most likely to meet the needs of most of the people, and the one most likely to work best for weight loss and health maintenance is a program based on four constituents: One, a nutritionally adequate meal plan with limited energy intake; two, new eating management skills. We heard the question raised, how to motivate. This would be concerned with behavioral change. Three, increased physical activity, an exercise program; and, four, a support system, which is a self-help group in a classroom setting.

The third point is how our program relates to the dietary goals. Our new program, launched in January 1976, well reflected the dietary guidelines that were to come out in December of 1977.

The dietary goals are consistent with our program. There is no refined sugar. The cholesterol consumption is limited. The average sodium intake is about 5–8 grams of salt a day, depending upon individual choices.

We commend USDA and USHEW on their seven dietary goals released February 4, 1980. These, too, are reflected in the Weight Watchers program.

As Ms. Foreman said, the simple way to develop guidelines is to bring them to the public from the scientific base.

The fourth point that I would like to make is the nutritional adequacy of the Weight Watchers program as it relates to the RDA.

A complete nutrient analysis of a typical 7 days' food supply, which reflects a member's average weekly intake, appears in "A Rational Approach to Weight Control" by Dr. William Henry Sebrell, medical director, Weight Watchers International.

I would like to submit this to the record.

Over the years, program changes have reflected changes based on new scientific data. The foods which make up the basic Weight Watchers food plan are enriched whole grain breads and cereals; eggs; fats and oils; fruits and fruit juices; low fat dairy products; poultry, lean meat, fish, and legumes; and vegetables providing adequate fiber intake.

This plan provides about 1,200 calories for women, 1,500 calories for men, and 1,600 calories for youth.

Senator METZENBAUM. Could you wind up in about 1 more minute?

Dr. FRANKLE. Thank you.

As education is a strong component of our program, we are currently bringing a nutrition education program to schools across the country. We take the stand that it is easier to foster good food habits in young children than to change them in later years.

In conclusion, I would like to say that the program is a nutritionist's dream and would well be a basic plan for all Americans. Those who do not have a weight problem could have additional servings of other foods but we would know that their nutritional needs were being met.

Thank you.

Senator METZENBAUM. Thank you.

Dr. Hershaft, we will be happy to hear from you on vegetarian information.

Dr. HERSHAFT. Thank you, Mr. Chairman. My name is Alex Hershaft and I am president of the Vegetarian Information Service, Inc., which is a nonprofit, public interest organization seeking to advise the American public on the merits of the vegetarian way of life.

I am grateful for this opportunity to present my views on the health aspects of a vegetarian diet.

I will present a summary of my written testimony which is before you and which I understand will be inserted in the record. I would also appreciate it if you would insert in the record the several supporting materials which I have provided to the staff.

In the absence of a major war or other catastrophe, 2 million Americans will have died by the end of this year. Of these, 7.7 percent will have died a violent death by accident, suicide, or homicide; 6.8 percent will have succumbed to respiratory and less common diseases; 13 percent will have perished of other and ill-defined causes. But fully 67.6 percent, or 1.3 million Americans, will have suffered and died quite needlessly of the three chronic killer diseases in which diet constitutes a major contributory factor. These are: heart disease, cancer, and stroke.

The foods that have been singled out for special concern in connection with these diseases are meat and animal fat. Others include sugar and highly refined carbohydrates, salt, and special additives.

In the next portion of my written testimony, I go through each one of these diseases and I explain the role of meat and animal fat in their incidence and development.

Apologists for the meat interests are fond of claiming that there is no consensus on these issues among nutritional and health scientists. However, during the past 10 years, a half dozen expert panels

have been convened to examine the available evidence and their findings all bear a striking resemblance to the key recommendations of the "Report on Dietary Goals for the United States" by Senator George McGovern's Senate Select Committee on Nutrition and Human Needs; that is, to increase the consumption of fruits, vegetables, and whole grains and to decrease the consumption of meat and animal fat.

What is even more significant is that there is not a shred of evidence to suggest the opposite conclusion; that is, to increase the consumption of meat and animal fat, and to decrease the consumption of fruit, vegetables, and whole grains.

The statements alluded to are all listed in the box which is in my written testimony. And I would just like to note something in this connection. The term "saturated fat" and "cholesterol" are used frequently as code words for "meat," in part to avoid upsetting the meat industry. The fact remains that saturated fat and cholesterol are found almost exclusively in meat and other animal products, and no other foods.

Senator METZENBAUM. Would they not be found in avocado?

Dr. HERSHAFT. I said almost exclusively. There is also saturated fat in coconut oil and olive oil. I am talking about common foods. In other words, the sort of things a person is likely to eat.

At this point, one may well ask a logical question: If meat is so bad for human health, how has it become the principal staple of the American diet? The answer goes to the very heart of what is wrong with the decisionmaking machinery of the Federal Government where issues are decided less on the basis of their scientific merit than on their economic and political consequences.

At this point, my written testimony goes on to trace the history of how the economic and political influence of the meat industry in cooperation with the U.S. Department of Agriculture has brought us to the point where we are one of the highest meat-consuming nations in the world.

And, finally, getting to our recommendations, it is high time that the Federal Government renounce its partisan proindustry stance, redress the injustices perpetrated against the consumer, and accept its responsibility to protect the public health. To those ends, we recommend that Congress require the USDA and other cognizant Federal agencies:

One, to cease all activities designed to promote the consumption of meat.

Two, to balance the past activities by providing funds for educational programs by advocates of a meatless diet.

Three, to provide a choice of meat alternatives in all their public and institutional feeding programs.

Four, to require an indication of all components of animal origin on food labels.

Five, to require labels on all meats and other animal products warning the consumer of any demonstrated health hazards that they may pose.

This ends my formal testimony, but I will be glad to join in the commentary on airline food. I was traveling recently and, having requested my usual vegetarian meal, I received a card that had about 12 different meals listed. Some of them were: low calorie, low

cholesterol, low fat, diabetic, salt free, kosher. I thought to myself: "These poor people have to prepare all these different meals," and then I looked at my own meal and realized that it was all of these. So, Senator Schweiker, the next time you want a nutritional meal, although not a very tasty one, because the airlines are not very good at preparing vegetarian meals, may I recommend that you request a vegetarian meal.

Thank you very much.

Senator METZENBAUM. Thank you, Mr. Hershaft.

Mr. Pritikin, with respect to your diet, which is a very restrictive one, do you think it is feasible for the average American to follow such a regimen, given that so many meals are eaten away from home? Aside from one restaurant in Chicago that offers your diet, how do we meet that problem realistically?

Mr. PRITIKIN. I mentioned a restaurant in Washington, D.C. If I said Chicago, it was a mistake. We have some in Chicago too.

The idea that our diet is restrictive shows that you do not have a full aquaintance with our diet. Our diet is by no means restrictive. It is like saying that the Italian diet is restrictive because it has a lot of pasta. Our diet is not restrictive. We have 150 gourmet recipes in my book. The diet, when you understand what it is, you can order it anywhere in the world. You can travel around the world with no problems at all. In fact, the better restaurants offer a better opportunity because you can ask for things to be done as you want them.

The diet, I am certain, in 5-years' time in this country, 50 percent of the people in this country are going to be on a large aspect of this diet.

Senator METZENBAUM. You say you can ask for your diet anytime you want. I ask for things to be done in margarine instead of butter.

Mr. PRITIKIN. Well, you should not ask for margarine.

Senator METZENBAUM. What should I do?

Mr. PRITIKIN. You should ask for no fat, no margarine, and no butter.

Senator METZENBAUM. Just have it broiled dry?

Mr. PRITIKIN. Broiled dry. That is what I got last night at my hotel, no problem at all. I had a broiled dry fish and baked potato without butter, and salad without the normal kind of dressing. I had two good pieces of honeydew mellon, no problem.

Senator SCHWEIKER. But you cannot get a low-cholesterol dressing either.

Mr. PRITIKIN. Dressings for salads, I usually have lemon or vinegar, although you learn to love the salads just for their taste and you do not cover it with something. You know, most people eat catsup all their life and do not know what is under it.

Senator METZENBAUM. Do you think the guidelines that HEW and USDA have announced are specific enough?

Mr. PRITIKIN. It is not a matter of not specific; in fact, it is going to lead to confusion, mass confusion. The public will not know specifically what you are recommending. When you say reduce fat, the public will think they eat less margarine. They do not understand that cheese has over 70 percent of its total calories in fat. They need better guidelines, more specific; what percent or quanti-

ties of fat and so on. They cannot do it under your general guidelines. That has been the trouble with the American Heart Association diet for the last 20 years. The diet has simply failed to reduce cholesterol levels adequately.

Senator METZENBAUM. In your testimony, you claim that your diet and exercise will not only prevent heart disease but actually restore normal heart function in serious cases. (a) How does that happen? (b) What is your scientific support for that statement?

Mr. PRITIKIN. First, the way that symptoms can be reversed, as Dr. Meyer Friedman who wrote the book on type A and type B personalities demonstrated 15 years ago, that if you take a large quantity of cream as your breakfast, you can detect changes in the conjunctival vessels in the eyes five hours later. The small vessels that were completely open before you started now have 25 blockages. And the same thing happens with safflower oil and a lot of your saturated fats. There is no difference at all in the sludging effects because the fat comes in and coats the red blood cells and platelets and makes them stick together in clumps which block the small vessels.

So the first thing that happens with our diet, you take the fat out of the blood and say you have 5 or 10 percent vessels that were blocked, now they are unblocked. That is why people with severe angina lose their angina in 2 weeks' time. That is the purpose of it.

Senator METZENBAUM. What is your scientific support for that?

Mr. PRITIKIN. It is Dr. Friedman's own study. This study was published, in the Journal of American Medical Association in 1965. And your own Department of Agriculture has established a similar scientific basis in the studies of Dr. James Iacono.

Senator METZENBAUM. You are saying the scientific basis for the statement that going on your diet is going to restore seriously affected patients that have had heart attacks?

Mr. PRITIKIN. You did not hear me out, sir.

Dr. James Iacona, who was in human research in the Department of Agriculture, did a study where he simply cut the amount of fat from 43 percent fat to 25 percent fat. It not only dropped blood pressures 10 percent, which is more than you can drop with salt, but he dropped what we call platelet aggregation 50 percent. That is the reason people are taking aspirin. Yet his results have not been followed in your own department. But he did the study twice.

Senator METZENBAUM. But that is the only scientific evidence that you have?

Mr. PRITIKIN. There is much more and I will submit it to you.

Senator METZENBAUM. I am talking about restoring seriously afflicted patients.

Mr. PRITIKIN. We did a study with our first 900 participants at the longevity center in Santa Barbara, Calif. We studied 66 of them who were scheduled or recommended for coronary bypass surgery. They decided to come to us instead. After 2 to 4 years going from our center, 90 percent of them had never had bypass surgery. There was only one death in the whole series. Fifty percent are still off medication for heart pain. I think that is a record even better than bypass surgery.

Senator METZENBAUM. Dr. Frankle, the Weight Watchers diet, you say, is well-established, proven safe and an effective weight reduction diet. How does that diet differ from the now popular Scarsdale diet?

Dr. FRANKLE. The Scarsdale diet, as I understand it, eliminates certain foods. And, based on our calculations, it is very difficult to get all of the RDA's, all of the essential nutrients, in a package of anything less than 1,000 calories. It would depend a lot on the amounts eaten, but there is a restriction, I think, on certain groups of foods.

Senator METZENBAUM. If you did not change your diet at all, but cut down your food intake, would you achieve the same objective?

Dr. FRANKLE. I think it would certainly be a good start, assuming you are choosing nourishing foods, and cutting out calories rather than nutrients.

Senator METZENBAUM. Speaking for Weight Watchers, do you support the dietary guidelines suggested?

Dr. FRANKLE. Oh, yes, I do very much. I think they are the beginning of a national nutrition policy, and I think people are going to understand them. I certainly think it will be a big help to the consumer.

Senator METZENBAUM. Dr. Hershaft, what is your reaction to the "dietary guidelines"?

Dr. HERSHAFT. I have a news release here for you which we sent out on the "dietary guidelines" which says, essentially, that the "dietary guidelines" offer too little and too late. We feel they are very vague, I feel they are motivated politically, rather than by the weight of scientific evidence. I think they fall far short of statements that have been made before, beginning with the 1961 statement by the American Medical Association, and ending with a statement made by the Senate Select Committee on Nutrition and Human Needs. And, finally, I think the framers of the "dietary guidelines" were very heavily influenced by what happened to Senator McGovern and his committee when he came out with a recommendation that Americans decrease their meat consumption.

Senator METZENBAUM. How important is it for a vegetarian to eat a variety of foods, and is it possible that a poorly balanced vegetarian diet is not only dangerous to your health but could lead to obesity?

Dr. HERSHAFT. The question of the adequacy of a vegetarian diet has been settled some time ago. It was first settled actually in 1946 by a scientist at Harvard University, who said a healthy adult who gets enough calories from a diet of cereals and vegetables is also getting enough protein. That scientist has gone on to bigger and better things, and today he is the Federal Government's chief nutritionist. His name is Mark Hegsted.

It took the National Academy of Sciences nearly 20 years to catch up with this early wisdom. The Academy gave its blessing to the vegetarian diet only about 5 years ago. But at this point there is no question but that the vegetarian diet is fully adequate. To answer your question more directly, no we do not have to be careful.

Senator METZENBAUM. Could not that turn into obesity?

Dr. HERSHAFT. The problem with obesity is as follows: A number of people who go on a vegetarian diet feel that this will solve their obesity problem by itself. Very often it does not because the American public has been pretty well brainwashed on the issue of protein. Whenever people switch to a vegetarian diet, their immediate concern is how to get enough protein. So they stuff themselves with cheeses and nuts and they end up getting more calories than they were getting before.

My advice to anyone going on this kind of diet is, first and foremost do not worry about protein. Eat a balanced diet which hopefully you were eating before, just eliminate the meat.

Senator METZENBAUM. Thank you. Senator Schweiker?

Senator SCHWEIKER. Thank you, Mr. Chairman.

Mr. Pritikin, you pointed out, one of the most vivid things in the whole education arena of diet and health. It is also something the Select Committee on Nutrition also pointed out early on. Two-thirds of our diet is composed of fats and sugar. A pretty serious indictment of our eating habits. Comparing that to other countries, it is one of the principal epidemiological factors as to why we are at high risk of certain diseases that others do not. We are trying to get away from the two-thirds fat and sugar diet and apportion it differently. As I see your diet compared with the dietary goals, the only really difference is basically the amount of fat. The dietary goals targeted at 30 percent, and yours 15 percent fat. Would you say that is one quantitative difference between you——

Mr. PRITIKIN. The principal difference that I am concerned with is the amount of cholesterol in the diet. You, in your dietary goals, say that it is OK to eat eggs and margarine, for example.

Senator SCHWEIKER. We say in moderation.

Mr. PRITIKIN. Let me tell you how moderation works. Chicken liver has 10 times as much cholesterol as fish or fowl. Brain, for example, has 20 times as much cholesterol. You just cannot eat eggs. They are just too high in cholesterol. One egg yolk is equivalent in cholesterol to a half a pound of steak. You cannot have a child eat an egg yolk a day because he might as well have a half a pound of steak a day. It is just too high.

Senator SCHWEIKER. Let me get back to my original question. I will not argue about that. I agree that with high cholesterol there is danger; 30 percent versus 15 percent fat, is that an accurate comparison of the Dietary goals versus your profile?

Mr. PRITIKIN. We prefer 15. When you give an ordinary person dietary guidelines, they cannot select 30 percent fat. They will select 40 percent just as easy as 30. Once you permit the use of oils, butter, or margarine, they cannot tell if they are taking a half ounce or ounce. You have to cut all fats out of the diet in order to make sure it is less than 15 percent.

Senator SCHWEIKER. I do not disagree with your percentage of fat. I suspect the dietary goals were perhaps too high on that. I am not really quarrelling with your lower amount. I think one side of the controversy is the difference between unsaturated and saturated fat. There is an honest difference inside the scientific community about whether unsaturated fat is as harmful to you as saturated fat. You, obviously, think it is, and I would like you to explain why.

Mr. PRITIKIN. Polyunsaturated fats have not demonstrated in any way significantly lower total deaths in any AHA trial.

Senator SCHWEIKER. What is the reason, in your judgment, for the emphasis on lower saturated fats? How did we get down to that?

Mr. PRITIKIN. I think we can get a lesson right now from the largest NIH study on heart disease that has ever been done in the world. Are you familiar with the MRFIT study?

Senator SCHWEIKER. The Framingham study.

Mr. PRITIKIN. It has cost the taxpayers $100 million. We should all know about it because it is a lot of money. It is a 6-year study and one main goal was to lower cholesterol 10 percent in 6 years. We can lower cholesterol 10 percent in 6 days on our diet. But after 3 years they failed to do that. So in the MRFIT Study the individual chapters now are recommending cholesterol intake of less than 100 milligrams a day, the maintenance recommendation of my diet.

Out of desperation, they are doing this all over the country. They call it their Progressive Eating Plan (PEP) diet, keeping cholesterol intake below 100 milligrams a day. If NIH recommending less than 100 milligrams of cholesterol a day to 6,000 participants, it is certainly justified to recommend this to the country.

Senator SCHWEIKER. I wonder if you would supply us your detailed analysis. I would like to have it.

Mr. PRITIKIN. I brought it with me and will submit it.

Senator SCHWEIKER. One of the things that gave joggers a lot of heart here just recently—being a new convert to jogging—was a study that came out of Houston Medical School this past week. It showed them high density protein, is a plus factor to avoid heart disease problems. Marathon runners had a fairly high level of this; joggers had an intermediate level of it; and people who were inactive with no exercise had a fairly low level of it. It has been found, of course, that a high density level of protein is the key to avoiding heart disease.

My question to you is, is this one of the premises underlying your program, or do you take issue with that study? How do you rate that study?

Mr. PRITIKIN. If you read the study very closely, you will note that sedentary people who have the highest cholesterol of 210 to 220 have the greatest intake of cholesterol fat. They analyzed all three diets.

The joggers who had average cholesterols between 180 and 190 had a medium ingestion of cholesterol and fat. And the runners, who had the least amount of cholesterol fat in their diet had cholesterol levels of 170 to 180.

Now the man who brought high density cholesterol back into popularity just a few years ago——

Senator SCHWEIKER. Those figures you gave, are they specifically high density—explain that.

Mr. PRITIKIN. On the high HDL the runners had the highest HDL of about 65 milligrams; the joggers had a lower HDL in the 50–55 range, and the sedentary had a HDL of 45.

But the high density cholesterol that I mentioned is not a linear relationship. The Framingham study indicated that if you go over

75 milligrams percent you have a greater coronary death rate than if it is under 45 milligrams percent. Data from the Framingham study indicate no deaths from heart disease with less than 150 milligrams percent of cholesterol which is not possible on the recommendations of the HEW level.

Senator SCHWEIKER. One other question that I think a layman gets confused about. We talk about cholesterol, we talk about fat, but cannot differentiate between the two.

Mr. PRITIKIN. Fat is something we burn for energy. You burn 100 percent of your fat for energy. Cholesterol cannot be burned. That is why joggers get confused and that is why they drop dead. Running cannot burn cholesterol. It cannot be confused with fuel. Cholesterol is only used to make sex hormones, vitamin D, but if you eat much cholesterol it will close your arteries. Anyone with a cholesterol level of 100 plus your age, more than 160, it is going to close your arteries.

Senator SCHWEIKER. When some label says it has no fat, it does not address itself to cholesterol at all?

Mr. PRITIKIN. No.

Senator SCHWEIKER. A lot of people are misled by that. They see a label that says no fat and yet the cholesterol content is overwhelming.

Mr. PRITIKIN. That is correct.

Mr. SCHWEIKER. You are saying that rather than break it down to high density, the total cholesterol level is a better indicator? Is that what you are saying?

Mr. PRITIKIN. It is a more important indicator. High and low density is interesting. I have taken my own high- and low-density figures for 25 years, longer than most people I know, but I am quite familiar with the whole concept.

Senator SCHWEIKER. But you are also saying that the relationship, which you described of the marathon runners, joggers, and people who have no exercise is remarkably similar in terms of basic cholesterol level and basic high density protein level——

Mr. PRITIKIN. High density does not protect you. The local Congressman, Goodloe Byron, died 2 years ago, having run six marathons, but he did not watch his diet. His coronary arteries were disastrous. He did not watch his cholesterol intake. For marathon runners it is a tragedy for them to be on vigorous activity if they do not watch their diet.

Senator SCHWEIKER. Some people argue that it is not just a matter of the cholesterol you eat, it is a question of the metabolic ability your body has to dispose of it. What is your response to that? That is controversial.

Mr. PRITIKIN. No, it is not very controversial.

Senator SCHWEIKER. Well, it is on the other side.

Mr. PRITIKIN. A newborn child has a cholesterol of 60. If you never ate cholesterol as an adult, you would never reach 120. Your body turns off its cholesterol mechanism when you get to 120. Anything above that is from your diet. In our country cholesterol of 330 will still be considered normal. It is a tragedy because when you have a cholesterol of 235 or 240 that is the average cholesterol level when people drop dead of heart disease.

Senator SCHWEIKER. We consider normal much higher than most other countries, I suppose.

Mr. PRITIKIN. Well, our normals are not normal; they are just average as far as this population. They are absolutely not normal. President Carter's physician thought that President Carter's cholesterol of 239 was normal. That is the same cholesterol level of people who drop dead of heart disease. Anything above 200 is a disaster.

Senator SCHWEIKER. In terms of labelling that is one of the things we ought to clearly single out.

Mr. PRITIKIN. The only way to get cholesterol down to a safe level, all of the authorities agree, is to eat less than 100 milligrams of cholesterol a day. Otherwise you can't do it.

The American Heart Association prescription and also the HEW prescription of 300 milligrams a day will never do it. That is why Dr. Levy of National Heart and Lung has abandoned the Heart Association diet, and offered the progressive eating plan diet to most participants who would like to have the most effective diet recommendations.

Senator SCHWEIKER. You recommend a level of 100, you say?

Mr. PRITIKIN. A maximum of 100 milligrams a day.

Senator SCHWEIKER. And the dietary standards are what?

Mr. PRITIKIN. 300 milligrams a day.

Senator METZENBAUM. Thank you very much, Mr. Pritikin, Dr. Frankle and Mr. Hershaft. You have been very helpful and your entire statements will be in the record.

[The prepared statements of Mr. Pritikin, Dr. Frankle, and Mr. Hershaft, along with additional material supplied by them follows:]

STATEMENT OF NATHAN PRITIKIN
TO THE SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH,
SENATE LABOR AND HUMAN RESOURCES COMMITTEE,
FEBRUARY 20, 1980

As Director of the Longevity Center, a live-in rehabilitation facility that has treated over 4,000 individuals with a low fat, low cholesterol diet, I have observed closely the profound therapeutic effect of this type of diet on reversal of symptoms associated with heart disease and other degenerative diseases. Heart disease ranks as the number one cause of death in our nation. Last year it claimed a million lives, more than the number due to all other causes of death put together. Health care costs to individuals, families and government on all levels, and financial losses due to loss of productivity associated with heart disease amount to many hundreds of millions of dollars annually. Control of this disease alone could affect major savings to public and private sectors of our economy, apart from the many lives that would be spared.

It is my belief that the high fat, high cholesterol diet consumed by the vast majority of Americans is responsible for almost all heart disease and is also the cause of many other lethal or debilitating degenerative diseases, including some cancers, hypertension, and adult-onset diabetes.

On the diet used at the Longevity Center, which is very low in fat and cholesterol because it consists primarily of unrefined plant foods, the following are typical reductions in health risk factors in just a four-week period:

- Cholesterol levels are reduced 25%
- Triglyceride levels are reduced 25%
- Diastolic blood pressures are reduced 10-15%
- Elevated blood glucose levels are reduced from 200-300 milligrams% to normal in adult-onset diabetics -- even without weight loss
- Weight loss of an average of 17 pounds and as much as 40 pounds is achieved in obese patients

These results obtained in just a four-week live-in period are based on the following premises:

So-called "normal" levels of serum cholesterol, so reported by clinical laboratories, are in fact not normal but average levels for a population, the adults members of which suffer from chronic asymptomatic hypercholesterolemia.

The cholesterol levels in developed nations are an average of 50-100% higher than values found in cultures that eat fat, meat, eggs and dairy only occasionally.

Generalized atherosclerosis may be prevented, its progress can be halted, and certain of its pathologic processes may even regress if risk factors (such as hypercholesterolemia, smoking, obesity and hypertension) are eliminated or controlled for a protracted period by a change in lifestyle.

Essential hypertension can be controlled or eliminated with appropriate nutrition,salt restriction and weight reduction.

The hyperglycemia of adult-onset diabetes mellitus and its attendant dependence upon insulin or oral hypoglycemic agents can be eliminated by appropriate nutrition and weight reduction.

Obesity is common because the typical American diet, which includes the ingestion of foods high in fat, salt and sugar and processed foods low in fiber leads to excessive consumption of calories and diminished feelings of satiety. Most weight loss efforts fail because the patient returns to the eating and activity patterns that originally caused obesity.

These premises are supported by a substantial body of medical literature and are consistent with our experience with patients who make the proper long-term dietary and exercise committments. A summary of some of the important supporting studies follows.

CARDIOVASCULAR DISEASE: The Framingham Study data indicates that if cholesterol levels are 260 milligrams% or more, there is a 400-500 percent greater incidence of cardiovascular disease than if these levels are 200 milligrams % or less. Many investigators have stated that cholesterol levels must be below 200 milligrams% to be out of the high risk range for heart disease and that an optimum level is below 160 milligrams %.

Dr. Robert Wissler of the University of Chicago Medical School observes: "Results to date in humans and in experimental animals indicate that substantial regression of advanced atherosclerosis is possible. They also indicate that advance atherosclerotic lesions respond more favorably with serum cholesterol concentrations reduced to a minimum that prevails in animals or people consuming a low fat, low cholesterol diet. In human subjects and in rhesus monkeys, this appears to be about 150 milligrams%, a level at which most of the lipid disappears from plaques and remaining fibrous tissue and cells condense and undergo remodeling, as in fractures and wound healing." (Current Status of Regression Studies, Atherosclerosis Reviews, vol. 3, edited by R. Paoletti and A. N. Gotto, Raven Press, N.Y., 1978)

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Dr. William Castelli, director of laboratories for the Framingham Studies, notes: "Diet could reverse coronary artery disease in 90 percent of the patients if we got everyone's cholesterol below 150 milligrams%. (Medical World News, 9/3/79.)

HYPERTENSION: Data on the first 893 patients at the Longevity Center (available upon request) have been analysed by the Loma Linda School of Public Health. Of these 893 patients, 218 had been on medication for high blood pressure for at least one year prior to their arrival at the Longevity Center. After four weeks at the Center, 85 percent had normal pressure and were off medication. The pressure drop was not dependent upon weight loss. Salt intake was 3 to 4 grams per day, which is normally not considered a salt-restrictive level.

A study done by Dr. James M. Iacano at the Lipid Nutrition Laboratory, Agricultural Research Service, United States Department of Agriculture, provides some clues as to the mechanism involved. He put adult men and women on the American diet (43 percent fat, 10 grams of salt per day) and then reduced their fat intake to 25 percent of total calories, keeping the salt intake and total calories as before.

During the forty days of his testing period, systolic and diastolic pressures dropped 10 percent and there was a reduction by half of platelet aggregation. When his subjects returned to their baseline diet, their blood pressure and platelet aggregation rose to their original values.

It is worth noting that Dr. Iacano's diet dropped fat levels from 43 to 25 percent of total calories. The diet used at the Longevity Center drops fat to 8 percent -- and blood pressures drop substantially more than those of Dr. Iacano's research subjects.

DIABETES: The officially recommended diabetic diets of this century have been low-carbohydrate high-fat diets. About five years ago, guided by literature studies, I began to use a high-carbohydrate high-fiber diet for adult-onset diabetics and encouraged and assisted James Anderson, M.D., chief of endocrinology at the University of Kentucky Medical Center, to initiate this approach at his center.

Our efforts were conducted independently of each other but produced almost identical results: At least half of our diabetics no longer required insulin. This in less than a month's time.

Dr. Anderson's data have appeared in the American Journal of Clinical Nutrition, Diabetes Care, and in a presentation recently at the annual American Diabetic Association Conference and is an excellent confirmation of our work.

Dr. Kelly M. West, professor of medicine at the University of Oklahoma College of Medicine, told the McGovern Hearings (Part I, p. 132) that Dr. Anderson's work was "one of the most exciting diabetes research programs going on in the world today" and that 2-1/2 million(or 62%) of the four million known adult diabetics now on drugs "could be safely freed from them entirely using this diet."

I believe my diet, as used at the Longevity Center, fulfills the requirements set forth by important investigators in degenerative diseases better than any conventionally recommended diet. The diet provides approximately 1800-2100 K-calories and is nutritionally complete with respect to essential aminoacids, fatty acids, vitamins and minerals. Carbohydrates in the diet are supplied in complex form, such as whole grains, vegetables, legumes, tubers, etc., and neither sweetening agents nor salt are added to the food. To keep simple sugar content of the diet relatively low, only small amounts of fruit are served daily. Protein is derived mainly from other than animal sources, though a small amount of skimmed milk and skimmed milk cheese is used in this diet, along with small amounts of fish or fowl.

The low calorie end of my diet which is used for weight loss does not create electrolyte imbalance or raise uric acid levels as do conventional weight loss diets. It also does not limit food quantity, permitting up to four pounds of food per day and still achieving weight losses up to four pounds per week.

While the diet of the Longevity Center is relatively austere and represents a great change, the majority of persons participating in the program learn in 2-3 weeks to enjoy the food. Menus are varied and a variety of international cuisines have been adapted. Many persons who have participated in the Longevity Center program "graduate" to a less austere recommended diet, called the "Maintenance Diet", which permits more animal food and a greater range of recipes and menus. A gourmet but still healthful cuisine based on this diet is being developed.

Hundreds of physicians, including cardiologists, cardiovascular surgeons, and some major clinics -- after reviewing results in patients who have pursued my dietary program -- are recommending it to their patients. Coronary care units are also using the program in preference to conventional dietary recommendations.

Data describing risk factor changes and dietary compliance achieved at the Longevity Center over a two-year period were presented to the 33rd Annual American Heart Association Conference in Anaheim, California, in November, 1979, by Cleaves Bennett, M.D., Medical Director of the Longevity Center, and me.

Some agencies concerned with public health have recognized the association between the diet consumed in this country by most Americans and the high incidence of degenerative diseases. The Senate Select Committee on Nutrition headed by Senator McGovern has called for dietary reforms in the direction of reduced consumption of foods contributing to our high fat and cholesterol intake, and increased consumption of whole grain foods and fruits and vegetables -- the complex carbohydrate foods. The American Diabetic Association, after many years of advocating a high fat intake for diabetics, in the last few months has increased the amount of carbohydrate and decreased the amount of fat called for in its recommendations.

A federal health agency, the National Cancer Institute, made its first dietary recommendations in October, 1979. Dr. Upton, Director of the Institute, called for increases in intake of whole grains, fruits and vegetables and substantial reductions of all added fats, including polyunsaturates. To support his position, Dr. Upton pointed to animal studies showing an increase in cancers when polyunsaturates are substituted for saturated fats. Dr. Upton stated, "Breast cancer strikes more women in the United States, Canada and Western Europe than any other form of cancer. Yet it is comparatively rare throughout the developing world. Some scientists have suggested that the fat content of today's diet in the industrialized countries alters the body's balance of sex hormones, which in some yet undetermined way increases susceptibility to breast cancer..."

He added: "Research on the initiation of mammary cancer in animals has supported this association. Despite differences in the type or quality of fat or various elements of experimental design, scientists have found consistently that a high intake of dietary fat increased the development of mammary cancer in rodents..." "It has also been proposed that fat, whether saturated or polyunsatured, may act as a solvent to enhance the effect of other carcinogens." (A Statement on Diet: Nutrition and Cancer, by Dr. Arthur Upton, National Cancer Institute, 10/2/79, McGovern Hearings.)

While the action by these agencies is encouraging, they are not in themselves sufficient to put a halt to the epidemic of degenerative diseases that rages in our nation. In this regard, new and effective dietary guidelines from the Department of Health, Education and Welfare and the U.S. Department of Agriculture can provide added and important leadership for the general public and can pave the way for implementing legislation and federal programs to help translate these guidelines into healthful daily diets for all citizens -- from school children to senior citizens.

It should be noted that the degenerative diseases are not a matter of concern to our older citizens alone. Many young people in their teens are already well on their way to becoming

hypertensives, as shown by recent studies. Artery closure, which is a result of the high fat and high cholesterol diet consumed in our country by young and old alike, begins to appear in children as young as eight years of age.

The dietary guidelines that have been proposed are well-meaning, but need to be clear, definite and specific in all critical areas in order to accomplish their goals. The recommendation to avoid too much fat and cholesterol is far too general. How much is too much? What kinds of fats are to be avoided? The American Heart Association has done the public a disservice in encouraging the substitution of polyunsaturated fats for some of its saturated fat intake; total fat intake reduction has not been stressed adequately in their guidelines. Polyunsaturated fats have been demonstrated to reduce cholesterol levels in the blood, but it is now known that the cholesterol is diverted to other tissues and organs, creating cholesterol gallstones and other problems. In the blood, polyunsaturated fats are as harmful as saturated fats in causing cell sludging and blockage of circulation in the small vessels. The National Cancer Institute in its recent dietary recommendations, specifically pointed to the possible relationship of colon cancer and the intake of large amounts of polyunsaturated fats, as demonstrated in animal studies.

The current American diet consists of about 43% of total calories in fat. From my experience at the Longevity Center and from conclusions drawn from my study of the medical literature, I would recommend that the proposed guidelines call for a drop in the American diet to a maximum total intake of 15% fat -- still more than 7% higher than the fat content of the diet used at the Longevity Center. In diets higher than this in fat content, cell sludging, oxygen deprivation, tissue edema and other sequellae become real health hazards. A change in fat intake of such magnitude from our present intake would require radically different food consumption patterns. Dairy products other than those made from skimmed milk, plant foods high in fat such as nuts, margarine and oil, eggs, meat and other animal foods would need to be de-emphasized. Whole grains, fruits and vegetables would, conversely, be consumed in larger amounts. The savings in health care costs and other government expenditures related to heart disease resulting from control of this disease would more than offset the cost of any government programs required to assist food producers and suppliers in a transition to kinds of food economy activity that would be compatible with the health needs of the nation.

A safe level of cholesterol intake should not exceed 100 milligrams per day. Amounts ingested in excess of this are stored in the tissues, organs and vessels, since the body cannot use up or eliminate more than this limited amount plus the amount of cholesterol formed in the body itself. The chief

constituent of the plaques that progressively block the arteries in cardiovascular disease is cholesterol. In heart disease, it is blockage by cholesterol plaques of the coronary arteries that brings on the disease symptoms, including angina. In human and animal studies, when a diet sufficiently low in cholesterol is ingested, the cholesterol in the plaques may be gradually withdrawn and with the shrinking of the plaques, blocked circulation is restored, reversing cardiovascular disease symptoms.

At this time, the only national diet recommendation for the reduction of cholesterol level given to the general public is contained in the American Heart Association diet. Since 1961, their diet has had only minimal results in reducing cholesterol level. In the largest intervention study ever done in our country, the MRFIT program, the first three years demonstrated a disappointing fall in cholesterol level. With three years left to go, this $100,000,000 study appears to be failing to meet its goal of a 10% cholesterol level drop in six years. On my diet, cholesterol level drops 10% or more in six days. In an attempt to correct this problem, many of the twenty MRFIT centers have now advised the same cholesterol intake that I have been advocating, less than 100 milligrams a day, one-third of the present recommendation. I congratulate these groups that have decided that they cannot wait for the American Heart Association or the National Institute of Health to come out with adequate official recommendations. It is a case of the tail wagging the dog.

The least that the Department of Health, Education and Welfare can do would be to offer the public the same cholesterol guidelines that the largest U.S. dietary trial is now offering its American Heart Association dieters.Only by substantial drops in cholesterol intake can Americans reduce their cholesterol blood levels below 160 milligrams %, the range in which heart disease is rare.

The general injunction in the proposed dietary guidelines to eat foods with sufficient starch and fiber also needs to be translated to a more concrete directive. Complex carbohydrate foods which provide maximum starch and fiber should comprise at least 70% of total calories. Diets that are this high and higher in complex carbohydrates seem to offer protection against not only cardiovascular diseases, but against many diseases of the gastrointestinal tract. In underdeveloped countries where the native population eats a diet with 70-80% of total calories in whole grains or other complex carbohydrate foods, diseases of the gastrointestinal tract, from constipation to cancer of the bowel, are almost non-existent.

The balance of the caloric intake -- about 15% -- should come from protein. This amount is adequate to support all normal needs. In fact, high protein diets have been incriminated as leading to osteoporosis. Many older Americans find that a propensity to broken bones instead of good health is the result of a high protein diet.

The American diet, almost unbelievably, has 2/3 of its calories in fat and sugar, which provide no natural vitamins, minerals or dietary fiber. Being concentrated in calories but low in bulk, they do not produce a sense of satiety and the result is overeating. High fat foods bring on cell sludging and underoxygenation. Drowsiness and lassitude often follow a high fat meal, discouraging activity and exercising. Thus, too many calories are taken in and too few calories are expended. No wonder obesity is such a problem for so many Americans.

A comparison of the typical American diet and the diet I am proposing for the dietary guidelines is shown in this table:

	Typical American Diet	Recommended Diet
Fat	40-45%	Less than 15%
Protein	10-20%	Less than 15%
Carbohydrates	40-50%	More than 70%
Cholesterol	600-750 mg.	Less than 100 mg.
Sodium	5-8 grams	3-4 grams
Fiber	4 grams	8-16 grams

It is my conviction that the weight of scientific evidence and the experience of the medical profession will propel us inevitably in the direction of the dietary changes I am recommending. By expediting the adoption of guidelines which will help our nation to reform its destructive dietary patterns, this committee can bring closer the day when degenerative diseases are rare in this country, as they are in those countries which have been spared the affluent diet. We can obliterate most degenerative disease as we have most infectious disease, if we have the will.

During my questioning at the hearing, I was asked to provide additional documentation to substantiate my testimony.

Of the seven dietary recommendations, No. 3, "Avoid too much fat, saturated fat, and cholesterol" is perhaps the most misleading and dangerous to the U.S. population. It tries so hard not to offend any food production group, that its value is lost.

First, it does not define "high cholesterol." Since many labs still define normal cholesterol levels at 160-330 mg%, and most doctors accept this, your reader would believe this is proper and find no need to modify his diet if he is in this range. In fact, if his cholesterol level is 250 mg%, he may increase his intake of eggs and organ meats, because the Guidelines say, "Some people can consume diets high in saturated fats and cholesterol and still keep normal blood cholesterol levels."

On May 22, 1979, during the Subcommittee on Nutrition Hearing, Dr. Robert Levy, Director of the National Heart, Lung, and Blood Institute of National Institutes of Health refused to make a clear recommendation on normal cholesterol levels. He said, "There is some confusion among the American physicians, confusing average cholesterol with safe cholesterol...the average American cholesterol is certainly not a normal cholesterol.... We do not have the bottom line in terms of cholesterol. We have not demonstrated in man that lowering cholesterol will prevent heart disease."

Senator McGovern stated, "I will call on Dr. Levy to exercise aggressively his Institute's mandate to educate the nation's health providers about the dangers of having a blood cholesterol above 200 mg%."

He failed to get such a statement from Dr. Levy, and the American public is left floundering with a meaningless cholesterol guideline.

Eggs and organ meats (which contain as much as 20 times more cholesterol as fish or fowl muscle meat) cannot be used if cholesterol levels are expected to drop to safe levels, i.e., below 200 mg%, as Senator McGovern tried to have Dr. Levy recommend, or below 160 mg% which is what Dr. Van Itallie recommended, and which I and many health professionals concur.

The guidelines are not as effective as the AHA guidelines, which have failed for 19 years to produce low enough cholesterol levels in our population. Various authorities have commented on this. A careful review of the literature suggests that the usual moderate dietary restriction of saturated fat and cholesterol (and addition of polyunsaturated fats) is

relatively ineffective in either reducing serum lipids or altering mortality statistics.

George V. Mann, Sc.D., M.D.: "...Clinical trials of prevention by diet, both primary and secondary have shown that diet has no more than a trivial effect on cholesteremia and has no real effect on morbidity and mortality." ("Coronary Heart Disease--The Doctor's Dilemma," American Heart Journal, Nov. 1978.)

Nemat O. Borhani, M.D., F.A.C.C., School of Medicine, Univ. of California, Davis, California: "It is clear that both secondary and primary prevention trials conducted to test the validity of the lipid hypothesis--that is, the efficacy of serum cholesterol-lowering measures (dietary or otherwise) on mortality or morbidity--have yielded either negative or inconclusive results...." ("Primary Prevention of Coronary Heart Disease: A Critique," The Amer. J. of Cardiology, August 1977.)

Henry Buchwald, M.D., Ph.D., Richard B. Moore, M.D., and Richard L. Varco, M.D., Ph.D.: "This cumulative review (of sixteen studies on the efficacy of circulating cholesterol level lowering by use of low saturated fat, increased polyunsaturated fat, low cholesterol principle) encompasses 2,516 patients, nearly evenly divided into 1,370 free-living and 2,246 confined individuals. The average circulating cholesterol level reduction by dietary means for these 2,516 patients is 12.68%. If we...subtract the control group serum cholesterol reduction from the gross test group average cholesterol reduction calculated above (12.68%), we are left with a net cholesterol lowering of 6-7% by dietary programs." ("Surgical Treatment of Hyperlipidemia," Circulation, May 1974.)

Compare the 6-7% lowering of cholesterol level to 25% lowering in four weeks on my dietary recommendations.

I submit the results of 893 patients on my recommended diet. This analysis was made by the Loma Linda University School of Health personnel.

LONGEVITY RESEARCH INSTITUTE

Evaluation of Longevity Center 26-30 Day Inpatient Program– An Analysis of 893 Patients.

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EVALUATION OF INPATIENT PROGRAM

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FOREWORD

This staff report presents a preliminary analysis of data resulting from the treatment of 893 patients for cardiovascular and other degenerative diseases at the Longevity Center from April, 1976 to October, 1977. Patients are admitted for 26 days (30 days before April, 1977) of multimodal treatment including medical supervision, diet therapy, exercise therapy, and health education.

We at the Longevity Center and the Longevity Research Institute are gratified by the often-dramatic acute improvement exhibited by most of the patients. At the very least, patients gain new hope for continued improvement and a new lease on life. At the most, they are adopting a lifestyle which may literally extend their longevity and the quality of life in their remaining years.

Beyond acute improvement, we make every effort to facilitate each patient's long-term health betterment. To this end, our intensive 40-hour educational program is designed to assist patients in translating the modified lifestyle into a form practical for use in their daily lives. Such intensive training is difficult, if not impossible, in the usual outpatient-physician relationship. Many patients have expressed real gratitude that their physicians, through referrals and continuing support, have provided them with a unique opportunity to embrace a more healthful lifestyle.

Our dietary recommendations are available for your patients at no charge. A sample copy is enclosed.

For the many hours of hard work involved in the preparation of this report, I wish to thank David Abbey, Ph.D., Associate Director of the Survey Research Service, Department of Biostatistics and Epidemiology, School of Health, Loma Linda University, whose independent evaluatory agency handled all the statistics and computerized analysis. I also wish to thank Hans A. Diehl, Dr. Health Sc., M.P.H., Director of Research at the Longevity Research Institute, and Don Mannerberg, Medical Director, and the staff physicians who so ably serve patients at the Longevity Center, along with the many other staff members. Their assistance was invaluable in study design, working with patients, gathering and analyzing data, and preparing this report. I gratefully acknowledge the support from the Lasser Foundation.

The reader is invited to contact us for further information or for details not covered in this report.

Nathan Pritikin
Santa Barbara, California
April, 1978

Evaluation of Inpatient Program
An Analysis of 893 Patients

GENERAL PROGRAM DESCRIPTION

During 1977 Loma Linda University's Survey Research Service collaborated with the Longevity Research Institute on an evaluation of the 26-30 day residential treatment program as conducted at the Longevity Center in Santa Barbara.

The medically supervised program emphasizes a low fat, low cholesterol, low sodium diet together with exercise and intensive patient education. The therapeutic modalities used are nutrition, exercise, education and medical care:

1. **Nutrition.** The Longevity diet introduces a radical restructuring of the American diet.

Diet	*Fat*	*Protein*	*Carbohydrate*	*Cholesterol*	*Sodium*
American	40-45%	12-15%	40-45%	600-750 mg	5-10 gm
Longevity	<10%	<15%	>75%	< 25 mg	< 3 gm

   In the Longevity Program, the carbohydrates are supplied totally in the form of vegetables, legumes, tubers, whole grains, and raw fruits rather than as degerminated grains and refined simple sugars. Protein in this diet is derived almost entirely from vegetable sources. Abstinence from smoking, caffeine and alcohol is encouraged, and weight management is promoted.

2. **Exercise.** Walking (occasionally jogging) is indicated by the clinical evaluation and the results of a submaximal stress treadmill electrocardiogram. Exercise is held within safe limits by continual monitoring and testing.

3. **Education.** In-depth educational instruction is given to help the patient better understand the nature of his disease and the rationale for the Center's approach, and to provide motivation toward a continuing adherence to the recommended life style under the supervision of his personal physician.

4. **Medical Care.** Six full-time physicians attend to the needs of the patients at the Center. The objectives are to give quality medical care and to rigorously document the findings during the stay at the Longevity Center. The treatment goal is to introduce patients to a modified way of life aimed at improving physiological function. (See Appendix for details)

PATIENT DESCRIPTION

Statistical evaluations were performed on all primary patients attending at least 21 consecutive days during April, 1976 to October, 1977. Most patients fell into the 50-70 year age range, were white and middle to upper middle class. They were either physician-referred or self-selected. More than half of the patients were accompanied by spouses. Prior to admission the medical records of each prospective patient were reviewed by a physician. Conditions for acceptance are:

1. Patient must be ambulatory and self-sufficient.
2. Disease should be amenable to improvement with diet and exercise therapy.

Two-thirds of the patients suffered from atherosclerotic heart disease with its classical manifestations. One-third had a history of myocardial infarction.

MODIFICATION OF RISK FACTORS AND CLINICAL VALUES

Preliminary analysis of data from the 893 patients indicates significant changes in risk factors and clinical indices. Mean levels are as follows:

1. **Serum Cholesterol** levels showed significant reductions. For instance: 111 patients in the 260-279 mg% cholesterol group at intake with a mean of 269 dropped to 190 mg%. Similarly, 153 patients in the 220-239 mg% group with an initial mean of 230 dropped to 173 mg%. The mean serum cholesterol of 235 mg% at intake dropped by 26% to 175 mg% at the end of the session. This was accomplished without the use of hipocholesterolemic drugs.
2. **Serum Triglyceride** levels in patients above 150 mg% at intake fell consistently for each subgroup. For instance: 108 patients in the 200-249 mg% group with a mean of 225 dropped to a new mean of 155 mg%. The 48 patients with intake levels of 300-500 mg% lowered triglycerides from an initial mean of 373 to 166 mg%. The mean serum triglyceride level in patients above 150 mg% at intake fell by an average of 35% within four weeks.
3. **Administration of Clofibrate or Cholestyramine** was no longer indicated in all 55 patients who had previously used these drugs. Although these hypolipidemic agents were removed at intake, the cholesterol levels responded well to the dietary and exercise program. For instance: initially drug-controlled cholesterol levels in nine patients in the 220-339 mg% range with a mean of 231 dropped to 184 mg%. Nine patients whose cholesterol levels ranged from 260 to 279 mg% dropped their initial mean of 269 to 197 mg%. Initital triglyceride levels above 150 mg% fell by more than 30% despite drug status modification.
4. **Uric acid** levels were lowered appreciably making gout medication no longer necessary for most gout patients who were on such medication at intake.
5. **Smoking** was discontinued by 85% of the smokers during their residential stay.
6. **Exercise enhancement** is reflected in the average walking distance of over six miles per day during the last two weeks.
7. **Weight control** showed favorable trends for most patients. The average weight loss for obese patients (>120% of ideal weight) was 13 lbs, while overweight patients (110-119% of ideal weight) averaged a ten lb loss in four weeks.
8. **Blood Pressure** at discharge was significantly reduced making antihypertensive drugs for long-standing hypertensives no longer necessary. Of the 218 confirmed hypertensives with blood pressure controlled by medication at intake, 186 left normotensive and drug-free.
9. **Blood Glucose** levels fell consistently. Non-diabetic glucose levels fell from an average of 100.4 to 93.6 mg%. Half of the confirmed insulin-using maturity onset diabetics left insulin-free with controlled glucose levels after the four week intervention program.

These data are presently under rigorous statistical analyses by the Survey Research Service of Loma Linda University in preparation of several papers for publication in scientific journals.

In an effort to evaluate life style adherence, participants in the Longevity Center Program are enrolled in a five-year clinical follow-up registry. At six-month intervals after leaving the Center, former patients have their blood chemistry, health status, and activity level monitored.

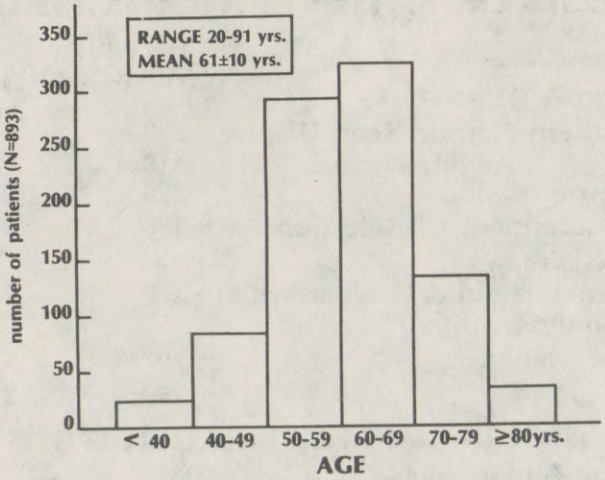
Certain selected abstracts of medical papers have been included in the appendix as examples of recent scientific publications discussing the value of dietary control as a therapeutic modality.

TABLE 1
DIAGNOSES OF PATIENTS AT ADMISSION

DISEASE	PATIENTS NUMBER	% OF TOTAL
Circulatory Diseases		
Atherosclerotic Heart Disease	590	66
Angina Pectoris	418	47
Hypertension	324	36
Intermittent Claudication	198	22
Arthritic Diseases		
Rheumatoid & Osteoarthritis	178	20
Gouty Arthritis	57	6
Diabetes Mellitus	107	12
Obesity	259	29
CLINICAL HISTORY— MAJOR CIRCULATORY EVENTS		
Myocardial Infarction		
(1 or more)	292	32
(2 or more)	77	9
(3 or more)	18	2
Cerebrovascular Accident	36	4
Arterial Surgery		
Coronary Bypass		
(1 or more)	77	9
(2 or more)	9	1
Femoral Bypass	27	3
Carotid Endarterectomy	24	3
Coronary Angiogram (no bypass)	193	22
TREADMILL STRESS TESTS AT ADMISSION		
positive	393	49
negative	317	40
equivocal	87	11
RECENT* RECOMMENDATIONS BY REFERRING PHYSICIANS		
Coronary Angiograms	56	6
Coronary Bypass	75	8
Femoral Bypass	9	1

*within 2 years preceding admission

FIG. 1
PATIENT AGE DISTRIBUTION*



*For Sessions 3-24, April 76- Oct 77

TABLE 2
CHANGES IN CLINICAL VALUES AND OTHER PARAMETERS

	NUMBER PATIENTS	MEAN VALUES ± S.D.** AT INTAKE	AT DISCHARGE
BLOOD CHEMISTRY			
BUN (mg %)	883	17.8 ± 5.8	14.6 ± 4.9
HEMOGLOBIN (gm %)	846	14.8 ± 1.3	13.8 ± 1.2
HEMATOCRIT (%)	845	43.8 ± 3.7	41.0 ± 3.6
WBC (mm^3)	845	6.8 ± 1.8	5.7 ± 1.5
PLASMA GLUCOSE*	768	100.4 ± 14.6	93.6 ± 10.1
RESTING HEART RATE (b/m)	586	67.8 ± 11.2	65.0 ± 9.4
EXERCISE (mi/day)**	827	nil	6.2 ± 3.4
SMOKING	880	191	28

*Diabetics excluded
**All ± values used in tables and figures represent one standard deviation.

FIG. 2
SERUM CHOLESTEROL LEVELS
AT ADMISSION AND DISCHARGE

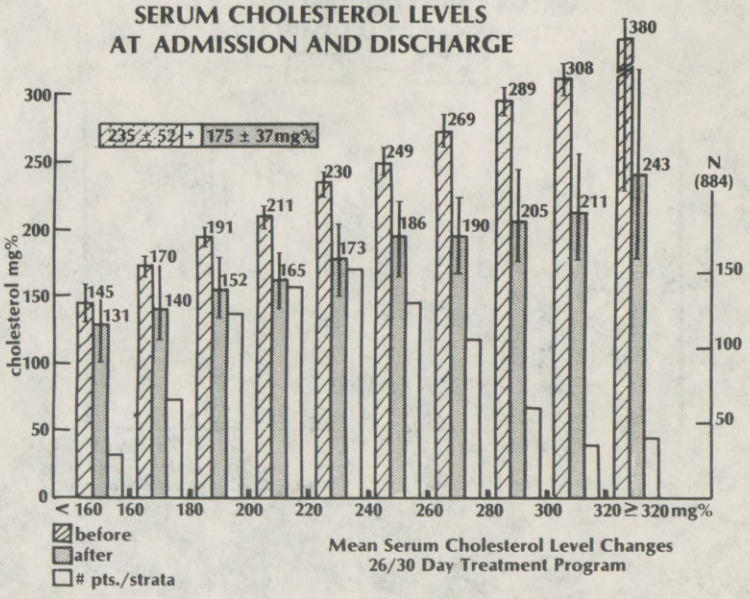
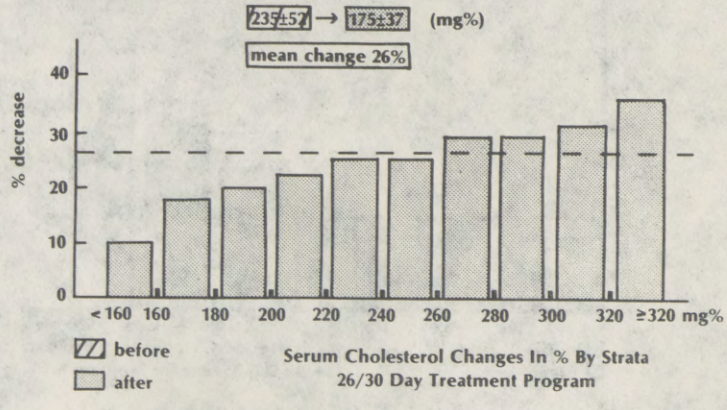


FIG. 3
SERUM CHOLESTEROL LEVELS; PERCENT
CHANGE FROM ADMISSION TO DISCHARGE



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61-331 O - 80 - 7

FIG. 4
SERUM TRIGLYCERIDE LEVELS AT ADMISSION AND DISCHARGE

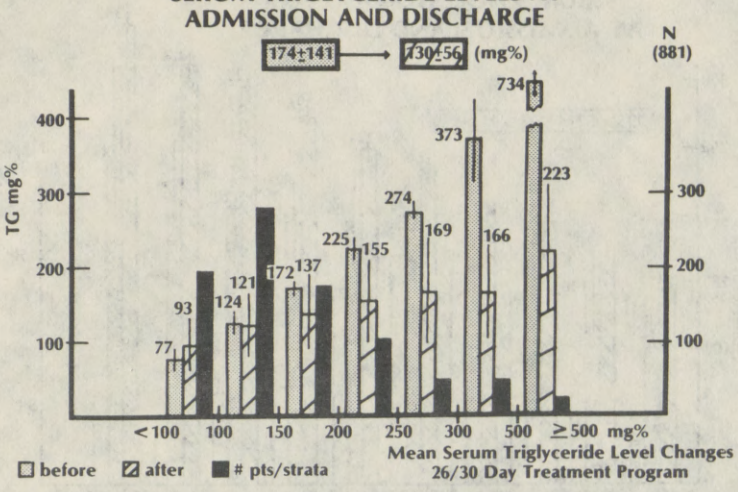


FIG. 5
SERUM TRIGLYCERIDE LEVELS;
PERCENT CHANGE FROM ADMISSION TO DISCHARGE

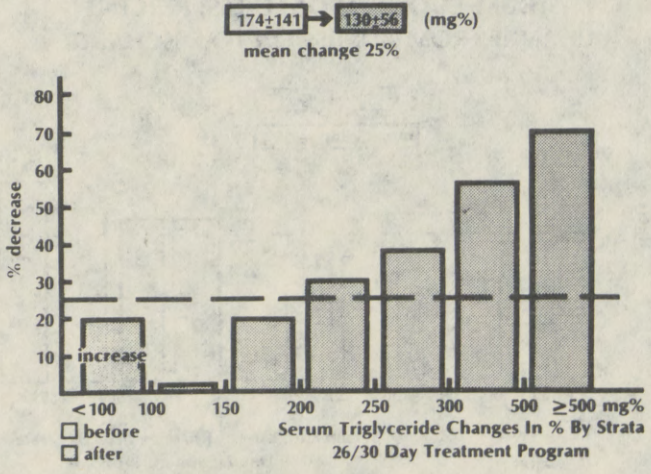


FIG. 6
SERUM CHOLESTEROL LEVELS AT ADMISSION AND DISCHARGE FOR PATIENTS USING CLOFIBRATE OR CHOLESTYRAMINE AT ADMISSION

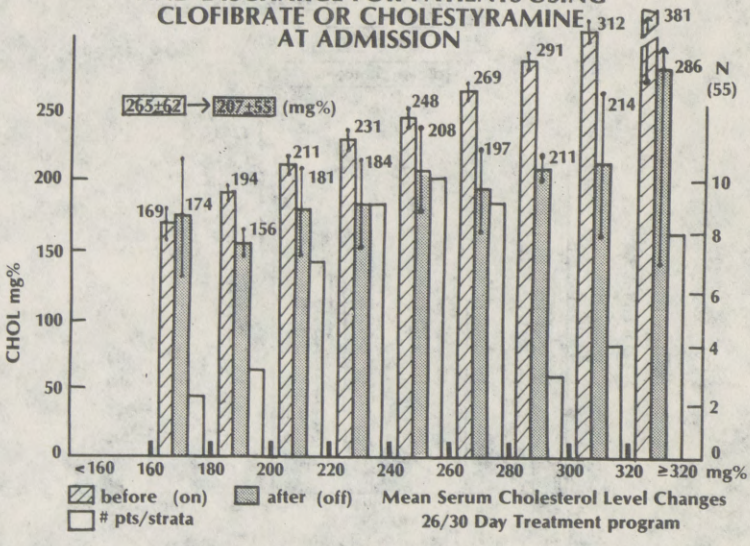


FIG. 7
SERUM TRIGLYCERIDE LEVELS; PERCENT CHANGE FROM ADMISSION TO DISCHARGE FOR PATIENTS USING CLOFIBRATE OR CHOLESTYRAMINE AT ADMISSION

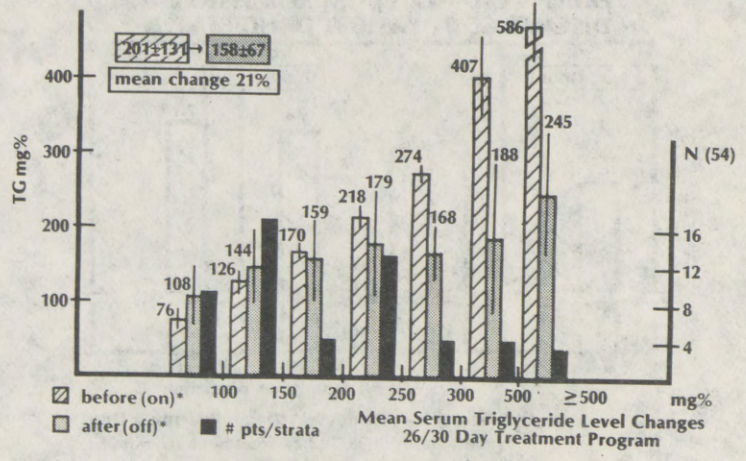


FIG. 8
TOTAL SERUM LIPIDS AT ADMISSION AND DISCHARGE

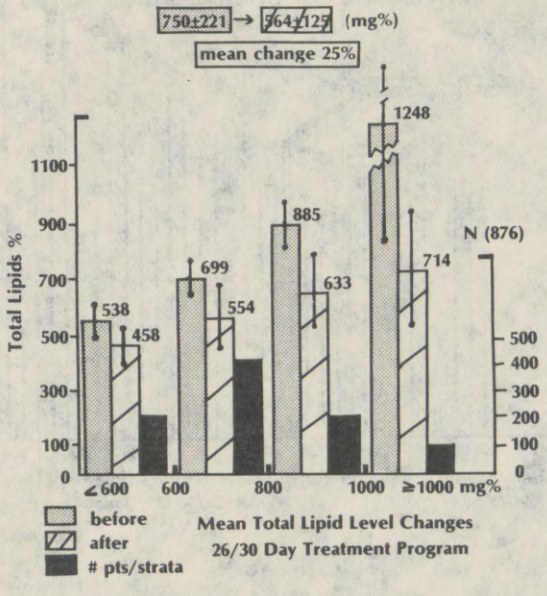
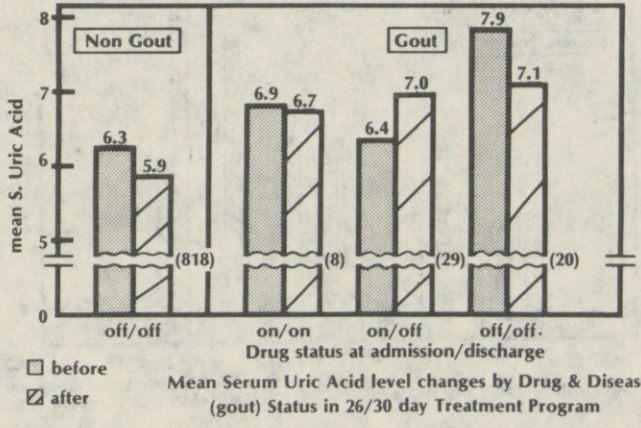


FIG. 9
MEAN SERUM URIC ACID LEVELS; PERCENT CHANGE FROM ADMISSION TO DISCHARGE BY PATIENT DRUG STATUS



HYPERTENSION

I. **DEFINITION OF HYPERTENSION** (as used in research protocol)

A. *Patients included:*

1) Persons hypertensive by medical history for at least one year *and* on antihypertensive agents at admission.

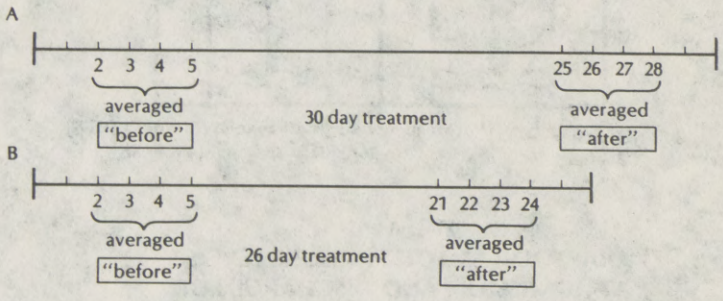
2) Persons hypertensive by medical history for at least one year *and* hypertensive (>140/90)* but not taking antihypertensive agents at admission.

B. *Patients excluded:*

1) Persons hypertensive by medical history but normotensive (<140/90)* and not taking antihypertensive agents at admission.

2) All others.

II. **DAYS FOR "BEFORE" AND "AFTER" BLOOD PRESSURE VALUES**



*Hypertension at admission is defined as average systolic values exceeding 140 or average diastolic values exceeding 90 for days 1-3 inclusive.

FIG. 10
SYSTOLIC BLOOD PRESSURE LEVELS
AT ADMISSION AND DISCHARGE FOR
HYPERTENSIVE AND NORMOTENSIVE PATIENTS

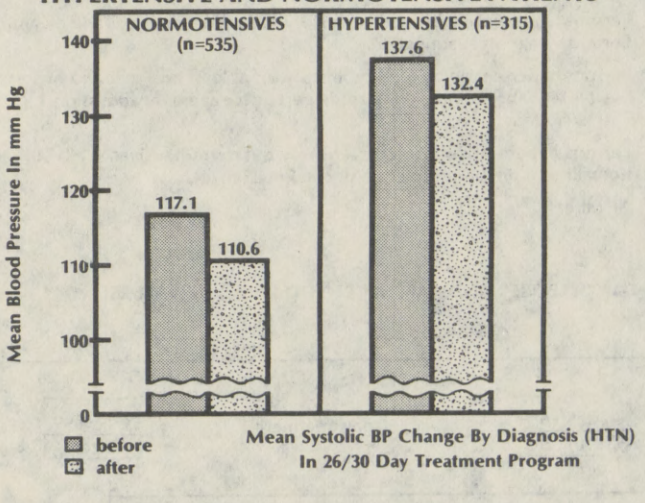


FIG. 11
DIASTOLIC BLOOD PRESSURE LEVELS
AT ADMISSION AND DISCHARGE FOR
HYPERTENSIVE AND NORMOTENSIVE PATIENTS

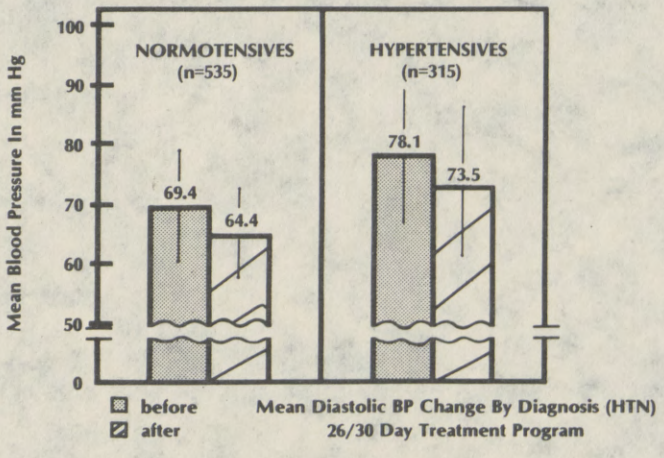
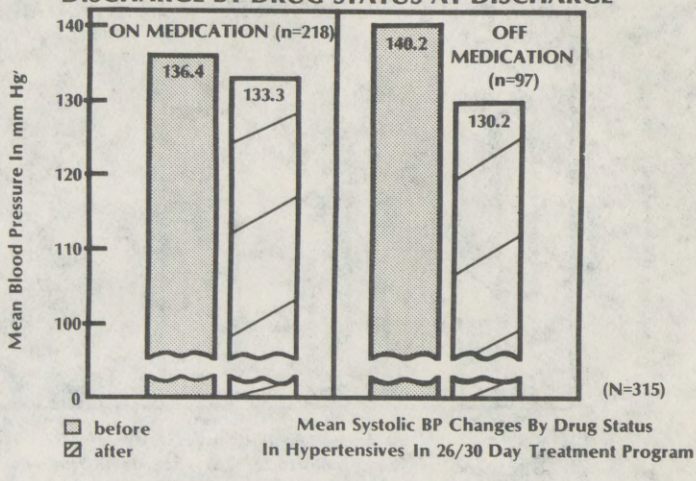
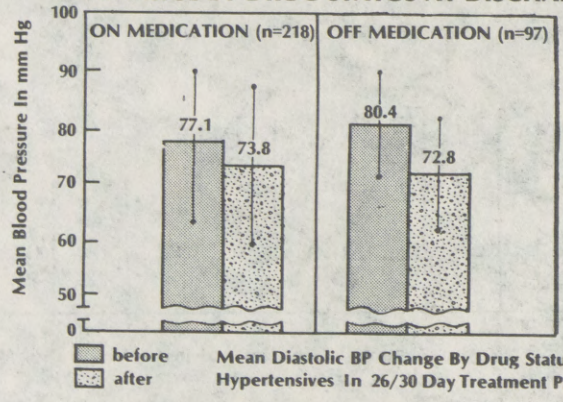


FIG. 12
SYSTOLIC BLOOD PRESSURE LEVELS OF HYPERTENSIVES AT ADMISSION AND DISCHARGE BY DRUG STATUS AT DISCHARGE



Mean Systolic BP Changes By Drug Status In Hypertensives In 26/30 Day Treatment Program

FIG. 13
DIASTOLIC BLOOD PRESSURE LEVELS OF HYPERTENSIVES AT ADMISSION AND DISCHARGE BY DRUG STATUS AT DISCHARGE



Mean Diastolic BP Change By Drug Status In Hypertensives In 26/30 Day Treatment Program (N=315)

FIG. 14
SYSTOLIC BLOOD PRESSURE LEVELS
OF HYPERTENSIVES AT ADMISSION AND
DISCHARGE BY SEX AND DRUG STATUS AT DISCHARGE

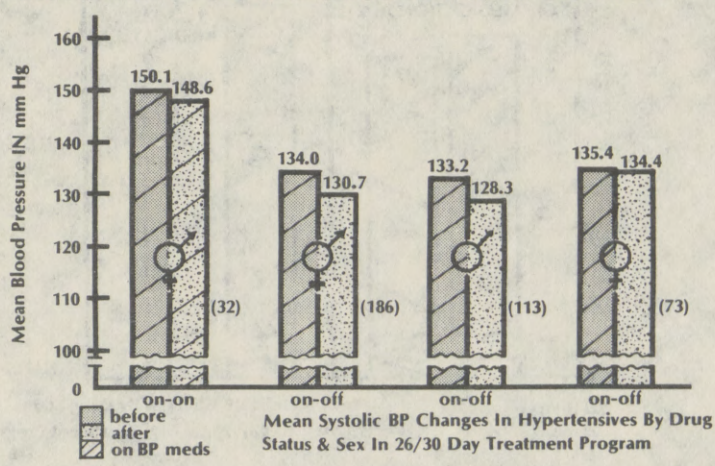


FIG. 15
DIASTOLIC BLOOD PRESSURE LEVELS
OF HYPERTENSIVES AT ADMISSION AND
DISCHARGE BY SEX AND DRUG STATUS AT DISCHARGE

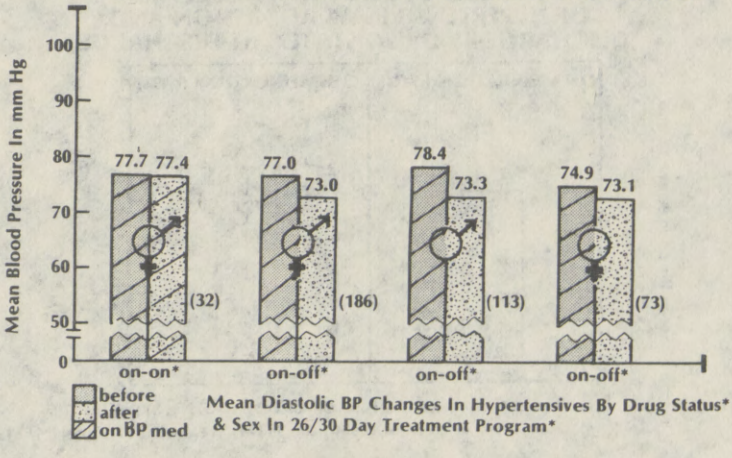
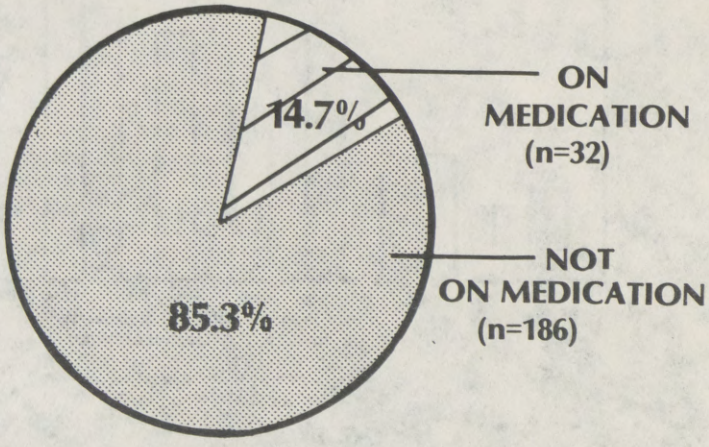


FIG. 16
MEDICATION STATUS OF HYPERTENSIVES AT DISCHARGE*



At Discharge:

- Hypotensive Medication Reduced Or Maintained
- Hypotensive Medication Discontinued

*according to BP med usage at the time of discharge from 26/30 day treatment program

FIG. 17
WEIGHT LOSS BY RELATIVE WEIGHT AT ADMISSION

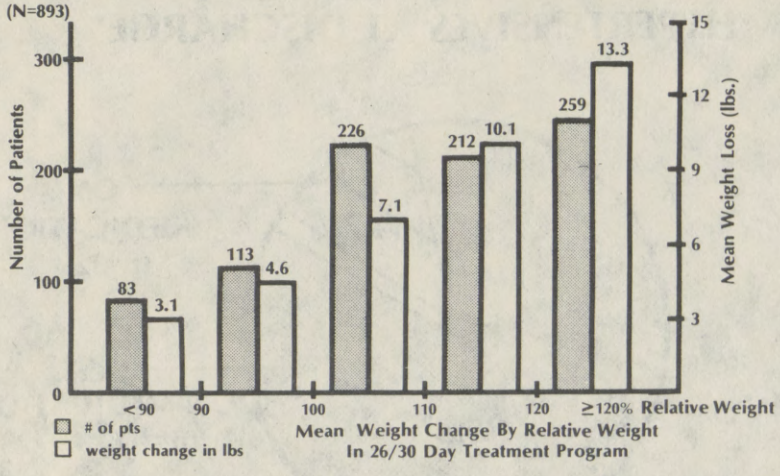


FIG. 18
SERUM CHOLESTEROL AND TRIGLYCERIDE
LEVELS AT ADMISSION AND DISCHARGE BY
RELATIVE WEIGHT AT ADMISSION

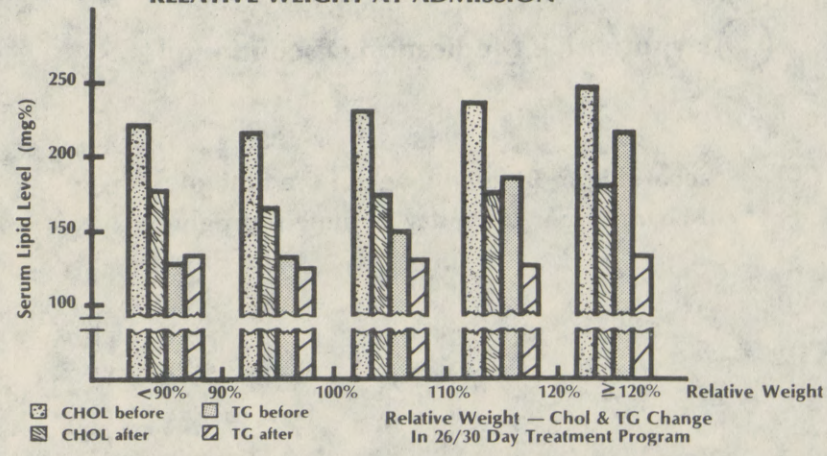


TABLE 3

MEDICATION STATUS OF 97 DIABETICS AT ADMISSION AND DISCHARGE

DESCRIPTION	DRUG STATUS AT ADMISSION NUMBER	AT DISCHARGE NUMBER	% OF TOTAL
TAKING INSULIN			
JUVENILE ONSET	16	12	75%
MATURITY ONSET	22	11	50%
TAKING ORAL HYPOGLYCEMICS	32	6	19%
NOT TAKING HYPOGLYCEMICS	27	27	100%

TABLE 4
CLINICAL CHANGES AMONG ADULT-ONSET DIABETICS USING INSULIN AT ADMISSION AND AT DISCHARGE

CASE NO.	WT. LOSS LBS.	CHANGE IN CHOLESTEROL	CHANGE IN TRIGLYCERIDE	MILES/DAY WALKED	CHANGE IN INSULIN DOSAGE
003	9	194-124	90-105	5	40N-26N
329	2	312-230	245-245	5	20L-18L
379	15	203-133	74-63	9	40N-29N
406	9	192-161	95-98	6	40L-5L
529	20	290-223	535-348	3	84L-20L
584	21	237-189	189-190	2	10N, 10R-15N
638	7	216-144	96-73	8	24N-17N
1108	10	281-195	127-126	3	40N-24N
1144	8	244-178	164-141	0	25N-4N
1260	0	466-209	775-444	1	28N-34L
1267	2	235-197	55-96	N.A.	750D-15N

TABLE 5
CLINICAL CHANGES AMONG ADULT-ONSET DIABETICS USING INSULIN AT ADMISSION BUT NOT AT DISCHARGE

CASE NO.	WT. LOSS LBS.	CHANGE IN CHOLESTEROL	CHANGE IN TRIGLYCERIDE	MILES/DAY WALKED	INSULIN DOSAGE AT INTAKE
006	27	650-254	2770-180	8	20N
168	18	260-198	119-129	0	35L
224	13	190-145	142-117	8	8R, 12L
372	1	243-161	501-267	1	35N
978	6	253-211	271-156	0	30N
1009	7	211-162	140-75	11	20L
1192	13	241-181	107-77	7	30N
1206	16	182-150	195-121	12	50N
1223	5	271-156	165-80	3	28N
1230	19	279-260	160-184	0	12N
1278	8	264-220	465-372	1	35L

D = Diabinese

L = Lente

N = NPH insulin

R = Regular insulin

The effectiveness of my dietary approach is confirmed by leading universities. At U.C. Davis, Drs. N.O. Borhani and H.S. Sodhi, after visiting my center and reviewing my data decided to use this approach at their university. A report on their work (Circulation, Part II, Vol. 58, No. 4, October 1978, Abstract No. 796) is entitled, "Hypocholesterolemic Response to Very Low Fat Diet in Subjects Resistant to American Heart Association and Other Prudent Diets." Dr. Borhani was involved in the MRFIT study and was personally knowledgeable of the failure of the AHA and prudent diets to adequately lower cholesterol levels for the U.S. population.

The fear of using high carbohydrate diets probably was not lessened by Dr. Donald Fredrickson's (Director of NIH) study (Clin. Res. 13:327, 1965) where he writes, "Rapid appearance of hyperlipemia was demonstrated to be the normal response to high carbohydrate intake in man." Dr. Fredrickson's use of simple carbohydrates produced the abnormal results, hut his conclusions have been far-reaching, and I believe one reason for high carbohydrate diet of complex carbohydrates not being accepted.

A diet practically identical to mine has been used for hundreds of years by the Tarahumara Indians of Northern Mexico. Average cholesterol levels are below 150 mg% and heart disease and other degenerative diseases are practically unknown.

Senator Schweiker was concerned about HDL. Here is a table from Preventive Medicine 8:654, 1979, indicating their HDL of 23, only half that of Iowa children (50). There is no relation between HDL and cardiovascular disease.

654 EPIDEMIOLOGICAL SECTION

TABLE 43
MEAN PLASMA CHOLESTEROL LEVELS (mg/dl) IN CHILDHOOD (11)

	Tarahumaras	Iowans
Total	118	163
LDL	75	103
HDL	23	50
VLDL	20	8
LDL/HDL	3.3	2.1
Total/HDL	5.1	3.3

Source. Reproduced, with permission, from Ref. (11).

The HDL's of the Framingham men and Honolulu Japanese are roughly the same, according to Castelli, but the latter group have only half the coronary heart disease of the former.

It may be that HDL is only important for those on the U.S. high fat, high cholesterol diet.

The scientific rationale for my diet recommendations is summarized in my article which follows.

HIGH CARBOHYDRATE DIETS: MALIGNED AND MISUNDERSTOOD

Nathan Pritikin

THE JOURNAL OF APPLIED NUTRITION

Volume 28, Number 3&4 Winter, 1976

HIGH CARBOHYDRATE DIETS: MALIGNED AND MISUNDERSTOOD

Nathan Pritikin
Santa Barbara, California

It is indeed a privilege to share this portion of the conference program with the distinguished Dr. Fredericks, but I think you will soon find that we hold little in common other than the same publisher—Grosset and Dunlap; our views on nutrition are poles apart.

Last year at the International Academy of Metabology Florida meeting, the banquet speaker, Dr. Emanuel Cheraskin, made a statement that deserves to be pondered: he said there is not a proper diet for arthritis, another completely different one for angina, and so on for other diseases. He said there is one optimal diet for man.

I am in complete accord; and it is my position that key characteristics of the optimal diet are the very low fat content and main dependence on food as grown—complex carbohydrates. Simple carbohydrates, as sugar, molasses and honey, are, of course, to be avoided.

An optimal diet should permit man to be free of the ravages of cardiovascular degenerative diseases, including angina and hypertension, and diabetes and arthritis, as one of its major attributes.

The low incidence of atherosclerosis in populations on low fat diets has been widely observed by many investigators. The coronary heart disease rate of Bantus in Africa who live on a 10% fat diet is almost zero. Hannah[1] reports that at the Nkana Nune Hospital, which has 300 beds for Africans and a high autopsy rate, no deaths were ascribed to coronary heart disease. In autopsies performed on 42 Bantus and 22 Europeans who died suddenly for any reason, only one Bantu had atherosclerosis; whereas 100% of the Europeans, even a youth of 15, had extensive artery damage. 35 of the Bantus lacked even a trace of fatty streak on the intima—the earliest clinical sign of artery damage.

Whyte[2] observed natives of New Guinea whose diet contained 10% fat and only 7% protein. Autopsies performed on 600 natives revealed only one case of death attributable to coronary heart disease. Blood pressure in New Guinea natives was found not only not to rise with age, but diastolic pressure dropped about 10 mm. when in their 60's.

Leaf[3] studied a population in Ecuador with an unusual number of aged people. Of the 800 villagers, a number were over 100 years old and one was 121, as authenticated by Catholic Church records. Cardiovascular disease was found to be virtually non-existent. The diet was mainly complex carbohydrate: corn, brown rice, beans, various other vegetables and fruits and a once weekly portion of animal protein.

Keys[4] has studied over 25 populations on a low fat diet: without exception, their heart disease rate was low.

Immunity to coronary heart disease lasts only so long as a low fat diet is maintained. Thus, in a study of Japanese who have changed their environments from their homeland to Hawaii and then to mainland United States, where different fat contents were consumed, it was found that as the fat intake increased, so did coronary heart disease death rates.

I would like to tell you about a small controlled study now taking place in Southern California where a diet such as is consumed by native atherosclerosis-free populations is being replicated with astonishing results. For this six month study, now almost half over, we selected 38 men with an average age of 60. Artery closure in all was so bad that most could walk only a few minutes on a 1½ MPH treadmill before calf pain stopped them. 80% of the men have had arterial reconstruction work and in most we found coexisting conditions of hypertension, diabetes, angina, cerebral ischemia and so on.

The extensive baseline testing done on all of the men has included an angiogram of all arteries from the aorta to the toes. The angiograms revealed very advanced atherosclerosis with occlusions in the larger arteries of each patient, even after their arterial bypasses and enarterectomies. Cholesterol levels for most were from 200 to 300 mg.%.

These normal western cholesterol levels contrast with the low cholesterol levels universal with atherosclerosis-free native populations. New Guinea natives have cholesterol levels around 100 mg.%, whether young or of advanced age; cholesterol levels of the African Bantus are 90-120 mg.%; the average cholesterol level of the Ecuadorian population studied by Leaf was 150 mg.% for a mature adult; and Keys found low blood cholesterol levels in all of the 25 atherosclerosis-free populations he studied.

In our study, half of the 38 men, the controls, have been instructed to walk daily and to try to cut out their smoking. They are having monthly examinations and are being given the best medical care—but their diet remains unchanged. The other half—the experimental group, for which I have dietary responsibility, have also been urged to walk daily and to cut out smoking, but, in addition, they are having all their meals at the study headquarters seven days weekly. Their diet simulates that of atherosclerosis-free populations in the world in that it is 80% carbohydrate, this being made up entirely of natural unrefined foods, so that no supplements are required.

We are getting some exciting results. In the first two weeks, blood cholesterol dropped an average of 30%. One triglyceride dropped from 360 to 85 mg.%. Our goal is to maintain cholesterol levels below 130 mg.% and triglycerides below 75 mg.%. At these levels, there is much evidence that atherosclerosis reverses.

After five weeks, treadmill performances increased 800%.

Even more gratifying were the drops in blood pressure in the nine hypertensives in the group. After a month, all nine—all of whom had been drug-treated for hypertension, were normotensive without drugs. One of them had been on

antihypertensive drugs for 20 years. In the fall of '73 he was taken off drugs when in the hospital for testing and his blood pressure rose to 210/110, staying there for ten days. He was put back on drug therapy and remained there—until his blood lipids were lowered recently on this experimental diet.

Repeat blood flow tests have demonstrated improvements. Repeat angiograms will be done in July at the end of the study and it is hoped that these will show that the regimen has caused the arterial damage to regress through plaque reversal.

The effect of the diet on the diabetics in our study's experimental group has been dramatic: the four diabetics were off their drugs in six weeks. This includes two who had been on insulin for 10 to 15 years. One of the two was taking 80 units daily for the last year and a half.

How can this fast reversal of diabetes be explained? Two studies in the literature clarify the diet relationships involved in the etiology of diabetes. Sweeney[5] put young medical students on different dietary regimens for two days. One group's diet was high in protein; another's was high in fat; a third group received no food; and a fourth group was fed a high carbohydrate diet. On the glucose tolerance test taken after the two day period, the high protein group tested borderline diabetic and the high fat and starvation groups were both quite diabetic with their two hour post glucose blood values exceeding 170 mg.%. Only one group tested normal: those on the high carbohydrate diet.

Anderson's study[6] required a longer period for ingested fat to raise the lipid level high enough to produce diabetes—two weeks instead of two days. Two diets utilizing corn oil as the fat and sucrose as the carbohydrate in varying percentages were used with 20 year old normal men. After two weeks, the group on the 80% sucrose and only 5% fat diet tested normal on a glucose tolerance test; but the second group, on a diet of 65% fat and 20% sucrose tested diabetic, with a glucose tolerance test two hour reading of 184 mg.%. Those on the low 5% fat diet continued this regimen for an additional seven weeks, and their glucose tolerance test at the end of this period was still normal. This result shows the efficacy of a low 5% fat diet in maintaining a normal glucose tolerance test response—even on a diet in which 80% of the total calories consumed were in the form of table sugar, sucrose. The heavy sugar intake did, however, reflect in steadily increasing triglycerides.

If a high fat diet can produce diabetes, can a low fat diet reverse it? Rabinowitch[7] used a 21% fat diet on thousands of diabetics in his Montreal hospital. In a five year controlled test 24% of insulin dependent diabetics on the low fat diet no longer required insulin, and those still on insulin had their dose reduced 58%.

Singh[8] used a diet of 12% fat and was even more successful. Starting with 80 insulin dependent diabetics, in less than five months, 72% of the diabetics were off insulin and the balance were on substantially lower dosages. Several were followed for five years, remaining unchanged.

With this historical background, our success in reversing diabetes with a low fat diet is no surprise. I believe our final angiographs will prove that a low fat diet can also reverse atherosclerosis. This confidence is based on primate and human

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studies that show that cholesterol level is the best predictor of artery damage in atherosclerosis, and that when cholesterol level is lowered sufficiently, plaque regression occurs in primates.

The Framingham Study[9] which started in 1948 with 5200 people is relied upon as one of the more respected predictors of risk factors. Data from this study indicates that an individual with a cholesterol level above 260 mg.% had 400% more cardiovascular events than one with a level below 220 mg.%.

Keys' Minnesota study, [10] started in 1947, confirms the Framingham results. Using the amount of heart damage observed with maximum cholesterol levels of 200 mg.% as a standard of comparison, in both studies cholesterol levels of 220 to 239 mg.% were found to produce 250% more heart disease; from 240 to 259 mg.%, there was 400% more heart disease; and above 260 mg.%, there was 560% more coronary heart disease than was found in patients with levels below 200 mg.%. The risk was found to be directly proportional to the cholesterol level.

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All major population studies provide indirect evidence of this correlation between cholesterol level and heart deaths, but now we also have direct angiographic proof in the form of x-rays of the arteries. Welch[11] did angiographic studies of 723 men under 40 years. Half had two main coronary arteries more than half closed; the relationships of the amount of artery closure to cholesterol level were found to be almost identical to those in Keys' Minnesota study.

Welch observed that with cholesterol levels of 250 mg.%, 300% more men had closed arteries than those with levels under 200 mg.%. Almost 90% of the men with levels over 300 mg.% had some closed arteries, and these men were all under 40 years old. The youngest man, 17 years old, with no symptoms, had excellent blood levels by U.S. standards: cholesterol 184 and triglycerides 122. Yet the angiogram demonstrated a total occlusion of the anterior descending coronary artery.

The angiographic work of Page[12], from the famed Cleveland Clinic, made possible the construction of a table for prediction of artery closure based on only 3 factors: age, cholesterol level and triglyceride level. For example, at age 28, cholesterol level 140 mg.% and triglycerides 60 mg.%, only half of 1% would have artery closure; but if the cholesterol level was 360 and the triglyceride were 540, 73% would have artery closure—even at age 28!

To check the reliability of his predictions, Page did a double blind test on 60 new patients. Based on the three factors: age, cholesterol and triglyceride levels, he predicted which patients would demonstrate closed arteries in angiography. Independent groups did the angiograms and tabulated the results to eliminate any

human bias. Page's track record for predictions was nearly perfect: 59 of the 60 predictions were correct—a 98% degree of accuracy!

The indirect evidence from the population studies confirmed by the direct evidence of angiography paints a grim prognostic picture for most adults in the western world: Cholesterol levels over 140 mg.% and triglyceride levels over 75 mg. % are the blood environment initiating atherosclerotic damage.

Primate cholesterol levels are very similar to those in man when primates are placed on comparable diets. Armstrong[13] evaluated low fat, high fat and high unsaturated fat diets as to their potential for producing or regressing the atherosclerotic state, using 40 monkeys as subjects. On the high fat diet, which was also high in cholesterol and contained an amount of fat common in American diets—41%, the monkeys developed plaques that closed the arteries 58%. The monkeys were then placed on two cholesterol-free regression diets: one with only 4% fat, and the other with 40% fat, but of the unsaturated kind. Regression of plaques on the 4% fat diet permitted 400% more blood flow; but the 40% polyunsaturated fat diet produced 65% less regression, and plaque analysis showed 50% more cholesterol esters.

Rhesus monkeys eating an average American diet develop average American plaques as was demonstrated by Wissler[14] using a diet based on the 25 favorite American foods in proportions judged from food consumption tables. Other monkeys ate a second diet, the prudent diet, which omitted eggs, beef and pork fat, liver, cheese, butter and bacon. After two years, when the monkeys on both diets were sacrificed, it was found that those on the 25-favorite-foods diet, equivalent to 36% fat American meals, had average cholesterol levels of 383 mg.%; while those on the prudent diet had average cholesterol levels of 199 mg.%. On the 25-favorite-foods diet, almost half the monkeys had plaques covering more than 90% of the inner surface of the aorta; whereas the same amount of monkeys on the prudent diet had 16% of the aorta covered with plaques.

The prudent diet resulting in a cholesterol level of 199 mg.%, which is very normal by current standards, looks good, until one checks out Armstrong's controls[13] on a cholesterol-free low-fat diet. The 135 mg.% cholesterol level of these monkeys at the end of the five year period produced no plaques.

Two studies suggesting plaque reversal in humans by simple means should be cited. Morrison,[15] using proven coronary infarct patients in a 12 year study, put closely matched groups of 50 each on two different diets. The controls stayed on their normal western diet and the experimental group was recommended to restrict fat intake to 15% of total calories and cholesterol to 100 mg. daily. At the end of the 12 year period, 38% of the lower fat diet group were still alive, whereas the entire control group had died.

Lyons[16] started 280 patients with previous infarcts on a similar program. 155 were on a low fat low cholesterol diet and the control group of 125 continued on their average American diet. Four years later, those on the high fat diet had suffered 400% more deaths and 400% as many new coronary infarcts as those on the low fat diet.

It might be argued that even if a low fat diet prevents and reverses diabetes and heart disease, a diet which depends for 80% of its calories on natural carbohydrates would destroy health and vigor because vegetable proteins are incomplete.

This erroneous concept was fostered by the work of Osborne and Mendel[17] in the early 1900's. Working with rats, they concluded that plant proteins have a low PER (protein efficiency ratio) and hence have a much lower biological value than animal proteins. Their work and later work by others also demonstrating sub-optimal growth in rats on vegetable protein diets led to the assumption that this would also be true with humans. The PER rating of proteins was based on their efficiency with rats.

But the nutritional needs of rats and humans are not analogous. If they were, then human milk should not be fed to human infants because rats do poorly on human milk, it being only 1.2% protein compared to the 12% protein of rat's milk.

When humans were used as subjects by later investigators, two important findings were made: 1. Vegetable proteins are as adequate as animal proteins for human diets; 2. The amount of protein required for humans has been overstated. This throws new light on the world's supposed protein shortage, which, in fact, is really a calorie shortage. If calorie intake is insufficient for energy needs, the protein in the diet will be used for calories first and protein second. With a calorie deficit, no protein, regardless of its biological value, will permit normal growth in children or a positive nitrogen balance in adults.

These later investigations with humans into the adequacy of vegetable proteins used subjects of all ages. Knapp's subjects[18] were infants from 5 to 14 months admitted for treatment for diarrhea to his metabolic hospital in Corpus Christi, Texas. After the diarrhea was controlled, he fed them various isocaloric diets at two grams of protein per kg. of weight per day for three months. The reference protein, milk, was compared to: 1. rice and cottonseed; 2. rice plus peanut; and 3. wheat. It was found that there was no difference in growth rates or nitrogen retention in balance studies. In fact, the percentage of nitrogen excreted as urea was lower in all babies fed vegetable proteins compared with those fed milk.

Reddy[19] studied children aged 2 to 5 years old in India. He was concerned with the use of wheat as their principal protein because compared to egg it is low in lysine and in animal studies the addition of lysine to wheat diets significantly increases animal growth. Two diets were tested: one with unfortified wheat, the other wheat plus lysine. Nitrogen balance studies on the children showed no difference in results of the two diets so long as adequate calories were given.

In rice as with wheat diets, in rat nitrogen balance studies, there is lysine deficiency, and when some chicken was substituted for the rice, the PER (protein efficiency ratio) became considerably improved. But again, what is true for rats is not true for humans. Lee[20] at Purdue University put male students aged 20 to 27 in three different diets for 59 day periods for nitrogen balance studies. One diet relied on rice alone to supply all the protein; another used 85% rice and 15% chicken; and a third used 70% rice and 30% chicken. The total protein for each of the three diets was 6.5% of total calories, far less than considered essential by our present standards.

The 30% chicken diet demonstrated a positive nitrogen balance of 1.04 gms., or 13%. 15% chicken wasn't as good—2% less, making an 11% positive nitrogen balance. The 100% rice diet produced the highest nitrogen retention—13.5%, even though the rice used in the study was white rice, completely milled and unenriched. Yet in Kik's[21] study with rats using rice, even a 1% chicken supplement greatly improved their growth rate. Protein requirement studies with rats are not necessarily valid for humans.

College women aged 17 to 31 years were studied by Fisher[22] at Rutgers University. Only 5 gms. of nitrogen or 31 gms. of protein per day was necessary to keep them in nitrogen balance. The amino acid pattern was deliberately modified so as not to be equivalent to whole egg protein. Leucine, methionine and valine requirements were reassessed on this low protein diet. In the case of leucine, it was found that the 40 mg. per day required was only 1/4th to 1/10th the amount established by Rose and Leverton. Rose's study used twice as much protein and the whole egg was used as the amino acid pattern. Earlier studies by Fisher demonstrated lower requirements for both lysine and tryptophan when college women were on the low 5 gms. of nitrogen daily. Nitrogen balance is dependent upon the amount of protein fed as well as the amino acid pattern.

Krofranyi[23] determined that it required less protein to keep adult men in nitrogen balance when potato and egg was used rather than egg alone as the sole protein source. In fact, the essential amino acid requirements were as much as 50% lower than reported by Rose when the protein came from a potato-egg mixture. Next time you look up the biological value of protein foods as reported by Mitchell[24] and find that egg has a value of 94% and potato 67%, remember that this is valid for rats, not humans.

To summarize: assuming adequate calories, the nitrogen balance studies with human subjects ranging from infants to adults show no protein shortage when total protein was even as low as 7% of total calories and even when the sole protein was polished white rice.

Metabolic ward experiments are helpful, but the true test is in real life. The 50,000 Tarahumara Indians of Mexico are famed for their wooden kickball races. Men run, kicking a small wooden ball, for 48 hours continuously covering 180 miles in the process. Balke[25] authenticated these examples of Tarahumara fortitude:

- A 500 mile round trip run in 5 days;
- Carrying a 100 pound pack for 110 miles in 70 hours;
- Indian women playing the kickball game, but running continuously for only 50 miles.

The Tarahumara diet consists of 10% protein, 10% fat and 80% complex carbohydrate and comprises corn, peas, beans, squash and various other native plants and fruits. Animal protein is eaten perhaps a dozen times a year.

An average 40 year old Tarahumara man 5'7" weighs 125 pounds. Cholesterol levels, as might be expected from their diet, fall mostly in the 100 to 130 mg.%

range. Many physicians have examined these people and find them to be completely free of cardiovascular disease, hypertension or diabetes. If an 80% complex carbohydrate diet would seem to invite obesity, it should be noted that there are no fat Tarahumaras and, for that matter, substantial weight losses have occurred in obese men in our California study, where a similar diet is followed. When fat intake is drastically reduced, it is hard to consume enough calories to create weight gains.

Can a diet restricting fat to 10% produce fat deficiencies? The only fat the body cannot manufacture is linoleic acid. Winitz[26] has shown the daily requirement for linoleic acid to be only two grams. Recent findings by Press[27] demonstrate that only .1% of total calories as linoleic acid is required as a therapeutic dose to correct essential fatty acid deficiency: that is only 1/300th of an ounce per day.

In our preoccupation with protein needs, the resultant excess intake of fat and protein has been overlooked. There is a direct correlation between protein intake and excretion of minerals in humans. Margen[28] has been testing this concept since 1965 with over 2,000 University of California at Berkeley students. Findings on calcium are revealing: increasing protein intake from 0 to 90 gms. of nitrogen per day results in an 800% increase of calcium excretion, regardless of the calcium intake, which varied from 100 mg. to 2300 mg. This effect was noted without exception in all the studies conducted and was also repeated with synthetic amino-acid mixtures.

Confirming studies on mineral loss through high protein, low carbohydrate diets come out of Farleigh Dickinson University, where Dr. Fredericks has taught. Dr Yacowitz[29] found significant excretion losses in calcium, phosphorus, iron and zinc, as well as increased magnesium loss. His evidence of loss of bone matrix along with the calcium loss could be a factor in osteoporosis.

Several studies have indicated that young animals develop bone demineralization on meat diets.[30]

Ellis[31] has measured less aging bone loss in elderly vegetarians than in those on mixed diets.

Mazess[32] measured the bone mineral content of forearm bones in mature Alaskan Eskimos traditionally on high protein diets. He studied 413 Eskimos of all ages and found that after 40 years of age, Eskimos had 10-15% less bone density than whites. With each decade of age, the Eskimos had a 50 to 100% greater bone loss than whites. Bone loss started almost 10 years sooner than it did with whites even though calcium intakes were over 2000 mg. per day.

These studies may help us understand why western populations on high protein diets require so many mineral supplements,while underdeveloped populations like the Bantus on a 10% mostly vegetable protein intake require no supplements. On average calcium intakes of 350 mg. per day, Walker[33] reports that Bantu mothers give birth to an average of 9 children and yet their bones and teeth do not show loss of density.

I have already discussed another danger of high animal protein intake—the resultant ingestion of excessive amounts of cholesterol, leading to elevated plasma

cholesterol levels. High animal protein intake implies also the resultant ingestion of much animal fat. Fat consumption over 10 to 15% of total calories is excessive and toxic.

Excess fats, whether animal or vegetable, create damage in three ways: 1. Interference with carbohydrate metabolism which is a prime factor in diabetes; 2. Elevation of cholesterol and uric acid plasma levels resulting in the shifting of these substances into the tissues and extra-vascular spaces; and 3. The production of tissue anoxia.

One of the first to observe tissue anoxia produced by a high fat meal was Swank[34] who fed hamsters cream meals and then, through their transparent cheek pouches, observed the effects on the erythrocytes. As the chylomicrons started to pour in from the cream meal, the erythrocytes began to adhere to each other. In 3 to 6 hours after the feeding, the aggregation, now in rouleaux and irregular formations, completely blocked many capillaries. The aggregations directly affected the oxygen-carrying capacity of the erythrocytes, decreasing the plasma oxygen level to 68% of the starting value. It took 72 hours without food before the oxygen level reached 95% of the original value.

Could such a cream meal precipitate an angina attack because the oxygen-carrying capacity of the blood is lowered? Kuo's study[35] with 14 angina patients tested this possibility. After an overnight fast, each subject drank a glass of heavy cream, then rested quietly while half hour blood samples were drawn. In 5 hours, the influx of chylomicrons had caused the transparent fasting blood to become 600% more turbid on a plasma lactescence scale. At peak lactescence, 14 angina attacks occurred, simultaneous with ischemic ECGs and abnormal ballistocardiograms. The amazing similarity in the reaction of many individuals to fat was shown in almost identical lactescence curves for 13 of the 14 angina patients.

These same patients on another morning drank a fat-free drink with identical calories and bulk. After 5 hours, no increased blood turbidity, no angina and no abnormal ECG tracings could be noted.

Are unsaturated fats less harmful? Friedman[36] compared the effects of saturated and unsaturated fats on erythrocyte aggregation and blocking of arteries by correlating a series of microphotographs of conjunctival capillaries while monitoring blood lipids. Sludging and capillary blockage occurred after his subjects, 44 firemen, ingested a butterfat cream drink following an overnight fast, but this also occurred when the same subjects following the same procedure another day substituted a safflower oil drink of equivalent fat content. The unsaturated safflower oil aggregated the erythrocytes and blocked the capillaries just as the cream had, but worse, the safflower drink kept the 4 hour post prandial triglyceride level elevated even longer than had the butterfat drink. After the butterfat drink, the triglyceride value had returned to normal within 9 hours in every person; after the safflower oil drink, in some the triglyceride level did not even start to drop after 9 hours.

Platelet aggregation occurs under the same conditions that produce erythrocyte aggregation. A U.S. Department of Agriculture study, directed by Iacano, [37] placed normals on a 25% fat diet instead of their usual 40-45% fat intake. Not only did blood pressure and cholesterol levels drop, but there was a 50% drop in platelet aggregation. When the diet of 40-45% fat was resumed, the platelet aggregation returned to previous levels. Dr. Iacano said, "There is no question that these changes result from the changes in the amount of fat in the diet."

Even the so-called "good" fats like arachidonic acid aggregate platelets. Arachidonic acid is only found in animal sources; human enzyme systems quickly convert it into short-lived endoperoxides and these are metabolized into prostaglandins, which are potent triggers of irreversible platelet aggregation and thrombosis. Silver[38] found that arachidonic acid used intravenously can produce rapid respiratory death in rabbits from platelet occlusion of the small pulmonary vessels.

Hazlett,[39] chief of the pulmonary functions lab at Fitzsimmons Army Hospital in Denver, repeated Silver's work using rabbits and also humans. Using a fat very familiar to most of us, soybean lecithin, he tested male subjects between 19 and 25 years of age, all with normal pulmonary function. The lecithin-induced hyperlipidemia reducing lung function and producing erythrocyte aggregation lasted up to 48 hours—a confirmation of Swank's hamster tests.

Rabbits made hyperlipidemic with lecithin had severe impairment of their alveolar capillary gas exchange. Photos of their lungs showed fat droplets lining the capillary walls, surrounding erythrocytes and filling some capillaries. The investigator, Hazlett, said that in such a low pressure circulatory system as pulmonary capillaries, this could easily lead to obstruction.

Two years later, Pirkle,[40] a pathologist, confirmed Hazlett's apprehensions. He described 6 specific deaths of healthy young people 17 to 40 years old. The only abnormal findings were platelet aggregation in the small pulmonary vessels. The deaths were sudden and were marked by extreme respiratory distress lasting up to 30 minutes. Some of the aggregates were free-floating and others were blocking vessels. Pirkle believes these cases may explain thousands of unexpected natural deaths that occur each year.

Perhaps polyunsaturated fat containers should be labeled like cigarettes—"Warning: this could be dangerous to your health." For that matter, so should the marbelled steak and package of cheese. Dietary changes will not come easily, but for a nation suffering a million cardiovascular deaths yearly, what are the options? . . . Surgical? Coronary bypass is worse than palliative: 20% of bypasses completely close in the first 12 months . . . Pharmaceutical? The massive 8,000 man 5 year double blind Coronary Drug Project[41] is over. This evaluation of the most promising drugs available to the coronary patient indicate that if he had taken placebos he would have been better off than had he followed any recommended drug therapies. The drug testing included nicotinic acid at 3 grams per day, which was not only of no benefit, but had toxic side effects ranging from visual damage to increased cardiac arrhythmias.

Suppose, for the moment, that all the evidence presented so far about the dangers of excess fat and cholesterol were unknown. All that would be needed to discover the reality of these dangers would be to observe the effects of western diets on the gallbladder and intestinal tract. Population studies indicate that cholesterol gallstones are found exclusively in populations on the western diet. Tanaka[42] fed squirrel monkeys cholesterol-free diets. One diet used butterfat; the other, safflower oil. After a year, none of the monkeys had developed gallstones. Repeating the same diets but adding cholesterol produced gallstones in over 80% of the monkeys on both diets.

Taylor[43] used prairie dogs obtaining the same results. Without cholesterol, no gallstones; with cholesterol added in the form of egg yolks, 100% of the animals developed gallstones. In an attempt to dissolve the stones, he fed them lecithin at 3.6% of total calories; no effect was observed. But upon eliminating the dietary cholesterol, the stones dissolved.

Den Besten[44] followed this experimentation with humans. She fed them two isocaloric diets, one cholesterol-free, and the other containing 750 mg. of cholesterol in the form of egg yolk. In only three weeks, the cholesterol diet led to significant elevation of cholesterol in the bile, bringing 40% of the subjects into the lithogenic range, and in most of these, cholesterol crystals were now found in their bile.

Lithogenic bile—bile containing more cholesterol than the combined action of bile salts and lecithin can solubilize, can be manufactured at will: just add enough cholesterol.

Let's jump from the gallbladder into the intestine. Hill[45] and his group have been actively searching for the causes of colon cancer. From World Health Organization statistics, Hill noted the correlation between high fat intake and colon cancer was extremely high—.99. Checking the feces from people in high incidence areas, he found 100 times more anaerobic bacteria than in those people from low incidence areas. This was an exciting find, since the anaerobics are able to convert bile acids into carcinogens. Those on low fat and cholesterol diets were found to have mostly aerobics as enterococci that were unable to perform the bile conversion. This observation was confirmed by Wynder[46] who placed subjects who were on western diets on a non-meat diet and measured the significant drop in anaerobic bacteria and total bile acids.

The rate of bile degradation is dependent upon the quantity of bile as a substrate. With a 40% fat intake, typical of western diets, the bile acid concentration measured by Hill was 300-400% higher than with a 10% fat intake.

Testing 44 patients with colon cancer, Hill[47] found 82% with high fecal bile acid concentrations and coexisting anaerobic bacteria. In the same hospital, among 90 patients with other diseases, only 9% had high bile acids.

In other studies, Binder[48] found that the important function of bile acids in inhibiting anaerobic bacterial growth was prevented by lecithin.

Still another finding on high fat diets is the action by the lecithinase-negative Clostridia bacteria in converting the bile into estrogens, which could stimulate

breast tumor growth. Hill[49] noted that the correlation of high fat diets to breast cancer was .8, almost as high as with colon cancer.

These revelations concerning the relationship of fat and cholesterol to gallbladder and colon diseases result from a few dozen investigators, in less than the past 10 years, having asked the right questions. Added to other recent knowledge about the role of fat and cholesterol in degenerative diseases, the urgency for radical diet reform in the direction the data indicates becomes clear.

I have appreciated the opportunity to bring to the members of this audience, who are in the forefront of preventive medicine, a rationale for a high carbohydrate diet.

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A convenient summary of the diet is as follows:

The Pritikin Diet

DESIGNED TO REDUCE CARDIOVASCULAR RISK FACTORS AND FOR WEIGHT MANAGEMENT

Pritikin Diet suggestions:

These dietary recommendations are based on experience with over 3,000 patients at the Longevity Center. Marked improvements resulting in return to normal function have occurred in many patients with angina, hypertension, diabetes, intermittent claudication, and other conditions.

Under supervision by your own physician you may also achieve substantial health improvements by following the Pritikin Diet suggestions. These provide for a nutritionally complete diet, high in complex carbohydrates*, low in fat and cholesterol, and containing an adequate supply of protein mostly from plant foods.

This diet obtains approximately 80% of its total calories from complex carbohydrates*, 10-15% from protein, and about 5-10% from fat. Cholesterol intake is kept under 100 mg. per day. The table compares approximate intake on this diet with intake on the conventional diet.

	PERCENT OF TOTAL CALORIES			CHOLESTEROL (mg./day)
	FAT	CARB*	PROTEIN	
Pritikin Diet	5-10	80	10-15	10-100
Conventional Diet	40-45	45	10-20	600-800

**Complex carbohydrates are present in foods as grown, such as whole grains, fresh fruits and vegetables. On the conventional diet, too few complex carbohydrates are eaten, and much of the carbohydrate consumed is in the form of simple carbohydrates (sugars) or refined carbohydrates, stripped of vitamins, minerals and fiber.*

Managing your weight while following the Pritikin Diet suggestions:

Are you overweight? Even though you will be eating mostly carbohydrates (starches) on the Pritikin Diet, you will begin to lose weight until you achieve your ideal weight because you will be consuming much less fat. Foods high in fat are very high in calories; by weight, starches have less than half the calories.

You can speed up your weight loss by emphasizing the lower calorie foods among those permitted, such as vegetables, and de-emphasizing the higher calorie foods such as grains. If you wish to gain weight, do the reverse. Thus, you would be following the same type of diet whether trying to lose, gain, or maintain weight, except that you would place more or less emphasis on particular foods, Remember, these recommendations are for a new permanent dietary lifestyle that will help you to avoid weight problems or problems with degenerative diseases in the future.

Some physical changes you may notice while following the Pritikin Diet suggestions:

Within one week, you should notice a change in your bowel habits due to the increased fiber in your diet and to a change in the intestinal bacteria. This may cause flatulence (gas), temporarily, and occasional feelings of fullness. Significant health improvements should be noted in one to three months with a lowering of serum cholesterol and blood fats.

Following the Pritikin Diet suggestions:

Adhere carefully to the "do's" and "don't's" of the Table of Foods to Use and to Avoid and to the following rules:

1. Eat two or more kinds of whole grains daily (e.g., wheat, corn, oats, brown rice, barley, buckwheat, etc.), in the form of cereals, side dishes, pasta, bread, etc.
2. Eat two servings of raw vegetable salad and two or more servings of raw or cooked green or yellow vegetables daily. In addition, potatoes may be eaten every day.
3. Eat beans or peas one to three times weekly, as you wish.
4. Eat one piece of citrus fruit daily and up to three or four additional fruits.
5. Limit protein intake from animal sources* as follows:
   Up to 24 ounces per week of low fat, low cholesterol meat, fish or poultry.
   Up to 8 ounces (1 glass) skim milk per day plus 2 ounces of nonfat cottage cheese or equivalents in skim milk products.
6. If your bowel elimination is hard or irregular, add some unprocessed wheat bran flakes (starting with 1 tablespoon daily) to your cereal, soup, or other foods.
7. Eat three full meals daily. Don't go hungry between meals; snacks are encouraged. For snacks, eat fruit (not exceeding daily fruit allotment), vegetables and raw salad, or whole-grain bread or crackers that are free of oil, fat, added wheat germ or sweeteners.
8. Normal salt (sodium) needs are provided by foods in their natural state. Limit added salt intake by not using salt shaker in cooking or serving. Flavor with herbs and spices, instead of salt. (Small amounts of salt in commercially-prepared food products are permitted).
9. Don't use sugar of any kind, including honey. When sweeteners are unavoidable, use pureed fresh fruit or fruit juices.

Vegetarians eating no animal protein at all may require a supplement of Vitamin B12 once every several weeks.

TABLE OF FOODS TO USE AND TO AVOID

CATEGORY	USE WITH THE FOLLOWING RESTRICTIONS		AVOID
FATS, OILS	None		All fats and oils, including butter, margarine, shortening, lard, meat fat, all oils, lecithin (as in vegetable spray)
SUGARS	None		Refined carbohydrates, e.g. sugar, honey, molasses, syrups fructose, dextrose and sucrose
POULTRY, FISH, AND MEAT	Chicken, turkey, Cornish game hen, game birds (white meat preferred; remove skin)	*Limit acceptable poultry, fish and meat to 1½ lbs. per week or an average of 3¾ oz. per day.*	Fatty poultry, e.g. duck, goose
	Fish (lean) and acceptable shellfish	*1 oz. shellfish = 2 oz. other animal protein*	Shrimp and fatty fish, e.g. sardines, herring or fish canned in oil
	Lean beef (range-fed ideal), leanest ground beef, veal		Fatty meats, e.g. marbled steaks, fatty hamburger and other fatty ground meat, pork, ham, bacon, spare ribs, sausage, frankfurters, luncheon meat, lamb, mutton, duck, goose
			Organ meats, e.g. liver, kidney, heart
EGGS	Egg whites	*7/week max. (raw: 2/week max.)*	Egg yolk, egg substitutes, fish eggs, e.g. caviar, shad roe
DAIRY PRODUCTS	Nonfat (skim) milk (fluid) Buttermilk, nonfat (or up to 1% fat by weight)	*8 oz./day max. (May exchange 2 oz. cheese/yogurt allotment for an additional 8 oz. skim milk or nonfat buttermilk allotment.)*	All cream, whole milk and lowfat milk products
			Sour cream
	Nonfat (skim) milk powder	*5 level tbsp./day max.; replaces entire skim milk or buttermilk allotment**	Cheeses containing over 1% fat by weight
	Evaporated skim milk	*4 oz./day max.; replaces entire skim milk or buttermilk allotment**	All non-dairy substitutes, e.g. creamers, whipped toppings
	100% skim milk cheeses, primarily uncreamed cottage cheese, e.g. hoop cheese or dry curd cottage cheese (or up to 1% fat by weight)	*2 oz./day max. cheese/yogurt allotment. (May exchange 8 oz. skim milk or buttermilk allotment for an additional 2 oz.)*	
	Nonfat yogurt (homemade)	*1-2 oz./week max.*	
	Sap Sago (Green) cheese	*1-2 oz./week max.*	
BEANS, PEAS NUTS, SEEDS	All beans and peas (except soybeans)	*Limit to 1½ lbs./week max. In addition, may substitute 8 oz. for each 3½ oz. serving of poultry, fish or meat.*	Soybeans (unless substituted for meat allotment)
	Chestnuts		All nuts (except chestnuts) and seeds (except in small quantities as seasoning)
VEGETABLES	All vegetables except avocados and olives	Vegetables high in Vitamin A, e.g. carrots, sweet potatoes: *1 large or 2 small servings/day max.* Vegetables high in oxalic acid, e.g. spinach, rhubarb, Swiss chard: *occasional use only.*	Avocados, olives
FRUIT **	All fresh fruits	*5 servings/day max.*	Cooked, canned or frozen fruit with added sugars Jams, jellies, fruit butters, fruit syrups with added sugars Fruit juices with added sugars
	Cooked, canned, or frozen fruit (unsweetened)	*3 servings (2-3 oz. each)/week max.*	
	Dried fruit, e.g. raisins, prunes, figs, dates	*1 oz./day max.*	
	Fruit juices (unsweetened)	*4 oz./day max. (28 oz./week max.) or 1 oz./day max. frozen juice concentrate (7 oz./week max.)*	
GRAINS (BREADS, CEREALS, etc.)	All whole grains	Emphasize whole grains and grain products, as whole-grain breads, flour, crackers, cereals, pasta Limit refined grains and grain products (i.e. with bran and germ removed), as white flour, white rice, white pasta, etc.	Breads, cereals, crackers, rice, pasta, baked goods and other grain products with added fats, oils, sugars or egg yolks Soy flour Bleached white flour
	All breads, cereals, crackers, rice, pasta, corn tortillas, baked goods and other grain products made without fats, oils, sugars, or egg yolks		
CONDIMENTS, SNACKS, DESSERTS, MISCELLANEOUS	Condiments, dressings, sauces, flavorings, snack and dessert items without fats, oils sugars, or egg yolks.	Liquor or wine for cooking: *2 times/week max. (2 oz. portion)* Flavoring extracts, as vanilla: *use in moderation* Plain gelatin (unflavored): 1 oz./week max. Soy sauce (regular salt content), pickles, pickled vegetables, other high-salt items: *use in moderation* Salt: *Limit to approx. 4 gms./day (average American intake is 10-15 gms.)* Spices: *watch for sensitivities to certain spices: limit use accordingly*	Condiments, dressings, sauces, flavorings, snack and dessert items containing fats, oils, sugars or egg yolks (e.g. mayonnaise, prepared sandwich spreads, prepared gravies and sauces, most seasoning mixes and bottled dressings, catsup, pickle relish, chutney, fried snack foods, package gelatin desserts and puddings, bakery goods, candy, gum, chocolate) MSG (monosodium glutamate) Salt added to cooking pot or serving plate Salt substitutes and artificial sweeteners Smoked, char-broiled, or barbecued foods
BEVERAGES ***	Mineral water, carbonated water	Limit varieties with salt	Alcoholic beverages Beverages with caffeine, as coffee, tea or cola Beverages with added sweeteners, as cocoa or soft drinks Diet and other soft drinks with artificial sweeteners
	Nonfat (skim) milk; buttermilk, nonfat	See restrictions under *Dairy Products* above	
	Fruit juices (unsweetened)	See restrictions under *Fruit* above	
	Vegetable juices	Carrot juice: *2 glasses/week max.*	
	Linden tea		

*Occasional use only.

** If triglycerides are above 125 mg.%, eat only fresh fruit in the permitted amount.

*** Recommendations on herb teas (other than linden tea), decaffeinated coffee, coffee substitutes are under study.

To demonstrate that my diet recommendations are practical now for the U.S. population, Governor Edwards of Louisiana has given me permission to put the town of Natchitoches on my diet. Twenty thousand people will be given the opportunity to volunteer to change their dietary life-style. Lectures and food demonstrations, newspapers, radio and TV will be used for education. Here is the Proclamation:

State of Louisiana

Edwin Edwards
Governor

Proclamation

WHEREAS, the degenerative diseases, primarily, heart disease, diabetes and stroke, are the leading causes of death in Louisiana, and these insidious diseases leave in their wake both personal misery and financial hardship for family, friends, and the State of Louisiana; and

WHEREAS, scientific evidence suggests a relationship between our diet and such diseases; and

WHEREAS, scientific research indicates that populations that eat a diet low in fat from animal and plant sources are remarkably free of these degenerative diseases; and

WHEREAS, any change in dietary habits requires the cooperation and consent of all those whose lives will be affected; and

THEREFORE, BE IT RESOLVED, that the City of Natchitoches and citizens thereof be designated the model community for a pilot research program in Louisiana whose ultimate goals are a long, healthy, productive life for all Louisianians and reduction of medical costs; and

BE IT FURTHER RESOLVED, that citizens of Natchitoches will be aided in making the necessary changes in their diets to affect a dramatic reduction in degenerative diseases in Natchitoches within one year from the date of this proclamation; and

BE IT FINALLY RESOLVED, that because the success of this health campaign and projected extension and support throughout the state necessitates full cooperation of all segments of the community, I call upon business, labor, schools, churches, media, medical and civic organizations to pledge their support to the program,

NOW, THEREFORE, I, EDWIN EDWARDS, Governor of the State of Louisiana, do hereby proclaim Monday, January 21, 1980, as

PRITIKIN DAY

for longer, healthier life, inaugurating the Natchitoches longevity project.

In Witness Whereof, I have hereunto set my hand officially and caused to be affixed the Great Seal of the State of Louisiana, at the Capitol, in the City of Baton Rouge, on this the 18th *day of* January *A.D.* 1980

Attest By
The Governor

Paul Hardy
Secretary of State

Edwin Edwards
Governor of Louisiana

The Natchitoches Times 20c

Where Louisiana History Begins

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NATHAN PRITIKIN

City Chosen for One-Year Diet Study

To Reduce Death Rate

Natchitoches has been chosen as part of a pilot study to research and demonstrate the possibility of reducing the death rate by restructuring dietary practices.

Dr C.B. Ellis and his wife, Dr. Donna Ellis, are co-chairmen of the local project, which will demonstrate to what degree the death rate can be reduced, and the problems with motivating people to change their eating habits.

Nathan Pritikin, who wrote the "Pritikin Program of Diet and Exercise," is internationally known for his research in nutrition and his diet will be the model for the study. One of his biggest fans is Governor Edwin Edwards, who is an avid proponent of nutrition.

Governor Edwards has often called Natchitoches the "microcosm" of Louisiana because of its diverse cultures, geographical location, and other factors. He was instrumental in having Natchitoches used in the pilot study.

The experimental study will primarily attempt to reduce the number of people dying from heart and cerebrovascular diseases. It will be particularly important for older people.

Discouraging the use of alcohol, tobacco, and sugar, the diet reduces fat consumption from about 40 percent of the diet to about 15 percent. It is based primarily on fruits and vegetables, no pork, little beef, more fish and fowl and little salt or sugar. Spices are used to enhance the flavor of foods.

Pritikin has called the national diet the "tragedy of America," saying our affluence allows us to eat too much and too rich foods.

A kick-off banquet has been scheduled Monday night in the Student Union ballroom for community leaders, and Governor Edwards will be here. Pritikin will be in town all day Monday, and will meet with the doctors at Natchitoches Parish Hospital at 7:30 a.m. He will address the Lions Club at noon and visit various other places.

Pritikin is director of the "Longevity Research Center," in Santa Monica, Calif. and he will donate his services to the project. Volunteers will be used to demonstrate the diet in schools and before various clubs and organizations. The state will provide some funds for promotion of the program.

A town similar to Natchitoches will be the control group for the demonstration project, and at the end of the year the death rate will be compared in Natchitoches, where the attempt has been made to alter eating habits and in that town, which has gone on eating as usual.

"This is a non-commercial intervention study," Ellis emphasized, "and no attempt will be made to sell anything or make anyone do anything. Dieting will be on a voluntary basis. We will simply try to educate our people on the advantages of eating properly."

Ellis said this is the first time an attempt has been made to study the effects of proper diet on healthy people. He said the project has gained the attention of the national news media, and CBS is expected to cover the banquet Monday night.

Anyone who wishes more information about the study may call Dr. Ellis at 352-2545 or 357-4414.

The project will last throughout 1980, and further information will be given out during the year.

Hopefully at the end of 1980, when the results are evaluated, the impact of proper diet guidelines can be demonstrated and may well serve as a model for the country.

Nathan Pritikin
P. O. Box 5335
Santa Barbara, CA 93108

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VEGETARIAN INFORMATION SERVICE, INC.
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VEGETARIANISM: THE WAY TO SUPERIOR HEALTH

Testimony Presented Before the Subcommittee on Health and Scientific Research, Committee on Labor and Human Resources, U.S. Senate

20 February 1980

by Alex Hershaft, Ph.D., President
VEGETARIAN INFORMATION SERVICE, INC.
Washington, DC

My name is Alex Hershaft and I am president of the Vegetarian Information Service, Inc., a non-profit, public interest organization seeking to advise the American public on the merits of the vegetarian way of life. I hold a Ph.D. in chemistry, have been engaged in nutrition education activities for the past five years, and am currently employed as a senior environmental scientist by a local consulting firm. I am grateful for this opportunity to present my views on the health aspects of a vegetarian diet.

What's Wrong With Meat?

In the absence of a major war or other catastrophy, two million Americans will have died by the end of this year. Of these, 7.7 percent will have died a violent death by accident, suicide, or homicide; 6.8 percent will have succumbed to respiratory and less common diseases; 13 percent will have perished of other and ill-defined causes. But fully 67.6 percent, or 1.3 million Americans will have suffered and died quite needlessly of the three chronic "killer" diseases in which diet constitutes a major contributory factor: heart disease, cancer, and stroke. Another 5.3 percent or 105,000 people will have succumbed to four lesser diet-related diseases: diabetes, cirrhosis of the liver, nephritis, and arteriosclerosis. The foods that have been singled out for special concern in connection with these diseases are meat and animal fat. Others include sugar and highly refined carbohydrates, salt, and special additives.

Heart disease, the #1 killer, is responsible for the deaths of 725,000 Americans annually. The risk factor for meat eaters is approximately three times that for vegetarians. Consumption of saturated fat and cholesterol, which are found almost exclusively in meat and other animal products, is generally regarded as the key factor in the development of the arterial plaque which eventually cuts off the blood supply to the heart and brings about the fatal heart attack. Stroke, accountable for 190,000 deaths, occurs when a similarly occluded artery interrupts the blood supply to the brain.

Cancer of the colon and the breast are among the deadliest form of the dreaded disease, responsible for 87,000 deaths annually. The risk factor for meat eaters is approximately twice that for vegetarians in the case of colon cancer and three times in the case of breast cancer. The mechanisms here are more complex. Meat may contain a number of carcinogenic substances, including arsenic and other heavy metals, various pesticides, growth hormones such as diethylstilbestrol (DES), cancer tissues and viruses, nitrites and nitrosamines, benzo(a)-pyrene, malonaldehyde, and methylcholanthrene. In addition, ingestion of meat and animal fat stimulates the secretion of large amounts of bile acids which are converted in the intestine to the carcinogenic deoxycholic acid. The higher incidence of breast cancer among meat-eating women is attributed to their earlier maturation and the increased release of the hormone prolactin.

Consumption of meat and animal fat is responsible for a number of other serious afflictions as well. Liver and kidney diseases frequently result from an excessive intake of protein. Deposition of uric acid from meat in the joints causes a painful crippling condition known as gout. The high phosphorus and protein content of meat depletes calcium from the bones promoting fractures and stooping in older people. Redeposition of the calcium in the soft tissues may lead to arthritis, skin wrinkling, and cataracts.

Finally, meat and animal fat contain a number of other toxic substances that may not necessarily produce clinical symptoms, but do contribute to a lowered resistance to stress and disease as well as to a vague feeling of malaise which the general population has grown to accept as the "normal" state of health. Among these substances are again heavy metals and pesticides, pathogenic organisms including trichinae larvae, and such metabolic waste products as lactic, phenolic, and uric acids, urea, adrenaline, and creatinine. Of the 200 diseases afflicting animals, approximately one half are transmissible to humans. Incidentally, meat inspection is of no value in reducing the disease hazards cited because of the lengthy examination required and the unavoidability of the harmful ingredients.

But the health benefits of a vegetarian diet go beyond a reduced risk of contracting a deadly disease and an increased life expectancy. They also encompass a slowing down of the aging process, freedom from the debilitating effects of chronic and other diseases, and a higher level of energy and physical endurance. This last effect is readily experienced after only a couple of weeks on a vegetarian diet and has been demonstrated in athletic events using human volunteers. It is little wonder then that vegetarians are said to die young... at a very advanced age.

Apologists for the meat interests are fond of claiming that there is no consensus on these issues among nutritional and health scientists. Nothing could be farther from the truth! During the past ten years, a half dozen expert panels have been convened to examine the available evidence (see box) and their findings all bear a striking resemblance to the key recommendations of the Report on Dietary Goals for the United States by Senator George McGovern's erstwhile Select Committee on Nutrition and Human Needs, i.e., to increase the consumption of fruit, vegetables, and whole grains and to decrease the consumption of meat and animal fat.

What's even more significant is that there is not a shred of evidence to suggest the opposite conclusion, i.e., to increase the consumption of meat and animal fat and to decrease the consumption of fruit, vegetables, and whole grains. Even the meat industry's fond description of meat as "such a neat nutrition package" has been pretty well exploded. Although its protein content ranks along with that of fish, cheese, peanuts, and soybeans, meat is totally devoid of carbohydrates which provide the body's principal source of energy, contains very little calcium required to build healthy bones, and its vitamin content is rather spotty.

What Can Be Done?

At this point, one may well ask the logical question: if meat is so bad for human health, how has it become the principal staple of the American diet? The answer goes to the very heart of what's wrong with the decision-making machinery of the federal government, where issues are decided less on the basis of their scientific merit than of their economic and political consequences.

Thus the record U.S. consumption of meat is largely a testimonial to our wasteful affluence, the resourcefulness of the meat industry, and the political allegiance of the U.S. Departments of Agriculture, Interior, and Treasury that have been virtually sustaining the industry through generous subsidies of grazing rights, technical know-how, administrative services, insurance and mortgage programs, special interest rates, tax writeoffs, price supports, and outright grants. Even as

we sit here, cattle growers all over America are going to the polls to approve the establishment of a USDA-sponsored Beef Board that will collect some $70 million in taxes on the sale of cattle to promote the consumption of more beef and to counter our desperate unfunded effort to alert the American people to the dangers of meat consumption.

Today, few politicians are willing to face up to the $35 billion meat industry and to the several million farmers who make their living from raising animals for food. The last one to make the attempt was Senator McGovern and the aftermath made his 1968 election battle against Richard Nixon seem like a Sunday picnic. When the dust finally settled, his Committee's original recommendation to decrease the consumption of meat had been scuttled and the Committee itself had been abolished.

This lesson was not lost on the framers of the Dietary Guidelines issued two weeks ago jointly by the U.S. Departments of Agriculture and of Health, Education and Welfare. Although the Guidelines bear a general resemblance to the McGovern Report, its ringing recommendations had been corrupted into such sterile phrases as "eat a variety of foods,""avoid too much fat," and "eat foods with adequate starch and fiber." Clearly, the Guidelines offer too little too late. Those individuals who are truly concerned with the effects of diet on their health will still have to review the available evidence and to form their own conclusions.

It is high time that the federal government renounce its partisan pro-industry stance, redress the injustices perpetrated against the consumer, and accept its responsibility to protect the public health. To those ends, we recommend that Congress require the USDA and other cognizant federal agencies:

- To cease all activities designed to promote the consumption of meat
- To balance the past activities by providing funds for educational programs by advocates of a meatless diet
- To provide a choice of meat alternatives in all their public and institutional feeding programs
- To require an indication of all components of animal origin on food labels
- To require labels on all meats and other animal products warning the consumer of any demonstrated health hazards that they may present.

What is Vegetarianism

Vegetarianism can mean as little as a dietary practice of abstaining from consumption of animal flesh (including poultry and fish) or as much as a comprehensive philosophy rooted in a loving relationship toward one's own body and all other forms of life. Perhaps 98 percent of all vegetarians, also known as lacto-ovo-vegetarians, partake of dairy products and eggs, whereas the remainder, referred to as vegans or total vegetarians, refrain from the use of all animal products.

Today, there are some 9-10 million vegetarians in the United States and another 40-50 million people who are "careful" about their meat consumption. What's even more remarkable is that nearly 80 percent of the population acknowledge the validity of one or more reason for being a vegetarian, even though they themselves have not made the commitment. The reasons for this unprecedented growth embrace a more sophisticated awareness of the intimate relationship between diet and health, a growing alarm at the rising price of meat, a renewed sensitivity to the enormous tragedy of world hunger, a greater concern for the quality of the environment, and a heightened compassion for the suffering of animals in factory farms.

What They Said About Consumption of Meat and Fat

- Editorial, Journal of the American Medical Association (3 June 1961)

  "A vegetarian diet can prevent 90 percent of our thromboembolic disease (stroke) and 97 percent of our coronary occlusions (heart attacks)."

- Report of the Inter-Society Commission for Heart Disease Resources (15 December 1970)

  Recommended more liberal use of grains, fruits, vegetables, and legumes, development of high quality vegetable protein products, and reduction of caloric intake from saturated fats.

- Joint Statement on Diet and Coronary Heart Disease by the National Academy of Sciences and the American Medical Association (July 1972)

  "It is important to decrease substantially the intake of saturated fat and to lower cholesterol consumption."

- Mark Hegsted, Administrator USDA Human Nutrition Center (14 January 1977)

  "The diet... rich in meat, other sources of saturated fat and cholesterol and in sugar is everywhere associated with high rates of ischemic heart disease, certain forms of cancer, diabetes, and obesity."

- Dietary Goals for the United States by the Senate Select Committee on Nutrition and Human Needs (February 1977)

  "Increase consumption of fruits and vegetables, and whole grains; decrease consumption of meat...; decrease consumption of fat"

- Survey of 214 of the World's Leading Specialists on Heart Disease by Kaare Norum (23 March 1977)

  99 percent were convinced that saturated fat and cholesterol contribute to heart disease.

- Healthy People by the U.S. Surgeon General (28 July 1979)

  "People should consume ... less saturated fat and cholesterol ... less red meat ... more complex carbohydrates such as whole grains, cereals, fruits, and vegetables."

- Arthur Upton, Director National Cancer Institute (2 October 1979)

  "Both breast cancer and colon cancer have been generally associated with the level of consumption of animal fat."

- William Connor, Chairman of Consensus Study, American Society for Clinical Nutrition (2 October 1979)

  "Meat should be used only as a condiment, rather than the main course."

- USDA-HEW Dietary Guidelines (4 February 1980)

  "Avoid too much fat, saturated fat, and cholesterol ... eat foods with adequate starch and fiber."

Note: saturated fat and cholesterol are found almost exclusively in meat and other animal products; these terms are used frequently as synonyms for "meat" in part to avoid upsetting the meat industry.

VEGETARIAN INFORMATION SERVICE, INC.
P.O. BOX 5888, WASHINGTON, D.C. 20014

NEWS RELEASE

FOR IMMEDIATE RELEASE CONTACT: Alex Hershaft, 301-530-1737

NEW DIETARY GUIDELINES OFFER TOO LITTLE TOO LATE

The Dietary Guidelines promulgated several days ago by the U.S. Departments of Agriculture and of Health Education and Welfare are welcome, but they offer too little too late and represent a classic bureaucratic compromise between the weight of scientific evidence and the economic demands of the food industry. The Guidelines are patterned closely on the 1977 Report on Dietary Goals for the United States published by the Senate Select Committee on Nutrition and Human Needs (the McGovern Committee) on the basis of extensive testimony by dozens of experts on the relationship of diet and disease. In fact, the first four of the seven Guidelines represent a restatement of the Report's principal recommendations that Americans eat less meat and more whole grains, vegetables, and fresh fruits.

However, the framers of the Guidelines were obviously mindful of the political might of the meat industry which forced the McGovern Committee to replace its recommendation "eat less meat" with the euphemism "eat less saturated fat." This ignored evidence which implicated both meat and saturated fat in the incidence of heart disease, cancer of the colon and breast, kidney disease, and bone disease, as well as the precursor conditions of obesity and high blood pressure. Accordingly, the Report's original ringing recommendations are paraphrased in the Guidelines by such vague admonitions as: "eat a variety of foods," avoid too much fat," and "eat foods with adequate starch and fiber."

The meaning of all this is that those individuals who are truly concerned with the effects of diet on their health will have to continue to review the available evidence and to form their own conclusions. In the meantime, however, the vast bulk of the population will continue to pursue a diet largely manipulated by the profit motive of the food industry and, consequently, to suffer the needless afflictions of general malaise, chronic diseases, and shorter lifespan.

The Vegetarian Information Service is a non-profit educational organization formed to enlighten the American public on the relative merits of a meatless diet. This work is funded entirely by contributions from private supporters.

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VEGETARIAN INFORMATION SERVICE, INC.
P.O. BOX 5888, WASHINGTON, D.C. 20014

DIET AND CANCER: EATING FOR LIFE

VEGETARIAN WORLD
Volume 2 Number 6

Alex Hershaft, Ph.D.

The role of meat eating in the incidence of several types of cancer has been a convincing argument in the dialog between vegetarians and their uninitiated peers. Yet, few vegetarians are fully aware of the scientific evidence for this important claim and even fewer can quote the references required to satisfy the skeptics. This article was designed to satisfy both these needs. Following a brief introduction to the nature and causes of cancer, it identifies the carcinogens found in meat and reviews the evidence for an association between meat eating and incidence of cancer of the colon and breast.

Cancer is the second largest killer in the U.S. (after heart disease), accounting for 675,000 new cases and 370,000 deaths annually. Some 25% of the people living in the U.S. today are expected to contract some form of cancer. (A.C.S., 1975). The resultant medical costs are estimated well into the tens of billions of dollars though additional damages associated with premature loss of services and emotional trauma are incalculable (U.S. P.H.S., 1975). Although much progress has been made in the early detection and treatment of cancer, the most effective solution appears to lie in its prevention.

Cancer is a generic term assigned to a large class of malignant diseases characterized by an uncontrolled growth in the number or size of cells. If unchecked, cancer cells metastasize (spread to other parts of the body), invade healthy tissues and rob them of vital nutrients, destroy the function of vital organs, and ultimately, cause death.

Induction (initiation) of cancer is generally attributed to chemical substances which attack and modify the growth-controlling DNA (deoxyribo-nucleic acid) molecule within the cell. These substances may be taken in through inhalation or ingestion, or may be formed within the body through various processes, such as digestion or irradiation. In fact, the World Health Organization and other authorities estimate that fully 60-90 per cent of all cancer cases are attributable to external factors over which we presumably have some control. (W.H.O., 1974).

The role of external factors in the incidence of cancer was first discovered in 1775 by Percival Potts who observed a relationship between exposure to soot and incidence of cancer of the scrotum. Since then, incidence of various forms of cancer has been associated with occupational exposure to a number of chemicals, including arsenic, asbestos, polychlorinated biphenyls, polyvinyl chloride, and various pesticides. Air pollution and smoking have been held accountable for cancer of the respiratory tract. And various components of our diet have been implicated in cancer of the gastrointestinal tract, as well as other vital organs.

During the past decade, there have been numerous attempts to characterize the role of diet in the incidence of cancer. Although much work remains, it appears that certain dietary components are definitely carcinogenic (capable of causing cancer), while the presence or absence of others can produce a predisposition to the induction of cancer or an acceleration of its development. In their search for the cause of the rising incidence of certain types of cancer, a number of investigators have turned to the consumption of meat and other animal protein which has been growing steadily since the 1930's. Current annual per capita consumption of red meats (beef, veal, lamb, and pork) in the U.S. is 190 lbs., among the highest in the world, and 70 per cent of protein is derived from animal sources (A.M.I., 1975; Gortner, 1975).

Carcinogens in meat may be introduced through animal feed or medication, or through the processing and preparation of meat. Those identified thus far are listed in Table 1, which specifies the source, the observed effects, and the documentary reference. Most of the indicated effects have been observed in laboratory animals or suspected through structural analogy with known carcinogens. Demonstration of large-scale effects on human populations requires the performance of massive epidemiological studies.

Examination of the relationship between a given dietary factor, such as ingestion of meat, and a specific effect, such as incidence of a particular form of cancer is performed with the aid of epidemiological studies, which compare incidence and mortality rates for similar populations with different dietary habits. The conclusions of these studies are frequently clouded by the long delay between the induction of cancer and its detection, the difficulty of characterizing diets over a long period of time, and the influence of cofactors. Cofactors, such as consumption of alcohol, coffee, and food additives, occur jointly with meat eating and may produce similar results.

For these reasons, epidemiological studies can only indicate an "association" between factor and effect that suggests a "causal" relationship. Such an association can be tested further by toxicological experiments or be rendered plausible by postulating a reasonable physiological mechanism. Toxicological experiments involve the deliberate administration of the suspected carcinogen to laboratory animals and observation of the resulting effect. A recently developed rapid test method for carcinogenicity, with an accuracy of 80 per cent, is based on observation of mutations induced by the suspected substance in a bacterial culture. This method circumvents ethical objections to animal experiments and, because of its low cost and time requirements, is much more suitable for screening of the large number of new substances introduced into our environment each year.

The most pronounced associations of meat eating have been found with incidence of cancer of the colon and breast. The former has the highest incidence of all forms of cancer in the U.S. (99,000 new cases per year) and the second highest mortality (49,000 deaths per year). The latter exhibits the highest incidence among women (89,000 new cases per year) and the highest mortality (33,000 deaths per year). (A.C.S., 1975).

The high correlation between per capita consumption of fat and animal protein and incidence of colon cancer was first disclosed ten years ago by two studies of 35,000 Seventh-Day Adventists, half of whom are vegetarians. These studies found that the Adventists' mortality rate from all forms of cancer, including cancer of the gastrointestinal tract was only 2/3 of that for the general population. (Lemon *et al.*, 1964; Lemon and Walden, 1966; Phillips, 1975).

These general findings were rapidly confirmed by an examination of dietary habits and health statistics of populations of 21 countries around the globe (Wynder and Shigematsu, 1967), a comparison of first and second generation Japanese immigrants to Hawaii (Wynder, 1969), a second examination of the populations of 37 countries (Drasar and Irving, 1973), and a number of other investigations (Haenszel and Kurikawa, 1968; Gregor *et al.*, 1969; Haenszel *et al.*, 1973; Wynder and Reddy, 1973; Wynder, 1975).

A complex physiological mechanism has been postulated to account for this relationship. It involves the formation of carcinogens in the colon through degradation by intestinal bacteria of bile acids and neutral steroids, secreted to aid in the digestion of fat and meat. Supportive evidence has been provided by several investigations of comparative compositions of feces from populations with high and low incidence of colon cancer (Gregor *et al.*, 1969; Hill *et al.*, 1971a; Reddy and Wynder, 1973; Reddy *et al.*, 1974). The increased transit time of a fiber-depleted diet, generally associated with the consumption of meat, provides additional opportunity for the formation and action of the carcinogens. (Burkitt, *et al.*, 1974; Payler, 1973).

The association between a high fat and meat diet and incidence of breast cancer was first pointed out in 1968 (Wynder, 1968) and has been since confirmed by the cited examination of the dietary habits and health statistics of the populations of 37 countries (Drasar and Irving, 1973). The proposed physiological mechanism here is the increased synthesis and activity of carcinogenic hormones in the adipose tissue of the breast and/or increased production of these hormones by the anaerobic bacteria in the colon (Hill *et al.*, 1971b).

Table 1 Carcinogens Associated With Consumption of Meat

Carcinogen	Source	Effects	References
Arsenic	Added to hog and poultry feed	Associated with cancer of the liver	Lander, 1975
Benzo(a)pyrene	Charcoal broiling of steaks	Produces stomach cancer and leukemia in laboratory animals; may be transmitted to fetus by pregnant mothers	Lijinsky and Shubik, 1964; Bulay and Wattenberg, 1970
Cancerous tissue	Meat containing cancerous growth which has been overlooked or inadequately excised	Suspected of carcinogenesis	Grace *et al.*, 1960
Diethylstilbestrol (DES) and other hormones	Administered to cattle to promote growth and regulate sexual activity	Produces renal cancer in laboratory mice; associated with vaginal cancer in women whose mothers had been treated with DES	Herbst and Scully, 1970; Herbst et al., 1975; Greenwald et al., 1973; Verrett and Carper, 1971
Leukemia virus	Meat from poultry and cattle harboring the virus	Suspected of causing human leukemia	Theilen *et al.*, 1968 Wolska, 1968
Malonaldehyde	Oxidation of polyunsaturated fatty acids	Produces cancer in laboratory animals	M.W.N., 16 June 1975
Methylcholanthrene	High temperature heating of animal fat	Predisposes laboratory animals to cancer; may be transmitted to fetus by pregnant mothers	Klase *et al.*, 1968 Neiman, 1968 Tomatis *et al.*, 1966
Nitrosamines	Reaction of sodium nitrite in cured meats with urea or amines produced by degradation of protein	Produces various types of cancer in laboratory animals; may be transmitted to fetus by pregnant mothers	Lijinsky *et al.*, 1972 Magee and Barnes, 1956 Mohr *et al.*, 1966
Pesticides	Ingestion and accumulation in animal tissues through consumption of contaminated forage and grains	Produce liver cancer in laboratory mice	U.S.D.H.E.W., 1969 Saffiotti, 1976

Conclusion

Although much progress has been made in characterizing the role of meat eating in the incidence of cancer, many mysteries remain, such as:

- Identity of other carcinogens in meat
- Specific effects of meat carcinogens
- Role of meat in causing predisposition to cancer or suppression of the immune response
- Time lag between conversion to a meat diet and induction of cancer.

In the meantime, vegetarians can relish the comforting thought that, in addition to its many other benefits, their diet also minimizes their likelihood of contracting the nation's most formidable forms of cancer.

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The VEGETARIAN INFORMATION SERVICE, INC. the tax-exempt organization is dedicated to public education on the merits of a vegetarian way of life in relieving suffering and violence, enhancing human health, alleviating world hunger, and improving environmental quality.

VIS relies on the financial support of charitable foundations, other institutions, and individuals who are in sympathy with its general objectives and programs. All contributors of $20 or more receive monthly mailings, reports on events, issues, laws, and agencies of vegetarian interest in the nation's capital, and foremost, the satisfaction of sharing in the effort to promote the vegetarian way of life.

VEGETARIAN INFORMATION SERVICE, INC.
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WASHINGTON REPORT
BY Alex Hershaft



HOW MANY VEGETARIANS?

The number of vegetarians in the U.S. has been growing rapidly in recent years as a result of the increased public awareness of the adverse impact of meat consumption on human health, cost of food, world hunger, environmental quality, and animal suffering. However, the question of just how many vegetarians there are at any given time has intrigued students of the subject both within and outside the vegetarian movement. Now, this question is being answered, to an extent, by two surveys undertaken by the Roper Organization of New York and the U.S. Department of Agriculture's Consumer and Food Economics Institute.

The Roper poll was conducted in October and November 1978 among a representative nationwide sample of 2000 adults for the McNeil-Lehrer Report, a public television interview show. The three questions on vegetarianism were part of a much larger survey dealing with a number of presumably unrelated topics to reduce cost. Results of the Roper poll are reproduced overleaf. Briefly, they indicate that there are nearly seven million vegetarians and another 37.5 million people who are careful about their meat consumption. However, much more important is the result of the last question indicating that fully 78 (100-10-12) percent of the total population acknowledges the merits of the health, economic, ethical, world hunger, or other reasons for being a vegetarian.

Even so, there are indications that these results may be unduly low. In the first place, the critical wording of the first question is loaded against a vegetarian response by implying that this is a rather extraordinary position to take. Moreover, the sample interviewed did not include people below the age of 18 who are traditionally more receptive to vegetarianism and represent nearly one-third of the U.S. population. Thus, a doubling of the percentage of vegetarians for the under-18 group to an eminently reasonable 6.3 percent would bring the total number of vegetarians to a total of over nine million. A similar extrapolation for the young "carefuls" would bring the total "careful" population to nearly 50 million.

The U.S.D.A. Nationwide Food Consumption Survey was conducted by the polling firm, National Analysts of Philadelphia in early 1978 among a nationwide sample of 15,000 households and additional samples of such special groups as the poor and the aged. The uncommonly comprehensive questionnaire contained hundreds of diet-related questions and took two hours to complete. The respondent was then requested to record in detail the dietary intake of each member of the household over a period of several days.

One of the questions asked was "Are you a vegetarian?" Those answering in the affirmative were then requested to indicate whether they ate poultry, fish, eggs, dairy products, fruits, nuts, dried beans or peas, vegetables, cereals or grain products, or vegetable-based meat substitutes. Although the specific question stopped here, the amount of pertinent information collected about each respondent can provide sufficient material for numerous studies of vegetarian eating habits. The bad news is that the results for this part of the survey will not be available until late this year.

The *Washington Report* provides a periodic update on events, laws, and institutions that affect vegetarian interests in the nation's capital. The *Report* is distributed without charge to vegetarian and kindred periodicals, active groups, and contributors to VIS. It may be reprinted in part or in its entirety by these groups and individuals, provided that full credit, including name and address, is given to both the author and VIS.

RESULTS OF THE ROPER POLL

Asked of total sample

48. Most people eat quite a lot of meat. But some people are vegetarians and don't believe in eating any meat. Would you describe yourself as a strict vegetarian, or pretty much a vegetarian, or one who eats meats but is careful about how much, or as one who eats meat quite often and regularly?

	%	# of adults	# of people
Strict vegetarian	0.55	825,000	1,210,000
Pretty much vegetarian	2.60	3,900,000	5,720,000
Careful	17.05	25,575,000	37,510,000
Often and regularly	78.15	117,225,000	171,930,000
Don't know	1.65	2,475,000	3,630,000

Asked of strict, pretty much and careful vegetarians

49. Which of these things do you avoid eating? (HAND RESPONDENT CARD)

	Total Sample	Strict and Pretty Much Vegetarians	Carefuls
a. Red meat	10%	100%	41%
b. Fowl	2%	30	8
c. Fish	2%	19	10
d. Eggs	3%	14	15
e. Dairy products	2%	3	9
Don't know	6%	0	38

Summary:	Total Sample	Strict and Pretty Much Vegetarians	Carefuls
Red meat	10%	100%	41%
Red meat & fowl	1%	30	2
Red meat, fowl and fish	1%	14	1
Red meat, fowl, fish and eggs	*	5	*
Red meat, fowl, fish, eggs and dairy products	*	0	*

* Less than 0.5%

Asked of total sample

50. Here are some of the reasons vegetarians have given for not eating meat. (HAND RESPONDENT CARD) Which of those reasons do you personally think are the best arguments for being a vegetarian?

	Total Sample	Strict and Pretty Much vegetarians	Carefuls
a. A vegetarian diet is better for your health	44%	56%	55%
b. A vegetarian diet is a lot more economical	22%	25	24
c. It's wrong to kill animals for food	12%	16	11
d. Grain will feed more of the world's population when it's eaten as grain than when it is used to feed livestock	9%	11	10
e. Other reasons	3%	14	5
None of those	10%	2	6
Don't know	12%	8	9

(values add up to more than 100% because more than one choice was permitted)

WEIGHT WATCHERS INTERNATIONAL, INC.
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EXECUTIVE OFFICES

STATEMENT OF DR. REVA T. FRANKLE, DIRECTOR OF NUTRITION, WEIGHT WATCHERS INTERNATIONAL, INC., BEFORE THE SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES, February 20, 1980.

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

It is an honor and privilege to appear before you to present the WEIGHT WATCHERS Program as it pertains to health and nutrition.

As a public health nutritionist, a nutrition educator and a registered dietitian, I am firmly convinced that nutrition is one of the most important factors in health promotion and disease prevention. And as nutrition is the cornerstone of the WEIGHT WATCHERS weight reduction and weight maintenance programs, how better to meet a number one public health problem, that of obesity, than to bring the WEIGHT WATCHERS Program to population groups.

Obesity is a hazard to health and a detriment to well-being. It is common enough to constitute one of the most important medical and public health problems of our time, whether we judge importance by shorter life expectancy, increased morbidity or cost to the community in terms of money and decreased productivity, as well as suffering to the overweight individual. Obesity is related to, or associated with the conditions of hypertension, diabetes, gout, heart size and function, menstrual and ovarian abnormalities, endometrial carcinoma, atherosclerosis, gallbladder disease and various psychological and social handicaps. Weight loss may reduce these risk factors as well as add to the individual's self-esteem.

Weight Watchers International operates in the United States and 26 foreign countries with about 16,000 classes per week reaching about 600,000 people weekly. There have been more than eleven million membership enrollments in WEIGHT WATCHERS classes since its inception. Our 5000 lecturers are trained to present our program which encompasses a three meal menu plan with sensible snacks, an exercise program and behavior modification.

STATEMENT OF DR. REVA T. FRANKLE, DIRECTOR OF NUTRITION, WEIGHT WATCHERS INTERNATIONAL, INC., BEFORE THE SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES, February 20, 1980.

There are many approaches to the treatment of obesity and overweight, but based on my thirty-five years' experience as a practicing dietitian and a nutritionist, the one most likely to meet the needs of most of the people, and the one most likely to work best for weight loss and the maintenance of the lost weight is a regimen with a four-pronged approach: 1) a nutritionally adequate meal plan with limited energy intake, 2) new eating management skills or behavior change, 3) increased physical activity, an exercise program, and 4) a support system. This is the WEIGHT WATCHERS Program.

The WEIGHT WATCHERS food plan well meets the seven dietary goals for the United States as prepared by the U.S. Senate Committee on Nutrition and Human Needs, December 1977. Our Program is designed to:

1. Address the problem of obesity.

2. About fifty percent of the energy intake is provided by complex carbohydrate and "naturally occurring sugars."

3. There is no refined sugar.

4. About thirty percent of the energy intake is provided by fat.

5. The distribution of fat is about 10% of the total energy intake for saturated fat, 10% for monounsaturated fat and 10% polyunsaturated fat.

6. Cholesterol consumption is limited.

7. The average sodium intake is about 5-8 grams of salt a day, depending upon individual choices.

We commend USDA and USHEW on their seven Dietary Goals released February 4, 1980. These, too, are reflected in the WEIGHT WATCHERS Program.

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A complete nutrient analysis of a typical seven day's food supply, which reflects a member's average weekly intake, appears in A RATIONALE APPROACH TO WEIGHT CONTROL, by Dr. W. H. Sebrell, Medical Director, Weight Watchers International, Inc. (attached). Over the years, the program has reflected changes based on new scientific data. The foods, which make up the basic WEIGHT WATCHERS food plan, are enriched whole grain breads and cereals; eggs; fats and oils; fruits and juices; low fat dairy products; poultry, lean meat, fish and legumes; and vegetables, providing adequate fiber intake. This plan provides about 1200 calories for women, 1500 calories for men and 1600 calories for youth. Rarely is a member hungry as the portion sizes are usually more than adequate. Key words, stressed in classroom sessions and printed materials, are VARIETY, MODERATION, AWARENESS.

Once a member has reached goal weight, other foods, avoided during the weight loss period, are introduced with instructions as to portion size and control. Members are advised that this is a critical time. The objective is to maintain the weight loss for life. Thus, the maintenance program is tailored to meet the individual needs of each person. Members may continue to attend classes free, once they have reached their goal weight and stay within two pounds of goal weight.

The Recommended Dietary Allowances are adequately, or more than adequately, met for almost all of the nutrients covered in 1974 RDA's of NRC. We are currently looking at the 1980 RDA's which introduce added nutrients. This enables us to keep the program scientifically up to date and thus, recommend it as a way of eating for one's entire life.

As education is a strong component of our program, a series of six pamphlets are available free as a public service. These are distributed nationally to any individual requesting them, to health departments, medical centers, WIC programs, professionals and many other agencies. A set of these are submitted with my testimony.

STATEMENT OF DR. REVA T. FRANKLE, DIRECTOR OF NUTRITION, WEIGHT WATCHERS INTERNATIONAL, INC., BEFORE THE SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES, February 20, 1980.

We believe the answer to weight control is the early establishment and long-term maintenance of properly controlled eating habits. Weight Watchers embraces the philosophy that it is easier to foster good food habits in children than to change food habits in later years. For this reason, as a public service, the "Child's Garden of Eating" has been developed for kindergarten or first grade, pilot-tested in 161 schools in 35 states and is now being used in communities across the country. This nutrition education kit consisting of nine parts was referred to by Congressman Fred Richmond in the November 8, 1979 Congressional Record. "This program exemplifies the best aspects of American education and of socially responsible American business. What I felt is particularly commendable about the 'Garden of Eating' is that it provides a clear guidepost to ways the private sector and public education can work cooperatively to strengthen the curriculum..."

In summary, obesity is a nutrition related disease requiring lifestyle changes. At a recent Obesity Conference, George Bray, M.D., Professor of Medicine, UCLA, reminded us that obesity is, largely, a result of lifestyle and that "...the task force predicted that leadership efforts to control obesity will pass from the medical field to nonmedical areas: business and industry, the communications media, the education system, government and volunteer agencies." Bray, G. Obesity in America, USHEW, November 1979.

The WEIGHT WATCHERS basic food plan for women, men and youth is a nutritionist's dream and would well be the basic plan for all Americans. Those who do not have a weight problem could have additional servings of other foods but we would know that their nutritional needs were being met.

VEGETARIAN INFORMATION SERVICE, INC.
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DIET AND CANCER: EATING FOR LIFE

VEGETARIAN WORLD
Volume 2 Number 6

Alex Hershaft, Ph.D.

The role of meat eating in the incidence of several types of cancer has been a convincing argument in the dialog between vegetarians and their uninitiated peers. Yet, few vegetarians are fully aware of the scientific evidence for this important claim and even fewer can quote the references required to satisfy the skeptics. This article was designed to satisfy both these needs. Following a brief introduction to the nature and causes of cancer, it identifies the carcinogens found in meat and reviews the evidence for an association between meat eating and incidence of cancer of the colon and breast.

Cancer is the second largest killer in the U.S. (after heart disease), accounting for 675,000 new cases and 370,000 deaths annually. Some 25% of the people living in the U.S. today are expected to contract some form of cancer. (A.C.S., 1975). The resultant medical costs are estimated well into the tens of billions of dollars though additional damages associated with premature loss of services and emotional trauma are incalculable (U.S. P.H.S., 1975). Although much progress has been made in the early detection and treatment of cancer, the most effective solution appears to lie in its prevention.

Cancer is a generic term assigned to a large class of malignant diseases characterized by an uncontrolled growth in the number or size of cells. If unchecked, cancer cells metastasize (spread to other parts of the body), invade healthy tissues and rob them of vital nutrients, destroy the function of vital organs, and ultimately, cause death.

Induction (initiation) of cancer is generally attributed to chemical substances which attack and modify the growth-controlling DNA (deoxyribo-nucleic acid) molecule within the cell. These substances may be taken in through inhalation or ingestion, or may be formed within the body through various processes, such as digestion or irradiation. In fact, the World Health Organization and other authorities estimate that fully 60-90 per cent of all cancer cases are attributable to external factors over which we presumably have some control. (W.H.O., 1974).

The role of external factors in the incidence of cancer was first discovered in 1775 by Percival Potts who observed a relationship between exposure to soot and incidence of cancer of the scrotum. Since then, incidence of various forms of cancer has been associated with occupational exposure to a number of chemicals, including arsenic, asbestos, polychlorinated biphenyls polyvinyl chloride, and various pesticides. Air pollution and smoking have been held accountable for cancer of the respiratory tract. And various components of our diet have been implicated in cancer of the gastrointestinal tract, as well as other vital organs.

During the past decade, there have been numerous attempts to characterize the role of diet in the incidence of cancer. Although much work remains, it appears that certain dietary components are definitely carcinogenic (capable of causing cancer), while the presence or absence of others can produce a predisposition to the induction of cancer or an acceleration of its development. In their search for the cause of the rising incidence of certain types of cancer, a number of investigators have turned to the consumption of meat and other animal protein which has been growing steadily since the 1930's. Current annual per capita consumption of red meats (beef, veal, lamb, and pork) in the U.S. is 190 lbs., among the highest in the world, and 70 per cent of protein is derived from animal sources (A.M.I., 1975; Gortner, 1975).

Carcinogens in meat may be introduced through animal feed or medication, or through the processing and preparation of meat. Those identified thus far are listed in Table 1, which specifies the source, the observed effects, and the documentary reference. Most of the indicated effects have been observed in laboratory animals or suspected through structural analogy with known carcinogens. Demonstration of large-scale effects on human populations requires the performance of massive epidemiological studies.

Examination of the relationship between a given dietary factor, such as ingestion of meat, and a specific effect, such as incidence of a particular form of cancer is performed with the aid of epidemiological studies, which compare incidence and mortality rates for similar populations with different dietary habits. The conclusions of these studies are frequently clouded by the long delay between the induction of cancer and its detection, the difficulty of characterizing diets over a long period of time, and the influence of cofactors. Cofactors, such as consumption of alcohol, coffee, and food additives, occur jointly with meat eating and may produce similar results.

For these reasons, epidemiological studies can only indicate an "association" between factor and effect that suggests a "causal" relationship. Such an association can be tested further by toxicological experiments or be rendered plausible by postulating a reasonable physiological mechanism. Toxicological experiments involve the deliberate administration of the suspected carcinogen to laboratory animals and observation of the resulting effect. A recently developed rapid test method for carcinogenicity, with an accuracy of 80 per cent, is based on observation of mutations induced by the suspected substance in a bacterial culture. This method circumvents ethical objections to animal experiments and, because of its low cost and time requirements, is much more suitable for screening of the large number of new substances introduced into our environment each year.

The most pronounced associations of meat eating have been found with incidence of cancer of the colon and breast. The former has the highest incidence of all forms of cancer in the U.S. (99,000 new cases per year) and the second highest mortality (49,000 deaths per year). The latter exhibits the highest incidence among women (89,000 new cases per year) and the highest mortality (33,000 deaths per year). (A.C.S., 1975).

The high correlation between per capita consumption of fat and animal protein and incidence of colon cancer was first disclosed ten years ago by two studies of 35,000 Seventh-Day Adventists, half of whom are vegetarians. These studies found that the Adventists' mortality rate from all forms of cancer, including cancer of the gastrointestinal tract was only 2/3 of that for the general population. (Lemon *et al.*, 1964; Lemon and Walden, 1966; Phillips, 1975).

These general findings were rapidly confirmed by an examination of dietary habits and health statistics of populations of 21 countries around the globe (Wynder and Shigematsu, 1967), a comparison of first and second generation Japanese immigrants to Hawaii (Wynder, 1969), a second examination of the populations of 37 countries (Drasar and Irving, 1973), and a number of other investigations (Haenszel and Kurikawa, 1968; Gregor *et al.*, 1969; Haenszel *et al.*, 1973; Wynder and Reddy, 1973; Wynder, 1975).

A complex physiological mechanism has been postulated to account for this relationship. It involves the formation of carcinogens in the colon through degradation by intestinal bacteria of bile acids and neutral steroids, secreted to aid in the digestion of fat and meat. Supportive evidence has been provided by several investigations of comparative compositions of feces from populations with high and low incidence of colon cancer (Gregor *et al.*, 1969; Hill *et al.*, 1971a; Reddy and Wynder, 1973; Reddy *et al.*, 1974). The increased transit time of a fiber-depleted diet, generally associated with the consumption of meat, provides additional opportunity for the formation and action of the carcinogens. (Burkitt, *et al.*, 1974; Payler, 1973).

The association between a high fat and meat diet and incidence of breast cancer was first pointed out in 1968 (Wynder, 1968) and has been since confirmed by the cited examination of the dietary habits and health statistics of the populations of 37 countries (Drasar and Irving, 1973). The proposed physiological mechanism here is the increased synthesis and activity of carcinogenic hormones in the adipose tissue of the breast and/or increased production of these hormones by the anaerobic bacteria in the colon (Hill *et al.*, 1971b).

Table 1 Carcinogens Associated With Consumption of Meat

Carcinogen	Source	Effects	References
Arsenic	Added to hog and poultry feed	Associated with cancer of the liver	Lander, 1975
Benzo(a)pyrene	Charcoal broiling of steaks	Produces stomach cancer and leukemia in laboratory animals; may be transmitted to fetus by pregnant mothers	Lijinsky and Shubik, 1964; Boyland and Wattenberg, 1970
Cancerous tissue	Meat containing cancerous growth which has been overlooked or inadequately excised	Suspected of carcinogenesis	Grace *et al.*, 1960
Diethylstilboestrol (DES) and other hormones	Administered to cattle to promote growth and regulate sexual activity	Produces renal cancer in laboratory mice; associated with vaginal cancer in women whose mothers had been treated with DES	Herbst and Scully, 1970; Herbst *et al.*, 1975; Greenwald *et al.*, 1973; Verrett and Carper, 1971
Leukemia virus	Meat from poultry and cattle harboring the virus	Suspected of causing human leukemia	Theilen *et al.*, 1968 Weiska, 1968
Malonaldehyde	Oxidation of polyunsaturated fatty acids	Produces cancer in laboratory animals	*M.W.N.*, 16 June 1975
Methylcholanthrene	High temperature heating of animal fat	Predisposes laboratory animals to cancer; may be transmitted to fetus by pregnant mothers	Klass *et al.*, 1968 Neiman, 1968 Tomatis *et al.*, 1966
Nitrosamines	Reaction of sodium nitrite in cured meats with urea or amines produced by degradation of protein	Produces various types of cancer in laboratory animals; may be transmitted to fetus by pregnant mothers	Lijinsky *et al.*, 1972 Magee and Barnes, 1956 Mohr *et al.*, 1966
Pesticides	Ingestion and accumulation in animal tissues through consumption of contaminated forage and grains	Produce liver cancer in laboratory mice	U.S.D.H.E.W., 1969 Saffiotti, 1976

Conclusion

Although much progress has been made in characterizing the role of meat eating in the incidence of cancer, many mysteries remain, such as:

- Identity of other carcinogens in meat
- Specific effects of meat carcinogens
- Role of meat in causing predisposition to cancer or suppression of the immune response
- Time lag between conversion to a meat diet and induction of cancer.

In the meantime, vegetarians can relish the comforting thought that, in addition to its many other benefits, their diet also minimizes their likelihood of contracting the nation's most formidable forms of cancer.

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A RATIONAL APPROACH TO WEIGHT CONTROL



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AND

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For many years, physicians have been aware of the great difficulty in controlling obesity. Efforts to control the condition by prescribing very low calorie diets have usually failed as the patients followed the diets only for a limited period of time and then returned to former habits of overeating with a resultant return of the excess fat.

The importance of psychological factors in controlling the obese patient's desire to eat has been appreciated only in recent years. The successful application of the techniques of behavior modification to the control of obesity constitutes a great step forward.

Success in controlling obesity should be evaluated not only on the basis of the loss of excess body fat, but also on the ability to maintain a normal body weight for a long period of time.

Newly developed programs for the control of obesity rely on four principal factors, all of which must be integrated and individualized to fit the particular case. These factors are psychological, dietetic, educational, and physical activity. (Table 1)

TABLE 1:
Principal Factors in Control of Obesity

- Psychological
- Dietetic
- Educational
- Physical Activity

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Psychological

The WEIGHT WATCHERS organization is unique in that for 15 years it has been using group interaction techniques to strengthen and maintain the motivation to lose excess body fat. Groups of overweight individuals are brought together under a trained leader for one to two hours for one or more sessions a week. Motivation is strengthened by rewards for achievement, group discussion of individual eating problems and how to meet them, education in correct eating habits and related subjects. In 1967, Dr. Richard B. Stuart published his important paper on the behavioral control of overeating.[1] This study resulted in 8 out of 10 patients losing large amounts of weight. Although there were no controls, the great loss of weight over a period of about a year is very impressive. This was accomplished on an outpatient basis with an interview 3 times a week for 4 to 5 weeks, then at 2 week intervals, then monthly sessions, and finally only as needed. The great contributions that Stuart made were in the nature of the interviews. These were designed to help the individual develop positive reinforcing responses to problem eating. A set of detailed instructions were given on how to overcome psychological difficulties and habits that lead to a desire to overeat. For example, how to avoid temptation, how to get help from the family, how to manage eating at home, and how to manage eating out.

Following Stuart's report, M. B. Harris[2] ran a controlled study based on behavior modification and also observed a significant weight loss in a group of overweight female college students.

Recent reviews of the results of the behavioral treatment of overeating conclude that it is the most effective available means of treating the mildly and moderately obese, Leon[3], Stuart[4]. Stunkard[5] has pointed out that the obese are

susceptible to social forces that affect the effectiveness of behavior modification programs. He[6] also has questioned the ability to maintain weight loss, but Stuart[7] has shown that the results of behavioral treatment are good when intervention is aimed at both curbing the urge to eat and directly modifying eating behavior, when treatment is extended to the achievement of goal weight, and adequate maintenance services are provided.

Stuart recently compiled his total approach in a book addressed to those who are having difficulties with weight control.[8] He has also published more data on the effectiveness of behavior modification[9] on members of WEIGHT WATCHERS classes. Data were collected from 721 members of WEIGHT WATCHERS classes about 15 months after reaching their goal weights. The group lost an average of 30.1 pounds in an average of 31 weeks (losing 19% of their body weight). After 15 months, only 28.9% were 11% or more above their goal weights. This is an extraordinary rate of success.

The failure of medical treatment for obesity before behavior modification was introduced is illustrated by the report of Christakis[10] who reported the experience of the Bureau of Nutrition in New York City Health Department in 1967. Over 21% of 2603 patients dropped out within two weeks and only 9.8% achieved goal weight.

Williams and Duncan[11] compared the results of obese patients treated in the Royal Adelaide Hospital in Australia with members of WEIGHT WATCHERS classes. They found the success rate in the WEIGHT WATCHERS classes was clearly superior to the hospital experience, although the hospital clinic offered individual therapy, anorectic drugs, diuretics, and inpatient treatment. In the clinic, only 1.6% of 241 women reached goal weight. In the WEIGHT WATCHERS classes 21.7% of 5446 women reached goal weight. The

clinic had 74% dropouts and WEIGHT WATCHERS 43%. The average weight loss in the WEIGHT WATCHERS classes was about double that in the clinic. They concluded that it is "highly questionable whether professional resources should be used at all in the routine treatment of obesity."

The fundamental basis for the improvement in the handling of obesity by behavior modification techniques is that it focuses on self-help by the individual in a group. Stuart[12] has defined the assets of a self-help group as shown in Table 2.

TABLE 2:

Assets of a Self-Help Group

1. Targets are defined as inappropriate behavior.
2. Developed a faith building morality.
3. Sufficiently informal to attain social objectives.
4. Leader serves as a role model.
5. Members can join and resign with ease.
6. Help members accept their problem as a normal reaction.
7. Payment of fees improves effectiveness of service.

The necessity for the obese individual to develop, strengthen, and maintain a strong motivation to lose weight cannot be overemphasized. Without success in this area, nothing can be accomplished. However, this is only the beginning. The diet is of equal importance and must be rigorously controlled by the individual in order to maintain the negative food energy balance which is essential.

Food Program

There are many factors to be considered in the design of a successful obesity control food program. The fallacy of the use of fasting as a method of treating obesity is well illustrated by a study by Johnson and Drenick.[13] They studied 207 morbidly obese patients. Half were fasted about 2

months, one-fourth less than 1 month, and one-fourth more than two months. Seventy-nine (38%) reduced to within 30% of their ideal body weight. The longer the patient was able to fast, the greater the weight loss. However, of the entire group, only 7 maintained reduced weight over the follow-up period and 50% reverted to their original admission weight within 2 to 3 years. In other words, in terms of maintaining their weight loss, the fasting program was a failure, and all groups regardless of the length of fast or extent of weight loss returned to their prefasting weights.

Many reducing diets fail to give attention to nutritional adequacy. They often are grossly distorted diets with high protein, no carbohydrate, or diets with periods of starvation.

If such diets create an energy deficit they, of course, cause weight loss. However, they fail in the important objective of changing the individual's behavior toward food. The weight lost is rapidly regained when the regime is discontinued

Restricted diets must be followed for long periods of time if morbidly obese individuals are to attain and maintain normal body weight. Therefore, attention should be given to every aspect of the diet's nutritional adequacy.

Some of the problems that may be encountered in such programs are well illustrated by the experience with a program which has been called protein-sparing modified fast. This type of program was popularized by a book entitled, "The Last Chance Diet," and has been widely used without proper medical supervision. It is based on a very low calorie intake and the use of a variety of liquid protein products of low nutritional quality derived from collagen or gelatin. Although this program results in a large weight loss, the general result has been disastrous. By April 1978, the U.S. Food and Drug Administration had reviewed reports of 58 deaths associated with very low-calorie protein diets.[14] The U.S. Center for Disease

Control[15] has found that 16 of these 58 deaths occurred in obese women, aged 23-51, after being on a liquid digested protein diet for 2 or more months. Eleven died suddenly while on the diet and two within two weeks after changing from the liquid diet to regular food. No underlying medical causes that could have caused death were detected and none had a previous history of heart disease or arrhythmias. The remaining deaths are still being investigated. A panel of expert consultants advisory to the U.S. Food and Drug Administration concluded that "very low calorie protein diets are not suitable for use in the absence of careful supervision by medical personnel trained in their use." Twelve of the deaths occurred in patients under medical supervision and 14 had been taking vitamin and mineral supplements.

It is undesirable to use any diet that is severely restricted in energy except under close medical supervision with nutrient and electrolyte supplementation as required. A moderate energy restriction not only makes the regime more acceptable, but also conserves nitrogen. A very restricted diet causes a greater proportionate loss of nitrogen. Since the objective is to lose the maximum amount of adipose tissue, with a minimum loss of nitrogen, the diet should be adequate in protein and only moderately restricted in energy. Furthermore, a severely restricted diet produces the symptoms of semi-starvation including lethargy, inattentiveness, decreased physical and mental activity and a decreased metabolic rate which tends to decrease the loss of adipose tissue.

The proper distribution of energy intake among protein, fat, and carbohydrate is also important. Diets should not be either unduly high or low in any of these nutrients.

In 1975, the Norwegian government was the first to announce a national nutrition food policy in a white paper by the Royal Norwegian Ministry

of Agriculture.[16], [17], [18] This comprehensive and important document relates nutritional problems to the food supply and proposes desirable changes, which take into account problems in food production, food marketing, and the economic impact.

Instead of recommending a decrease in energy intake from the present average 2900 Kcals/day, an increase in physical activity is recommended. It is also recommended that the fat intake be reduced to about 35% of the food energy with an increase in the proportion of polyunsaturated fatty acids and a decrease in saturated fatty acids. It is proposed to increase the consumption of high starch foods such as grains and potatoes and reduce the intake of refined sugar.

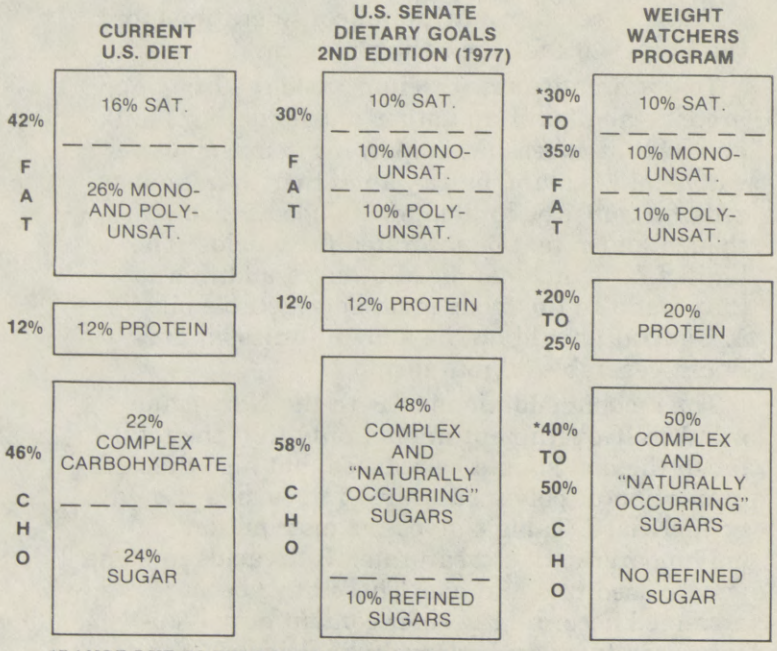
The Select Committee on Nutrition and Human Needs of the U.S. Senate recently published recommended dietary goals for the United States[19] This publication has led to a great deal of discussion and differences of opinion among professionals about the proposed changes. Many nutritionists feel that the present U.S. diet of about 42% of the energy from fat, 12% from protein, and 46% from carbohydrate, with 16% of the fat energy from saturated fatty acids, and 24% of the carbohydrate energy from refined sugars is responsible for many of our nutritional problems, with obesity the greatest and most important. The U.S. Senate Committee has proposed goals of 30% of energy from fat (only 10% saturated) and 58% of the energy from carbohydrate (only 10% from refined sugars). It is also recommended that the cholesterol intake be reduced to about 300 mgm/day and salt to about 5 grams per day. The attainment of these goals would make important changes in the food supply. It would mean a considerable reduction in the use of eggs, butter, beef, pork, and sugar, with skim milk replacing much of the whole milk.

The WEIGHT WATCHERS Program closely

approximates these goals with certain adaptations to fit the special needs of the obese individual. (Table 3)

The percent of energy from fat is 30-35% with only 10% from saturated fatty acids, as recommended by the Senate Committee. The carbohydrate is adjusted to about 40-50%, rather than 58%. The 10% refined sugar is omitted because of the difficulty in getting adequate amounts of all nutrients in the limited total energy intake. These adjustments of fat and carbohydrate require an intake of protein of 20-25% of the energy. This is desirable because of the nutrient value and acceptability in a program of limited total food energy.

TABLE 3:
U.S. Senate Committee Dietary Goals and Weight Watchers® Program



**RANGE DUE TO WIDE VARIETY OF FOOD ALLOWED*

Consideration also must be given to an adequate intake of all vitamins, minerals, and trace nutrients. The Weight Watchers eating plan is designed to produce a moderate weekly weight loss of ½ to 1 Kilogram average. It provides a proper and adequate intake of all vitamins, minerals, and trace nutrients. The accepted basis for nutritional adequacy in the United States is the Recommended Dietary Allowances of the National Research Councils' Food and Nutrition Board. These recommended allowances are designed to meet the nutritional needs of practically all normal individuals in the United States.[20]

The Weight Watchers diet program follows an acceptable meal pattern wherein adequacy is attained through proper food selection which can be adjusted within carefully prescribed guidelines to allow for individual ethnic habits and preferences, cost and availability.

These necessary nutritional considerations form the framework for the eating pattern.

To obtain adequate calcium, good quality protein, riboflavin and other nutrients, skim milk and low fat cheese are important items. However, whole milk, cream, butter, and other sources of milk fat, must be limited or excluded because of their high content of saturated fatty acids. The limited fat which can be allowed in addition to that found in the foods must be vegetable oils. Margarine should not be allowed unless it is a liquid vegetable oil margarine.

The recommendations of both the Norwegian and U.S. Government are not only that the total fat in the diet should be reduced, but also that the proportion of polyunsaturated fatty acids should be increased. Table 4 gives the distribution of polyunsaturated and saturated fatty acids in some widely used fats and oils. These have been arranged according to their content of polyunsaturated fatty acids (largely linoleic acid), and

shows the wide variation in ratio from safflower oil of about 8:1 to those with a high negative ratio. Olive oil is unique in that, although it has about a 1:1 ratio, it has the highest content of monounsaturated fatty acids (73%), and only about 12% of polyunsaturated fatty acids.

The fatty acid distribution in margarine varies according to the method of preparation. The fatty acid content of four different margarines is compared with butter in Table 5.

Cholesterol is another controversial nutrient. The goal recommended by the U.S. Senate is about 300 mgm/day. Since one egg yolk contains about 250 mgm of cholesterol, this means that to attain the goal, egg consumption by adults will have to be very greatly reduced. Many people habitually eat two or more eggs for breakfast containing somewhat more than 500 mgms of cholesterol.

Since cholesterol is an essential nutrient found only in animal products, restricting its intake means a great reduction in various kinds of meats, fish, shellfish, and dairy products. The older methods of analysis gave high figures for some

TABLE 4:
% Fatty Acids in Fats and Oils*

NAME	POLY-UNSAT.	MONO-UNSAT.	SAT.	P/S RATIO
SAFFLOWER OIL	76	14	10	8/1
SUNFLOWER OIL	70	19	11	6/1
SOY BEAN OIL	62	24	14	5/1
CORN OIL	57	29	14	4/1
COTTONSEED OIL	52	22	26	2/1
PEANUT OIL	30	49	21	1.5/1
OLIVE OIL	12	73	15	1/1
LARD	10	46	44	—
PALM OIL	7	36	57	—
TALLOW (BEEF)	4	45	51	—
BUTTER	3	30	67	—
COCONUT OIL	1	6	93	—

**ADAPTED FROM: FOOD, FATS AND OILS, INSTITUTE OF SHORTENING AND EDIBLE OILS, INC., WASHINGTON, D.C. (1974)*

shellfish because of the presence of other sterols, however, newer analyses have lowered these early estimates.

Tables 6 and 7 give the cholesterol content of selected fish, shellfish, and animal products so that those with the lowest amount of cholesterol can be selected, and those with a very high content avoided.

The visible fat must be trimmed from beef, lamb, and pork, which can be allowed only in limited amounts because of the high saturated fatty acid content of the fat. Meat should be cooked so that the fat is drained off.

A high intake of fish and seafood is desirable because of the good quality protein, relatively low calorie value, and fat that contains polyunsaturated fatty acids.

Eggs, although high in cholesterol, are good sources of iron and high quality protein, so that up to 4 eggs a week may be desirable.

Refined sugar must be strictly limited or eliminated because it adds energy without nutrients. It is very difficult to construct a limited calorie, nutritionally adequate diet which includes sugar.

TABLE 5:
Fatty Acid Content of Four Margarines and Butter*

NAME	% TOTAL FAT	GMS./100 GMS.		
		POLY-UNSAT.	MONO-UNSAT.	SAT.
MARGARINE (Hydrog. Soy Bean Oil, Hard)	80	14	47	15
MARGARINE (Corn Oil, Soft)	80	32	30	14
MARGARINE (Corn Oil, Hard)	80	23	39	14
MARGARINE (Safflower Oil, Soft)	82	48	16	13
BUTTER	80	3	23	50

**ADAPTED FROM: DIETARY GOALS FOR THE UNITED STATES (2ND EDITION), U.S. GOVERNMENT PRINTING OFFICE, WASHINGTON, D.C. (1977)*

All of the foregoing planning and calculation are still a long way from an acceptable meal pattern, which must be adjusted to individual habits and preferences.

A complete analysis of a typical seven day's food supply suitable for an obese woman is given in Table 8. The daily average is compared with the Recommended Daily Allowances of the National Research Council.

The seven day analysis allows for day to day variations and for the use of items that are not

TABLE 6:
Cholesterol Content of Selected Foods*

SEAFOOD	MG/100 GM	CHEESE	MG/100 GM	EGGS MILK PROD.	MG/100 GM
OYSTERS	50	COT. CHEESE	19	MILK NONFAT	2
CODFISH	50	RICOTTA	51	MILK WHOLE	14
TUNA (CAN)	65	NEUFCH.	76	ICE CREAM	57
HERRING	85	CAMEMB.	92	CUSTARD (BAKED)	105
CRAB	100	PARMESAN	95	CREAM (WHIP)	133
SALMON	120	MOZARELLA	97	BUTTER	250
SARDINES	140	SWISS	100	EGGS	504
SHRIMP	150	PROVOLONE	101	EGG YOLK	1480
CAVIAR	> 300	EDAM	102		

**CHOLESTEROL CONTENT OF FOODS, FEELEY, R.M. CRINER, P.E. AND WATT, B.K., JOUR. AM. DIETETIC ASSN. 61:134-149 (1972)*

TABLE 7:
Cholesterol Content of Selected Foods*

MEAT OR POULTRY	MGM/ 100 GM	ORGAN MEATS	MGM/ 100 GM
FRANKFURTER	62	HEART, CHICKEN	231
TURKEY BREAST	77	HEART, TURKEY	238
CHICKEN BREAST	80	HEART, BEEF	274
PORK, LEAN	88	LIVER, BEEF	438
BEEF, LEAN	91	THYMUS	466
RABBIT	91	LIVER, TURKEY	599
VEAL, LEAN	99	LIVER, CHICKEN	746
LAMB, LEAN	100	KIDNEY, LAMB	804
		BRAINS (RAW)	> 2000

**CHOLESTEROL CONTENT OF FOODS, FEELEY, R.M., CRINER, P.E. AND WATT, B.K., JOUR. AM. DIETETIC ASSN. 61:134-149 (1972)*

TABLE 8: Weight Watchers Program— Analysis of 7 Day Food Supply (Women)[1]

BREAD & CEREALS	Serv Size	Wt gm	Energy[2] Kcal	Prot gm	CHO gm	Fat gm	Sat F.A. gm	Mono UFA gm	PUFA gm	P/S Ratio	Chol mg	Ca mg	Phos mg	Zinc[4] mg	Fe[3] mg	Na mg	K mg	Mg mg	Vit A R.E.	Vit E I.U.	Thia min mg	Ribo flav mg	Nia cin mg	Vit[4] B6 mg	Fola cin[4] mcg	Vit B12 mcg	Vit C mg
Bread, White, Enrich.	3 sl	85.0	225.0	6.6	44.1	2.1	0.3	0.9	0.3			54	78	0.6	2.1	534	93	15.0		2.2	0.3	0.2	2.0	0.2		0.1	
Bread, Rye	2 sl	57.0	149.0	4.8	29.0	1.4	0.1	0.1	0.5			32.7	67	0.8	1.4	291	80.7	14.5		2.0	0.2	0.1	1.4	0.1			
Bread, Cracked Wheat	2 sl	57.0	152.0	4.6	29.4	2.0	0.4	0.9	0.4			12	74	2.1	0.6	280	70	20.0		2.1	0.1	0.1	0.8				
40% Bran Flakes	1 oz	28.0	70.0	2.9	22.0	0.5	0.1	0.1	0.3			14	125	1.0	5.0	141	139	59.0	250.4		0.4	0.4	4.8	0.5			15.0
Cornflakes	½ oz	14.0	55.0	1.1	12.1	0.5						2.5	6.5		0.2	127	17	2.5			o.1		0.3		6.0		
Oatmeal, Instant	1 oz	28.0	101.0	3.8	19.2	1.7	0.3	0.5	0.8			22	105	0.2	1.0	255				0.6	0.2	0.1	0.3	0.1	14.8		
Pumpernickel	1 sl	28.0	72.0	3.0	14.3	0.9	0.2	0.5	0.3			54	90	0.7	0.8	76	139	19.0		1.0	0.1	0.1	0.1	0.1	46.0		
Rice, Brown	½ c	84.0	96.0	2.1	20.7	0.5	0.1	0.3	0.2			4	67	0.8	0.8	1	55	24.0			0.1		1.2	0.1	13.0		
Roll, Enriched, Soft	1 oz	28.0	87.0	2.6	14.6	2.0	0.4	1.1	0.2			20	35	0.1	0.7	136	42	6.0	2.4	2.2	0.1	0.1	0.7	0.1			
Tortillas	2-6"	66.0	139.0	3.0	30.0	1.2	0.1	0.3	0.7			130	91		1.7	1	26	7.0	0.6	0.1	0.1		0.7				
Wheat Germ	½ oz	14.0	44.0	3.2	5.6	1.3	0.2	0.2	0.8			4	103	2.0	0.5		108	40.0		1.3	0.3	0.1	0.7	0.1	39.4		
EGGS																											
Eggs	4 med	176.0	278.0	21.3	2.1	19.7	6.0	7.2	2.3	.4/1	964	99	317	1.8	3.7	243	229	21.0	183.0	0.8	0.1	0.5	0.2	0.2	196.0	2.3	
FATS & OILS																											
Corn Oil	1 Tb+1t	18.0	161.0			18.2	2.3	4.5	10.6	4.6/1										3.2							
Marg., Liq. Corn Oil	2 Tb+2t	25.0	181.0	0.2	0.2	20.1	3.3	9.8	6.1	1.9/1		2	2	0.1		198	3		177.0								
Mayonnaise	3 Tb	42.0	307.0	0.4	0.5	33.7	4.9	8.1	19.0	3.9/1	20		7		0.1	210	5	1.0	13.8	31.7						0.1	
FRUITS & JUICES																											
Apple	1 med	50.0	87.0	0.3	22.2	1.0						10	15	0.1	0.4	1	165	12.0	27.0	0.4	0.1		0.1		8.0		6.0
Applesauce	½ c	125.0	51.0	0.2	13.5	0.2						5	6		0.6	2	97	6.0	10.0	0.3							1.0
Apricots	2 med	75.0	38.0	0.8	9.6	0.1						13	17		0.4	1	211	9.0	405.0	0.4			0.4	0.1			7.0
Banana	½ med	60.0	51.0	0.7	13.3	0.1						5	16	0.1	0.4	1	222	20.0	22.8	0.3			0.4	0.3	14.0		6.0
Blueberries	½ c	75.0	47.0	0.5	11.5	0.4						11	10		0.7	1	61	4.0	15.0			0.1	0.4	0.1	3.0		10.0
Cantaloupe	1 med	300.0	90.0	2.1	22.5	0.3						42	48	0.4	1.2	36	753	48.0	2040.0	0.4	0.2	0.1	1.8	0.3	60.0		99.0
Cherries, Red	½ c	74.0	43.0	0.9	10.5	0.2						16	14		0.3	1	141	10.0	147.2	0.1	0.1	0.1	0.3	0.1	6.0		7.0
Cranberries	1 c	100.0	46.0	0.4	10.8	0.7						14	10		0.5	2	82	8.0	8.0				0.1	0.1	2.0		11.0
Grapes	12 med	80.0	55.0	1.0	12.6	0.8						13	10		0.3	2	126	10.0	16.0	0.7	0.1		0.2	0.1	3.2		3.0
Grapefruit Juice	½ c	125.0	51.0	0.6	12.2	0.1						10	17	0.1	0.5	1	202	11.0	2.6	0.2	0.1		0.2		26.0		42.0
Orange	2 sm	242.0	119.0	2.4	29.5	0.5						99	48	0.4	1.0	2	484	27.0	96.8	0.7	0.3	0.1	1.0	0.2	60.0		121.0
Orange Juice	½ c	125.0	56.0	0.9	13.4	0.1						11	20	0.1	0.1	1	232	12.0	50.0		0.2		0.4	0.1	132.0		56.0
Peach	2 med	200.0	76.0	1.2	19.4	0.2						18	38	0.4	1.0	2	404	20.0	532.0	1.2	0.1	0.1	2.0		16.0		14.0
Pear	1 sm	100.0	61.0	0.7	15.3	0.4						8	11		0.3	2	130	7.0	4.0	0.6		0.1	0.1		9.0		4.0
Plums	2 med	100.0	75.0	0.8	19.7	0.2						12	18		0.5	1	170	9.0	60.0				0.5	0.1	12.0		4.0
Prunes	3 large	30.0	76.0	0.6	20.2	0.2						15	24		1.2	2	208	12.0	96.0			0.1	0.5	0.1	16.0		1.0
Strawberries	1 c	150.0	56.0	1.0	12.6	0.8						31	31	0.1	1.5	1	246	18.0	18.0	0.4	0.1	0.1	0.9	0.1	16.0		88.0
Tangerine	1 large	135.0	62.0	1.1	15.7	0.3						54	24		0.5	3	170	15.0	113.4	0.4	0.1		0.1	0.1	21.0		42.0
Tomato Juice	2 c	486.0	92.0	4.4	20.9	0.5						34	88	0.2	4.4	973	1104	49.0	778.2	0.6	0.3	0.2	3.9	0.9	127.4		78.0
MILK PRODUCTS																											
Skim Milk	7 c	1714.0	600.0	58.3	82.3	3.4	1.7				34.3	2108	1731	8.8		891	2845	188.2	699.0		0.7	2.4	1.7	0.7	91.0	6.5	17.1
Yogurt, Plain	2 c	493.0	310.0	26.2	34.4	7.8	5.0	2.0			30.0	902	710	2.8	0.4	344	114	84.0	65.2	0.1	0.2	1.0	0.4	0.3	34.0	2.9	4.0
Buttermilk	2¼ c	551.0	223.0	18.2	26.4	4.9	3.3	1.1			26.0	639	490		0.6	578	832	61.0	36.3	0.1	0.2	0.8	0.6	0.2		1.2	6.0
Swiss Cheese	1 oz	28.0	107.0	8.1	1.0	7.8	5.1	1.7	0.3	1/1	26.0	273	172	1.1	0.1	74	32	10.0	48.0	0.2		0.1			2.0	4.8	
American Cheese	2 oz	57.0	228.0	14.0	0.8	18.8	12.0	4.4	0.6	1/1	60.0	410	290	1.7	0.4	352	56	16.0	120.4	0.3		0.2		0.1	4.0	0.5	
Limburger Cheese	1 oz	28.0	93.0	5.7	0.1	7.8	4.8	2.0	0.1	1/1	26.0	141	112	0.6		227	36	6.0	72.8	0.2		0.2	0.1		16.0	0.3	

Footnotes:

1 Data from USDA Handbooks 8, 72, & 456, Dietary Information Foundation Extended Tables of Nutrient Values and Other Sources.

2 Kcals are computer derived and more accurate than approximate values of 4 Kcals per gm of protein and CHO and 9 Kcals per gm of fat.

3 100% RDA cannot be met by usual foods without supplementation.

4 Values less than 100% RDA because analytical data not available for many foods. Total probably closer to RDA.

TABLE 8-*continued*

POULTRY, FISH, MEAT & LEGUMES	Serv Size	Wt gm	Energy[1] Kcal	Prot gm	CHO gm	Fat gm	Sat F.A. gm	Mono UFA gm	PUFA gm	P/S Ratio	Chol mg	Ca mg	Phos mg	Zinc[1] mg	Fe[1] mg	Na mg	K mg	Mg mg	Vit A R.E.	Vit E I.U.	Thia min mg	Ribo flav mg	Nia cin mg	Vit[4] B6 mg	Fola cin[4] mcg	Vit B12 mcg	Vit C mg
Beans, White	8 oz	227.0	166.0	17.6	48.0	1.4						113	334	2.3	6.1	15.6	940	84.0			0.4	0.2	1.6				
Beef, Chopped, Lean	4 oz	113.0	248.0	31.1		12.8	5.4	4.6	0.7	.1/1	91.0	14	261	4.0	4.0	54.0	633	28.0	4.6	0.1	0.1	0.3	6.8	0.3	5.3	1.0	
Chicken, Broiled	4 oz	113.0	154.0	27.0		4.3	1.2	1.7	0.7	6/1	99.0	10	223	4.5	4.0	75.0	310	30.0	20.5	0.1	0.1	0.2	10.0	0.4	4.0	1.0	
Chicken Liver	4 oz	113.0	189.0	28.9	4.3	5.4	1.8	1.6	2.1	1.2/1	815.0	18	347	3.4	11.6	103.0	253	26.0	3553.8	1.5	0.2	3.3	13.5	0.6	320.0	18.4	12.0
Herring, Canned[5]	3 oz	85.0	131.0	13.4	3.1	7.4	1.3	4.4	0.6	5/1	78.0		206	0.8	1.4						0.1	0.1	3.0	0.1	0.1		
Lentils	6 oz	170.0	182.0	13.3	32.1	0.5	0.2	0.2	0.3			43	202	1.7	3.6	15.0	424	43.0	6.4		0.2	0.1	0.9	0.2			
Mackerel, Raw	5 oz	142.0	234.0	26.9		14.0	3.5	5.2	3.5	1.0/1	133.0	7.1	339	1.0	1.6			40.0	127.0		0.2	0.5	11.6	0.8			
Pork Chops	4 oz	113.0	288.0	33.3		16.1	5.4	6.7	1.7	.3/1	67.0	15	352	4.5	4.3	74.0	442	33.0		0.1	1.3	0.4	7.7	0.3	6.7	0.4	
Salmon, Canned[5]	4 oz	113.0	207.0	18.0		14.9	3.6	6.4	3.0	.8/1	40.0	142	267	1.0	0.9		337	30.5	42.2		0.1	0.1	6.8			27.0	
Sardines, Canned[5]	4 oz	113.0	225.0	27.0		13.0	3.0	6.4	2.0	7/1	165.0	496	564	1.2	3.4	932.0	668	48.0	48.0			0.2	6.1	0.2	18.0	4.0	
Tuna, Canned in Oil[5]	3 oz	85.0	168.0	24.5		6.9	1.1	1.6	3.9	3.6/1	55.5	7	199	0.9	1.6		204	21.0	13.5	0.9	0.1	0.1	10.1	0.4	15.0	1.9	
Veal	4 oz	113.0	265.0	29.9		15.0	7.0	6.7	0.5	1/1	119.0	12.5	254	4.5	3.6	74.0		21.6			0.1	0.3	6.1	0.6	4.0	4.0	
VEGETABLES																											
Acorn Squash, Cooked	8 oz	227.0	143	4.1	35.0	0.9						64	109	0.6	1.8	22	1047	38.0	1907.0	6.0	0.1	0.3	1.6	0.1			29.0
Artichoke, Raw	4 oz	113.0	46	2.6	17.0	0.1						48	60	0.4	1.5				2.5				0.2				8.0
Asparagus, Canned	4 sp	80.0	17	1.9	2.7	0.3						15	42	0.8	1.5	189	133	11.0	128.0	2.4	0.1	0.1	0.6	0.1	30.0		12.0
Beans, Green, Frozen	½ c	62.0	16	1.0	3.4	0.1						31	23	2	0.4	2	94	9.0	67.4	0.1		0.1	0.2		20.0		6.0
Beets, Canned	4 oz	113.0	42	1.2	9.9	0.1						21	20	0.4	8	267	188	16.8	4.6				0.1	0.1	52.0		3.5
Brussels Sprouts	4 oz	113.0	41	4.7	7.4	0.4						36	81	0.4	1.2	11	309	24.0	118.0	0.9	0.1	0.2	0.8	0.1	24.0		99.0
Cabbage, Red, Raw	½ c	45.0	19	1.4	4.2	0.1						32	27	0.2	0.7	2	120	11.0	3.6		0.1		0.3	0.1	17.0		38.0
Cabbage, Wh., Cooked	½ c	85.0	15	0.9	3.4	0.2						36	14	0.3	0.3	11	129	11.0	20.4				0.1	0.1	9.0		20.0
Carrots, Cooked	1 c	155.0	48	1.4	11.0	0.3						51	48	0.5	0.9	51	345	29.0	3259.2	0.4	0.1	0.1	0.8	0.1	24.0		9.0
Celery, Raw	¼ c	30.0	5	0.3	1.2							12	8		0.1	38	102	7.0	14.4	0.2			0.1		3.0		3.0
Corn, Creamed	½ c	128.0	105	2.7	25.6	0.8	0.1	0.1	0.4	4.0/1		4	72	0.5	0.8	302	124	24.0	34.6	4.0		0.1	1.3	0.3			6.0
Cucumber, Raw	¼ med	28.0	4	0.3	1.0							7	8		0.3	2	45	2.0	14.0				0.1		20.0		3.0
Dill Pickles	2 med	130.0	14	0.9	2.9	0.3						34	27	0.4	1.3	1856	260	16.0	26.0	0.1							8.0
Green Pepper, Raw	½ med	37.5	8	0.4	1.8	0.1						3	8		0.3	5	80	7.0	31.6				0.2	0.1	10.0		48.0
Irish Potato, Baked	3 oz	85.0	79	2.2	18.0	0.1						8	55	0.2	0.6	3	429	25.0			0.1		1.4	0.1			17.0
Lettuce, Raw	3 c	228.0	30	2.0	6.6	0.2						45	50	0.8	1.1	20	398	25.0	150.0	0.8	0.1	0.1	0.7	0.1	148.0		14.0
Onions, Fresh, Raw	4 oz	113.0	43	1.7	9.9	0.1						31	41	0.4	0.6	11	178	14.0	9.0	0.3		0.1	0.2	0.2	28.0		11.0
Romaine, Raw	2 c	110.0	20	1.4	4.0	0.4						78	28		1.6	10	300	12.0	220.4	0.4	0.1	0.1	0.4		358.0		10.0
Spinach, Frozen	1 c	180.0	41	5.4	6.5	0.5						167	68	1.3	4.0	90	583	117.0	2916.0	3.4	0.1	0.3	0.9	0.3	91.0		50.0
Tomato, Raw	½ med	62.0	14	0.7	2.9	0.1						8	17	0.1	0.3	2	150	9.0	110.6	2			0.4	0.1	20.0		14.0
BEVERAGES																											
Coffee, No Sugar	1 c		54									75	160		2.4	30.3	1367	191					0.3	13.0			
Cocoa, No Sugar	2 Tb+1t		28	2.3	6.8	1.6						18	86		1.4			53						0.1	0.2			
TOTAL			8199	541.1	962.9	281.8	84.2	91.5	63	.8/1	2848.8	7045.8	9736	64.4	105.9	10941	20721	1958.1	18964	76.7	8.7	14.7	137.1	11.3	2220.9	76.3	1062.6
Per Day			1171	77.3	137.5	40.3	12	13	9	.8/1	407	1006.5	1390.9	9.2	15.1	1563	2960	280	2709	11	1.3	2.1	19.6	1.6	317.3	10.9	151.8
RDA			2000	46								800	800	15	18			300	800	12	1.0	1.2	13	2	400	3	45
% of RDA			59	168								126	174	62	84			93	339	92	130	175	151	80	79	363	337
% of Calories				25	45	30																					

Footnotes:

1 Data from USDA Handbooks 8, 72, & 456, Dietary Information Foundation Extended Tables of Nutrient Values and Other Sources.

2 Kcals are computer derived and more accurate than approximate values of 4 Kcals per gm of protein and CHO and 9 Kcals per gm of fat.

3 100% RDA cannot be met by usual foods without supplementation.

4 Values less than 100% RDA because analytical data not available for many foods. Total probably closer to RDA.

5 Drained solids.

6 In tomato sauce, drained solids.

required every day. A selected one day meal pattern based on this food supply is shown in Table 9.

Education

The third important factor in the control of obesity is the *education of the patient* in correct eating habits. But what are "correct" eating habits? Very often the physician has not had enough training in nutrition to be able to provide the patient with accurate information on the nutrient composition of foods, nor to put foods together in combinations that will give a desirable distribution of food

TABLE 9:
Sample 1 Day Menu (Women)

Morning Meal

½ Cup Orange Juice
1 Slice Pumpernickel
1 Tsp. Liq. Veg. Oil Margarine
28 gm 40% Bran Flakes
1 Cup Skim Milk

Midday Meal

85 gm Herring, drained
1 Slice Cracked Wheat Bread
½ medium Tomato
½ medium Cucumber
1 Tsp. Vegetable Oil
1 Cup Spinach
1 medium Apple

Evening Meal

113 gm Veal, broiled
113 gm Acorn Squash
1 Tsp. Liq. Veg. Oil Margarine
½ Cup Cabbage, cooked
½ Cup Green Beans, cooked
2 medium Plums

Snack

½ Cup Plain Yogurt

energy between protein, fat, and carbohydrate. Because of the lack of knowledge about nutrition by physicians in the United States, a considerable effort is being made to improve nutrition education in our medical schools.

Dr. Reva T. Frankle[21] has compiled a curriculum plan which provides a valuable guide for establishing a medical school program for professional education in nutrition.

Dr. Frankle's model provides teaching-learning units for the first, second, and third academic periods of undergraduate medical education, each building upon the other. The first academic period is the science of nutrition in basic science with a clinical correlation which is an introduction to problem solving techniques of patient care.(Table 10)

Learning how to eat properly is of the utmost importance to the obese individual. Unless the individual is taught what foods to select and the amounts to be eaten, there is little hope of maintaining good health and a normal body weight. This involves menu planning, portion control, and exact information about the nutrient value of food available in the market. An individual cannot just be told to eat 50 gms of

TABLE 10:
Dr. Frankle's Model:
Medical Education in Nutrition

1ST ACAD. PERIOD	2ND ACAD. PERIOD	3RD ACAD. PERIOD
OBJECTIVE Nutrition in Basic Science Problem Solving in Patient Care	**OBJECTIVE** Community Problems	**OBJECTIVE** Nutrition in Clinical Practice
SUBJECTS Specific Nutrients Body Composition Food Requirements Metabolism	**SUBJECTS** Family Sociology Econ. of Family Food Maternal, Child Health Community Food Program	**SUBJECTS** Pediatrics, Obstetrics Medicine, Neurology, Surgery, Psychiatry

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cheese a day. The difference between high fat and low fat cheeses, and how much of which varieties to eat must be explained. Meat must be specified as to kind, quantity, and frequency because of varying fat content. Cooking procedures are often a source of extra calories. For example, patients should be taught cooking methods that drain the fat from meats. It is details of this kind that make the difference between success and failure. It is difficult in the beginning, but as new habits are established with foods that the individual likes, in combinations that make satisfying meals, they learn to apply what they have been taught to their food purchases, and to eat only the quantities allowed. Nutrition education and reeducation must be continued as a necessary adjunct to continued motivation. Food diaries reinforce the above suggestions.

It is best to confine nutrition educational efforts to teaching *what foods to eat,* and *in what quantities,* as the Weight Watchers member is taught, stressing the fact that ordinary foods in the proper mixture and proper amounts make special dietary or nutritional supplements unnecessary for the normal healthy individual.

Physical Activity

There are many studies which indicate the great importance of physical activity in obesity and much obesity in young people may be due more to reduced activity than to overeating.[22], [23], [24], [25]

Although reduced activity may be a contributory factor to obesity because of decreased energy expenditure, it cannot be the major cause of obesity.[26]

The energy expenditure from various forms of physical activity has been carefully measured and interpreted in terms of food and the possible effect on obesity. The chemical composition of subcutaneous adipose tissue from 55 obese subjects

was calculated by Garrow[27] to have a weighted mean of 13.6% water, 83.2% fat, and 2.3% protein. On this basis, the Kcal value of 1 kg of adipose tissue is approximately 7488 Kcal (31329 kJ).

Gwinup[28] found that obese women lost a substantial amount of weight on a program of walking without deliberately restricting the diet. However, the walking had to exceed 30 minutes daily over a year or more, and of the 34 subjects who started, only 11 women completed the study.

Stuart[29] has reviewed the use of exercise in the management of obesity. He concludes that the inclusion of an exercise prescription increases the likelihood that nutritional management will succeed, and also offers physiological, psychological, and social advantages.

The approximate energy expenditure from various activities by a man, together with the food equivalent, is given in Table 11.

When looked at in this light, it seems that the relatively small amount of fat lost by exercise is not worthwhile. This is not the case. One can say that it is necessary to ride a bicycle 22 hours

TABLE 11:
Energy Expenditure and Food Equivalents for Activity (70 KG Male)

ACTIVITY	KCAL/MIN.	TIME MIN.	TOTAL KCAL (KJ)	SERVING SIZE
LIGHT: Walking or Golf	3.3	60	200 (840)	1 Baked Apple **or** 1 Tortoni **or** 1 Spumoni **or** 200 Ml Table Wine
MEDIUM: Cycling, Dancing or Tennis	6.0	60	300 (1260)	1 Serv. Onion Soup (Au Gratin) **or** 200 gms Fried Rice **or** 1 Baked Potato **or** 1 Cup Yogurt (Fruit Flavored) **or** 1 Eclair **or** 90 Ml Brandy, Vodka, Gin or Whiskey
HEAVY: Football or Swimming	10.0	30	300 (1260)	

without stopping. Bicycling one hour a day for 22 days will use the same amount of energy, and will be much more pleasant. In the course of a year, this would add up to a loss of more than 16 kgs of adipose tissue. People forget that their excess body fat was accumulated in just this way—that is, by a few extra Kcals each day, often over several years. This is the best way to lose it. Exercise should be done under medical supervision in order to avoid exceeding the patient's capacity.

There are several parameters to be considered in measuring the effectiveness of any obesity control program. The first of these is whether the program is one which the obese individual will follow until the body weight approximates the desirable weight. Another, is whether the individual is emotionally comfortable, stable, and satisfied with the result. Another, is how long ideal weight is maintained. It often happens that the individual gives up the program before attaining ideal weight for one of many reasons. However, many return later, and after one or more failures, suceed in controlling their body weight.

Medical and Surgical Treatment

The use of drugs in handling obesity has been very controversial among physicians. The types of drugs that have been used are 1) appetite depressants, 2) diuretics, 3) thyroid preparations, 4) cardiac stimulants, and 5) hormone preparations.

None of these are completely satisfactory in the long term handling of obesity. The appetite depressants frequently have undesirable side effects and lose their effectiveness in a short time. The diuretics cause loss of water, not fat. Therefore, they may have psychological benefit because of the rapid weight loss, but this soon

ceases, and no fat has been lost. Since there is usually normal thyroid function in the obese, the use of thyroid preparations and cardiac stimulants is undesirable and may produce serious side effects such as tachycardia or other cardiac arrhythmias. Hormone preparations, such as chorionic gonadotropin hormone, have been shown to be worthless.

Therefore, the best that can be said for medication is that it may be temporarily useful in strengthening and sustaining the individual's motivation. It may have deleterious side effects, and successful treatment still must rest on psychological self-help and the provision of a satisfactory food regime.

About 20 years ago, the surgeons introduced an operation on the intestine for obesity which has been widely used in the United States and Great Britain. The operation consists in tying off a segment of the small intestine so that the intestine available for digestion is considerably shortened. The operation is therefore called the intestinal bypass. The surgical procedure has changed over the years and several operations are in use that differ in the location and the length of the intestine that is bypassed.

The operation has resulted in a number of complications and deaths. Mortality has been reported to vary from 0 to 10% in the United States[30] and to be about 5% in Britain.[31]

In addition to the mortality, many complications have been reported[32], [33], [34] as a result of the operation. The more common and important ones are given in Table 12. The frequency of these complications varies widely among different case series and their causes are not well understood.

Because of these complications, patients must be carefully selected for the operation. Since, in most cases there is a large loss of weight as a result of the decreased food intake following the operation, and all other methods of weight reduction have failed, there are some patients in whom the

chances of benefit may outweigh the surgical risks. Some of the indications and contraindications for the operation are given in Tables 13 and 14.

Many obese individuals have complicating diseases such as diabetes, coronary artery disease, hypertension, arthritis, and other conditions which require medical supervision and treatment.

The preferred method for handling obesity is a team approach led by a physician who treats any complicating disease and decides that weight loss is indicated. He then calls on a paraprofessional group trained in handling obesity to take care of the problems of diet and menu detail, and behavior modification, until the patient attains the desired weight and learns weight maintenance. The patient remains under the care of the physician for continued observation and treatment of any complicating disease, should it be present.

The paraprofessional, in this case, Weight Watchers, never prescribes therapy of any kind. If supplements such as additional iron or other nutrients, or medication are considered to be necessary, these should be prescribed by the physician.

It is doubtful that there is any one individual anywhere who can successfully handle all of the complex factors required to control obesity.

TABLE 12:
Complications of Intestinal Bypass Surgery

VOMITING	HYPOALBUMINEMIA
DIARRHEA (STEATORRHEA)	ANEMIA (VITAMIN B_{12})
HEMORRHOIDS	HEPATIC DISFUNCTION
G.I. HEMORRHAGE	LIVER CIRRHOSIS
CHOLECYSTITIS	RENAL CALCULI
CHOLELITHIASIS	POLYARTHRITIS
INTEST. OBSTRUCTION	PULMONARY EMBOLISM
HYPOCALCEMIA	WOUND INFECTIONS
HYPOKALEMIA	HAIR LOSS
HYPOMAGNESEMIA	MAJOR EMOTIONAL UPSETS

TABLE 13:
Major Indications for Intestinal Bypass

1. Morbid Obesity (45 kg over ideal wt.)
2. Conventional Treatment Has Failed
3. Congestive Heart Failure
4. Respiratory Insufficiency
5. Poorly Controlled Diabetes
6. Ventral Hernia

TABLE 14:
Major Contraindications for Intestinal Bypass

1. **Alcoholism**
2. **Liver Disease**
3. **Renal Failure**
4. **Cushings Syndrome**
5. **Hypothyroidism**
6. **Recurrent Pul. Embolism**
7. **Psychiatric Conditions**
8. **Inability to Follow Post Operative Care**

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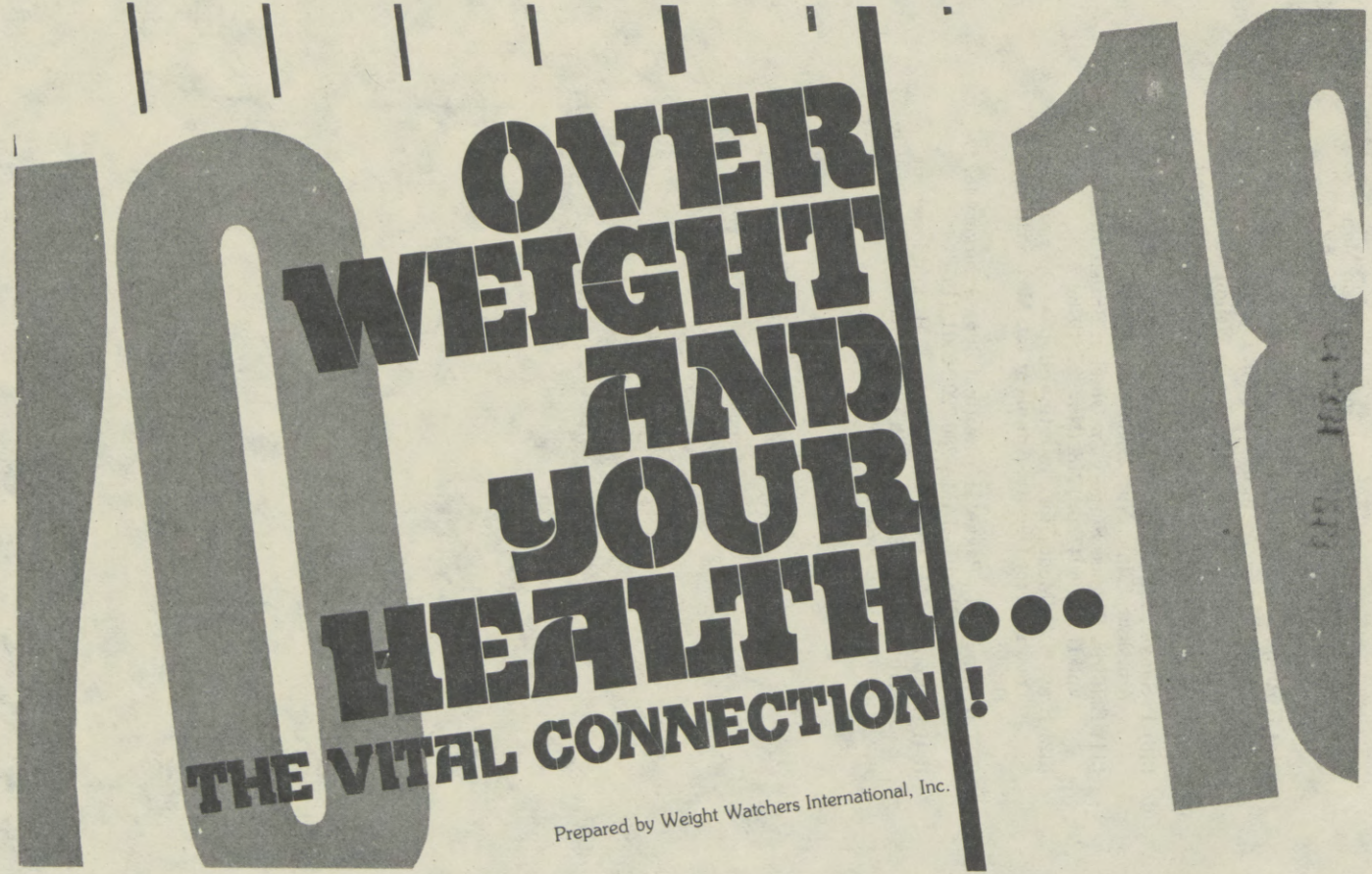
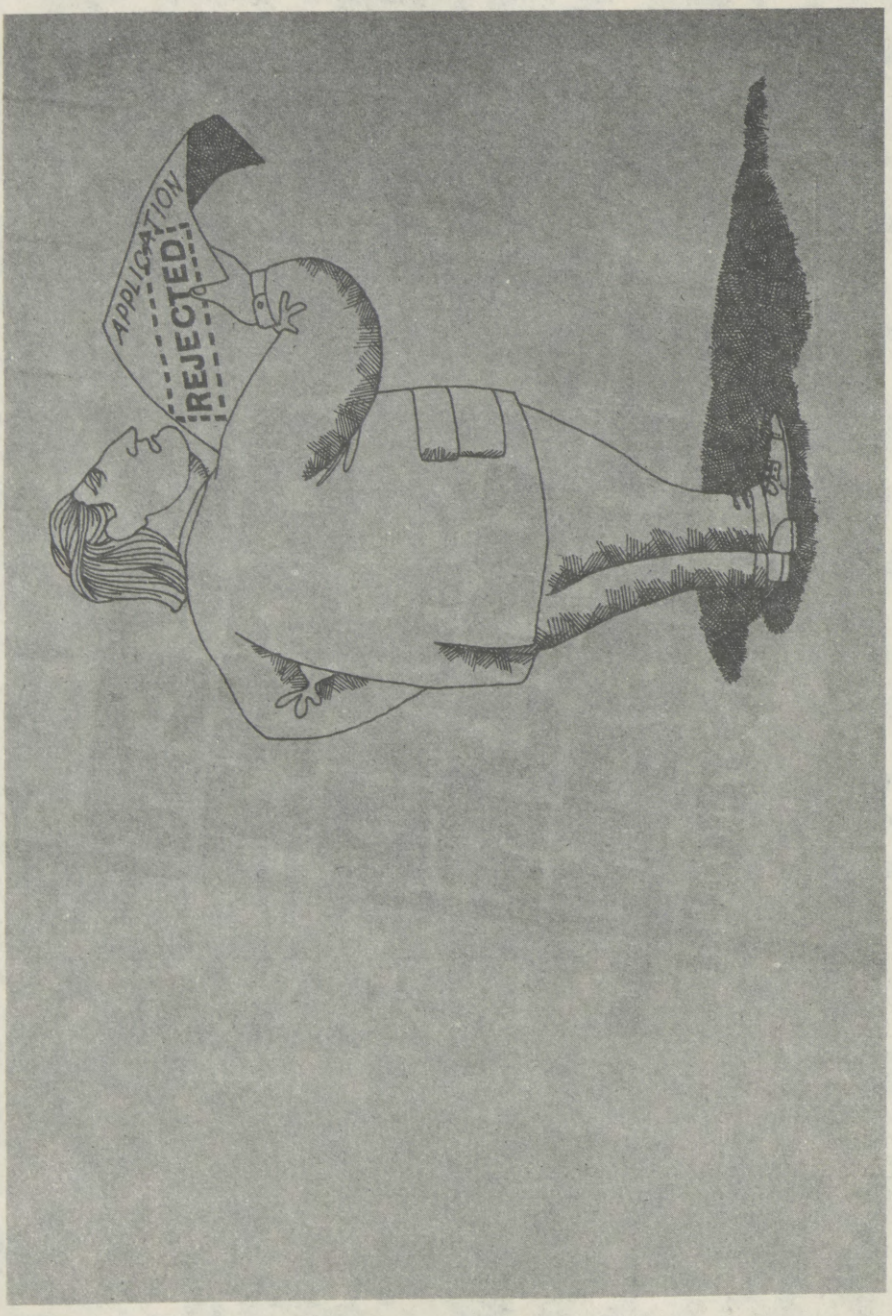

OVER
WEIGHT
AND
YOUR
HEALTH...
THE VITAL CONNECTION!
Prepared by Weight Watchers International, Inc.


APPLICATION
REJECTED!

If you're somewhat overweight, you already know that extra weight keeps you from looking your very best.

If you are noticeably overweight, you may even have encountered professional, social, and psychological problems because of it. Surveys have shown that some employers and college admission boards are more likely to accept non-obese applicants than obese applicants, though they are equally qualified. And you know better than anybody the self-disappointment and lack of confidence that can come from being fat.

All this should be reason enough to make you want to lose weight. But, if that isn't enough, there is another very important consideration: OVERWEIGHT IS A TRUE HAZARD TO HEALTH!

Because you should be aware of the effects of overweight on your health, Weight Watchers International, Inc. has prepared this booklet.

The purpose is to inform you, not to frighten you. Fright rarely motivates anyone to begin a weight control program. More often than not, comfort is sought in eating even more than usual. We believe, however, the more information people have, the better they can arrive at an intelligent evaluation of themselves, and an intelligent decision for themselves.

This booklet has been developed under the supervision of Dr. W. Henry Sebrell, Medical Director of Weight Watchers International, Inc.

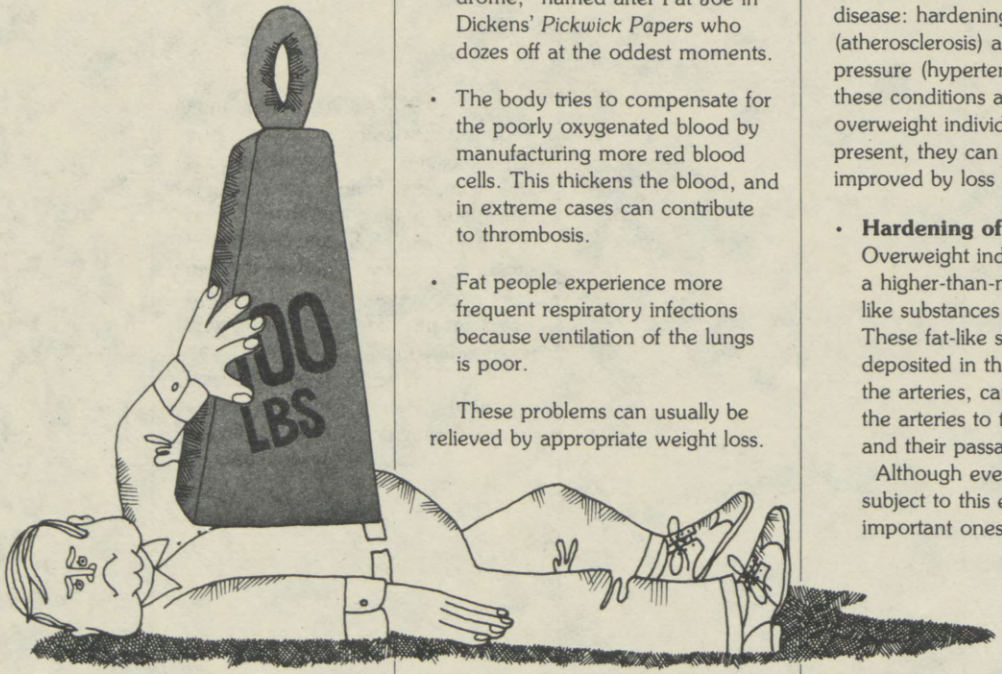
In it, you will learn about various diseases associated with overweight—including the health hazards connected with certain fad weight-loss schemes.

It is not always certain whether excess weight *causes* a particular disease ... *adds* to the chances of developing it ... or just *complicates* it after it has developed. But statistics prove that many diseases occur more often and to a worse degree in people who are more than 20% over their normal weight. The result is that life expectancy is actually shorter for most stout individuals, and the heavier you are, the shorter your life expectancy.

Respiratory Problems

Obese people have excess accumulations of fat on their chest wall. The weight of this extra fat can actually make it difficult to breathe, so that there cannot be efficient passage of air (ventilation) through the lungs. It also takes greater exertion to move this excess weight. As a result, the blood—which normally takes oxygen from the lungs and carries it to all the tissues of the body—is not provided with a sufficient amount of oxygen. And so the body's tissues become oxygen deprived. The results:

- Fat people tire more easily during physical exercise since muscle activity requires oxygen. For the very fat, even exercise as simple as walking may be a strain.



- Lack of oxygen and the resultant build-up of carbon dioxide in the body cause lethargy and sleepiness. In its extreme, this condition is called the "Pickwickian syndrome," named after Fat Joe in Dickens' *Pickwick Papers* who dozes off at the oddest moments.
- The body tries to compensate for the poorly oxygenated blood by manufacturing more red blood cells. This thickens the blood, and in extreme cases can contribute to thrombosis.
- Fat people experience more frequent respiratory infections because ventilation of the lungs is poor.

These problems can usually be relieved by appropriate weight loss.

Cardiovascular Disease

There are two main conditions that underlie most cases of heart disease: hardening of the arteries (atherosclerosis) and high blood pressure (hypertension). Although these conditions are not limited to overweight individuals, if obesity is present, they can usually be improved by loss of weight.

- **Hardening of the Arteries** Overweight individuals often have a higher-than-normal level of fat-like substances in the blood. These fat-like substances may be deposited in the inner lining of the arteries, causing the walls of the arteries to thicken and harden, and their passageway to narrow.

  Although every artery may be subject to this effect, the most important ones are the coronary

arteries that supply oxygen-carrying blood to the heart muscles, and the arteries that feed the brain and the kidneys. When narrowed coronary arteries carry less than the needed amount of blood to the heart, the result is pain in the chest known as "angina pectoris." If the coronary arteries become obstructed, a heart attack (myocardial infarction) can result. Stroke occurs when brain arteries rupture.

- **High Blood Pressure**

  In most cases of high blood pressure (hypertension), the cause is not known. But it is known that blood pressure tends to increase with an increase in body weight and to decrease when excess fat is lost.

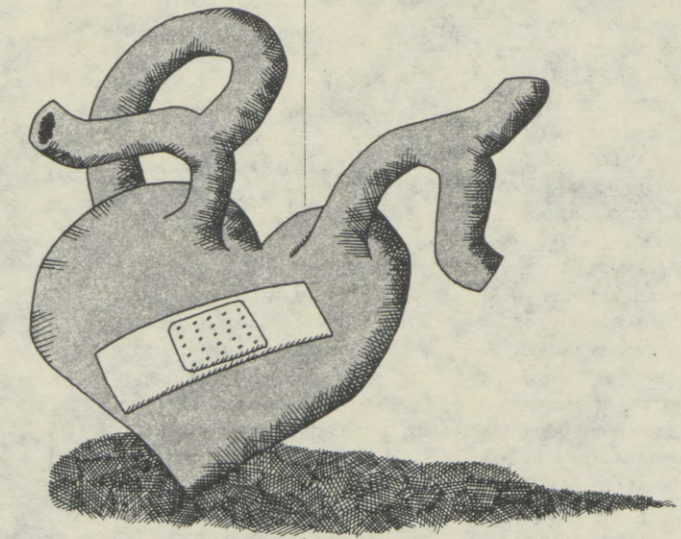
Each pound of fat tissue in our bodies is laced with approximately two miles of tiny blood vessels (capillaries). That means that for every extra pound of fat you carry, the heart has to pump the blood another two miles. Also, overweight people have a greater volume of blood than people of normal weight. One theory is that the increased "out-put" or work required by the heart may be a factor in high blood pressure.

Where hardening of the arteries and high blood pressure exist together, they intensify the effects of each other. In particular, high blood pressure increases the risk of stroke. By reducing the blood supply to the kidneys, it also may decrease kidney function, even causing kidney failure in severe cases.

In cases of mild hypertension, blood pressure usually returns to normal when weight is lost. At the same time, fat-like substances in the blood are generally decreased.

Congestive heart failure

The extra burden that obesity places on the heart can have other effects besides hypertension. It can cause the heart first to enlarge, and then to weaken. The heart's pumping may become less effective. Blood can back up in the pumping chambers. Fluid may collect in the lungs and other parts of the body (edema). Then the heart has to work even harder and may eventually fail (congestive heart failure).



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Diabetes

Normally the carbohydrates (sugars and starches) we eat are broken down in our body with the help of the hormone insulin. That way they can be used for energy or stored for future use. Diabetes is a condition in which there is an insufficient supply of insulin. The glucose that builds up in the blood is excreted, and the carbohydrate energy lost.

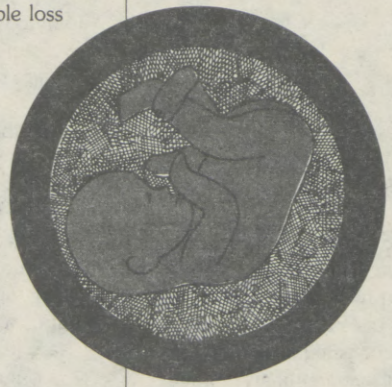
The cause of diabetes is still obscure; but it is known that the disease is four times more common in obese than in lean adults. It is also known that diabetes tends to develop in adults who are obese or have been obese before the disease was diagnosed. Body fat cells are resistant to insulin.

It is believed now that the increased demand for insulin over many years in overweight persons may lead to exhaustion of the pancreas (where insulin is made), resulting in diabetes. It has been found that weight loss and careful diet relieve the burden on the pancreas, and are often enough to control mild diabetes without the use of medication.

Gynecologic Problems

- **Pregnancy**
  Obesity is considered a definite hazard in pregnant women. There is a high risk of eclampsia, a condition which is marked by high blood pressure, excess fluid in the tissues (edema), and loss of protein. It complicates delivery and results in a higher rate of stillbirths than in normal weight mothers. It often forces the physician to resort to a Cesarean delivery to save mother and child. The surgery, itself, can be an added risk to the overweight mother. Babies of overweight mothers usually become overweight, as they tend to be overfed by the overweight mothers.

- **Other**
  In women with significant obesity, there is often excessive growth of facial and body hair. Also menstruation may become irregular or stop. Although these abnormalities may be due to a hormonal disorder, they may be improved by a suitable loss of weight.



Gallbladder Disease

The gallbladder stores and concentrates bile, which is used to help in the digestion of fats. Sometimes the gallbladder may become inflamed. Other times, for reasons that are not clear, the bile fluid is concentrated and forms painful gallstones.

In any age group over 25, gallbladder disease in general is more frequent in obese people, and increases in frequency with the level of body weight. Gallstones are also more frequent in the markedly overweight.

It is thought that eating large amounts of fat may be one factor in the development of gallstones. Diet and loss of weight are usually recommended as part of the treatment.

Osteoarthritis

This is a condition in which the cartilage in the joints begins to deteriorate. As the cartilage is lost, the bones at the joint enlarge and do not line up properly with each other. This causes pain and difficulties when the joints are moved.

Osteoarthritis is considered by many authorities to be part of the normal aging process. However, the additional physical burden of overweight can cause the condition to begin earlier and become worse during its course. Most affected by overweight are the weight-bearing joints—the hips, knees and ankles.

Varicose Veins

After the blood has delivered its oxygen to the tissues of the body, veins return the "used" blood to the heart. In the legs, the blood must actually travel against gravity, "uphill," to the heart. Valves, located in the veins, help prevent backflow, and keep the blood moving in the right direction.

Sometimes the valves do not work properly. Then the blood pools, and causes the veins to swell. The veins, which are not made of as strong material as arteries, become permanently swollen and distorted and can be seen on the surface of the legs as varicose veins.

Marked obesity may often be accompanied by varicose veins. It is thought that the increased pressure caused by excess fat may contribute to both the development and worsening of the condition.

Skin Conditions

In obese persons, certain areas of expanded skin (thighs, underarms, etc.) produce a great deal of perspiration and friction. This often results in irritation, furuncles (an infection of the hair root) and other painful inflammations.

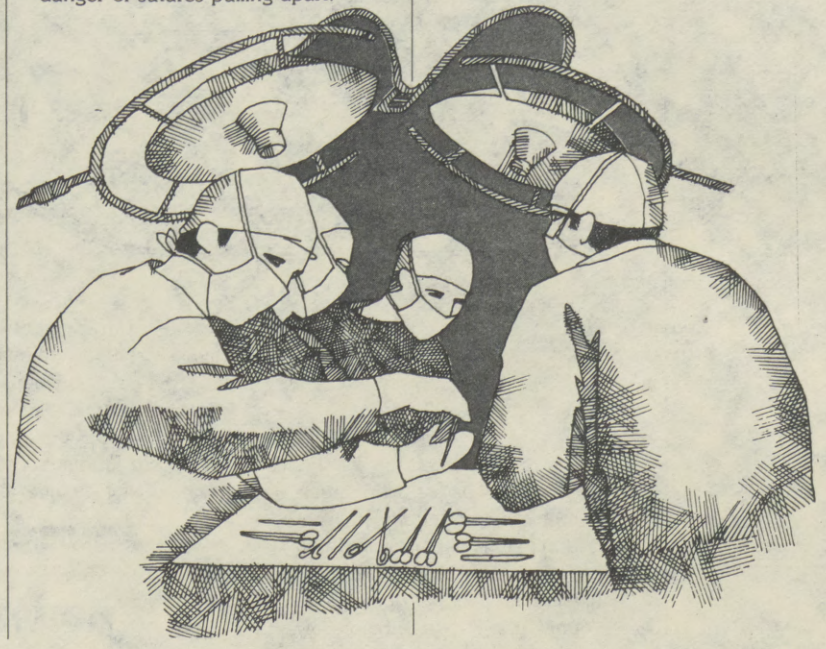
Another condition found in fat persons is stria (streaks or stretch marks), especially in the upper thigh and abdomen. They are caused by stretching and rupture of the elastic fibers in the skin.

Although the reason is unclear, many obese people also develop a peculiar darkening of the skin (*Acanthosis Nigricans*). In addition, some of these same individuals show signs of hormonally-caused skin problems such as abnormal body hair and acne.

Surgical Risks

In order to avoid problems in other than emergency situations, surgeons generally advise obese people to lose weight before an operation. The fatter the surgical patient, the more fatty tissue must be cut through, the more tiny blood vessels must be clamped off to keep the surgical field clear, and thus the more complex the operation becomes. In addition, overweight patients require extra anesthesia, which can cause respiratory and heart problems during the operation.

When the operation is over, overweight persons generally spend more time in the recovery room because of the increased levels of anesthesia. Also because of the nature of fatty tissue and the pressure it may exert, there is a greater danger of sutures pulling apart.

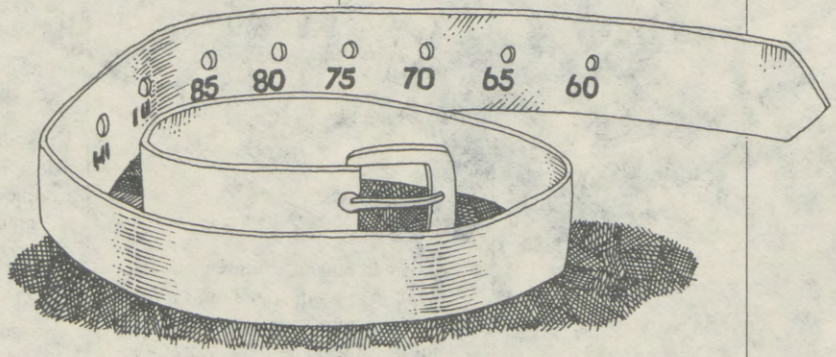


Shortened Life Expectancy

There is a saying: "The longer the waistline, the shorter the lifeline." In fact the greater the degree of overweight, the shorter the life expectancy.

Fortunately, appropriate weight reduction can reverse this.

According to a long-term study, people who reduced their weight significantly, and kept it reduced, had practically the same life span as those of normal weight with a standard life expectancy.



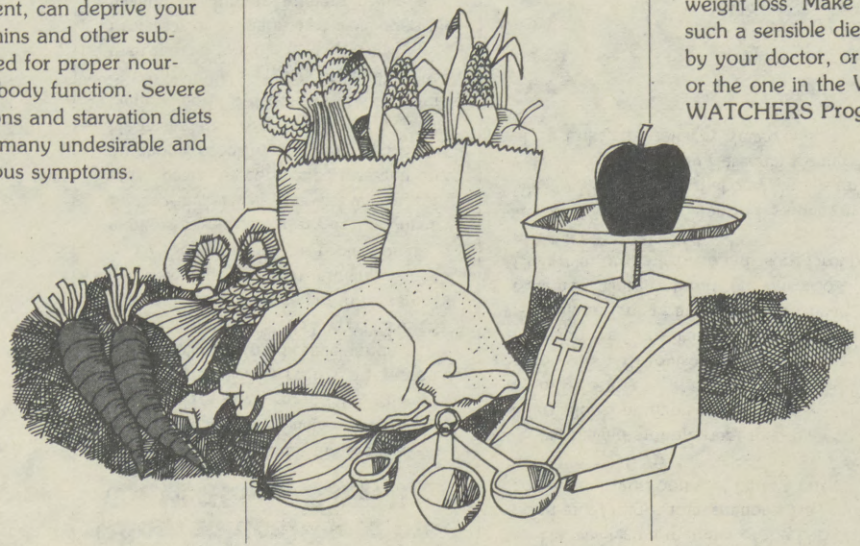
Health Hazards From Improper Dieting

Clearly, it is in the best health interest of the overweight person to lose weight. However, certain approaches to losing weight may be harmful to the health. Fad diets, which usually emphasize one kind of food or nutrient, can deprive your body of vitamins and other substances needed for proper nourishment and body function. Severe food restrictions and starvation diets can produce many undesirable and even dangerous symptoms.

Choose a Sensible Program

Weight reduction cannot promise or guarantee good health and long life. But just as good hygiene practices of washing, bathing, brushing your teeth, and enough rest and exercise can contribute to the quality of life, so too can a body that carries just enough weight for its height and structure.

A scientifically up-to-date behavior modification program and a doctor developed exercise plan should be part of a weight reduction program. In addition, a truly sound weight control program aims to provide a nutritionally balanced diet, geared to moderate but steady weight loss. Make sure you choose such a sensible diet as provided by your doctor, or nutritionist, or the one in the WEIGHT WATCHERS Program.



Biographical Note on Dr. W. Henry Sebrell

Dr. Sebrell has been the Medical Director of Weight Watchers International since 1971 and is responsible for keeping the WEIGHT WATCHERS® Program nutritionally and medically sound.

He came to WEIGHT WATCHERS after a distinguished career in research and teaching in human nutrition.

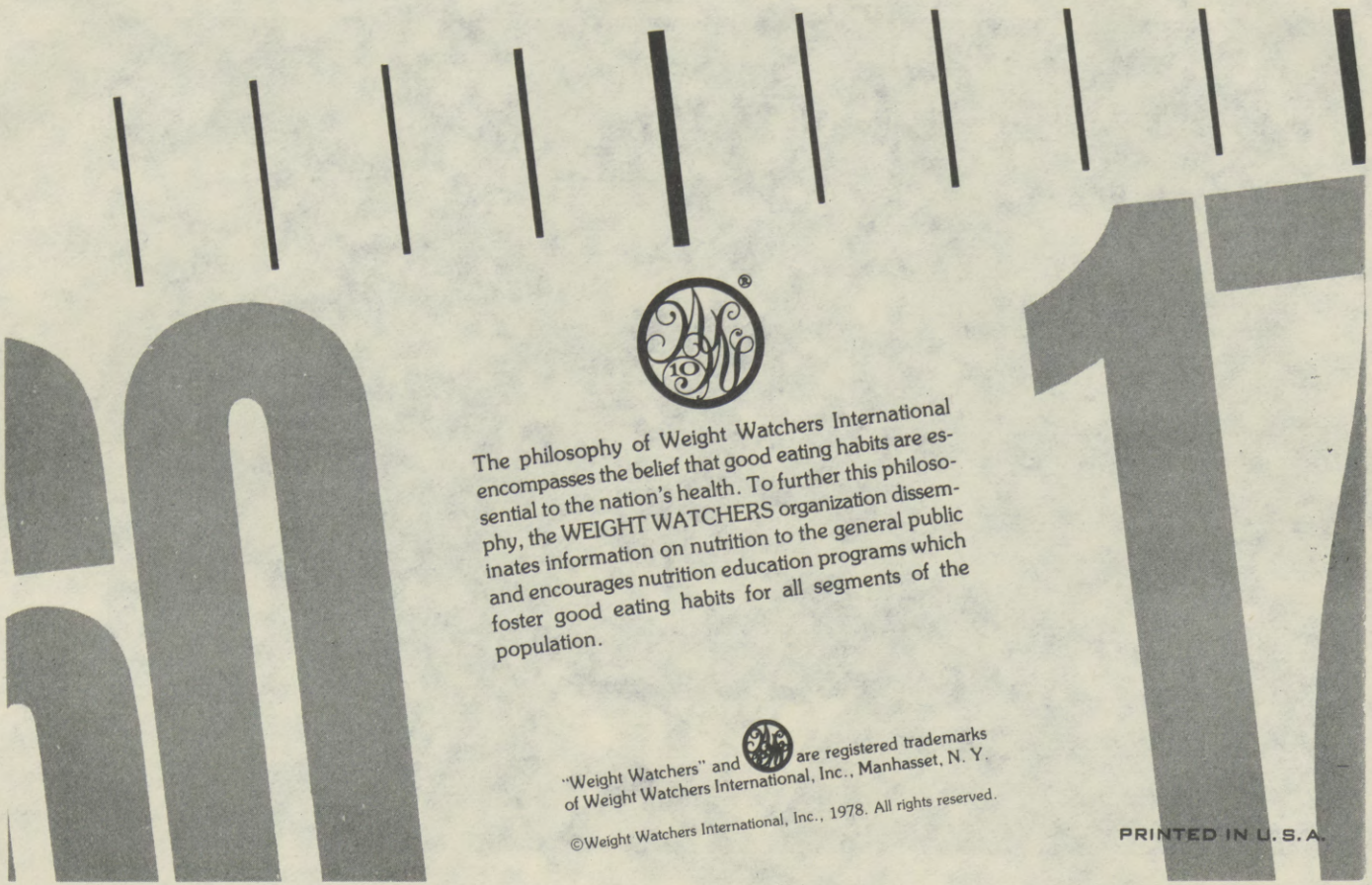
Dr. Sebrell began his professional work as a Medical Officer in the United States Public Health Service where, for many years, he conducted research on nutritional problems in the United States. He became an Assistant Surgeon General and for five years was Director of the National Institutes of Health. He then moved to Columbia University as Professor of Nutrition and developed the Institute of Human Nutrition in the College of Physicians and Surgeons.

He was, for many years, a member of the Food and Nutrition Board of the National Academy of Sciences—National Research Council, and was Chairman of the Committee that prepared the 1968 Recommended Dietary Allowances.

He was also a member of the U.S. Food and Drug Administration's National Advisory Food and Drug Committee in 1975-76.

He played an important role in international nutrition problems as a member of the World Health Organization's Expert Advisory Panel on Nutrition, as Consultant to the Food and Agriculture Organization and the United Nations Children's Fund. He was also Chairman of the Protein Advisory Group of WHO/FAO/UNICEF.

Dr. Sebrell in addition to his duties at Weight Watchers International, Inc. is an Advisor to the Obesity Research Center at St. Luke's Hospital in New York.



The philosophy of Weight Watchers International encompasses the belief that good eating habits are essential to the nation's health. To further this philosophy, the WEIGHT WATCHERS organization disseminates information on nutrition to the general public and encourages nutrition education programs which foster good eating habits for all segments of the population.

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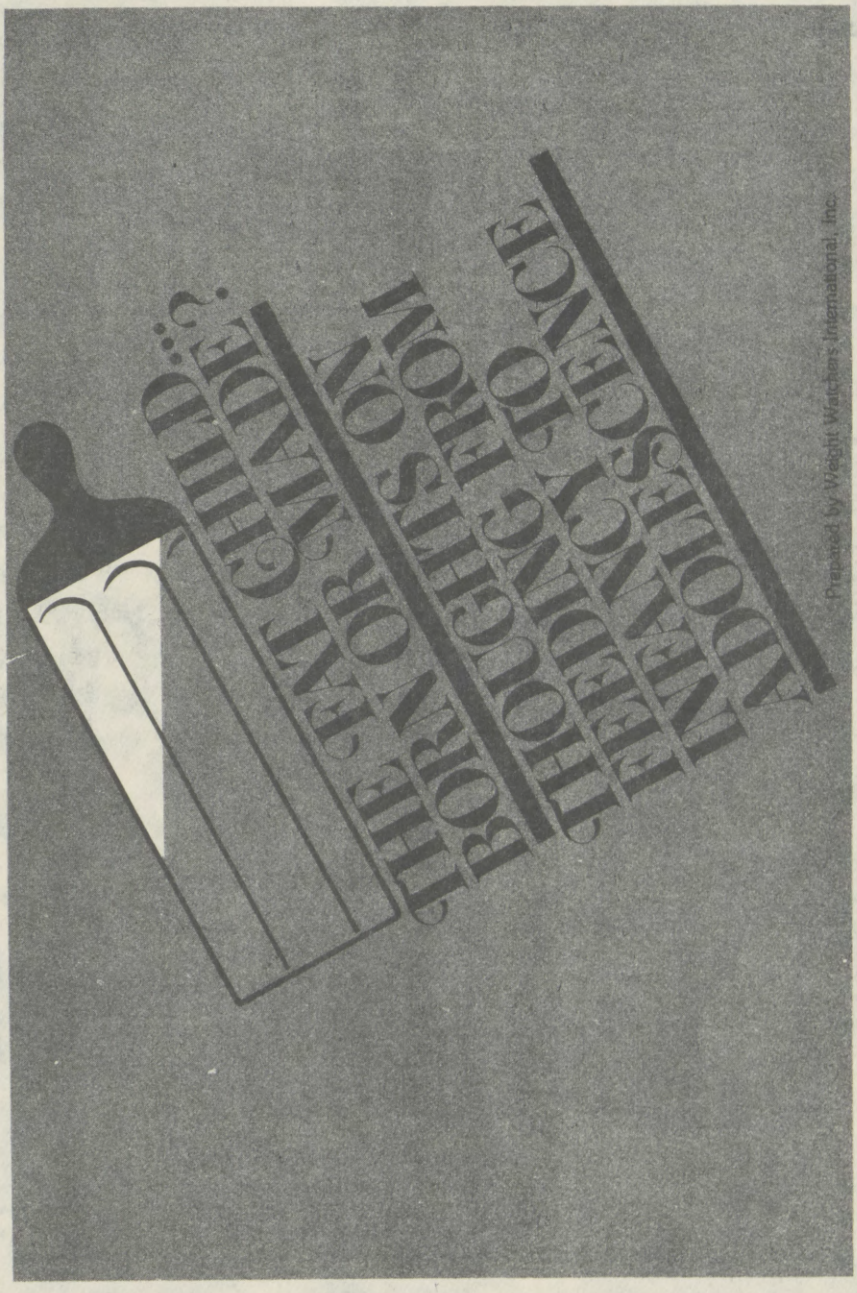
THE FAT CHILD:
BORN OR MADE?
THOUGHTS ON
FEEDING FROM
INFANCY TO
ADOLESCENCE
Prepared by Weight Watchers International, Inc.

Years ago, a plump baby was thought of as "robust" and "cute." As the baby grew, any concern for his overweight condition was usually dismissed with the comment: "He'll outgrow his baby fat."

Today we have learned that neither of those attitudes is correct. Far from being "robust" and "cute," many fat children are sluggish or less active than their thinner counterparts... and, by school age, often have been the target of ridicule by other children.

What's more, that so-called "baby-fat" may be here to stay. Though not conclusively supported by data, some believe that fat infants have a greater chance of becoming fat children. And today's fat children may actually be tomorrow's fat adults.

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Are fat children born or made?

Heredity *can* affect how our bodies use food. So, it is possible that heredity has *some* influence on why a child becomes fat ... and stays fat. But experts have recently become convinced that the most important factor in childhood obesity is how the child is fed during infancy and the early childhood years.

Children *become* fat because many of today's infants and young children are just plain overfed. This may be the result of our affluent lifestyle ... or misunderstanding in feeding practice ... or of an ethnic culture that places undue emphasis on food ... or of parents who are overweight themselves and impose their own eating habits on their children.

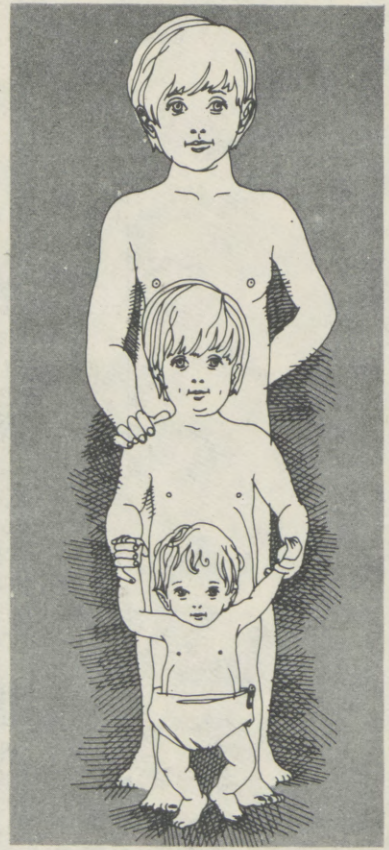
These children *stay* fat for at least two reasons. First, because eating patterns and attitudes that

are formed in early life tend to continue. Second, it is thought by some that some fat babies create more fat cells in their bodies than normal babies. An overweight toddler may have more than twice the number of fat cells of a normal weight toddler of the same age. Once developed, the number of fat cells does not decrease under any conditions. And the number of fat cells influences the amount of fat that is ultimately stored in the body.

Early feeding practices are important

Obviously, then, preventive measures *now* can help your child avoid the frustrations of trying to lose weight as a fat adult.

Weight Watchers has prepared this booklet as a general guide to



what and *how* to feed your child. It has been developed under the supervision of Dr. W. Henry Sebrell, Medical Director of Weight Watchers. In conjunction with any special advice you may be given by your doctor or pediatrician, the following recommendations will help provide the basics of good nutrition—and will help establish good eating patterns that will last a lifetime.

The first year of life



What your baby will eat

The best food for your baby is breast milk. Among the many benefits of breast feeding, one important benefit is that breast-fed babies tend to be lighter in weight. However, how and what you feed your infant will most likely be determined by your doctor. If you are not breast-feeding (and sometimes in addition to breast-feeding), the doctor will prescribe a formula—usually a mixture of a milk, water and some kind of sugar, fortified with vitamins and iron. As your baby grows, the amount of formula will increase, and on certain rare occasions, the "strength" of the formula (its caloric value) will be increased too. Your baby will drink water, and will probably start to take orange juice at several months of age for its vitamin C. Your baby may also receive a vitamin supplement.

Usually between 3 and 6 months, your doctor will have you introduce solid foods. Although many babies are given solid food earlier, current recommendations are to wait to begin solids until 6 months of age. You'll probably be told which ones and in which order. By the end of the first year, your baby will be eating: milk, fruit juice, cereal, egg, toast (zwieback), bread, and easily swallowed forms of fruit, vegetable, potato, macaroni, meat and fish.

What to avoid

Beverages and foods other than those specifically recommended should probably be avoided. For instance, your baby doesn't need "sweet treats" such as water with sugar or syrup, flavored ades, or soda pop. Not only do they favor development of dental cavities, they

can build a liking for "empty-calorie" sweets. "Grown up" desserts such as cookies, ice cream and cakes are undesirable for the same reason. While puddings may help replace milk if your baby loses his desire for it, most of the prepackaged cornstarch puddings sold for family use are excessively sweetened, and are best not used.

Tips on when and how

Babies know instinctively how much food is good for them. They know when they're hungry, how much they want, and when they've had all their digestion can handle. So, the most important rule is: DON'T FORCE YOUR BABY TO TAKE MORE FOOD ... OR TAKE FOOD MORE OFTEN THAN HE OR SHE WANTS. With constant urging, your baby will either lose interest and become a balky "feeding problem" ... or will accept the additional food, and a bad pattern of eating beyond hunger will be established.

In particular:

1. **Don't insist that baby finish every bottle.** Your infant doesn't have to have a certain amount at each feeding. It has been shown that breast-fed babies may take as much as 10 ounces at one feeding and 4 ounces at another. Similar variability in your bottle-fed baby is perfectly normal and permissible. Your baby may not be able to take the entire bottle, and shouldn't be pushed.
2. **Don't worry if your baby refuses or sleeps through a feeding.** Babies tend naturally to lengthen the interval between feedings as they grow bigger and older. Help reinforce this progress by *not* giving formula between established feeding times—which leads to the next important point.
3. **Don't use formula to quiet baby every time he cries.** Hunger is not the commonest reason for crying. Babies cry for a variety of reasons. It may be thirst, it may be an air bubble in the stomach, it may be colic, it may be a soiled diaper, it may be a need to suck not associated with hunger, or it may simply be that the baby wants to be picked up. If you can't determine what in particular is bothering your baby, leave him be. Or pacify him with a bottle of water, with your voice, or by cuddling and holding him. But do *not* offer food.
4. **Don't mistake thirst for hunger.** Babies need lots of water because their large body surface area (as compared to their body weight) permits a great deal of evaporation. This is especially so in hot weather or climates. If your baby is restless between feedings, offer *water* periodically instead of milk.

5. **Don't start your baby on solid foods before your doctor suggests it.** The medical trend today is to introduce solids between 3 and 6 months. And many authorities feel that the closer to 6 months the better. Despite what your friends or relatives may say, there is no proof that solids help an infant sleep better. And there is some concern that the addition of calorie-dense solid food too early overnourishes the infant and may not be desirable.

6. **Don't compare your baby with neighbors' babies.** Every infant's needs are different. Feeding your baby is not a race, and you shouldn't compete with other young mothers to see whose child is "out in front."

There will undoubtedly be times when your baby loses his normal appetite. Between 3 and 9 months, a relative decrease in growth rate and the start of teething may result in decreasing appetite. A sudden resistance may develop to a food that he loved last week. Even if you do nothing, the situation will correct itself.

In short: Even if your baby isn't eating as much as you think is proper, if he appears satisfied, healthy and happy, and is growing normally, you shouldn't give it another thought. Calling your doctor, however, is always the safest way and can provide you with peace of mind.

The overweight baby

If the doctor thinks your baby is putting on too much weight too fast, he will adjust your baby's caloric intake. He may make certain recommendations concerning solid foods and the amount of formula to be given. He probably will *not* recommend a skim milk diet, because the fatty acids provided in regular milk are generally needed for proper growth and health in the first year of life. It is most important that you follow the doctor's instructions—and THAT YOU DON'T TRY TO PUT YOUR BABY ON A DIET WITHOUT MEDICAL SUPERVISION.

Some things you can do to help:

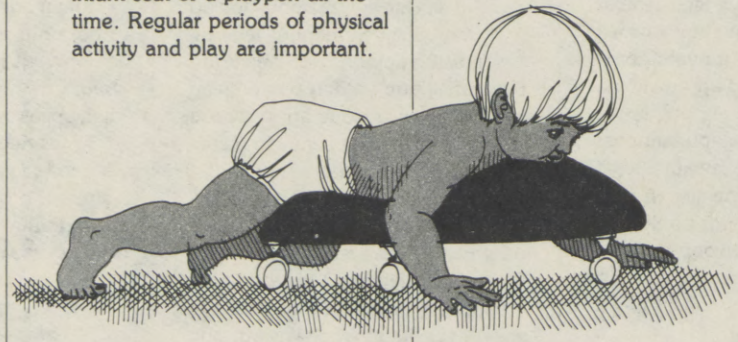
1. **Remember that for fat babies, unlike fat adults, the goal is not weight *reduction*.** All you want to do is *slow* your

baby's rate of weight gain so that he will grow into a normal weight as his length increases. Therefore, don't underfeed or severely restrict your baby's feeding, as you could adversely affect your baby's growth.

2. **Read baby-food labels carefully, and become generally familiar with calorie content.** Buy those foods that have no sugar (or salt) added. Avoid prepared "dinners" that contain too much cornstarch. Similarly, avoid "meat soups" which usually consist of small amounts of meat and vegetables, with larger amounts of cereal such as rice or barley. Buy vegetables that have only water added; not the "creamed" ones that usually contain cornstarch or refined rice.

3. **Offer water between feedings to satisfy sucking and thirst needs.**

4. **Try to increase baby's activity.** Don't confine your infant to an infant seat or a playpen all the time. Regular periods of physical activity and play are important.



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The toddler and young child

Now is the time when your child is learning and forming habits and attitudes about lots of things—including food. The basic rule is to teach him good eating habits by making available nutritionally, well-balanced food. Discourage bad habits by limiting access to "empty-calories" junk foods. These will fill him up and crowd out nutritious foods your youngster needs.

What to feed your child

Food contains proteins, carbohydrates, fats, vitamins, minerals, roughage and water. Your child needs all these things for growth, health, energy and proper digestion. Since no one food or group of foods contains all these substances, he should be given daily servings, in the proper amounts, from each of the following basic food groups.

MILK GROUP—3 or 4 SERVINGS DAILY: Includes milk and cheese. Provides protein for muscle development and growth, minerals (calcium and phosphorus) for good bones and teeth, and vitamin A, riboflavin and vitamin D (in fortified milk).

MEAT GROUP—2 OR MORE SERVINGS DAILY: Includes meats, poultry, fish and eggs. (Dried beans, dried peas and nuts may be used as alternatives.) Provides protein, energy, iron for healthy blood, and the B vitamins.

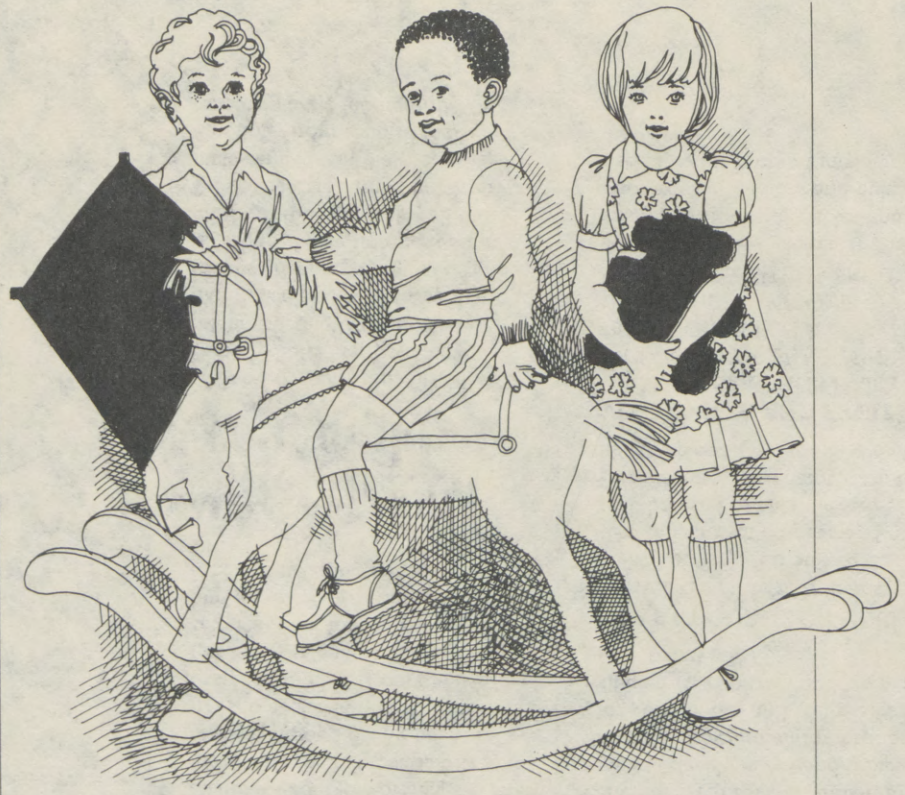
VEGETABLES AND FRUIT—4 OR MORE SERVINGS DAILY INCLUDING AT LEAST ONE GREEN OR YELLOW VEGETABLE, AND ONE SERVING OF CITRUS FRUIT OR JUICE: Provides vitamin A and vitamin C. Raw vegetables and fruit also provide the fiber and bulk necessary for proper functioning of the bowels.

BREAD AND CEREAL—3 SERVINGS DAILY: Includes bread, cereal, noodles, rice, pasta. Provides energy. Whole grain breads and cereals, and converted rice are also excellent sources of vitamin B and iron.

A continued lack of even one of the food groups may cause a nutritional deficiency. If not corrected, this can actually prevent your youngster from growing and developing properly.

What about desserts and snacks?

These too can contribute to good nutrition if properly chosen. Routinely serve fruit, fruit cup, apple sauce, etc. For snacks—which the active young child may need midmorning, midafternoon and even again before bedtime—



keep on hand plenty of hardcooked eggs, raw vegetables, especially carrots and celery, cheeses, fruit and cold meats. Cookies, cake, and candy should be offered only rarely and in limited amounts. A glass of water or fruit juice will satisfy thirst.

How important is breakfast?

Even more important for children than for adults. Children burn up their food faster than adults. So a poor breakfast will leave your child without energy way before noon, and perhaps less alert than he should be.

What if he doesn't eat?

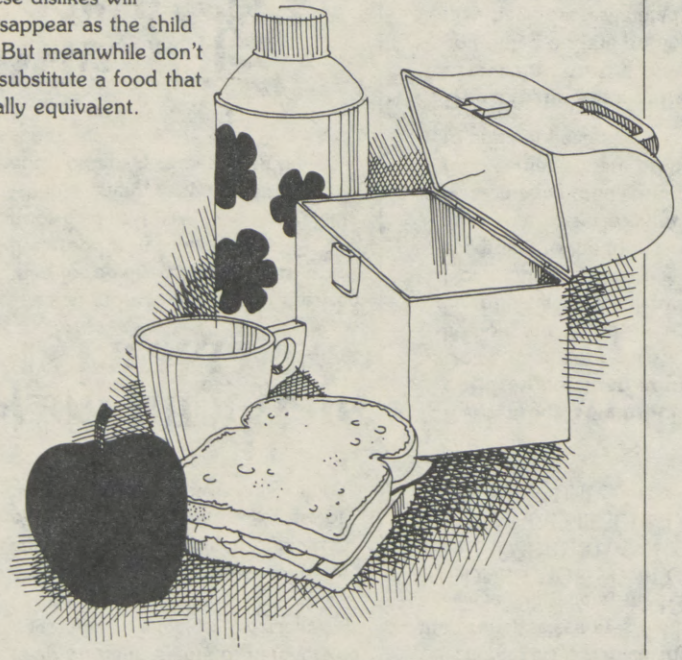
Just as with infants, most normal children will instinctively eat what they need—both in quantity and selection. This is particularly so if the proper selection is made easily available. So, again, the basic rule is: DON'T URGE YOUR CHILD TO EAT MORE THAN HE WANTS; DON'T MAKE MEALTIMES A BATTLEGROUND.

In particular:

1. **Remember how much less children eat than adults.** Don't judge your child's portion by how much you serve yourself, your husband or older children. Nor should you judge it according to the food container size. That was all right when he was on baby food. But *adult food* containers are proportioned to *adult* appetites.
2. **Don't insist your child eat everything on the plate.** If *you* doled out the portion, you may have overestimated his capacity. If *he* served himself, children's eyes are notoriously "bigger than their stomachs." Furthermore, children who are urged to "eat another forkful for Daddy" or who are told they're "good" for cleaning their plate, learn to equate eating with parental approval and love rather than hunger.
3. **Don't worry if your child's appetite falls off.** Activity level in the 2-5 year old group can fluctuate dramatically. Therefore, so will appetite. Your child should eat every meal, but your child will not become ill or "starve" simply because he skips a meal. Of course, if the situation persists, it is always best to check with your doctor.
4. **Don't offer dessert as a reward for finishing the main course.** This implies to the child that dessert is really the best part of the meal. It also "tricks" him into eating more than he's really hungry for. Serve nutritious desserts. Then even if he picks at the main course, he'll still be getting needed nutrients and vitamins.

5. **Keep junk food out of the house. No one needs it.**

6. **Remember that children have a more acute sense of taste than adults.** Their dislike for certain foods can be very strong. These dislikes will probably disappear as the child gets older. But meanwhile don't battle; just substitute a food that is nutritionally equivalent.



Once your child goes to school, he may be exposed to other eating situations. But the same rules apply. Give him a good breakfast. Pack a nutritious lunch, including a piece of fruit to satisfy any craving for sweets. Do not allow, or at least limit, the amount of "junk" food he eats. Explain that excess sugar in the form of cookies, cakes and candies is not good for teeth. If a sweet is in order, ice cream is probably preferable since it does have some nutrition value apart from just calories.

The overweight child to adolescence

If a lifelong problem of overweight is to be avoided, the fat child should start a program of weight control as early as possible. BUT, NO CHILD SHOULD BE PLACED ON A DIET WITHOUT MEDICAL SUPERVISION. Your doctor will individualize your youngster's eating plan. He will specify appropriate portion size, and most likely tell you to limit second helpings and fattening desserts. He will probably limit your child's consumption of milk to no more than one pint a day. And he undoubtedly will recommend a regular program of both social and physical activity, including walking to and from school where possible, swimming classes, etc. If the child is old enough, he may even recom-





mend a weight control group for peer support ... but your doctor's advice is essential.

Some things you can do to help:

1. **Prepare meals that can be eaten by the overweight child and the rest of the family too.** That way your youngster won't feel excluded. Try not to criticize or discuss diet at the table, or you'll make eating an emotionally-charged, guilt-filled subject.

2. **Learn to prepare attractive, yet calorie-controlled foods.** Meats should be trimmed of all fat; lean cuts are preferred. Consult recipes developed by Weight Watchers, nutritionists, or other authorities for low-calorie substitutes for high-calorie foods.

3. **Serve meals in measured-out portions rather than family style.** This helps avoid excessively large portions and second helpings. You can actually make portions look bigger than they are by serving on smaller plates, and by using generous amounts of lettuce, celery and parsley as fillers.

4. **See that high-calorie foods are not accessible.** Don't prepare rich gravies and sauces. Mayonnaise, jams, jellies and syrups should not be left on the table during mealtime. And make sure the refrigerator is stocked with plenty of low-calorie, nutritious snack food such as raw vegetables, fruits and cheese.

5. **Accentuate the positive.** Emphasize to your child what he *may* eat, rather than what is forbidden. Emphasize the progress he is making rather than the weight problem.

Remember...

Early eating patterns can affect your child for the rest of his life. The youngster who becomes accustomed to overeating, eating for reasons other than hunger, and gorging on junk food will probably continue to do so. He may also develop a physical make-up that actually favors storage of fat ... and will probably have to struggle against overweight his entire adult life. On the other hand, by tempering your child's diet during his early formative years, you can help establish healthful eating habits now and for the future.

Biographical Notes

Dr. W. Henry Sebrell

Dr. Sebrell has been the Medical Director of Weight Watchers International since 1971 and is responsible for keeping the WEIGHT WATCHERS® Program nutritionally and medically sound.

As a Medical Officer in the United States Public Health Service, Dr. Sebrell conducted research on nutritional problems in the United States. He has served as Director of the National Institutes of Health. He then moved to Columbia University as Professor of Nutrition and developed the Institute of Human Nutrition in the College of Physicians and Surgeons.

Dr. Sebrell played an important role in international nutrition problems as a member of the World Health Organization's Expert Advisory Panel on Nutrition.

Dr. Sebrell is also an Advisor to the Obesity Research Center at St. Luke's Hospital in New York.

Dr. Reva T. Frankle

Dr. Reva T. Frankle, a nationally-known nutritionist, educator and writer on health subjects, is Director of Nutrition for Weight Watchers International, Inc.

As a former public health nutritionist with the Bureau of Nutrition, New York City Department of Health, she was nutritionist-in-charge of the City's Nutrition Clinic serving overweight children and their families.

Dr. Frankle has also been with the Office of Education of the Department of Community Medicine at the Mount Sinai School of Medicine of the City University of New York. She has held a joint appointment as a faculty member of this medical school and the Nutrition Program of Teachers College, Columbia University.

In 1967, Dr. Frankle was the staff nutritionist in the Office of Economic Opportunity's Project Head Start in New York City designing and implementing nutritional guidelines for comprehensive nutrition services for all existing programs.

Dr. Richard B. Stuart

Dr. Stuart has been the Psychological Director of Weight Watchers International, Inc., since 1972. He is responsible for helping members of WEIGHT WATCHERS® classes to learn skills in self-management that allow them to follow the recommendations in the nutritionally sound food plans offered in class.

In addition to his work with Weight Watchers International, Inc., Dr. Stuart is Professor of Psychology and Social Work at the University of Utah.

Dr. Stuart has had a long and distinguished career in research concerned with weight control. He pioneered the development of behavior modification techniques for the self-management of eating.

Snacking



ON A WEIGHT-CONTROL PROGRAM

Prepared by Weight Watchers International, Inc.



So you've made a decision to control your weight: congratulations! We hope you have chosen a program that will help you accomplish a *gradual weight loss* through learning how to manage your urge to eat, how to increase the level of your physical activity in a healthful way, and how to plan nutritionally balanced meals. If the food plan that you are following has been recommended by your family physician, or by a registered dietitian, it probably has three regular meals just as the one offered by Weight Watchers International; three satisfying meals which provide you with the nutrients your body needs for sound functioning. But even with three well-planned meals each day, you may feel the urge to snack. Is snacking all right? How can snacks be planned wisely?

Unless carefully planned, eating between meals can be dangerous for weight losers. Its temptations can sabotage your good intentions, and the "empty calorie" foods that most people choose for snacks can interfere with good nutrition. Therefore, it is best to avoid eating between meals if at all possible. Unfortunately, however, we do not live in an ideal world. Our modern life-style, with its coffee breaks and cocktail hours, bridge parties and business meetings, is full of opportunities for snacking. And lest we forget that snack foods are available, TV commercials and print ads in newspapers, magazines, and billboards everywhere remind us of things we can but should not eat.

Fortunately, there is a way to snack without sabotaging a weight-control program. Weight Watchers International has prepared this booklet to show you how. In it you will learn—

how to snack without risking loss of control;

when to snack without building a constant urge to eat;

and what to choose as snack food without endangering your chances of following the food plan you have chosen.

Follow the simple guidelines offered in this booklet and you can reduce the likelihood that snacking will be a danger that will hurt your chance of dieting success. Instead, you can learn how to turn the urge to snack into a tool that can actually contribute to good nutrition and to weight loss.

Snacks Count

Food provides energy so that your body can do its work. When you take in *more* food than is required by your body the excess is usually stored as fat, so you *gain* weight. When you take in *less* food than your body requires, your body has to get energy from the energy it has stored, usually in the form of fat. Therefore, you *lose* weight as this stored energy is literally "burned up."

A food plan designed to promote weight loss provides less energy than your body needs daily. To stay within this daily limit, *snacks must be counted* as part of your overall eating plan.

Important Rules for Controlling the Urge to Snack

Snacks often pose a threat to weight control because they are unplanned, because they are taken at times when resistance is low, and because they reinforce thinking about food at different times of the day. Therefore, it is important for everyone who seeks weight control to gain some control over the urge to snack. The following six rules can help reduce your urge to snack:

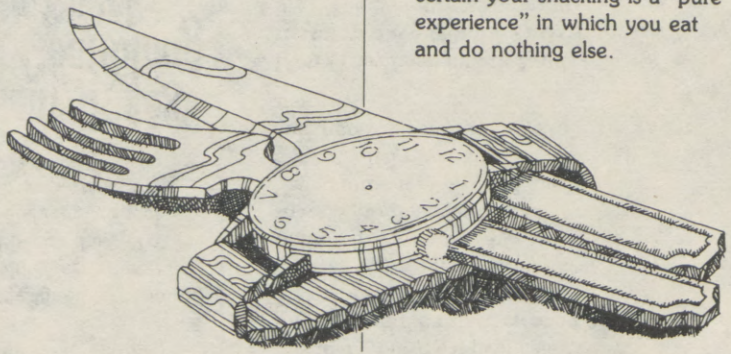
1. **Never skip nor skimp at a meal.** If you skip a meal or eat less than your meal plan calls for, you run the risk of creating a "caloric debt." You may "owe" yourself some energy in the form of food and overeat while snacking to repay the debt. Eating three well-planned meals daily can help to reduce this common source of the urge to snack.
2. **Don't purchase snack foods that you have trouble resisting.** The presence of problem foods in the house is a constant temptation. Do yourself a favor by not allowing this temptation to arise. Plan your food shopping with a list, shop after having had a full meal, and avoid aisles in the market that contain foods which tempt you but that you shouldn't buy. If others in your family wish to eat these foods, please ask them to make their own purchases, and request that they eat them outside of the house, keeping available for their snacks at home the same healthful foods that you can eat.

3. **Minimize contact with foods between meals.** Don't allow your kitchen to become a showplace of earthy delights: keep foods out of sight so that you are less likely to be tempted by them. Allow your children to take their own snacks, so that you can avoid contact with food when they wish to eat. When at parties, try to find a place to sit or stand where snack foods are out of sight or at least out of reach.

4. **Keep yourself interested in stimulating activities.** More often than not, the urge to take a snack is motivated by boredom: it is rarely an urge that is born of true hunger. As long as you are involved in stimulating activities you are unlikely to be bored and therefore unlikely to find your thoughts and desires turning to food.

5. **Eat snacks at predetermined times.** If you find that—try as you may—you must have snacks, plan to have them at specific times which you plan in advance. If you train your body to expect food at certain times of the day and not at others, you are likely to think of food at those times and not through the day or night. In addition, if you have planned the time of your snacks, you are also more likely to be able to plan their contents and amounts.

6. **Do nothing but eat while you are snacking.** Just as eating at odd times of the day can train your body to expect food—and therefore, become "hungry" at those times—so, too, can you train your body to expect food when you engage in activities that you have associated with snacking. For example, if you watch TV while snacking, turning on the television set can cue the urge to eat. So you won't have to struggle to fight down your appetite during activities like watching television, reading or talking on the phone—activities that should normally divert your attention from food—make certain your snacking is a "pure experience" in which you eat and do nothing else.



In order to discover when and in what situations you experience the urge to snack, you may wish to keep a record of when your urge to eat is the strongest and what you are doing when the urge arises. This will help you build a plan of counterattack which will help you keep your snacking urge within manageable bounds.

Following these six rules can help you to cut down the number of times that you decide to take a snack. Now it is time for you to learn what foods to choose as snacks.

The Proper Foods

If you are following a food plan provided by your physician, a registered dietitian, or Weight Watchers International, you have probably learned which foods you can choose as snacks. If not, in choosing snacks you must follow this all-important rule:

Choose as snacks only those foods which would be acceptable as selections in the general food plan you are following, choosing them only in the portions that are allowed.

If you do not have a clear idea of which foods you should choose as snacks, the following recommendations from Weight Watchers International can serve as *useful guides*.

Snacks in portion sizes may be chosen from the following groups consistent with the food plan you are following.

1. In the *milk group*, choose skimmed milk, skimmed evaporated milk, buttermilk, or plain unflavored yogurt. The skimmed milk may be made from nonfat dry milk or may be commercially prepared liquid skimmed milk.
2. In the *vegetable group*, snacks may include asparagus, bamboo shoots, broccoli, cabbage, carrots, cauliflower, celery, chicory, cucumber, eggplant, endive, escarole, green beans, greens, kohlrabi, lettuce, mushrooms, peppers, radishes, sauerkraut, string beans, summer squash, tomatoes, and watercress.
3. In the *fruit group*, use fresh, canned or frozen fruit or fruit juice with *no sugar added*. Among juices, choose grapefruit, orange, orange/grapefruit, prune, tangerine, tomato, or mixed vegetable juice. The fruits you may eat are apple, applesauce, apricots, banana, berries, cantaloupe, cherries, currants, figs, fruit cocktail or salad, grapefruit, grapefruit sections, grapes, honeydew or similar melon, mandarin orange, nectarine, orange, peach, pear, pineapple, plums, prunes, rhubarb, tangerine, watermelon.
4. *Beverages* may include reasonable amounts of artificially sweetened carbonated beverages, club soda, coffee, and tea.

Also, choose clam juice, mixed vegetable juice, tomato juice, bouillon, and broth.

These suggestions govern the foods you might choose as snacks. But bear in mind that too much of even the right foods can be a problem, so it is essential that you take only the amount of any of these foods that is permitted by the food plan you are following.

Some Important Tips for Keeping Snacks in Bounds

So far we have discussed ways to reduce the urge to snack and what foods can be chosen when snacking is your desire. Now we would like to offer some important tips for making certain that you eat only the planned amount of the snacks you take. We have four suggestions to help you toward this goal:

1. **If you know you are going to have a snack, bring pre-measured portions of well-chosen snacks with you.** If you take your snacks to work or to school, for example, you will reduce the likelihood that you will confront the coffee cart or lunch counter with their tempting foods that you should not eat. You can even bring your own snacks when you are a guest in other people's homes. (But if you should fail to bring your own snacks, don't hesitate to ask for foods which are all right for you to eat in place of unacceptable ones that are offered.)

2. **Eat snacks in the same place where you normally have your meals.** If you snack at home, have your snacks at your normal place at the kitchen or dining-room table. If you snack at work, don't eat at your regular work station: go to a "neutral"place where all you do is eat. This will remind you to use the controls which normally help you to choose foods according to plan. It can also help reduce the likelihood that you will train yourself to experience "hunger" at other places in your living and work surroundings.

3. **Make snacks as attractive as possible.** Satisfaction with food is at least in part determined by expectations about the food. Food which appears tasty and interesting will create positive expectations and make satisfaction more likely. Using the recipes supplied in this booklet, you can create attractive snacks which you can enjoy and which can lead you to feel that you have had enough to eat without overeating.

4. **Eat snacks slowly and elegantly.** It takes a set amount of time for food to reach your stomach and for your stomach to set up the chemical reaction that tells your brain you have had enough to eat. You can eat very quickly and consume a great deal of food before this signal is sent; or you can eat slowly and

allow the signal to be sent after a small amount has been eaten. Slowing down the pace at which you eat can therefore cut down the amount that you eat. You can slow your eating rate by using utensils whenever possible, and by concentrating on the taste and texture of the foods you eat by chewing them thoroughly and by pausing a few seconds between bites.

A Few Reminders

We have offered you some suggestions that can help to build your control of snacking. A few reminders can help you further along the way toward weight control.

Alcohol. Alcohol is relatively high in calories—containing almost twice the calories in an equal measure of protein or carbohydrate—and it has virtually no nutritional value beyond the calories it supplies. Therefore, alcohol has no place on a weight-loss program, and it is important to resist the temptation to substitute a pre-dinner cocktail or a glass of wine for a well-planned and nutritious snack.

"Health foods." The fact that a food is grown organically or has no preservatives does not automatically make it desirable for a weight-loss program. For example, many of the often-recommended snack foods like granola, nuts, and raisins may be high in calories. Therefore, it is important that you consider so-called "health foods" in the same way that you would evaluate other foods before including them in the food plan you choose to follow.

Planning is of the essence. Don't allow eating to catch you unaware. Plan what you eat during your mealtimes so that you reduce the chance of between-meal hunger. And plan your snacks so you won't choose foods when you are feeling "hungry," bored, or otherwise hampered in making wise food decisions.

Remember

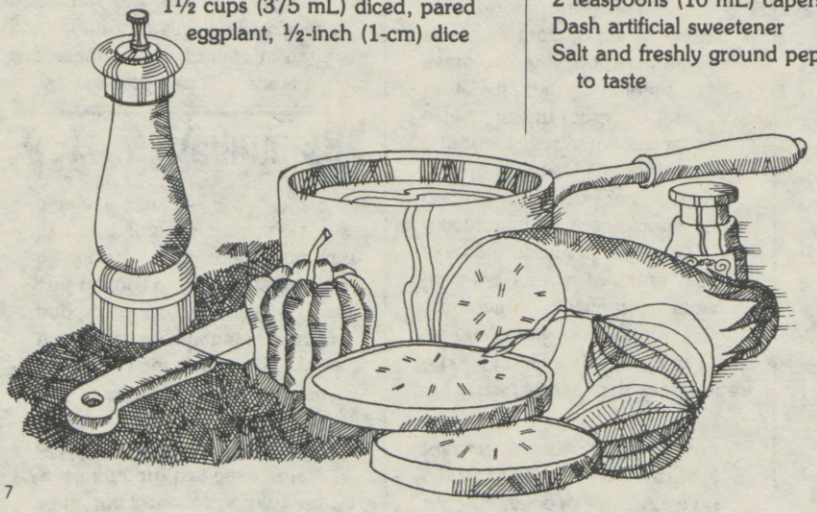
Try to reduce the urge to snack. But if you must snack, choose foods wisely and take the necessary steps to keep to the portions of snack foods that you know you should eat.

The snack suggestions that you will find in this booklet have been prepared with two goals in mind: they are all nutritious foods and they are all compatible with weight loss *and* weight control. Therefore, weight losers can find them to be of great benefit; so, too, can those who are working to maintain their weight. With overeating and overweight being among the major health problems in this country today, sensible snacking should be a matter of concern for everyone in the family.

Snack Recipes

Caponata

6 ounces (180 g) diced onion
1 medium green pepper, seeded and cut into ½-inch (1-cm) dice
1½ cups (375 mL) diced, pared eggplant, ½-inch (1-cm) dice
1½ cups (375 mL) sliced zucchini, ½-inch (1-cm) slices
1½ cups (375 mL) canned chopped tomatoes
1 cup (250 mL) tomato puree
1 packet instant chicken broth and seasoning mix
1 teaspoon (5 mL) basil
½ teaspoon (2 mL) oregano
⅛ teaspoon (0.5 mL) garlic powder
1 cup (250 mL) red wine vinegar
2 teaspoons (10 mL) capers
Dash artificial sweetener
Salt and freshly ground pepper to taste



In a medium saucepan combine onion and green pepper. Add water to cover. Bring to a boil; lower heat. Simmer until green pepper is tender. Drain; set aside. In a medium saucepan combine eggplant and zucchini. Add water to cover. Bring to a boil; lower heat. Simmer until eggplant is tender. Drain; set aside. In a medium saucepan combine tomatoes, puree, broth mix, basil, oregano and garlic powder. Bring to a boil; lower heat. Simmer 1 hour. Add cooked vegetables, vinegar, capers, sweetener, salt and pepper. Mix well. Chill. Makes 4 servings. Divide evenly.

Each serving is equivalent to:
1½ ounces (45 g) Limited Vegetable
1¼ cups (313 mL) Vegetables
½ serving Bonus (¼ cup or 62.5 mL tomato puree)
¼ serving Something Extra (¼ packet broth mix)

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Pimento Dip

1 cup (250 mL) pimentos
2 tablespoons (30 mL) cider vinegar
2 tablespoons (30 mL) prepared mustard
Artificial sweetener to equal 4 teaspoons (20 mL) sugar

Combine all ingredients in blender container; process until smooth. Chill. Makes 4 servings. Divide evenly.

Each serving is equivalent to:
1/4 cup (63 mL) Vegetables

Yogurt-Cucumber Dip

1 cup (250 mL) plain unflavored yogurt
1/2 cup (125 mL) shredded iceberg lettuce
1/4 cup (50 mL) finely chopped, pared and seeded cucumber
1 large garlic clove, minced
1 teaspoon (5 mL) salt
1 teaspoon (5 mL) chopped fresh mint leaves or 1/2 teaspoon (2 mL) dried
1/4 teaspoon (1 mL) white pepper, or to taste

In a small bowl combine yogurt, cucumber and lettuce. In a small cup, combine garlic and salt to make a paste; stir in 2 tablespoons (30 mL) yogurt mixture. Add to remaining yogurt mixture; mix well. Season with mint and pepper. Makes 4 servings. Divide evenly.

Each serving is equivalent to:
1/2 serving Milk (1/4 cup or 62.5 mL yogurt)
3 tablespoons (44 mL) Vegetables

Tarragon Cucumbers

1/4 cup (50 mL) cider vinegar
1/4 cup (50 mL) water
Artificial sweetener to equal 2 teaspoons (10 mL) sugar
1/2 teaspoon (2 mL) tarragon
1/4 teaspoon (1 mL) salt
1/8 teaspoon (0.5 mL) garlic powder
2 cups (500 mL) sliced, pared cucumbers

Combine all ingredients except cucumbers in a small bowl. Add cucumbers; toss to coat. Chill at least 2 hours. Makes 2 servings. Divide evenly.

Each serving is equivalent to:
1 cup (250 mL) Vegetables

Onion Soup

1½ pounds (720 g) onions, thinly sliced
6 packets instant beef broth and seasoning mix
3 packets instant chicken broth and seasoning mix
1 tablespoon (15 mL) Worcestershire sauce
2 teaspoons (10 mL) paprika
1 bay leaf
½ teaspoon (2 mL) browning sauce
⅛ teaspoon (0.5 mL) freshly ground pepper
1½ quarts (1.5 L) water
Salt to taste

Combine all ingredients, except water and salt, in a 2-quart (2-L) saucepan. Cook, stirring occasionally, until onions are transparent. Add water. Bring to a boil; lower heat. Simmer about 30 minutes. Add salt. Makes 6 servings. Divide evenly.

Each serving is equivalent to:
4 ounces (120 g) Limited Vegetable
1½ servings Something Extra (1½ packets broth mix)



Strawberry Milk Shake

½ cup (125 mL) cream-flavored dietetic soda
2 tablespoons plus 2 teaspoons (40 mL) nonfat dry milk
½ cup (125 mL) frozen strawberries, no sugar added, thawed
Artificial sweetener to equal 2 teaspoons (10 mL) sugar
1 cup (250 mL) crushed ice

Combine all ingredients, except ice, in blender container; process until smooth. Add ice; process. Makes 1 serving.

Each serving is equivalent to:
½ serving Milk (½ cup or 125 mL skim milk)
½ serving Fruit

Piña Colada

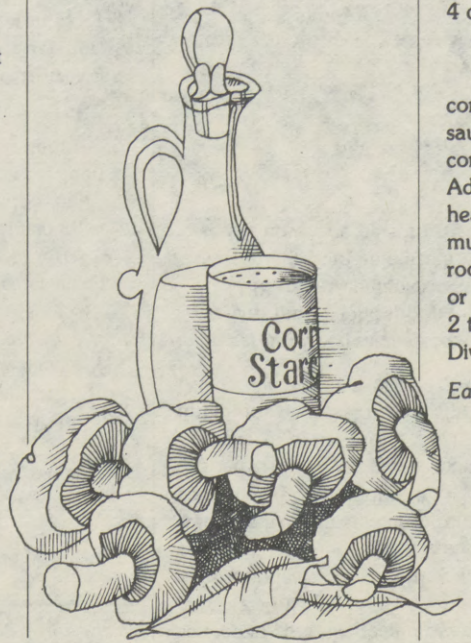
1 cup (250 mL) cold evaporated skimmed milk
1 cup (250 mL) cold water
½ cup (125 mL) canned crushed pineapple, no sugar added
½ teaspoon (2 mL) rum extract
½ teaspoon (2 mL) coconut extract
¼ teaspoon (1 mL) vanilla extract
Artificial sweetener to equal 4 teaspoons (20 mL) sugar
4 ice cubes

Combine all ingredients except ice cubes in blender container; process until smooth. Add ice cubes, one at a time, processing after each addition, until all ice is crushed. Makes 2 servings. Divide evenly.

Each serving is equivalent to:
1 serving Milk (½ cup or 125 mL evaporated skimmed milk)
½ serving Fruit

Marinated Mushrooms

¾ cup (175 mL) red wine vinegar
½ cup (125 mL) water
1 teaspoon (5 mL) salt
½ teaspoon (2 mL) oregano



5 peppercorns, crushed
2 cloves
1 bay leaf
1 garlic clove, crushed
2 teaspoons (10 mL) cornstarch, dissolved in 2 teaspoons (10 mL) water
4 cups (1000 mL) quartered mushrooms

Combine all ingredients except cornstarch and mushrooms in a saucepan. Bring to a boil. Stir in cornstarch; cook 1 to 2 minutes. Add mushrooms. Cover. Lower heat; simmer 5 minutes. Allow mushrooms to cool in liquid, at room temperature. Transfer to glass or plastic container; cover and chill 2 to 3 days. Makes 4 servings. Divide evenly.

Each serving is equivalent to:
½ serving Something Extra (½ teaspoon or 2.5 mL cornstarch)
1 cup (250 mL) Vegetables

Molded Vegetable Salad

1½ cups (375 mL) finely grated cabbage
½ cup (125 mL) grated carrot
¼ cup (50 mL) finely diced green pepper
1 teaspoon (5 mL) dehydrated onion flakes, reconstituted in 1 teaspoon (5 mL) water
Artificial sweetener to equal 2 teaspoons (10 mL) sugar
2 teaspoons (10 mL) cider vinegar
Salt and white pepper to taste
1 envelope unflavored gelatin
1½ cups (375 mL) lemon-lime flavored dietetic soda, divided
6 drops green food coloring, optional

Combine cabbage, carrot, green pepper, onion flakes, sweetener, vinegar, salt and pepper in a medium bowl. Set aside. In a small saucepan sprinkle gelatin over ½ cup (125 mL) soda to soften. Place over low heat; cook, stirring constantly, until gelatin dissolves. Remove from heat. Stir in remaining soda and food coloring, if desired. Add to vegetable mixture. Transfer to a wet mold. Chill until firm. Makes 4 servings. Divide evenly.

Each serving is equivalent to:
½ cup plus 1 tablespoon (138 mL) Vegetables
½ serving Something Extra (¼ envelope gelatin)

Pears with Chocolate Sauce

2 teaspoons (10 mL) water
1¾ teaspoons (8 mL) unsweetened cocoa
1¼ teaspoons (6 mL) cornstarch
½ cup (125 mL) evaporated skimmed milk
Artificial sweetener to equal 3 teaspoons (15 mL) sugar
8 canned pear halves with 8 tablespoons (120 mL) juice, no sugar added

Combine water, cocoa and cornstarch in a small saucepan; stir until completely dissolved. Stir in milk and cook, stirring constantly, until mixture comes to a boil.

Remove from heat; add sweetener. Cover and chill. Place 2 pear halves and 2 tablespoons (30 mL) juice in each of 4 dessert dishes. Top each with an equal amount of chilled sauce. Makes 4 servings.

Each serving is equivalent to:

- 3/4 (7/10) serving Something Extra (7/16 teaspoon or 2 mL cocoa, 5/16 teaspoon or 1.5 mL cornstarch)
- 1/4 serving Milk (2 tablespoons or 31.25 mL evaporated skimmed milk)
- 1 serving Fruit

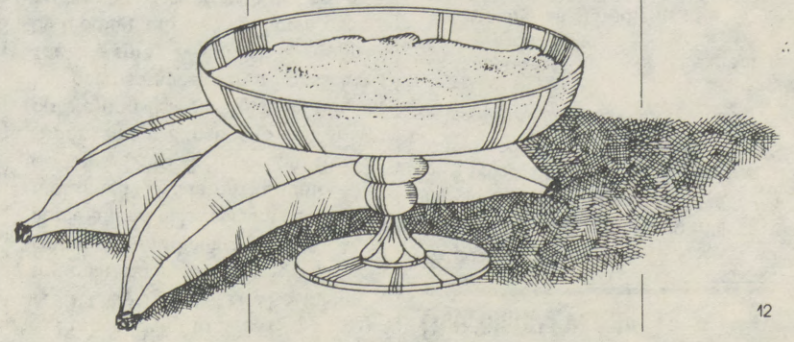
Banana Bavarian Mousse

1 envelope unflavored gelatin
1/4 cup (50 mL) cold water
1/4 cup (50 mL) boiling water
1 ripe medium banana, divided
2/3 cup (150 mL) nonfat dry milk
1/2 teaspoon (2 mL) coconut extract
Artificial sweetener to equal 6 teaspoons (30 mL) sugar
6 to 8 ice cubes

In blender container sprinkle gelatin over cold water to soften. Add boiling water; process to dissolve gelatin. Add 3/4 of the banana, all of the milk, extract and sweetener. Process until smooth. Add ice cubes, one at a time, processing after each addition, until all ice is crushed. Finely dice remaining banana; fold into blended mixture. Evenly divide mixture into 2 dessert glasses. Serve immediately or chill if desired. Makes 2 servings.

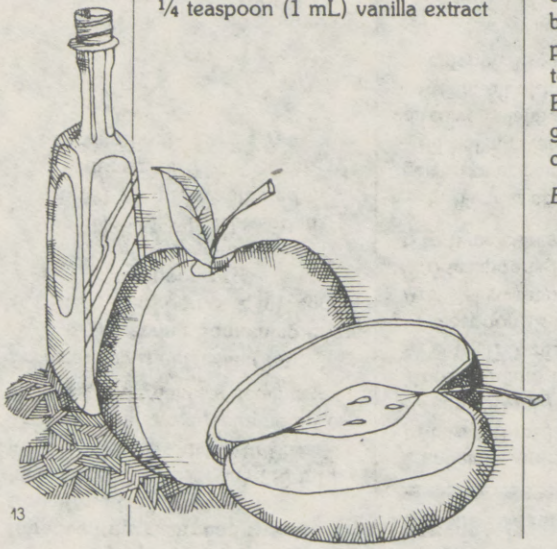
Each serving is equivalent to:

- 1 serving Something Extra (1/2 envelope gelatin)
- 1 serving Fruit
- 1 serving Milk (1 cup or 250 mL skim milk)



Apple Chews

⅓ cup (75 mL) nonfat dry milk
1 tablespoon (15 mL) flour
Artificial sweetener to equal 2 teaspoons (10 mL) sugar
¼ teaspoon (1 mL) cinnamon
¼ teaspoon (1 mL) baking powder
½ medium apple, pared, cored and grated
¼ teaspoon (1 mL) vanilla extract



Preheat oven to 375°F. (190°C). In a small bowl combine dry milk, flour, sweetener, cinnamon and baking powder. Add apple and vanilla; stir until evenly moistened. Divide mixture into 4 portions. Drop each portion, from a spoon, about 2 inches (5 cm) apart, onto a nonstick baking sheet, which has been sprayed with a nonstick cooking spray. Wet back of spoon by dipping it in water. Flatten each portion by pressing with wet spoon to about ¼-inch (5-mm) thickness. Bake for 10 to 12 minutes or until golden. Remove from baking sheet; cool on wire rack. Makes 1 serving.

Each serving is equivalent to:
1 serving Milk (1 cup or 250 mL skim milk)
3 servings Something Extra (1 tablespoon or 15 mL flour)
½ serving Fruit

Chocolate Pudding

¾ cup (175 mL) water
⅓ cup (75 mL) nonfat dry milk
Artificial sweetener to equal 4 teaspoons (20 mL) sugar
2 teaspoons (10 mL) cornstarch
1 teaspoon (5 mL) unsweetened cocoa
¼ teaspoon (1 mL) vanilla extract

Combine all ingredients in a small saucepan. Stir until cornstarch and cocoa are dissolved. Place over low heat; cook, stirring constantly, until mixture thickens. Pour into a dessert dish; chill. Makes 1 serving.

Each serving is equivalent to:
1 serving Milk (1 cup or 250 mL skim milk)
3 servings Something Extra (2 teaspoons or 10 mL cornstarch, 1 teaspoon or 5 mL cocoa)

Biographical Notes

Dr. Richard B. Stuart

Dr. Stuart has been the Psychological Director of Weight Watchers International, Inc., since 1972. He is responsible for helping members of WEIGHT WATCHERS® classes to learn skills in self-management that allow them to follow the recommendations in the nutritionally sound food plans offered in class.

In addition to his work with Weight Watchers International, Inc., Dr. Stuart is Professor of Psychology and Social Work at the University of Utah. He has held professorships at several major universities including the University of Michigan, University of British Columbia, and State University of New York at Stony Brook.

Dr. Stuart has had a long and distinguished career in research concerned with weight control. He pioneered the development of behavior modification techniques for the self-management of eating. He is also a well-known and widely-read author whose work has culminated in his recently published best-selling book, and in over 80 papers published in professional journals.

Dr. W. Henry Sebrell

Medical Director of Weight Watchers International—former Director of the National Institutes of Health, and of the Institute of Human Nutrition at Columbia University.

Dr. Reva T. Frankle

Director of Nutrition of Weight Watchers International—former member of the faculty at Mount Sinai School of Medicine and Teachers College, Columbia University, and Public Health Nutritionist, New York City Department of Health.

"...THE PUBLIC IS CONFUSED ABOUT WHAT TO EAT TO MAXIMIZE HEALTH. IF WE AS A GOVERNMENT WANT TO REDUCE HEALTH COSTS AND *MAXIMIZE THE QUALITY OF LIFE* FOR ALL AMERICANS, WE HAVE AN OBLIGATION TO PROVIDE PRACTICAL GUIDES TO THE INDIVIDUAL CONSUMER AS WELL AS TO SET NATIONAL DIETARY GOALS FOR THE COUNTRY AS A WHOLE. *"...SUCH AN EFFORT IS LONG OVERDUE."*

George McGovern,
Chairman Select Committee,on Nutrition and Human Needs
United States Senate—January, 1977

Weight Control and Nutrition Needs: An Important Message for You and Your Family

Prepared by Weight Watchers International, Inc.

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INTRODUCTION

After many years of careful study, painstaking research and extensive public hearings, the United States Senate Select Committee on Nutrition and Human Needs projected a series of laudable goals, notably:

- The conquest of obesity and the physical and emotional anguish the problem entails.
- Improved nutrition education programs for the entire community.

The elimination of obesity remains one of the nation's most pervasive needs. Nonetheless, a concerted and vigorous effort by both government and private industry can bring to bear the experience and proven weight control techniques that represent a positive approach toward the management and ultimate solution of this major health problem.

This brochure was prepared as a public service by Weight Watchers International to provide the public with new and valuable information about diet and nutrition needs, and to call attention to the Senate Committee's advocacy of programs to help overweight citizens to conquer their weight problem and, thereby, enhance overall health.

MALNUTRITION:
The Number One Problem

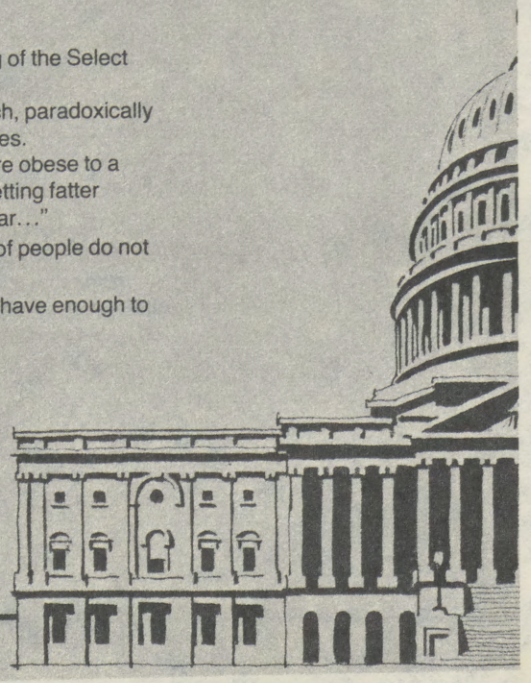
On February 2, 1977, Senator McGovern opened a meeting of the Select Committee with this startling observation:

"We are going to be talking this morning about obesity, which, paradoxically enough, is the No. 1 malnutrition problem in the United States. Thirty million Americans are overweight and 15 million Americans are obese to a degree that actually shortens their lives. Moreover, the obese are getting fatter and the absolute number of obese Americans is increasing each year..."

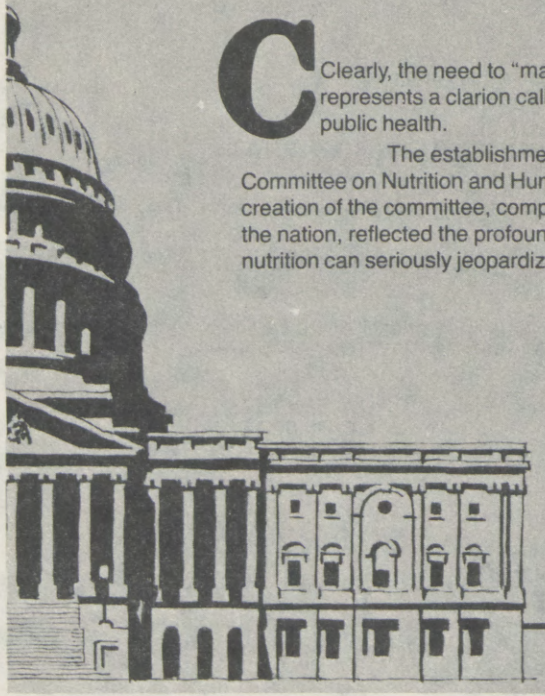
It is an extreme irony that in a nation of abundance, millions of people do not eat wisely.

It is tragic that ours is a society in which some people do not have enough to eat, while others eat to excess.

It is shocking that the obese may acutally be suffering from nutritional starvation!



A CALL FOR ACTION



Clearly, the need to "maximize the quality of life for all Americans" represents a clarion call for action . . . to combat an awesome threat to public health.

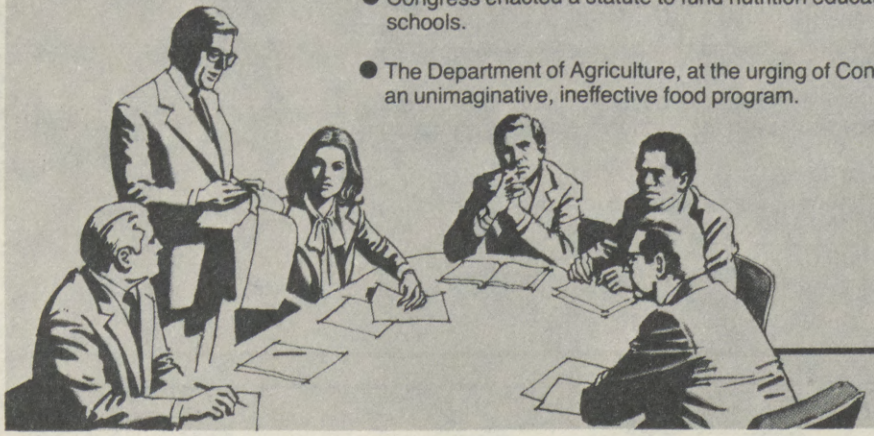
The establishment by the U.S. Senate, in 1968, of a Select Committee on Nutrition and Human Needs was a landmark development. The creation of the committee, comprised of some of the most prestigious legislators in the nation, reflected the profound government concern over the fact that poor nutrition can seriously jeopardize health.

A NATIONAL FORUM

A primary purpose of the Committee: to provide a national forum where scientists, physicians, legislators, government and industry leaders, educators and the general public could testify and provide the evidence to corroborate the urgent need for new and expanded programs to better meet the nutrition requirements of all Americans.

Over the years, this Senate Committee has made substantial progress in the development of programs to benefit the public. Largely as a result of the Committee's efforts...

- Congress enacted a statute to fund nutrition education in public schools.
- The Department of Agriculture, at the urging of Congress, revamped an unimaginative, ineffective food program.



- The W-I-C program (for women, infants and young children) was created to combat the lifelong problems caused by malnutrition during infancy.

- The Food and Drug Administration introduced a new system of nutrition labelling aimed at enhancing consumer education.

- A uniform, national, free and reduced-price school lunch program was established. Of the 27 million children now participating, 12 million receive free or reduced-price lunches.

- In 1969, the summer food program reached fewer than 100,000 children. It now serves over 2½ million.

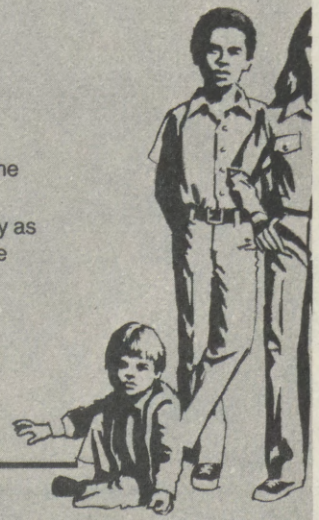
- The school breakfast program grew from 330,000 school children in 1969 to 2½ million in 1977; 2.1 million of whom come from households with incomes below 125 percent of the poverty level and who receive free meals.

- The 1977 farm bill established nutrition research as a separate and distinct mission within the Department of Agriculture.

- The 1977 school lunch amendments created our first national nutrition education program. With an allocation of 50 cents per student per year, it provides for a system of grants to state educational agencies for the development of comprehensive nutrition education programs for school children.

The most signal achievement of this Committee, however, was to delineate a series of *Dietary Goals for the United States*... goals, which, if achieved, could lead to a quality of life that has been the promise offered by the technological and industrial progress of America.

Paramount among these goals: to avoid overweight, consume only as much energy (calories) as is expended; if overweight, decrease energy intake and increase energy expenditure.





There are ample reasons why the Committee made this the primary goal.

- An individual is considered obese if he or she is 20 percent overweight based on height, sex and age.
- Obesity becomes a major risk factor for individuals who are 30% or more overweight.
- There is a significant correlation between obesity and ill health.

As Sen. McGovern forcefully stated:

"Too much fat, too much sugar or salt, can be and are linked directly to heart disease, cancer, obesity and stroke... among other killer diseases."

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In line with this objective,
the Committee urged the following:

1. Increase the consumption of complex carbohydrates and "naturally occurring" sugars.
2. Reduce the consumption of refined and processed sugars.
3. Reduce overall fat consumption.
4. Reduce saturated fat consumption, and balance that with polyunsaturated and mono-unsaturated fats.
5. Reduce cholesterol consumption.
6. Limit the intake of salt.

The goals suggest the following changes in food selection and preparation:

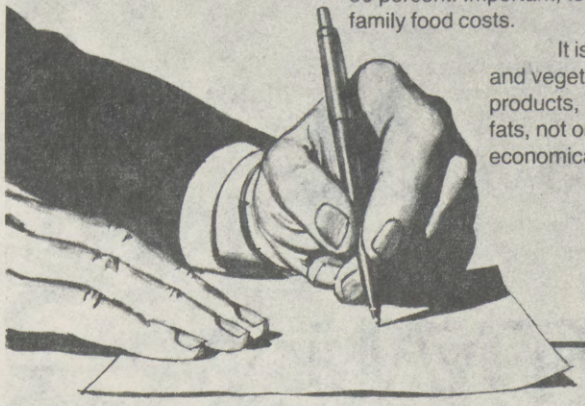
1. Increase the consumption of fruits and vegetables and whole grains.
2. Decrease consumption of refined and other processed sugars and foods high in such sugars.
3. Decrease consumption of foods high in total fat, and partially replace saturated fats, whether obtained from animal or vegetable sources, with polyunsaturated fats.
4. Decrease consumption of animal fat, and choose meats, poultry and fish which will reduce saturated fat intake.
5. Except for young children, substitute low-fat and nonfat milk for whole milk, and low-fat dairy products for high-fat dairy products.
6. Decrease consumption of butterfat, eggs and other high cholesterol sources.
7. Decrease consumption of salt and foods high in salt content.

'PRUDENT DIET' URGED

In issuing what Sen. McGovern called "the first comprehensive statement by any branch of the federal government on RISK FACTORS in the American diet," the Senate Committee went on record as advocating a "prudent diet" to combat the alarming prevalence of obesity in the United States.

The Committee observed that a prudent diet could reduce the heart attack rate by 25 percent, cancer incidence and infant mortality by 50 percent. Important, too, is the fact that such a diet could reduce family food costs.

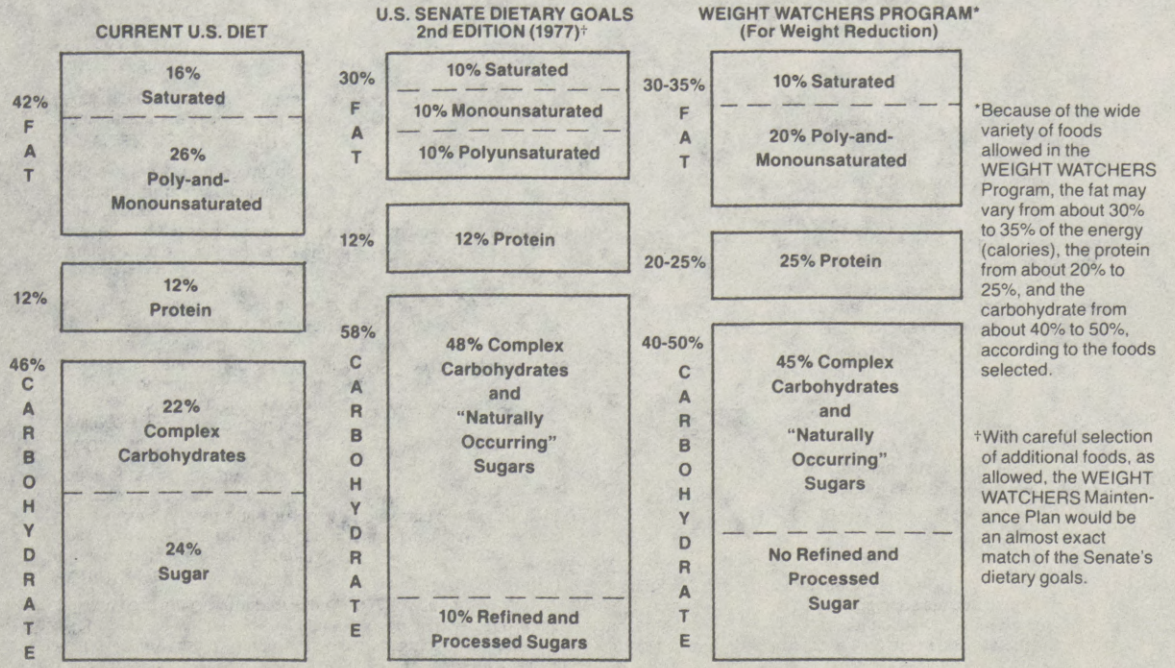
It is significant that the basic foods, such as fruits and vegetables, eggs and cheese, milk and dairy products, poultry, meat, fish and legumes, and some fats, not only provide necessary nutrients but, also, are economical.



AN INVALUABLE SERVICE

Weight Watchers International, Inc. applauds the Select Committee for performing a truly invaluable service.

The work of this Committee must be supplemented by renewed efforts by the private sector to make even greater inroads into the problem of obesity.



*Because of the wide variety of foods allowed in the WEIGHT WATCHERS Program, the fat may vary from about 30% to 35% of the energy (calories), the protein from about 20% to 25%, and the carbohydrate from about 40% to 50%, according to the foods selected.

†With careful selection of additional foods, as allowed, the WEIGHT WATCHERS Maintenance Plan would be an almost exact match of the Senate's dietary goals.

MENU PLAN

As the Dietary Goal #1 addresses the problem of obesity, the following meal pattern is for an obese woman on a weight reduction program and would suit most individuals in the U.S. (approximately 1200 calories):

MORNING MEAL:
A fruit or fruit juice rich in Vitamin C
Cheese or an egg or breakfast cereal (with skim milk)
One slice of enriched white bread or whole grain bread with liquid vegetable oil margarine
Coffee or tea without cream or sugar

MIDDAY MEAL:
Poultry or fish, cooked, 3 ounces
One vegetable, such as tomato, celery, broccoli or spinach
One glass of skim milk
One slice of enriched white bread or whole grain bread with liquid vegetable oil margarine
A fruit, such as an apple, pear, orange, peach, nectarine
Coffee or tea without cream or sugar

EVENING MEAL:
Poultry, meat or fish, cooked, 4 ounces
Two vegetables, such as carrots, peas, cucumbers, tomatoes, onions, string beans, asparagus
Fruit, such as berries, cantaloupe, pineapple
Coffee or tea without cream or sugar

BETWEEN MEALS OR WITH MEALS:
Bouillon, tomato juice, mixed vegetable juice, raw vegetables and skim milk, if not taken with meals

(NOTE: The above was taken from the Nutritional Adequacy of the Weight Watchers Food Plan)

For those who are at goal weight and would like to maintain their present weight, the following additions may be made at mealtimes or at snacks:

3 fruit servings

3 bread servings (or cereals, grain products, pasta, rice, etc.)

3 fat servings

In addition, this menu plan would allow a small serving of cake, pie, cookies, frozen desserts or custard.

About three teaspoons of sugar or other sweets, such as syrups, honey, jams and jellies may be used.

Meat, poultry, fish and legumes are served on alternate days. Drippings and all fat that can be trimmed from the meat should be discarded.

These additional foods will contribute nutrients in an approximate pattern suggested by the Senate Select Committee on Dietary Goals and result in about 1900 calories.

Nutrition, weight control and you!



Prepared by Weight Watchers International, Inc.

In this land of plenty, millions of people aren't eating wisely . . . some, because they don't have enough food; others, because they are eating too much! Overweight is a form of malnutrition, caused by eating too much of the wrong foods instead of correct amounts of the right ones.

Nutrition is a very personal matter. Why is nutrition personal? Because it is the way your body uses the food you eat. "You are what you eat."

You came to a WEIGHT WATCHERS® class to learn what foods to eat, and the proper amount to eat, to help you lose weight and keep it off. You may not have even considered nutrition a reason to join WEIGHT WATCHERS. However, by selecting WEIGHT WATCHERS, you have embarked upon a weight reduction program that is based on sound nutrition.

Obviously, we need food to live. It provides us with the energy needed for everyday living. It affects our weight and our strength.

Good nutrition is provided by a variety of foods. In order to be well-nourished while losing or maintaining weight, it is important to select and consume the right combinations and amounts of foods.

If everyone could be trained as a nutritionist and understand which foods are the best sources of the various nutrients, we could all combine them into a healthful, balanced diet. At WEIGHT WATCHERS, our nutrition staff has done this for you. We have designed a Program that helps you lose weight while providing the proper nutritional balance.

To make this as clear as possible, we've asked Dr. W. Henry Sebrell, Medical Director of Weight Watchers International, Inc. to respond to a series of questions concerning the nutritional aspects of the WEIGHT WATCHERS Program.

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What are the basic nutrients in food?

Food contains proteins, carbohydrates, fats, vitamins, minerals and water. Some foods contain more nutrients in larger amounts than others. However, it is important to remember that no one food contains all the nutrients needed for good health and well-being.

Through our knowledge of the nutrients contained in different foods and the amounts of the various nutrients required, we have selected the proper combination of foods for you.

How can you obtain all the required nutrients and still lose weight?

The Food and Nutrition Board of the National Academy of Sciences has established Recommended Dietary Allowances (RDA's) which state the amounts of the most important vitamins, minerals and protein which should be consumed daily.

The U.S. Food Drug Administration uses the RDA as the basis for the control of nutrition labels on commercially prepared foods. Read the label to know what you are getting nutritionally.

A daily intake of a proper variety of foods will supply the nutrients in adequate amounts. The WEIGHT WATCHERS Food Program controls your caloric intake to help you lose weight and is structured to supply all the essential nutrients needed for adequate nutrition.

What about calories? Isn't it necessary to reduce calories in order to lose weight?

Losing weight involves limiting your caloric intake so that you expend more calories than you consume. All foods contain calories. A "calorie" is a unit that measures the energy in food. Just as a degree measures temperature, and a watt measures electricity, a calorie measures the energy in food

The caloric value of a food is calculated from the protein, fat and carbohydrate it contains. Fat and carbohydrate provide energy in addition to other factors. Protein also provides for building and maintaining body tissues.

People who select foods, merely by "counting" calories, can't be sure of getting all of the necessary nutrients. The WEIGHT WATCHERS Food Program counts the calories for you and, at the same time, makes sure that you get all of the required nutrients while you lose weight.



What are the differences between protein, carbohydrate and fat?

Carbohydrate and fat are needed, basically, for energy. Any amounts of carbohydrate and fat and some protein which you consume, beyond what you need for energy, can be turned into fat—which means becoming overweight.

Per unit of measure, fat provides nearly 2½ times as many calories as carbohydrate and protein. When you are restricting the amount of calories, it is important to limit the fat in your diet. For this reason, WEIGHT WATCHERS requires you to drink skim milk instead of whole milk.

Fish, a good source of protein, is lower in fat than beef. This is why we ask you to have three to five fish meals per week.

Protein has an important difference from carbohydrate and fat. Protein is made up of building blocks called amino acids. Your body can manufacture some amino acids, but there are eight essential ones which can only be obtained from the food we eat.

Which foods supply protein?

Fish, meat, poultry, milk, eggs and cheese are excellent sources of protein. Some vegetables, especially legumes, are good sources of protein, but no vegetable protein contains enough of all eight essential amino acids. Vegetable, bread, rice, pasta and similar foods, also contain protein.



Why can't we just live on protein and forget about fat and carbohydrate?

That's impossible, because foods that contain protein also contain fat or carbohydrate—or both.

Some fat and carbohydrate are essential for providing energy. By using fat and carbohydrate for energy, the body can reserve protein for growth and repair of body tissue. Fat and carbohydrate are also necessary for proper metabolism, which is what we call the body's mechanism for getting the energy out of food, water and oxygen.

Why not reduce the amount of fat and carbohydrate even further?

The basic elements of fats are referred to as "fatty acids." Some fatty acids are essential for good health, as well as for making food palatable.

Most people consume far more fat than they need. Since fat provides more than twice as much food energy per ounce as either protein or carbohydrate, limiting our intake of fats will keep them from being turned into body fat. The WEIGHT WATCHERS Program limits fat intake primarily to those foods containing the essential fatty acids; such as fish, poultry, vegetable oils, and liquid vegetable oil margarine.

Carbohydrate contains no more food energy than protein. We have moderately restricted carbohydrates to those providing important nutrients. The WEIGHT WATCHERS Food Program is designed as a practical food plan that one can live with while losing or maintaining weight.



But aren't carbohydrates "fattening"?

Whether or not a food is "fattening" depends on how much of it you eat.

Carbohydrates are starches and sugars. Some carbohydrates, like table sugar, provide food energy but nothing else. The complex carbohydrates provide, in addition, some valuable nutrients. Bread and pasta products, rice, potatoes, peas, beans and soybeans all contain complex carbohydrates along with proteins, vitamins and minerals.

Skim milk, for example, not only contains sugar (lactose) but it also contributes other valuable nutrients to the daily food intake. Fruit is another good example. Any food that supplies a large amount of "empty calories" (such as alcohol or table sugar) can have no place in a weight-loss program.



Are some fats better for you than other fats?

Yes, because they are made up of different kinds of fatty acids. Some are called saturated fatty acids. These are the ones in animal fats.

The American Heart Association advises that we should not only limit the total amount of fat in our diet, but we should especially limit our intake of fats which are high in saturated fatty acids.

Butterfat, beef, pork and lamb contain fats that are high in these saturated fatty acids. While there is no need to eliminate beef, pork and lamb from the diet, they should be limited. Butter should be replaced with liquid vegetable oil margarine.

Some fatty acids are called polyunsaturated. These—especially one called linoleic acid—are the ones the American Heart Association recommends that we consume.

Fish contains large amounts of polyunsaturates. So do poultry, corn oil, safflower oil, cottonseed oil and soybean oil (but not coconut oil, palm oil or olive oil). This is why we also specify that the margarine you consume should be the "liquid" vegetable oil variety, so that you will be sure to get all the linoleic acid you need.

What about cholesterol?

Cholesterol is one of several fatty substances (lipids) which circulate in the blood. Having a certain amount of cholesterol in the blood is normal, but high blood levels of cholesterol and other lipids have been associated with increased risk of heart disease.

Some foods are high in cholesterol, and for many people the intake of such foods should be restricted. In addition, your body produces cholesterol in the liver and other tissues.

Some foods which are high in cholesterol are also high in valuable nutrients, so they should be included in a good nutritional food program. Eggs, cheese, and liver are good examples. There are good nutritional reasons for including these foods in our Program, but there are also good reasons for not eating any of them beyond a certain limit. Four eggs, four ounces of hard cheese and one serving of liver are provided weekly in the WEIGHT WATCHERS Food Program.

What is the basic function of vitamins?

Contrary to popular belief, vitamins do not supply energy. However, they do regulate the body's metabolism—that process by which food energy is converted into body energy.

Metabolism is actually a series of chemical reactions. The reactions are accomplished by enzymes. Certain vitamins work with the enzymes to make the chemical reactions happen, and to control these reactions.

What are the most important vitamins?

They are all important, and are provided in amounts adequate for normal human needs by following the WEIGHT WATCHERS Program. However, a few vitamins call for special attention.

Vitamin A is essential for good vision, clear skin, healthy lungs and normal growth. This vitamin is abundant in fish, liver and eggs, and is added to margarine. Vitamin A is also produced by the human liver from a substance called carotene that occurs in some fruits (notably apricots, peaches and cantaloupes) and in many vegetables (notably asparagus, broccoli, carrots and squash).



Vitamin C, or ascorbic acid, is necessary to help the body resist infection. This vitamin plays a role in several enzyme reactions. A diet devoid of fruits (especially citrus fruits) and vegetables (especially cabbages, tomatoes, peppers and potatoes) will be lacking in vitamin C, although the vitamin is also found in some animal organ meats. A large percentage of the vitamin C in food is destroyed by cooking or exposure to air, so fresh or frozen foods are better sources of the vitamin than cooked foods.

The requirements of the WEIGHT WATCHERS Food Program provide more than half a dozen B vitamins, as well as ample

sources of good protein. Thiamine, riboflavin and niacin are the B vitamins named on many food labels. All three of these major B vitamins are provided by whole grain breads, enriched white bread and liver. Meat is a good source of thiamine and niacin, while the best source of riboflavin is a dairy product, such as milk; preferably milk not exposed to sunlight.

And other vitamins?

Folacin (folic acid) Pyridoxine (vitamin B_6), and Cobalamin (vitamin B_{12}) are B vitamins which play important roles in blood formation or in the nervous system. Normal human needs for these three vitamins are amply supplied by a judicious diet which contains a variety of food, including good sources of protein.



Vitamin A is a fat-soluble vitamin. It requires some dietary fat for its absorption. This is also true of vitamin D, vitamin E and vitamin K. Vitamin D prevents some bone malformations and some tooth problems. This vitamin is often added to milk, which is, therefore, a good source.

Vitamin E and vitamin K are also fat-soluble. There is no clear evidence of benefits to be obtained by taking more vitamin E than is found in the WEIGHT WATCHERS Food Program.

Vitamin E plays an important role in red blood cell formation. Vitamin K is needed for blood coagulation.

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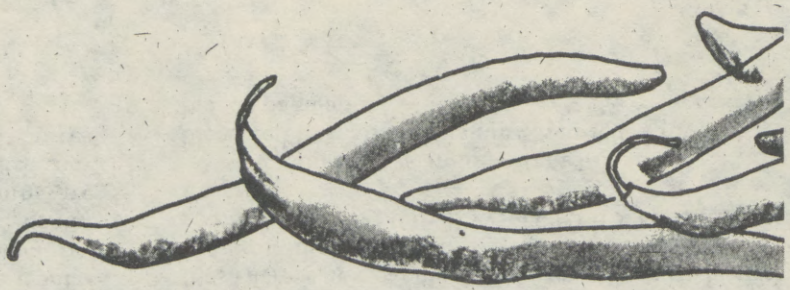
Why are minerals important?

Calcium, magnesium and iron are the three minerals most essential to human nutrition, but more than a dozen others are required in at least trace amounts. Some minerals play important roles in creating cell tissue. All minerals function with vitamins in the chemical reactions that release and utilize energy from protein, fat and carbohydrate.

Minerals must be obtained from dietary sources, including water.



Why are calcium, magnesium and iron the most essential minerals?

The body contains more calcium, and needs more of it, than any other mineral. Calcium's main function is to build and maintain bone and tooth structures, but the mineral has many other important functions, including the regulation of blood clotting. Vitamin D, whose importance we have noted, is essential primarily for the distribution of calcium to the bones and teeth.

Magnesium is also important for proper bone development, and for the regulation of muscles, including heart muscle and nerves.

Iron is an essential part of hemoglobin,

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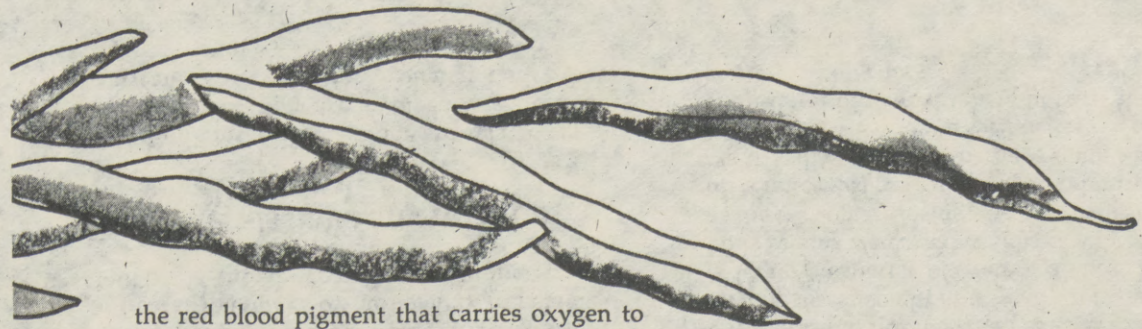
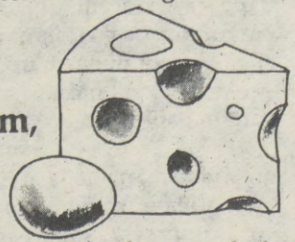


the red blood pigment that carries oxygen to body tissue. A diet deficient in iron reduces the amount of hemoglobin in the blood and causes a form of anemia common among menstruating women.

What foods supply calcium, magnesium and iron?



Milk and other dairy products are the best sources of calcium. Milk, fortified with vitamin D, enables the calcium to be utilized. Two cups of skim milk per day provide close to the Recommended Dietary Allowance (RDA) of calcium for adults over 18. We specify skim milk, rather than whole milk, because it is lower in fat while still providing calcium and other valuable nutrients.

Cheese also provides calcium. Cooked collard greens, turnip greens and mustard greens are other good sources of calcium.

Collard greens also supply magnesium. Swiss Chard and parsley are other good sources of this mineral; as are beet greens, black-eyed peas, soybeans, whole grain breads, coffee and tea.

Many foods are said to be rich in iron, but some of the iron in foods such as eggs, spinach and whole grain breads is not in a form your body can use. So your best food sources of available iron are liver, fish, lean meat, poultry or beans.

What other minerals are important — and why?

Calcium, iron and magnesium are not the only minerals we need. Most of the others—zinc, copper, sodium, potassium, manganese and phosphorous—are widely available in many foods. Therefore, if you eat a variety of foods you will have an adequate supply of these minerals.

Iodine is a mineral element needed in tiny (trace) amounts by the thyroid gland to avoid goiter. Iodine is found in fish and iodized salt.

Sodium and potassium are also important, largely in connection with the body's water balance. Sodium occurs naturally in most foods, and additional amounts of sodium are often added to foods in processing. Potassium is liberally supplied by meats, milk, vegetables and fruits—notably bananas and oranges.

Do minerals have any relation to weight control?

Sodium and potassium are related, in a sense because they are involved in water balance and water retention. You may notice that



some people lose weight more quickly than others, or that you may lose several pounds one week and nothing the next week. Hardly anyone loses weight at a steady rate, and this is largely a matter of water balance. If your body retains water that weighs exactly as much as the fat you are losing, the scale will show no difference. After a period of retention, the water will empty out—perhaps quite suddenly—and you will show a weight loss. You may then level off for a while before showing another weight loss.

What about fiber?

Fiber is a mixture of indigestible substances such as cellulose, hemi-cellulose, lignin, pectin, gums and other consituents of plant cell walls. The composition varies with the food and has not been accurately measured. The fiber (bran) from whole grain differs from that in vegetables and fruits.

The WEIGHT WATCHERS Program contains adequate fiber according to the best medical opinion. If you want more fiber, select whole grain breads, and cereals, such as 40% bran flakes or all-bran.

What about exercise?

Weight control is a balance between energy intake and output. Physical activity burns up food energy that might otherwise be stored as fat.

A nutritious eating plan, supplemented by *appropriate* exercise, speeds fat loss, firms the body, and provides an increased feeling of vitality.

The WEIGHT WATCHERS Program includes a *voluntary* exercise plan called PEPSTEP. It is based on walking and/or stair-climbing, and is designed specifically to meet the needs of overweight individuals. PEPSTEP is a low-level, long-duration program.

WEIGHT WATCHERS strongly recommends checking with a physician before embarking on any exercise program.

Won't I lose weight faster if I eat less than the amount of food on the WEIGHT WATCHERS Program?

If you do, you may soon begin to develop symptoms of semi-starvation because you won't be getting adequate amounts of essential nutrients. You will feel less energetic, less healthy. You will start to lose nitrogen (meaning muscle tissue) rather than fat. On a starvation diet, you lose proportionally more muscle than you do fat. On the WEIGHT WATCHERS Food Program, you lose more fat and a lesser amount of muscle tissue. Most important, on a starvation diet, you do not learn anything about proper eating habits.

The WEIGHT WATCHERS Food Program with its three to five fish meals, one liver meal, two cups of skim milk and all of the other measured components lets you eat enough to feel satisfied, while providing the nutrients needed for good health.

How can you eat so much food on the WEIGHT WATCHERS Program and still lose weight?

Even though the volume of food seems large, the specific foods selected for the Program are low in fat and moderate in carbohydrate, and the total intake of food energy (calories) is restricted.

Why is it important to eat breakfast?

Food intake should be distributed through the day, so that you take in food energy while expending physical energy. When you get up in the morning you have not eaten for six to eight hours. Roughly one-fourth of your total daily intake of food energy should be taken at breakfast. Most of this energy will be used as you go through the morning. Eating breakfast is an important part of a system of controlling the amount of food intake. Food should be digested during your active hours and converted, in large part, into physical energy—rather than stored as fat.

How does everything work together?

The body can pick and choose what it needs from the nutrients in your diet, and sees to it that each organ or part of the body gets exactly the right amount of nutrients—neither more nor less. However, if the diet lacks some of the needed nutrients, the body has no way to get them. The body keeps busy, working 24 hours a day—always building, repairing and discarding waste products. The body needs a constant supply of nutrients to do its job, and it distributes the nutrients where they are needed.

Therefore, for a diet which provides all the needed nutrients, nutritionists suggest eating appropriate amounts of a wide variety of foods—including milk and other dairy products; meat, fish and poultry; fruits and vegetables; bread and cereal; and a certain amount of fats and oils.

The foods you eat must sustain you for today and help build you body for a lifetime.

The WEIGHT WATCHERS Food Program meets all of these goals, and at the same time helps you with the weight reduction you seek.

Our program also provides you with psychological help to overcome the temptation to over-eat. It also teaches you how to maintain your goal weight for life. After all, isn't that what it's all about?

Biographical Note on Dr. W. Henry Sebrell

Dr. Sebrell has been the Medical Director of Weight Watchers International since 1971 and is responsible for keeping the WEIGHT WATCHERS® Program nutritionally and medically sound.

He came to WEIGHT WATCHERS after a distinguished career in research and teaching in human nutrition.

Dr. Sebrell began his professional work as a Medical Officer in the United States Public Health Service where, for many years, he conducted research on nutritional problems in the United States. He became an Assistant Surgeon General and for five years was Director of the National Institutes of Health. He then moved to Columbia University as Professor of Nutrition and developed the Institute of Human Nutrition in the College of Physicians and Surgeons.

He was, for many years, a member of the Food and Nutrition Board of the National Academy of Sciences and was Chairman of the Committee that prepared the 1968 Recommended Dietary Allowances.

He also was a member of the U.S. Food and Drug Administration's National Advisory Food and Drug Committee in 1975-76.

He played an important role in international nutrition problems as a member of the World Health Organization's Expert Advisory Panel on Nutrition, as Consultant to the Food and Agriculture Organization and the United Nations Children's Fund. He was also Chairman of the Protein Advisory Group of WHO/FAO/UNICEF.

Dr. Sebrell in addition to his duties at Weight Watchers International, Inc. is an Advisor to the Obesity Research Center at St. Luke's Hospital in New York.

If you have additional questions regarding Nutrition and the Weight Watchers Program, write to:

Nutrition
Weight Watchers International, Inc.
800 Community Drive
Manhasset, N.Y. 11030

Be the Best



How high is your Interest in your own potential

Answer Yes or No to the following:

Do you...

Look for the best haircutting places around? _____

Dream about dating or being
(a) one of Charlie's Angels (b) Diane Keaton
(c) Rocky (d) Robert Redford? _____

Spend time selecting the perfect outfits? _____

Need enough energy to cover schoolwork, chores, and still have an active social life? _____

Hope to live to a ripe old age? _____

Want to be the best at something? _____

If you answered yes to any of these questions, then turn the page...
You care about yourself, so this pamphlet's for you

. . . This pamphlet is for you because it deals with nutrition. Of course, eating right won't turn you into the best looking girl or guy in the world; it won't up your brain power, or develop you into the new Superman or Wonder Woman.

But Proper nutrition can HELP YOU BE ALL YOU CAN BE. It can give you a shot at reaching the top of your looks, your strength and your talent. How much time do you spend on your looks, your personality? Doesn't it make sense to spend just a fraction of that time to insure your body gets all the food it needs so you grow to your potential—both physically and mentally.

Because when you stop and think about it, if you believe that the chemistry *between* people is complex, you can be sure that the chemistry *within* people is even more so. Without the right foods, in the right quantities, you'll be going through life with a self-made handicap.

So, take a few minutes; glance through this book. It's a series of questions and answers on nutrition that teens seem to ask most frequently. The questions come from across the country, out of seminars held at Weight Watchers® camps, high school classrooms, and from hundreds of letters received at Weight Watchers International. Your questions might be among them. Why don't you check it out?

Prepared by Weight Watchers International, Inc.
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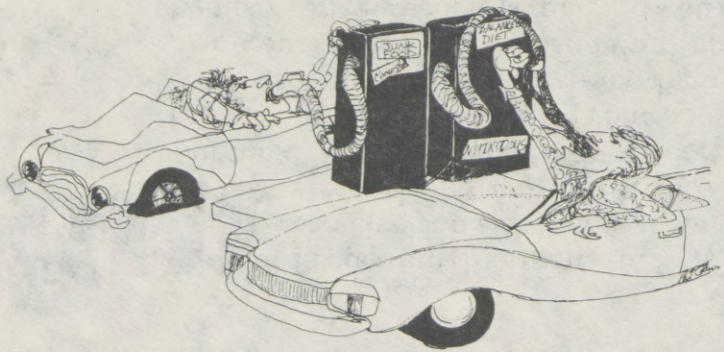
Q: I know that a "Balanced Diet" is supposed to be the healthiest. But, I've been eating my own way all my life, and I'm still here. Isn't this hassle a bit much?



A:

The human body is an incredible machine, and it shares similarities with other machines. Like a car, for instance, the human body won't stop running for the lack of the perfect fuel—at least not immediately. And like that car, the body won't be turned into something it is not by the intake of proper food, any more than a Ford can be turned into a Ferrari by the intake of the proper gasoline.

However, anything but the precise fuel in the precise mix can cause a great many problems in a car's works. Sometimes they show up immediately, sometimes much later. A car can develop knocks, stop running smoothly, or be incapable of performing up to its horsepower, all because the quality of the gas it is being fed is poor.

Your body works the same way. If you don't get the proper foods, in the right proportions, you won't be running to capacity, and some of the harm you may be doing to yourself may not show up for a number of years.

Give yourself the best chance possible. Care about what and how much you eat, and put the odds in your favor for running your longest and performing your best. You are important.

Q: **Even with all the information out today, I still don't know what I should eat. What is a balanced diet?**



A: You feel confused because putting together the right quantities of every nutrient for your daily food intake is a highly complex task.

There are six major types of nutrients contained in food; water, protein, fats, carbohydrates, vitamins and minerals. For a balanced diet, these nutrients are needed in the proper amounts and proportions.

But don't worry about having to put fresh batteries in your pocket calculator to figure our your daily nutritional requirements. Weight Watchers International has put together the following sample menu. It will ensure your meeting the nutritional requirements recommended by the Food & Nutrition Board of the National Research Council, as well as the dietary goals established by the Senate Select Committee on Nutrition and Human Needs.

Teen Menu Plan

The meal pattern below is suitable for all teenagers, even those who are overweight. If you wish to maintain your current weight, follow the meal plan in the left column, and add to it the food in the right column. If you wish to lose weight, follow the plan in the left column only, and don't choose any additional foods from the right column.

MORNING MEAL:
A fruit or fruit juice rich in Vitamin C
Cheese or an egg or breakfast cereal, not presweetened (with 4 fluid ounces of skim milk)
One slice of enriched white bread or whole grain bread with one teaspoon liquid vegetable oil margarine
Eight fluid ounces skim milk

MIDDAY MEAL:
Poultry, meat or fish, cooked, 3-4 ounces, or 6 ounces cooked legumes
One vegetable, such as tomato, celery, broccoli or spinach
Eight fluid ounces skim milk
Two slices of enriched white bread or whole grain bread with one teaspoon liquid vegetable oil margarine
A fruit, such as an apple, pear, orange, peach, nectarine

EVENING MEAL:
Poultry, meat or fish, cooked, 4-6 ounces, or 8 ounces cooked legumes
Two vegetables, such as carrots, cucumbers, cauliflower, eggplant, green beans, asparagus
One slice enriched white bread or whole grain bread with one teaspoon liquid vegetable oil margarine
Fruit, such as berries, cantaloupe, pineapple
Eight fluid ounces skim milk

BETWEEN MEALS OR WITH MEALS:
Bouillion, tomato juice, mixed vegetable juice, raw vegetables, 3-4 glasses (8 fluid ounces each) of skim milk if not taken with meals, and
3-5 fruits daily, also if not taken with meals

Note: Meat, poultry, fish and legumes are served on alternate days. Skin from poultry and drippings and all fat that can be trimmed from the meat should be discarded.

(The above was taken from the Nutritional Adequacy of the Weight Watchers Food Plan)

3 fruit servings
3 bread servings (or cereals, grain products, pasta, rice, etc.)
3 fat servings

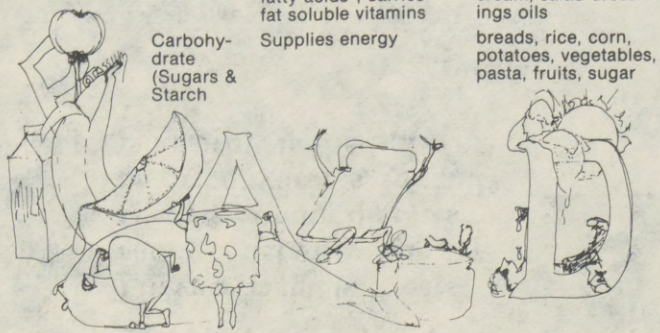
In addition, this menu plan would allow a small serving of cake, pie, cookies, frozen desserts or custard.

About three teaspoons of sugar or other sweets, such as syrups, honey, jams and jellies may be used.

These additional foods will contribute nutrients to the food plan on the left, in an approximate pattern suggested by the Senate Select Committee on Dietary Goals and result in about 2500 calories per day.

Q: Can you tell me the difference between carbohydrates, fat, proteins, vitamins and minerals?

NUTRIENT	FUNCTION	FOOD SOURCE
Water	Medium of all body fluids; carries nutrients; removes waste regulates temperature	water, coffee, tea, fruits and vegetables
Protein	Builds and repairs tissues in body; helps form "antibodies" to fight infection; supplies energy	meat, fish, poultry, eggs, cheese, milk, legumes, grains, nuts
Fat	Supplies "essential fatty acids"; carries fat soluble vitamins	margarine, butter, cream, salad dressings oils
Carbohydrate (Sugars & Starch	Supplies energy	breads, rice, corn, potatoes, vegetables, pasta, fruits, sugar



A:

Proteins, carbohydrates and fats are nutrients that, along with water, supply the body with some of the necessary substances it needs to function. They are contained in foods which are eaten, digested, absorbed, transported to cells and, within the cells are metabolized, in part turned into energy, and the end products are excreted.

At the cellular level, vitamins and minerals, the remaining nutrients, are also needed for metabolic processes.

For a chart of vitamins and minerals, their functions and food sources, as well as the problems created through deficiencies and excesses, write to the Teen Department, Weight Watchers International, Inc., 800 Community Drive, Manhasset, N.Y. 11030.

Q: **I have a friend who eats candy constantly. She says that 58% of our diet has to be carbohydrates, so candy is healthy. Is she right?**

A: She's right in saying that about 58% of our diet should be carbohydrates, if we are not overweight. However, there are two types of carbohydrates, simple and complex. Most candy is almost entirely sugar, and contains no other nutrients —only calories. Fruits, vegetables, breads, pasta, cereals, and the like, contain not only a source of energy, but vitamins and minerals, as well. You should try to consume no more than 10% of your daily carbohydrates from refined sugar.

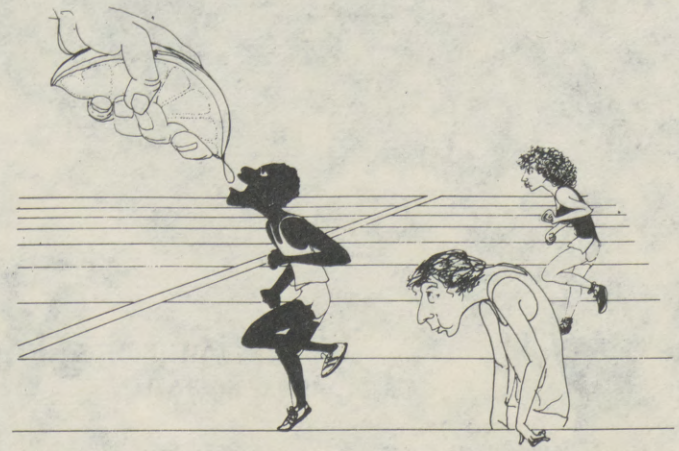
Q: **I take a vitamin pill every day. Doesn't that provide me with all the vitamins and minerals I need?**



A: The value of vitamin supplements is a controversial subject and you should really rely on your doctor for advice. However, most doctors will agree that there is no substitute for a well balanced diet. There are at least 50 nutrients known to be essential for human health, and fewer than 50% of them can be included in supplements.

Further, while a moderate intake of excess vitamins can't harm you, vitamins A and D may prove harmful in megadoses, since they are stored in the body.

Q: **A magazine I read gave a high protein/low carbohydrate diet as the answer to the need for more energy. I'm very active in sports. To improve my energy and my game, should I be eating more protein?**



A: This is one of the few "new" wives tales that has sprung up in today's scientific age. Protein needs don't change with activity. Once you've had enough protein for the body to use in building and replacing tissues, excess protein will simply be turned into fat for storage as an energy reserve. Extra protein has no special miracle properties, and if eaten in great excess, can actually overburden the kidney.

The best thing to do, if you feel you don't have your fair share of energy, is to see your doctor. He can tell you if your diet is deficient, or if you have a minor infection or some other physical cause for feeling low.

If what you need is simply special energy spurts for sports, then what your body does need to give it ultimate efficiency during physical activity is the replacement of the water it loses from perspiration. It also needs some quickly absorbed and quickly released carbohydrate food during the course of the play. Fruit juices are an excellent answer to both needs, and can be quickly consumed.

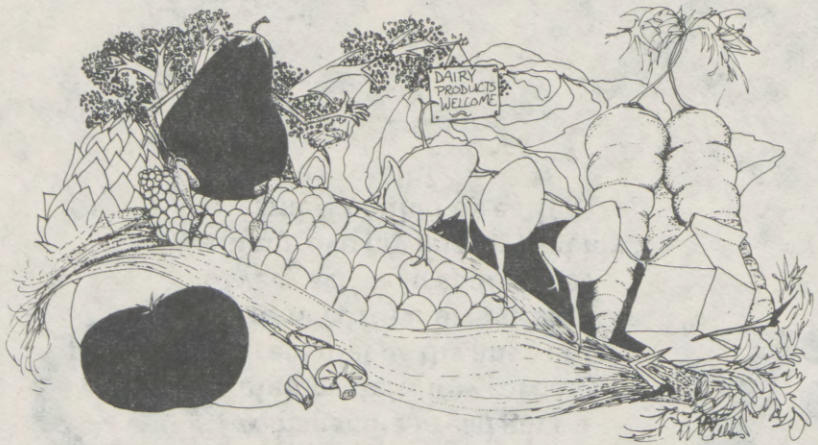
Q: Are vegetarian diets healthy?

A:

It really depends on the type of diet you're on. A vegetarian diet that permits eggs, cheese, milk and milk products can be adjusted to supply the proper amounts of nutrients.

Those diets that exclude dairy products, however, tend to be deficient in vitamin B12.

Before going on any vegetarian diet, see your doctor to ensure that the diet will be balanced.



Q: **I don't eat as much as my best friend. Yet she's really thin and I'm always overweight. Isn't it mostly heredity, about which there's not much you can do? Both my parents are overweight.**

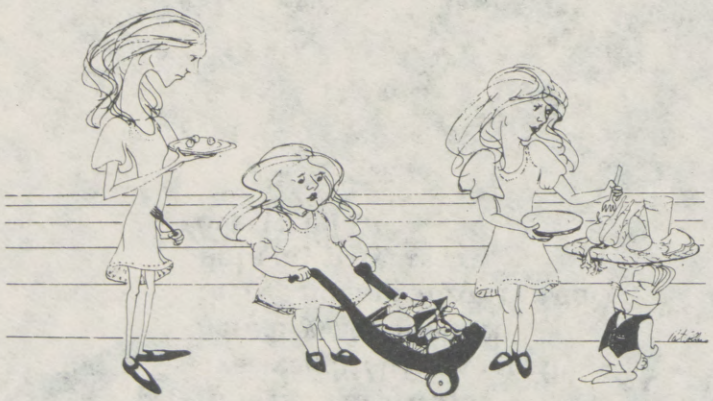


A: It's very possible that your friend, who's eating so much more than you are, is also a lot more active. While it's now believed that heredity may play a small part in overweight, it's pretty well understood that eating habits, and activity levels play much bigger parts.

In fact, studies done by TV tape monitoring of overweight and normal weight teen-age girls, indicate that even when both are involved in a ballgame, for instance, the normal weight teen does a lot more running around after the ball than her overweight counterpart, who was usually found waiting for the ball to come to her.

Remember, it's not only the food you take in, but also the energy you expend, that determines your weight.

Q: What's the fastest way to lose weight?



A:

Studies are proving daily that quick-weight-loss diets are the most susceptible to the equally quick regain of weight. Most of these "9-day-wonder" diets do nothing to retrain your eating habits. You'll quickly go back to your old patterns, regaining the lost weight, and have to start all over again. What's more, this "up and down" weight loss is hazardous to your health.

We know it's very hard to come to terms with the lack of miracles in this field, particularly when there's a special event coming up, or you meet a special person you want to impress. But the idea is to look your best all the time, not just for a short period. That means looking for the *best* diet around, not the quickest.

And the best program diet is one, like Weight Watchers, that includes sound nutrition, a system to help you incorporate increased physical activity into your lifestyle, and a behavior modification plan to assist you to alter your attitudes toward food. It's the type of program that can see you through an entire lifetime.

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Q: **I know I'm overweight. But when my friends go out to eat at one of the local fast food restaurants, I really feel out of it if I don't go along or don't order. Are these foods really so bad?**



A: The key to food selection—diet or unrestricted—in a restaurant or at home, is knowing what you are being offered, and then making intelligent choices about what will be right for you.

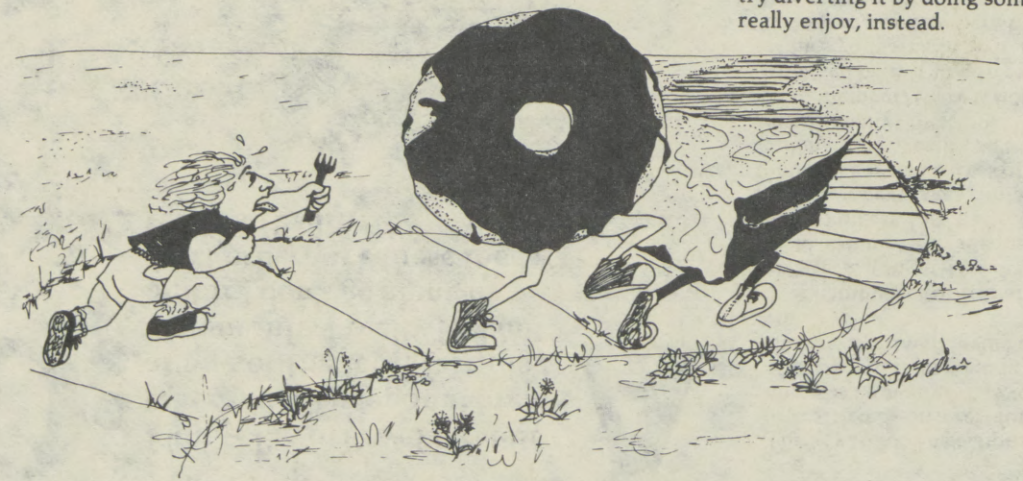
A hamburger or frankfurter broiled on a rack, a sugar-free drink and a salad, can make an adequate meal. But when you ask for fried foods, special sauces or beverages containing sugar, you will have an excess of calories not pulling their weight, so to speak, nutritionally.

Remember, there is nothing to be ashamed of in trying to control or reduce your weight. When you are with friends in a place where there is nothing you can comfortably order, stick to coffee, tea, fruit juice or a sugar-free drink. Joining others by eating what they do, is not going to make you seem thinner in their eyes, and the calories you are consuming with your friends are not going on to <u>their</u> stomachs or hips.

Q: **I'm dieting, but it's really hard to control my sweet tooth. So I was wondering, if I did some extra exercise, whether I could have a donut or a piece of cake when I wanted?**

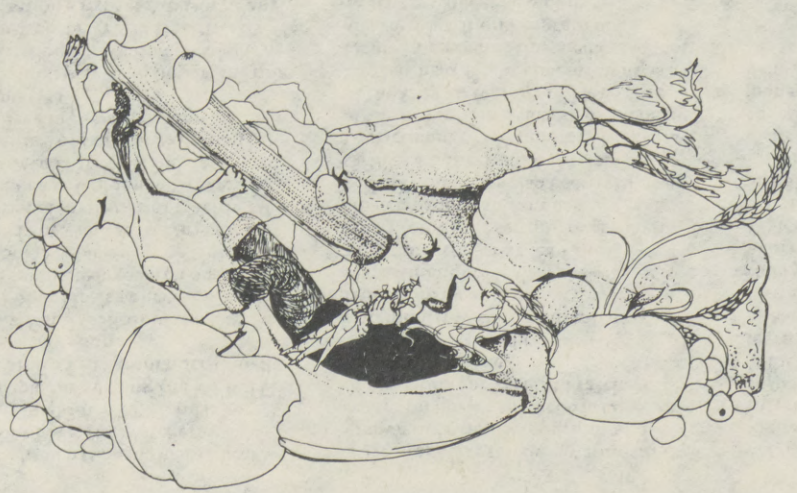
A: Do you really realize how much extra activity you need to work off even one donut? You would have to walk almost four miles for it. Even a small piece of layer cake would cost you 32 minutes of swimming laps.

So, although increasing your activity level is a part of weight control, the most practical solution to your sweet tooth is to satisfy it with something like fruit and desserts designed for the overweight dieter. Or try diverting it by doing something you really enjoy, instead.



Q: **I hear so much about fiber. What, exactly, is it, and how do I get enough?**

A: Scientists are still trying to come up with a definition for fiber. We do know, however, that fiber is a mixture of indigestible substances, such as cellulose and other constitutents of plant cell walls. If you eat a good variety of fruits, vegetables, whole grain breads and cereals, as you would on the menu plan laid out for you on page 5, you'll get adequate fiber in your diet. This will work to help proper elimination.



Biographical Notes on Dr. W. Henry Sebrell

Dr. Sebrell has been the Medical Director of Weight Watchers International since 1971 and is responsible for keeping the WEIGHT WATCHERS® Program nutritionally and medically sound.

As a Medical Officer in the United States Public Health Service, Dr. Sebrell conducted research on nutritional problems in the United States. He has served as Director of the National Institutes of Health. He then moved to Columbia University as Professor of Nutrition and developed the Institute of Human Nutrition in the College of Physicians and Surgeons.

Dr. Sebrell played an important role in international nutrition problems as a member of the World Health Organization's Expert Advisory Panel on Nutrition.

Dr. Sebrell is also an Advisor to the Obesity Research Center at St. Luke's Hospital in New York.

Biographical Notes on Dr. Reva T. Frankle

Dr. Reva T. Frankle, a nationally-known nutritionist, educator and writer on health subjects, is Director of Nutrition for Weight Watchers International, Inc.

As a former public health nutritionist with the Bureau of Nutrition, New York City Department of Health, she was nutritionist-in-charge of the City's Nutrition Clinic serving overweight children and their families.

Dr. Frankle has also been with the Office of Education of the Department of Community Medicine at the Mount Sinai School of Medicine of the City University of New York. She has held a joint appointment as a faculty member of this medical school and the Nutrition Program of Teachers College, Columbia University.

In 1967, Dr. Frankle was the staff nutritionist in the Office of Economic Opportunity's Project Head Start in New York City designing and implementing nutritional guidelines for comprehensive nutrition services for all existing programs.

Biographical Notes on Dr. Richard B. Stuart

Dr. Stuart has been the Psychological Director of Weight Watchers International, Inc., since 1972. He is responsible for helping members of WEIGHT WATCHERS® classes to learn skills in self-management that allow them to follow the recommendations in the nutritionally sound food plans offered in class.

In addition to his work with Weight Watchers International, Inc., Dr. Stuart is Professor of Psychology and Social Work at the University of Utah.

Dr. Stuart has had a long and distinguished career in research concerned with weight control. He pioneered the development of behavior modification techniques for the self-management of eating.

The philosophy of Weight Watchers International encompasses the belief that good eating habits are essential to the nation's health. To further this philosophy, the WEIGHT WATCHERS organization disseminates information on nutrition to the general public and encourages nutrition education programs which foster good eating habits for all segments of the population.



WEIGHT WATCHERS INTERNATIONAL, INC.
800 Community Drive, Manhasset, NY 11030

As a finale for this book, why don't you test yourself on the daily diet you're eating. Answer the following questions and see how well you're really treating yourself:

	YES	NO
1. I manage to get enough fruit, canned or fresh, for the equivalent of at least 3 pieces.	_____	_____
2. Milk products, to make the equivalent of approximately 3 glasses, are in my diet either through drinking milk or through eating yogurt or ice cream.	_____	_____
3. I usually consume about one serving each of dark green leafy and dark yellow vegetables, through juice or salads or as side dishes.	_____	_____
4. I eat about 7 ounces of fish, meat or other protein food.	_____	_____
5. I have at least 4 ounces of breads, cereals, pasta or rice.	_____	_____
6. Polyunsatured fats, like vegetable oil are part of my diet either through salad dressings or cooking.	_____	_____
7. My intake of calories balances with my energy expenditure, so that I'm not overweight.	_____	_____

Just one "no" on this list makes you a potential for some form of malnutrition. That's a pure and simple truth. You are what you eat, from the day you are born—and it's cumulative. The sooner you understand nutritional factors, and modify your diet accordingly, the better your chance of not having food related health problems at any age.

We've tried to give you the facts. What you do with them can affect the quality of your whole life. This knowledge can only go as far as your *action* will take it.

If you would like to know more about this exciting and vital question of nutrition, please write to Weight Watchers International, 800 Community Drive, Manhasset, New York 11030, ATT: Teen Department. We will be glad to send you a list of books that are as interesting as they are valid, as well as the nutrient chart offered on page 6.

"WEIGHT WATCHERS" AND  ARE REGISTERED TRADEMARKS OF WEIGHT WATCHERS INTERNATIONAL, INC., MANHASSET, NY.

Printed in U.S.A.

NATIONAL MEAT ASSOCIATION
Formerly The National Independent Meat Packers Association
734 15TH STREET, N.W., WASHINGTON, D.C. 20005
202/347-1000

March 3, 1980

The Honorable Edward M. Kennedy
2241 Dirkson Senate Office Building
Washington, D. C. 20510

RE: February 20, 1980 testimony by Alex Hershaft, Ph.D., president of Vegetarian Information Service, Inc., Washington, D.C., presented to the Labor and Human Resources' Subcommittee on Health and Scientific Research.

Dear Senator:

The National Meat Association has no quarrel with vegetarians, nor those who advocate vegetarianism as a life style. We do, however, feel it is our responsibility and right to object when a vegetarian uses a prestigious U. S. Senate subcommittee hearing as a personal forum to denigrate meat's contribution to the American diet and vilify it as the root cause for many of the diseases suffered by this country's population. It is especially distressing when such accusations go into the record unchallenged by the distinguished lawmakers who conduct such hearings.

Dr. Alex Hershaft, testifying before the Health and Scientific Research Subcommittee, made some rather startling charges against the long-established practice of consuming meat. His blanket indictment included, among other things, these statements:

- "The risk factor for meat eaters (of suffering heart disease) is approximately three times that for vegetarians."
- "The risk factor for meat eaters is approximately twice that for vegetarians in the case of colon cancer and three times in the case of breast cancer."
- "Consumption of meat and animal fat is responsible for a number of other serious afflictions as well." (He included liver and kidney diseases, gout, soft bones, arthritis, skin wrinkling and cataracts.)

Dr. Hershaft was extremely careful to sidestep or avoid any specific and documented scientific proof for such allegations. Admittedly he did allude to a "half dozen expert panels" and very selectively picked statements from their reports as his evidence. Without reading these reports in their entirety, it is impossible to know in what context the statements were made.

It is interesting to note that he quotes Dr. Arthur Upton, director of the National Cancer Institute, as stating, "Both breast cancer and colon cancer have been generally associated with the level of consumption of animal fat."

Yet, we find that the National Cancer Institute, according to Dr. Upton, is undertaking a study of Utah's Mormon population to determine why its colon and rectal cancer rate is some 22 percent below the national average. While having this below average cancer rate, Mormons' beef consumption is on par with the national average. (Source: The Drovers Journal, October 11, 1979, p. 1)

Despite all the ballyhoo about reducing meat consumption to avoid heart attacks, we were told just last month by the National Heart, Lung and Blood Institute of the National Institute of Health that it can not prove that lowering a person's meat consumption will reduce the risk of heart attack, nor can it prove that a reduction in meat consumption will lower a person's cholestoral level.

The American Council on Science and Health (ACSH), a non-profit New York organization composed of an independent group of scientists representing many disciplines, has conducted "an extensive review of the scientific and popular literature on the relationship of diet to coronary heart disease."

ACSH concluded: "It is premature to recommend basic changes in the diets of most Americans as a means of preventing coronary heart disease." (Source: "Diet Modification: Can it Reduce the Risk of Heart Disease?", published January 1980)

To bolster his cancer causing theory, Dr. Hershaft stated that "meat may contain a number of carcinogenic substances." Included on his list was diethylstilbestrol (DES). Anyone familiar with the cattle industry knows this substance was banned November 1, 1979.

But, to illustrate how far Dr. Hershaft had to reach to make his "scare" point, it should be noted that "the daily estrogen dose in oral contraceptives now used (with no evidence of carcinogenicity) by 35 percent of U.S. women of reproductive ages is several million times the dosage those women would receive from eating meat from animals fed DES." (Source: Gary C. Smith, Ph.D., Animal Science Department, Texas A&M University, in a speech given to the Newspaper Food Editors Conference, October 5, 1979)

Dr. Hershaft also points a finger at nitrites and nitrosamines. Did he do that knowing that "a vegetarian diet will not decrease a person's intake of nitrite? In fact, the opposite may be true." (Source: A speech "Sola Dosis Facit Venenum [Only the dose makes the poison] given by Charles D. Nyberg, May 3, 1979 at Fort Dodge, IA)

Nyberg, secretary and director of public relations, Geo. A. Hormel & Co., Austin, MN, substantiated his statement by pointing out the Council for Agricultural Science and Technology (CAST) at Iowa State University "estimates that 2 percent or less of our exposure to nitrite comes from cured meats. The other 98 percent comes from other sources, including our body's own manufacturing processes."

The allowable nitrite level for curing bacon is 120 parts per million (ppm)-yet lettuce has 100 to 1,400 ppm; beets, 1,200 to 1,300 ppm; spinach, 500 to 1,900 ppm; and the list goes on, according to Nyberg and others.

There is no need to elaborate on the nutritional benefits meat provides to a normal diet. Its role in this respect is very well documented. We can and will supply such information if you so desire.

In conclusion, we candidly concede the National Meat Association has a bias in this issue. It would be foolish and naive on our part to pretend otherwise. Just, as it would be very unbelieveable for anyone to assume that Dr. Hershaft's arguments spring from anything other than a personal bias.

However there is a major difference. Neither this association, nor its individual members (about 300 which represent more than 70 percent of the beef industry and a substantial portion of the pork, and processed meats industry) advocate Americans eat only meat. We firmly believe that good nutrition requires a balanced-diet--one that does not promote over indulgence nor exclusion of any of the basic food groups.

The National Meat Association could not let Dr. Hershaft's demeaning statement go into the record unanswered. To do so would be an abrogation of our responsibility. It is essential that statements which exaggerate or mislead be challenged. And, before we are branded guilty, we believe the proof necessary to convict must be demonstrated, Dr. Hershaft failed to do this.

Very truly yours,

John G. Mohay
President

JGM/daf

Senator METZENBAUM. We will conclude our hearing today with a panel of five witnesses: Nancy Steorts, president, Nancy Steorts and Associates; Dr. Esther Winterfeldt, president and head, Department of Food, Nutrition, and Institution Administration, Oklahoma State University and also president of the American Dietetic Association; Eleanor Williams, Ph. D., Department of Food and Nutrition, University of Maryland, representing the Society for Nutrition Education; Janet E. Tenney, coordinator of nutrition programs, Giant Foods; Dr. Gloria Kinney, director of nutrition education, National Dairy Council.

I am going to ask each of you to confine your remarks to 5 minutes. We are going to be strict about that because it is now almost 12 o'clock and there are some other commitments that Senator Schweiker and I have.

Ms. Steorts, we will be happy to hear you.

STATEMENTS OF NANCY HARVEY STEORTS, PRESIDENT, NANCY HARVEY STEORTS & ASSOCIATES, WASHINGTON, D.C.; ELEANOR WILLIAMS, PH. D., DEPARTMENT OF FOOD AND NUTRITION, UNIVERSITY OF MARYLAND, REPRESENTING THE SOCIETY FOR NUTRITION EDUCATION; ESTHER WINTERFELDT, PH. D., PRESIDENT AND HEAD, DEPARTMENT OF FOOD, NUTRITION, AND INSTITUTION ADMINISTRATION, OKLAHOMA STATE UNIVERSITY, PRESIDENT OF THE AMERICAN DIETETIC ASSOCIATION; JANET E. TENNEY, COORDINATOR OF NUTRITION PROGRAMS, GIANT FOODS; GLORIA KINNEY, PH. D., DIRECTOR OF NUTRITION EDUCATION, NATIONAL DAIRY COUNCIL, ROSEMONT, ILL.

Ms. STEORTS. Thank you, Mr. Chairman.

I am Nancy Harvey Steorts, formerly Special Assistant to the Secretary of Agriculture for Consumer Affairs and now president of Nancy Harvey Steorts & Associates, specialists in consumer affairs. I am speaking to you today as an individual.

I will summarize my statement and submit it to you for the record in its entirety.

The general public is very concerned today about the relationship of their diet to their health and seems to be groping for assistance in making more intelligent diet decisions.

Consumers today want answers to their dietary questions in language which is easy to understand and to apply. They want nutrition information which is accessible to them in their communities. They want information which is relevant to the special needs of their families—their children, their elderly parents and to them as individuals.

The dietary guidelines are a very important first step in the development of a strong nutrition information program. They stress balance, moderation, and variety in the diet.

In reviewing the specific guidelines, it is very apparent that although they lay a very solid foundation, they are only the beginning of a well-coordinated nutrition information program.

In my testimony I have detailed each one of the dietary guidelines and asked specific questions of each.

Where do we go from here?

The dietary guidelines, as I said, are a good foundation for a solid nutrition information program, but the key to their success will be how they are applied by the individual consumer.

What is the best way to provide consumers with the specific information they need to make these dietary guidelines effective?

I feel the label on the product is a very important tool for the consumer. Presently, it is very complex and contains a great deal of confusing information. The label of tomorrow needs to be simple, easy to understand, and should provide valuable nutrition information to the consumer so they can make wise dietary decisions.

In order for these guidelines to work, the total food label needs to be reviewed carefully, and not just on a piecemeal basis. And, again, I have listed my recommendations in my prepared statement more specifically.

A real challenge lies ahead. No single food obviously will give the consumer all the necessary nutrients for good health, but a variety of different foods which are balanced nutritionally and eaten in moderation will improve the health of the American consumer.

So that consumers will know and understand what foods have what nutrients and how they can achieve a balanced diet in moderation, it is necessary that there be a massive, well-coordinated nutrition education program.

So, therefore, I would like to recommend to this committee that a Nutrition Education Council be formed with the specific responsibility of formulating an exciting, well-coordinated nutrition program for the United States.

I would recommend that the Nutrition Education Council be modeled after the Food Safety Council, which is a nonprofit organization established to develop viable standards for determining the safety and wholesomeness of food and food ingredients. This Nutrition Education Council should be comprised of equal numbers of the public and industrial sector, and should be chosen from academia, government, professional societies, consumer organizations, and industry in order to provide a broad and balanced representation of society.

Many organizations I know are addressing this issue today—but I envision this Council serving as the catalyst in developing an overall plan and strategy that will tap all nutrition resources—or should I say that will tap all resources in a unified manner to most effectively bring nutrition information to the consumers of this country, and which will encourage new marketing and communication strategy.

Consumers, food manufacturers, producers, restauranteurs, academicians, nutritionists, Government officials, advertising and public relations executives need now to work together and form a partnership to develop a strong, effective nutrition education program which will effectively meet the needs of the individual.

A solid foundation has been laid; let us now build the framework together.

[The prepared statement of Ms. Steorts follows:]

For Further Information
Contact:
Nancy Harvey Steorts
at
(202)229-1766

STATEMENT OF

NANCY HARVEY STEORTS
President, Nancy Harvey Steorts & Associates
Specialists in Consumer Affairs

Formerly Special Assistant to the Secretary of
Agriculture for Consumer Affairs

Before the:
Senate Committee on Labor and Human Resources
Subcommittee on Health and Scientific Research
United States Senate
February 20, 1980

x x x x x x x

Hearing on Dietary Guidelines

x x x x x x x

Mr. Chairman and Member of the Committee: I am Nancy Harvey Steorts, formerly Special Assistant to the Secretary of Agriculture for Consumer Affairs and now President of Nancy Harvey Steorts and Associates--Specialists in Consumer Affairs. I am speaking to you today as an individual.

It is noteworthy that this Subcommittee is holding a hearing today on the Dietary Guidelines which were recently released by the U.S. Department of Agriculture and the U.S. Department of Health, Education and Welfare.

CONSUMER CONCERNED TODAY ABOUT HEALTH

The general public is very concerned today about the relationship of their diet to their health and seems to be groping for assistance in making more intelligent diet choices. In a recent study in "Family Health in an Era of Stress" by Yankelovich, Skelly & White, Inc., it showed that indeed families in the United States do, in fact, care about their health and are willing to do something about it, but they need and want better information upon which to base these decisions.

High blood pressure, heart problems, cancer, obesity and allergies are all major health concerns today and we must address these serious health problems in a very intelligent manner and with all the information possible to assist the consumer in making correct buying decisions in both the marketplace as well as in the restaurant in order to help prevent or correct some of these major health problems.

Consumers today want answers to their dietary questions in language which is easy to understand and to apply. They want nutrition information which is accessible to them in their communities. They want information which is relevant to the special needs of their families--their children, their elderly parents and to them as individuals.

DIETARY GUIDELINES STRESS BALANCE, MODERATION, AND VARIETY IN DIET

The Dietary Guidelines are a very important first step in the development of a strong nutrition information program. They stress Balance, Moderation, and Variety in the diet.

In reviewing the specific guidelines, it is very apparent that although they lay a very solid foundation, they are only the beginning of a well-coordinated nutrition information program.

1. When we say "Eat a variety of foods," what do we mean? What are the component parts of specific foods? What nutrients are in which foods? How much of each food should one have?

2. To Maintain Ideal Weight is very important, but I question the suggested body weights on the enclosed chart. There seems to be too much variance within the individual ranges. For example, it does not seem reasonable that a man who is 5' 10" would have a weight range between 140 to 174 lbs., nor does it seem reasonable for a woman who is 5' 6" to have a weight range from 114 to 146 lbs.

3. The Dietary Guidelines recommend avoiding too much fat, saturated fat, cholesterol, sugar, and sodium. What is too much? Different individuals do have different requirements. What I think is important here is to reduce the consumption levels of these substances, but not to eliminate them totally. If these substances are eaten in moderation, consumers should be able to avoid unnecessary health problems. This point, I think, needs to be made very clearly and concisely in the follow-up nutrition-education program.

4. Eat Foods with Adequate Starch and Fiber. This is a new concept to many consumers. There have been many misconceptions in the past, but again new solid nutrition information can correct some of these misconceptions. As an example, the Potato Board has done a very effective information program educating consumers about the positive nutrient value of the potato, and as a result has corrected some of the incorrect myths about the potato.

5. If You Drink Alcohol, Drink in Moderation. Does this also apply to wine and beer? Alcoholic beverages presently have no specific nutritional information on the beverage label which could be helpful to the consumer.

WHERE DO WE GO FROM HERE?

The Dietary Guidelines are a good foundation for a solid nutrition information program, but the key to their success will be how they are applied by the individual consumer.

What Is the Best Way to Provide Consumers with the Specific Information They Need to Make These Dietary Guidelines Effective?

The label on the product is a very important tool for the consumer. Presently, it is very complex and contains a great deal of confusing information. The label of tomorrow needs to be simple, easy to understand, and should provide valuable nutrition information to the consumer so they can make wise dietary decisions.

THE TOTAL FOOD LABEL

In order for these guidelines to work, the total food label needs to be reviewed carefully, and not just on a "piecemeal" basis. The format on the label is very important, and information should be presented in a manner which is easily understood by all consumers. The print should be large enough to read easily, the picture of the product should be an accurate one. The key informational elements I recommend are:

1. Statement of Declaration which lists all ingredients in descending order of predominance by weight.
2. Listing the percentage of ingredients for the principle ingredients.
3. Nutrition Information for the macro-nutrients (protein, carbohydrate, fat) as well as Total sugar, sodium, potassium, and cholesterol.
4. Standardized serving sizes.
5. Number of calories per serving.

6. Open-date labeling, with standardized language.
7. Drained weight figures.
8. Storage information.

The improved food-label is just one more step which will help consumers improve their dietary decisions.

A REAL CHALLENGE LIES AHEAD

No Single food obviously will give the consumer all the necessary nutrients for good health, but a Variety of different foods which are balanced nutritionally and eaten in moderation will improve the health of the American consumer.

So that consumers will know and understand what foods have what nutrients and how they can achieve a balanced diet in moderation, it is necessary that there be a Massive, Well-Coordinated Nutrition Education Program.

RECOMMEND A NUTRITION EDUCATION COUNCIL

I would like to recommend to this Committee that a Nutrition Education Council be formed with the specific responsibility of formulating an exciting, well-coordinated nutrition education program for the United States. I would recommend that the Nutrition Education Council be modeled after the Food Safety Council, which is a nonprofit organization established to develop viable standards for determining the safety and wholesomeness of food and food ingredients. This Nutrition Education Council should be comprised of equal numbers of the public and industrial sector, and should be chosen from academia, government, professional societies, consumer organizations and industry in order to provide a broad and balanced respresentation of society.

Many organizations I know are addressing this issue today--but I envision this Council serviing as the catalyst in developing an overall plan and strategy that will tap all resources in a unified manner to most effectively bring nutrition information to the consumers of this country.

IS ANYTHING BEING DONE AT THIS POINT?

There are some exciting exmaples of some innovative programs now being tried by some of our major companies. For example, Quaker Oats Co. held, under the direction of Dr. Robert Nesheim, Vice President, Science and Technology, an all-day Nutrition Seminar last year for all of their chief executives. Seminar

speakers addressed the nutritional concerns of the adult population on the basis of their own scientific expertise or knowledge. As a result, very frank and open discussions were held on how this food manufacturer should respond to help develop a healthier adult population.

Kraft, Inc., under the direction of their Vice President of Consumer Affairs Dorothy Holland, has formed a Nutrition Advisory Council, composed of independent experts from throughout the United States. This group met jointly with the Corporation's Nutrition Task Force and planned an in-house Nutrition Seminar for all of their chief executives with a major focus on the important nutrition issues.

Pillsbury, Inc., under the direction of Dr. Howard Bauman has developed a computer of nutrition information.

General Mills, Inc., has sponsored a series of research reports conducted by Yankelovich, Skelly, & White, Inc., on The American Family. The most recent of these focused on "Family Health in an Era of Stress." In addition to the report, they hold Family Forums throughout the country in order to discuss the results with people of various disciplines. These participants make major recommendations for the improvement of the delivery system of health information.

The Food Marketing Institute, Community Nutrition Institute, and Family Circle magazine have jointly sponsored for the last three years a most effective Conference on Nutrition and the American Food System.

Giant Food has been a real leader in the Washington, D. C., area in the development of some very exciting Comumer Education programs--most especially their cooperative effort with the Heart and Lung Institute on "How to Have a Healthy Heart."

Jewel Food Stores in Chicago have been putting some very informative nutrition information in their weekly food ads, along with the very helpful week consumer column which focuses on nutrition written by Jane Armstrong, Vice President of Consumer Affairs.

Hunt-Wesson, Inc., a food manufacturer in California has initiated a "How to Buy" series, which has assisted many consumers.

The Sheraton Hotels in one of their restaurants in Boston developed a menu which listed the nutritional composition and calories of their menu items.

Each of these individual initiatives is to be commended and is helpful, but what we need today is a coordination of nutrition education efforts.

COORDINATED EFFORT

Consumers, food manufacturers, producers, retauranteurs, academicians, nutritionists, government officials, advertising and public relations executives need to work together now and form a partnership to develop a strong, effective Nutrition Education program which will effectively meet the needs of the individual.

A solid foundation has been laid; let us now build the framework together.

* * * * * * * *

For further information contact
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(202)229-1766

Senator METZENBAUM. Thank you very, very much Ms. Steorts. We will be very happy to hear from you, Dr. Winterfeldt.

Dr. WINTERFELDT. Thank you very much.

I do appreciate this opportunity to present our statement for the American Dietetic Association, which is a professional society with 40,000 members, having been established in 1917. The objectives of The American Dietetic Association are: to improve the nutrition of human beings; to advance the science of dietetics and nutrition; and to promote education in these and allied areas.

We were pleased to hear earlier references made to National Nutrition Month. I would point out that the American Dietetic Association did initiate this first as National Nutrition Week, and it is now National Nutrition Month. And I cannot resist adding that we have sought congressional endorsement for the concept of National Nutrition Month.

Senator METZENBAUM. I want to point out the subject of a discussion yesterday at the Judiciary Committee—national this or something or other month or week or day—it was not directed at National Nutrition Month, it no longer means as much. I have taken a minute of your time.

Dr. WINTERFELDT. As nutrition educators and trainers of others who conduct nutrition education, we are involved in taking leadership in providing nutrition information; in interpreting nutrition facts accurately; and stating these in terminology that people can understand and apply; in reducing the time lag between the discovery of nutrition knowledge and its application to food practices; and recognizing and utilizing human motivation to bring about change in food practices.

Nutrition education is the process by which beliefs, attitudes, environmental influences, and understanding about food lead to practices that are scientifically sound, practical, and consistent with individual needs and available food resources.

The American Dietetic Association takes the position that nutrition education should be available to all individuals and families. The fundamental philosophy of nutrition education is that efforts should focus on the establishment and protection of nutritional health rather than on crisis intervention. It is needed, regardless of income, location, or cultural, social, or economic practices or level of education. Nutrition education must be a continuing process moreover through the life cycle as new research brings additional knowledge.

Nutrition education must help to close the gap between available nutritional knowledge and its application to the quality of life.

The American Dietetic Association recommends that:

One, nutrition education be identified as a part of every program that educates for personal, family, and community health.

Two, consumers participate in defining their expectations and needs for nutrition information which can be met by nutrition education.

Three, persons who conduct nutrition education should be qualified by specific training in human nutrition and educational techniques.

Four, nutrition education with adequate funding be a regular part of the training of teachers, medical and dental professions and allied health personnel.

Those who teach nutrition must not only be well educated in nutrition and food sciences, but they must also develop skills in the selection and use of the appropriate behavioral science and educational approaches to motivate changes in food selection.

The nutrition educator must be ready to utilize a variety of media to assist the consumer in making wise food choices. Nutrition messages must be credible, authoritative and thought provoking.

Label information must be concise, clear information, with specific ingredients related to caloric content of the recommended portions.

Aware of the limitations of time to present our views, we have attached a copy of the full text of this paper in which we have specified and defined content areas for nutrition education.

Thank you for inviting us to participate in this hearing.

[The prepared statement of Dr. Winterfeldt with attachments follows:]

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THE AMERICAN DIETETIC ASSOCIATION
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TELEPHONE: (312) 280-5000 (312) 280-

Statement of
The American Dietetic Association

Delivered by
Esther Winterfeldt, Ph.D., R.D.
President
The American Dietetic Association

at the
Oversight Hearing on Nutrition Education and Health

Before

Committee on Labor and Human Resources
Subcommittee on Health and Scientific Research
The United States Senate
Washington, D.C.

February 20, 1980

THE AMERICAN DIETETIC ASSOCIATION
430 NORTH MICHIGAN AVENUE, CHICAGO, ILLINOIS 60611
TELEPHONE: (312) 280-5000 (312) 280-

My name is Esther Winterfeldt, Ph.D., R.D. I am the President of The American Dietetic Association and I am employed as Professor and Head of the Department of Food, Nutrition and Institution Administration at Oklahoma State University in Stillwater, Oklahoma. My statement before the Committee today is made as the representative of the 40,000 members of The American Dietetic Association. Established in 1917, the objectives of the Association are: to improve the nutrition of human beings; to advance the science of dietetics and nutrition; and promote education in these and allied areas.

Members of The American Dietetic Association are specialists educated for a profession responsible for the nutritional care of individuals and groups. This care includes the application of the science and art of human nutrition in helping people select and obtain food for the primary purpose of nourishing their bodies in health or disease throughout the life cycle. This participation may be in single or combined functions; in foodservice systems management; in extending knowledge of food and nutrition principles; in teaching these principles for application according to particular situations; or in dietary counseling.

Dietetics is a profession in which objectives are accomplished through working with people. Knowledge of food and nutrition qualifies the dietitian as the health professional equipped to help individuals, families, and groups improve their food practices and their nutritional status. The dietitian is a translator of the science of nutrition into

the skill of furnishing optimal nourishment to people. As nutrition educator and as trainer of others who conduct nutrition education, the dietitian:

1. Takes leadership in providing nutrition information.
2. Interprets nutrition facts accurately.
3. States them in terminology that people can understand and apply.
4. Aims to reduce the time lag between the discovery of nutrition knowledge and its application to food practices.
5. Recognizes and utilizes human notivation to bring about change in food practices.

We believe that consumers can be helped to improve their nutritional health through nutrition education with emphasis in school and community programs and the use of a wide variety of media.

Nutrition education is the process by which beliefs, attitudes, environmental influences, and understanding about food lead to practices that are scientifically sound, practical, and consistent with individual needs and available food resources.

The American Dietetic Association takes the position that nutrition education should be available to all individuals and families. The fundamental philosophy of nutrition education is that efforts should focus on the establishment and protection of nutritional health rather than on crisis intervention. It is needed, regardless of income, location, or cultural, social, or economic practices or level of education. Nutrition education must be a continuing process through the life cycle as new research brings additional knowledge.

Research increasingly supports the many roles of nutrition in physical and mental development and in achievement of high-level "wellness" and productivity. Epidemiologic, clinical, and experimental evidence

shows that faulty nutrition and diet are important risk factors precipitating current crippling and killing diseases. The public is asking more searching questions about: The relationship of dietary factors to health; the quality of the food supply; and national policies regarding the use of world food and energy resources. These observations spotlight the challenge to close the gap between available nutritional knowledge and its application to the quality of life.

The American Dietetic Association recommends that:

1. Nutrition education be identified as a part of every program that educates for personal, family, and community health.
2. Consumers participate in defining their expectations and needs for nutrition information which can be met by nutrition education.
3. Persons who conduct nutrition education should be qualified by specific training in human nutrition and educational techniques.
4. Nutrition education with adequate funding be a regular part of the training of (a) teachers, (b) medical and dental professions, (c) allied health personnel.

The objective of nutrition education is to transmit knowledge to consumers about their nutritional needs and the nutritive value of foods in a way which will motivate them to transform this knowledge into eating behavior which promotes health and well-being.

Food contributes much more than life-sustaining nutrients. It can serve as an emotional outlet; a means of communication; a symbol of status or hospitality. Food is useful in striving to satisfy needs for security, comfort, enhancement of ego. It may even be used to express or alleviate pain. Eating patterns evolve from: Tradition; ethnic background; social and economic influences; religious practices; and food

availability. With improved methods of food production, processing, and preservation, rapid transportation and communication, a wide variety of foods is now available everywhere, expanding food choices. Increased population mobility and more interaction between people have resulted in exchanges of traditional food experiences.

Because eating behavior is so deeply woven into the fabric of daily living, it does not yield easily to new knowledge about nutrition. The nutrition educator must be keenly aware of the many meanings and uses that individuals may make of food, as well as of its general availability and acceptability. Those who teach nutrition must not only be well educated in nutrition and food sciences, but they also must develop skills in the selection and use of the appropriate behavioral science and educational approaches to motivate changes in food selection.

Today, the nutrition educator must be ready to utilize a variety of media to assist the consumer in making wise food choices. Radio, television, newspapers, books, pamphlets and magazines are reaching the public with nutrition information. Each has its important place in bringing a message that must be credible, authoritative and thought-provoking. Written information can provide more in-depth scientific information that may be re-read and studied.

At this time I should like to explore, briefly, the potential of food labeling as a nutrition education medium.

Food labeling as a method of protecting consumers by informing them of the content of food products has been in existence since the passage of the Federal Food, Drug and Cosmetic Act of 1938. Interest in this communication medium was revived as a result of the recommendations made at the 1969 White House Conference on Food, Nutrition and Health. These recommendations plus the growing public awareness of the

relationship of food and nutrition to health have resulted in greater public concern for more and better nutrition information on food labels.

Food labeling that includes both ingredient and nutrition labeling can be a vehicle for consumer nutrition education.

In 1978, The American Dietetic Association published a policy statement on Nutrition Labeling and I should like to quote from that statement:

"The American Dietetic Association is committed to the establishment and maintenance of standards and regulations for the labeling of processed foods which will provide the consumer with information relative to the nutrient content and nutritional quality. The information on the label should be worded in such a manner and based on such units of measurement that the consumer will know the nutrients in the food he purchases and use this information in selecting a nutritious diet."

The American Dietetic Association wants to underscore that the language should be clear and concise, easily found and easily read and interpreted. For example, the energy value of foods are of prime importance today as the public begins to understand the need for controlling body weight. The term "Calorie" is generally well understood by the consumer, and should receive special emphasis on the label.

Nutrients stated on a label should be for a designated serving or amount of the food. They should include total Calories per serving as well as a breakdown of calories from protein, fat, and available carbohydrates. The amount of sodium and cholesterol should be declared, and other nutrients present in a food if in amounts of 5% or more of the U.S. Recommended Dietary Allowances (U.S. RDAs).

When ingredients are listed in percentages we recommend that they be for commonly served portion sizes, not for the full content of the

package. When designating portion size we recommend that the language most understood by consumers, e.g., cups, tablespoons, etc., be used rather than grams and milligrams.

Nutrition labeling is an important tool to be used by the knowledgeable consumer and the counselor who instructs those needing assistance in planning and implementing modified diets. Whatever information is given the consumer will need help in interpreting it and applying it to a daily regimen. Such instruction should be a part of nutrition education programs and should be kept current as labeling changes are made.

Registered Dietitians are probably the largest group of instructors of those who need assistance with special dietary needs. Labels on foods for special dietary uses should bear a statement of usefulness consisting of a list of dietary properties upon which special use is based. The list of nutrients should be confined to those which are of significant value and need in human nutrition. Long lists of nutrients tend to unduly influence the consumer. While those having special dietary requirements may eventually become more sophisticated in their ability to interpret information, we recommend that for these consumers the portion, nutrient and ingredient information should be given in terminology similar to that for the general public.

Learning to read and understand the nutrition information on labels is one way consumers can assume some responsibility for their nutritional health. Nutrition education can be the first step in so assisting the consumer.

I appreciate this opportunity to express the attitude and recommendations of The American Dietetic Association related to nutrition education. In developing my statement I have quoted extensively from a 1978 position paper of our association entitled, "Position Paper on the Scope

and Thrust of Nutrition Education". Aware of the limitations of time to personally present our views I have attached a copy of the full text of this paper in which we have specified and defined content areas for nutrition education.

Thank you for inviting us to participate in this hearing. I would be happy to answer any questions you might have at this time.

Attachments:2

Position Paper on the scope and thrust of nutrition education[1]

Research increasingly supports the many roles of nutrition in physical and mental development and in achievement of high-level "wellness" and productivity. Epidemiologic, clinical, and experimental evidence shows that faulty nutrition and diet are important risk factors precipitating current crippling and killing diseases. The public is asking more searching questions about: The relationship of dietary factors to health; the quality of the food supply; and national policies regarding the use of world food and energy resources. These observations spotlight the challenge to close the gap between available nutritional knowledge and its application to the quality of life. Leaders in government and industry now speak of nutrition education as a critical issue.

Philosophy and definition

Nutrition education was defined in The American Dietetic Association's 1973 Position Paper on "Nutrition Education of the Public" (1) as "the process by which beliefs, attitudes, environmental influences, and understanding about food lead to practices that are scientifically sound, practical, and consistent with individual needs and available food resources. The American Dietetic Association takes the position that nutrition education should be available to all individuals and families. The fundamental philosophy of nutrition education is that efforts should focus on the establishment and protection of nutritional health rather than on crisis intervention. It is needed, regardless of income, location, or cultural, social or economic practices, or level of education. Nutrition education must be a continuing process throughout the life cycle as new research brings additional knowledge."

It is timely for The American Dietetic Association to expand its position to delineate the scope and thrust of nutrition education and the qualifications of those given the responsibility for designing and implementing curriculum and programs.

Content of nutrition education

The objective of nutrition education is to transmit knowledge to consumers about their nutritional needs and the nutritive value of foods in a way which will motivate them to transform this knowledge into eating behavior which promotes health and well-being.

Food contributes much more than life-sustaining nutrients. It can serve as an emotional outlet; a means of communication; a symbol of status or hospitality. Food is useful in striving to satisfy needs for security, comfort, enhancement of ego. It may even be used to express or alleviate pain. Eating patterns evolve from: Tradition; ethnic background; social and economic influences; religious practices; and food availability. With improved methods of food production, processing, and preservation, rapid transportation and communication, a wide variety of foods is now available everywhere, expanding food choices. Increased population mobility and more interaction between people have resulted in exchanges of traditional food experiences.

Because eating behavior is so deeply woven into the fabric of daily living, it does not yield easily to new knowledge about nutrition. The nutrition educator must be keenly aware of the many meanings and uses that individuals may make of food, as well as of its general availability and acceptability. Those who teach nutrition must not only be well educated in nutrition and food sciences, but they also must develop skills in the selection and use of the appropriate behavioral science and educational approaches to motivate changes in food selection.

In this paper, The American Dietetic Association specifies and defines content areas for nutrition education. Consumers must be informed as to the current status of knowledge of nutrition, as well as the areas under scientific investigation. Given the flow of research findings in nutrition and food sciences; the shifting availability of food products and nutrient alternatives; and the complexity of eating behavior and the environment, consumers must be motivated to continually seek and apply new knowledge. Nutrition educators, using behavioral science skills, recommend a systematic approach, building on a continuum of knowledge. Knowledgeable use of the existing food supply dictates that consumers acquire some understanding of the following areas of nutritional science and food economics:

(a) How the body uses food in health and disease, including: Ingestion, digestion, absorption, and metabolism; functions and interactions of nutrients in the body; interrelationships of foods and drugs; and nutrient and caloric composition of food.

(b) Components of a nutritionally sound eating pattern, with appropriate modifications for the vari-

[1]Approved by the Board of Directors on December 1, 1977 as Position Paper No. 0000T.

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ous periods of life in both health and disease.

(c) Criteria for critically analyzing published nutritional information and understanding areas of honest controversy.

(d) Factors affecting the economics, availability, and quality of the food supply.

(e) Social and emotional influences on personal use of food.

In addition, the nutritionally articulate consumer, the community leader, and the opinion molder must acquire the capability to:

(a) Relate nutritional facts to conditions in the community and availability of nutrition services.

(b) Develop community awareness that nutrition is one of the most important components of major health maintenance and promotion programs and strategies.

(c) Organize concerned individuals to actively influence legislators to propose needed legislation related to health, food, and nutritional issues.

With rapidly changing conditions influencing life styles and sources of nutrients, the consumer must be educated to accept nutritional well-being as a personal responsibility.

Strategies and settings for nutrition education

The American Dietetic Association recommends that priority be given to the development of a national nutrition policy that will include a comprehensive nutrition education program for the public integrated into: Educational systems, food assistance programs, the health care delivery system, and mass media programming. Policy-making at the national level by recognized nutrition professionals, working with informed lawmakers, is needed to overcome the current problems of fragmentation, conflict, and inconsistency which bewilder the public and contribute to food faddism on one hand and apathy on the other.

The structure for the system should be developed at the federal level to assure continuity and to identify gaps, providing appropriately for implementation at the state and local levels. The structure must allow flexibility for regional and local needs.

Educational systems

PRIMARY AND SECONDARY EDUCATION. Nutritional concepts introduced to children sequentially as an important element of their basic education can provide them with a sound knowledge base and influence lifelong attitudes and habits. Developing nutritional concepts concurrently with the child's growing understanding of the biologic and social sciences can provide the broad understanding needed by today's consumer. Nutritional concepts can be integrated into on-going classroom curricula, as well as in the school foodservice and school health programs. Federal legislation should fund nutrition education in schools. The American Dietetic Association recommends that a systemized approach include:

(a) Sequential nutrition concepts taught from kindergarten through grade 12.

(b) Utilization of the most appropriate learning environment and strategies.

(c) Integration of nutritional concepts into appropriate subject matter areas and/or as a separate series of instructional units, depending on the educational curriculum and needs of the students.

(d) Development of appropriate methods and materials by educators familiar with the educational process, the science of nutrition, and curriculum development.

(e) Coordination with appropriate state and local agencies.

Nutrition education specialists must be employed in school systems to develop, implement, and coordinates plans for nutrition education. They should:

(a) Plan the nutrition education program with the school administration, teachers in related subject matter areas, and school foodservice personnel, in order to select and use appropriate content and educational techniques consistent with the school system's educational philosophy.

(b) Conduct continuing staff in-service education regarding current nutritional information needed by teachers and school health workers.

(c) Serve as consultants to administrators on nutrition and child nutrition legislation and funding sources for nutrition education.

(d) Cooperate with the physicians, dentists, and nurses providing school health services, so that nutritional risk-factor screening and recommendations for follow-up can be part of health care.

(e) Educate parents to provide continuity from school to home, and acquaint parents with the information provided to their children.

(f) Utilize other community food and nutrition education agency personnel, such as Cooperative Extension, voluntary health agencies, and food industry home economists.

(g) Coordinate efforts of all personnel within the school system in disseminating nutritional information, using reliable educational materials to assure consistency.

(h) Refer families needing food or financial assistance to the social services in the school or community.

PROFESSIONAL EDUCATION. Physicians, dentists, nurses, public health workers, and teachers need to understand the relevance of nutrition to their own professional goals. The American Dietetic Association recommends that basic course content and continuing education for health-related professionals include current nutritional information and the appropriate physical and social sciences. Health professionals should be oriented to the nutrition education role of the registered dietitian on the health care team. With the increasing level of sophistication of nutritional

knowledge, health workers should be prepared to utilize the expertise of the registered dietitian as a consultant and educator for themselves and their patients or clients.

ADULT EDUCATION. It is recommended that nutrition departments of colleges and universities be encouraged to offer basic nutrition courses as electives for all students majoring in elementary and secondary education, as well as for all other interested students.

The American Dietetic Association further recommends employment of professionally qualified nutrition education specialists to develop and teach the nutrition courses offered in any adult education programs in the community. The goal of these courses should be to teach adult consumers current nutrition facts that will help them make knowledgeable food choices.

Cooperative Extension home economics and 4-H programs traditionally have provided homemaker groups and youth with information about normal nutrition and family food management. As these and other groups in the community expand the scope of their programs and outreach, all nutrition education efforts need to be planned cooperatively and closely coordinated for consistent nutrition content.

Foodservice workers in public and private eating establishments increasingly influence consumer food choices. Suitable nutrition education opportunities must be offered to workers employed in foodservice industries through their trade associations and educational institutions.

Health care delivery systems

Quality health care requires that nutrition education be an essential component of all preventive, maintenance, treatment, and rehabilitative programs. The American Dietetic Association recommends that:

(a) Third-party reimbursement plans of both public and private health insurers should specify nutrition and dietary counseling as required, reimbursable services.

(b) Nutrition education and dietary counseling should be part of the array of services offered in all private or public health care settings.

(c) Public health agencies at all levels of government should be funded to strengthen their leadership in developing the nutrition education component of preventive services.

(d) Public, voluntary, and private health agencies' efforts should be coordinated to reach specified nutritionally vulnerable segments of the population. High-risk and vulnerable population groups needing special attention include: Pregnant women (especially the adolescent); infants and children; the elderly; the poor; those at risk of chronic disorders, such as obesity and heart disease; individuals with disorders that require dietary modification, whether institutionalized or at home; and individuals with addictions, such as drugs and/or alcohol, that may affect the intake and utilization of nutrients.

(e) Nutritional surveillance to monitor nutrition education in the health services delivery system should be managed through interagency and governmental cooperation.

(f) Demonstration projects should be funded to determine the costs and effectiveness of comprehensive nutritional care.

Food assistance programs

Food assistance programs, by definition, serve target populations known to be at high nutritional risk. Because their delivery systems provide a continuity of contact with their clients, all food assistance programs offer an opportunity for an organized approach to nutrition education. The American Dietetic Associaton recommends that all federally funded nutrition and meal assistance programs, as a part of their stated objectives, mandate nutrition education and provide appropriate funding. Regulations should specify quality standards for the content and relevance to the target population.

Mass multi-media campaigns

Research is needed to determine ways to use media more effectively in nutrition education and to integrate its use into the comprehensive nutrition education system. Nutrition education in the media must be credible, authoritative, and thought-provoking. The mass media (radio, television, newspapers, and magazines) reach a large segment of the population and can provide opportunities for increasing the public awareness of the importance of nutrition. Television and radio lend themselves to a sequential series of single message-spots. The printed media can provide consumers more in-depth scientific information on nutrition and its relation to health and disease.

The multi-media have not been adequately explored as avenues to present credible nutritional information. While the ability of media to accomplish actual behavioral change may be debatable, they can be used to increase awareness of ideas and services, provide factual information needed to put sound nutritional principles into practice, and correct misleading information.

Qualifications of the nutrition educator

The American Dietetic Association takes the position that qualified personnel should be assigned leadership responsibility to plan, direct, coordinate, and evaluate nutrition education through the various delivery networks. This would include both the public and private sectors. To protect the public and insure valid programs, the qualifications of the nutrition educator must be specified in any legislation providing for nutrition education.

The registered dietitian is the health professional

uniquely prepared to design and develop programs to prepare educators and health professionals and to educate and motivate individuals, families, and groups, for the utlimate goal of achieving eating practices that contribute to optimum nutritional status. Nutrition education for the various educational systems must be developed as a specialty area in dietetics. Competencies for the registered dietitian specializing in nutrition education would include more in-depth education in curriculum development, behavioral science, and communication skills. Knowledge of program planning, evaluation, and organization and management of educational systems and public health and community resources are necessary.

Evaluation

Each nutrition education program must be designed to meet the needs of a specified target audience. Evaluation must be a part of all nutritional endeavors, with measurable objectives constructed to determine the effectiveness of the programs. Depending on resources, facilities and methods of evaluation will vary. Appropriate stated measurements of indicators may be: Increased nutritional awareness; attitudinal changes; increased nutritional knowledge; changes in food purchasing and selection; behavior and actual health outcomes as reflected in objective physical measurements or biochemical data. Resources should be allocated for meaningful and objective data collection and analysis so that the program can be restructured as necessary to achieve stated goals.

Summary

In the words of Robinson (2), The American Dietetic Association takes the position that "Nutrition affords one of the greatest opportunities for the individual to control the quality of his health and well-being. Education implies action that will result in change of behavior. In this area, it can settle for nothing less than the creation of an awareness and interest, the seeking and acquisition of knowledge, the motivation to change, and the adoption of new behavior patterns. The great challenge for the dietitian in nutrition education is to achieve a balance between the emphasis on nutritional adequacy on one hand and the primary prevention of diet-related diseases by the avoidance of dietary excesses on the other."

To summarize: The American Dietetic Association recommends legislation to authorize and fund nutrition education programs designed by qualified professionals as an integral part of those educational, health, and food delivery systems where it can provide impact and ultimately prove cost effective. Because nutrition education has implications for the total population, program evaluation must address the size, characteristics, and special needs of the populations served. The effectiveness of the methodology must be measured according to the strategy and setting. Studies should give attention to validity, appropriateness and consistency of content, coordination within or between agencies engaged in nutrition education, and their efficiency of operation. Support of applied research in more effective approaches to nutrition education in its many settings is urgently needed.

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THE AMERICAN DIETETIC ASSOCIATION

The Statement of The American Dietetic Association on Food Labeling

JADA, Vol. 73, December 1978

Food labeling: A.D.A. comments to the Food and Drug Administration

In September and October, the Food and Drug Administration held a series of open hearings for the public on food labeling in five cities: Wichita, Kansas; Little Rock, Arkansas; Washington, D.C.; San Francisco; and Boston. Announcement of these hearings in the June 9, 1978 issue of the Federal Register *(Vol. 43, No. 112, page 25296) posed a number of questions to be addressed at these meetings.*

Early in the summer, A.D.A. *members in the above cities were alerted to the dates and places of the hearings and the topics to be discussed and were provided with a bibliography listing earlier comments by the Association on this subject. Also, in response to these hearings, the following summary of the Association's statements in the past ten years were sent by Clara Zempel,* A.D.A. *Executive Director, to the* FDA. *Her letter read:*

In 1973, The American Dietetic Association commended the Food and Drug Administration for promulgating new regulations on food labeling. At that time, we concurred with the Commissioner that it was an auspicious beginning. We expressed our expectation that, with the rapidly accumulating knowledge of food and nutrition, periodic reviews of regulations would be in order. The 1978 public hearings are a most positive step in involving the consumer in the development of useful nutrition labeling.

The members of The American Dietetic Association provide nutrition counseling for consumers and assist them in translating information concerning the nutrient content of foods into appropriate food choices. Dietitians are also purchasers of large quantities of food for numerous institutions.

In the past, The American Dietetic Association has supported nutrition labeling and has commented regularly on proposed changes and modifications. We continue our support of measures which will establish standards for labeling all processed foods. The following comments are made in the order of the listing in the *Federal Register,* June 9, 1978.

Ingredient labeling

Each ingredient in a product should be listed on the label in descending order of the amount in the product. While ingredients are presently listed in this descending order of importance, this fact is not generally known and should be so stated on the label.

The common names of fats, oils, and starches, as well as the common or usual names of colorings, spices, and chemical preservatives together with the actual sweetening agents, should be listed. It is often more important to know each ingredient present than it is to know the amount of the ingredient present.

Because The American Dietetic Association has declared its support for full disclosure of ingredients on food labels, we would support a requirement that sugar, sodium, and any added trace minerals and added vitamins be listed on the labels of processed foods. This information will assist consumers and those with medical problems who must avoid specific ingredients, e.g., salt, spices, pepper, or thickening agents which may be potential allergens, in evaluating their purchases. A cost/benefit study of implementation of such a program appears unnecessary at this time.

A declaration of the percentage of the characterizing ingredients as part of the name of a food should be required. Such foods as beef, chicken, and turkey pies; macaroni and cheese products; hash, meat, and gravy products should have the percentage of the characterizing ingredient listed on the label. The meat, poultry, and cheese in such products are the most costly ingredients, and the consumer should know how much is being paid for this source of nutrients.

Specific names of some ingredients may be confusing. However, they should be listed on labels. When appropriate, the chemical name should be listed followed with an abbreviation in parentheses. An explanatory term, such as "emulsifier" or "preservative," seems unnecessary and may only confuse the consumer.

The addition of artificial coloring in butter, cheese, or ice cream should be included in label information.

From a cost/benefit viewpoint, it appears reasonable to allow flexibility in the declaration of fats and oils in a food product. Declaration on a food label that the product contains "one or more of the following: Soybean, palm, and/or corn oil" should be permitted. Variation in the cost of fats and oils makes this suggestion both reasonable and economical.

When ingredients are listed in percentages, we recommend that they be for commonly used portions as served, not for the full content of the package. Percentage labeling of the ingredients in all food products will be a costly process. The value to the consumer in using this form of disclosure, as well as the degree of accuracy that can be maintained, is subject to question.

Nutrition labeling

The American Dietetic Association is committed to the establishment and maintenance of standards and regulations for the labeling of all processed foods which will provide the consumer with information relative to the

nutrient content and the nutritional quality as well as to ingredients. The information on the label should be worded in a manner and based on units of measure so as to provide the consumer with this information in order to be easily used in purchasing and planning a nutritious diet. Nutrients should be stated for a designated serving or amount of the food and include calories, protein, fat, available carbohydrate and other nutrients present if in amounts of 5 per cent or more of the U.S. Recommended Daily Allowances (U.S. RDAs).

The nutritional value of the food as served is more meaningful and less confusing to the consumer than the nutritional value of a raw product, because the method of handling and preparation may alter the available nutrient content. When possible, the recommended method of preparation to retain the maximum nutrient content should be provided.

To declare all nutrient amounts in the metric system per 100 calories will delay the full use of labeling information until the consumer in the U.S. understands the metric system.

The "nutrient density" concept is an excellent method of conveying comparisons of the amounts of nutrients in identical portions of foods from the same as well as differing food groups, e.g., fruits, vegetables, cereals. This is particularly true when the nutrient content of a food is listed in percentages in descending order and water is the first ingredient listed.

Nutrition labeling is an important tool to be used by the knowledgeable consumer and the counselor who instructs those needing assistance in planning and implementing modified diets. Whatever information is given, the consumer will need help in interpreting it and in applying it to a daily regimen.

The American Dietetic Association supports the position of the Food and Drug Administration that it would be misleading to suggest the use of a specific food, a nutrient, or other ingredient in prevention of a disease. Nutrition is complex. While there is scientific evidence supportive of some general statements, as well as claims for specific nutrients and their contribution to health, each individual has particular needs based on his current state of health and life style. We believe that no disease-related or other such claim should be made in food labeling.

When an individual's health status indicates need for a dietary modification, it is the responsibility of the professionally educated provider of health/medical care to give counseling that will assist the individual in translating nutritional needs into food. Consumers should not be presented with misleading claims that, when rigorously followed, may result in severe consequences to their health.

Labeling with unsubstantiated claims could lead consumers to purchase such foods believing them to be a "bargain" and to consume them to the detriment of their health. Precise regulations governing the "safety" of food as to content, labeling, and sale are necessary to protect the health and interests of the public.

For those on "special" diets, we recommend that particular attention be drawn to some facts on the labels in regard to the non-nutritive content, e.g., pure cellulose—how this has been achieved and clarifying the comparative claims with any other non-fabricated or non-altered food of a similar nature. "This____contains one-fourth fewer calories than____," is not sufficient information.

When a label presents the size of serving, calories per serving, and protein, fat, and carbohydrate in grams per serving, we question the need to state "low calorie." The consumer requiring this food and specific information should be able to judge sufficiently the content without this added statement. Emphasizing "low calorie" on a label without full disclosure of the ingredients comprising the caloric content can be deceptive.

We also recommend that the percentage weight of non-nutritive sweeteners be required. Milligrams per 100 gm. is useful in nutritional calculations. Some products contain both nutritive and non-nutritive sweeteners. Because the present use of available non-nutritive sweeteners is "ordinarily slight" (1), we cannot assume that this will be true in the future, especially if tolerance levels should be established requiring an individual to quantify intake.

We recommend that the term "sugarless" be restricted to those products which are absolutely carbohydrate free. Such claims as "sugar free," "sugarless," and "no sugar" should be followed by a statement, "Not a reduced-calorie food."

Special labeling inferring that a product is "better" or "desirable" in the diet of the person with well regulated diabetes is also false and misleading.

The use of adjectives to state the nutrient content of foods could result in very few foods being listed as excellent sources of a nutrient, e.g., if a food must contain 30 per cent of a nutrient to be listed as an excellent source of a nutrient, an 8-oz. glass of vitamin D-fortified milk would not meet the requirement as an excellent source of either calcium or vitamin D.

Developing a nutrition score for every food does not appear to be needed at this time. Such scores tend to be judgmental rather than authoritative.

Graphic or pictorial forms of nutrition labeling run the risk of being oversimplified and not giving complete, accurate information or of being too complex, requiring interpretation.

Nutrition labeling without nutrition education programs to prepare the public to understand and apply this knowledge will not reach the goal for which it is intended, namely, "to use nutrition information in selecting well balanced diets and to minimize consumption of those food components that some customers may wish to avoid for health and other reasons" (2).

Open date labeling

Open date labeling should be required for all foods except possibly for the various types of refined sugars. Open date labeling is important, but nutrition labeling is equally important and should be so considered in providing information for the consumer.

The use of a "sell by" date labeling for perishable and semi-perishable foods in packaged form has considerable merit as a service to the consumer. This is especially true for perishable products, such as bakery items, dairy products, and certain processed meats, e.g. bacon and cold cuts. An explanation of the date shown on the package should be required, e.g., "Sell by ____."

The "sell by" date gives the consumer more assurance as to the quality of the product being purchased and is meaningful. Including more than one type of open dating on a product can lead to confusion. A "sell by" date will need to be established for different products, depending on whether they are perishable or semi-perishable. A "sell by" date on frozen food products does not indicate the total safety or the nutritional value of an item, because it provides no information concerning the handling and storage of the food during distribution. Extreme fluctuations in temperature and the resulting refreezing of some items alter not only the flavor, color, and texture but the nutrient content and the actual safety of the product. Future technology should provide some type of color-change tape or label sensitive to thawing and refreezing to alert both the distributor and the consumer to this condition.

To make open dating useful and effective, storage and handling instructions should be included on all food labels.

Because packages, containers, and so forth vary in shape, size, and texture, both the placement and the application technique used must vary in applying labels. In some cases, ink marking will suffice; in others, pressure embossing would be recommended.

An alpha-numeric date (Sept. 12) would be better than only a numeric date (9/12). Without stating a specific year, the numeric date may be read in reverse; using the example given, December 9 rather than September 12. For products having a relatively long shelf-life, the year must be stated (Sept. 12, 1978).

Imitation and substitute foods

The American Dietetic Association accepts the present Food and Drug Administration identification of "imitation" foods as those nutritionally inferior to the "real" foods (2).

Margarine is a product that has been accepted by the consumer as a table spread and butter/shortening alternative in food preparation. To identify margarine as an "imitation" food would imply nutritional inferiority to butter. We do not believe it necessary to label margarine an "imitation" food.

A food that does not conform to a Standard of Identity should be named an "imitation" until such time as a Standard of Identity has been established.

The name and label of substitute foods should conform to the same regulations as those established for the "real" food, including full disclosure of ingredients, characterizing important ingredients, and the criteria for nutritional equivalence. The judgment as to the nutritional inferiority of substitute foods should be based on the comparison of the nutrient content of the same portion of the "real" food, and this finding should be made known on the label. The word "imitation" is not sufficient information for the consumer, who would be provided no basis for judgment of the nutritional quality of the product.

Consumers have the right to know if they are selecting a substitute or an imitation food. The label should provide the same full ingredient disclosure as that recommended for "real" foods.

Food products are customarily marketed under brand names with colorful labels. We recommend that the words "imitation" or "substitute" be prominently displayed on the label, so that consumers may easily recognize this fact and make their choices. The use of a common descriptive name for a particular product that falls into either of these categories should aid in preventing any deceptive pictures or misleading statements which could cause confusion on the part of consumers.

Fortification

A food selected for fortification with a nutrient or nutrients should be a staple food in the diet of a significant segment of the population. It should be a suitable carrier for the nutrient or nutrients. The form of the nutrient (nutrients) added should be physiologically available from the food and stable under proper conditions of storage and use. Some food or foods should be fortified when there is evidence that the intake of a nutrient or nutrients is low in significant groups in the U.S. The nutrient or nutrients added should not adversely affect the color, flavor (taste), or cooking properties or unduly increase the cost. We recommend that the nutrient level in the unrefined product be restored to flour, cereals, rice and cornmeal.

Accessory foods, such as sweeteners, candy, soda, and tonic waters, should not be fortified because their nutrient contribution is/should be insignificant.

The government should regulate food fortification to prevent excessive fortification that could cause an imbalance of nutrients. In the case of vitamins A and D, in particular, regulation should prevent against excessive intake to a level of toxicity.

The base level for the kind and amount of nutrient fortification might well be established as the level in the usual or customary version of the "real" food. A standard such as the U.S. RDA is needed.

If the government regulates food fortification, prior approval should be required before a food is fortified and marketed. Approval after the fact is not recommended.

The Standard of Identity is the kind of regulation that the government should continue to use in regulating food fortification. Like other established standards, it should be changed only following documented evidence of the need to do so.

In 1974, The American Dietetic Association supported the increase in the iron content of enriched flour and enriched bakery products. At that time we said: "The small percentage of the population for whom additional iron presents a health hazard should be under the care of a physician with specific nutritional counseling and monitoring of the individual's iron intake. It is further recommended that differences in the availability of iron

be taken into consideration in setting standards for iron enrichment."

There is value in the fortification of fluid milk with vitamins A and D. For those who have problems in using this product, there is the option of using reconstituted dry milk that is not so fortified.

"Imitation," "substitute," "engineered" foods, as well as the "almost ready to eat," when designed to be used singly or in combination with another food to provide the main item in any meal, should be fortified/enriched/restored, e.g., soy protein isolate when substituted for ground beef should have iron and B-complex vitamins at approximately the same level as the traditional item. When mineral or any nutrient content is substantially greater than would be expected, that information should be disclosed, e.g., soy isolate protein is apt to be considerably higher in sodium than the "real" food.

Levels of fortification should be within a relatively narrow range. Iodine fortification is a needed public health measure. Because of the use of sodium iodate as a mold inhibitor in some breads and rolls, a high total iodine content may result.

The state of the art and science of human nutrition is such that, although "chemically defined" formula diets can sustain growth and may be useful, even life-preserving in cases of medical/surgical acute care, careful physiologic monitoring is required.

Varied diets offer the best protection against trace element deficiency and/or risk of naturally occurring or added potentially harmful substances.

Total food label

The American Dietetic Association appreciates the concern of the food manufacturer and processor for both the size and cost of nutrient labeling. The restraint as to possible ingredient changes is also an economic factor that cannot be ignored.

The longer and more complicated the message becomes, the less useful it is to the consumer. When consumers require specific information other than that provided as we have previously recommended, processors and manufacturers should make this information readily available. Changes in formulation should be immediately and prominently displayed on food labels.

Nutrition labeling alone will not educate the consumer to make wise food choices. The public should be provided with nutrition education materials at the point of sale, responsible educational advertising claims supported by the information on the label, and nutrition education programs in schools that will help to create a more positive attitude about the usefulness of nutrition education materials, such as labeling.

Until the public is educated to appreciate the importance of good nutrition to good health, it will make neither the effort to understand nor to apply the information on labels that could be of assistance in improving food choices.

Safe and suitable ingredients

Dietitians support total ingredient disclosure, including those foods for which Standards of Identity have been established. Standards of Identity help assure consumers that the "traditional" foods on the market contain the ingredients that they have become familiar with, have enjoyed, or have become discriminating in using.

Standards of Identity are needed for processed or manufactured foods so that the name given to a class of food or foods will indicate that the ingredients are similar, no matter who the manufacturer or processor may be. Standards of Identity may allow flexibility in the use of optional ingredients if there is full disclosure of content prominently displayed on the label in language easily understood by the consumer.

As long as only safe ingredients can be used in any food and the basic character of the food is not altered by a change in ingredients, the consumer should feel assured that the public interest is being met by the "safe and suitable" policy.

We believe that Standards of Identity should be continued and more ingredient information should appear on the label. Each serves a different purpose.

The basic character of a food is altered when the nutrient content is altered: Additives are incorporated that have not been present previously; fortification has been newly included; or additives, fortification, and the like have been deleted.

New ingredients may not alter the basic character of the food as to color, texture, taste, and so forth; but the nutrient content, potential allergens, and acceptability by some consumers may be considerably altered. The consumer has the right to this information and should be alerted by a prominent statement on the label, e.g., "new formula" or something similar.

If all ingredients deemed "safe and suitable" have a function, a requirement that the function be specified seems superfluous.

References

(1) Federal Register 42: Pt. III, No. 138 (July 19), 1977.
(2) Federal Register 43: Part IV, No. 112 (June 9), 1978.

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March 11, 1980

Senator Richard S. Schweiker
U.S. Senate
Washington, D.C. 20510

Dear Senator Schweiker:

At the hearings on Nutrition and Health conducted on February 20 before the Senate Subcommittee on Health and Scientific Research of the Committee on Labor and Human Resources, you raised the question regarding assistance the American Dietetic Association might provide in nutrition education in medical schools. In further thought, I would like to render these further suggestions.

1. We support all efforts aimed toward acceptance of the concept that nutrition is an integral and essential aspect of health care. This is a concept which needs to be accepted by physicians and medical administrators for the successful integration of nutrition into medical education.

2. We believe a nutrition education program must be interdisciplinary in nature because nutrition cuts across multiple areas of health care. We therefore support the inclusion of related disciplines in the development and implementation of the nutrition education program.

3. We support and recommend training and educational incentive grants and fellowships for both dietitians and physicians to assure the expertise needed at the academic level appropriate for provision of optimal educational programs.

4. We submit that qualified nutritionists/dietitians should head the development and implementation of the nutrition education programs. Clinical dietitians are already employed in medical center settings and can help provide this expertise.

5. We believe in, and would help develop, model curricular and teaching materials (indeed have already assisted in such developments). The further development of education model projects that demonstrate the coordination and successful integration of nutrition into present medical school curriculi would provide incentives for others. We feel that dietitians have a role to play as educators looking seriously at curricula and knowing that the curriculi in medical schools in full and has restraints.

6. We hope for the enactment by Congress of provision for nutrition services as a reimbursable service to third party payers. We believe physicians would then view nutrition in a more serious light as a treatment modality and would likely refer more patients for nutrition counseling.

7. We propose a seminar or series of seminars among physicians and dietitians initiated by the American Dietetic Association for dialogue toward recognition of nutrition services and expertise of dietitians in patient care in clinical settings. The current interest in nutrition and the recent release of the "Dietary Guidelines" by USDA-HEW might be focal point for discussion of dietary management of patients.

8. Interaction with the Liasion Committee on Medical Education toward development of an awareness of and sensitivity toward inclusion of nutrition on the National Board Examinations.

Also enclosed are a copy of "Proposed Recommendations on Interdisciplinary Training in Nutrition under the Health Professions Educational Assistance Act" which were prepared earlier by a committee of the American Dietetic Association.

Thank you for this opportunity of presenting our further thoughts in this important area of medical education.

Sincerely,

Esther Winterfeldt

Esther Winterfeldt, Ph.D.
President, American Dietetic
Association

EW:sb

Enc.

Senator METZENBAUM. Thank you very much, Dr. Winterfeldt. It will be included in the record.

Dr. Williams of the University of Maryland.

Dr. WILLIAMS. Thank you. I am Eleanor Williams. I was asked to appear here today for the Society for Nutrition Education, an organization of about 6,000 nutrition educators.

Time constraints prevented my obtaining official approval of my remarks by the society's board of directors. Therefore, today I am speaking for myself alone. However, I plan to submit my remarks to the board for official approval, after which they may be placed in the record.

I have been asked to speak today about how nutrition educators can reach members of the public. And I have chosen to concentrate on the problem of changing behavior because when we are thinking about getting the idea across on nutrition guidelines, we do have to address ourselves to the problem of changing the way people behave.

I want, before I begin on that, to take note of the fact that we are all I think very well aware that one of the best ways, one of the most effective ways to modify what people consume is to modify the food supply. I do want to take note of that, that it is very important for the food industry to change foods that are made available in order for the guidelines really to be met by the public.

However, I am focusing on what nutrition educators might be able to do to bring about behavioral change. And first I am just going to list the steps that an educator takes in doing this.

First, the educator decides on target groups. The reason for focusing in on target groups is that you must know who your learners are. You must try to find out what motivates them. Let me just say, parenthetically, if you are focusing on the general consumer, nutrition educators have a little more difficulty I think in focusing on that large population than they do on smaller groups. That is largely because today the consumer is very much influenced by advertising on television and radio and print, as was pointed out earlier.

Those industry people who use the media so much are very well versed in techniques for finding out what people want. Their data on that are not made available to nutrition educators, and nutrition educators are without funding to ascertain those things themselves.

Furthermore, very few nutrition educators have expertise in the use of television and radio as effective media for reaching large numbers of consumers and, as has already been pointed out, we certainly lack funding.

It seems to me that any steps that the Government takes to make spot announcements available to the public are certainly to be commended. In the future I hope we will have more encouragement for use of the media by nutrition educators.

Now, having decided upon a target group, the educator's next sets up objectives. In other words, the educator has to decide what the learner should be able to do once they actually accomplish the learning that has been set up for them.

In order to set up those objectives, one has to find out what motivates the learner. What does the learner want to get out of it?

It is very important to be able to find out where the learner is and what exactly they want. You cannot impose things upon people. You cannot impose learning upon people.

In finding out what motivates the learner, actually you want to find out what turns people on to nutrition. If the program demands only a small change in lifestyle, then the motivation does not have to be so strong. But if, for example, your program requires an enormous change in lifestyle, as Mr. Pritikin recommends, 15 percent of the calories as fat, I submit that that really is a pretty drastic change in lifestyle.

What it actually means is that you have to do your own cooking, and a lot of people in this country do not do their own cooking. You have to make your own bread, for example, because most breads have some fat in them. I do not mean to be putting down his program. I am not saying that at all. What I am focusing on is the motivation that is necessary. When you have people who actually have heart disease, they are highly motivated to stick to that program. But the difficulty would be in getting well people who have no disability that they are aware of to actually adopt that great a restriction in diet. That is difficult from the standpoint of motivation.

Actually to meet the "U.S. Dietary Goals," which did set some restrictions, the change in lifestyle would not be as severe. There would not have to be such a severe motivational problem. Many people are faced with severe motivation problems for weight control.

Now, the next thing we want to do——

Senator METZENBAUM. One more minute.

Dr. WILLIAMS. Thank you.

The next point is to get people very involved in what they are doing and behind the nutrition education. One of the very best things to do is get them involved with foods. For example, in elementary schools, the best thing you can do with children is get them working with foods.

That will end my remarks.

[The prepared statement of Dr. Williams follows:]

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HEARINGS ON DIET AND HEALTH
FEBRUARY 20, 1980

SENATOR KENNEDY
SENATOR SCHWEIKER (IN EITHER OR BOTH ABSENCE, MR. CHAIRMAN)
MEMBERS OF THE COMMITTEE:

STATEMENT OF THE SOCIETY FOR NUTRITION EDUCATION

MY NAME IS ELEANOR WILLIAMS AND I THANK YOU FOR THE OPPORTUNITY TO PARTICIPATE IN THIS PANEL DISCUSSION ON THE AVAILABILITY AND EFFECTIVENESS OF NUTRITION INFORMATION AND EDUCATION SERVICES FOR THE CONSUMER. I AM SPEAKING ABOUT THESE CONCERNS ON BEHALF OF THE SOCIETY FOR NUTRITION EDUCATION (SNE).

SNE REPRESENTS 6000 NUTRITION EDUCATORS CONCERNED WITH HELPING PEOPLE TO MAKE DECISIONS AS THEY RELATE TO FOOD CHOICES AND HEALTH STATUS. NUTRITION EDUCATION IS THE PROCESS OF USING AVAILABLE INFORMATION TO DEVELOP EACH INDIVIDUAL'S NUTRITIONAL KNOWLEDGE IN SUCH A WAY THAT S/HE WILL HAVE SUFFICIENT INFORMATION TO CHOOSE AN ADEQUATE DIET. IT IS THE RIGHT OF THE CONSUMER TO HAVE ACCESS TO ADEQUATE INFORMATION ON WHICH TO MAKE INFORMED FOOD CHOICES. THIS GOAL CAN BE ACHIEVED THROUGH ASSISTING THE FOOD PRODUCERS AND PROCESSORS WITH ADEQUATE GUIDELINES AND

REGULATIONS WHICH WILL RESULT IN USEFUL FOOD LABELING. WITH TODAY'S HEIGHTENED CONCERN ABOUT NUTRITION AND ITS RELATION TO HEALTH, THE FOOD LABEL GIVES THE FOOD PRODUCER OR PROCESSOR AN OPPORTUNITY TO PRESENT PRODUCT INFORMATION.

THE ROLE OF THE LABEL IS TO PROVIDE THE CONSUMER WITH INFORMATION ON WHICH TO BASE A DECISION. EFFECTIVE NUTRITION EDUCATION CANNOT BE ACCOMPLISHED UNLESS THE CONSUMER HAS THE FACTS EASILY AVAILABLE. THIS TOOL, THE FOOD LABEL, ASSISTS THE NUTRITION EDUCATORS TO DO A BETTER JOB. TEACHING CONSUMERS HOW TO USE THE FOOD LABEL INFORMATION IS IMPORTANT BECAUSE TRADITIONAL FOOD SELECTION GUIDES LIKE THE "BASIC 4" OR EVEN THE NEW "DIETARY GUIDELINES" JUST RELEASED BY THE JOINT COMMITTEE OF HEW AND USDA DO NOT PROVIDE THE CONSUMER WITH ADEQUATE INFORMATION TO MAKE COMPARATIVE SELECTIONS FROM FOODS IN THEIR VARIOUS FORMS, AND DURING DIFFERENT STAGES OF HANDLING.

TODAY, THERE ARE NUTRITION EDUCATION COMPONENTS IN FEDERALLY FUNDED PROGRAMS SUCH AS THOSE FUNDED BY THE CHILD NUTRITION ACT INCLUDING NUTRITION EDUCATION IN SCHOOLS AND THE SUPPLEMENTAL FEEDING PROGRAM FOR WOMEN, INFANTS AND CHILDREN (WIC) AND THE CONGREGATE FEEDING PROGRAM FOR THE ELDERLY AND FOOD STAMPS. ALL OF THESE PROGRAMS ARE ASSISTING THE CONSUMER, AT ALL AGES, TO MAKE CHOICES IN THE MARKETPLACE. AN INFORMATIVE FOOD LABEL CAN REINFORCE THE

TEACHING IN THESE PROGRAMS AND HELP THE CONSUMERS TO EFFECTIVELY IMPLEMENT THEIR KNOWLEDGE.

FOOD LABELS ARE INTENDED TO INFLUENCE CONSUMER PURCHASING DECISIONS THROUGH THEIR INFORMATION CONTENT. BECAUSE NUTRITION EDUCATORS RECOGNIZE THE IMPORTANCE OF THE FOOD LABEL, SNE RESPONDED TO THE FDA, USDA, FTC REQUEST FOR REVIEWING THE FOOD LABELING REGULATIONS IN 1978 AND SUBMITTED THEIR POSITION ON THE TOTAL FOOD LABELING PROGRAM TO THE FDA HEARING CLERK ON NOVEMBER 9, 1978. THIS STATEMENT PRESENTS A SERIES OF PRIORITIES FOR FOOD LABELING. WHEN THE FOOD LABEL CONTAINS INFORMATION ON THE COMPONENTS OF CURRENT CONCERN IN THE U.S. DIET, CALORIES, TOTAL SODIUM, CHOLESTEROL, TYPE AND AMOUNT OF FAT, PROTEIN CONTENT, IRON AND CALCIUM AND TYPE AND AMOUNTS OF CARBOHYDRATES, IT BECOMES A USEFUL TOOL IN ASSISTING THE CONSUMER TO MAKE INFORMATIVE AND HEALTHY FOOD CHOICES.

HOWEVER, SNE ALSO FEELS THAT ANY SYSTEM OF LABELING MUST BE ACCOMPANIED BY A COMPREHENSIVE EDUCATION PROGRAM TO ASSIST THE CONSUMER IN UTILIZING THE INFORMATION. THE PROVISION OF INFORMATION DOES NOT SUBSTITUTE FOR OTHER EDUCATIONAL EFFORTS. THE FOOD LABEL IS NOT BY ITSELF TO BE INTERPRETED AS AN EDUCATIONAL PROGRAM BECAUSE THE PROVISION OF INFORMATION ALONE RARELY PROVIDES THE MOTIVATION FOR BEHAVIOR CHANGE IMPORTANT FOR HEALTH OUTCOMES.

IT IS IMPORTANT THAT THE INFORMATION ON THE FOOD LABEL BE USEFUL AND NOT CONFUSING TO THE CONSUMER. NEITHER THE FOOD INDUSTRY, NOR NUTRITION EDUCATORS, NOR THE CONSUMER WANTS INFORMATION OVERLOAD. IT IS IMPORTANT TO HAVE CONSISTENT FORMATS FOR COMPONENT PARTS OF THE LABEL AND TO ESTABLISH PRIORITIES FOR LABEL INCLUSIONS. THE NUTRITION INFORMATION PANEL COULD INCLUDE A SHORT SENTENCE EXPLAINING THAT THE LISTED NUTRIENTS ARE NOT THE ONLY ESSENTIAL NUTRIENTS NEEDED, AND THAT A VARIETY OF FOODS ARE RECOMMENDED TO BE INCLUDED IN THE DIET. IN ORDER TO ASSIST THE CONSUMER FURTHER, SOME INFORMATION DELIVERY SYSTEM (POINT OF SALE POSTERS OR BROCHURES) IS ENCOURAGED FOR THE LARGE CATEGORY OF PRESENTLY UNPROCESSED FOODS SUCH AS FRESH FRUITS AND VEGETABLES, MEATS AND SOME DAIRY PRODUCTS WHICH CURRENTLY HAVE ALMOST NO EXTENSIVE INFORMATION SYSTEM.

ANY FOOD LABELING PROGRAM SHOULD BE FLEXIBLE ENOUGH TO ALLOW FOR INCLUSION OF INFORMATION THAT IS CURRENTLY NOT AVAILABLE, AND THE U.S. RDA'S USED IN LABELING SHOULD BE RE-EVALUATED AFTER EACH OF THE PERIODIC REVISIONS OF THE RECOMMENDED DIETARY ALLOWANCES DEVELOPED BY THE NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMY OF SCIENCES SO THAT THE LABEL REFLECTS CURRENT KNOWLEDGE IN NUTRITION SCIENCE. RECENT SURVEYS HAVE SHOWN THAT CONSUMERS HAVE AN INCREASED LEVEL OF INTEREST IN THE INFORMATION ON THE LABEL. THIS IS ENCOURAGING BECAUSE NUTRITION LABELING IN

ITS CURRENT FORM HAS BEEN IN EXISTENCE FOR A RELATIVELY SHORT TIME AND HAS HAD ALMOST NO EDUCATIONAL SUPPORT SYSTEM. ADDITIONALLY IT HAS COVERED ONLY CERTAIN SEGMENTS OF THE FOODS SOLD IN THE MARKETPLACE. IN SURVEYS, SUCH AS THAT CARRIED OUT BY FDA*, SIGNIFICANT NUMBERS OF CONSUMERS INDICATED THAT THEY WOULD BE WILLING TO PAY FOR THE NUTRITION INFORMATION PROVIDED BY A FOOD LABEL.

SINCE ITS INCEPTION ABOUT 12 YEARS AGO, THE SOCIETY FOR NUTRITION EDUCATION HAS WORKED TO ENCOURAGE IMPROVEMENT IN THE QUALITY AND EFFECTIVENESS OF NUTRITION INFORMATION AND EDUCATION AVAILABLE TO CONSUMERS. NUTRITION ACTIVITIES, INCLUDING THE PROVISION OF INFORMATION, ARE NUMEROUS. HOWEVER, THERE ARE INADEQUATE NUMBERS OF BROAD BASED COMPREHENSIVE NUTRITION EDUCATION PROGRAMS THAT ARE INTEGRATED INTO NEW AND EXISTING PROGRAMS IN SCHOOLS, OR INTO THE VARIOUS PUBLIC AND PRIVATE-SECTOR EDUCATIONAL SERVICES FOR CONSUMERS, OR EVEN OTHER PROFESSIONALS. THE FOOD LABEL IS NOT A SIMPLISTIC SUBSTITUTE FOR THESE PROGRAMS. HOWEVER, NUTRITION EDUCATORS CAN AND WILL USE THE FOOD LABEL AS AN INFORMATIVE TOOL TO ASSIST CONSUMERS IN TAKING RESPONSIBILITY FOR FOOD CHOICES THAT SUPPORT AN ADEQUATE DIET.

THANK YOU FOR THIS OPPORTUNITY TO PARTICIPATE IN THE DIET & HEALTH HEARINGS.

* "TESTING CONSUMERS' FOOD IQ", FDA CONSUMER NUTRITION KNOWLEDGE SURVEY, REPORT II, 1975, U.S. DEPT. HEW, PUBLIC HEALTH SERVICE, FOOD & DRUG ADMINISTRATION, DHEW PUBLICATION NO. (FDA) 76-2059.

Senator METZENBAUM. Thank you very much.

The Chair apologizes for having to hold the witnesses to a time limit but the time constraints here are a continuing problem.

Ms. TENNEY. Mr. Chairman and Mr. Schweiker, I am coordinator of nutrition programs for Giant Food, a regional supermarket chain. I am pleased to be here today to discuss some of my experiences with nutrition labeling and nutrition education in the marketplace.

In the interest of time, I will focus on nutrition education and my formal testimony which I understand will be put in the record.

Based on my experience, consumers want clear, basic nutrition information. We get inquiries about anything from additives to special diets.

Many of the questions we receive are about the food label, but the label alone cannot possibly educate the consumer who has no understanding of nutrients, calories, or the relationship between diet and health.

However we cannot really expect manufacturers to provide nutrition education, nor I believe should we. Manufacturers have expertise in products, not in education. They should provide the tools with which to educate, that is sound information about the products' ingredients and nutrients. These should be readily accessible to consumers and health professionals in the retail industry.

Consumers and nutrition educators are wary of nutrition education by the food industry. The line must be clearly drawn between education and promotion.

In our department, we regard the use of a particular brand in recipes as promotional, but there are certainly much more flagrant abuses that go on in the marketplace. Therefore I feel that guidelines are very important to draw this line between promotion and education.

In our department, we keep our flyers as nonpromotional as possible, and also our recipes and radio spots. Many people ask us, "Do you have to pay for your announcements when Odonna Mathews goes on the radio?" We certainly do because she is a consumer advisor to Giant Food, but we are giving basic consumer information not product promotions.

Our aim is to promote the interests of consumers and help them get some information on wise food buys and to inform him through labels, newspapers, radio spots, recipes, and sometime instore demonstrations, all designed to teach nutrition and shopping concepts.

We work closely with Government agencies to translate scientific information about foods, nutrition in practical consumer terms.

At Giant, we support the consumer's right to be informed, and this includes information about nutrition. We recognize, however, that most consumers just want to get in and out of the foodstore with whatever they came for. Therefore, we emphasize graphics and visual appeal in our consumer information. Take, for example, the bite out of our bag it-guide to packing nutritious lunches. Our best known program is foods for health, also put this heavy emphasis on graphics.

Foods for health ran in the Washington area in Giant food stores from October 1978 until October 1979. The response from consum-

ers as well as health professionals, educators, and people in the food industry has been tremendous.

We are now offering the program in the Baltimore area because of its success. Last year Baltimore served as the control group, so they did not get the program.

Although the final results from the study on buying patterns are not yet available, a preliminary review of the consumer knowledge survey indicated a change. We are encouraged by this even if we demonstrate no change in buying patterns.

Influencing consumer behavior is not a 1-year process. People do not change food habits overnight. However, interest was high. In the first 2 weeks of the program alone, we received over 700 comment cards from consumers. At the end of the program, the last on that contained a two-page questionnaire. We received over 6,000 of those questionnaires back from consumers. That is over a 6-percent return rate. I'm told for magazines; a 2-percent return rate is excellent for questionnaires.

In our departmental, perspective we receive between 300 to 450 letters a year, so to receive 6,000 questionnaires back from consumers just to tell us their views is phenomenal.

The program has received tremendous consumer support. And we think it will provide us a great deal of material to work with in future programs.

Senator METZENBAUM. What percentage of supermarkets have nutrition consultants on their staff?

Ms. TENNEY. Very few actually have nutritionists. We have consumer advisers in many. Some of them now are beginning to hire outside nutrition consultants not on fulltime paid staff as I am. It is relatively unusual to have a person in my position.

[The prepared statement of Ms. Tenney follows:]

TESTIMONY

BEFORE THE
SENATE SUBCOMMITTEE
ON HEALTH AND SCIENTIFIC RESEARCH

BY

JANET E. TENNEY
COORDINATOR OF NUTRITION PROGRAMS
GIANT FOOD INC.

FEBRUARY 20, 1980

Mr. Chairman and members of the Subcommittee on Health and Scientific Research, I am Janet Tenney, Coordinator of Nutrition Programs for Giant Food Inc., a regional supermarket chain. I am pleased to be here today to discuss some of my experiences with nutrition labeling and nutrition education in the marketplace.

As the nutritionist in Giant's Office of Consumer Affairs, I listen to and work with consumers and the food manufacturing and supermarket industry on these issues. At Giant we receive between 300-450 letters a month from consumers. We also meet with consumers through Advisory Committees, speaking engagements and other community programs. I also meet frequently with producers and suppliers through work on our various nutrition information programs. In just the past two months, I've sent out several hundred letters to manufacturers and suppliers, and talked with many of them about specific nutrition information on foods available in Giant Food stores.

Based on this experience I have some comments on the status of nutrition labeling and Bill S. 1652. First, let me state that Giant supports universal nutrition labeling on a mandatory/voluntary basis. Our work on labeling issues with consumers, producers and manufacturers dates back to the early 1970's. We have gone beyond the requirements of proposed legislation and have encouraged the development of nutrient data bases for fresh produce so that consumers might have more nutrition information at the retail level. We have worked closely with the United Fresh Fruit and Vegetable Association and the U.S. Department of Agriculture to set up sampling procedures for several commodities.

Despite such successes, we have a long way to go. As yet, the mandatory/voluntary aspects of nutrition labeling cannot be successfully expanded. The FDA and some Congressional staff are reportedly very interested in the nutrient data bases; however, such encouragement needs financial support. Industry should cooperate once assured of the direction the government is going to take. Money talks--and in this case, it will speak volumes about the level of importance being accorded nutrition labeling.

Once controls are established and data bases are approved for general use, mandatory/voluntary labeling requirements can be met. Labeling should expand quickly, and universal nutrition labeling could be reached at a reasonable cost to consumers and the food industry.

The data bases are crucial. From my experience after contacting hundreds of suppliers and manufacturers, many are not prepared to provide consumer information on calories, let alone sodium, cholesterol, and polyunsaturated and saturated fats. (I realize the latter are not addressed in the bill, but as a nutritionist, I feel that data on cholesterol and polyunsaturated and saturated fats cannot be separated. If anything, cholesterol has a lesser effect on blood cholesterol levels than these fats. One should not be addressed without the other.) Many manufacturers also do not feel that the data they have will meet the requirements for nutrition labeling.

The lack of data, however, is not the only problem. The label format that reaches consumers most effectively is still an open question. The bill recognizes the need for testing label formats and Giant supports that position. Our understanding is built on a decade of experience, but we recognize there is a great deal about label communication which we do not know. Only marketplace testing will ultimately provide that information. Such testing will not be an inexpensive process. The government, industry and consumers must work together.

The label however is only a tool, a small piece of food and nutrition information. It cannot possibly educate a consumer who has no knowledge of nutrients or calories, or the relationship of diet to health. Therefore, the support of nutrition education by the Federal government is crucial.

Nutrition labeling alone is burden enough for many in the food industry. If we expect food manufacturers to do the proper checking of the quality of their products and help develop the proper labels with the most useful format, can we reasonably expect them to nutrition educate as well? In fact, I question whether many of them should. Manufacturer expertise is in products--not in education. They should provide the tools with which to educate, i.e., sound information on product ingredients and nutrients which should be readily accessible to consumers, health professionals, and the retail industry.

Manufacturers that wish to go beyond this and move into nutrition education should do so only under careful guidelines. Consumers and nutrition educators are wary of nutrition education by the food industry. The line must be clearly drawn between product promotion and education. In our department, we regard the use of a specific brand product, whether private label or name brand, in a recipe as promotional. Since more flagrant abuses occur in the marketplace, guidelines are clearly needed.

At Giant we keep the Consumer Affairs Department fliers, recipes and radio spots as unpromotional as possible. Some describe policies and labels as they apply to Giant, but to promote consumer understanding not to promote the product.

In the food production and distribution system, we feel supermarkets have a responsibility to help inform consumers about the vast array of choices available to them. Most supermarkets have anywhere from 8,000 to 15,000 items from which to choose. Supermarkets also provide enough variety that they do not have to promote specific products. Our department's aim is to promote the interests of consumers--to help them get sound information on the wise use of their food dollar. Full disclosure, not full promotion, is our watchword.

At Giant, we support the Consumer's Right to be Informed--and this includes information about nutrition. Since many consumers come into our stores at least once, if not twice a week, we have an unique opportunity to reach them.

To inform the consumer, we use food labels, brochures, radio spots, newspaper ads, recipes and sometimes in-store demonstrations. We work closely with government agencies such as the Food and Drug Administration, the National Heart, Lung and Blood Institute and the U.S. Department of Agriculture to translate scientific information about foods and nutrition into practical, consumer terms, so that we can reach consumers at the point of purchase.

Our best known nutrition program was "Foods for Health", a cooperative pilot nutrition education program with the National Heart, Lung and Blood Institute. This program started in Washington area Giant Food stores in October 1978 and ended one year later in October 1979.

The response from consumers as well as health professionals, educators and others in the food industry has been tremendous. Since the Washington response was so good, we are now offering the program in the Baltimore area, which last year served as the control group. Currently the National Heart, Lung and Blood Institute is planning to make the core of the program, the 27 brochures called "Eaters' Almanacs", available to supermarkets nationally.

Although the final results from the study of buying patterns are not yet available, a preliminary review of the consumer knowledge survey indicates that we may have effected some change. We are encouraged by this even if we demonstrate no change in behavior.

Influencing consumer behavior is not a one-year process. People do not change food habits overnight. The soft indicators of consumer interest are almost as important. In the first two weeks of the program alone, we received over 700 comment cards. At the end of the program, the last Almanac contained a two page, tear-off, questionnaire. If consumers filled it out and returned it to us, they received a booklet of all the Almanac recipes. Consumers returned over 6000 questionnaires, better than a 6% return rate. I have been told that in the magazine business a two percent questionnaire return is considered excellent.

From our department's perspective, we receive between 300-450 letters and comment cards a month or about 4500 a year. To receive over 6000 consumer questionnaires in two and a half months is, therefore, truly astonishing. Many people who write us are strongly motivated because they have a complaint and expect some kind of satisfaction. The more than 6000 people who sent in questionnaires may have wanted the recipe booklet, but they took the time and trouble to give us their opinions.

Although the final results are not in, Foods for Health is an unique example of a cooperative program between government and industry which has received tremendous consumer support. It has provided a great deal of experience on which we plan to build. The future is bright and we plan to use these techniques and others in new programs in the months to come.

Thank you for the opportunity to speak to you today. I would be happy to discuss any points in further detail, if you wish.

Senator METZENBAUM. Dr. Kinney, you are our final witness.

Dr. KINNEY. Thank you, Senator Metzenbaum.

I am Gloria Kinney. I am director of nutrition education for the National Dairy Council.

I would like to talk about our nutrition education programs and the way in which we have delivered these programs to the consumers at the local level.

Our Council is an educational and scientific organization, supported by the dairy industry, by handlers, by equipment supply manufacturers and processors.

We have a staff of approximately 30 professionals at national headquarters in Rosemont, Ill. These are almost equally divided between our research division and people in our education division.

The scope of the Dairy Council's program is to conduct nutritional research and also develop and conduct nutrition education programs.

I might point out that our emphasis is on normal nutrition. We do not get into therapeutic nutrition.

We have developed since about 1915 a wide variety of materials and programs. We have this listed in catalogs. The current catalog has about 75 pieces of material that range all the way from materials directed toward consumers and those in the health professions to those for educators, primarily for use with schoolchildren.

I might say too that our basic philosophy is to encourage the consumption of a wide variety of foods to meet the recommendations of the Food and Nutrition Board of the National Academy of Sciences, National Research Council. And we encourage the intake of nutrients at the level which is consistent with ongoing health. So we, too, are concerned about what foods should be eaten but in the amounts and quantities to approach a nutritionally adequate diet.

Since about 1974 we have not only produced nutrition materials but we have also produced multimedia packaged programs.

Our most important program to date is a program that is a sequential. The segment for K–6 (kindergarten to grade 6) is out and has been out for the last few years. This is a self-contained packaged program which has materials for teachers, for students, take-home materials for their parents, and also contains the resources teachers need to conduct this program in the classroom.

As we progress up through the grades, we will bring out the junior and senior materials this year, in 1980. We will begin to teach nutrition not only in home economics but in the general education classes. We will also develop materials for use in science, health, and social studies.

Senator METZENBAUM. I am interested in your zeroing in on the question, how do you deal with ice cream, whole milk, fatty cheeses. How do you handle that from a nutritional standpoint? Do you advise teachers and others that there are risks in eating whole milk products and that there are concerns expressed by many in the scientific community?

Dr. KINNEY. We have not based our programs specifically on the dietary goals and "Dietary Guidelines." We have based our programs on the RDA's, with emphasis on food consumption at appropriate caloric levels and use the 1969 White House Conference concepts that came out on food, nutrition, and health. We do base many of our lessons on a four-food group approach and the categories of food which usually do not fit into those basic four.

Senator METZENBAUM. I have tried for years to get the Department of Agriculture to require ice cream companies to label products as to the butterfat content or the cholesterol content.

I would guess that the Dairy Council has been one of the most successful in preventing that kind of labeling from coming to pass. Would you not support, as a nutritionist, an effort along the line of seeing to it that the American public is advised as to what the content of food is?

Dr. KINNEY. We would be in favor of having full disclosure of all the nutrient components. I guess it is not, from our point of view, one of the most significant questions—it is a matter of variety and balance in the diet, not having a specific food in it, in particular.

For example, if you want to restrict your diet to reduce your percentage of fats, or cholesterol and salt, what you need to do is choose foods in accordance with that particular guideline. You say to yourself, "What are we trying to do?" What we are trying to do is put students in a position where they can make those decisions in terms of their own personal values and in terms of their own needs.

Senator METZENBAUM. Am I correct in understanding that the American Dairy Council would support the labeling of ice cream and dairy products as far as food content?

Dr. KINNEY. First of all, we are the National Dairy Council as opposed to the American Dairy Association. The American Dairy Association is a promotion organization. The National Dairy Council is a nutrition education and research organization.

Senator METZENBAUM. Having said that, your answer to my question is yes, you would support the labeling?

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Dr. KINNEY. Absolutely. The other answer to your question is that one of the first packaged programs we developed in 1974 was in response to the labeling law. I will have to be quite honest and say that we have not achieved a great deal of success with that labeling package, however. For the most part consumers do not understand the labeling law and I think there are some needs for changes and additions to it.

I might add also, my background is not as a nutritionist. My background is in education.

[The prepared statement of Dr. Kinney follows:]

HEARING ON NUTRITION EDUCATION

UNITED STATES SENATE COMMITTEE

ON LABOR AND HUMAN RESOURCES

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

February 20, 1980

Statement by

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I am Gloria Kinney, Director of Nutrition Education, National Dairy Council, Rosemont, Illinois. I am pleased to have the opportunity to participate as a member of this panel, and to share with you some information concerning the nutrition education programs and activities of Dairy Council.

The National Dairy Council is an educational/scientific organization which has been conducting a nutrition education program since its founding in 1915. Supported by dairy producers, handlers, processors, and equipment and supply manufacturers, the Council maintains a staff of approximately 30 professionals at its headquarters in Rosemont, Illinois. Staff members are drawn from the fields of nutrition, education, dietetics, home economics, communications, graphics design, and production. National Dairy Council sponsors research related to human nutrition and utilizes this research base in the development of nutrition education materials, programs, and communications.

The nutrition education materials and programs produced by the Council are implemented by a nationwide network of 32 affiliated Dairy Council units. These units maintain offices in 127 cities and have a combined staff of approximately 300 professionals. This staff works with leaders at the community level in education, government, health care professions, and consumer groups, providing them with nutrition information and conducting nutrition education programs.

National Dairy Council's basic nutrition education philosophy is to encourage the consumption of a variety of foods to meet the recommended intake of nutrients as established by the Food and Nutrition Board, National Academy of Sciences/National Research Council, at a caloric intake consonant with optimum health. Normal nutrition is emphasized in the development of educational materials, programs and activities.

National Dairy Council helped to evolve and supports the following definition of nutrition education:

> Nutrition education is a multidisciplinary process by which scientifically sound information about food and nutrition is imparted in such a manner that the individual will understand the principles of nutrition and seek to maximize personal well-being through food consumption practices consistent with optimum health.

This definition is consistent with that used for the term "nutrition education program" in the National Nutrition Education Act of 1974, (Senate Bill 3864) which was introduced in July, 1974 by Senator George McGovern, and in the nutrition education and training components of Public Law 95-166, The National School Lunch Act and Child Nutrition Amendments of 1977.

National Dairy Council has produced a wide variety of nutrition education materials and programs since 1915. The Council's 1980 catalog contains a listing and description of the 75 nutrition education materials currently available to educators, health professionals, and consumers. It also lists the locations of affiliated Dairy Council units where the materials may be obtained. A teacher/leader guide is available to accompany many of these materials. Approximately 30 million pieces of educational material are placed annually with leaders across the nation by our affiliated unit professional staff.

Since 1974 a number of multimedia packaged programs have been produced by National Dairy Council. In most communities, these programs are supported by workshops conducted locally by Dairy Council staff for the teachers and leaders who use the programs with their students or client groups. Copies of National Dairy Council's 1980 materials catalog and an insert sheet giving descriptions of the multimedia programs currently available have been forwarded to the Committee's staff for reference.

In addition to developing materials and programs, the Council's activities include conducting conferences, workshops, and seminars, supporting nutrition research and nutrition education research, field testing and validating educational materials and programs, providing scientific and technical nutrition information, providing public service announcements for radio and television, cooperating with other agencies and organizations involved in nutrition education and research, and conducting continuing education programs for affiliated unit staff members.

National Dairy Council's most extensively used education program is a sequential curriculum known as FOOD...Your Choice. The first three levels of this nutrition learning system for grades kindergarten through six were introduced in the fall of 1977 to the nation's schools by affiliated Dairy Council units. The fourth level of the curriculum for junior and senior high schools students is currently in development and will be introduced later this year. Special Topics in nutrition for students in the upper levels of senior high school, grades 11 and 12, will complete the FOOD...Your Choice curriculum in 1982.

FOOD...Your Choice uses the seven key concepts identified by the 1969 White House Conference on Food, Nutrition, and Health as its basic organizational framework. A needs assessment of educators conducted by National Dairy Council in conjunction with the Office of Evaluation Research, University of Illinois, Chicago Circle highlighted the need for a sequential program which would teach nutrition at all grade levels.* In addition, an analysis of existing curricula conducted by the Society for Nutrition Education for National Dairy Council in 1975 revealed that this need was not being met by the fragmented program offerings currently available to the schools.** Working with a panel of experts in nutrition and education, National Dairy Council developed FOOD...Your Choice to meet these identified needs.

* Eash, M. and Rasher, S. 1976. A Needs Assessment of Nutrition Education. University of Illinois, Chicago Circle.

**Cooper, K. and Go, C. 1976. Analysis of nutrition curriculum guides at the K-12 level. Journal of Nutrition Education.

As part of the development process, FOOD...Your Choice was field tested with 2900 students at 19 sites across the country during 1976-77. These field tests were conducted with the assistance of affiliated Dairy Council units and the Office of Evaluation Research, University of Illinois, Chicago Circle. After the introduction of the program to the schools, additional curriculum evaluation studies were conducted during 1977-78 at five new test sites. A copy of the summary report* of the results of this study has been forwarded to the Committee's staff for reference. In general, the study revealed that students using the FOOD...Your Choice curriculum gained significantly in nutrition knowledge and developed positive attitudes and behaviors related to food.

FOOD...Your Choice, Levels 1, 2, and 3, is a self-contained comprehensive nutrition learning system for students in kindergarden through grade six. It consists of Student Materials, Teacher Materials (a guide which outlines student learning activities and contains background information on nutrition for the teacher), Resource Materials needed to conduct the program, and Take-Home Materials for parents. In addition, a Program Overview is included as a part of the learning system which shows how the White House Conference Concepts have been translated into learner outcomes appropriate to the developmental level of elementary school students in kindergarten through grade six.

The FOOD...Your Choice learning system:

- develops key nutrition concepts in a systematic, sequential manner
- contributes to students' learnings in other elementary school subjects
- uses the school food service as a learning resource
- involves students actively in the learning process
- supports multicultural education
- contributes significantly to students' nutrition knowledge, and helps develop positive attitudes and behavior related to food.

FOOD...Your Choice has been reviewed and is considered by the Society for Nutrition Education to be scientifically sound and educationally useful for the intended audience. In addition, the American School Food Service Association passed a resolution of support and endorsement of FOOD...Your Choice at its convention in July 1977. In 1979, the learning system was selected as the nutrition education component of the Primary Grades Curriculum Project (Seattle Project). This national health education curriculum was developed by the American Lung Association with HEW funding, and is now being disseminated by the National Center for Health Education of San Francisco. A number of states have selected FOOD...Your Choice for use in their Nutrition Education Training (NET) programs which are funded through U.S.D.A. under PL 95-166.

* Talmage, Harriet 1978. FOOD...Your Choice, Levels 1, 2, and 3, Summative Evaluation Technical Report No. 98. University of Illinois, Chicago Circle.

The implementation of FOOD...Your Choice in the schools is supported by in-service education programs conducted by affiliated Dairy Council units for the teachers using the program. In the two and one-half years since its introduction, the FOOD...Your Choice learning system has been implemented by schools in all 50 states. It is estimated that the first three levels of the curriculum for kindergarden through grade six are currently in use by approximately eight million students.

In 1980-81, the next level of the FOOD...Your Choice learning system will be introduced to junior and senior high school students in grades seven to ten. Level 4 of the curriculum will continue the development of the seven key nutrition concepts from the 1969 White House Conference on Food, Nutrition and Health. The learning activities for adolescent students in Level 4 build on the first three levels of the program.

Level 4 of FOOD...Your Choice consists of four separate nutrition education programs -- programs which have been designed to teach nutrition in Home Economics, Health, Science and Social Studies. These four subject-areas were selected because of the opportunities they present for: 1) integrating nutrition concepts into existing curricula, and 2) reaching a wide spectrum of the student body during the junior/senior high school years. To avoid repetition for the student who might encounter nutrition in all four subject areas, the nutrition education program for each subject area consists of a unique set of learning activities. Each set of learning activities has been designed to teach the same nutrition concepts, but to do so in a manner which is appropriate to a particular subject area.

The student activities for the four programs were learner verified in the spring of 1979 and the curriculum was field tested in prototype form last fall. The field test involved 596 students at 16 sites and was conducted with the assistance of affiliated Dairy Council unit personnel and the Office of Evaluation Research, University of Illinois, Chicago Circle. At the present time, revisions based on the field tests results are being completed in the Home Economics and Health programs. These programs will be available to the schools in the fall of 1980. The Science and Social Studies Programs will be revised this spring and summer and will be ready for the schools in early 1981.

In 1982, the development of Special Topics in nutrition education for use by upper level high school students will complete the FOOD..Your Choice curriculum for kindergarten through grade 12. These Special Topics will explore such areas as food chemistry, food economics, food and athletic performance, and weight control.

The newest nutrition education program developed by National Dairy Council is FOOD...Early Choices, a nutrition learning system for three and four year olds and their parents. This program has just been completed and was introduced last month, January 1980, to Dairy Council staff at an in-service education program in Chicago. The FOOD...Early Choices program for early childhood is based on the same conceptual framework as our K-12, FOOD...Your Choice Program -- the 1969 White House Conference

Concepts. The same general steps which guided the development of FOOD... Your Choice were used in developing the new program -- involvement of outside consultants in early childhood education and nutrition, learner verification of program activities and materials with teachers and students, involvement of affiliated Dairy Council staff in developing and field testing the program and national review. A curriculum study of FOOD... Early Choices is currently under way at five test sites across the country and study results will be available in July of this year.

FOOD...Early Choices is a multimedia packaged program which contains a teacher guide, 22 learning activity cards for the teacher's guidance in conducting student lessons, a set of communications for parents, and a wide variety of learning materials for the children -- food picture cards, games, puzzles, posters, and a record of nutrition songs. A central figure in the program is a puppet named Chef Combo, who helps the children begin to learn about food -- to be food tasters, to be clean and careful when preparing food, to understand that food helps them grow and have energy and that their bodies need certain things found in foods to stay healthy.

National Dairy Council produced the FOOD...Early Choices program for use in nursery and day-care centers in response to needs expressed by early childhood educators. In the last 10 years the enrollment in nursery schools and day-care centers has more than doubled even though the population of three- and four-year-olds has declined by 22%. It is currently estimated that approximately 50% of three- and four-year-old children are enrolled in some type of nursery school or day-care center. Learning about food and teaching with food can be a vital and integral part of early childhood education.

The FOOD...Early Choices program provides nutrition learning experiences for young children. It also provides nutrition information for their teachers and parents. The important role that parents of young children play in their nutrition education is well recognized. Parents not only control a young child's access to food, but they are also the primary role models in the formation of the child's food attitudes and food behaviors. For a program of nutrition education to have a lasting effect on a young child, it must be supported and extended by the child's parents.

It is hoped that active parental involvement will become a key element in the FOOD...Early Choices nutrition education program for young children. Such involvement is strongly encouraged. To assist the teacher in creating a nutrition learning partnership with children and their parents, a number of communications to parents have been included as a part of the learning system. These materials are designed to help establish a linkage between the school program and the home environment in helping young children to develop positive attitudes toward food and appropriate eating patterns.

In-service education workshops for preschool teachers will be conducted by Dairy Council staff at the community level to introduce the program and facilitate its use.

Program overviews of FOOD...Your Choice, Levels 1, 2, and 3, and FOOD... Early Choices have been forwarded to the Committee staff for reference. In addition, copies of pre-publication "Fact Sheet" on Level 4 of the FOOD...Your Choice program for junior/senior high school students have also been forwarded for the staff's information.

Senator METZENBAUM. Thank you very much.

I just have a couple of questions.

Ms. Tenney, your company offers the public an alternative cut of meat, "Giant lean," that is less fatty than other meat products. How do you accomplish this? Does it cost the consumer any more?

Ms. TENNEY. We introduced lean beef in 1975, and it has been quite successful. We went into it at a time there was quite a bit of support for it due to the Russian grain deals. A lot of people from churches and elsewhere were concerned about world hunger and the problem of large amounts of grain being fed to cattle. We were able to offer Giant lean at a time when people really wanted it not just for health reasons, but also for other reasons. It does very well. It is lower in cost. It is 5-cents-a-pound cheaper than choice grade when it is not on sale and it is 10-cents cheaper when it is. That may not always be to our economic advantage, but it is something that we have agreed to do.

Senator METZENBAUM. How do you achieve it? Do you trim the fat?

Ms. TENNEY. No, no, it is from cattle that are raised for about 100 days on feed grain, as opposed to 150. Prior to grain feeding they are range fed as ordinary cattle would be.

Senator SCHWEIKER. Do you have a figure on what the cholesterol difference is?

Ms. TENNEY. No, unfortunately not. I would imagine it is not too very different. The level of fat, however, we had tested a couple of times on chucks. It was about 21-percent fat in choice grade, and the Giant lean chuck was about 14 percent. In that cut, we were getting about a one-third reduction in fat. We did not have the cholesterol tested.

Senator METZENBAUM. An FTC staff reported that 75 percent of Saturday morning food commercials were for sugar cereals, candied snacks directed at our Nation's youth. What do you think we can do to offset this?

Ms. STEORTS. I think there is a "new tomorrow" in advertising which lies ahead. I think this is a very good example of where, if a Nutrition Education Council were set up, it could serve as a leadership catalyst, which should bring about some positive changes in the way food is advertised and promoted.

I have recently seen some very good examples of how some companies are beginning to focus their attention on nutrition. I have included these examples in my prepared statement. I think now that we have the "Dietary Guidelines," we will see some more very positive changes in the future.

Senator METZENBAUM. Senator Schweiker.

Senator SCHWEIKER. Following up that last question, what do you think such a council would accomplish? What do you see as its goals, objectives, or possible achievements?

Ms. STEORTS. Senator Schweiker, I think there is a great deal going on in the country right now in nutrition education but it is very fragmented. I would see the overall objective of the Nutrition Education Council as setting up a very forward-looking, exciting, well-coordinated nutrition education program that would meet the need of all consumers. But in order to do this, we have to bring all the different factors together. It might be possible for this Nutrition Education Council to be a nonprofit foundation. Time does not allow me to go into details on this concept this morning, but I feel strongly it bears further discussion and investigation.

Senator SCHWEIKER. A question I want to direct to anybody who wants to comment on it. Recently the FDA, the FTC, and USDA have gotten together on this labeling, and they have made a proposal published in the Federal Register, and they are going to have hearings in the future on it. My particular question is whether the proposal they made is realistic? Are we omitting any critical information? Are they covering too much? Is it too complex to understand? I will be glad to get any comments as to its impact from anybody.

Ms. TENNEY. As I understand it, they do not necessarily have legislative authority for all——

Senator SCHWEIKER. Is it something you could put into effect immediately? The question is directed on the content and specific impact.

Ms. TENNEY. I think from our consumers point of view, all the consumers we work with—and we try to get comments from consumers all the time, they are right on target. We certainly have recommended previously that more information on fats and cholesterol be contained on the labels. These are the type of questions that come to me. Sodium is highest in the special diet area. So I would say the recommendations are right on target.

Whether nutrition labeling should be done as percentage of calories, I can't say for sure. I know consumers relate to calories. They have more trouble relating to percentage. They get confused. Perhaps if you work on it they can be educated to understand it.

Senator SCHWEIKER. Will it be easier to understand? My wife says why be the only one who understands the label.

Ms. TENNEY. I think this has been something that has been left up to the FDA to do a lot of study on. We are very supportive of it. You have got to do some marketplace testing of label formats.

Just the other day I got another label that is being tested out in Holland. They have come up with another format, which they are using now. We are very interested in this and I know the FDA is. We would be interested in participating in that testing process.

Senator SCHWEIKER. Does anybody else want to comment?

Ms. STEORTS. I support a good strong label that gives the consumer specific information. I would not want to think, however, that what we would put on this label today would be totally changed 5 years from now. I think it is rather sad to think that today we have all this nutrition information on the label and many consumers have no concept of what it means. So when the final label has

been developed for the product, I think you need to bring the best marketing people together to be sure that this approach is going to give the consumer the info he/she wants to make a good buying decision.

Senator SCHWEIKER. Dr. Winterfeldt, in your testimony you provide that nutrition education become a regular part of training of teachers and health professionals. As you probably heard from the previous panel, I view this as very important. It is something I have been working on for some time. It is an effort to get some of the health professionals plugged into this.

I introduced a bill, S. 2144, health professionals education assistance. It is a mere training act. What might the ADA do to promote increased attention to nutritional education in terms of medical schools? I realize you do not have jurisdiction over medical schools, but it seems we are going to have to have a lot of facets by interface to impact if we are going to move some of these medical schools that are so drug-oriented and disease-oriented into this area. Do you have any suggestions as to what either you can do or what associations like yourself can do to accomplish this objective which you agree is very good?

Dr. WINTERFELDT. Specific suggestions as to how to help accomplish that are support, and to try to help by working with the people who are providing that support though teaching of medical students. We would like to be involved in some of the teaching aspects. We would like to see the program expanded. We want to lend support in any way we can.

Senator SCHWEIKER. Are we making any progress with the new doctors that are entering the profession? What is your judgment? Do you see much in terms of new people coming in?

Dr. WINTERFELDT. Yes, I believe we are seeing progress. I think much of the impact on now that we have "Dietary Guidelines" and the great emphasis that has been given to nutrition education in the Surgeon General's reports make an impression on medical school people.

In further thought, I would like to add these suggestions regarding assistance the American Dietetic Association might render:

1. We support all efforts aimed toward acceptance of the concept that nurtition is an integral and essential aspect of health care. This is a concept which needs to be accepted by physicians and medical administration for the successful integration of nutrition into medical education.

2. We believe a nutrition education program must be interdisciplinary in nature because nutrition cuts across multiple areas of health care. We therefore support the inclusion of related disciplines in the development and implementation of the nutrition education program.

3. We support and recommend training and educational incentive grants and fellowships for both dietitians and physicians to assure the expertise needed at the academic level appropriate for provision of optimal educational programs.

4. We submit that qualified nutritionist/dietitians should head the development and implementation of the nutrition education programs. Clinical dietitians are already employed in medical center settings and can help provide this expertise.

5. We believe in, and would help develop, model curicular and teaching materials (indeed have already assisted in such developments). The further development of education model projects that demonstrate the coordination and successful integration of nutrition into present medical school curriculi would provide incentive for others. We feel that dietitians have a role to play as educators looking seriously at curricula and knowing that the curriculi in medical schools in full and has restraints.

6. We hope for the enactment by Congress of provision for nutrition services as a reimbursable service to third party payers. We believe physicians would then view nutrition in a more serious light as a treament modality and would likely refer more patients for nutrition counseling.

7. We propose a seminar or series of seminars among physicians and dietitians initiated by the American Dietetic Association for dialog toward recognition of nutrition services and expertise of dietitians in patient care in clinical settings. The current interest in nutrition and the recent release of the "Dietary Guidelines" by USDA–HEW might be focal point for discussion of dietary management of patients.

8. Interaction with the Liaison Committee on Medical Education toward development of an awareness of and sensitivity toward inclusion of nutrition on the National Board Examinations.

Senator SCHWEIKER. Well, as you know, we have a long way to go. The last time I surveyed the medical schools, only 5 or 6 out of a 100 or so even had a department or curriculum of either disease prevention, health education or nutrition or diet-disease relationships. We have got an awful long way to go. I realize that is not directly your problem.

Thank you very much.

We thank you all very much for coming here today.

Let me just put in the record a statement by Senator Hatch, a member of this committee who, unfortunately, had a conflict this morning with some other Senate business. His questions and statement are submitted for the record.

[The statement and questions from Senator Hatch and additional information submitted for the record follow:]

(from Senator Orrin G. Hatch)

Questions for Hearing on Diet and Nutrition, February 20, 1980

The U.S. Department of Agriculture has proposed regulations that would govern and influence the consumer's choice of foods.

A rule governing the sale of Competitive Foods in the School Lunch Program was recently finalized (Fed. Reg. 1/29/80). The rule establishes a nutrient density standard for Competitive Foods, stipulating that any Competitive Food must provide 5% of the USRDA for one of eight specified nutrients per serving and per 100 calories. Soft drinks and some candies are banned from school vending machines under this rule as they do not meet the standard.

A recent USDA proposal would establish control over the kinds of cereals available in the Special Supplemental Feeding Program for Women, Infants and Children (WIC, Fed. Reg. 11/30/70). The proposal would establish a maximum sugar content for WIC cereals of 6 grams of sugar per ounce of cereal.

USDA has also established guidelines for limiting the amount of fat, salt and sugar in school lunches.

All of these actions single out certain foods and attempt to limit their consumption. There is no scientific justification for this approach.

According to Dr. Gilbert A. Leveille, Chairman, Dept. of Food Science and Human Nutrition, Michigan State University:

> "Single foods cannot be labeled as good or bad. It is the total diet that is adequate or inadequate. Any food item can be incorporated into a sound diet, and by the same token any food item can be abused. The selection of individual foods depends upon the personal

> preferences of the consumer, while the overall quality of the diet is dependent upon the consumers' knowledge of foods and their ability to combine foods into a daily diet pattern which meets nutrient needs. Sugar-containing foods can play an important role in the selection of a balanced diet, and there is no evidence available to suggest that such foods make any negative contribution to the diet of man." (Food Technology, January 1980.)

The U.S. Department of Health, Education and Welfare recently issued, Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention. This report makes dietary recommendations--eat less fat, salt, cholesterol, sugar--but cites little relevant evidence.

In considering the Surgeon General's report and the newly issued Dietary Guidelines, it is important to understand the limitations of the scientific evidence on which they are based. A report entitled "Research Needs for Establishing Dietary Guidelines for the U.S., Population," recently issued by the National Academy of Sciences, suggest that many questions seemingly basic to dietary guidelines have been studied insufficiently or not at all. It is clear "that no single recommendation to the public regarding appropriate intakes of energy, protein, fat, carbohydrate, and sodium could be made," the report said.

QUESTIONS FOR WITNESSES

Carol Foreman/Julius Richmond

The Surgeon General's report gives the good news that Americans have never been healthier. USDA data released with the Dietary Guidelines shows that the nutrient density of the American Diet has increased since the 1960's. What is the basis for your

expressed concern about the quality of the American diet?

The Dietary Guidelines are quite general and avoid specifying how much of what foods to eat. Is it appropriate or even possible to use the Guidelines to evaluate individual foods? Wouldn't it be more appropriate to use the guidelines to evaluate the total diet rather than individual foods?

Julius Richmond

How do you respond to criticism of the Surgeon General's report that there is not sufficient scientific background for making specific dietary recommendations for the population?

Carol Foreman

You have said that the Dietary Guidelines and improved food labeling will help people make their own informed food choices. Isn't this contradictory to your position that USDA should be telling consumers what to eat through increased government regulations?

In light of the broad delegation given to the Secretary of HEW in S.1652 and to the Secretary of Agriculture in S.1651, does the Dept. of Agriculture plan to use the Dietary Guidelines as the foundation for other regulations specifying what certain consumers can eat?

GUIDELINES FOR A NATIONAL NUTRITION POLICY

by

THE NATIONAL NUTRITION CONSORTIUM

January 21, 1980

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SPECIAL REPORT

GUIDELINES FOR A NATIONAL NUTRITION POLICY

by

The National Nutrition Consortium *

The National Nutrition Consortium is a nonprofit organization composed of the major professional societies in food, nutrition and dietetics. In 1974, a special committee of the Consortium Board composed of Grace A. Goldsmith, Dean of Tulane University School of Public Health and Tropical Medicine; Jean Mayer, official Coordinator for the U.S. Senate Select Committee on Nutrition and Human Needs, and William J. Darby, President, The Nutrition Foundation, prepared a working paper on national nutrition policy for the Select Committee on Nutrition and Human Needs.[1] In his preface to the document, Dr. D. Mark Hegsted, then President of the Consortium Board, said:

> "The past year may represent a turning point in history. Numerous developments including the energy crisis, inflation, rising food costs and depletion of our food reserves have convinced many knowledgeable people that we are now entering an era which will be characterized by a shortage of resources including food. The high energy cost of producing food makes it clear that food and the energy supply are inextricably linked. For the first time, the capacity of the United States to feed itself and meet its world food commitments is being seriously questioned. A world food crisis exists at this time, and this will have serious repercussions in this country.
>
> "The first requirement of a food supply is that it provide a nutritionally adequate diet for the population. We must first supply what we need even if we cannot supply what we want.
>
> "New attitudes, priorities, and a restructuring of responsible governmental agencies and their programs will be required if we are to deal effectively with food and nutrition problems that we face now and in the future. We must create the social and political climate which will make this possible and this will be a complex process. This statement on a national nutrition policy by the National Nutrition Consortium indicates the essential components of such a policy and we urge that action be taken now to initiate its development."

On the occasion of entering this Consortium document into hearings of the Senate Select Committee, the chairman, Senator George McGovern, said:

> "The National Nutrition Consortium—an organization eminently qualified to deal with these kinds of questions—has been studying this problem for some time. I am delighted that they have provided the Select Committee with the fruits of their work, "*The Guidelines for National Nutrition Policy*". I am especially delighted that the Select Committee is publishing the Consortium's guidelines in advance of our hearings in June of this year on national nutrition policy, and I believe that the Consortium's guidelines can serve as a valuable document for all those participating in the Select Committee Study and hearings."

At that time, the set goals of an enlightened national nutrition policy were 1) to assure an adequate and wholesome food supply at reasonable cost to meet the needs of all segments of the population, 2) to maintain food resources sufficient to meet emergency needs and to fulfill a responsible role as a nation in meeting world food needs, 3) to develop a level of sound public knowledge and responsible understanding of nutrition and foods that will promote maximal nutritional health, 4) to maintain a system of quality and safety control that justifies public confidence in its food supply, and 5) to support research and education in foods and nutrition with adequate resources and reasonable priorities to solve the important current problems and exploratory basic research.

Some of the measures recommended for attaining these goals included 1) surveillance of nutrition status of population; 2) development of programs within the health care system to prevent and rectify nutritional problems; 3) assistance to the health professions in coordinating

* *Approved by the Board of the National Nutrition Consortium, Inc.*

efforts to improve nutritional status of the population; 4) determination of the nutrient composition of foods and the assembly of information on the food supply; 5) development of programs for nutrition education and 6) promotion of food labeling. Nutrition education was particularly emphasized as an inherent part of attaining these goals for the public and for students at all levels from elementary school through the university.

During the past five years there has been a great deal of activity by voluntary health organizations, educational institutions, congressional committees and government agencies to implement certain components of this national nutrition policy, particularly in the area of diet modification to improve the nation's health. One such recommendation, "Dietary Goals for the United States" put forward by the Senate Select Committee on Nutrition and Human Needs in 1977[2,3] elicited great interest, discussion and some controversy.[4-9]

In view of these recent developments, the National Nutrition Consortium decided to review and update its 1974 statement on national nutrition policy. The following statement represents its current position:

The Consortium Board reaffirms its recommendations for a sound national nutrition policy put forward in 1974. It endorses the principle of dietary guidelines which emphasize weight control, and stress moderation in the use of alcohol, fat, sugar and salt.

The Consortium Board believes that there is a need for the development of quantitative guidelines for healthful diets dealing with the intake of non-essential nutrients (for example, saturated fat, sugar, fiber and cholesterol) and essential nutrients above the requirement (for example, water, salt, vitamins, trace minerals and polyunsaturated fats). The Consortium Board is concerned, however, about the strength of the data base which underlies some of the recommendations currently being made to the American people. As already indicated, recommendations to reduce the amount of sugar, salt, fat and cholesterol in the American diet are being made in the hope that these changes will prevent a variety of chronic degenerative diseases. Since all of these diseases are multifactorial and none of them purely nutritional, preventive measures based on diet alone are not sufficient. That diet plays some role in the development of these diseases particularly in metabolically susceptible individuals is not disputed. The Consortium Board is concerned about promising benefits beyond those supported by existing data; for example, several dietary intervention studies featuring modification in the kind and amount of dietary fat have not reduced mortality from a variety of chronic degenerative diseases.[10] The Consortium Board appreciates the fact that absolute proof of the effect of dietary change on a complicated disease process will be difficult to obtain, but cautions against public health action to change some dietary practices on the basis of epidemiological data alone.

Although the Board members are not fully in agreement about the value of specific dietary guidelines in preventive medicine, they do agree that such guidelines represent a step in the right direction. Certainly, weight control and restriction of salt to 8 g or less per day are examples of prudent dietary guidelines. Equally important is the recommendation that each person take a diverse and nutritious diet supplying all of the essential nutrients in adequate amounts. For example, too rigorous adherence to the goal of reduction of saturated fat may result in the elimination of animal foods rich in protein and essential vitamins and minerals. It cannot be assumed that the amount of cholesterol in the diet and the proportions of saturated and unsaturated fat are of universal importance to good health in all individuals. Most important is the concept that diet is only one aspect of programs for health maintenance which must stress attainment of physical fitness through increased physical activity, active immunization, cessation of cigarette smoking and avoidance of drug abuse.

The Consortium Board believes that nutritional guidelines cannot be the sole basis of a national nutrition policy. It urges continuing nutrition research to define quantitatively the optimum levels of fat, carbohydrate, protein, salt, sugar and fiber needed to maximize health and improve the quality of life for all segments of our population. Continuing research into the causes and pathogenesis of the major degenerative diseases should go hand in hand with nutritional investigations.

It believes that nutritional guidelines, in line with all public health policies, will be evolutionary with the advent of new scientific information and clinical experience and will require periodic review and updating. Risk-benefit considerations for any recommended change in the American diet, or lack of such change, should be a part of all nutrition policy decisions.

Finally, the Consortium Board supports strong nutrition education programs which are scientifically based, forthright with response to controversy and well-formulated in order to keep the public informed about the current state of knowledge with respect to diet and the prevention of disease.

January 21, 1980

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2. Select Committee on Nutrition and Human Needs, U.S. Senate: *Dietary Goals for the United States*, Government Printing Office, Washington, D.C., 1977
3. Select Committee on Nutrition and Human Needs, U.S. Senate: *Dietary Goals for the United States*, 2nd ed., Government Printing Office, Washington, D.C., 1977
4. Diet Related to Killer Diseases, III, IV, V, VI. Hearings before the Select Committee on Nutrition and Human Needs of the U.S. Senate, 95th Congress, First Session. Government Printing Office, Washington, D.C., 1977
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9. D.M. Hegsted: Rationale for Change in the American Diet. *Food Technol.* 32: 44-49, 1978
10. E.H. Ahrens, Jr.: The Management of Hyperlipidemias: Whether Rather than How. *Ann. Int. Med.* 85: 87-93, 1976

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THE NATIONAL NUTRITION CONSORTIUM

The National Nutrition Consortium is a non-profit organization comprising the major professional societies in food, nutrition and dietetics. The cumulative membership of these societies totals approximately 80,000 scientists, physicians, educators and dietitians who have education, expertise and experience in nutrition.

Policy and programs of the Consortium are determined by a board composed of three voting delegates from each sponsor society and one non-voting delegate from each liaison society. Board members serve for a three-year term. New members to fill expiring terms are nominated by their member organizations and elected by the current Board at the meeting prior to July 1 of each year.

Positions are taken and statements made by the Board of the National Nutrition Consortium. Official statements must be approved by two voting members from each of the sponsor societies. Liaison organizations do not vote on Board positions. Board statements and positions are not approved by the governing councils of the member organizations but they are communicated via the Board members to all member organizations. Board statements on a particular topic take into consideration existing positions of member organizations when such are available.

As a Consortium of organizations, there are no individual members of the National Nutrition Consortium. The Board of the Consortium meets regularly to review staff and committee activities, to initiate new programs and to determine Consortium policy.

The President and Executive Officer of the Consortium are authorized and encouraged to communicate with the public and policy makers on matters related to foods and nutrition.

Sponsor Organizations

American Dietetic Association
American Institute of Nutrition
American Society for Clinical Nutrition
Institute of Food Technologists
Society for Nutrition Education

WALNUT ACRES, INC.
PENNS CREEK, PA. 17862
NATURAL FOOD PRODUCTS BY MAIL
PAUL KEENE, President

4 March 1980

The Honorable Senator Edward M. Kennedy
2241 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Kennedy:

I am writing to request that the enclosed information, a copy of which we already sent to you, be entered into the record of your sub-committee hearings on the Nutrition Labeling bill.

Thank you very much for your continuing support.

Very sincerely,

Paul Keene/awg

Paul Keene
WALNUT ACRES, INC.

PK:awg
Enclosure

Spring, 1980

WALNUT ACRES, Penns Creek, Pa. 17862

Telephone 717/837 - 6635

PLEASE LET US LIVE

The Concerns of One Small, Troubled Food Processor

RE: Nutritional Labeling

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SUMMARY

PART I - An American Saga - Pages 1, 2, 3

Background material on one small food processor.

PART II - Two Insolvable Problems for the Small Food Processor Created by Mandatory Nutritional Labeling - Pages 3, 4, 5

PART III - Life-Preserving Suggestions Pages 5, 6, 7

Prepared by Paul Keene

Walnut Acres, Inc.

Penns Creek, Pa. 17862

PART I -BACKGROUND MATERIAL

In 1946, thirty four years ago, Mrs. Keene and I moved onto our newly-acquired farm, named Walnut Acres. We came out of a background of rural and village living, and of teaching. My training was in Mathematics, Chemistry and Physics, with four years study at Yale. I hold B.S., M.A., And Sc.D (Hon.) degrees, and was for several years head of the Math Department in a college in New Jersey.

While teaching for several years in India we had become deeply interested in the land and our relation to it. We felt we had to know more, so we decided to leave teaching altogether and make our living and raise our family on a farm. So for four more years we studied all branches of organic farming, and living on the land in general, at two separate schools then in existence.

We had only $200.00 to start with, plus university debts, a team of horses, and some old pieces of equipment, not including a tractor. But we were able to borrow the money to buy our lovely farm, and move with our children onto it. The going was not always easy, but in the best 'Mom-and-Pop' tradition we were determined to make a "go" of it in our great free-enterprise system. Nothing could stop us. We were moving against the tide by never using synthetics or artificials, either on the soil or plants, or in any product we prepared to sell. (It is interesting now to note modern trends in this direction.)

The years have gone by all too rapidly. Grandchildren now play around our knees. Yet we have remained true to our principles, and have shown many fascinating things about insect control, for example. We have seen great results in both soil and crops. We were among the pioneers in this field in modern times. We became one of the best-known and most-trusted sources for specially grown and prepared foods. We have always tried to make small, fresh lots of our foods, and have seen a reputation for quality develop all about us.

We never claimed our way to be a universal panacea, or to be applicable in all circumstances everywhere. But we had the freedom to try out what we felt to be a valid approach. A number of giant companies have tried to buy us out, but we were

not interested. One of the wonders of doing business in this country, we learned, was the way in which little persons like ourselves could hold up our heads proudly, making our meager way among enormous companies and conglomerates, with as much integrity and unselfishness as we could muster. With us, all around quality of products has always come ahead of quantity and large incomes.

People soon began coming and writing from the cities for our products. They wanted us to ship by mail. Here they could contact directly the people who did it all, from the ground up. We could attempt to answer all their questions about growing and processing methods. As they became more sophisticated in their requests for knowledge, experience led us to more sophisticated answers. We had first one customer, then two - and then a hundred, a thousand - and now there are many thousands, all over the country and out of it. We make no special claims for our products. We tell how we grow and process, and consumers decide if they want what we produce. They keep pushing us for more products all the time.

Their sensing that we want only to supply what they desire, in brotherliness and honorableness, has caused a bond to be formed which ties us all together into one large, consumer-supplier family where true concern for the other comes first.

We couldn't do it all alone, so we reached out to our neighborhood farm and rural-village people to help. Most of us are of hard-working, simple, frugal Pennsylvania Dutch stock. Our lives will be spent in this depressed Upper-Appalachian mountain region. Incomes in our work average from $7,000.00 to $8,000.00 yearly. We are all stockholders - working, owning our company in common. No person or family holds a majority of the stock. There are no non-working stockholders. It is really ours. We've brought millions of dollars into the area, and are highly respected everywhere.

As normal, public-office-holding, community-serving people we've tried to conserve the soil, and those special values inherent in rural community living. We borrowed money from the Fm.H.A. to build a lovely community center which is unique in the whole of central Pennsylvania. Its program reaches people for miles around, up-

building, enlightening.

We've seen much joy and growth come as a fulfillment of earlier dreams. Only in this country could something as wonderful as this have developed. It is so typically American. We thank God every day for it.

Yet now, through our ever-present tendencies to force all people into moulds, this whole way of life is most seriously threatened with complete extinction. If nutritional labeling is made mandatory, we are finished. If it is imposed, and five years later other "findings" force relaxation of its severity, it will be too late, not only for Walnut Acres, but for a host of other small food processors, all over this great nation. What a pity to see the small things forced by law to die, that only the large might remain. We think of Nature's attempts with the dinosaurs, and weep.

In the following we try to point up the problems, and make bold to suggest procedures which would still allow the small food processor to carry on doing his good work in peace.

PART II - PROBLEMS

1. Whatever method is finally determined as being the best to convey nutritional information to the consumer, the small food processor may find it impossible to carry it out successfully.

If extremely costly per-batch testing is required, either by in-plant laboratory facilities and technicians, or by sending samples to an outside laboratory, costs for the small food processor will be astronomical and impossible.

If the data bank procedure is followed, and if this required only one test per year, on each of our 500 products, the cost could run (counting at least $150.00 per sample) to an annual total of $75,000.00. This is about 275% of our average net profit after taxes, and is of course also an impossibility for us.

In addition it would cost us thousands of dollars in extra competent labor costs in monitoring such a system. We think we would have to hire one to two full-time persons to gather from 6 to 12 samples of at least 2 items every working day of

every year. These would have to be sent to a distant laboratory for the testing. Reports should be coming back every day on earlier submittals. There would be collating, filing, reporting to the Regulatory Agency, plus endless correspondence over misconceptions, regulations, required changes in labeling,use of outdated bags-tins - bottles when any changes are necessary, etc.

Further, we would have to spend thousands of dollars more for our actual annual cost in sending away "free" samples and in paying the postage on them. We would presumably be required to send away thousands of samples every year.

All this is aside from inconceivable amounts of record keeping, unsettled disputes, unavoidable time lapses between us and the analyzers and Washington, and unusable bags and labels. The total extra costs to us just for the testing of our products could run over $100,000.00 (one hundred thousand dollars), which is several times our net profit after taxes. This adds up to a nightmarish impossibility.

2. Once nutritional information for a product has been determined, how do small food processors go about the logistics of the actual labeling itself? They make up one batch of the product, then send away a representative sample to a distant laboratory for sampling. Upon receipt of the results, labels are printed. The batch, which has been sitting around awaiting the arrival of the labels, must then be packaged. Weeks have gone by. It is simply impossible to operate this way. If however there is a Nutrition Data Bank, the small processor can presumably determi for himself the necessary labeling information. He now turns to the container problem.

Suppose in our case we package 240 different items in printed paper bags, in three or four different sizes each. If each bag had to be printed with full nutritional labeling information to cover its contents, we would have to stock, say 840 different kinds of bags. Minimum orders of printed bags often run 25,000 each. Conceivably we could have in stock a maximum of 21,100,000 bags, worth at least $2,000,000.00. Because we handle extremely small amounts of many products, one order of bags for some of our products could last us from five to ten years. Our strength comes only from our large variety of items, even though we average currently

only about $5,000.00 worth of sales per item annually.

So inventory costs, storage space, bag deterioration, formula changes, and governmental mandate changes all add up to an impossible situation. Granted that our case is extreme, other small packers with only 10% of our item variety would be faced with a proportionate difficulty which would still put them out of business.

PART III -SUGGESTIONS - with comments to follow.

(1) Leave the situation as it is for the small food processor, who is not generally required to label nutritionally unless he makes special claims. Anything other will drive some firms out of business.

(2) Or, exempt from mandatory labeling all products of any processor who manufactures less than $500,000.00 worth of said products, if no special claims are made.

(3) The appropriate regulatory agency could provide a service under which small food processors could send in a formula or a product sample and receive back a nutritional analysis. Once an original determination was made,duplicate lots using the same formula would carry the same labels.

(4) Should testing be mandated, the only way a small food processor could hope to meet requirements would be for the Regulatory Agencies to set standards for each product, above and/or below which the contents of certain food elements found in the product would not be permitted to fall. The concerned agency should be responsible for picking up samples of products to be tested and paying regular retail prices for them. The agency would test the samples, and report results to the small processor. This of course would still leave the impossible burden of the actual labeling itself, referred to in Problem 2 above.

(5) Even if a Regulatory Agency paid for all the costs of analyses, the ultimate defeating hang-up is the passing on of the information to the consumer. Having received analysis details from the Data Bank, or as suggested under (3) above, to avoid the practical impossibility of printing each bag and label as outlined earlier, let the processor have information on hand to give or send to anyone requesting it. This would avoid the impossibility of the small processor to have the information available at the point of sale.

(6) Instead of mandating nutritional labeling on each product, require retail outlets to have on display a chart showing label information on all products of a certain manufacturer, to which consumers could refer.

(7) As a variation on (6) above, retail outlets could have on display charts showing general percentages of desired nutritive elements to be found in each class of foodstuff.

PART III - COMMENTS

Suppose products not labeled nutritionally remain on the market. Such consumers as feel concern for nutritional information would simply cease purchasing non-nutritionally labeled products. There are consumers who are content with their knowledge of nutritional matters, or who feel other factors are more important to them than knowing fine details on the sodium content of a food. They probably do not even refer to the information given.

A rapidly increasing number of persons would far rather be informed about the soil in which the crop was raised; about the use or non-use of any of a great variety of synthetics on the crop, some of them quite toxic; about the use of lye in peeling food products; about the method of blanching used; about whether or not the food was freshly prepared in small lots, left as whole and complete as possible; about the percentage of the contents of a product which come solely from real foods, compared with that which came from highly-concentrated extracts or from non-food synthetics, artificials or imitations. These are matters on which the future will be dwelling. There is growing concern with efforts to equate the non-food with the real food elements in modern products.

Cigarette manufacturers, purveying a product now generally accepted as being harmful to health, may still sell this product by placing a disclaimer on the package. Also, flammable materials are marked as such - they are not removed from the market because of their flammability. If people want inflammable materials they merely have to choose them. It seems completely incongruous to legislate what people shall eat. It seems logical to assume that consumers should learn from various sources all through life which foods are high or low in certain nutrients.

But this cannot be legislated to be the job of the small food processor, who has a difficult enough time of staying alive as it is. Could not small purveyors of foods they cannot possibly afford to label nutritionally under any system be permitted to stay in business through the printing of some sort of disclaimer on their labels?

HELP! We feel we are struggling against mighty odds. As so often happens when something small comes up against something much larger, it becomes a matter of life or death for the small. This is truly not an apology for a desire to cheapen our products, to lessen food value. Instead we feel we produce much better than average foods, and it is all real food - not synthetic or imitation.

WE'D LIKE TO HELP. We'd like to sit down on a one-to-one basis with anyone, to give more details on the plight of the small food processor in this matter. We'll go anywhere at any time we can. We'd like to speak in hearings. We're fighting for our lives, and those of a multitude of others. We beg for the privilege of presenting our case. We understand your problems and those of all consumers, as well as our own, and those of our many fellow small food processors. Justice and right cry to be heard. Surely Democracy's ears are still open to the people's pleas!

Thank you.

Paul Keene, President
Walnut Acres
Penns Creek, Pa. 17862
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Senator SCHWEIKER. The committee will stand in recess until our next of the series of hearings on this matter.

[Whereupon, at 1:40 p.m. the hearing was recessed.]

NUTRITION LABELING AND INFORMATION AMENDMENTS OF 1979 TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

WEDNESDAY, MARCH 19, 1980

U.S. SENATE,
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:45 a.m., in room 4232 Dirksen Senate Office Building, Senator Donald W. Riegle, Jr., presiding, pro tempore.

Present: Senators Riegle and Schweiker.

OPENING STATEMENT OF SENATOR RIEGLE

Senator RIEGLE. The committee will come to order. Let me invite those who are standing to find seats if they can, and let me welcome everyone to the committee today.

Today the Subcommittee on Health and Scientific Research holds its second day of hearings on nutrition policy. We will focus on Senator McGovern's nutrition labeling bill, S. 1652, which I have cosponsored along with Senators Kennedy, Metzenbaum, Williams, Javits, Lugar, and Leahy.

On February 20, Dr. Julius Richmon, the Surgeon General of the United States, reported to this subcommittee that diet has been identified as a risk factor in 6 of the 10 leading causes of death in this country.

Dr. Arthur Upton, formerly Director of the National Cancer Institutes, has stated that improper diet is related to as many as 50 percent of all cancer.

The legislation before us today is designed to provide American consumers with the information they need to make informed choices about the food they eat.

To accomplish that objective the bill strengthens existing labeling laws in order to provide consumers with objective, easily understandable nutrition and ingredient information.

That information will specifically include data on the quantities of protein, fats, carbohydrates, sodium, and cholesterol in each item purchased.

At the same time, the legislation attempts to do this without imposing burdensome and costly requirements on industry.

We are especially pleased and honored that Senator McGovern will be our leadoff witness this morning. First as the chairman of the Senate Select Committee on Nutrition and now as the chair-

man of the Subcommittee on Nutrition of the Agriculture Committee, Senator McGovern has been in my view the top national leader in increasing the public awareness of the vital relationship between good nutrition and good health.

I think we owe him a great debt of gratitude for his leadership and outstanding work in this area.

We will also hear this morning from Dr. Mark Novitch, Acting Deputy Commissioner of the Food and Drug Administration, as well as from representatives of three major food companies and a panel representing food manufacturers, food retailers, and consumers.

Before beginning, I would ask if Senator Schweiker has any statement he'd like to make at this time.

Opening Statement of Senator Schweiker

Senator Schweiker. Thank you very much, Mr. Chairman.

Last month this subcommittee heard testimony on the importance of nutrition in diet. Americans are increasing their awareness of the fundamental relationship between a nutritious diet and better health. However, the absence of opportunities for nutrition education—which not only informs but instructs—leaves a serious gap between the public's concern about diet and their ability to make informed decisions in the marketplace. Our desire is to fill that gap, bringing us here today.

My longstanding interest in nutrition education not only prompted my request for last month's hearing, but it also prompted me to include incentives for medical schools to improve the nutrition education of health professionals in legislation I recently introduced, S. 2144. In spite of research linking diet and disease, medical schools have neglected to give this subject the attention it deserves. It is time to move ahead in this area as well.

Well trained health professionals are not a replacement but a tool to satisfy the public's need for nutritional education. Likewise, another tool is food labeling. Together we will consider the potential of food labeling and the appropriateness of S. 1652 in that educational process.

I support food labeling. I believe that consumers want to know exactly what they are buying and how it will affect their families health. In the past, I have actively sought greater disclosure of the salt and sugar content of food products. Americans probably consume a greater excess of sodium in the form of salt than any other essential ingredient. My concern about sugar stemmed from the lack of information on the sweetener content of ready-to-eat cereals which in some cases exceeds more than 50 percent of a product until the Food and Drug Administration moved to correct this labeling oversight.

America may have the oldest food labeling law in the world, but there is still room for improvement. Basically, the flaws in current food labeling policies lie in their inconsistency, the inadequacy of data concerning the usability of food labeling by consumers, the lack of consideration given to the relationship of food labeling to nutritional needs, and most fundamental, the lack of consumer education. These flaws are costly and wasteful.

After working with Senator McGovern on the former Senate Select Committee on Nutrition and Human Needs, I have no doubt that Senator McGovern has sought to address the problems I have highlighted in the proposal before us today. I commend him for his objectives to give the consumer useful nutrition information at the same or less cost than the current system, to increase industry participation in the development of food labeling policy and to reduce regulation that has prevented the market from functioning on a competitive basis.

These are broad policy issues that deserve our careful scrutiny and our best judgment. I welcome today's witnesses with the understanding that they will give us some practical insight into the correct value of our judgments. Only then can we hope to make some sense out of how we can meet our dual objectives of giving the consumer necessary information about nutrition and also giving him food at the lowest possible price.

Thank you, Mr. Chairman.

Senator RIEGLE. Thank you, Senator Schweiker, for an excellent statement. I want to associate myself with it and also to acknowledge your leadership in the area of nutrition education.

Senator McGovern, could we invite you to share your thoughts with us at this time. We are pleased to have you.

STATEMENT OF HON. GEORGE McGOVERN, A U.S. SENATOR FROM THE STATE OF SOUTH DAKOTA

Senator MCGOVERN. Thank you very much, Mr. Chairman, and Senator Schweiker, and I want to thank both of you for the privilege I've had of working with you over the years on nutritional concerns.

I will hold a hearing, Mr. Chairman, before the Nutrition Subcommittee on the latter bill on April 1. I'd like to just take a minute to outline how we have arrived at this point.

S. 1652 is the product of what is now a 2-year initiative and the heir to other Senate efforts earlier in this decade. The process began in August 1978 with hearings before the Agriculture, Nutrition, and Forestry Committee. Then in the fall of 1978 the Department of Agriculture, the Food and Drug Administration, and the Federal Trade Commission held 10 days of hearings in five cities on the topic of food labeling. Those agencies testified both at the outset and again at the end of the oversight hearings held by the Subcommittee on Nutrition that totaled some 6 days ending in February of last year.

In the spring of 1979 staff from the Committees on Agriculture, Commerce, Science, and Transportation, and Labor and Human Resources began meeting informally with individual food companies, trade associations, consumer groups, and the three agencies that I've mentioned. Finally, on August 2 of last year, S. 1651 and S. 1652 were introduced with cosponsors from those three committees.

With the depth and breadth of effort over the last 2 years, I believe that these two bills offer the best proposal to date on the nutrition labeling and information issue. They represent a spirit of cooperation among the agencies administering the laws and the committees of the Congress who have legislative jurisdiction. They

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also equally reflect, Mr. Chairman, the interests of the food industry and the consuming public.

I particularly want to underscore this last point. This legislation, in my opinion, represents a very constructive and ongoing initiative that is based on industry/government cooperation. I think it is exemplary of the kind of productive and equally beneficial outcome that can occur when the private and public sectors sit down to solve their mutual problems.

Therefore, the enactment of this legislation is in the best interest of all Americans. The ability of consumers to select a more nutritious diet is critical in preventing disease and promoting good health because diet is a risk factor as we now know in 6 of the 10 leading causes of death in the United States, and it is a causative factor in obesity and dental caries. Furthermore, more optimal diet selection can help slow mounting medical care costs because healthier people obviously need less medical attention.

Mr. Chairman, the Congress has never before specifically enacted nutrition labeling legislation. As a result, the current nutrition labeling is based on the existing statutes of the Federal Food, Drug and Cosmetic Act, an act which is essentially punitive in nature because of the very real food and drug safety concerns that it addresses. However, the consumer's need for nutritional labeling is on a totally different plane from that of regulating toxic substances in our foods. Our hearings have demonstrated that in fact because the Congress has not taken direct action on nutrition labeling, we have overregulated this matter by overemphasizing the classic compliance aspects of food regulations, as over against the informational and educational aspects of labeling.

This legislation addresses the problem of inappropriate regulation by directing the focus away from compliance and toward the vital information function of nutrition and ingredient labeling. Thus, this bill embraces a classic principle of American democracy, the Government's responsibility to encourage the flow of vital information in the marketplace. By so doing, we can achieve better market competition and less Government regulation by giving people necessary information with which to make their own informed choices.

I will close out my testimony this morning by briefly indicating three modifications that I think will further improve S. 1652.

First, the central working principle of this bill is the establishment of a nutrition data base approach to food labeling. Since I expect the details of this method will be discussed by this morning's witnesses, at this time I will only make the following two points:

I would recommend that an altered time frame and implementation sequence be added to the bill. I would also recommend that in addition to evaluating labeling formats, the demonstration projects in section 5 include testing and studies of so-called off-label methods of disseminating nutrition information. One proposal recently made by the food industry for achieving this objective is by means of a reference book that would be made available to consumers.

Second, S. 1652 needs to include a new section authorizing the President to establish a joint USDA/FDA committee that will oversee the development of the data base and the demonstration proj-

ects and the dissemination of the nutrition information by means of labels and off-label methods. This joint committee would have industry and consumer input.

Finally, S. 1651, the USDA companion bill before my subcommittee, drops the existing criminal penalties for the mislabeling of nutrition and ingredient information. As currently drafted, S. 1652 does not do this. I believe that we should match the penalty with the crime. Whereas food safety concerns require that criminal penalties be applied to many parts of the Food, Drug and Cosmetic Act, I seriously question whether such a severe penalty is appropriate for inaccurate nutrition and ingredient labeling.

If we are serious about developing a new regulatory philosophy in this area that emphasizes information dispersal, rather than compliance, then examining where we might modify or eliminate criminal penalties under S. 1652 for the nutrition and ingredient labeling provisions is an important consideration.

Thank you, Mr. Chairman, and Senator Schweiker, for letting me be the leadoff witness at these hearings.

Senator RIEGLE. Thank you, Senator McGovern. We appreciate your testimony. It's important testimony for us.

I believe you have additional material that you may wish to submit as part of the record.

Senator MCGOVERN. I do have some additional material to submit, Mr. Chairman. As I indicated before, we have an ingenious way of having two or three committees meeting at one time around here, and I have a major farm bill that I have to go fight for now. So if you will excuse me without the usual vigorous interrogation, I would appreciate it.

Senator RIEGLE. We will indeed. We appreciate your contribution today, and we wish you as well before the Agriculture Committee.

Senator Schweiker.

Senator SCHWEIKER. Well, I just want to again commend Senator McGovern for his work. I enjoyed working on our Select Committee on Nutrition before we had to break it up. I commend his leadership in this area.

Senator MCGOVERN. Thank you, Senator Schweiker and Mr. Chairman.

Senator RIEGLE. Thank you.

[The following was received for the record:]

PREPARED STATEMENT OF SENATOR MCGOVERN

Mr. Chairman, I am pleased to be here this morning to open this hearing on nutrition labeling and information. I particularly want to thank you and Senator Kennedy for your support of both S. 1652, "the Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug and Cosmetic Act"; and S. 1651, the "Department of Agriculture Nutrition Labeling and Information Act of 1979." I anticipate holding hearings before the Nutrition Subcommittee on the latter bill before the end of April.

If I could take a minute, I would like to outline how we arrived at this point. S. 1652 is the product of what is now a two year initiative, and the heir to other Senate efforts earlier in this decade. The process began in August 1978 with hearings before the Agriculture, Nutrition and Forestry Committee. Then in the fall of 1978 the Department of Agriculture, the Food and Drug Administration, and the Federal Trade Commission held 10 days of hearings in 5 cities on the topic of food labeling. Those agencies testified both at the outset and again at the end of the oversight hearings held by my Subcommittee on Nutrition that totalled 6 days ending in February 1979.

In the spring of 1979, staff from the Committees on Agriculture, Nutrition, and Forestry; Commerce, Science, and Transportation; and Labor and Human Resources began meeting informally with individual food companies, trade associations, consumer groups, and the three agencies. Finally, on August 2, 1979, S. 1651 and S. 1652 were introduced with co-sponsors from those three Committees.

With the depth and breadth of effort over the last two years, I believe that these two bills offer the best proposal to date on the nutrition labeling and information issue. They represent a spirit of cooperation among the agencies administering the laws, and the committees of Congress who have legislative jurisdiction. They also equally reflect the interests of the food industry and the consuming public.

I particularly want to underscore this last point. This legislation represents a very constructive and ongoing initiative that is based on industry/government cooperation. I think it is exemplary of the kind of productive and equally beneficial outcome that can occur when the private and public sectors sit down to solve their mutual problems.

Thus, the enactment of this legislation is in the best interest of all Americans. The ability of consumers to select a more nutritious diet is critical in preventing disease and promoting good health because diet is a risk factor in 6 of the 10 leading causes of death, and it is a causative factor in obesity and dental caries. Furthermore, more optimal diet selection can help slow mounting medical care costs because healthier people need less medical attention.

The passage of these bills is also in the best interest of the American food industry. This legislation focuses on removing overly restrictive regulation that has prevented the market from functioning on a more competitive basis. The food market can only be truly competitive if consumers have sound, objective and relevant nutrition and ingredient information with which to make an informed choice. As a possible additional benefit, by being able to make such a choice, consumers will feel more confident about the American food system which in turn will enhance the credibility of our number one industry.

The Congress has never specifically enacted nutrition labeling legislation. As a result, current nutrition labeling is based on the existing statutes of the Federal Food, Drug, and Cosmetic Act—an act which is essentially punitive in nature because of the very real food and drug safety concerns that it addresses. However, the consumer's need for nutrition labeling is on a totally different plane from that of regulating toxic substances in our foods. Our hearings have demonstrated that, in fact, because the Congress has not taken direct action on nutritioning labeling, we have overregulated this matter by over-emphasizing the classic compliance aspect of food regulations.

I recognize that the public usually associates more legislation with more regulation. But this is not always the case. In this instance, this legislation is aimed specifically at ridding us of overly restrictive labeling regulations that have evolved as a result of trying to use inappropriate statutory language to meet an unintended purpose. This legislation addresses the problem of inappropriate regulation by directing the focus away from compliance and toward the vital information function of nutrition and ingredient labeling. Thus, this bill embrances a classic principle of American democracy—the government's responsibility to encourage the flow of vital information in the marketplace. By so doing, we can achieve better market competition and less government regulation by giving people necessary information with which to make informed choices.

With this in mind, we have sought to meet three key objectives. First, the consumer's need and desire for objective and useful nutrition information that is suitably accurate, and that can be provided on food labels or labeling at the same or less cost as the current system. Second, the food industry's need for greater flexibility and full participation in the development process. And third, both groups stated position that a person has the right to know what is in the food that he or she chooses to eat, as well as the right to choose those foods that he or she desires to eat. Furthermore, we have examined the problem comprehensively by considering it as an information system that includes all types and sources of food.

I will close out my testimony this morning by discussing four key modifications that I believe will further improve S. 1652.

First, Section 7, Notification to and Report by the Federal Trade Commission, should be dropped from S. 1652. The more time I spend with this legislation, the more I have realized the importance of matching the desired objective with the best means to attain that particular objective. In this case, the best method that I have seen to convey a modest amount of accurate, objective nutrition information is on food labels. This does not mean of course that nutrition is not suitable as a topic in advertising. Rather, I don't think we should ask advertisers to attempt to provide

nutrition information via a medium that is not best suited to effect the desired objective.

Second, the central working principle of S. 1652 is the establishment of a nutrition data base approach to food labeling. Since I expect the details of this method will be discussed by this morning's witnesses, at this time I will only make the following two points. I would recommend that an altered time frame and implementation sequence be added to the bill. Specifically, as currently drafted, mandatory nutrition labeling for all processed foods would go into effect two years after enactment of S. 1652. I would recommend instead that after two years we adopt a new labeling format based on the findings from Section 5, Demonstrations and Evaluations, but that no food would be required to provide nutrition information until it was in the nutrition data base. Of course, if a nutrition claim is made about a food by the producer, then nutrition labeling would be required even if that food is not already in the date base.

The projected timetable for establishing the data base and thus shifting over to a predominantly mandatory nutrition labeling system in five years after enactment.

In addition to evaluation label and labeling formats, I would also recommend that the demonstration projects in Section 5 include testing and studies of so-called off label methods of disseminating nutrition information. One proposal recently made by the food industry for achieving this objective is via a reference book that would be made available to consumers. Such a text is a natural extension of a food label. It solves the problem of having only a finite amount of sapce on a label. It would be particularly valuable to people who require far more detailed nutrition information because they have health problems. It would also be useful as a resource in the nation's schools for teaching our children about food labels and nutrition. Once a comprehensive, national nutrition education program is developed, the demand for a text of this kind could make it as commonplace in kitchens as a cookbook. Such a document is one means by which FDA could meet the requirements of Section 6, Consumer Education Program on the Use of Labels and Labeling.

Third, S. 1652 needs to include to include a new section authorizing the President to establish a joint USDA/FDA committee that will oversee the development of the data base and the demonstration projects, and the dissemination of the nutrition information via labels and off-label methods. This joint committee would have industry and consumer input.

Finally, S. 1651, the USDA companion bill before my subcommittee, drops the existing criminal penalties for the mislabeling of nutrition and ingredient information. As currently drafted, S. 1652 does not do this. I believe that we should match the penalty to the crime. Whereas food safety concerns require that criminal penalties be applied to many parts of the Federal Food, Drug and Cosmetic Act, I question whether such a severe penalty is appropriate for inaccurate nutrition and ingredient labeling. If we are serious about developing a new regulatory philosophy in this area that emphasizes information dispersal rather than compliance, then examining where we might modify or eliminate criminal penalties under S. 1652 for the nutrition and ingredient labeling provisions is an important consideration.

Senator RIEGLE. Our next witness is Dr. Mark Novitch, who is the Acting Deputy Commissioner of the Food and Drug Administration.

We are pleased to have you and your associates here.

I might just say as you are being seated, it's important to note that we have a very significant bipartisan coalition in support, of the legislation before us today. It's not often enough that we're able to manage strong bipartisan effort and coalition behind vital legislation; but that is present in this case, and I think it illustrates the merit of the objective of the legislation.

STATEMENT OF MARK NOVITCH, M.D., ACTING DEPUTY COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY SANFORD A. MILLER, PH. D., DIRECTOR, BUREAU OF FOODS, FOOD AND DRUG ADMINISTRATION; AND ROBERT P. BRADY, ASSOCIATE CHIEF COUNSEL, FOOD AND DRUG ADMINISTRATION

Dr. NOVITCH. It is certainly good to know that, Mr. Chairman.

Mr. Chairman, I would like to introduce my colleagues, if I may.

On my right is Dr. Sanford Miller, who is Director of FDA's Bureau of Foods; and on my left is Bob Brady, our Associate Chief Counsel.

Mr. Chairman, I have a statement that I would like to submit for the record and if you will permit, I will just briefly summarize it.

Senator RIEGLE. That would be helpful. We'll make your entire statement a part of the record.

Dr. NOVITCH. Thank you.

I welcome the opportunity to appear before the subcommittee today to discuss and support S. 1652, the Nutrition Labeling and Information Amendments of 1979.

I do not believe there is any disagreement among us that a proper well-balanced diet aids not only in the maintenance of good health, but also plays a vital role in the prevention of disease.

The Senate Select Committee on Nutrition and Human Needs clearly recognized the relationship of diet to disease in its publication, Dietary Goals for the United States, and this relationship also figured prominently and properly in the recent HEW/USDA publication, Dietary Guidelines for Americans.

Recognizing the role of nutrition in good health, however, may be insufficient without the knowledge that allows consumers to choose a good diet.

Furnishing concise information on the packaging of food we buy is certainly one way and an important way to provide this knowledge that leads to informed decisions, a fact evident in the legislation now before this committee.

In our testimony I intend to bring you up to date on our efforts to improve food labeling and to provide what I hope will be useful and responsive comments on the legislation before you.

Within the limits of our current authority, we have taken a number of actions to improve food labeling.

For example, we have established a uniform format for nutrition labeling which includes information about the fat, protein, and carbohydrate content of a serving of a food and the amounts of vitamins and minerals expressed as a percentage of their U.S. recommended daily allowances.

We have established a common labeling format for fat, fatty acid and cholesterol content.

We have published regulations governing common or usual names for certain nonstandardized foods, including the provision that the product name include a statement of the percentage by weight of any characterizing ingredient.

An example would be the proportion of shrimp in shrimp cocktail.

We have been revising food standards to make as many ingredients as possible optional and have required that all of these optional ingredients be declared; and we have published a policy statement asking manufacturers to follow food fortification guidelines when foods are nutritionally improved.

More recently, as Senator McGovern just pointed out, as part of a major reevaluation of Federal food labeling laws and regulations, we worked with USDA and the Federal Trade Commission to de-

velop a new set of labeling proposals that we believe reflect the desires and the needs of consumers.

At regional hearings across the country we asked consumers for their views on labeling. We heard testimony from over 450 people and more than 9,000 people responded to our request for comment.

In the December 21, 1979, Federal Register, the three agencies jointly published their tentative positions on food labeling; and Mr. Chairman, I think it would be helpful, since those positions bear on the legislation before you, for that document to be made a part of the record, as well.

Senator RIEGLE. Without objection, it will be made a part of the record.

Dr. NOVITCH. Thank you.

[The following was received for the record:]

federal register

Friday
December 21, 1979

Part VII

Department of Health, Education, and Welfare

Food and Drug Administration

Department of Agriculture

Food Safety and Quality Service

Federal Trade Commission

Bureau of Consumer Protection

Food Labeling; Tentative Positions of Agencies

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Ch. I

DEPARTMENT OF AGRICULTURE

Food Safety and Quality Service

7 CFR Ch. XXVIII; 9 CFR Ch. III

FEDERAL TRADE COMMISSION

Bureau of Consumer Protection

16 CFR CH. I

[Docket No. 78N-0158]

Food Labeling; Tentative Positions of Agencies

AGENCY: Food and Drug Administration, Food Safety and Quality Service, and FTC's Bureau of Consumer Protection.

ACTION: Advanced Notice of Proposed Rulemaking.

SUMMARY: The food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the staff of the Federal Trade Commission's Bureau of Consumer Protection (FTC) announce their tentative positions on a variety of food labeling issues. The positions are the result of the agencies' analysis and evaluation of written and oral comments received in response to a notice published in the Federal Register on June 9, 1978 (43 FR 25296), requesting the public's views on several food labeling issues. The FDA, USDA, and FTC held public hearings across the nation between August and October 1978 to elicit public comments on improving food labeling, and they accepted written submissions until November 10, 1978. These positions also grow out of (1) FDA's Consumer Food Labeling Survey, conducted in autumn 1978 to gather consumers' views on food labeling and (2) the agencies' consideration of these food labeling issues. This notice is intended to prompt further comment from the public about the agencies' tentative positions and other food labeling issues on which the agencies have not yet reached tentative positions. It serves further to announce a public hearing (to be conducted by representatives of FDA, USDA, and FTC) to hear oral testimony on these positions and issues. The hearing will be conducted in accordance with Title 21 of the Code of Federal Regulations, Part 15—Public Hearing Before the Commissioner.

DATES: Public hearing on March 4 and 5, 1980, beginning both days at 9:30 a.m. requests to appear at public hearing by February 22, 1980. Written comments by March 20, 1980.

ADDRESSES: The hearing will be held at the main auditorium of the Department of Commerce, Fourteenth Street and Constitution Avenue NW., Washington, DC.

Written comments to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

For Information Concerning the Public Hearing and Scheduling of Presentations: Gary Dykstra, Regulatory Operations Staff (HFC-22), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3470.

For Information on the Technical Aspects of this Notice,

Taylor Quinn, Bureau of Foods (HFF-300), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20240, 202-245-1057

or

Irwin Fried, Acting Director, Meat and Poultry Standards and Labeling Division, Compliance Program, Food Safety and Quality Service, U.S. Department of Agriculture, Rm. 202, 300 12th St. SW., Washington, D.C. 20250, 202-447-6042.

For Copies of the Documents Described Below and Referred to in this Notice,

Curtis Noah, Consumer Communications Management Staff (HF)-10), Office of Policy Coordination, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3170

or

Annie Johnson, Executive Secretariat, Food Safety and Quality Service, U.S. Department of Agriculture, Rm. 3807, South Agriculture Building, Washington, D.C. 20250, 202-447-6735.

SUPPLEMENTARY INFORMATION: This document reports on the comprehensive review, a cooperative venture of the FDA, USDA, and the FTC's Bureau of Consumer Protection, of current food labeling laws and regulations. The proposals it contains result directly from the agencies' commitment to full public participation in the consideration and development of new or revised food labeling laws and regulations; they also result from the first joint effort of the three agencies with responsibility for food labeling and advertising to review the entirety of the food labeling laws and regulations. (Previous efforts, usually initiated by an agency on its own, have been largely ad hoc.)

This document states the agencies' tentative positions on a variety of food labeling issues. In the interest of full public participation, the agencies have decided not to make the positions final until there has been an additional opportunity for public comment. At the same time, however, the agencies will continue to consider (and in some cases to prepare) proposed changes in their food labeling regulations. Thus, the development of regulations to implement many of the tentative positions described here complements the comprehensive review of food labeling laws and regulations.

Unless public comment on this notice presents compelling arguments or substantial new evidence against these tentative proposals, USDA and FDA intend to begin the process of implementing certain of them as soon as possible after the close of the comment period on this notice. After 1½ years of study we find the issues break down into three categories. (Detailed information on the issues is given in the sections titled "Tentative Positions" and "Digest" that appear later in this notice.) The first category is where the issues seem clear, the agencies have authority to act, and there appears to be major need for action. Therefore, it is the intention of USDA and FDA to propose changes in a number of the food labeling regulations, including the following, according to the approximate schedule given below:

Regulation To Be proposed, Expected Publication After Close of Comment Period

USDA

1. To require mandatory percentage labeling for significant ingredients—60 days.
2. To require a statement that ingredients are listed in descending order of predominance—60 days.
3. To require that foods containing 10 percent or more total fat on a dry weight basis declare the specific source of the fat or oil—120 days.
4. To require nutrition labeling—including information on calories, fat, carbohydrate, protein, cholesterol, sugars, sodium and other nutrients of public health concern—on foods about which nutrition claims are made or to which nutrients are added—150 days.
5. To propose serving sizes for various foods—150 days.
6. To require open dating on perishable and semiperishable foods—60 days.

FDA

1. To amend the remaining standards of identity to require declaration of all optional ingredients—60 days.
2. To require a statement that ingredients are listed in descending order of predominance—60 days.
3. To require that foods containing 10 percent or more total fat on a dry weight basis

declare the specific source of the fat or oil—120 days.

4. To require quantitative declaration of total sugars as part of nutrition labeling when the food contains them above a specific level—150 days.
5. To require quantitative declaration of sodium and potassium as part of nutrition labeling—150 days.
6. To define the terms "low cholesterol," "reduced cholesterol," and "cholesterol free"—90 days.

The second category of changes in food labeling regulations that FDA and USDA favor will require changes in legislation. The agencies will propose, therefore, to seek additional legal authority:

1. To require the declaration of mandatory ingredients in standardized foods.
2. To require the declaration of specific spices and colors in all foods.
3. To provide explicit discretionary authority to require the declaration of the specific flavoring used in a product when this declaration is considered necessary for providing important health information (as in the case of a potential allergen).
4. To provide explicit discretionary authority to require quantitative ingredient labeling as part of the ingredient statement.
5. To require nutrition labeling on more foods.
6. To provide explicit discretionary authority to require open date labeling.
7. To provide explicit discretionary authority to control fortification of foods when this control is of public health significance. (FDA is issuing guidelines for fortification entitled "General Principles for the Addition of Nutrients to Foods.")

Finally, there is a category of issues upon which, even after a long period of study and discussion, the agencies have not yet reached tentative positions. In these cases, they are either asking for additional comments or they will act to ensure the adoption of reasonable and sensible positions. These issues include:

1. The labeling of imitation and substitute foods. Here, in the absence of a tenative position, the agencies want comments on a number of options.
2. The format for nutritional labeling. This document outlines the agencies' plan for resolving remaining issues.
3. The information to be required on a nutrition label. Should the present mandatory list of nutrients be retained, expanded, or made more flexible?

The "Food Labeling Tentative Positions" and "Digest" sections more fully discuss these and other food labeling issues.

The following documents, upon which this notice is based, are available upon request and are also on file with the FDA Hearing Clerk and the USDA Docket Room, Food Safety and Quality Service, U.S. Department of Agriculture, Rm. 3805, South Agriculture Building, Washington, DC 20250:

1. Food Labeling: Report on the Analysis of Comments. (The following subordinate material is on file with the FDA Hearing Clerk and the USDA Docket Room:

a. The June 9, 1978 **Federal Register** notice announcing the public hearing and requesting comments on various food labeling issues.

b. The coding booklet describing the categories used in the coding process.

c. The coding sheet.

d. A computer printout of total coded data.)

2. Report of the FDA 1978 Consumer Food Labeling Survey.
3. Food Labeling Background Papers.
4. A Review of Adverse Reactions from and Hypersensitivity to Peanut and Tree Nuts (prepared for FDA by the Life Sciences Research Office, Federation of American Societies for Experimental Biology).

Background

In early 1978, FDA, USDA, and FTC[1] agreed that it was time to consider whether the existing food labeling laws and implementing regulations needed to be updated. The Federal laws governing the labeling of food are enforced by the USDA (for meat, poultry, and egg products) and FDA (for all other foods). FTC's interest in food labeling rests upon its responsibility for regulating food advertising.

Congress enacted the Federal food laws in 1906, and although it has revised them occasionally since then, the basic concepts of food labeling have remained unchanged for many years. The last major revision of the food labeling provisions of the Federal Food, Drug, and Cosmetic Act, for example, occurred in 1938. FDA administers this act (hereafter called the FD&C Act) and USDA administers the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act (hereafter called the FMI Act, PPI Act, and EPI Act, respectively).

Since these food laws were enacted, significant changes have occurred in the food industry, in Americans' attitudes toward the food supply, and in their dietary habits. Widespread and rapid advances in food processing and distribution have made a greater variety of foods available to more people. This new technology has so increased the number of processed foods on the market that such products now account for more than half of the American diet; at the same time, a far greater number of Americans eat a substantial number of their meals in restaurants.

The Federal agencies have attempted to anticipate and respond to industry's technological advances and to consumers' demand for increased information about food products through amendments to their labeling regulations. This approach has produced a complex set of food labeling rules that, because of the different statutes FDA and USDA enforce and their different regulatory responsibilities, have sometimes been duplicative or inconsistent. FDA, USDA, and FTC realized the need to pause and assess existing food labeling laws and policies before implementing further regulatory changes. Therefore, the agencies set out to develop an overall labeling strategy that will provide consumers with the information they want and need about today's foods.

To achieve this goal, the agencies reviewed current regulations and solicited the views of the public on various food labeling issues by holding a series of public hearings and by asking for written comments. To supplement this information, FDA sponsored a survey of food shoppers to find out their views on certain aspects of food labeling. In this comprehensive review, the agencies have also attempted to determine how adequately existing food labeling laws and policies meet the needs of today's consumers and they have attempted to eliminate inconsistencies between FDA's and USDA's approaches.

On the basis of the information obtained and their review of current regulatory laws and policies, the agencies have developed tentative positions on various food labeling issues. These positions include proposals for legislation, new and revised regulations, and further research. This document also describes the agencies' food labeling rationale, summarizes the public comments and the results of the food labeling survey, and explains how the agencies reached their tentative conclusions.

Food Labeling Rationale

The purpose of food labeling is to enable consumers to select and use products that meet their individual

[1] All the references to the FTC in this notice refer to the Commission's Bureau of Consumer Protection, whose staff members participated in the public hearings, in the analysis of public comments, and in the preparation of this notice. Although the Commission itself supports this effort, it has not taken a position on the various issues involved, and the views expressed in this document do not necessarily represent the views of the Commission or any individual Commissioner.

needs and preferences. To achieve this purpose, labeling must provide sufficient information to enable the public to identify foods and their characteristics, including their ingredients and nutritional value. Effective labeling, moreover, must also present this information so that consumers can understand and use it in deciding what foods to buy. In their deliberations about recommending specific changes in food labeling requirements to make labels more informative and more easily understood, the agencies have followed the following principles:

1. *Public Health Importance*—Human health depends on good eating habits; effective food labeling can contribute to the nation's health by helping consumers choose foods with the appropriate caloric and nutrient values. Because advances in technology have created more processed and fabricated foods, and because the relationship of nutrition to certain diseases is becoming better understood, accurate and informative labeling about a product's nutrient content and its other characteristics has even greater public health significance now than in the past. Furthermore, disease or other abnormal physiological conditions such as allergies compel many Americans to follow special diets. These people especially need informative food labeling so they can make informed food choices.

In considering each proposal for changing the way foods are labeled, the agencies considered very seriously its public health implications. They are convinced that in those instances when food labeling is the most effective method for providing health protection (the labeling of a food's sodium content, for example) society will find the additional cost acceptable.

2. *The Consumer's Right-to-Know*—Innovations in food processing and packaging have made it increasingly difficult for consumers to judge a product's actual contents from its appearance, even for traditional foods. The agencies have therefore concluded that law or regulation must strengthen those policies that guard consumers' right-to-know about the foods they eat. Acknowledging that food labels play a crucial role in providing the information consumers need to make intelligent choices about foods, and that labels provide a significant educational tool, however, does not mean that food labeling should be either the sole vehicle for educating the public about basic nutrition or the government's only tool for influencing the eating habits of Americans. In short, labeling is only a part of the system that delivers information about food and educates the public about how to choose foods wisely. Responsibility for providing this kind of information and education does not rest with regulatory agencies alone, for many institutions—both public and private—must cooperate to provide the basis for informed choices about food.

3. *Economic protection*—The potential overall economic impact of any proposals to amend Federal food labeling requirements demands careful analysis. Any requirement intended to prevent economic deception or designed to offer savings to consumers, for example, would be counterproductive if the added labeling cost exceeded the projected savings. Determining exactly the relative costs and benefits of specific labeling provisions, however, is difficult—particularly on a national scale. The agencies have concluded, for example, that providing consumers with much of the information—such as declaration of ingredients, identity of the product, and the name of the manufacturer or distributor—essential to saving money on food has relatively little impact on the cost of the packaged product. Percentage ingredient labeling and nutrition labeling, however, may be difficult. Only quantitative labeling can provide the kind of information consumers need to get the most for their money when direct examination does not reveal the food's quality or content, but furnishing a large amount of such labeling information may be costly.

Even where requiring labeling information may, on balance, save consumers money, the requirement may encourage monopolistic practices or make it harder for small businesses to compete. (Requiring certain labeling information that only well-equipped laboratories of large firms could develop, for example, might adversely affect smaller companies.) Although the agencies will attempt to avoid such problems, as a general rule they are convinced that labeling requirements should not change with the size of the manufacturer: if labeling information is necessary for informed decisions about food, it should be provided regardless of the manufacturer's size. Moreover, enforcing a regulation based on the size of the regulated firm would be expensive for USDA and FDA.

The Public Hearings

In the **Federal Register** of June 9, 1978 (43 FR 25296), FDA, USDA, and FTC announced joint hearings and requested written comments by November 10, 1978, on a series of food labeling topics. The public hearings were held in Wichita, Kansas (August 22–23, 1978); Little Rock, Arkansas (September 18–19, 1978); Washington, D.C. (September 27–29, 1978); San Francisco, California (October 12–14, 1978); and Boston, Massachusetts (October 25–26, 1978). The hearings and the request for written comments were intended to elicit the views of individual consumers about what information they wanted or needed on food labels, and what additional costs, if any, they would be willing to pay for this information.

The agencies sought the public's views on the following topics:

1. Ingredient labeling.
2. Nutrition labeling and other dietary information.
3. Open date labeling.
4. Food fortification.
5. Imitation and other substitute foods.
6. Safe and suitable ingredients.
7. The total food label (as a communication device).

The three agencies made a substantial effort to encourage individual consumers to participate in the hearings or to submit written statements expressing their opinions on improving food labels. More than 2,800 people attended the hearings, and 452 individuals and group representatives testified. The agencies received more than 9,000 written comments.

A team of representatives from FDA, USDA, and FTC reviewed and analyzed the public comments. This group also developed a computerized system for analyzing the public's written comments and oral testimony. The following section summarizes that analysis; more information on the comments on particular issues appears below in the appropriate sections of the "Tentative Positions of Food Labeling." For a detailed analysis and tabulation of the comments, you may consult the final report, "Food Labeling: Report on the Analysis of Comments," on file with the FDA Hearing Clerk and the USDA (FSQS) Docket Room, and available from the FDA Consumer Communications Management Staff and the USDA (FSQS) Executive Secretariat at the addresses given above.

Summary of the Analysis of Oral and Written Comments

The agencies recognize that the testimony received at the hearings and the written comments do not represent a random sample of the American public's views. The testimony and comments came from those who knew of the government's request for consumers' opinions and who were able and motivated to testify or write either for a particular reason or set of reasons (a food-related medical problem, for example) or for an interest in

changing—or perhaps maintaining—existing food labeling policies. Moreover, these views were comparable to the results of FDA's 1978 Consumer Food Labeling Survey, a random survey of American food shoppers.

Nonetheless, the public hearings provided FDA, USDA, and FTC with the opportunity to reach consumers at the "grassroots" level and to hear their opinions on food labeling. It was one of the few times that the three regulatory agencies responsible for food labeling have cooperated to solicit the views of the public in the policy-making process. This process complemented other information-gathering methods such as studies and surveys that are useful in developing public policy.

Few commenters addressed all of the food labeling issues. Most discussed those topics of particular concern to them personally or to the groups they represented, or they addressed specific issues spelled out in the various media releases about the hearings. Thus, while each of the following summary statements represents the opinion of at least a plurality of those commenters who discussed a certain issue or question, that group is only a smaller percentage of the total number of commenters.

A. Ingredient Labeling

Eighty-five percent of all commenters discussed ingredient labeling, making it the most frequently mentioned labeling issue. Most of those who commented on which foods should bear ingredient labeling said that all foods should carry this labeling. the majority further urged that ingredient labeling be precise and easily understood by the average consumer. Nearly half of those who commented on ingredient labeling metioned quantitiative declaration of ingredients, with most favoring percentage listing.

Commenters also asked for more specific labeling information on sugars, salt, fats and oils, spices, and artificial colors and flavors. Those who wanted more ingredient information on food labels often cited a specific health problem as the basis for their request.

B. Nutrition Labeling

Of the 52 percent of all commenters who discussed nutrition information issues, the majority wanted food labels to include nutrition information, and they asked most often for a food's calorie content. Although only a few people commented on whether nutrition labeling should be mandatory as opposed to voluntary, the overwhelming majority of this group wanted a mandatory system. Here, too, commenters said that nutrition labels—and the terms they employ—should be understandable.

C. Open Date Labeling

The majority of the 45 percent of commenters who discussed it favored using an open dating system to some extent; most of those who addressed whether open date labeling should be voluntary or mandatory favored a mandatory system. Commenters emphasized the need to make open date labeling more effective, including an explanation of the date used, storage and handling instructions, and use of an alpha-numeric code (e.g., "Do not use after December 25, 1979").

D. Imitation/Substitute Foods

Almost 19 percent of all commenters expressed concern about imitation and other substitute foods. The majority of those who discussed this issue made general statements about naming or identifying imitation and substitute food products. Some commenters made specific suggestions on how to label substitute foods that are not nutritionally inferior to their traditional counterparts, and some offered their recommendations for labeling substitute foods that are nutritionally inferior to the traditional products they are designed to replace.

Of those commenters who specified what to call a substitute product resembling and intended to substitute for a traditional or standardized food, 75 percent said that such a food should be labeled "imitation." Definitions of the term "imitation" varied: Some thought the word meant nutritionally inferior, and some thought it indicated the food was inferior in some other way. Others said that "imitation" signifies that a substitute food differs in some way from its traditional counterpart or that it does not conform to a standard of identity.

E. Food Fortification

Approximately one commenter in six discussed issues related to food fortification, with most of them giving at least conditional support for the practice. Those who had some reservations about fortification often specified which foods should or should not be candidates for fortification. Other commenters cautioned against over-fortifying foods; some added that only appropriate foods should be fortified, and then only for valid reasons.

F. Quantity of Contents

Approximately 12 percent of the commenters discused the quantitative declaration of a product's contents; almost all supported some form of weight declaration, and many were concerned about possible deception resulting from the several current quantitative content formats. Of those who supported some form of weight declaration, most expressly requested that labels provide a product's drained weight, particularly for canned fruits and vegetables. Other suggestions included declaring net weight, liquid weight, or fill weight.

G. Costs

Although the majority of commenters asked for additional or improved food labeling information, relatively few (14 percent) considered the economic impact of such changes on food prices. Of those commenters who acknowledged the potential for increased costs, 46 percent said they were willing to pay more, but 31 percent said they were not.

H. Food Standards and Safe and Suitable Ingredients

Food standards and safe and suitable ingredients together attracted remarks from 4 percent of commenters. Of those discussing food standards, 41 percent wanted them eliminated; 28 percent favored continuing the current policy; 23 percent wanted standards applied to more foods; and 9 percent wanted standards applied to fewer foods.

Many of those who opposed the use of standards said they objected to manufacturers not being required to identify all ingredients used in standardized products. Some commenters who favored retaining food standards also said that a standardized product's label should provide more information. Several people specifically mentioned retaining standards for staple foods and developing stricter standards for some foods, such as ice cream.

The majority of commenters who expressed their views on the use of safe and suitable ingredients in standardized foods said FDA's existing safe and suitable policy should be less flexible. Some advocated stricter control over the use of certain ingredients—such as artificial flavors, colors, sweeteners, preservatives, flavor enhancers, and sodium compounds—in standardized foods.

1978 Consumer Food Labeling Survey

To supplement the joint public hearings, FDA sponsored a Consumer Food Labeling Survey, conducted in October and November 1978 by the Response Analysis Corporation, Princeton, New Jersey. The FDA's Bureau of Foods, Division of Consumer Services, later analyzed the responses. The survey included 1,374 personal

interviews with "primary food shoppers," the persons who do most of the food purchasing for a particular household.

To the extent possible, the survey avoided direct questions, such as, "Would you like X information?" because direct questions can lead to results that overestimate the extent of concern. Instead, nearly all survey questions were open ended, allowing consumers to provide their own answers rather than requiring them to select among predetermined alternatives. This type of questioning usually leads to minimum estimates, and in some cases to underestimates, since some individuals may not known about a given type of information or may not think of particular information at the moment of questioning.

A summary of the survey results is presented below. These results can be projected to the national population at an accuracy of plus or minus 3 percent (with a confidence level of 95 percent). The results are divided into four areas; scope of consumer concern with food and food labeling; usage of currently available information; sources of confusion and difficulties with food labels; and consumer desires for food label revision.

Scope of Consumer Concern With Food and Food Labeling

The first question in the survey asked, "Aside from prices, please tell me about any particular problems, difficulties, or concerns which you have with food these days." Forty-nine percent reported no problems other than price. Forty-seven percent, however, mentioned one or more specific problems.

Most of these consumers mentioned problems involving the food itself: 14 percent expressed general concerns about product quality (e.g., food is simply not as "good" as it could be); another 14 percent were concerned about possible adverse health consequences of some food ingredients, and 8 percent said that the food they purchase is not as fresh as it should be.

In addition to concerns about food itself, 8 percent of respondents mentioned specific food labeling problems, and 9 percent mentioned damaged containers, insufficient stock in the store, and similar concerns.

Of the 14 percent of respondents who expressed concern about the health consequences of food ingredients, 35 percent are worried about preservatives, 29 percent are concerned about "additives" or "chemicals" in general, 20 percent are apprehensive about the sugar content of their food, 8 percent expressed concern about artificial colors, 7 percent about salt content, and 4 percent about use of artificial flavors. Only 8 percent of those mentioning the health implications mentioned any problem with the nutritional value of their food.

The survey findings suggest that many American consumers have some degree of apprehension about the safety of their food supply. While relatively few people (about 1 percent of the total surveyed) appear concerned about the nutritional value of food, a large number are concerned about the apparent proliferation of substances that may pose a health risk.

Of the 8 percent who expressed concern about food labeling, 32 percent mentioned the ingredient list, 25 percent mentioned freshness information, 20 percent expressed concern about deceptive or inaccurate labeling, and 19 percent had some concern with the information on the nutrition label (most of these mentioned calorie information).

The second question in the survey was, "Are you satisfied with the kind or amount of information available on food packages and cans?" Consumers who gave negative answers were then asked to state why they were not satisfied.

Fifty-nine percent said they were completely satisfied. Thirty-three percent, however, saw a need for at least some improvement in food labeling.

Twenty percent of those surveyed said the ingredient list could be improved. They most frequently requested the following improvements: listing all ingredients; simplifying the language; providing ingredient information on all products; making the list more legible (e.g., larger print), and listing ingredients by percentages.

Eight percent said nutrition labeling should be improved, and 3 percent wanted open date labeling extended to more products. About 2 percent mentioned a need for drained or fill weight labeling on canned goods. Fewer than 1 percent expressed a desire for information about the specific sources of fats and oils.

Use of Currently Available Information

Consumers were asked what information they looked for on food packages other than product name, brand name, and price. Forty-one percent mentioned the ingredient list. Nutritional information was mentioned by 22 percent, size or quantity information by 18 percent, and open dates by 11 percent. Eleven percent reported not using any label information at all.

When asked directly whether they pay attention to the ingredient information, 77 percent of the consumers surveyed said that they do. This group was then asked whether they use this information to avoid certain ingredients. Seventy-one percent of them, or 54 percent of all those surveyed, responded affirmatively. The ingredients most frequently mentioned were sugars (mentioned most often), salt, fats and oils, and preservatives. Other substances often named were artificial colors, artificial flavors, artificial sweeteners, starches, seasonings, cholesterol, and monosodium glutamate.

When consumers were asked why they avoid these substances, twenty-nine percent of all consumers (53 percent of those who do avoid certain substances) cited a belief that the substances might be harmful or hazardous. Many consumers also mentioned dietary reasons (most often weight control) and personal preferences (tastes and religious reasons). A few people mentioned diabetes, the effects on child health and behavior, or allergy problems as reasons for avoiding the substances.

With regard to the nutrition labeling, 64 percent responded "Yes" to the question "Do you pay attention to the nutrition information?" Most of those who use the nutrition label said they use only part of it; only 6 percent claimed to use the entire nutrition label. According to the survey, consumers look most often for information on calories, followed by information on vitamins, protein, fats, carbohydrates, and minerals, in that order.

Those who reported using nutrition information were asked the direct question, "Assuming that there may not be enough room for all different kinds of nutrition information, would you rather have information about things that people often get too much of (like calories, cholesterol, fat) or things people often get too little of (like protein, vitamins, and minerals)?" By a two-to-one margin (68 percent versus 32 percent) respondents selected information about substances that people often get in excess. (This correlates with survey results showing consumer concerns about possible negative health effects of food.)

On the question of open date labeling, 74 percent reported using dates, when available, to help decide which specific food items to buy. The preferred type of dating (at least for perishable and semiperishable products) appears to be an expiration or "use by" date, which was selected by 40 percent of the respondents. The quality assurance date and the pull or sell-by date were each selected by under 25 percent of the

respondents, and only 15 percent chose pack date.

Sources of Confusion or Difficulty With Food Labels

Consumers were asked, "Do you find any of the information on food packages and cans confusing or difficult to understand?" Twenty-seven percent said they found one or more sources of confusion on labels. (Due to the tendency of survey respondents to be unwilling to admit they are unable to understand something, this response probably underestimates actual problems with current food labeling.)

The most frequently cited problem was the use of technical and chemical names in the ingredient list, noted by a third of those expressing problems with labels. Other sources of confusion were the lack of quantitative information in the ingredient list, the metric system, U.S. RDA's, percentages, other nutrition information, date codes, and the use of small print.

It is also worth noting that at least 23 percent of consumers reported they pay no attention to the list of ingredients, and at least 36 percent reported they do not use the information on the nutrition label. (These respondents were not asked why they do not use this information.)

Consumer Desires for Food Label Revision

Consumers were asked directly whether they would like to have more information, less information, or the same amount now available on food labels. Twenty-five percent said they wanted more information, and only 2 percent said labels already have too much information.

Respondents most often wanted quantified ingredient information. This was followed by requests for simplified ingredient statements and calorie information on all products. There was also interest in greater use of specific ingredient names as opposed to general terms such as "spices." Finally, consumers expressed interest in declarations of sugar content, more open date labeling, declarations of salt content, listing of all preservatives, extending vitamin/mineral information to all products, and listing the ingredients in all products. Interest in declarations of drained or fill weight was relatively low.

In summary, about 10 percent of those surveyed were seriously critical of the current food label and saw a need for significant changes. An additional 15 percent expressed a desire for some changes, but appear less concerned. The remaining 75 percent are divided among those who appear to be satisfied with the food label as it is, are not concerned, or simply find the food label to be confusing for one reason or another.

Based on the information obtained from the survey, the following food label revisions have the highest priority among food shoppers.

Calorie information on all products.
Simplified ingredient names.
Quantitative ingredient listing (preferably in percentages).
Complete listing of all ingredients.
More extensive open date labeling.
Quantitative declarations of sugar content.
Full ingredient labeling for all products.
A simplified nutrition labeling format.
Expiration-type open date labeling for perishables.

The full report of this survey is on file with the FDA Hearing Clerk and the USDA (FSQS) Docket Room. Copies can be obtained from the FDA Consumer Communications Management Staff or the USDA (FSQS) Executive Secretariat. The addresses of these units are provided at the beginning of this document.

Comparison of Public Hearing Comments With Data From the 1978 Consumer Food Labeling Survey

The tables that follow compare the consumer views from the public hearings and the written comments with the responses obtained in the Consumer Food Labeling Survey. The comparison reveals that the concerns expressed by the two groups were often similar. For example, Table A shows that both groups care more about ingredient labeling than ay other general area, and that nutrition labeling is the area of second greatest concern. The main difference between the two groups lies in the level of concern. Even though ingredient labeling is the top concern of both groups, it was mentioned in 85 percent of the hearing comments and in only 20 percent of the survey responses. This pattern is much the same for each table.

The following conclusion can be drawn from the comparison: although the hearing commenters and those who submitted written comments are not statistically representative of the general public, they do reflect the shopping public's concerns about the food label. The higher level of concern exhibited in the hearing and written comments may be due primarily to the fact that these commenters represent a self-selected group with sufficient interest in labeling to submit their views. In contrast, the Food Labeling Survey includes many consumers who do not appear to be concerned about food labeling.

Table A.—*Major Areas of Concern With Food Labels* [1]

	Hearings and comments (percent)	Food labeling survey (percent)	
		Open question [2]	Semidirect question [3]
Ingredient list	85	3	20
Nutrition label	52	2	8
Open dating information	45	2	3
Quantity of contents information	12	1	3

[1] Percentages are based on all respondents in the survey and the commenters in the hearings and written views.
[2] The question titled "open" asked respondents what problems, difficulties, or concerns they have with foods.
[3] The question titled "semi-direct" asked respondents what information on the food label needed improvement.

Table B.—*Label Changes Most Desired* [1]

	Hearings and comments (percent)	Food labeling survey (percent)	
		Open question [2]	Semidirect question [3]
Quantify the ingredient list	35	1	4
Give ingredients of all products	35	1	3
List all ingredients	32	1	5
Give amount of sugar	27	1	2
Give amount of salt	25	1	1
Give nutrition information on all products	10	1	1
Give source of fats and oils	9	1	1
Give drained or fill weights on cans	8	1	2
Use larger print on labels	6	1	2
Simplify the ingredient list	1	1	4

[1] Percentages based on all respondents in the survey and the commenters in the hearings and written views.
[2] The question titled "open" asked respondents what problems, difficulties, or concerns they have with foods.
[3] The question titled "semi-direct" asked respondents what changes or additions they would like on food labels.

Table C.—*Nutrition Information Mentioned as Important* [1]

	In percentage	
	Hearings and comments	Food labeling survey
Calories	62	55
Vitamins/minerals	39	48
Fats	28	32
Cholesterol	24	11
Carbohydrates	22	22
"All nutrition information"	21	9
Protein	20	36
Serving size	10	3
Number of servings	6	1

[1] Percentages are of those who named the types of nutrition information they consider important or valuable.

Table D.—*Substances That Respondents or Commenters Report Avoiding* [1]

	In percentage	
	Hearings and comments	Food labeling survey
Sugar	47	50
Salt	43	26
Artificial colors	33	10
Fats and oils	23	23
Artificial flavors	23	6
"Chemicals"	19	8
Preservatives	17	21
Seasonings	13	5
"Artificial things"	6	18
Starch	2	5
MSG	2	3
Artificial sweeteners	1	6

[1] Percentages are of those individuals who reported avoiding one or more substances.

Table E.—*Preferred Method of Quantifying the Ingredient List* [1]

	In percentage	
	Hearings and comments	Food labeling survey
By percent	85	78
By weight	15	22
Total	100	100

[1] Percentages are of those who specified a preference for percentage versus weight listing.

Table F.—*Preferred System of Open Dating* [1]

	In percentage	
	Hearings and comments	Food labeling survey
Pack date	25	15
Pull (sell-by) date	23	23
Quality assurance (best-if-used-by) date	14	22
Expiration (use-by) date	38	40
Total	100	100

[1] Percentages are of those who specified a preferred dating system. Food Labeling Survey respondents were discussing perishables and semiperishables.

Background Papers

Following the hearings and survey, the agencies developed background papers on each of the key food labeling issues. These papers describe in some detail the questions involved and the options considered by the agencies in arriving at the tentative positions discussed in this notice. While not intended to be an exhaustive review of the subject, the background papers do provide a general overview of the major considerations involved in each food labeling issue. They cover the following areas:

1. Mandatory Ingredients in Standardized Foods and Spices, Flavorings, and Colors.
2. Ingredient Labeling of Restaurant Foods.
3. Ingredient Labeling of Fresh Fruits and Vegetables.
4. Quantitative Ingredient Labeling.
5. Grouping Ingredients by Function and "and/or" Labeling.
6. Mandatory Information in Nutrition Labeling.
7. Nutrition Labeling Format.
8. Sodium and Potassium Labeling.
9. Sugars Labeling.
10. Fiber Labeling.
11. Cholesterol and Fatty Acid Labeling.
12. Composite Data Bases.
13. Serving Sizes.
14. Food Standards—Safe and Suitable.
15. Imitation and Substitute Food Labeling.
16. Open Date Labeling.
17. Country of Origin Labeling.
18. Name and Address of the Manufacturer, Packer, or Distributor Labeling.
19. Natural and Organic Labeling Claims.

These papers are on file with the FDA Hearing Clerk and the FSQS (USDA) Docket Room, and can be obtained from the FDA Consumer Communications Management Staff or the FSQS Executive Secretariat. Addresses are provided at the beginning of this document.

Criteria for Analysis

The agencies used the following criteria in developing the background papers and their tentative conclusions [2]

1. Health Implications:
- What are the risks—allergies, diabetes, high blood pressure, hyperkinesis, heart/circulatory, etc.?
- What is the severity of the risk (high, medium, low); what is the size of the affected population?
- Will improved food labeling assist consumers in eliminating or reducing any known or potential health-related problems associated with foods and food ingredients?

2. Consumer Acceptability:
- What is the public attitude towards the various aspects of the improved food labeling?
- Does it meet the consumer's right-to-know?
- Are consumers capable of using the information?
- Will consumers use the information?

3. Industry Acceptability:
- Will industry accept or oppose the change?
- For what reasons?
- Will the change to require disclosure of it violate "trade secrets"?
- Will the proposed action be feasible to implement?

4. Legal Aspects:
- Does it require a change in the law?
- Does it require a change in existing regulations or a new regulation?
- How does it correspond with our sister agencies? Are there jurisdictional problems? Differences?

5. Political Aspects:
- What will be the reaction from Congress?
- If legislation is required, is Congress in favor and willing to act? Now? In the future?
- How does any proposed action correlate with the Administration's initiative to reduce or eliminate any unnecessary regulations?
- What will be the reaction from the States?

6. Economic Implications:
- Will the information help to prevent economic deception?
- What are the costs to the government to develop, implement, and enforce?
- Will the information help to maximize consumer purchasing power?
- What are the costs to industry to implement? How much?
- Will the label modification cause increased costs to consumers? How much?

7. Efficacy:
- Will the labeling modification actually solve the specific problem it is introduced to address?
- What other methods can be used to meet the same wants or needs (e.g., more consumer education, food formulary, etc.), perhaps at less cost to all segments of society?

8. Timing:
- Is it something that can and should be done now? In the future?
- Is it something that will require a change in law, and thus need to be delayed pending passage of legislation?
- Is it something that can be done now (by regulation) but should be delayed pending further study?
- Is it something for which more specific legislative authority is needed although certain aspects can be implemented by regulations, guidelines, or policy statements?

[2] These criteria are general in nature and the discussion in the background papers does not necessarily completely correlate to every one of the criteria.

Tentative Positions

As a result of the information gained from FDA's Consumer Food Labeling Survey, the oral and written comments, and the agencies' review of the issues, the agencies have reached tentative

positions on a number of food labeling issues. In their deliberations, the agencies considered the views of the public; the feasibility and costs to consumers, government, and industry; and the potential public benefits. These tentative positions are presented in the sections that follow.

Many of the proposed changes will require future regulatory or legislative actions, which are also discussed below. Before any final regulatory actions are taken, the agencies will carefully consider the comments on this document, and each agency will proceed in accordance with the Administrative Procedure Act (5 U.S.C. 551 et seq.) and other legal requirements.

Ingredient Labeling

Ingredient labeling was the issue discussed most frequently by the public at the hearings, in written statements, and in response to FDA's Food Labeling Survey. For example, 85 percent of the commenters in the hearings and their written submissions addressed the topic of ingredient labeling. This is a large issue, with a number of different facets, each of which will be discussed in turn.

Labeling of Mandatory Ingredients in Standardized Foods

In their oral and written statements, the public made it clear they want to know what ingredients are used in foods. Most commenters stated that at least some standardized foods need full ingredient labeling. Many of them simply asked for "full ingredient" labeling on foods.

Several reasons were given for wanting to know all of the ingredients in foods. Some wanted to avoid certain ingredients. Others wanted to be able to identify the presence of specific ingredients for health or medical reasons. Still others said they have the right to know the ingredients in a food. The respondents to the Food Labeling Survey also indicated considerable desire to have ingredients listed for all foods.

Certain Federal regulations called standards of identity, which are established by FDA, define the composition of many foods. The standards identify the mandatory ingredients (which must be used) and the optional ingredients (which may be used). Under the FD&C Act, only optional ingredients in such foods can be required to be declared on the label. If an ingredient is mandatory (e.g., peanuts in peanut butter), it does not have to be listed on the label. FDA has issued about 275 standards of identity. They include standards for canned fruits and vegetables, milk, cheeses, ice cream, breads, and margarine. Standardized foods make up 45 percent of the wholesale value of food shipments regulated by FDA (excluding fresh fruits and vegetables). For a number of years FDA has sought authority to require label declaration of mandatory ingredients in standardized foods but no legislation has passed. (There are two bills now before Congress that would provide this authority: S. 1651 or the "Department of Agriculture Nutrition Labeling and Information Act of 1979" and S. 1652 or the "Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug, and Cosmetic Act".)

Foods for which FDA has issued no standard of identity, such as cookies, cakes, and pizza, must have ingredient statements on the label. All ingredients in nonstandardized foods, except for colors, spices, and flavors, must be listed specifically by name in the order of predominance.

Under USDA regulations, the ingredients in meat, poultry, and egg products must be listed on the label in order of predominance. Colors, spices, and flavors may be generally identified, but all other ingredients must be specifically identified. This is true even if the food is subject to a USDA food standard.

In the absence of authority to require the listing of mandatory ingredients, FDA has been expanding the use of its authority with respect to optional ingredients. Most standards have been revised, or are presently being revised, to require declaration of all optional ingredients. Moreover, if two or more forms of a mandatory ingredient may be used, then the form is deemed to be optional and the ingredient must be declared on the label. For example, the flour that goes into bread may be enriched flour, bromated flour, phosphated flour, or a combination of these. Whatever form is used must be declared on the label. FDA has also encouraged industry to list mandatory ingredients voluntarily (21 CFR 101.6), and many manufacturers have complied.

Proposed Actions: FDA will seek or support legislation to amend the FD&C Act to require that mandatory ingredients in standardized foods be declared on product labels. (USDA regulations already require such declarations.)

Pending any such legislative change, FDA will expedite its revision of the remaining standards of identity to require declaration of all optional ingredients including the form of the mandatory ingredients where more than one form is available for use. FDA plans to publish a document within the next year which, when completed, would require declaration of approximately 97 to 98 percent of ingredients used in standardized foods.

Colors, Spices, and Flavors

According to the hearing record and written comments, many people would like to see colors, flavors, and spices listed on labels by their specific names (e.g., "FD&C Yellow No. 5" as opposed to "artificial color"). The desire for specific label information on artificial colors was mentioned most frequently (1,868 commenters), followed by flavors (1,315 commenters), and spices (654 commenters). In addition, 587 commenters discussed the provision in the law which exempts butter, cheese, and ice cream labels from declaring the presence of artificial colors; 91 percent of these commenters wanted this exemption eliminated. The respondents to the Food Labeling Survey also expressed an interest in color, flavor, and spice labeling.

The FD&C Act requires the presence of colors, flavors, and spices to be declared on the label. However, they may be listed simply by their general names ("colors," "spices," or "flavors"). In other words, FDA cannot require specific identification of such ingredients. In the case of cheese, butter, and ice cream, FDA cannot require declaration of even the presence of an artificial color.

USDA has much wider authority in this area. Under current statutes, the Secretary of Agriculture may require that colors, spices, and flavors be identified by their specific names (21 U.S.C. 453(h)(9) and (12); 21 U.S.C. 601(n)(9) and (12) and 21 U.S.C. 1036(a)).

The general position of the agencies is that most ingredients should be declared by specific names on food labels. This position appears to present no significant problems with respect to spices and colors. Most products that include spices contain no more than four or five. (Some meat and poultry products contain a greater number.) The same is true of colors: only a few are used in any one food, and listing them should present no practical problem. Under the provisions of the Fair Packaging and Labeling Act (administered by FDA), cosmetics are now required to list specific colors on their labels, and no serious practical problems have been encountered.

Label declaration of flavors does present a problem, however. There are about 1,700 flavors, and as many as 125 flavors can be used in a single processed food. The average number of flavors used in a processed food (excluding meat, poultry, and egg

products) is about 40. Not only are there numerous flavors, but there are also an overwhelming number of substances that can be combined to form a single flavor ingredient. Since one food may contain many flavors, it would be impractical to identify them fully on the label, and it would be difficult for the government to establish an all-inclusive labeling policy for these ingredients.

Nevertheless, the agencies support label declaration of those flavors that are known to cause health problems, such as allergic reactions in particular segments of the population. This principle was followed in FDA's action to require foods to declare the presence of FD&C Yellow No. 5, a known sensitizer. (See the **Federal Register** of June 26, 1979 (44 FR 37212).) Of course, a flavor (or spice or color) that is unsafe for the general population would be banned from the food supply under current law.

Industry has argued that mandatory disclosure of all colors, flavors, and spices would be an onerous burden because it would overload labels, making them incomprehensible to consumers. Manufacturers also have contended that label declaration of the specific colors, flavors, and spices used in a food will divulge trade secrets.

In the case of colors and spices, the agencies have concluded that labeling specific ingredients would not reveal trade secrets and that the benefits to consumers of knowing the identity of these ingredients would be substantial. Nevertheless, the agencies welcome further comments.

Proposed Actions: (1) Colors and spices. FDA will seek or support legislation to require that all colors and spices be declared on food labels by their specific names. USDA believes it has such authority, but will support legislation to provide more explicit authority for both agencies.

The agencies invite comments from the public on the feasibility of their proposal, particularly for labeling of spices.

FDA will seek or support legislation to eliminate the exemption under which the labels of butter, cheese, and ice cream are not required to declare the presence of an artificial color.

(2) Flavors. FDA will seek or support legislation to provide it with the discretionary authority to require label declaration of a flavor when such declaration is considered necessary to provide important health information, e.g., when a flavor ingredient may cause an allergic reaction. USDA believes it has such authority but will support legislation to provide more explicit authority for both agencies.

Quantitative Ingredient Labeling

The vast majority of the hearing and written comments mentioned ingredient labeling, and nearly half of these had suggestions on how to specify the quantities of ingredients. Of those with suggestions, over 75 percent favored percentage ingredient labeling, 19 percent favored listing ingredients indescending order of predominance, and 6 percent wanted to know percentages of characterizing ingredients (e.g., the shrimp in a shrimp cocktail). The Food Labeling Survey results were similar to the hearing and written comments, thus confirming the strong consumer interest in quantitative ingredient labeling and the preference for percentage listing.

At present, FDA generally does not require quantitative labeling, except for certain valuable and characterizing ingredients that are part of a product's name (e.g., shrimp in shrimp cocktail or orange juice in orange juice beverages). It has been argued that FDA may have across-the-board authority to require quantitative ingredient labeling. But if such authority exists, it is not explicitly stated in the present law.

A more serious limitation may be FDA's inability to monitor quantitative labeling under the present law. FDA could use two approaches to verify quantitative ingredient labeling. The first is by factory inspection. This approach is of limited value at present because manufacturers are not required by law to show FDA their records on what actually goes into a product. The second approach is laboratory analysis. FDA can determine some ingredients by analysis, such as shrimp in shrimp cocktail, but it cannot readily determine others, such as ingredients that may dissolve in a soup. Moreover, analysis can be expensive. Because factory inspection represents the more practical approach to monitoring, FDA in the past has supported legislation to provide authority to review company records related to production.

Under its statutes, USDA already has some authority to require quantitative ingredient labeling in meat, poultry, and egg products. Moreover, USDA can review product formulas and related information through its mandatory label review and inspection programs. The meat, poultry, and egg product statutes require recordkeeping by processors, and provide access to records and inventory. These provisions make it easier to enforce quantitative ingredient labeling rules. USDA also has issued voluntary guidelines for quantitative ingredient labeling and requires percentage labeling of some products purchased for domestic food assistance programs (e.g., cooked turkey rolls and dried egg mix).

Proposed Actions: FDA and USDA will continue their efforts to encourage or require the use of quantitative ingredient labeling on more foods.

FDA will take the following specific actions:

Expand the use of percentage labeling for valuable and characterizing ingredients as part of the names for standardized foods and nonstandardized foods;

Publish guidelines for voluntary quantitative ingredient labeling as part of the ingredient statement;

Seek or support legislation explicitly giving FDA authority to require quantitative ingredient labeling as part of the ingredient statement;

Seek or support legislation giving FDA records and reports authority: access to a company's product formulas, quality control records, and related records in order to ensure that such expanded quantitative ingredient labeling is truthful and accurate.

While USDA already has limited authority to require quantitative ingredient labeling, it shares FDA's belief that legislation establishing the general authority of the two agencies to require such labeling is desirable. USDA will also propose regulations to provide for more quantitative ingredient labeling. The regulations will propose mandatory percentage labeling of certain important ingredients in meat, poultry, and egg products.

Listing Ingredients by Order of Predominance

The results of the Food Labeling Survey and the hearing and written comments suggest that many consumers may not be aware that ingredients must be listed on food labels in descending order of predominance. Although some labels carry an explanatory message stating that ingredients are listed in order of predominance, there is no requirement that they bear such a message. The agencies believe that an explanatory statement of this type would be helpful to consumers, and would neither prove costly to manufacturers nor overload labels.

Proposed action: FDA and USDA will amend their current regulations to require that food labels bear a statement to the effect that ingredients are listed in descending order of predominance.

Use of "And/Or" Labeling To Declare the Source of Fats and Oils

"And/or" labeling is designed to provide manufacturers with flexibility to modify food ingredients without revising

their labels. Under current regulations, this type of labeling is permitted for fats and oils when they are not the predominant ingredient. A label might bear the statement, "vegetable oil (may contain cottonseed oil, soybean oil and/or palm oil)." The manufacturer would then be free to use any one of the three specific oils, or a combination of them, without changing the labels. The choice would likely depend on availability and price.

The hearing and written comments on ingredient labeling flexibility focused mainly on the declaration of fats and oils. Of the 1,060 commenters who discussed flexible labeling of fats and oils, 86 percent said that the "and/or" type of labeling should not be permitted. Most people opposed this concept due to special diets, allergies, or for religious reasons. Some commenters also expressed dissatisfaction with general source designations such as "animal fat" or "vegetable oil."

About 14 percent of the commenters supported labeling flexibility for fats and oils. Some of these commenters qualified their approval by stating that only those fats with the same saturation should be allowed to be interchanged. Other commenters noted the cost savings to consumers that may result from current rules permitting flexibility.

Respondents in the Food Labeling Survey, on the other hand, showed relatively little concern with this issue; only a very few mentioned labeling flexibility.

FDA's present regulations were published in 1976. Previously, FDA permitted fat and oil ingredients to be declared in the ingredient list by the generic terms "vegetable oil," "animal fat," and "marine oil," or as "shortening," without naming the specific fat, oil, or type of shortening. In 1971 FDA proposed requiring the declaration of fat and/or oil ingredients by specific common or usual names instead of genric names (e.g., "coconut oil" instead of "vegetable oil" or "shortening"). This proposal was made in response to repeated requests from consumers and consumer organizations, as well as from health professionals.

The 1971 proposal, as well as a revised proposal published in 1974, was opposed by a number of industry members. Opposition was based mainly on two contentions: (1) manufacturing techniques alter fats and oils so that the ingredients in finished form do not differ greatly regardless of source; and (2) requiring more specific ingredient listings would increase food costs because manufacturers would have to reprint labels whenever fat and oil ingredients were changed due to fluctuations in price or supply.

After considering the comments, FDA, in 1976, issued the regulations that are currently in effect (21 CFR 101.4(b)(14)). Under these rules, some flexibility in declaring fats and oils is permitted when these ingredients are not predominant, i.e., when they do not constitute the largest proportion by weight of any ingredient in a food. A manufacturer may declare the blend of fats and oils on the list of ingredients by use of a generic term, followed by a parenthetical listing of the common or usual name of each fat and oil ingredient that might be used in the blend. Therefore, any fat or oil that may be present in the product is specifically identified. Where fats or oils are the predominant ingredient, specific declaration of any fat or oil actually present is required.

USDA currently allows the use of general terms such as "animal fat" or "vegetable oil" on meat and poultry product labels without reference to the specific source of the fat or oil (e.g., cottonseed oil"). The egg product regulations contain no specific references to how fats and oils should be identified, but require that all ingredients be listed if two or more are used (7 CFR 2859.411(c)(1)). However, USDA's policy for egg products labeling allows the labeling of fats and oils on an "and/or" basis consistent with FDA's current requirements.

There appears to be at least one problem with the present system for declaring fats and oils: it may result in the listing of ingredients that are not actually present. As a result, it may narrow the choice of products available to people who wish to avoid certain substances. Thus, although "and/or" labeling does not cause health problems, it does not allow those people suffering from allergies or other medical conditions to deal most effectively with their problems.

The agencies recognize and sympathize with those individuals who may be allergic to the protein fractions in some fats and oils. Although the agencies know this medical problem occurs, they do not know the extent of the problem. The agencies also are aware of religious concerns and personal preferences centering on the use of certain fats and oils. However, even if the use of "and/or" labeling were eliminated, there still would be no guarantee that foods containing more desirable fats and oils would be available. Moreover, the requirement for more specific labeling could impose higher costs on all consumers by restricting manufacturers' ability to respond to marketplace factors (availability and price) without having to change their foods' labels. Finally, if there is a significant need for products containing only a specific fat or oil, the competitive marketplace is likely to make them available (usually at a premium price).

Recognizing public concerns and these economic factors, the agencies have weighed the potential benefits of requiring more specific labeling of fats and oils against the adverse impact such a change could have on industry and consumers.

Proposed Action: FDA and USDA will amend current regulations to require that foods containing 10 percent or more total fat on a dry weight basis declare on their labels the specific source of the fat or oil, e.g., "corn oil" or "palm oil." Foods containing less than 10 percent fat on a dry weight basis may use the "and/or" approach, e.g., "vegetable oil (may contain cottonseed oil, soybean oil and/or palm oil)."

The position adopted by the agencies is based in part on the current FDA regulation covering fatty acid and cholesterol labeling (21 CFR 101.25). This regulation provides that a food containing 10 percent or more fat on a dry weight basis and at least 2 grams fat in an average serving may bear labeling declaring the quantity of fatty acids. A food containing less than this level of fat is not considered to be important in regulating the intake of fatty acids because it is not a significant source of dietary fat.

Use of a 10 percent total fat cutoff level would result in the listing of specific fats and oils on the labels of a substantial number of foods that now bear "and/or" labeling. For example, most crackers, cookies, imitation meats and cheeses would no longer be able to use "and/or" labeling.

The agencies are not aware of any data suggesting that the demarcation line should be higher than 10 percent total fat on a dry weight basis. In fact, it is possible that a lower level (e.g., 2 percent or 5 percent) may be more appropriate. The agencies welcome comments on alternative percentage cutoff levels. Economic data on the effects of various levels on the marketplace will be particularly helpful. Comments are also invited on the question of whether "not less than 2 grams of fat in an average serving," the second part of the present standard for the fatty acid declaration, should be used in conjunction with the 10 percent level as the cutoff for listing fats and oils specifically, or whether some other serving quantity and percentage cutoff should be used.

Functions and Names of Ingredients

The hearing record and written comments suggest that many people find many ingredient names confusing and meaningless. Comments differed, however, on the type of labeling terminology considered most useful. Of the more than 1,000 commenters specifying the terminology that should be used, over half the suggestions favored individual, familiar names, while a third of them favored designation by function, e.g., emulsifier, preservative. Twenty-seven percent supported the use of an ingredient's chemical name on the label. The central point that emerges from the comments is this: as the number of processed foods and the number of unfamiliar ingredients in these foods has grown, the task of interpreting names of ingredients and their functions has become extremely difficult for many consumers.

The FD&C Act requires that optional ingredients in standardized foods, and all ingredients in nonstandardized foods, be declared on the label by their common or usual names ("nonfat dry milk," "celery," "enriched flour"). The exceptions are spices, flavors, and colors, which may be listed on labels by their general names (e.g., "spices"). A limited number of dairy, egg, and oil ingredients are exempt from the specific name requirement and may be designated collectively on labels (e.g., "whey" can be listed when it is reconstituted whey).

Much of the present confusion over ingredient listing may stem from lack of knowledge among consumers of the purposes served by many ingredients. The agencies have received suggestions that the government publish a list of all food ingredients and their functions. This publication might be made available to consumers through outlets such as supermarkets, libraries, etc. Consumers with questions about ingredients would be able to consult this "ingredient dictionary."

Proposed Action: The agencies will explore the feasibility of an "ingredient dictionary." They will determine how it should be compiled and distributed, and what it will cost.

An ingredient dictionary would satisfy the needs of consumers who want to know more about the function of different ingredients, and would not increase manufacturers' labeling costs or overload product labels with complex terminology and explanations.

Labeling of Fresh Fruits and Vegetables

Less than 2 percent of the hearing and written comments requested information on the growing, processing, and handling of fresh fruits and vegetables. Most of these comments concerned the use of fertilizers, pesticides, and other chemicals during growth, and the use of waxes, colors, and gasses.

Under the FD&C Act and FDA regulations, all ingredients added to raw agricultural products, except pesticides, must be declared in labeling (21 U.S.C. 343). If these commodities are shipped in a bulk container and the product is sold at retail from that container, the declaration must be visible to the purchaser. If the raw commodities are sold from a container other than the shipping box, then placards or signs must be used to convey information on colors, preservatives, and waxes (21 CFR 101.22(e) and (f)).

Although the Federal law requires labeling declarations at the retail level of substances added to fesh fruits and vegetables, as a practical matter FDA does not have the resources to enforce this requirement. The agency focuses its compliance attention on manufacturers, processors, and distributors. Retailers, nevertheless, have a responsibility to comply with the law.

If current law or regulations were amended to require the labeling of fertilizers and pesticides used on fresh produce, FDA's lack of compliance resoures would prevent the agency from enforcing such requirements. Even with adequate resources, enforcement would be difficult. For example, pesticides may be present in such small amounts that they cannot be readily detected. In fact, pesticide may be applied to a commodity and not be present at all when the product is marketed. Finally, the fact that fresh produce sold at retail usually consists of mixed lots makes accurate pesticide labeling virtually impossible.

Proposed Action: FDA will continue to encourage compliance with the requirements of Federal law that the presence of colors, preservatives, and waxes be declared on placards and leaflets at the point of sale of fresh fruits and vegetables. however, FDA will not seek the statutory authority to impose similar requirements for pesticides and fertilizers. The policy with regard to pesticides and fertilizers wil be reexamined in the future as necessary.

Ingredient Labeling for Restaurant-Served Foods

Very few commenters (76) discussed the issue of ingredient labeling for restaurant foods. All but one of these commenters said that restaurants should provide ingredient information on their foods.

Although the agencies can understand why some consumers want ingredient information about restaurant-served foods, enforcing such a requirement in the more than 350,000 restaurants in the United States would not be feasible. Not only is there a multitude of ingredients in each food on a menu, but many restaurants also vary menus frequently or change recipes according to the availability of raw commodities. Ingredient labeling would increase cost for restaurateurs, and be a particularly burdensome requirement for small restaurant operators. These costs ultimately would be passed on the restaurant customers.

State and local governments have primary authority over eating establishments. The Federal agencies considered preparing a model code for restaurant ingredient labeling, similar to the Food Service Model Code, for States to adopt. The agencies have concluded, however, that the costs involved in developing such a code outweigh the potential benefits to consumers.

The agencies, of course, support the efforts of many State and local authorities to provide accurate descriptions of restaurant-served foods.

Proposed Action: The agencies will not at this time initiate any action to require that ingredients in restaurant-served foods be declared. This policy will be reexamined in the future as necessary.

Incidental/Secondary Ingredients

A few (118) commenters said they wanted information on ingredients, such as adhesives, that may migrate from packaging materials (incidental or indirect additives) and ingredients, such as calcium silicate in salt used in making bread, that may be components of ingredients used in manufacturing a finished food (secondary ingredients).

Under the FD&C Act, FDA requires that optional ingredients in standardized foods and, with few exceptions, all ingredients in nonstandardized foods be declared on labels. Current FDA regulations (21 CFR 101.100(a)(3)), however, exempt incidental food additives from the statutory labeling requirements. "Incidental additives" are defined by this FDA rule as those substances that are present in a food at insignificant levels and that do not have any technical or functional effect in that food. USDA follows the same general policy.

FDA, USDA, and FTC have considered requiring that such potential additives be declared on food labels. However, the possible presence of incidental additives is not believed to be of any public health significance. Their

presence in food is not always predictable, and even so, their safety is fully assessed. The agencies have concluded, therefore, that such a requirement would not be necessary, and may not be practical or worthwhile. It would require analysis of food lots for potential incidental additives between harvest or manufacture and consumption. Conducting screening analyses for possible additives would be extremely difficult and costly for both government and industry, and the costs ultimately would be passed on to consumers, with little or no benefit obtained.

Proposed Action: The current policy of not requiring the declaration of incidental/secondary ingredients will be continued. This policy will be reexamined in the future as found necessary.

Nutrition Labeling

Nutrition labeling figured prominently in the White House Conference on Food, Nutrition, and Health held in late 1969; nutritionally labeled foods began appearing in grocery stores 4 years later, and they are now quite common.

Even though nutrition labeling is relatively new, the public response it generated was second only to that of ingredient labeling: 52 percent of the commenters discussed some aspect of nutrition labeling, and 3,288 commenters said they want nutrition information on food labels. Those favoring nutrition labeling said they wanted "all" nutrition information to appear on labels, and the rest discussed specific features of nutrition labeling that particularly concerned them. They most frequently mentioned processed or packaged foods as specific food category needing this labeling.

Three main questions characterize this issue: (1) Should nutrition labeling be required on foods? (2) If so, what information should it furnish? (3) Finally, what form should that information take?

Mandatory, Discretionary or Voluntary Nutrition Labeling

This issue concerns whether the government's current, primarily voluntary nutrition labeling policy should be changed either to make nutrition labeling mandatory or to provide FDA and USDA with the authority to require nutrition labeling at their discretion. Much food, of course, already carries nutrition labeling. An FDA survey based on 1976 sales showed that, on a dollar basis, approximately 40 percent of all packaged processed foods and 24 percent of all foods in supermarkets carried nutrition labeling, and that 60 percent of foods with nutrition declarations were labeled voluntarily.

Under FDA regulations (21 CFR 101.9), a food label is not required to bear nutrition information unless (1) a manufacturer makes a nutrition claim about that product on its label or in its advertising or (2) a producer adds nutrients to the food. These FDA regulations define how nutrient content must be disclosed when nutrition labeling is used on a food. USDA does not have nutrition labeling regulations for meat and poultry products, but it accepts and uses FDA's approach on a voluntary basis, and also allows the use of an abbreviated format. Egg product regulations, however, do require nutrition labeling when nutrients have been added to the product or when a nutritional claim is presented on the label, unless the product is specifically exempted. Otherwise, nutrition labeling for egg products is also voluntary (7 CFR 2859.411(e)).

Of the 855 comments on this issue, 88 percent favored a mandatory system. A few commenters suggested that mandatory nutrition labeling should apply only to specific products such as (1) foods that are fortified or for which nutrition claims are made, (2) processed foods, and (3) foods produced by companies with a business volume of more than $500,000 annually per product, but the public preference for mandatory nutrition labeling is clear.

It is less clear whether FDA and USDA have authority to go further to require nutrition labeling on all food products.

Proposed Actions: FDA and USDA will seek or support legislation to clarify their authority to require nutrition labeling on all foods.

USDA will propose regulations that would require nutrition labeling where nutrition claims are made for a product or where certain nutrients have been added to the product.

The three agencies also are forming a task group to develop criteria for determining which additional foods should bear nutrition labeling. The criteria will primarily reflect (a) the significance of the food in the diet; (b) the potential for misleading the public when a food does not have nutrition labeling; and (c) other matters of public health significance.

The agencies invite public comment on these criteria, or others, and their task group will consider these comments in developing the criteria—a task they expect will take 4 months from the close of the comment period.

Nutrition Labeling Format

FDA's regulations on nutrition information (21 CFR 101.9), in effect for over 5 years, provide that if a food's label bears nutrition information, then the data must be accurate and must follow FDA's prescribed format. However, the public has long been interested in improving the format for presenting nutrition information, and industry has considered experimenting with alternative formats.

The 416 commenters on this issue were divided on the type of nutrition label format that would be the most useful. The most popular format was some form of a pictorial/graphic system. Other suggestions included the present FDA system, a rating system, nutrition scores, nutrient density, and food group systems. One hundred seventy of the 195 commenters who expressed their views on the comprehensibility of current nutrition labeling said that some aspect of this labeling puzzles them, and they indentified the U.S. Recommended Daily Allowances (U.S. RDA) most often as the primary source of confusion.

Similar points were made in FDA's Consumer Food Labeling Survey. Twenty-three percent of those surveyed who use nutrition labeling information said they find some aspects of the label confusing, and they identified the confusing elements as terminology (79 percent), use of the metric system (27 percent), use of "big words" (16 percent), use of U.S. RDA's and percentages (15 percent), and not knowing how to use this information (8 percent).

The agencies have concluded that the current nutrition labeling system, a good first step, needs revising to make it more useful to consumers. However, there is a lack of consensus and research on what types of changes should be made.

Proposed Actions: The agencies, therefore, propose to retain the present nutrition labeling system pending the outcome of research to determine which format consumers find most useful and convenient and what changes, if any, are appropriate. The agencies will encourage and facilitate voluntary experimentation, by industry, with graphic and other formats that are consistent with the principles of the current quantitative system, or with new concepts that this research produces. Such studies are to be carried out under carefully controlled conditions and in collaboration with FDA and USDA. The agencies will establish an interagency task group to work with industry and consumers to develop proper experimental designs and the

appropriate criteria for evaluating these experiments.

FDA will participate in the research and experiments by studying various labeling formats, including those formats suggested during the hearings and in the written submissions, to determine which ones best convey nutrition information to consumers. USDA will cooperate fully in, and, if necessary, supplement this research, which the agencies expect to continue for 2 years. (The "Total Food Label" section below provides more information on this research program.)

The interagency task group will complement this research program. It will ensure close collaboration among the agencies, it will hold open meetings frequently, and it will invite full participation by both industry and consumers. The agencies hope that, as a result of the task group's efforts, industry will voluntarily undertake some pilot programs to test—under real market conditions—the proposed new label formats. The agencies will collect data from these pilot programs; the task group which will start working immediately after the next public hearings, will analyze and evaluate this research, and will invite comments and participation during this process before selecting no more than two or three alternative label formats for nationwide use. It will select label formats upon which some pilot programs could be based by November 1980 and will begin evaluating these pilot programs a year later. The agencies welcome comment on the role and functions of the task group.

Mandatory Information for Nutrition Labeling

This issue involves two questions: Should the government change the list of nutrients that must be declared on nutrition labels? Should nutrients present only in small quantities be declared on food labels?

Current rules require nutrition labeling of FDA-regulated products only when nutrients are added to a food or when nutrition claims are made in its labeling or advertising. 21 CFR 101.9, however, requires any FDA-regulated product that bears nutrition labeling to declare the serving size, number of servings in the container, and number of calories in a serving; the quantity of the macronutrients (protein, carbohydrates, and fat) expressed in grams in a serving; and eight nutrients (protein, vitamin A, vitamin C, thiamine, riboflavin, niacin, calcium, and iron) expressed as percentages of the U.S. RDA. Declaring quantities of any or all of 12 additional vitamins and minerals (vitamin D, vitamin E, vitamin B_6, vitamin B_{12}, folic acid, phosphorus, iodine, magnesium, zinc, copper, biotin, and pantothenic acid) and mentioning other nutritional characteristics are voluntary.

The only specific USDA regulations requiring nutrition labeling apply to certain egg products, but producers of meat, poultry, and egg products may voluntarily provide nutrition labeling. In the absence of regulations, USDA uses the same nutrition labeling format as FDA, and it further accepts, in the case of meat and poultry products, an abbreviated format consisting of the macronutrients (protein, fat, and carbohydrates) and calories. (Approximately 75 companies now use nutrition labeling for about 275 different meat and poultry products USDA regulates; luncheon meats, pizza, and canned foods most frequently bear this labeling.)

Evidence from the hearings, the written comments, and FDA's Food Labeling Survey suggests that the public is most interested in the information that appears at the top of nutrition labels: calories, fat, carbohydrates, and protein. The 3,450 commenters who specified what nutrition information they consider important identified calorie content most often, but they also said that cholesterol content, carbohydrate content, protein content, and vitamin/mineral content were important. Only 6 percent of those polled in the FDA Food Labeling Survey claimed using the entire nutrition label. These comments show that some consumers do not use much of the nutrition information currently available, and, when they do, generally find only one or two facts useful. These results suggest at least two possibilities: labels currently contain too much information, or consumers do not know how to use what is there. Accepting the second possibility would further suggest the need for providing more information about nutrition labeling and education on how to use it.

The response also raises a number of very important basic issues involving mandatory nutrition labeling. The public's extensive interest in caloric content undoubtedly reflects the weight consciousness of the American people. Accordingly, the agencies considered allowing a calorie declaration in the absence of full nutrition labeling. They concluded, however, that because it would fail to provide a balanced presentation of foods' nutrition characteristics, this would be inappropriate as a general rule. Industry is producing—and people are eating—more low-calorie foods, but this trend does not diminish the body's need for an adequate supply of vitamins, minerals, and other nutrients. Calorie information by itself generally does not provide adequate information for making sound dietary decisions: The agencies agree that nutrition labeling should usually provide a general nutrient profile of the food.

The views expressed on mandatory information also raise interesting questions about how much flexibility the government's policy should allow. Some have argued that declaring vitamin and mineral content on all nutrition labels is unnecessary because consumers use this information less often and consider it less important. Some said that because most nutrition labeling is voluntary, a requirement for an extensive list of food components on labels could actually discourage use of nutrition labeling. Others, however, emphasized the importance of a more complete nutrient profile to inform consumers of food characteristics having possible public health significance.

Part of this question involves the declaration of mandatory nutrients available in small quantities (less than 2 percent of the U.S. RDA per serving). Currently, nutrients present in such small amounts must be listed as providing "zero" percent of the U.S. RDA or identified by a statement that the product contains less than 2 percent of the U.S. RDA of the nutrient—a policy that reflects the principle that declaring what is not in the food can sometimes be as important as declaring what is in it. Moreover, increasing concern about the adequacy of the amounts of certain micronutrients such as zinc, folic acid, and copper in many diets gives greater urgency to the question of mandatory or voluntary declaration of these nutrients.

Proposed Actions: FDA will continue its current policies for declaring mandatory nutrients (protein, carbohydrates, fat, and certain vitamins, and minerals), calories, and other information pertaining to serving size and servings per container.

USDA will continue to permit use of both the format similar to FDA's and the abbreviated format consisting of macronutrients, calories, and other information deemed useful to consumers. USDA will also propose nutrition labeling regulations to provide information on calories, carbohydrates, protein, fat, sugars, cholesterol, sodium, and other nutrients of public health concern.

The data from the FDA survey, hearings, and written comments—as well as those from other sources—suggest that a review of the information in current nutrition labeling is appropriate. Accordingly, the agencies

invite aspecific comments from the public on the following questions:

(1) Should they retain the present mandatory listing, or should they expand it to include certain other micronutrients such as folic acid, copper, and zinc?

(2) Should they make it more flexible to allow for declaration of certain nutrients on an optional basis? (For example: Should they require only that a nutrition label list serving size, servings-per-container, calories, protein, fat, and carbohydrates? Should a listing of a food's vitamin/mineral content be optional when no nutrition claims are made and no vitamins or minerals are added?)

(3) Should nutrition labeling mention a nutrient when one serving of the food provides less than 2 percent of a U.S. RDA?

Composite Data Base for Use in Nutrition Labeling

The issue here is whether FDA and USDA should continue to require food manufacturers and producers to insure that their food labels accurately reflect the nutrient composition of their products, principally by analyzing individual lots of products, or whether they should allow manufacturers and producers to shift to the composite data base concept for deriving appropriate nutrient values for labeling.

Although FDA's Consumer Food Labeling Survey and the hearings and written comments showed that consumers want nutrition labeling on more foods, only 53 commenters discussed what degree of accuracy should be required in nutrition labeling. Most of those said they preferred the statement of nutrient content by an "exact value"; others said that "representative values" or a "range of values" would be acceptable degrees of accuracy.

The current policy of FDA and USDA assigns each manufacturer the responsibility for assuring the validity of a product's stated nutrient values. A number of firms have complained that the required nutrient analyses are expensive, and they argued for a data base to help them determine the nutrition values to be declared on their products' labels. Such a data base would be compiled for common use by food processors who would then not have to carry out nutrient analyses on their products as often as they now do. The net result of such an approach, the argument runs, would be an increase in the number foods bearing nutrition labeling. The agencies agree that nutrition labeling on more foods is the goal, but they also agree that having more information is scarcely helpful if that information is inaccurate.

Much attention has focused on the National Nutrient Data Bank maintained by USDA and on USDA Handbook 8, used for deriving appropriate nutrient values for nutrition labeling. Smaller segments of the food industry, producers of fresh or minimally processed foods, and (to a lesser extent) all food processors would presumably benefit from a change in current policy. Although the agencies agree that a current valid composite data base would be acceptable, the data available for some foods are inadequate for nutrition labeling.

Proposed Actions: FDA and USDA will maintain for now the current policy that products be labeled according to compositon, and that the manufacturer is responsible for insuring the validity of nutrient content expressed on the food label.

FDA and USDA agree, however, that as reliable data bases are developed, they will be suitable for helping determine the values to be declared on many foods. The agencies strongly support the development and use of modern data bases for nutrition labeling, and their inclusion in the National Nutrient Data Bank. USDA and industry are working to improve these data bases and to bring them up to date; FDA has also been assisting in the developing of data bases for nutrition labeling. This work is progressing: the dairy orange juice, fresh potato, and potato chip/snack food industries, to name a few, have already developed useful data bases.

To clarify their position and to encourage further work, USDA and FDA have prepared the following statement setting forth their policies on nutrient data bases:

Statement of Policy Concerning the Use of Nutrient Data Bases

FDA and USDA encourage industry to develop and maintain meaningful data bases that may be useful guides for determining the nutrient vlaues of indigenous nutrients.

FDA and USDA likewise encourage industry to submit such data bases to them so that they may judge their applicability for use in nutrition labeling. The sampling plans and statistical factors to be used in developing the accuracy of the nutrient profile appearing on the label will be determined, according to the food and the nutrient, for each data base. This evaluation will not constitute approval, but it will assist industry in developing and interpreting a data base for nutrition labeling.

FDA and USDA encourage the use of properly evaluated data bases for all appropriate segments of industry.

The use of a suitable nutrient data base does not exempt a manufacturer from assuring that a product meets its labeled nutrient content within established limits. The agencies consider this provision necessary to ensure proper handling of foods and their proper processing to prevent gross nutrient loss (loss of unstable nutrients, for example). The establishment of reasonable ranges of nutrients to accommodate natural variation is under consideration.

If products bearing nutrition labeling in accordance with properly evaluated nutrient data bases and manufactured in accordance with good manufacturing practices are found not to be in compliance with applicable nutrition labeling regulations, the agencies will work with the firms responsible for the product in question and with the appropriate authorities who are maintaining the applicable nutrient data base to correct the problem before initiating compliance provisions actions. The agencies will continue to reexamine compliance of the nutrition labeling regulations and will consider appropriate revisions as new knowledge, data, and methodology become available.

Industry should submit the data base information it develops to the National Nutrient Data Bank.

Serving Sizes

FDA regulations (21 CFR 101.9(b)(1)) define "serving size" as "that reasonable quantity of food suited for or practicable of consumption a part of a meal by an adult male engaged in light physical activity, or by an infant or child under 4 years of age when the article purports or is represented to be for consumption by an infant or child under 4 years of age." Serving size plays a crucial role in nutrition labeling, because the nutrient information is declared in relation to the average or usual serving or portion consumed. The question here is whether the agencies should standardize serving sizes.

In 1974, FDA proposed setting reasonable and uniform serving sizes for certain products, including fluid milk beverages, noncarbonated breakfast beverages, hot and ready-to-eat cereals, and formulated meal replacements. FDA also asked for information in order to set appropriate serving sizes for canned tuna and canned and frozen fruits and vegetables. FDA announced its intention to establish reasonable serving sizes for other foods if industry failed to petition to establish them. Since then, FDA has

proposed serving sizes for soft drinks, and some industry groups have submitted petitions to set serving sizes or portions for other foods. FDA has taken no final action on any of these petitions, and USDA has not yet established a serving size regulation.

FDA and USDA believe that some serving sizes currently used on labels are not reasonable or uniform within a product class, and consumers have expressed similar views. For example, some manufacturers use overly large serving sizes to inflate the nutritional value of their products; others keep serving sizes rather small, to avoid giving the appearance that the foods contain large quantities of undesirable components. different serving sizes within a product class, moreover, make product comparisons difficult.

Although serving size was not a major issue among the many discussed at the FDA/USDA/FTC food labeling hearings or in the written comments, those comments that did address this issue implied that the public would welcome standardization of serving sizes. Three hundred ninety-one commenters said that serving size is an important element of nutrition labeling, and some people noted that the current serving sizes on nutrition labels are misleading.

Because serving size information is important in meaningful nutrition lageling, because of their commitment to make uniform serving sizes for some foods, and because industry has failed to set useful serving sizes in many cases, the agencies have concluded that they should establish serving sizes for foods needing them.

Proposed Actions: FDA will publish final serving size regulations for some beverage products, cereal, and meal replacements. FDA and USDA will propose regulations to establish serving sizes for additional product classes and/or types of foods.

Labeling of Sugars

This issue concerns whether to increase information food labels give about sugars and how to express this information.

No Federal regulations specifically govern the quantitative labeling of a food's content of sugars. Segments of the food industry, notably the cereal industry, voluntarily include a breakdown of carbohydrates in their foods into complex carbohydrates and simple carbohydrates (sugars). They add this information to these foods' nutrition labeling.

Over the past few years, consumers have become increasingly concerned about the quantity of sugars they are consuming. This concern results from a desire to reduce caloric intake, from the acknowledged relationship of sugars to dental caries, and from the possible association of consumption of sugars with other diseases. Some also believe that consumption of sugars is responsible for deteriorating eating habits and a perceived decline in the health of Americans. The only demonstrated hazard that sugars pose to the public health, however, remains their contribution to dental decay.

The results of the food labeling initiative absolutely confirm this increased public interest. (The following discussion groups together all comments on sugars labeling, whether they were made in the context of ingredient labeling or nutrition labeling.) Of all those who commented orally and in writing in response to the agencies' request for comments on food labeling, 27 percent asked for information about sugars—making sugars the food component that generated the most public concern. Eighty-two percent of the 892 people specifying which foods should bear sugar labeling wanted this information on "all" foods. Nine hundred eleven commenters specifically requested that the content of total sugars (61 percent) or added sugars (23 percent) be declared on product labels. More than half of the 1,135 commenters who discussed how to declare the amount of sugars in a food wanted to know the percentage of sugars; 8 percent wanted the amount by weight; 3 percent wanted the amount for both percentage and weight. Approximately 34 percent of the commenters on this question asked generally for the "amount" of sugars in a food without specifying a method for listing. Relatively few commenters (444) expressed a preference for the location of this information about sugars on labels. Over 65 percent of those said they wanted this information on a product's ingredient label, while 28 percent wanted it on the nutrition label.

In the Food Labeling Survey, sugar was the food component of most concern to consumers. It was the most frequently avoided substance (by a reported 24 percent of all consumers), it was the ingredient whose presence in the ingredients list was noticed most often, and it was the substance about which the consumers most frequently wanted information.

Proposed Actions: FDA will propose to amend the nutrition labeling regulations (21 CFR 101.9) to require quantitative declaration of total sugars as part of nutrition labeling. USDA will propose regulations to require, as part of nutrition labeling, quantitative declaration of the total sugars a food contains.

Recognizing that some foods provide insignificant quantities of sugars, the agencies are seeking information on the amount of sugars (grams per serving or percentage by weight) that should trigger the label declaration. FDA, USDA, and FTC have established a task group to develop criteria for determining such a level of sugars. In developing its proposal on this issue, the task group will consider comments it receives in response to this request. The agencies estimate that this assignment will be completed in 4 months after the close of the comment period.

USDA and FDA will seek or support legislation to provide them with explicit discretionary authority to require quantitative labeling of sugars on the basis of public health significance.

To complement their actions on labeling of sugars, the agencies will conduct an educational program to increase consumers' understanding of how sugars are declared on food labels.

This rather involved issue deserves further explanation. FDA has jurisdiction over most sugar-sweetened products, but it does not have explicit authority to require across-the-board quantitative labeling of sugars on all foods. The current authority, among other things, does allow FDA to amend the nutrition labeling regulations to include quantitative declaration of sugars—and the first part of the agencies' proposal shows FDA intends to do so. Public preference on this issue is so clear, however, that a full response to it requires FDA and USDA to seek or to support legislation for discretionary authority to require quantitative labeling of sugars on the basis of public health significance—a second action they propose to take. The agencies have concluded that the declaration of sugars (triggered by a level to be specified) should be based on the total amount rather than the amount of added sugars because (1) a declaration on the basis of added sugars would not provide the complete picture of the total content of sugars in a product, (2) the body cannot differentiate between sugar molecules, whether they are added or not, and (3) analysis to distinguish added from total sugars is difficult, if not impossible, in most instances.

The agencies have further concluded that labeling information on the content of sugars belongs more properly with nutrition labeling because the total sugar content of the product is of foremost importance to the consumer. If the labeling of sugars appeared in the ingredient statement, only added sugars would be declared, even though

indigenous sugars contained in the other ingredients could constitute the bulk of sugars in the product. The agencies have not ruled out the possibility of requiring those foods containing a large amount of sugars to declare this information in the product name, e.g., "Cereal X, contains —— percent sugars."

The form of quantitative declaration (percentage by weight, grams per serving or other units) remains at issue because percentage labeling alone is potentially misleading. A food declaring a higher percentage of sugars than another may in fact provide a lesser amount of sugars per serving than a product with a lower percentage by weight of sugars. Researchers at FDA are now working on this problem.

Sodium and Potassium Labeling

Current FDA (21 CFR 105.69) and USDA (9 CFR 317.2(j)(2) and 381.124, and 7 CFR 2859.411(e)) regulations make the declaration of a food's sodium content voluntary, in the absence of a claim about the sodium content of a food. When a product does bear sodium labeling, its label must list the number of milligrams of sodium per 100 grams and per serving. The regulations do not require sodium declaration as a part of nutrition labeling, and under the present rules, labeling of sodium content does not make full nutrition labeling mandatory.

The sodium content of foods provoked a significant public response. This discussion groups together all of the comments on sodium and potassium labeling whether they were made in the context of ingredient or nutrition labeling. Nearly 25 percent of all commenters discussed this issue in their oral and written statements, making it second only to sugars as the food component whose label declaration most concerned the public.

Public concern about the levels of sodium in the American diet has increased in recent years. This interest arose after several reports concluded that current intake levels exceed physiological needs. The basic question involves the relationship of sodium, derived from salt or other sodium-containing compounds, to hypertension and other physiological disorders. Clinical conditions such as renal disease, requiring control of sodium intake, frequently require the simultaneous control of potassium, and control of potassium often requires sodium control as well. An estimated 20 to 30 million Americans have diseases or disorders for which controlling sodium intake, potassium intake, or both, is important. As a result, many consumers believe that product labels need to display more information about the sodium and potassium content of foods.

Six hundred thirteen commenters specifically addressed whether total or added sodium content should be declared on product labels; 60 percent wanted content declared for total sodium, 23 percent favored listing only added sodium, and 17 percent advocated the declaration of both.

Although 1,063 commenters discussed how to declare the amount of sodium in foods, their suggestions were divided. Forty-nine percent wanted to know the amount of sodium in a product but did not specify what form this information should take. Of those commenters expressing a preference, 24 percent wanted it listed as a percentage and 25 percent wanted it listed by weight. (A few wanted both.)

Finally, as with sugars, not many commenters offered opinions on the placement of quantitative sodium labeling on food labels. Four hundred fifty commenters discussed this question; 60 percent preferred that sodium content appear in the ingredient statement, nearly 35 percent wanted it on the nutrition label, and 5 percent wanted it as a distinct designation on the principal display panel.

The views expressed in FDA's Food Labeling Survey parallel the hearing and written comments. Sodium was second only to sugars as the food component of concern: 13 percent of the respondents reported attempting to avoid consuming sodium whenever possible.

Proposed Actions: FDA will propose to amend its nutrition labeling regulations to require the declaration of sodium and potassium content as part of nutrition labeling.

USDA intends to propose reguations that would require sodium labeling as a part of nutrition labeling, and it will consider including potassium labeling in this proposal.

FDA and USDA will propose regulations to define "low sodium." They will also consider defining "reduced sodium" foods and standardizing the claims appropriate for foods containing no added sodium.

FDA will seek or support legislation to provide it with explicit discretionary authority to require quantitative labeling of sodium and potassium on the basis of public health significance. USDA believes it has such authority but will support legislation to provide more explicit authority for both agencies.

In their deliberations, the agencies considered various options for increasing labeling information on sodium and potassium content. They have concluded that information on sodium and potassium would be better addressed as a part of nutrition labeling because knowing the total sodium and potassium content of the product is most important to consumers. Placement of the sodium and potassium content labeling in the ingredient statement, for example, would require only added sodium and potassium to appear, even if the indigenous sodium and potassium contained in the other ingredients represented the bulk of these elements in the product. In addition, issuing regulations defining "low sodium" and "reduced sodium" foods and standardizing the claims appropriate for foods containing no added sodium should also help consumers monitor their intake of sodium and encourage manufacturers to formulate foods with lower sodium content.

Fatty Acid and Cholesterol Labeling

Fatty acids are present in all fats, and their composition determines whether a fat is "saturated" or "unsaturated." Cholesterol is a fatty substance called a steroid. Consumers are interested in both because of the possible association between their consumption and coronary heart disease. At issue here is (1) whether food labels should present more information about fatty acid and cholesterol content and (2) if so, what such information should include.

FDA regulations (21 CFR 101.25) permit the voluntary inclusion of fatty acid and cholesterol content as part of nutrition information. They allow a food's label to include information on fatty acid content provided the food contains 10 percent or more fat on a dry weight basis and not less than 2 grams of fat in an average serving. If a food product makes any claims about fatty acids and/or cholesterol, the information required by this regulation then becomes mandatory. The label of a food bearing this information must also state the following: "Information on fat (and/or cholesterol, where appropriate) content is provided for individuals who, on the advice of a physician, are modifying their dietary intake of fat (and/or cholesterol, where appropriate)." It is now obvious, however, that many people want to modify their consumption of fat and cholesterol—and are doing so—without specific medical supervision. Such instructions may not, therefore, always be necessary. No specific USDA regulations cover fatty acid or cholesterol labeling, but the labeling of meat, poultry, and egg products follows FDA's guidelines. FTC's Division of Food and Drug Advertising has recommended that the Commission require certain fatty acid and cholesterol

information in advertising making claims in this area.

The public's concern about coronary heart disease, and the belief that this disease may be related to dietary factors—including the consumption of fatty acids and cholesterol—has aroused interest in the amount and kind of fat and cholesterol contained in foods.

Nearly 14 percent (1,346) of all commenters mentioned the labeling of fats and oils in foods. (As in the discussions of sugars and sodium, the comments on fatty acids and cholesterol—whether they were made in the context of ingredient or nutrition labeling—have been combined.) One thousand one hundred and forty-six wanted to know the quantity of fats and oils in food; 1,302 wanted to know the their source; and 458 wanted to know the amounts of unsaturated and saturated fats in foods. Relatively few specified where this information should appear on the food label; of those 321 commenters who specified location, 69 percent wanted this information in the ingredient statement, 28 percent favored locating it on the nutrition label, and 3 percent preferred the principal display panel.

The results of FDA's Consumer Food Labeling Survey confirm this public concern about cholesterol and fat content. Twelve percent of the respondents who claimed they read nutrition labels said that cholesterol is an important item. Given a list of 38 nutrients, 65 percent of the respondents listed cholesterol information as "very important," while 52 percent listed polyunsaturated fats as "very important" and 50 percent said the same for saturated fats. The mandate of consumers is clear, and the agencies agree that increased food labeling information about fatty acids and cholesterol is in order.

Proposed Actions: FDA will continue to require that the cholesterol or fatty acid content of a food be included on nutrition labeling when claims about these substances are made.

FDA will propose to amend the fatty acid/cholesterol regulation to require fatty acid labeling whenever cholesterol is declared and cholesterol labeling whenever fatty acids are declared.

FDA will propose to amend the present fatty acid/cholesterol regulation to eliminate the requirement for the statement "Information on fat (and/or cholesterol as appropriate) content is provided for individuals who, on the advice of a physician, are modifying their dietary intake of fat (and/or cholesterol as appropriate)."

FDA will propose a regulation to define the terms "low cholesterol," "reduced cholesterol," and "cholesterol free." FDA will also consider proposing regulations to govern claims about fatty acid content.

FDA will seek or support legislation to provide it with explicit discretionary authority to require cholesterol/fatty acid content labeling on the basis of significance to public health. USDA believes it has such authority but will support legislation to provide more explicit authority for both agencies.

USDA will propose regulations to require cholesterol labeling as part of nutrition labeling.

Fiber Labeling

Fiber is an essential dietary component for normal bowel function. Some advocates of high fiber diets have theorized that the incidence of bowel cancer and other intestinal diseases may be related to the decreased amount of fiber in Western diets, and these theories have gained a measure of public currency. Some segments of the food industry, especially cereal manufacturers, have increased the use of fiber declaration on product labels in response to the increased public interest. The question here is whether to increase information food labels provide about fiber content.

Until recently, scientists and consumers had only a limited interest in the fiber content of foods. The biomedical aspects of fiber in its various forms are unsettled and the subject still generates considerable controversy. There is no scientific consensus on a definition of "fiber". Both the government and industry are still conducting research to solve the methodological problems related to the several types of dietary fiber. The only official method of analysis currently available is for "crude fiber," which is just a fraction of total dietary fiber. Finally, the relationship of dietary fiber to health remains controversial. FDA regulations (21 CFR 105.3(d)) now require that any disclosure of fiber content must be expressed as "crude fiber" and declared as a percent by weight.

Two hundred seventy-eight commenters (or 8 percent of those commenters specifying what kinds of nutrition information is most important) thought that knowing a food's fiber content is important. Although some consumers have said they want food labels to provide more information about the fiber, many appear to have limited knowledge about fiber content of foods and scant understanding of the differences between crude and dietary fiber. As a result, many may be unable to evaluate information on fiber adequately.

This state of affairs is not surprising, given the scientific uncertainty and controversy involving various aspects of fiber. FDA, USDA, and others currently are conducting research on methodologies for measuring fiber and on the relationship of dietary fiber constituents to health.

Proposed Action: FDA and USDA will not require dietary fiber labeling as part of nutrition labeling until there is a clearer consensus on a definition of dietary fiber, until methods of analysis are developed, and until its significance in the diet is better understood.

Disease-Related Claims on Food Labels

Should FDA and USDA alter their general policy of not allowing medical claims on food labels? FDA regulations (21 CFR 101.9(i)(1)) specifically prohibit claims in labeling that a food is adequate or effective in the prevention, cure, mitigation, or treatment of a disease or a symptom. Similarly, the FTC has challenged such claims in food advertising, and the FTC staff has proposed that the Commission prohibit the use—in advertising—of claims that violate this FDA regulation.

Only 42 commenters expressed views on allowing food labeling or food advertising to make medical claims, and the majority opposed permitting claims such as "this low cholesterol food is beneficial in preventing heart disease" or "this low calorie food will help you lose weight."

Interest in specialized food products available for medical conditions, however, continues to increase. FDA is developing a proposal concerning the labeling of these specialized foods, sometimes called "medical foods." This proposal will cover special foods specifically marketed for use under medical supervision; it will permit those foods—such as products used to treat phenylketonuria—to bear therapeutic labeling.

Some consumers have also shown interest in dietary regimens and special food products for use in preventing colds, causing weight loss, and the like. The current state-of-the-art in nutrition and disease treatment remains insufficiently developed to allow manufacturers of less specialized dietary preparations or conventional foods to make medical claims without being misleading to the consumer. Furthermore, it is the total diet, not an individual food item, that establishes the role of nutrition in determining health and reduces the risk of diet-related diseases.

Proposed Actions: FDA and USDA therefore intend to maintain the present policy of not allowing disease-related claims to appear on the labeling of conventional food products, but they will reexamine this policy if the need arises.

FDA will proceed to develop proposed regulations covering "medical foods" (foods for use under medical supervision), permitting the use of appropriate therapeutic claims about such foods.

Open Date Labeling

The term "open date labeling" refers to readable, understandable dates on food packages that can be used by consumers to tell when a product's quality will change. Traditionally, most dates on food packages have been "closed," which means they are written in code and intended only for the use of manufacturers, distributors, or retailers.

There is widespread consumer interest in open date labeling. Approximately 45 percent of all commenters discussed the issue, putting it third in the hierarchy of public concern, behind ingredient and nutrition labeling. Almost all those who commented on open date labeling favored it for at least some foods. Forty-three percent of those in favor said that all foods should bear open date labels; about 12 percent, however, said that open date labeling should apply only to perishable foods.

In the food labeling notice, the public was also asked what form this date should take. Of the 3,352 commenters addressing this question, some of whom gave multiple answers, 49 percent of the commenters favored expiration dates; 33 percent preferred knowing the date the food was packed; 28 percent supported "pull" dates (the date a product should be removed from the shelf); 16 percent supported freshness/quality assurance dates; and 4 percent recommended that different dates be used for different foods. Of the relatively few (672) commenters who discussed whether open date labeling should be mandatory or voluntary, 94 percent wanted mandatory rules.

Respondents in FDA's Food Labeling Survey also reported widespread interest in open date labeling and a desire to see more foods labeled with such dates. Their responses also parallel the hearing and written comments by expressing a strong preference for an expiration date rather than a pack date or a quality assurance date.

Open date labeling is voluntary under present Federal law. The FD&C Act does not contain any specific provision that requries open date labeling, and FDA currently has no open date labeling regulations. Under the adulteration and misbranding provisions of the act, FDA may require an expiration date when a product would violate the act if it were not sold by a certain date and there is a substantial possibility the violation would occur before sale. This concern is particularly applicable to deterioration that would cause a food to become a health hazard. FDA believes that explicit authority is desirable before it establishes any general requirements in this area.

USDA regulations provide for voluntary open date labeling on meat and poultry products. When an open date is used, USDA requires that it be accompanied by the explanatory phrase, "packed on," "sell by," or "use before" (9 CFR 317.8(b)(32) and 381.129(c)). USDA allows processors to label meat and poultry products with additional statements such as "full freshness 10 days beyond date shown when stored at 40° F or below." USDA egg products regulations require only that the label be marked with the production code or lot number from which the pack date can be determined (7 CFR 2859.411(c)(3)).

Many State and local jurisdictions have taken the lead in requiring open date labeling on certain foods. These requirements, however, often differ from jurisdiction to jurisdiction, and the variation is costly for manufacturers and confusing for consumers. It should be pointed out that the meat, poultry products and egg products inspection acts specifically prohibit State and local governments from imposing labeling requirements on federally inspected products that are in addition to or different from those imposed on federally inspected establishments or plants that operate under the acts. Nevertheless, the agencies recognize the important role that the States and localities have played in requiring open date labeling.

The agencies have agreed that open date labeling is a sound idea, and that the Federal government should act to extend open date labeling to more foods. Further study and discussion is needed to determine which foods should have open date labels and what kinds of open dating ("packed on," "sell by," etc.) should be used. In addition, uniformity in approach is essential. The Federal agencies will work closely with State and local governments to develop a consistent approach that will minimize manufacturers' costs and eliminate consumer confusion.

Proposed Action: FDA will seek or support legislation to provide it with explicit discretionary authority to require open dating on classes of foods as is found necessary. USDA believes it now has such authority but will support legislation to provide more explicit authority for both agencies.

USDA will propose regulations to require open dating on perishable and semiperishable foods to the extent that authority under current law permits.

Imitation/Substitute Foods

This issue concerns the proper labeling of those foods that resemble and are intended to substitute for traditional or standardized products, but do not contain the same ingredients or the same proportion of ingredients. For example, "imitation mayonnaise," resembles the traditional food known simply as "mayonnaise," but the imitation product usually does not contain the same amount of fat, may omit eggs or other ingredients, and may contain ingredients not present in the standardized "mayonnaise."

Under the FD&C Act, an imitation food is considered misbranded if it does not bear the work "imitation" followed by the name of the food it copies. This provision is intended to prevent consumers from being misled into thinking that imitation foods are the same as traditional or standardized products.

Judging from the hearing and written comments, there is considerable public interest in the issue of imitation and substitute foods. Nearly one-fifth of all commenters discussed some aspect of imitation and substitute foods. Of the 1,350 commenters who addressed the issue of naming imitation and substitute foods, the overwhelming majority (75 percent) said that they should be labeld "imitation." Less than one-fifth of the commenters said that such products should be given a new, descriptive name. A few said either approach would be acceptable or that such foods should be given a new name plus the "imitation" label.

Although the comments clearly demonstrate the importance of imitation labeling to the public, they were too general to provide a definitive guide for policy. Imitation labeling is a rather complex issue, and some facets of the issue are very controversial.

Therefore, the agencies are taking no position on the issue at this time, but instead are presenting five possible options to stimulate further public comment. As background to the discussion of these options, both a summary of the main elements of controversy and a description of how the present Federal policy has evolved are in order.

The first element of this problem concerns the meaning of the word

"imitation." Because label space is limited, a single word such as "imitation" is valuable if it can be used in place of several descriptive words. The word "imitation," however, may not mean as much to consumers as its adherents believe, and may even be misleading. The Final Report of the 1969 White House Conference on Food, Nutrition and Health said that the "imitation" label was potentially misleading to consumers; the report noted that this term failed to inform the public about the actual characteristics and properties of a new food, and in some instances unfairly implied inferiority.

Another aspect of the problem concerns innovation. There is nothing in the FD&C Act, the FMI Act, or the PPI Act that explicitly mentions the government's proper role in food innovation. However, the mere presence of governmental regulation, and hence involvement in industry processes, makes the effect on innovation an important issue. Various groups in industry as well as consumers stand to gain or lose depending on governmental policies affecting food innovation. The producers of new and modified products obviously have an interest in governmental policies that make the introduction and marketing of these products as easy as possible, while producers of traditional foods may have their markets reduced by these kinds of policies. Some new and modified foods may have a significant health or price advantage over currently available products, while others may have health and cost disadvantages. Since consumers may stand to gain from one type of new food and lose from another, it is important that they have a basis for perceiving the difference.

A third point concerns the fairness of allowing new products to "co-opt" the names of traditional products. One side argues that new products should be required to establish a market based on their own qualities and intrinsic ability to attract customers, rather than by relying on the goodwill associated with the names of other products whose manufacturer may have spent years developing a market. The other side contends that the consumer is better served by facilitating comparisons among products that are similar and letting the marketplace decide whether the traditional products should have an advantage. Because there are strong arguments on both sides, it is difficult to decide the best government policy. Unfortunately, neutrality is impossible; even a decision to do nothing would be a policy decision that would have consequences in the marketplace.

The Federal policy on substitute foods has evolved over a number of years. As new food products developed, the agencies concluded that some new products were used for the same purposes as traditional foods, but were sufficiently different from their traditional counterparts to make the "imitation" label inappropriate. They also realized that the term "imitation" often connoted inferiority, and that consequently the imposition of "imitation" labeling was probably inhibiting new product development.

A 1973 FDA regulation (21 CFR 101.3) narrowed the use of the term "imitation." Before 1973, "imitation" had to appear on the label of all substitute foods except for a few that went through the process of obtaining a new standard of identity or common or usual name. This policy did not directly take into account nutrient content. Under the 1973 regulation, which is in effect today, however, only nutritionally inferior substitute foods have to be labeled "imitation." Nutritional inferiority is determined by protein content and the content of those 19 vitamins and minerals for which U.S. RDA's have been established. If a substitute food has essentially the same amounts of these nutrients as the traditional food, then it can be labeled with an accurate common or usual name (but still not the traditional name), instead of "imitation." This interpretation of section 403(c) of the FD&C Act has been upheld on judicial review.

It should be noted that the determination of nutritional inferiority under the 1973 regulation does not take into account such factors as carbohydrate, fatty acid, sodium, cholesterol, fiber, and trace element content.

Present Federal policy is based primarily on the 1973 regulation. FDA and USDA make decisions on names for substitute foods that have essentially the same amount of U.S. RDA nutrients on a case-by-case basis. These decisions are usually made in response to a petition for a standard of identity or a common or usual name, or after a manufacturer has gone ahead and given a name to a new food and there is no regulation prescribing a specific name. The FD&C Act does not provide for, and FDA does not require, preclearance of names. USDA, through its prior approval system for labels, does require preclearance. Under certain circumstances, the comon or usual name for a substitute food can include the name of a traditional food and, in some cases, must include the percentage of the characterizing ingredient.

The Federal policy on imitation labeling has attracted considerable interest as the public has become more concerned about the nutritional quality of substitute foods. Of particular interest is the standard for determining nutritional inferiority. Some are concerned that the standard does not take into account the quantities of fiber, all trace minerals, or other micronutrients that may be available in the traditional food. They contend that a person on a diet of substitute foods might develop dietary deficiencies due to the absence or insufficiency of these nutrients. They therefore would prefer use of the "imitation" designation on all substitute foods. In response to these concerns, it should be noted that although these deficiencies are theoretically possible, the data now available do not indicate there currently is a problem.

Some members of the public have also expressed the view that the term "imitation" should be applied to substitute foods that offer no perceived health advantages, but not to foods that do offer such an advantage, e.g., a substitute food containing less fat, sugar, salt, or cholesterol. Still others believe that any change in the proportions of the characterizing or valuable ingredients in a traditional food should render a food an imitation, regardless of its nutrient content. Finally, some people object to including the name of a traditional food as part of the identification of a substitute food, even if preceded by "imitation". They prefer using new names for all new and modified foods.

Just as there are differing views among consumers, industry members also disagree on the issue of substitute foods. Producers of traditional foods naturally tend to believe that totally new names should be used for nontraditional foods. On the other hand, producers of new substitute foods often would prefer to tie their product names as closely as possible to those of traditional foods.

The existing policy does permit manufacturers some flexibility in development and marketing new foods. If the new food meets certain nutritional standards, then it may use a name that affirmatively describes the product. The agencies believe the current policy represents one practical solution to a complex and a controversial issue. They recognize, however, that it has limitations and is not the only possible solution. After reviewing the recent public comments, the agencies also believe that the government has not

adequately explained the policy in the past. Therefore, the agencies want to obtain more comments from the public. They are soliciting comments on the following five options and welcome other suggestions as well:

1. *Maintain the existing policy.* Foods that are not nutritionally inferior to foods for which they substitute do not have to be labeled as imitations but can be given new names that are not misleading. ("Not nutritionally inferior" is defined to mean providing essentially the same amounts of protein and 19 vitamins and minerals for which U.S. RDA's have been established as the foods for which they substitute. It does not include constituents such as fats, fiber, sugars, etc.)

Under this definition, foods that are nutritionally inferior to the foods for which they substitute must be labeled as imitations.

Pro: Manufacturers are encouraged to maintain nutritional quality while affirmatively labeling the product; innovation in food technology is encouraged.

This policy has been upheld by the courts, thus ensuring stability and conserving resources that might have to be devoted to legal challenges if the policy were changed.

It would be the least expensive option because it is already in place.

Con: This policy does not necessarily provide as much information about the substitute food as some consumers may want; it may confuse consumers as to how the substitute food differs from the traditional or standardized food and therefore makes it difficult to shop. It also may be misleading about nutritional value.

It does not differentiate substitute foods that may offer a health advantage from other substitute foods.

It may result in the use of a traditional food's name as part of the common or usual name of the substitute food and, therefore, does not satisfy those who object to use of the name of the traditional food as part of the name of the substitute food.

2. *Expand use of imitation labeling.* (Pre-1973 policy.) Any food that resembles and is intended to replace a traditional or standardized food, regardless of its nutrient content or other characteristics, would be called "imitation" or alternatively, there must be established for this food a common or usual name or a standard of identity. This was the policy before the 1973 regulation.

Pro: It would alert consumers that such foods are not the "real thing" and are intended to replace traditional or standardized foods.

It would avoid the difficult task of determining the adequacy of the criteria used to judge nutritional inferiority.

Con: It would not satisfy those who do not want any use of the traditional name.

The term "imitation" does not tell consumers much about a food because its focus is on what the food is not rather than on what it is. Therefore, consumers will not be adequately informed as to the identity or intended use of the substitute food. It does not differentiate between substitute foods that have a lower nutrient content than the foods they are intended to replace and other substitute foods or between those that may offer a health advantage (e.g., foods that contain less fat or sugar) and those that do not.

The use of the term "imitation", because of its negative connotation, discourages new food innovation and removes the incentive to maintain U.S. RDA nutrient content.

If a common or usual name or standard of identity is sought for such a product, the laborious and expensive administrative process inherent in both approaches could also discourage new food innovation. (Both methods involve notice and comment rulemaking, and the standard of identity approach additionally allows an opportunity for a public hearing.)

3. *Expand use of imitation labeling as described in option 2 but add to the "imitation" designation a common or usual name that explains what the product is.*

Pro: It better informs the consumer about what the product is or is not.

Con: It would not satisfy those who do not want any use of the traditional name (which might be part of the common or usual name.)

It does not differentiate between substitute foods that have a lower nutrient content than the foods they are intended to replace and other substitute foods.

It would call for long labeling (e.g., "imitation cheese and sausage pizza made from 30 percent vegetable oil and soy flour and sausage-flavored isolated protein") that could cause space problems and make labeling less understandable.

4. *Expand use of imitation labeling as described in option 2 but add to the "imitation" designation an explanation (not necessarily as part of the product's name) of how the substitute product differs from the traditional food.*

Pro: It better informs the consumer about what the product is or is not.

Con: It would not satisfy those who do not want any use of the traditional name.

It does not differentiate between substitute foods that have a lower nutrient content than the foods they are intended to replace and other substitute foods.

It could call for even longer labeling than option 3. For example, the name of the product mentioned in option 3 could be "imitation cheese and sausage pizza—this product contains vegetable fat and soy flour instead of milk fat and milk protein normally found in cheese and contains isolated protein rather than sausage." This approach also could label space problems and make labeling less understandable.

5. *Establish a policy based on the proportion and type of characterizing or valuable ingredients.* This option has two components. First, if the proportion of characterizing or valuable ingredients in the food has been changed from that in the traditional or standardized food, the name of the product must consist of the word "imitation" folllowed by the name of the food copied. For example, a substitute for strawberry jam in which the percentage of strawberries has been decreased would be labeled "imitation strawberry jam."

Second, if characterizing or valuable ingredients are replaced, then an accurate common or usual name must be used. This name could include the traditional name only if it described how the substitute food differed from the traditional food. For example, a breakfast meat substitute might be lebeled "bacon-flavored soy protein breakfast strips."

In both cases, fanciful names would also be permitted. For example, the label of the soy protein breakfast product referred to in the preceding paragraph might also include the fanciful name, "Morning Openers." In neither case could the fanciful name include the name of the traditional product, e.g. "strawberry jam" or "bacon."

Pro: Substitute foods would be distinguished from traditional and standardized foods. Substitute foods with different characterizing ingredients would be distinguished from foods with reduced characterizing ingredients. Consumers would receive more information than they now do about substitute foods with different characterizing ingredients.

The policy would partially satisfy those who object to the use of traditional names as part of the name of a substitute food.

It would avoid the difficult task of determining the adequacy of criteria used to judge nutritional inferiority. Criteria based on valuable or characterizing ingredients might be

simpler to administer and communicate to consumers.

Con: Use of the term "imitation" would be retained for some substitute foods. The term "imitation" does not tell consumers much about a food because its focus is on what the food is not rather than what it is.

It would not differentiate between substitute foods on the basis of nutrient content. This would reduce the present incentive to maintain the U.S. RDA nutrient content of substitute foods.

It might not differentiate between those that may offer a health advantage and other substitute foods.

There might be disagreements as to which ingredients in a traditional or standardized food are characterizing or valuable.

It might require a legislative change in the current statute.

Food Fortification

Food fortification involves the enrichment of foods, the restoration of nutrients, and any other addition of essential nutrients to foods; the agencies sought the public's views on whether to increase labeling and quantitative control of fortification.

FDA amd USDA currently have limited control over food fortification, directly through food standards and special dietary food regulations, and indirectly through regulation of imitation and substitute foods and through exercising their authority to prevent misleading labeling. FDA lacks, however, express general authority to control the fortification of foods. USDA under current policy prohibits the addition of vitamins and minerals to meat and poultry products, unless specific regulation permits their addition (as in the case of adding vitamin A to margarine) because no need to fortify these products has been demonstrated. USDA's egg product regulations do allow the addition of vitamins and minerals to products in the way FDA's standards and regulations would allow—unless the purpose of this addition is to make the egg products appear to be better or of greater value than they are (21 U.S.C. 1033(a)(8), 7 CFR Part 2859). Industry has generally added nutrients to foods in a rational way, except in a limited number of special instances involving such products as certain beverages, snack foods, and certain cereals.

Approximately 15 percent of all commenters discussed some aspect of food fortification; 84 percent of the 1,103 commenters who discussed the advisability of fortifying foods gave their unqualified or conditional approval to permitting food fortification.

Of the 340 commenters who gave reasons for fortifying foods, 72 percent favored it to replace nutrients lost in processing, 30 percent to protect the public health, and 14 percent to enhance general nutritional value of the food. (Commenters could list more than one reason.) The most frequent argument against fortifying foods was overfortification, which could cause an imbalance of nutrients in the diet or their excessive intake. Commenters also registered fears that people would replace naturally nutritious foods with fortified foods, that fortification could lessen manufacturers' concern for nutrient retention, or that it could lead to overpromotion of a product. Ninety-four percent of the 401 people who discussed government regulation of fortification supported it.

Public reservations thus stem largely from concern about overfortification and the potential for inappropriate fortification; some experts regard deficiency diseases as a concern of the past, and argue that nutrient excesses pose a more substantial problem. Analysis of American dietary practices suggests that this view has some validity, but the subject is complex. Some individuals doubtless consume excessive amounts of some nutrients, such as sodium and phosphorous; but many of these excesses involve personal eating habits and not fortification. And yet a change in the food industry's current restraint toward fortification would be a cause for serious concern, as would an increase in consumption of dietary supplements.

The consumption of fabricated foods intended to substitute for traditional foods does seem likely to increase, and with it the need to ensure that these substitute foods are properly fortified. Furthermore, as Americans reduce their caloric intake, assuring that their diet provides adequate nutrients becomes increasingly important.

Proposed Actions: FDA and USDA will therefore seek or support legislation giving them explicit discretionary authority to control the fortification of food when exercising this control is deemed of public health significance. In the interim, FDA will publish guidelines on food fortification and encourage manufactures to adhere to them.

The agencies agree that any useful food fortification policy must address a number of needs:

1. The need to add nutrients to staple foods to correct deficiencies in a clearly-defined population.

2. The need to avoid adding certain nutrients to foods that are not appropriate vehicles for added nutrients.

3. The need to maintain the total original nutrient profile of foods by restoring nutrients lost in processing.

4. The need to assure that substitute foods are not nutritionally inferior to the foods they replace.

5. The need to require that fabricated foods replacing large portions of the diet or the entire diet have a complete balance of nutrients relative to their calorie content.

6. The need to prevent misleading promotions of fortified foods that present no advantages over other foods.

FDA, USDA, and FTC agree that future food fortification requires appropriate guidance, and they are convinced that such guidance should derive from the legislative authority to control, when public health significance requires it, fortification of foods. The agencies intend to seek this authority, but in the meantime FDA will soon issue a separate **Federal Register** notice entitled "General Principles for the Addition of Nutrients to Foods." Besides providing general guidance on fortifying foods, this notice also explains which foods, such as meat and poultry products and snack foods (carbonated beverages, candies, etc.), FDA considers to be inappropriate for fortification.

Safe and Suitable Ingredients and Food Standards

Understanding this issue requires briefly sketching the history of food standards. Since the early 1940's, FDA has issued regulations called standards of identity which describe what ingredients may or must be used in making many traditional foods. These standards initially were almost strict recipes, although they allowed some minimal flexibility for the use of certain optional ingredients such as colors, flavors, and spices. In other words, they listed the specific mandatory and optional ingredients that the food could contain. These early standards, some of which covered breads, canned fruits, and vegetables, were designed to guarantee the uniform quality and compostion of traditional foods familiar to the American household, to control the use of food and color additives, and to control the basic nutritional quality of standardized foods.

This policy changed significantly in 1961, when FDA issued the breaded shrimp standard (21 CFR 161.175). This standard shifted regulatory focus from all ingredients to the characterizing (mandatory) ingredient(s), which in this case involved the amount and nature of the shrimp. Thus, while this standard specified that such a product must contain 50 percent shrimp, it permitted the use of any "safe and suitable" batter

ingredients. This move toward safe and suitable optional ingredients initiated a period of greater flexibility in FDA's food standards. Standards of identity now allow manufacturers to use any safe and suitable ingredient that performs the function specified in the standard. For example, instead of specifying a preservative by name (calcium propionate, sodium benzoate, etc.), a standard allows any safe and suitable preservative. (Of course a standardized food's label must declare the particular preservative used.) The shift in policy was made possible by enactment of the Food Additives Amendment of 1958 and the Color Additive amendments of 1960 to the FD&C Act, amendments requiring that FDA approve the safety of food and color additives before they could appear in foods. Therefore, FDA no longer had to rely on food standards for premarketing review of the safety of substances added to food. (Before these amendments, only ingredients in standardized foods were subject to premarket approval.)

The phrase "safe and suitable," as defined by regulation (21 CFR 130.3(d)), means that the ingredient it describes:

1. Performs an appropriate function in the food in which it is used;

2. Is used at a level no higher than necessary to achieve its intended purpose in that food; [and]

3. Is either (a) not a "food additive" or "color additive" as defined in section 201(s) or (t) of the FD&C Act as used in that food, or (b) if it is a food additive or a color additive as so defined in those sections, its use conforms with regulations established in accordance with section 409 or 706 of the act.

Thus, the "safe and suitable" policy is applicable only to optional, functional indgredients in standarized foods that are (1) approved food or color additives, or (2) prior sanctioned, or (3) generally recognized as safe—a category known by the acronym "GRAS." These ingredients are generally, but not always, used in small quantities. At the heart of this FDA policy is the principle that manufacturer choice among safe and suitable ingredients in a food with a stardard of identity is not appropriate if the use of the safe and suitable ingredients alters the basic characteristics of the food, whether by degrading its taste, smell, appearance, or nutritional characteristics. The food's label, further, must specifically identify any "safe and suitable" ingredient it contains—except for colors, spices, and flavors, which may be declared generally.

In marked contrast to other food labeling issues, food standards and the related matter of "safe and suitable" ingredients generated a response from only 4 percent of all commenters. They generally sought more information on the ingredients involved. Of 217 comments on the issue of food standards, 41 percent wanted standards eliminated, 23 percent wanted standards applied to more foods, and 9 percent wanted food standards applied to fewer foods. Only 213 comments focused on the flexible uses of safe and suitable ingredients in standardized foods: 62 percent favored making the present "safe and suitable" policy less flexible, 10 percent wanted it more flexible, and 29 percent thought it sufficiently flexible.

The limited amount of public reaction on this issue suggests either that the "safe and suitable" policy concerns consumers relatively little or that their understanding of it is insufficient to permit meaningful comment. Such confusion as exists, the agencies believe, may well be partly due to their failure to explain the concept adequately. They therefore believe it is necessary (1) to explain the policy more accurately and (2) to propose certain modifications to clarify it and to ensure it is applied where appropriate.

Essentially, a standard of identity, according to FDA's current "safe and suitable" policy, only generally identifies certain categories of functional ingredients a food may contain, and it leaves the selection of the specific functional ingredients to the manufacturer. The types of food ingredients in this category would be optional in a standardized food and serve only a functional purpose; the particular functional safe and suitable ingredient a manufacturer chooses must be specifically identified on the food's label (unless, once again, it is a color, spice, or flavor).

One of the major effects of FDA's "safe and suitable" policy, some have alleged , is to shift the burden for establishing the safety of an ingredient from the manufacturer to FDA. Some confusion may result from the name itself, for "safe and suitable" may suggest to some people that FDA exercises only limited control over ingredients in a standardized food. In reality such ingredients generally have undergone the same form of approval, before they reach the market, as ingredients used in nonstandarized foods—prior approval, GRAS, or food and color additive review. The name "safe and suitable" may also imply that FDA's review of a food standard includes an explicit safety review of each ingredient, when in fact questions of ingredients safety are resolved in accordance with other sections of the FD&C Act for ingredients in both standardized and nonstandardized foods. The food and color additive regulations, for example, specify the functions for which these substances may be used and limit the amounts that can be used. Because of the misunderstanding surrounding the name "safe and suitable" the agencies are considering alternative terminology, such as "permitted functional ingredient," which would more accurately describe the policy.

USDA regulations and standards identify acceptable food additives somewhat differently, according to (1) class of substance, (2) specific substance, (3) purpose, (4) product for intended use, and (5) quantity of use. USDA enforces a number of standards of identity or composition and through its label approval system requires minimum amounts of major ingredients in meat and poultry products. For egg products, USDA relies on the standards FDA regulations have established. USDA has, in addition, the authority to preclear labels for meat, poultry, and egg products and to review formulations to determine how food ingredients are used (21 U.S.C. 607, 21 U.S.C. 457, and 21 U.S.C. 1036). FDA does not have authority to preclear food labels (an authority some feel it should have), but assures the safety of food ingredients under other sections of the FD&C Act. Moreover, because FDA is responsible for more foods than USDA, and because of the large number of foods involved, FDA would have insufficient resources to review food labels before a food is marketed, even if it had this authority.

This approach to the approval of "safe and suitable" ingredients saves money—for FDA, for industry, and ultimately for the consumer—without any loss in the integrity of a food. It eliminates the need for lengthy and expensive administrative proceedings to amend a food standard each time a manufacturer wants to use a new or different ingredient in a standardized food. Amending a standard, for example, under the normal administrative procedures of the FD&C Act takes at least a year (and costs a minimum of $40,000); a more complex amendment may take 6 or 7 years. FDA completes the processing of about seven amendments annually. The costs to industry for petitioning to change a single standard also are high. The true cost of the amendment process becomes evident when one recognizes that FDA has issued about 275 stardards of

identity, each encompassing at least one food.

Allowing the use of optional functional ingredients permits a manufacturer of food processor to use different ingredients in response to seasonal changes, economic conditions, or the availibility of a new ingredient. The manufacturer must, of course, change the ingredient statement on the food label accordingly. The important point to remember is that this flexibility can translate into savings for consumers without reducting the quality of a food; furthermore, this policy is fairer because it allows the same flexiblity for certain functional ingredients in standardized foods that the FD&C Act permits for all ingredients in nonstandarized foods.

The agencies will *propose* the following modifications in the current policy, but before doing so, they would like to have the public's comments on the revised policy. The new policy would:

(1) Apply only to optional, functional ingredients used in quantities of less than 5 percent. For the purpose of this policy, the term "functional ingredients" would be defined as ingredients that do not alter the basic characteristics of the food.

(2) Require the declaration, on the product's label, of any ingredient that product contains (as now required for nonstandarized foods regulated by FDA and all USDA regulated foods except for colors, flavors, and spices.)

(3) Change the descriptive phrase "safe and suitable" to one, such as "permitted functional ingredient," that is less confusing and that more accurately describes this concept.

Miscellaneous Food Labeling Issues

Label Declaration of Country of Origin for Imported Foods

A small number of commenters (117) discussed whether the country of origin should be declared in the labels of imported foods. Most of them were concerned that the label on meat products does not have to list the country of origin if this product was made from imported meat combined with domestic meat, e.g., Argentine beef combined with American beef in ground beef.

Under the Tariff Act, administered by the U.S. Bureau of Customs, Department of the Treasury, an imported product entering the United States must bear the English name of the country of origin to inform the "ultimate purchasers" where the product was made. Generally, "ultimate purchaser" is defined as the last person in the country who will receive an article in the form in which it was imported. If the product is repackaged or porcessed further in the United States, the repackager or processor becomes the "ultimate purchaser," and the repackaged or converted product need not declare the country of origin. However, if the food is sold at retail in its imported form, then the product must bear the name of its country of origin.

The laws administered by USDA and FDA require that imported products meet the same standards as American-made products. FDA laws do not contain any provisions pertinent to country of origin labeling. USDA laws and regulations are consistent with the Tariff Act provision on country of origin labeling.

Problem would arise if the country of origin labeling requirement were extended to imported foods that are repackaged or further processed in the United States. Food producers generally purchase ingredients from several foreign sources and use them in a variety of products. For example, cacao beans are purchased from several countries in South America and Africa and are used in making cocoa and chocolate, which are in turn used in making a multitude of products. A country of origin requirement in such cases could be expensive, both in terms of industry's ability to comply and the agencies' ability to monitor. Furthermore, it could cause label space problems. The agencies do not believe that the costs to industry, which ultimately would be passed along to consumers, as well as the enforcement costs for the Federal government would result in any substantial consumer benefits.

Proposed Action: USDA and FDA will continue the present policy requiring that the country of origin be declared on the label for foods imported in packages and sold in such packages at retail. The policy will be reexamined in the future if necessary.

Label Declaration of Name and Address of Manufacturer, Packer, or Distributor

The current laws administered by FDA and USDA require that food labels bear the name of the manufacturer, packer, or distributor. In addition, USDA requires meat, poultry, and egg products to bear an inspection legend and a number identifying the establishment or plant that prepared the product. A few commenters (40) said they wanted labels to list the food's manufacturer or packer in those cases where the label bears only the distributor's name. Their reason for wanting this information was based primarily on their right to know, although a few wanted it so they could write directly to a manufacturer for further information.

The required listing of manufacturer or packer would have a major impact on firms such as chain supermarkets that buy a product from a manufacturer and then sell it under their own label. Many of these stores purchase from different sources at different times depending upon competitive bids. They would incur the additional costs of maintaining a large label stock, revising labels, and segregating products during labeling. The agencies have concluded that the potential costs of such a requirement to food labelers would outweigh the projected benefits to consumers.

Proposed Action: USDA and FDA will continue the present policy of requiring declaration of the name and address of the manufacturer, packer, or distributor. The policy will be reexamined in the future as found necessary.

Natural and Organic Labeling Claims

At the present time, FDA and USDA take differing approaches to the use of "natural" and "organic" claims on food labels. FDA does not attempt to restrict such claims because it believes that the development and enforcement of standards in this area would be difficult and might unjustifably imply to consumers that food labeled "organic" or "natural" are inherently superior to other foods in nutrient content and safety. USDA, on the other hand, does attempt to control the use of "natural" and "organic" claims on meat, poultry and egg products because it believes such claims are generally misleading. USDA enforces this approach through its prior lable review program.

In late 1974, FTC proposed a trade regulation rule to eliminate the possibly unfair and deceptive use of a number of different types of claims in food advertising, including claims that foods are "natural" or "organic." In proposing this rule, the Commission stated its concern about the ability of consumers to understand natural and organic claims which are used in a wide variety of confusing and conflicting contexts. The Commission called for public comment on ways to improve this situation, including comment of a staff proposal to prohibit the use of the terms "natural" and "organic" and on the possibility of setting standards to prevent the unfair and decepuve use of natural and organic advertising claims.

In late 1978, after extensive written comments and testimony by scientists, consumer and industry representatives, and others, the staff of the Division of Food and Drug Advertising recommended that the Commission promulgate a final rule. This rule would,

among other things, establish standards to prevent the unfair or deceptive use of natural and organic food claims (i.e., foods not meeting these standards could not be advertised as natural or organic) and prohibit claims that foods advertised as "natural" or "organic" are inherently superior to other foods in their nutrient content or safety.

The recommendations of the Division of Food and Drug Advertising are based on evidence that current uses of "natural" and "organic" claims are confusing and misleading to consumers and frequently violate the public's legitimate expectations about their meanings. The staff also concluded that these claims could provide useful information if unsupportable superiority claims were prohibited and if the claims met standards embodying the major elements of each concept. The basic elements in these standards are as follows:

A food may not be represented as natural or a natural food if (a) it has undergone more than minimal processing or (b) it contains any artificial or synthetic ingredient.

A food may not be represented as organic, an organic food, or as having been organically grown if (a) the soil in which it was grown was subjected to fertilizers other than organic materials or certain minerals or (b) any artificial or synthetic chemical (e.g., a pesticide or herbicide) has been directly applied in its production.

The Director of Bureau of Consumer Protection and the Commissioners have not yet decided whether or not to accept these recommendations. Final Commission deliberations are expected to take place in the near future.

Proposed action: USDA and FDA will continue their current policies for regulating "natural" and "organic" claims pending their evaluation of FTC's rulemaking efforts. They will then determine whether additional action on such labeling claims is necessary.

USDA and FDA agree with the FTC staff that because it is false and misleading to claim that foods described as natural or organic are inherently superior in nutrient content or safety, such claims should be prohibited.

Quantity of Contents Declaration

Approximately 12 percent of all the commenters addressed issues related to the declaration of quantity of contents on food labels. At least 71 percent of those focusing on how this declaration should be made favored some form of solid or liquid weight labeling. About half expressly requested the use of drained or solid weight content, particularly for canned fruits and vegetables. Almost 27 percent of the commenters wanted a product's net weight to appear on the label, either alone or in conjunction with the package's drained or fill weight. Approximately 11 percent wanted to know the amount of liquid in a product, while 6 percent wanted a product's fill weight declared on the label.

In FDA's Food Labeling Survey, 60 percent of the users of canned food products did indicate a desire for drained or fill weight labeling when asked directly if they would like to have this information. Only 3 percent mentioned wanting this information when asked what additional information they would like to have on canned food labels.

On November 7, 1975 (40 FR 52172), in response to a petition from Consumers Union, FDA published a proposal to require label declaration of the drained weight of canned fruit and vegetables. (Drained weight is the weight of the food in a can after thermal processing and does not include the weight of the packing medium.) FDA received more than 6,000 comments on this proposal, mostly from consumers who favored drained weight label declaration.

The National Food Processors Association later petitioned for an alternative to drained weight: declaration of fill weight. (Fill weight is the weight of the food in a can, exclusive of the packing medium, when placed in the can.) A study by one industry organization and a similar study conducted under contract for FDA showed that drained weight labeling would cost about 10 times more than fill weight labeling. The cost difference between drained weight and fill weight labeling is approximately $100 million versus $10 million.

On December 9, 1977 (42 FR 62282), FDA proposed that manufacturers be allowed to use fill weight or drained weight labeling under certain prescribed conditions. The comment period on FDA's proposal ended July 1, 1979. This lengthy comment period gave the canning industry two packing seasons to test its ability to comply with the proposed requirements, and gave consumers an opportunity to become familiar with the type of labeling proposed and to comment on its usefulness. FDA is now evaluating the comments, and will publish a final regulation shortly.

The USDA follows a policy that requires the net weight of canned products to reflect the solid weight only, unless the packing medium has nutritive value.

The Total Food Label

Labels have a limited amount of space on which to put a large quantity of information. Some of this information is required by law: common or usual name of the food; name and address of packer, manufacturer, or distributor; listing of ingredients for most foods; presence of artificial flavoring, coloring, or chemical preservative; and the amount of food contained in the package. Nutrition labeling is required by regulation if vitamins, minerals, or protein are added to the food or if nutrition claims are made. The nutrition label may contain up to 28 pieces of information, including the amount of vitamins, minerals, calories, protein, carbohydrate, and fat present in the food. In addition, the label may contain other information that the manufacturer wishes to put on it, such as a brand name, the price, vignettes or product photographs, serving directions, recipe suggestions, offers to send information, premium offers, product guarantees, product coupons, advertising/benefit claims, ethnic symbols, the universal product code, dating, patent numbers, and/or storage directions.

Comments

Although there were not a large number of comments on the total food label, the agencies have drawn some general impressions from the public's responses. Commenters emphasized the need to make food labels more intelligible to the average consumer. They generally recommended that labels be written clearly and concisely and that they use simplified, standardized, nontechnical language.

A number of commenters offered suggestions for improving the format of food labels: 352 commenters specifically stated that the type size on labels should be increased. In support of this request, commenters pointed out that much of the small print on labels is illegible, so individuals with sight problems, particularly the elderly, cannot read it. Commenters also said that better contrasting colors should be used to make information more readily distinguishable, that information should be placed in a uniform location on all labels, and that overcrowding or cluttering information should be eliminated. Some suggested that some information now appearing on labels could be eliminated to make room for more necessary information and to prevent "information overload" on food labels. They suggested that special recipes, cooking instructions, advertising or promotional information, special gift or coupon offers, and fanciful labeling in

general be eliminated. In fact, several commenters specifically expressed their support for the "no frills" labels or the "plain package" product, as long as the quality of the product remained unchanged.

In contrast, other commenters remarked that they would like to have much of the descriptive information remain on or be added to food labels. The items requested were product identification, cooking instructions, unit price, recipes, pictures, and religious identification.

A number of consumers also said they wanted symbols to indicate the presence of certain ingredients, e.g., foods high in sugar, foods high in salt/sodium, or foods containing artificial colors or flavors. The agencies will explore further the practicality and desirability of using symbols for various purposes.

Some commenters advised the agencies to proceed cautiously before substantively overhauling existing regulations. They pointed out that the food label could not reasonably be expected to provide all the information requested by consumers and that any changes should be implemented only after the agencies have carefully evaluated the potential benefits relative to possibly increased costs. Some stressed the need for stability in food labeling, emphasizing that consumers would learn to utilize the information only if there are relatively few changes so they can become familiar with them. Moreover, some commenters emphasized that label changes should fulfill clearly defined objectives and supported development of a total food labeling strategy rather than implementing a piecemeal series of changes.

Label Format Research

The public hearings, written comments, and consumer research have focused on "what" information should be communicated to consumers. The next question is "how" to communicate this information. To answer that question, FDA will conduct a research program, supported by USDA, to help decide what labeling format is the most comprehensible to consumers. This program will employ professional communications experts in the private sector to design alternative labeling formats that will be subjected to consumer testing. Designing alternative labeling formats has begun, and the actual consumer testing will begin this fall and extend into 1980. Nutrition labeling and ingredient labeling will be the primary focal point for this research.

Nutrition labeling research will center on developing a number of graphic or pictorial formats, including bar charts, pie charts, etc., that can be compared with the current systems. Ingredient labeling research will include the design and testing of formats for declaring ingredients by percentage and weight, as well as various organizational schemes aimed at communicating more intelligibly what the food ingredients are, e.g., listing names of the characterizing ingredients.

After the formats for the nutrition and ingredient labels are designed, alternative formats for the total food label will be designed. These will include all the information required by law, plus that information that currently is discretionary (e.g., vignettes, cooking directions, premium offers, etc.) in an effort to determine the best overall format.

Other areas of food labeling research probably will include possibilities for "flagging" ingredient changes on food labels and the use of symbols and summary statements to assist in identifying foods containing high or low quantities of sugars, sodium, cholesterol, or calories.

The various formats decribed above will be tested on different types of consumers, including those with limited education, the elderly, and the poor. This is an opportunity for industry to demonstrate its cooperation in improving food labels. The agencies invite industry to participate in the development of an improved nutrition labeling format. They also encourage and will consider their well-conceived studies by industry on other parts of the food label, such as quantitative ingredient labeling, type size, better contrasting colors, and labels that are simpler and easier to read. Like the agencies' suggestion for nutrition labeling format, a joint cooperative study program would be most effective and efficient and in the consumer's best interest.

Digest

Below are tables that summarize how the agencies propose to proceed in addressing the food labeling issues.

Issue	Legislation	New or revised regulations	Consumer education/ industry guidance	Action deferred pending research, study or future reexamination
I. Ingredient Labeling				
A. Labeling of Mandatory Ingredients in Standardized Foods.	FDA proposes to seek or support legislation to amend the FD&C Act to require declaration of mandatory ingredients in standardized foods. (The regulations issued under statutes administered by USDA already so provide.).	FDA intends to expedite amendment of the remaining food standards of identity to require declaration of all optional ingredients including the form of the mandatory ingredients where more than one form is available for use.	.....	
B. Label Declaration of Colors, Spices, and Flavors.	FDA proposes to seek or support legislation to require that all colors and spices be declared on food labels by their specific name.	.....	.....	
	USDA believes it has authority to require the declaration of spices and colors by their specific name but will support legislation to provide more explicit authority for both agencies.	.....	.....	
	FDA proposes to seek or support legislation to eliminate the exemption under which the labels of butter, cheese, and ice cream are not required to declare the presence of an artificial color.	.....	.....	
	FDA proposes to seek or support legislation to provide it with discretionary authority to require label declaration of a flavor when it is considered necessary for providing important health information, e.g., it has a potential for causing an allergic reaction.	.....	.....	

Issue	Legislation	New or revised regulations	Consumer education/ industry guidance	Action deferred pending research, study or future reexamination
	USDA believes it has authority to require declaration of flavors, but will support legislation to provide more explicit authority for both agencies.	.....	.....	
C. Quantitative Ingredient Labeling.	FDA proposes to seek or support legislation explicitly giving it authority to require quantitative ingredient labeling as part of the ingredient statement and to seek or support legislation giving FDA records and reports authority—access to a company's formulae, quality control records and related records in order to ensure that such expanded quantitative ingredient labeling is truthful and accurate.	FDA intends to expand the use of percentage of valuable and characterizing ingredients according to its regulations on common or usual names for nonstandardized foods. USDA intends to issue regulations that would provide for more quantitative ingredient labeling.	FDA intends to publish guidelines for voluntary quantitative ingredient labeling as part of the ingredient statement.	
	USDA currently has limited authority to require quantitative ingredient labeling in some cases, and it shares FDA's belief that legislation establishing the authority of the two agencies generally to require such labeling is desirable.	.....	.....	
D. Ingredient Order of Predominance Statement.	.....	FDA and USDA intend to amend the regulations to require that food labels bear a statement to the effect that the ingredients are listed in descending order of predominance.	.....	
E. Use of "and/or" Labeling to Declare the Source of Fats and Oils.	.....	FDA and USDA intend to amend the regulations to require that food containing 10 percent or more total fat on a dry weight basis declare the specific source of the fat or oil. Food containing less than 10 percent fat on a dry weight basis may use the "and/or" approach, e.g., vegetable oil (may contain cottonseed oil, soybean oil, and/or palm oil)".	.....	
F. Functionality and Names of Ingredients.	.....	.....	.....	The agencies intend to explore the concept of an "ingredient dictionary," a reference volume that would describe ingredient functions, and how such a publication should be compiled, distributed and funded.
G. Labeling of Fresh Fruits and Vegetables.	.....	.....	FDA will continue to encourage compliance with the Federal law which requires that the presence of colors, preservatives, and waxing be declared in labeling (e.g., placards and leaflets) at the point of sale of fresh fruits and vegetables.	The labeling of fresh fruits and vegetables as to pesticides and fertilizers will be reexamined in the future as necessary.
H. Ingredient Labeling for Restaurant-Served Foods.	.....	.....	.....	The agencies will not initiate any action at this time to require that ingredients in restaurant-served foods be declared. This issue will be reexamined in the future as necessary.
I. Incidental/Secondary Ingredients.	.....	.....	.....	The current policy of not requiring the declaration of incidental/secondary ingredients will be continued. This issue will be reexamined in the future as necessary.
II. Nutrition Labeling				
A. Mandatory, Discretionary, or Voluntary Nutrition Labeling.	FDA and USDA propose to seek or support legislation to clarify their authority to require nutrition labeling on all foods. (The agencies are establishing a task group to develop criteria for determining which foods should bear nutrition labeling).	USDA intends to propose regulations that would require nutrition labeling where claims are made for a product or where certain nutrients have been added to the product.	.....	
B. Nutrition Labeling Format ...	.....	.....	The agencies encourage industry to experiment voluntarily, under controlled conditions and in collaboration with FDA and USDA, with graphics and other formats that are consistent with the current quantitative system.	FDA will conduct research, with support from USDA, to determine which format is most useful and convenient for consumers: the present nutrition labeling system will be retained pending research results and conclusions about what (if any) changes in labeling format are appropriate. (An interagency task group will be established to coordinate the research efforts with industry experimentation.)
C. Mandatory Information for Nutrition Labeling.	.....	USDA intends to propose regulations that would require nutrition labeling providing information on calories, protein, carbohydrates, fat, sugars, cholesterol, sodium, and other nutrients of public health concern insofar as permitted by current authority.	.....	FDA and USDA will maintain their current policies on declaring nutrients. Comments are requested on aspects of the present policies.

Issue	Legislation	New or revised regulations	Consumer education/ industry guidance	Action deferred pending research, study or future reexamination
D. Composite Data Base for Use in Nutrition Labeling.			FDA and USDA are issuing a statement of current policy concerning use of suitable nutrient data bases in nutrition labeling.	The agencies propose to maintain the current policy that products be labeled according to composition and that it is the manufacturer's responsibility to assure the validity of nutrient content expressed on food labels. The agencies encourage industry to develop suitable data bases for use in nutrition labeling.
E. Serving Sizes		FDA intends to publish final regulations for some beverage products, cereals, and meal replacements.		
		FDA and USDA intend to propose regulations to establish serving sizes for additional product classes and/or types of foods.		
F. Sugars Labeling	FDA and USDA propose to seek or support legislation to provide them with explicit, discretionary authority to require quantitative labeling of sugars on the basis of public health significance.	FDA intends to amend the nutrition labeling regulations to require quantitative declaration of total sugars as part of nutrition labeling when contained above a specified level.	The agencies propose conducting an educational program to promote better understanding of declaration of sugars.	
		USDA intends to propose regulations to require the declaration of sugars content as part of nutrition labeling. (The agencies have established a task group to develop criteria for determining the threshold level for this declaration).		
G. Sodium and Potassium Labeling.	FDA proposes to seek or support legislation to provide it with explicit discretionary authority to require quantitative labeling of sodium and potassium on the basis of public health significance.	FDA intends to amend the nutrition labeling regulations to require sodium and potassium labeling.		
	USDA believes it has such authority, but will support legislation to provide more explicit authority for both agencies.	USDA intends to propose regulations to require sodium labeling as part of nutrition labeling. USDA will consider the inclusion of potassium labeling.		
		FDA and USDA intend to propose regulations to define "low sodium." Consideration will be given to defining "reduced sodium" foods and standardizing the claims appropriate for food containing no added sodium.		
H. Fatty Acid and Cholesterol Labeling.	FDA proposes to seek or support legislation to provide it with explicit discretionary authority to require cholesterol and fatty acid labeling on the basis of significance to public health.	FDA will continue to require cholesterol or fatty acid content to be included on nutrition labeling when cholesterol or fatty acid claims are made.		
	USDA believes it has such authority but will support legislation to provide more explicit authority for both agencies.	FDA intends to amend the fatty acid/cholesterol regulation to require fatty acid labeling whenever cholesterol is declared and vice versa.		
		FDA intends to amend the fatty acid/cholesterol regulation to eliminate the physician advice statement.		
		FDA intends to propose regulations to define the terms "low cholesterol," "reduced cholesterol," and "cholesterol free." FDA will consider proposing regulations to govern claims about fatty acid content.		
		USDA intends to propose regulations to require cholesterol labeling as part of nutrition labeling.		
I. Fiber Labeling				FDA and USDA will not require dietary fiber labeling as part of nutrition labeling until dietary fiber can be better defined, methods of analyses can be developed, and its significance in the diet determined.
J. Disease-Related Claims on Food Labels.		FDA intends to propose regulations covering "medical foods," that is, foods which are intended for use under medical supervision; the regulations will permit the use of appropriate medical claims about such foods.		FDA and USDA will maintain the present policy of not allowing disease-related claims to appear on the labeling of conventional food products. This policy will be reexamined in the future if found necessary.

Issue	Legislation	New or revised regulations	Consumer education/ industry guidance	Action deferred pending research, study or future reexamination
III. Open Date Labeling	FDA proposes to seek or support legislation to provide it with explicit discretionary authority to require open dating on classes of foods as is found necessary.	USDA intends to propose regulations that would require open dating on perishable and semi-perishable foods to the extent that authority permits.		
	USDA believes it now has such authority, but will support legislation to provide more explicit authority for both agencies.			
IV. Imitation/Substitute Food Labeling.				The agencies have not taken a tentative position pending consideration of further comments on the policy direction they should follow.
V. Food Fortification	FDA and USDA propose to seek or support legislation aimed at providing explicit discretionary authority to control fortification of food when deemed of public health significance.		FDA will publish "General Principles for the Addition of Nutrients to Foods," and encourage manufacturers to adhere to these guidelines.	
VI. Safe and Suitable Ingredients and Food Standards.		FDA intends to revise its "safe and suitable" ingredients policy as follows in order to clarify the policy and ensure that it is only applied where appropriate: this policy is applicable only to optional, functional ingredients used in quantities of less than 5 percent; the descriptive phrase "safe and suitable" will be changed to one that is less confusing and more accurately describes the concept, e.g., "permitted functional ingredient".		
VII. Miscellaneous				
A. Label Declaration of Country of Origin for Imported Foods.				USDA and FDA propose to continue the present policy that the country of origin be declared on the label only for those foods imported and sold in consumer packages as such. This policy will be reexamined in the future as necessary.
B. Label Declaration of Name and Address of Manufacturer, Packer, and/or Distributor.				USDA and FDA propose to continue the present policy of requiring the declaration of the name and address of the manufacturer, packer, or distributor. This policy will be reexamined in the future as found necessary.
C. Natural and Organic Labeling Claims.				USDA and FDA propose to continue their respective policies for regulating "natural" and "organic," claims pending their evaluation of FTC's rulemaking efforts on advertising making such claims.
D. Quantity of Contents Declaration.		FDA will publish a final regulation.		

Request for Economic Information

Before taking specific action to change the current legal requirements for food labeling, the agencies want to allow further public comment on these tentative proposals. Although in some instances making these changes may require additional explicit legislation, FDA and USDA will act promptly, after fully reviewing the comments, to do what they can under their current legal authority and mandate to implement their proposals.

Detailed analysis of the economic impact of these initiatives is warranted before the agencies select specific proposals and courses of action. The agencies are therefore asking the public for information, data, or analyses to help them predict and quantify the economic impact of their proposals on industry and consumers. This information may relate to product categories, package types, characteristics of firms or establishments, manufacturing and distribution practices, etc. The agencies are particularly interested in the cost implications of the following initiatives:

Ingredient Labeling

1. Expanded label identification of ingredients in standardized foods.

2. Expanded quantitative label identification of valuable and characterizing ingredients of foods.

3. Restricted use of "and/or" labeling for fats and oils.

4. Compilation and distribution of a standard ingredient handbook or dictionary explaining the functions of ingredients used in food products.

Nutrition Labeling

1. Mandatory inclusion of sodium and potassium content as part of nutrition labeling.

2. Mandatory inclusion of sugars content as part of nutrition labeling.

3. Mandatory fatty acid labeling when cholesterol content is declared, and mandatory cholesterol declaration when fatty acid content is declared.

4. Other revisions in the mandatory list of nutrients.

5. Mandatory nutrition labeling, regardless of a food's specific content.

6. Optional use of composite data bases for nutrition labeling.

A number of the preceding initiatives may have common economic impacts. But some are alternative impacts, and in those cases the agencies will be interested in trade-off analyses. Specifically, they would like to know whether various actions might lead to:

a. More frequent label changes (possibly requiring multiple label inventories and switching, one-time or continuing cost increments for printing plates, or other costly responses);

b. Reduced flexibility in selection or substitution of ingredients;

c. Increased control of ingredient quantity and/or quality;

d. Increased control of nutrient quantity or stability; or

e. Increased testing for nutrient content.

Data on these (and any other) cost impacts will be most meaningful if they assess individual initiatives. In at least two areas, however, more general data will be useful if they are reliable and detailed:

1. Direct costs of a label change and how these may vary with type of packaging, extent of redesign, number of different sizes or types of package per product, in-house versus outside labeling, lead time available, and so on. Information on this point should specify the steps entailed in changing the label, and the cost of each.

2. Costs of testing for nutrient content and how these may vary with the number and identity of the nutrients to be tested, sample size and number of samples, nature of the product, frequency or regularity of testing, degree of precision or reliability required, and the like.

To aid the presentation of information and data about, an analyses of, each initiative's economic impact, the agencies have outlined their preliminary views on potential issues and questions of cost impact—and the public is invited to comment on these views as well:

1. *Identification of mandatory ingredients in standardized foods*—This initiative requires legislation to amend the FD&C Act to require that mandatory ingredients in standarized foods be declared on product labels. It also simply affirms FDA's intention to complete the continuing effort to amend food standards to require the identification of as many ingredients as possible (1) by making specific forms and varieties of mandatory ingredients "optional" (only "optional" ingredients in standardized foods must be declared) and (2) by requiring that all optional ingredients be declared. This effort will make certain standardized foods conform with the great majority of foods, whose labels already identify all ingredients. This initiative affects a limited number of products because it involves only standardized foods, because some standards have already been amended, and because some manufacturers now voluntarily declare mandatory ingredients. Moreover, because manufacturers already have the requisite information from their own recipes, the cost impact appears to be limited to a one-time label change.

2. *Quantitative ingredient labeling*—Expanded quantitative listing of valuable and characterizing ingredients would require food labels to declare percentage amounts of ingredients that have a material bearing on consumers' acceptance of the product or on its price. Actual quantities may exceed declared values. Although the direct cost will be that of a label change based on the receipe, other costs may be incurred, such as those involving (1) stricter adherence to good manufacturing practices (to maintain a product's uniformity) and (2) keeping the proportions of ingredients more constant.

3. *Restricted use of "and/or" labeling for fats and oils*—Limitation of "and/or" labeling to products in which fats constitute less than 10 percent of the dry weight appears to affect relatively few product categories in the jurisdiction of FDA and USDA; the most obvious are cookies and crackers, blended flour preparations such as cake mixes, canned seafoods, and soups. The agencies are seeking information that will identify the full range of products affected by a 10 percent cutoff level, a 5 percent level, and a 2 percent level—along with the nature of any cost impacts these levels produce. The agencies also are asking for any cost impact information on the effect of combining a labeling requirement for foods with 2 grams of fat per serving with any of these percentage cutoff levels. FDA and USDA will consider these economic data in conjunction with comments received on the nutritional and health considerations as they evaluate the possibility of setting an appropriate cutoff level.

The agencies are assuming that the economic advantage of "and/or" labeling is that it enables firms to switch fats and oils, or their proportions in the product, in response to their price or availability, without necessitating label changes. It would be instructive to have information on how frequently food producers actually make such substitutions and how frequently label changes would be required in the absence of the "and/or" option.

The agencies also need evidence about the kind and degree of cost impact that could result from industry's response to eliminating the "and/or" option. More frequent label changes and the maintenance of multiple label inventories would represent an incremental cost; reduce flexibility of substitution among fats and oils, possibly expressed in higher average costs, more variable and unpredictable costs for total fats and oils used; increased lot purchase sizes and storage costs; or in a combination of these.

4. *Functionality of ingredients*—An ingredient "dictionary" appears to be an efficient means of explaining to interested consumers the function of ingredients used in food products. This could be a voluntary enterprise of the food industry or a project of the government, using—as necessary—data supplied by industry. The resulting publication could be widely distributed (available at no or little cost at most food stores, for example) or somewhat less readily available by offering it for sale, or even free, as a government or private document. (Free distribution to all public libraries is also an option here.) The feasibility of such a project would seem to depend on industry's willingness to cooperate, the number of substances requiring coverage, the frequency of revision and updating, and the expense. The expense would in turn depend on the costs of compiling the data, printing the dictionary, and distributing it—and they would vary with the size of the publication and the scale of its distribution. Because compiling an ingredient dictionary provides an alternative to listing on food labels the functions of ingredients, appraisal of the comparative merits and costs of the two approaches particularly interests the agencies.

5. *Increasing information on sodium, potassium, sugars, fatty acids, and cholesterol content*—The agencies are proposing to require mandatory declaration of sodium and potassium content, and the amount of sugars a food contains, as part of nutrition labeling. In addition, FDA will amend its regulations to require fatty acid labeling whenever cholesterol is declared, and to require labeling of cholesterol content when the food label declares fatty acids. USDA intends to propose nutrition labeling that would include information on the sodium, sugars, and cholesterol foods contain. Because this labeling will require declaring the total content of these substances, the initial establishment of reliable values would probably entail incremental costs. In products to which the manufacturer adds all or most of the substances directly, such testing costs might be nil

or virtually so. In products with food ingredients containing significant and variable amounts of these substances, more frequent testing could be necessary to obtain accurate information. The agencies therefore request evidence on the identities of food products that will require frequent testing; they are particularly interested in products that are believed to present unusual testing requirements because of wide natural variation in the substances these foods contain.

The agencies are seeking comments on the allowable range of variation in a food label's declaration of these substances. Selecting a reasonable tolerance level can reduce costs of testing to ensure compliance; frequency of reformulation could also affect cost, because it might require multiple testing and different labels. Therefore, manufacturers could be faced with a trade-off between the cost of reformulating foods (and keeping multiple label inventories) and the cost of reduced flexibility in altering ingredients that change the nutrient composition of the food.

The agencies also need (a) data on the incremental unit costs of preparing and testing samples for each of these additional substances, both individually and as part of a comprehensive nutrient assay, and (b) estimates of absolute and percentage increases in total testing expenses, for various products, that might be generated by adding these substances to the list of nutrients. They welcome information about any related costs, such as increased requirements for quality control or stabilization of content.

8. *Other revisions in mandatory list of nutrients*—As they assess possibilities for a specific proposal to revise the mandatory list of nutrients, the agencies wish to consider cost implications, as well as the utility to consumers, of alternative requirements. They request three kinds of cost data. First, assuming that any additions to the list would most likely be certain micronutrients such as folic acid, cooper, and zinc, evidence is needed on the extent of additional testing that might be required in various products or product groups, the incremental costs of such testing, or any unusual problems that might arise. A second possibility is reducing the mandatory list to serving size, servings per container, calories, protein, fat, carbohydrates, sugars, sodium, potassium and cholesterol/fatty acids. Added vitamins or minerals, or those about which claims are made, would also require a statement of content, but declaring all others would be optional. The agencies seek comments and estimates on how, and to what extent, such a change might reduce costs and on any problems that might arise from reducing the uniformity of information. A third possibility might exempt mandatory nutrients present at less than 2 percent of the U.S. RDA per serving from disclosure on the label. The agencies also want information on the nature and size of any cost savings this exemption offers.

7. *Composite data bases*—Giving formal recognition to adequately supported data bases providing the nutrient content of various foods may reduce the cost, and thereby increase the attractiveness, of nutrition labeling for firms that do not now consider it economcially feasible. Ample reasons suggest why a manufacturer using such data bases to support label statements could not be relieved of any further responsibility for the reliability of those statements; they include greater than expected degradation of labile nutrients due to inadequate attention to good handling, storage, and manufacturing practices. Nevertheless, for many foods a well-researched data base could be used with high reliability in conjunction with good manufacturing practices. FDA and USDA would like to encourage the development and use of such data bases where they offer significant cost savings. They are therefore seeking evidence and estimates on the costs of developing scientifically and statistically sound data bases, the identity of the foods and food products that lend themselves to this approach, and the economic advantages such data bases might (or might not) offer over existing approaches to the statement of nutrient content—preferably using specific product examples. The degree of interest food companies, trade associations, and other industry organizations express in such opportunities is, of course, highly relevant to the ultimate decision about their use.

Costs of establishing data bases depend on the amount and reliability of available information, the variability of nutrients naturally occurring in agricultural produce, and the stability of nutrients during processing and storage. The cost of developing data bases could be reduced, for example, by pooling resources within a segment of the food industry to centralize the research and data collection. The sizes of firms and the resources they have will also affect the development of data bases. The agencies are therefore asking that comments address the costs and feasibility of developing industry data bases.

Request for Comments/Notice of Public Hearing

The agencies are providing a 90-day comment period and will hold a public hearing to gather views on their tentative positions and the issues discussed here. Last year's five public hearings and written submissions produce information on what the public wants in the way of improved food labeling; the additional opportunity for comment will give the public a chance to provide views on how the agencies should proceed on the basis of this information. Additional information submitted at this stage is very important, because the decisions it will help shape will establish food labeling policy for the foreseeable future. The agencies therefore welcome comments on their tentative proposals to revise food labels, including their feasibility, their cost and their necessity.

The 1978 food labeling hearings were designed primarily to gather the views of unassociated individuals. At that time, the agencies encouraged others to submit their comments in writing. Having had the opportunity to review and analyze the information thus gathered, the agencies have agreed that an additional public hearing will provide organized consumer groups, state associations, industry, and trade associations—as well as individuals—with an opportunity to testify.

The public hearing will be held before representatives of FDA, USDA, and FTC on March 4 and 5, 1980, beginning both days at 9:30 a.m., in the main auditorium, Department of Commerce, Fourteenth St. and Constitution Ave. NW., Washington, D.C. It will be conducted in accordance with Title 21 of the Code of Federal Regulations, Part 15—Public Hearings Before the Commissioner. For scheduling purposes, we ask those who want to give a presentation to let us know, no later than February 22, 1980, by writing to:

Mr. Gary Dykstra, Regulatory Operations Staff (HFC–22), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3470.

Written comments should be submitted to the Hearing Clerk, Food and Drug Administration (HFA–305), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857 by March 20, 1980.

Written submissions will also be accepted at the hearing from participants who want additional information included in the record. The submissions should be identified with

the docket number found in the brackets in the heading of this document. These submissions may be seen in the office of the Hearing Clerk, Food and Drug Administration, from 9 a.m. to 4 p.m., Monday through Friday.

Following evaluation of these comments, FDA and USDA will begin to implement food labeling revisions in accordance with their respective authorities and procedures. Those issues that can be resolved through new or revised regulations will be handled by the notice and comment rulemaking process: publication in the **Federal Register** of a proposal for comment, review of comments, and issuance of a final regulation. Any requests for legislation will be handled through each agency's normal channels; the agencies will coordinate all actions to ensure consistency.

Dated: December 8, 1979.

Jere E. Goyan,

Commissioner of Food and Drugs.

Dated: December 10, 1979.

Carol Tucker Foreman,

Assistant Secretary for Food and Consumer Service, USDA.

Dated: December 17, 1979.

Albert H. Kramer,

Director, Bureau of Consumer Protection, FTC.

[FR Doc. 79-39185 Filed 12-19-79; 10:00 am]

BILLING CODE 4110-03-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Ch. I

DEPARTMENT OF AGRICULTURE

Food Safety and Quality Service

7 CFR Ch. XXVIII; 9 CFR CH. III

FEDERAL TRADE COMMISSION

Bureau of Consumer Protection

16 CFR Ch. I

[Docket No. 78N-0158]

Food Labeling; Tenative Positions of Agencies; Extension of Comment Period

AGENCY: Food and Drug Administration, Food Safety and Quality Service, and FTC's Bureau of Consumer Protection.

ACTION: Extension of comment period.

SUMMARY: This documents extends the comment period for submitting comments on the advance notice of proposed rulemaking stating the agencies' tentative positions on a variety of food labeling issues. All three agencies have agreed to this extension, which is based upon requests received from trade associations.

DATE: Written comments by April 21, 1980.

ADDRESSES: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gary Dykstra, Regulatory Operations Staff (HFC-22), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3470.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 21, 1979 (44 FR 75990), the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the staff of the Federal Trade Commission's Bureau of Consumer Protection (FTC) announced their tentative positions on a variety of food labeling issues. The positions are the result of the agencies' analysis and evaluation of written and oral comments received in response to a notice published in the Federal Register on June 9, 1978 (43 FR 25296), requesting the public's views on several food labeling issues. The notice was intended to prompt further comment from the public about the agencies' tentative positions and other food labeling issues on which the agencies have not yet reached tentative positions. The notice announced a public hearing to be held on March 4 and 5, 1980 and invited the submission of written comments by March 20, 1980.

On January 25, 1980, a group of 23 food trade associations submitted a joint request (on file with the Hearing Clerk, Food and Drug Administration) that the public hearing be postponed to at least May 1, 1980, and that the period for submitting written comments be extended to July 1, 1980. In their request, the trade associations asserted, among other things, that if the affected segments of the food industry are to supply meaningful factual data on the complicated, interrelated labeling and economic issues involved, the timing requirements with respect to the public hearing and submission of written comments are impossible of achievement and unreasonable.

The December 21, 1979, notice provides additional advance notice of the agencies' intent to modify food labeling requirements and additional opportunity for public participation early in the rulemaking process before any changes in the food labeling regulations are actually proposed. This opportunity is in addition to, not in lieu of, the ample opportunities that the public will have later to participate fully, in the agencies' rulemaking proceedings when new or modified food labeling regulations are proposed. Therefore, the agencies have concluded that the lengthy delays requested by the trade associations are not warranted.

The agencies have further concluded, however, that because of any disruption in beginning to prepare responses which they have caused by publishing the food labeling document shortly before Christmas, an extension of the period for submitting written comments is in order. Accordingly, the period for submitting written comments is extended to April 21, 1980. Comments may be seen in the office of the Hearing Clerk, Food and Drug Administration, from 9 a.m. to 4 p.m., Monday through Friday.

Dated: February 12, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

Dated: February 13, 1980.

Carol Tucker Foreman,

Assistant Secretary for Food and Consumer Services, USDA.

Dated: February 13, 1980.

Albert Kramer,

Director, Bureau of Consumer Protection, FTC.

[FR Doc. 80-5292 Filed 2-15-80; 8:45 am]

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Dr. NOVITCH. That document announced a public hearing on these positions and that was held just a few days ago, March 4 and 5, and called for a period of public comment that expires on April 21.

We believe that our proposals for revising current law reflect the concerns expressed by consumers, and we are also happy to find them consistent with the provisions of S. 1652.

For example, the bill would require the listing of all ingredients, including colors and spices, in descending order of predominance by weight, with the exception that flavors could be designated as artificial or natural with specific names required when necessary to provide health information to consumers; and ingredients that are present in amounts of 5 percent or less by weight would not have to be declared in order of predominance.

At the hearings and in comments, declaration of ingredients generated more public interest than any other labeling issue.

Consumers clearly want to know what is in their food and we wholeheartedly support these ingredient listing requirements.

While S. 1652's exemption of ingredients comprising 5 percent or less of a food from the requirement that they be declared in the order of predominance may be appropriate in most cases, there are some situations in which this exemption of ingredient declaration may be inappropriate.

I might cite examples such as when consumers are particularly concerned, about the amount of such as salt in their food, or when a lot of ingredients, may be present in small amounts.

We also support the requirement in S. 1652 that foods bear a statement that all ingredients are listed in the order of declining predominance.

S. 1652 would require nutrition labeling on essentially all foods. Because our current authority to require nutrition labeling on all foods has not been clearly defined, we support this provision; but at present the bill appears to exempt foods from this kind of labeling only by exclusion, which is a difficult process for us. That is, all food would be required to bear nutrition labeling, unless a specific finding was made that nutrition labeling was not necessary.

We recommend instead, clarifying the bill so that it gives the Secretary discretionary authority to determine which foods should be so labeled and to establish appropriate priorities.

We also recommend that the bill give clear discretionary authority to the Secretary to require sodium and cholesterol labeling for foods bearing nutrition labeling when such declaration is deemed to be of public health significance.

S. 1652 would require labeling that sets forth the total number of calories per serving, as well as the quantities of fats, proteins and carbohydrates per serving in caloric terms.

We support that provision, but we do not believe that the labeling of macronutrients should be required in terms of caloric content until the experiments, authorized under section 5 of the bill, are completed and we better understand the value of that particular approach.

S. 1652 mandates the use of nutrition data bases to indicate representative nutrient values where their use is feasible and appropriate.

We support the discretionary authority in this provision. We believe that the development of accurate data bases will facilitate more widespread nutrition labeling, particularly by smaller food processors.

I do not think the economic benefits of adopting a nutrition data base approach can be overlooked nor should be overlooked.

S. 1652 would require States to adhere to Federal statutes in establishing or continuing nutrition and ingredient labeling, and it provides FDA authority to exempt a State or local initiative, one, if doing so will enhance the public's use and understanding of food labeling; and, two, if the exemption does not impose an undue burden on interstate commerce.

We concur with both the provision and its exemption, because they offer an opportunity for local experimentation in labeling.

On the other hand, we believe the demonstration and evaluation and consumer education programs, at least as required in S. 1652, are not necessary. Current law already gives the Secretary such authority.

We strongly urge that the bill be amended to include authority for FDA to have access to manufacturers' records and reports.

This would certainly help assure that nutrition labeling and ingredient labeling, including quantitative ingredient declarations, are both truthful and accurate.

Laboratory analyses of finished food products cannot always provide this information and, furthermore, such analyses are often extremely time consuming and expensive.

So this, too, could be a cost-saving measure.

The more practical approach to monitoring nutrient and ingredient content is to supplement factory inspections with a review of records related to production.

Mr. Chairman, our actions to change current law and our strong support of S. 1652 stem from a regulatory philosophy that emphasizes the importance of improving food labeling to help people make better dietary choices; the need to assure that food labeling requirements keep pace with advances in food processing and technology; the desirability of food labeling formats that are consistent from one food or one class of food to another; the importance of labels that provide usable information about food, especially if that information significantly affects the quality of food, its acceptability to consumers, its cost or the public health; the voluntary role of industry in testing nutrition and ingredient and other labeling information.

In summary, Mr. Chairman, we concur with the objectives of S. 1652 and with the modifications outlined above, we support its provision.

We are convinced that it will do much to assure that the consumer has appropriate labeling information in choosing foods that are the best buy, not only economically, but more importantly, for their health benefits.

That concludes my testimony, Mr. Chairman. My colleagues and I would be most willing to answer questions on these or any other topics.

Senator RIEGLE. One of the key issues concerning the legislation is whether nutrition labeling should be mandatory or voluntary on the part of the industry.

You are proposing something of a middle ground by asking Congress to give the FDA discretion over which products should have nutritional labeling.

If that were to happen, what criteria would you likely use in making that determination?

Dr. NOVITCH. Well, there are basically three things that we would have in mind, Mr. Chairman.

First is the extent of the use of the product. If we are going to impose a requirement that will have some cost, it ought to be usable to as many people as possible.

The second, of course, is public health significance. We would like to have nutrition labeling on those products where there is a clear public interest in knowing what is on that label and some public health benefits, as well.

Third, as Senator McGovern has pointed out, the use of data base is important. We would like to phase these requirements in as adequate nutrition data bases become available so that we can keep the cost of these requirements as low as possible.

Those are basically the three priorities that we have in mind.

Mr. RIEGLE. Do you have any information about the cost of the existing voluntary labeling system as compared to the cost of either a mandatory program or a discretionary program?

Dr. NOVITCH. Well, unfortunately, the costs vary so widely they are not of much help.

Our estimate for imposing nutrition labeling on a volume of processed foods that would be close to $100 billion a year, will be something on the order of $25 to $100 million.

Industry estimates, even for the voluntary program that is in effect now, are much higher. So I am afraid we are not in accord on what it will cost.

We think that we are close to the mark on an estimate of $25 to $100 million for the entire program.

Mr. RIEGLE. I gather from what you say, though, that the new program would probably be less expensive, or are you not prepared to say?

Dr. NOVITCH. I am convinced that it will be less expensive to do the rest of nutrition labeling than it has been up to now.

If we use the nutrition data base approach, the cost per label will obviously be much less than if each processor has to determine the nutrient values on his own.

Mr. RIEGLE. Well, I think that's a key fact. What we're after is not only to provide a needed and useful public gain in terms of information, but also to try to do this while keeping costs down to the bare minimum; and I gather you feel that that is accomplished if we go this way.

Dr. NOVITCH. Absolutely. One of the great values of the hearings that we held around the country, and more recently the hearings that we held on the tentative positions of the three agencies was that we heard very clearly from processors and food manufacturers about the cost.

We are very sensitive to it. We did not need to hear that in order to keep our sensitivity level high. We are very sensitive to it, and we think that our position is a good middle ground.

Mr. RIEGLE. Now, one of the witnesses today is going to testify that it may be unfair for processed foods to have mandatory labeling requirements while fresh foods have voluntary guidelines; and I'm wondering if you could comment on the issue of fresh foods?

Dr. NOVITCH. Well, labeling fresh foods is a very difficult thing to carry out.

Fresh foods are required to have some ingredients labeled, and I must say it is honored more in the breach than in the observance. It is a very difficult thing to police, and it may be that the experiments that are in the bill and that Senator McGovern mentioned this morning may give us the answer, to have off-label methods of getting the nutrition information about fresh fruits and vegetables.

It is just practically of great difficulty.

Mr. RIEGLE. Let me raise one other item with you. The legislation today before us focuses on providing consumers with information on macronutrients on sodium and cholesterol.

I'm wondering as a result of all the work that you have done in the nutrition area if you think that this is the correct focus?

Dr. NOVITCH. Yes. We think that macronutrients ought to be declared on labels. We think that sodium and cholesterol ought to be there where there is a need.

Again, thinking of the cost, every time you add a requirement, there is a cost to it.

At the present time we also think that micronutrients, that is, vitamins and certain minerals, ought to be listed on the label, but we have an open mind on that.

The comment period is closing next month on our proposals. We will look at that very carefully and come to a conclusion about micronutrients.

We think that there are many consumers that really want to know the micronutrient quality of the food they buy.

So we are certainly in accord with what is in the bill, and our present position is that there is more to be gained beyond that.

Mr. RIEGLE. Senator Schweiker.

Senator SCHWEIKER. Thank you, Mr. Chairman.

Doctor, the proposed bill preempts State and local food labeling laws, but allows several major exemptions, such as open dating or separate requirements necessitated by compelling local conditions.

My question is: Do these exemptions take away many of the advantages of preemption?

Dr. NOVITCH. Well, open dating traditionally has been a matter for State and local jurisdiction, so that neither takes away nor adds.

There are no Federal requirements for open dating. Now we think that there ought to be one, but we are not quite certain. We are certainly openminded on how the dating should be accomplished.

It is a very sensitive business, the issue of States rights versus Federal preemption, and there is a cost attached to that.

The more discretion that the States and jurisdictions have in setting local requirements and the more foods travel in interstate

commerce to all parts of the country, the greater the cost there is to consumers who are going to have to pay for varying labeling in varying parts of the country.

We hope that there will be few exemptions asked and relatively few but very good exemptions offered. I do not think it is going to interfere with commerce generally. At least we hope not.

Senator SCHWEIKER. Particularly if you get to compelling local conditions. I mean, having State exemptions, at least, is an arguable thing because of States rights, and as you said, it's rather delicate; but if you talk compelling local conditions, I would shudder to think that we'd have a lot of those.

Dr. NOVITCH. Well, we would be very sensitive to that and I suspect the States are as well. They know what the implications are as well as we do.

Senator SCHWEIKER. Now the bill proposes the use of a nutrition data base as a mechanism to reduce economic and regulatory burden.

My question to you is how do you assess that, its pluses and minuses and what's your position on that?

Dr. NOVITCH. Well, we think it is an essential, and as I said to Senator Riegle earlier, it would be one of the important priorities that would govern the expansion of nutrition labeling.

We are setting up a joint working group with the U.S. Department of Agriculture to set up priorities for the development of data bases.

We want to work closely with industry. There is a great interest on the part of industry in doing this as an alternative to more expensive individual analyses.

It can cut down the number of analyses that firms have to do to make sure their products are in compliance. I do not think there is any doubt in our minds that it is the way to go. I do not hear much argument that there is a better approach to it.

Senator SCHWEIKER. New labeling regulations would necessitate consumer education before food labeling could be used effectively. How do we plan to provide that kind of consumer education?

Dr. NOVITCH. I would like Dr. Miller, if he could, to respond.

Dr. MILLER. At the current time the Agency has a rather extensive program in attempting to determine the best ways to provide information for the consumer, not only in terms of what is on the label, but how to inform the consumer of the best way to use this information on the label.

In fact, for some time one of the priorities of the Bureau has been in that particular area.

A number of proposals have been made, some of which were mentioned by Senator McGovern in his statement, including, for example, the reference book.

But it seems to us that this has to go far beyond the providing of information. We are going to have to teach people how to use it and use it effectively.

The label itself is only part of a very complicated process by which people are going to use this.

Senator SCHWEIKER. On page 11 of your testimony you indicate that in the case of sodium and cholesterol that you would want discretionary authority as opposed to mandated authority.

My question to this is why? It seems to me if there is any rationale for a labeling program, these are probably the two biggest items where the cost benefit is the highest because of the definitive specific link we've established between cholesterol and heart attacks and heart disease, and the specific link we've established between excess sodium and hypertension.

Why on earth would you want discretionary authority in the two areas that I think you'd get the biggest dividend on?

Dr. NOVITCH. Well, we would certainly want that labeling on most foods, but there are a number of foods where it is just not needed.

I think you would not need it or indeed need nutrition labeling altogether on spices or things where people do not expect to get nutrition.

Senator SCHWEIKER. A lot of people don't expect to get it in catsup, and yet that's where an awful lot of it is, for example.

Dr. NOVITCH. Yes, that is true indeed. And on the matter of salt, I think we could agree that that might be by exception rather than discretionary authority.

But in cholesterol there is a cost to doing those determinations and where there is no usable information to be gained, we would rather not have it; but it is a matter that we can discuss further.

Senator SCHWEIKER. Doctor, I think you can make an awful lot bigger case for sodium and cholesterol labeling than whether you want all the colors and spices and all the other miscellaneous microingredients on the label that nobody has established a link to almost anything yet. That's my only point.

It seems to me if you're going to set up a big burdensome system, the biggest payoff would be in sodium and cholesterol.

I can't think of a bigger payoff in labeling than just sodium and cholesterol; and it's very difficult, particularly in the case of sodium today, and cholesterol, too, to have any idea of what's in that food unless you've done some reading.

It just seems to me that's where your biggest dividend would come and that's where the most health benefits would accrue, and I have trouble understanding why we wouldn't put that as one of the highest priorities compared to some of these miscellaneous things, ingredients in descending order of importance and spices and colors that yet don't have a link between health and nutrition.

Dr. NOVITCH. Yes, I think there are a lot of people who agree with you and we will certainly pay close attention to that; but our thinking was that there will be a number of foods for which there is no expectation of finding cholesterol and for which there is probably no need to declare cholesterol content. But we are very sensitive to your views.

Senator SCHWEIKER. Do you have any feeling yet as to just what kind of a system might be evolving here?

One of the things I'm concerned about is I happen to be one who reads all the cans if I do see them on the shelf or at the supermarket. My wife says I'm the only one that does.

My point is do we really have any conception of just how we might simplify this and really make it useful so that people don't have to be labeling addicts to really understand what's going on in terms of nutrition?

Dr. NOVITCH. Well, I think we have to look very carefully at what is to be required. For example, consumers seem to be much more interested in the caloric content and the breakdown of the macronutrients, protein, carbohydrate and fat, than they are about what proportion of their minimum daily requirements are being obtained from their food.

So that is one area. I think that we have to look very closely at the kinds of things that appear on the label. We also want to take a look at formats.

We are conducting a rather extensive program of experimentation to see if there is a better way to display this information to communicate with people so that they can make the most effective use of it.

Senator SCHWEIKER. You are conducting a program?

Dr. NOVITCH. Yes, indeed. Yes; we are.

Senator SCHWEIKER. I think that's very important because I just get the feeling that a lot of people don't understand what a label can do for them and we sort of strike out by not really impacting on the consumer in a meaningful way; and I think it takes that kind of study or some new graphic presentation—I realize Senator McGovern has a graphic suggestion in his bill—on three or four key things is a lot more effective than whole charts of tables that nobody but a few of us in the business really look at.

Dr. NOVITCH. Well, I think we have made a good start. I do not think there is anyone who has studied the experience so far that does not feel that what we have done thus far has not represented substantial progress.

But we do not think we have the last answer. I think that one of the great advantages of the bill before you is that it provides for some experimentation to improve the system. We take that very seriously and we have been doing it under the authority that we have now to see if we can improve the existing system.

Senator SCHWEIKER. The Select Committee on GRAS—and I want to say that's Generally Recognized As Safe substances—recommended last July that the FDA remove salt from the GRAS list and develop guidelines for restricting sodium in processed food.

What's FDA doing to implement this recommendation?

Dr. NOVITCH. I would like to ask Dr. Miller to answer that one, too.

Dr. MILLER. Within the limits of our own authority, we are taking some action; for example, our tentative position is sodium and potassium labeling was one of the important areas that were covered.

We are considering the definition of what constitutes low-salt foods in terms of labeling. There is in some respects little we can do about restricting the amount of salt which is added to food; nevertheless, we are trying to at least provide the consumer with as much information as possible as we can in terms of the amount of salt in food so that they can make these decisions.

Senator SCHWEIKER. It just disturbs me that here is one real specific link. We vested a lot of money in hypertension research. I fought to get money for this research and now we find there is a positive link between hypertension and diet. We know this, people

are dying because of it, and yet we seem awfully slow to implement the knowledge that we pay a high price to get.

Dr. MILLER. Well, sir, I suspect a part of the problem lies in exactly how far we can go in restricting use of substances such as salt or materials of this kind.

We recognize the problem and are struggling with it in many different ways, and I think we would support any action which would allow us to handle it.

Senator SCHWEIKER. Well, of course now, you folks didn't have any trouble restricting vitamins. I had a big battle with you about how you wanted to restrict vitamins, put a maximum limit on how many vitamins people could take.

It just seems to me if you had the authority at some point to restrict vitamins, you ought to have the authority to restrict salt.

Dr. NOVITCH. Another thing that we have in mind, and which was expressed in the December 21 position statement, Senator, is the possibility of labeling which defines low-salt, reduced-salt and salt-free, so that people who want low-salt food can know exactly what those terms mean and be able to make those choices.

And I should just say parenthetically, the Department of Agriculture, in the food programs that it supports, the school food programs and others, is experimenting with reduced salt content in those foods. So that there is some attempt, at least in a large segment of the population for which Federal funds are spent.

But I think that educating, getting salt labeling on processed foods and defining low salt and making it possible for people to recognize what that means, can accomplish what you are setting out to do.

Senator SCHWEIKER. In your NPR hearings I believe that some people testified that some products may contain as many as 15 to 20 spices, not the 4 to 5 that I think was originally envisioned with this regulation.

Yet the NPR proposes to require that all spices be declared on labels by their specific names.

My question is: Is that really realistic? It gets back to the sodium versus the spice argument.

Dr. NOVITCH. We have heard that. I was at the hearings and heard that there are some products with multiple names. I think we would simply have to deal with that by exception.

I think the general rule is that there are only a few spices. I do not believe that an exception such as that ought to stand in the way when that information can be of importance to consumers.

Senator RIEGLE. Thank you very much. We may have additional questions that we'll submit to you for the record, but your testimony has been helpful and we appreciate it.

Dr. NOVITCH. Thank you, Mr. Chairman.

[The prepared statement of Dr. Novitch follows:]



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

STATEMENT

BY

MARK NOVITCH

ACTING DEPUTY COMMISSIONER

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

March 19, 1980

61-331 O - 80 - 25

Mr. Chairman:

We are pleased to appear before the subcommittee today to discuss S. 1652, the "Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug, and Cosmetic Act." Improving food labeling is a matter of great importance to the Food and Drug Administration (FDA), and we welcome and encourage the benefits we believe will be derived from the enactment of this bill.

The Federal Food, Drug, and Cosmetic Act, originally titled Food and Drugs Act of 1906, will be 75 years old in 1981. With the exception of 1938 amendments, the food labeling provisions of the law have changed little. We believe it most fitting and appropriate that improvements, such as those delineated by S. 1652, be made in the labeling sections of this Act on the eve of its 75th anniversary.

The importance of improving food labeling information to help people make better dietary choices cannot be overemphasized. We know that proper eating habits contribute to the maintenance of good health and even to the improvement of health. On the other hand, we recognize that certain aspects of some diseases can be traced to poor dietary habits. The Senate's Select Committee on Nutrition and Human Needs recognized this when it published its "Dietary Goals for the United States." The U.S. Department of Health, Education, and Welfare and the U.S. Department of Agriculture recognized this when they published their "Dietary Guidelines for Americans." The authors of S. 1652 recognized this when they drafted this proposed legislation. We

strongly encourage the continuation of providing consumers with information about nutrition and its influences on health and believe more informative food labels are one of the most effective methods of accomplishing this.

Before discussing several of the provisions in S. 1652, I would like to take a few moments to highlight some of our current food and nutrition labeling activities.

Current FDA Activities

We have been working within the limitations of our authority to improve the labeling of foods. FDA has completed a number of actions within the last decade that should be of great benefit to the consumer. For example, during that period we proposed and put into effect regulations for nutrition labeling of foods. These establish a uniform format by which manufacturers can tell consumers about the serving size of the food; its fat, protein, and carbohydrate content; and the proportion of the U.S. Recommended Daily Allowances (U.S. RDA) of protein and certain vitamins and minerals a serving of food will provide. The use of nutrition labeling is voluntary unless a manufacturer adds one or more nutrients to a food and/or makes nutritional claims about the food.

We also issued regulations establishing a uniform method of labeling foods with information about their fat, fatty acid, and cholesterol content. This information is of great importance to many consumers

who wish to follow a low or moderate cholesterol diet and/or restrict the types of fat ingested.

Current law requires that all ingredients be listed on the labels of most foods. However, there are certain exemptions from this requirement, the principal example of which is the exemption that allows standardized foods to be marketed with labels that do not list "mandatory" ingredients. Mandatory ingredients are those that must always be present in a food for which a standard of identity has been established. However, FDA can require "optional" ingredients to be declared. Optional ingredients are used at the discretion of the manufacturer. To give consumers as much information as possible about the ingredients in standardized foods, we have taken several actions. Early in the past decade, we published a statement of policy urging manufacturers to voluntarily provide this ingredient information on standardized foods. We also have been revising all food standards to make as many ingredients as possible optional and to require that all optional ingredients are declared. This has been an extremely time-consuming procedure.

Other examples of our efforts to improve food labeling include the establishment of regulations for common or usual names for nonstandardized foods and a policy statement concerning the nutrition fortification of foods.

The common or usual name regulation provides for a statement in the name of the product of the percentage by weight of any important or characterizing ingredient--such as shrimp in shrimp cocktail--where such information would have a material bearing on price or consumer acceptance.

Our recently published food fortification policy statement is intended as a guide to manufacturers to promote the rational addition of nutrients in foods to preserve proper balance in the diet of American consumers. It is not intended to encourage wide-spread nutrient fortification of foods but to provide a consistent set of guidelines to be followed when foods are nutritionally improved.

Interagency Activities

Probably the greatest step in food labeling improvement taken by this Agency in the past decade involves a cooperative effort with the U.S. Department of Agriculture (USDA) and the Bureau of Consumer Protection of the Federal Trade Commission (FTC). We have been working with those Agencies to determine consumers' needs and desires and to bring federal food labeling policy into accord with these desires and needs. Another purpose of this project is to assure that food labeling requirements keep pace with food processing and technology of the 1980's.

One of the most important actions taken by the three Agencies to get the public's views on a variety of food labeling issues was the holding of public hearings in five different cities in the United

States in 1978. More than 2,800 people attended the hearings, 452 testified, and more than 9,000 responded with written comments. In addition to this consumer input, FDA also surveyed food shoppers to obtain additional information on how they feel about food labeling matters.

Basing their conclusions on these public responses and a review of current laws, regulations, and policies, the three Agencies agreed that major changes are needed in the way foods are labeled. Thus, on December 21, 1979, FDA, USDA, and FTC published in the Federal Register tentative positions on food labeling. Written comments on these positions were invited and will be accepted through April 21, 1980. In addition, the three Agencies held a public hearing on these issues on March 4 and 5. Because of its relevance to the bill we are discussing today, I would like to submit for the record a reprint of the December 21 Federal Register announcement.

The Administration soon will submit to the Congress an omnibus bill which will encompass many of the food law amendments found in S. 1652. These include: authority for the Secretary to require percentage ingredient labeling when such labeling would be in the public interest; the requirement that ingredients be listed in decreasing order of predominance on the labels of all foods; and the repeal of the exemption in the current Act which permits butter, cheese, and ice cream to be artificially colored without having this fact declared on the label.

S. 1652

As indicated previously, certain of the changes in food labeling requirements found in the Agencies' tentative positions can be accomplished administratively. However, a number of these changes would require Congressional action to amend existing law. Many of our proposed changes parallel those intended by S. 1652. In discussing the provisions of your pending legislation, I will include information obtained in the development of our tentative food labeling positions.

Ingredient Labeling

Ingredient labeling was the issue most frequently addressed by the public at the hearings, in written statements, and in response to FDA's food labeling survey. For example, 85 percent of the oral and written hearing comments discussed this topic. We found that the public wants to know all of the ingredients in foods, wants quantitative ingredient information, and desires colors, flavors and spices to be specifically declared. Currently, the Federal Food, Drug, and Cosmetic Act exempts mandatory ingredients of standardized foods from having to be declared. It also exempts spices, flavors, and colors from being declared other than by these general terms; and colorings added to butter, cheese, and ice cream from being declared in any manner.

With two exceptions, S. 1652 would require the listing of all ingredients, including colors and spices, in descending order of predominance by weight. The requirement would apply to both

standardized and nonstandardized foods. The bill's two exceptions to the ingredient declaration are: flavors could be designated as artificial or natural with specific names required when necessary to provide health information to consumers; and ingredients that comprise 5 percent or less of a food's composition could be listed at the end of the ingredient statement rather than in order of predominance. We agree that such labeling should be as informative as possible and we support the ingredient listing requirements embodied in S. 1652.

Quantitative Ingredient Declaration

Over half of the comments we received on ingredient issues included suggestions on how to specify quantity of ingredients. FDA currently requires a label statement of the percentage of a characterizing ingredient under certain circumstances. The bill provides for a quantitative ingredient statement when such information significantly affects the quality, consumer acceptability, or cost of the food. We support the bill's granting of discretionary authority to the Secretary to provide by regulation more information on the amounts of ingredients present in food.

Exemptions of Ingredients

While S. 1652 exempts ingredients comprising 5 percent or less of a food from the requirement that they be declared in order of predominance may be appropriate in most cases, there are some situations in which this exemption in method of ingredient declaration may be inappropriate. Examples include food ingredients about which

consumers are particularly concerned and which generally are present in small amounts, such as salt, and foods that are made up of small amounts of many different ingredients. As an addition to this provision of S. 1652, we would recommend that the bill specifically provide the Secretary with discretionary authority to require the quantitative listing of ingredients comprising less than 5 percent of the finished food product.

Colors and Flavors

We support the requirement that colors be specifically identified on all food labels including the labels for butter, cheese, and ice cream as well as the provision requiring the specific identification of all spices on food labeling.

As you recognize, current law does not require the specific identification of a food flavoring. We support the provisions which provide the Secretary with discretionary authority to require the declaration of individual flavors when necessary to provide health information to consumers and which require the retention of the mandatory designation of flavors as natural or artificial. In our opinion, these are the proper approaches to this matter of food labeling.

Nutrition Labeling

Nutrition labeling is of major interest to consumers. Fifty-two percent of all the written and oral comments received in response to

the food labeling hearings touched on some aspect of this topic. As stated before, FDA currently requires nutrition labeling only if nutrients are added to a food and/or claims are made about the nutrient content of the item. Our authority to require nutrition labeling on all foods has not been clearly defined. While we believe this type of information is generally very important and encourage its use, we also recognize nutrition labeling is of little value on some foods, such as spices.

S. 1652 would provide the Secretary with additional authority to require nutrition labeling on foods. If its intention is to require nutrition labeling for all foods, but provide the Secretary with the authority to grant exemptions, we believe the greatest benefits of nutrition labeling would not be realized. The process of defining by exclusion which foods must be so labeled is administratively cumbersome. However, if it is the bill's intent is to grant the Secretary discretionary authority on which foods should bear nutrition labeling, such labeling could be gradually phased in where needed and where it would be the greatest benefit to consumers. We, therefore, recommend that S. 1652 be clarified to provide the Secretary with discretionary authority of which foods should bear nutrition labeling.

Declaration of Nutrients

The public has told us that the portions of nutrition labeling they are most interested in are those dealing with calories, fats,

carbohydrates, and protein. When nutrition labeling is used, current regulations require statements of the total number of calories; amounts of protein, fats, and carbohydrates; plus information on the content of certain vitamins and minerals per serving.

S. 1652 would require labeling information setting forth the total number of calories per serving as well as the amounts per serving of protein, fats, and carbohydrates in terms of caloric content. We generally support the requirements in S. 1652 relating to the declaration of calories and the three types of nutrients per serving, provided the Secretary has authority to specify what, if any, additional nutrition labeling information should appear on food containers. However, we do not believe the bill should require protein, fats, and carbohydrates to be declared in terms of caloric content until additional information is obtained and the value to consumers of this approach is better understood.

Nearly 25 percent of the commenters responding to our food labeling hearing announcement indicated a concern about sodium content. Fourteen percent of the commenters discussed label information on fats and oils, including the importance of knowing the amounts of cholesterol and saturated and unsaturated fatty acids in food. We agree that listing sodium and cholesterol data on certain foods is necessary to provide health information to consumers. We recommend the bill be amended to give clear discretionary authority to the Secretary to require sodium and cholesterol content labeling for foods

bearing nutrition labeling where such declaration is deemed to be of public health significance.

Nutrition Data Bases

We are pleased that the value of nutrition data bases is recognized in S. 1652. These data bases are general nutrition composition tables for specific foods or classes of foods, developed from the range of nutrient values that can occur in a given food. In the future a food processor should be able to utilize an accurate nutrition data base to aid in meeting nutrition labeling requirements without having to conduct continuing extensive and expensive nutrient analyses. The development of accurate nutrition data bases should facilitate more widespread nutrition labeling, and sharing this data will tend to minimize the disproportionate impact that nutrition labeling might have on small food processors.

We have encouraged the development and use of suitable data bases as guides to consumers on the meaning of nutrition labeling of indigenous nutrients in fresh and minimally processed foods. In fact, FDA has worked closely with the dairy, orange juice, fresh potato, and potato chip/snack food industries in developing useful data bases. Furthermore, FDA and USDA jointly issued a policy statement in the Federal Register of December 21, 1979, concerning the use of nutrient data bases. The intent of this policy is to encourage industry to develop such information. With additional research, it may be possible to use nutrition data bases in the future for many foods.

However, the present nutrition data base is outdated and inadequate for many nutrients and foods. Furthermore, it should be recognized that some foods are poorly suited to the use of nutrition data bases (for example, foods to which nutrients are added and multi-ingredient foods). We should also point out that the effects on nutrient density of processing and ingredient interaction are not fully understood at this time.

S. 1652 authorizes the Secretary to allow the use of nutrition data bases that indicate representative nutrient values at supermarkets and other points of purchase. Because the bill grants the Secretary the discretion to use nutrition data bases where "feasible and appropriate," we do not oppose enactment of this provision.

Nutrition Information Symbols

S. 1652 authorizes the Secretary, where appropriate, to prescribe a system of symbols, figures, or other devices that will enable consumers to comprehend readily the nutrition information on labels. We would not oppose this provision of the bill and, in fact, have a research program in progress to determine how such types of labeling can benefit consumers.

Preemption

S. 1652 would prohibit the establishment or continuation of nutrition or ingredient label or labeling requirements that differ from Federal statute. However, it would provide the Secretary with authority to exempt from this provision a State or local requirement determined to

enhance the public's use or understanding of food labeling and which does not impose an undue burden on interstate commerce. We concur with both of these provisions. However, we believe that an opportunity for experimentation in labeling should be preserved, but not without restriction. This is consistent with that provision of the bill which authorizes the Secretary to approve demonstration labeling as a means of determining the most effective methods of organizing food labeling and conveying to consumers information that is or may be required by other sections of the Federal Food, Drug, and Cosmetic Act.

The bill also requires the Secretary to implement a program of consumer education on how to use nutrition labels and labeling effectively and to notify the Federal Trade Commission of labeling information that should be required to be included in food advertising. The effectiveness of either of these provisions could be undermined by a myriad of differing State and local labeling requirements. The preemption provision, coupled with the exemption provision, should provide a reasonable accommodation of these competing interests.

Demonstrations and Evaluations

S. 1652 authorizes the Secretary to approve studies to determine the most effective methods of organizing food labels and conveying information to consumers. This provides an opportunity for industry and others, on a voluntary basis, to pilot test nutrition, ingredient,

and other food labeling information. Prior approval prevents the proliferation of uncontrolled, diverse experimental labeling that can create consumer confusion. However, we believe we already have the authority to approve experimental labeling and, therefore, we do not believe that the inclusion of this provision in the bill is necessary.

Consumer Education Programs on the Use of Labels and Labeling

The Secretary, in consultation with the Secretary of Agriculture and other appropriate public and private entities, is required by S. 1652 to develop, test, and implement a program of consumer education on the effective use of nutrition labels and labeling. The Department already has authority to undertake such activities and, in fact, FDA is carrying out various consumer awareness programs. We, therefore, do not believe this provision is necessary.

Notification To and Report By the Federal Trade Commission

We defer to the Federal Trade Commission on the provision that would require that Agency to prepare a formal report to the Congress on how it has responded to recommendations from the Secretary about nutrition information which the FTC should require to be included in food advertising. We agree that the relationship between food advertising and nutrition labeling is an important one. The Department is committed to make every effort to coordinate its regulations with those of the FTC to assure the product claims made in advertising are consistent with those made in labeling. This commitment is

exemplified by the recent cooperative food labeling hearing effort. While such a coordination now exists, formalization of the current relationship between the two Agencies would be beneficial.

Records Inspection

We also strongly urge that the bill be amended to include authority for FDA to have access to manufacturers' records and reports to assure that nutrition labeling and ingredient labeling, including quantitative ingredient declarations, are truthful and accurate. Laboratory analyses of finished food products cannot always provide this information. Furthermore, such analyses are often extremely time-consuming and expensive. The more practical approach in monitoring nutrient and ingredient content is by factory inspection with review of records related to production. The Administration will be submitting shortly a series of amendments to the Federal Food, Drug, and Cosmetic Act which include specific authority to inspect such quality control records and reports.

Summary

In summary, Mr. Chairman, we concur with the objectives of S. 1652 and, with the modifications outlined above, support its provisions which will do much to assure that the consumer has appropriate labeling information to use in choosing foods that are the best buy from an economic standpoint and, more importantly, the most beneficial to health.

This concludes my testimony Mr. Chairman. My colleague and I would be most willing to answer any questions on these topics.

Senator RIEGLE. Let me now call our next panel to the table. Dr. Howard Bauman, vice president of science and technology for Pillsbury Co.; Mr. Arthur Schulze with General Mills; and Mr. Andrew Schroder with General Foods.

I must shortly leave for another hearing. When I leave Senator Schweiker will assume the chairmanship of the committee for the remainder of the hearing.

Before you make your statements, I would like to address to each of you a couple of quick questions that I'd like to have your response to on the record.

Your firms, together, represent a very substantial part of the food industry. As I understand your testimony, although you have some concerns about what might be included in the labeling program, you are not opposed to the concept of mandatory nutrition labeling. Is that the correct inference on my part?

STATEMENT OF HOWARD E. BAUMAN, PH. D., VICE PRESIDENT, SCIENCE AND TECHNOLOGY, PILLSBURY CO.; ARTHUR R. SCHULZE, GROUP VICE PRESIDENT, GENERAL MILLS, INC.; AND ANDREW J. SCHRODER III, VICE PRESIDENT, PUBLIC AFFAIRS, GENERAL FOODS CORP.

Dr. BAUMAN. I think it's fair to say that we're not opposed to it, providing there is a national nutrition data base established. Everything hinges on that, as far as we're concerned.

Senator RIEGLE. Mr. Schroder.

Mr. SCHRODER. General Foods would echo that sentiment, Mr. Chairman. We would have some other specific revisions to suggest as well in the nutritional labeling requirements of the proposed bill; but if those were made, the concept of a mandatory system does not concern us.

Senator RIEGLE. Mr. Schultze.

Mr. SCHULZE. The concept of mandatory nutritional labeling would have very little effect on General Mills because most of our products already carry such labeling. I think the exact figure would be something like 95 percent.

I would agree with the two gentlemen on my right. I would say, though, that there might be smaller companies, smaller manufacturers who might have far more difficult problems than we in implementing such a program; and I think both of you have touched upon a very, very important subject.

It is the subject of fresh food labeling, and my concern would be that if you adopted a system of mandatory labeling today, that the country really might not be ready for it.

I'm thinking particularly of fresh meat, fresh fruits and vegetables and things like that.

I think there's a major opportunity, though, to work with the major companies in that area and maybe some of the smaller ones to develop adequate programs.

Senator. RIEGLE. Let me take that point and raise it with the other two witnesses here. In developing a labeling system, we want to do it in a way that's not going to drive the smaller manufacturer out of business.

I'm wondering if it would be your belief that the mandatory system has the potential to do this?

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Dr. BAUMAN. Yes; I think the system could do that if it's mandatory, but I also think there's a way around it, and that is utilize our universities and other laboratories to aid and assist some of the smaller manufacturers.

This country has had a history of doing that, and certainly the large manufacturers aren't going to object to it.

Also, I think with the national nutrition data base established that the small manufacturer can draw on this data base, and the cost of pulling information out of a data base is relatively cheap. It's the cost of getting it in there that's expensive, and I'm sure the large corporations will bear the brunt of that very willingly.

Senator RIEGLE. So you think if we go the route that you've just described, that would not place an undue burden on smaller manufacturers?

Dr. BAUMAN. Yes; I believe so.

Senator RIEGLE. Mr. Schroder.

Mr. SCHRODER. I would agree with that. I think that we are certainly talking about an additional burden. I think the notion is minimizing that burden and in fact balancing it against benefits that would be incurred.

We would suggest in addition to the data bank that in effect what we try to do is look at the specifics of nutritional labeling that are being proposed here and insure that those are based on a real need.

Senator RIEGLE. Let me just raise one other concern regarding mandatory labeling, a concern over the possibility that additional costs associated with labeling be might passed on to the consumer.

Do you foresee that the system under consideration today will be any more costly than the current system?

Dr. BAUMAN. I'll start out again and say it will be a lot less than it's costing us right now. I have figures which I'd like to submit. They are not in the right form right now, but submit them within the month to this subcommittee showing this.

For example, right now under the voluntary system, it costs between—well, a particular product. I'll just cite our pizza alone. We have 19 different pizzas produced in three different plants. The nutritional labeling, the analysis for this, costs us $600,000, and approximately $300,000 to maintain.

Once that information is in the data base where we can draw on it, then it's just the cost really of your terminal time and then verification tests to make sure it's done.

So I'm sure instead of the $600,000, that on a continuing basis it can be done for less than $5,000.

Senator SCHWEIKER. I just want to understand that. Is that because you would put the same figures on each of those plant units because of one data base, or is it because they are supplying you information and you'll still put variations on your labels for those different producing units? I'm not clear.

Dr. BAUMAN. With a national nutrition data base what we'll end up with is a large pooling of samples. I cover that a little bit in my data, that the larger the pool of samples, the more the inequities of manufacturing variations, raw material variations wash out.

So that over a year's time, using the data base, the nutrition that the consumer gets is going to be more accurate than what we can

do just by sampling one time out of say 1 or 2 weeks, because we miss all those variations.

Senator SCHWEIKER. But under the present system, do you have a different label for each of those producing units in terms of ingredients, or is it the same label for all?

Dr. BAUMAN. It's the same label. What we have to do is to round down or round up the figures, and many of the labels are inaccurate up to 20 percent just because of the potential penalties of declaring something that may not be there.

Senator RIEGLE. So what you're saying is that under the proposed arrangement here, you can actually have greater accuracy at less cost?

Dr. BAUMAN. Absolutely.

Senator RIEGLE. So we really come out ahead on both counts. To the extent that we can accomplish these savings, that would have an ultimate consumer benefit at some point.

Dr. BAUMAN. There's no question about that. It can also have an effect on productivity, because right now we have a certain number of nutritionists that are doing nothing but manipulating calculators, and I'd rather see those nutritionists working in laboratories and with new products and on research, rather than doing the type of thing they're doing now.

The system as we have it now is a tremendous drain on scarce resources.

Mr. RIEGLE. Well, that's what we're trying to correct here.

Dr. BAUMAN. It's an intangible but it's very important.

Mr. RIEGLE. The data that you've developed is going to be very important to us. I appreciate your putting it together. You don't have it in the complete form yet, but you'll provide it to the committee as soon as you do have it in a complete form?

Dr. BAUMAN. Yes; within the next few weeks.

Senator RIEGLE. Mr. Schroder.

Mr. SCHRODER. Mr. Chairman, we're really in the same position in terms of developing our cost information, and the reason why I think we're all probably where we are on this is because the Federal agencies who are conducting their review of food labeling have asked for economic data to be provided in our comments on those tentative labeling proposals, and that's due the end of next month.

So I think we're all coming to grips with this economic data at about the same time.

The information that we've developed, which again is rough, tells us that for each one of these nutritional analysis tests that we would run in-house, it's costing us between $10 and $40 per test to do that.

Now if we're in the position of having to do those tests outside, as opposed to doing it inside, we know that it's three to four times higher to conduct that test.

Now, what that means is just our cereal business alone for the last 12 months, where there were some 18,000 of these tests conducted at two plant sites, we're talking between $300,000 and $350,000. Now that represents the majority of tests being done internally. If we were to have to do that testing outside, and I think that's the thing to recognize in terms of many small food

manufacturers which would be forced to have these tests conducted outside, you could be talking about a significantly higher figure for a business the size of our cereal business.

Senator RIEGLE. Let me take one more comment and then I'd like to go back to the formal order here.

Mr. SCHULZE. Yes, I'll make it brief, Mr. Chairman, because we, too, would endorse the concept of the data bank.

But I think there are other practical problems that you would run into. We happen to own one of these smaller companies, a company that makes fish products that are by and large very nutritious and very wholesome.

It is very, very difficult, it would be very, very difficult to put nutrition labels on those products, because we are using different species of fish for one given product, for one thing; and then, second, there are major differences within a species in terms of nutrient content.

I think my plea would be that there would be some system here of granting exceptions that would be looked at on a case-by-case basis to make sure that the information on the label is commensurate with the cost involved.

Senator SCHWEIKER. Well, would the data base help or not help?

Mr. SCHULZE. Yes; it would help it very much, Senator. It would help us very much.

Senator SCHWEIKER. I mean in the fish case?

Mr. SCHULZE. Yes; it would help. We would probably end up with a range that would be useful, and I think it would be information consumers would find——

Senator RIEGLE. And would your judgment then be, too, that on balance that's a more accurate yardstick to use and probably could be generated at a lower cost?

Mr. SCHULZE. Certainly the cost is there. In terms of accuracy, I can't answer that, because I know our own analyses are done very thoroughly and I think they're quite accurate.

Senator RIEGLE. But wouldn't you have the same problem that's just been cited here, and that is you're not doing it for every batch? You're not doing it every day, so you're working with a range. It would seem to me that it's almost that if you're applying sort of sound statistical analysis and you've got enough of the data base so that you can really have a good prediction that on the average that's what somebody is going to get, that it would probably be more accurate.

Mr. SCHULZE. Certainly. The larger the base statistically, the more accuracy that you would have.

Senator RIEGLE. Well, thank you for those responses.

Dr. Bauman, why don't you begin with a summary of your testimony.

Dr. BAUMAN. Mr. Chairman, Senator Schweiker.

I'm Dr. Howard Bauman, vice president of science and technology of the Pillsbury Co., Minneapolis, Minn.

I appreciate the opportunity to address this subcommittee on behalf of the Pillsbury Co. concerning the very important subject of labeling of food products.

The Pillsbury Co., as you probably know, is an international marketing company participating in three segments of the food industry: Agri products, restaurants, and consumer foods.

I'm confining this testimony primarily to the consumer foods division because the legislation does not affect the others very much.

The consumer foods division manufactures a broad range of products from packaged goods to frozen to refrigerated, canned goods and so forth, under trademarks such as Pillsbury and Green Giant.

I mentioned previously that I wanted to submit some more detailed information in a few weeks to this subcommittee, and this is predicated on having put together some comprehensive group of technical, marketing, legal and other types of people to pull together information in response to the USDA, FDA, and FTC proposals.

We do have a considerable amount of cost information developed there.

The Pillsbury Co. agrees basically with the aims and aspirations of the bill, and have always had the philosophy of providing truly meaningful label information to the consumers in a cost effective manner; and I think throughout we should keep in mind that we must strive for cost effectiveness in whatever we're doing.

I've said I would confine my remarks to three basic issues because of the time element that's involved. I'd like to first take up the national nutrition data base.

We support nutritional labeling and further, as I mentioned before, will support mandatory nutrition labeling of macronutrients, providing that a national nutrition data base is established.

A data base of this nature offers a tremendous opportunity for cost effectiveness because it eliminates the costly and unnecessary current practices whereby each and every corporation, such as the three of us, must establish the variability or standard deviation for each of its ingredients and/or food products. It's a tremendous amount of duplication that we're doing.

If this information could be pooled, it would make the information more accurate and would be much less of a drain on our resources because we are all duplicating resources as well as the monetary cost.

I've attached to this testimony some graphs indicating how much more accurate the information will become as the number of samples go up.

I might add, it just occurred to me as we were talking earlier that for many years feed manufacturers have been manufacturing feed on a least-cost formula based on nutritional data bases; and certainly, the animals that have been getting these feeds have been thriving very well.

I think this illustrates to a large degree that a nutrition data base can serve the purpose for which it's being discussed here.

The other area that we're concerned with is in the quantitative ingredient labeling. It has been proposed that percentages of all ingredients be listed.

We're against that for a number of reasons. One is that we don't, first of all, believe it's necessary for everyone to know the exact percentage of an ingredient that's in a product.

Second, by establishing percentages, it's going to increase analytical costs, and will decrease the flexibility that the manufacturers have in coping with raw materials that will vary in their functional characteristics because they come from a different part of the country or they've been processed in a slightly different way. We just have to have the flexibility of being able to deal with those issues.

We think that quantitative information that's necessary for health reasons—this would deal with the salt issues or others—ought to be on the information panel and not on the ingredient itemization. We have no quarrel with that.

We of course recognize that many consumers do not realize the ingredients are listed in order of predominance. I don't think there's ever been an educational program to try to tell them that, but I think it might be the best way to handle it.

However, we do feel that if it is necessary to have statements of that nature, we would prefer to see a first section with a statement such as, these ingredients in order of predominance, and then a second statement that would say, minor ingredients, or ingredients at less than 5 percent, or whatever percentage level might be selected.

This can help, I think, the consumer distinguish the ingredients that are present in large quantities versus those that are present in traces.

We'd also recognize that there should be exceptions for valuable ingredients, and I use the illustration of table syrup that contains a blend of maple syrup and a sugar syrup; and obviously, it is a valuable constituent and the consumer should know how much maple syrup am I getting.

Food and Drug has already gone in that direction by requiring the percentage of shrimp in shrimp cocktail, and I think that's a very legitimate use of the percentage figures.

Federal preemption is the other one that we are concerned with. Being a company that transmits all of its products across all State lines, we are concerned with requirements in different States that can affect particularly labels; and open dating is one that can cause us some great deal of problems.

We would support a Federal requirement that perishable foods be open dated and would like in fact Federal preemption over the total food packaging labels.

Obviously, there may be some exceptions that are necessary, but I think those can be dealt with.

Manufacturers, if they had to comply with different regulations in 50 different States on just open dating alone would have an effect of decreasing productivity and increasing costs dramatically, and would obviously interfere with interstate commerce.

Thank you very much for the opportunity to testify.

[The prepared statement of Dr. Bauman follows:]

Testimony of Howard E. Bauman, Ph.D.,
on Behalf of The Pillsbury Company

Mr. Chairman, members of the Subcommittee on Health and Scientific Research. I am Dr. Howard Bauman, Vice President of Science and Technology of The Pillsbury Company, Minneapolis, Minnesota. I appreciate the opportunity to address this Subcommittee on behalf of The Pillsbury Company concerning the very important subject of labeling of food products.

The Pillsbury Company is an international marketing company participating in three segments of the food industry: Agri products, restaurants and consumer foods. Our testimony will concentrate on the consumer division since the Agri products and restaurants divisions are not significantly affected by this proposed legislation. The Consumer Foods Division manufactures a broad range of packaged grocery, refrigerated, frozen and canned products marketed under the well known trademarks of Pillsbury and Green Giant, and distributed at retail through grocery stores.

As you know, the Food and Drug Administration, United States Department of Agriculture and Federal Trade Commission have recently proposed potentially significant changes in the current labeling regulations. These changes touch on much of what is being addressed by this legislation. The proposals are far reaching and significant, consequently we have asked our technical, marketing, legal, regulatory, advertising, packaging and management people to prepare comprehensive comments on these proposals with a view towards submitting a definitive statement by Pillsbury regarding the philosophy and practical impact of the proposal.

Because of this later submission our testimony will be confined to what we consider to be the three most important aspects of this legislation; the nutrition database; the quantitative ingredient labeling; and the federal pre-emption for labeling.

The Pillsbury Company agrees with the aims and aspirations of the bill which are to provide truly meaningful label information to consumers in a cost effective manner. We believe that cost effectiveness is of significant concern since, as we all know, consumers ultimately pay for all labeling expenses. We also strongly believe that the information on a label is not useful unless consumers are educated enough to understand the information. However it is important to distinguish Pillsbury's perception of a nutrition education effort versus information to consumers on packaged goods.

Nutrition is a complex subject and requires an organized effective education program for all ages. Furthermore, basic concepts and beliefs about good nutrition have changed over the years with the growth of scientific knowledge in this field, and we expect that pattern to continue. Information on labels is part of an education effort, but the main role of labels is to provide information which will allow knowledgeable consumers to make intelligent choices.

Pillsbury has long had an interest in nutrition and is proud to have been the first major food company to use nutrition labeling on its products. Green Giant was the first vegetable processor to label its products. In fact, the merger of Green Giant and The Pillsbury Company has resulted in a corporation that has been developing nutrition labeling since World War II.

Additionally, Pillsbury has, for a number of years, maintained both Nutrition and Consumer Affairs Departments to assist consumers in answering nutrition-related questions about our products. The Pillsbury Company has also utilized mini-computer technology for nutrition education purposes in libraries, science museums, scientific society meetings and schools. The mini-computer contains nutrition data on approximately 135 commonly consumed foods and food components. By using this system, which we make available to the public, a person can quickly obtain nutrition information on meals, snacks or a daily diet. The computer also makes suggestions as to how the diet might be improved. Pillsbury has been working actively with the Honeywell Company to incorporate the information contained in the U.S. Department of Agriculture Handbook 456 nutrition database into Honeywell's nationwide computer network. As you know, Handbook 456 provides nutrition information on approximately 2,500 foods and ingredients. This data is currently being used by some food editors of magazines and newspapers to provide readers the nutritional value of recipes they recommend, thus extending nutrition labeling beyond packaged foods. Pillsbury has also used this system to develop and publish a cookbook which contains nutrition information for each of its recipes. (Copies have been supplied for Subcommittee perusal.) This recipe information allows the nutrition conscious consumer to adjust recipes with regard to the specific content of such items as sodium, potassium, fat and other nutrients.

Pillsbury's experience with nutrition labeling and its awareness of consumer perceptions has enabled us to formulate beliefs on the most cost effective method of labeling which provides consumers with relevant and practical information. Pillsbury believes that cost effectiveness is essential for wide use and dissemination. It is Pillsbury's philosophy to provide disclosure of relevant nutrition information to the consumer.

National Nutrition Database

Pillsbury supports nutrition labeling and further, will support mandatory nutrition labeling of macronutrients provided that a national nutrition database is established. A database of this nature offers a tremendous opportunity for cost effectiveness because it eliminates the costly and unnecessary current practices whereby each and every corporation must establish the variability or standard deviation for each of its ingredients and/or food products. The current duplication of effort is a drain on scarce technical resources. Appendix I contains graphs that depict this by showing that the number of samples used in the analyses to establish the variability of nutrients in food products will largely determine the accuracy of the information that appears on the nutrition information panel. The fewer the number of samples used to establish the variability, the greater the standard deviation or the variability between products. The larger the number of samples the narrower this difference becomes. Under current law, each manufacturer must establish his own database. Consequently manufacturers are operating on a very wide variability which results in the necessity to "round down" the declared nutrient levels and to "round up" items such as calories and sodium. Depending on sample size, many labels are inaccurate by 20-30% on the conservative side. A nutrition database that is established through the pooling of many samples can result in quite accurate information that will take into account varietal and regional differences in food items, as well as manufacturing variations that may occur. With the variability established for a large number of samples, the manufacturer merely has to composite a number of samples to determine whether or not his product falls within the range of the database. Variations will occur from lot to lot or even from day to day that will deviate from the norm;

however, over a period of time, the nutrition information provided will be far more accurate than under the present system. Compliance can be handled by the manufacturer through the maintenance of appropriate records showing how composite samples were generated and tested, and how the composite samples fit within the national sample. These would be available for evaluation by the Food and Drug Administration or the Department of Agriculture. The manufacturer of course should demonstrate that the process utilized to produce any particular food ingredient or food product does not significantly alter the nutrients in the products. For instance, if a manufacturer uses enriched rice in a frozen product and the process removes some of the enrichment, then either the process should be changed to protect the enrichment or he should be allowed the option of adding back the lost nutrients to restore the product to levels indicated by the national nutrition database.

A problem that should be taken into account prior to the establishment of mandatory nutritional requirements is the effect on the small manufacturer who has neither the money nor resources to carry out extensive testing. Some means of supplemental help either through regional laboratories or direct subsidies may be necessary. Exemptions could be proposed for extremely small packages where nutrition information cannot be included.

Quantitative Ingredient Labeling

Labeling the percentage of each ingredient in a product would be costly to the consumer and will provide them with information that is relatively meaningless. Pillsbury believes that the amount of a particular ingredient in a food product is more important on the nutrition information panel rather than in the ingredient itemization. We feel that the important quantitative

ingredient information is already on the information panel and providing percentage levels on the ingredient itemization is an unnecessary and confusing duplication of information. Many consumers do not realize the ingredients are listed in order of predominance. To correct this problem Pillsbury thinks it would be more effective to inform the consumer through an education program carried out jointly by Industry and the Government. However, if it is deemed essential to inform the consumer directly on the package, Pillsbury would propose that the ingredient itemization be split into two sections. The first section would require a statement such as "Ingredients in order of predominance" followed by the ingredients. The second section would be entitled, "Ingredients at less than 5%" followed by these ingredients. The requirement for this statement would be for a finite period of time, say two years (which is the requirement to establish a common or usual name) in order to free up space on the label which is always scarce.

Pillsbury recognizes that there would be exceptions for valuable ingredients. For example, a product such as a table syrup which contains a blend of maple syrup with other syrups. Since the consumer cannot tell by taste or visual examination the amount of maple syrup, it is appropirate to percentage label the maple portion. The FDA currently follows this practice.

While Pillsbury believes it is important for consumers to have relevant information we do not believe it is necessary for consumers to know the percentage level of all the ingredients. Persons with allergy problems associated with particular ingredients should avoid the item regardless of percentage. The practical problems associated with percentage labeling are,

however, significant to the manufacturer because of wide variations that can occur in moisture content, bulk density, etc. found in raw materials. This would often cause a technically inaccurate label. Order of predominance labeling allows sufficient flexibility for these variations.

Federal Pre-emption

This bill would pre-empt state labeling requirements except for open dating. Pillsbury's position is for total label pre-emption, including open dating. Currently, a number of States are establishing their own open dating laws which vary considerably in scope and enforcement. We would support a federal requirement that perishable foods be open dated. Because food manufacturers like Pillsbury distribute food products nationally, differing labeling requirements among states would be extremely costly and would require a large number of labels to be held in stock. Careful and costly control over shipments of products from regional warehouses destined for interstate commerce would be inevitable if states required different open dates. An additional factor is that special production runs would have to be made for specific states which could result in a waste of food products if the manufacturer was unable to accurately predict the number of units that would be sold within a state. Inevitably manufacturers would end up with outdated product that, in turn, would have to be destroyed. The law that regulates the Department of Agriculture and the Fair Packaging Labeling Act do have label pre-emption and Pillsbury believes it has been a factor in the increased market for meat and poultry food products because of the uniformity that is allowed. Again thank you very much for the opportunity to testify.

APPENDIX I

NATIONAL NUTRITIONAL DATA BASE

The National Nutritional Data Base would be an accurate and cost-effective method of providing nutritional information to a manufacturer for nutritional labeling. The National Data Base would reflect the benefit and accuracy derived from utilization of a very large number of samples.

In determining nutritional values for products, a manufacturer in the first instance must establish the variability of these nutrient values for a wide range of product samples (by plant, region, etc.). The larger the number of samples in this initial phase the more accurate is the data. However, the larger the number of samples the greater the number of analyses that have to be carried out and hence the greater cost.

The second phase, the monitoring phase, may be carried out after the nutrient data variability is established in order that the manufacturer can confirm that he is running within the values determined initially. This would not involve a great number of samples and consequently would be less expensive.

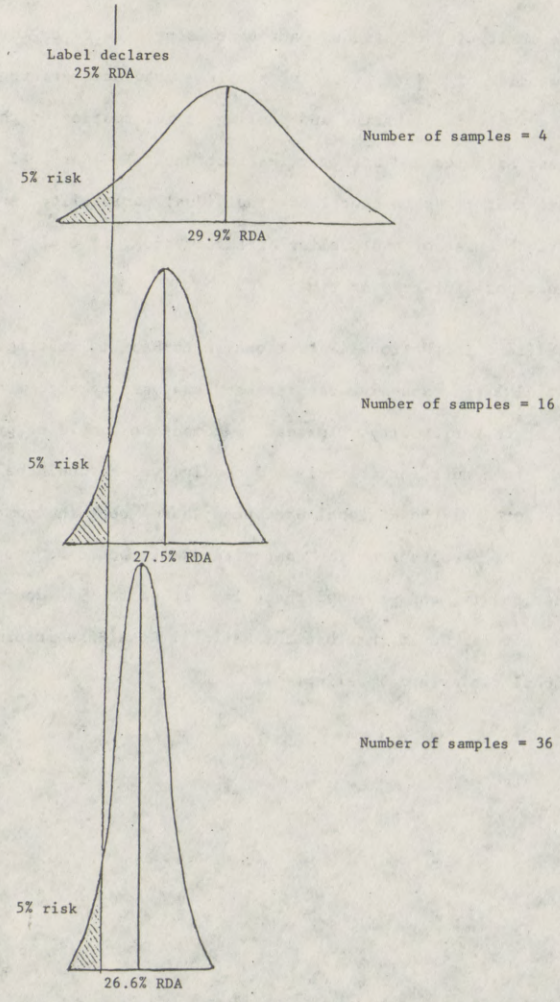
Figure 1 shows the benefits and merits of a national nutritional data base over one established by each manufacturer. Referring to the upper curve, the manufacturer who used 4 samples to establish his variability would have to add 20% more nutrient than he can actually declare (that is, 29.9% compared with 25%).

The lower curve conversely illustrates that with 36 samples, the actual nutritional value (26.6%) approaches very closely to the declared value of 25%.

The merit of the National Data Base is predicated on the basis that it is a composite of a large range of samples (manufacturer, region, plants, varieties). It is a sharing and pooling of information by the food industry, government agencies and academic institutions. The National Nutritional Data Base thus tends to cancel out individual variability, and for given nutrients, because of the pooling of information, is truly more representative of the national intake over time.

Utilizing the National Nutritional Data Base in practice eliminates the initial large expensive sampling and analyses by each manufacturer to establish his variability. Instead, a composite sample of product is analyzed for each given nutrient criteria. Secondly, values would be derived for the nutrient from the National Data Base, based upon the components of the product. The results from the composite sample would be compared with the data base result, and provided these lay within the 95% confidence limit, the manufacturer would then use the National Data Base information for nutritional claims and labeling.

FIG. 1



The curves from top to bottom of mean value distribution indicate the effect of increasing sample size on the accuracy of actual and declared nutritional values. The shaded portions represent the risk that the nutritional mean value lies below the declared value.

Senator SCHWEIKER. All right. Mr. Schroder.

Mr. SCHRODER. Thank you, Mr. Chairman. We appreciate the opportunity to appear today and give you General Foods comments regarding S. 1652.

We've submitted more detailed testimony for the record and we'd appreciate your including that. In the interest of time, I'll limit my comments to just a few areas of that testimony.

Over all, we believe S. 1652 demonstrates a praiseworthy commonsense approach to regulation. Where we have differences with the bill, they involve means and not ends.

While our written testimony sets forth each of these differences, I'll comment on just a few of them at this point.

One such point is preemption. We strongly support the concept. You already have included it in this bill. It simply does not go far enough.

We would like to see the concept extended to include open dating. We feel that Federal standards are absolutely essential in the labeling area and without them, conflicting and contradictory State and local efforts will lead to a multiplicity of open dating formats without any demonstrable benefit.

Last year General Foods was involved with more than a dozen open dating proposals being advanced in various States.

One of these bills introduced in California would have demanded a pull date approach to open dating, while another being contemplated at the same time by New York would have required a pack date approach.

The variety of approaches at the State level just does not make sense. It can only result in increased consumer confusion, higher costs due to lost efficiencies and additional pressures on food prices.

Another point to make is the inherent limits of nutritional labeling and other dietary information. Voluntary nutritional labeling was designed to help consumers prepare more nutritious meals, but it really hasn't worked, as least so far; and in our view there are two reasons why.

One is that it hasn't been accompanied by the educational efforts needed to make that labeling useful to the consumer.

We have suggested that an integrated effort is needed in this area by the private, voluntary, educational and public sectors of our society, and that this would be the most effective way to harmonize differing viewpoints on nutrition and develop a common information base to support nationwide nutritional education programs.

General Foods would be most willing to participate in such an effort.

The other reason, we feel, for the ineffectiveness of nutritional labeling thus far has been the cost, including the cost of the quality control procedures such labeling requires.

Such costs can be exorbitant, particularly for small manufacturers, as we've referred to earlier, in our comments this morning.

In our written testimony we support the concept of mandatory nutrition labeling, provided that such labeling is tied in with the permitted use of nutrition data bases referred to in the bill.

In our opinion, the concept of nutritional data bases represents an example of enlightened regulation. What's being done in this

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particular instance is to focus on the objective of providing consumers with more nutrition information on their food packages and then asking industry what the Government can do to help it provide that information without incurring unreasonable costs in the process.

However, there are other instances in S. 1652 where we feel this kind of commonsense approach has not been applied.

One is the proposal to include colors and spices in ingredient labeling. Most of these substances are present in foods in minute quantities, ranging from roughly one-tenth of 1 percent to less than one-thousandth of 1 percent.

If each specific constituent of these substances had to be listed, any change, even one representing one-thousandth of 1 percent or less of the total product, would require a label change.

General Foods believes that the present exemption from ingredient labeling for colors, spices and flavorings should be continued. Consumer concern usually involves a class of ingredients, not the specific component of a class.

Where there is an appropriate identification of a specific color, spice or flavor as an allergen to a significant segment of the population, then and only then, in our opinion, does such specific labeling make sense.

The other instance where this commonsense approach should be used is where foods are not consumed for nutrition purposes.

We see no reason for full nutrition labeling to be required for such foods as coffee, for example, or recipe type products like pectins or coconut.

Nevertheless, we feel that it could be useful with these products to provide calorie information for consumers. However, we were prohibited from doing this in 1973 by the FDA, which advised us that we would have to provide all specified nutritional labeling information or none of it.

We suggest that the nutritional labeling exemptions in the bill be clarified to allow commonsense exemptions from full nutritional labeling requirements based on intended product use.

In drawing up our testimony today, we in General Foods have tried to make suggestions that would help balance the cost of regulation with its benefits. We stand ready to provide any further assistance we can as your important deliberations continue.

Thank you.

[The prepared statement of Mr. Schroder follows:]

Testimony of Andrew J. Schroder, Vice President, Public Affairs, General Foods Corporation, Before The Subcommittee on Health and Scientific Research of the Committee on Labor and Human Resources of the United States Senate.

Mr. Chairman and Members of the Subcommittee, my name is Andrew J. Schroder, and I am Vice President of Public Affairs for General Foods Corporation.

We welcome this opportunity to present our position on S. 1652--the "Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug and Cosmetic Act." General Foods is one of the world's leading processors of packaged grocery products and markets a variety of such products throughout the world. Among the retail food products it processes and distributes in the United States are: frozen fruits and vegetables, ready-to-eat cereals, rice products, flour mixes, coffee, chocolate and cocoa products, desserts and toppings, breakfast beverages, soft drinks, syrup, baking powder, pectins, coconut, salad dressing mixes, meat and poultry coating mixes, and meat analogs. There are hundreds of different labels to encompass the variety, sizes, and flavors of these domestic products.

General Foods products are sold primarily at retail, and the company has always tried to be responsive to consumer interests and needs. In 1925 the Corporation (then the Postum Company) formed an education department with two home economists whose task was to provide consumers and teachers with nutrition information about the company's products. As the company and its product lines expanded, so did this department whose staff now numbers more than 90 and performs a wide variety of consumer and marketing services. Nutritionists in this department (now called the General Foods Consumer Center) provide nutrition information to consumers and are active in nutrition counseling for General Foods brands.

As a result of its correspondence with consumers on nutrition-related subjects, the General Foods Consumer Center is able to monitor consumer desires. When issues are raised often enough to reflect a genuine concern in a significant segment of the population, we attempt, where feasible, to

provide that information in our labeling. For example, years ago we determined that the most requested piece of information was the calorie content of our food products. As a result, calorie information was included on all our food labels many years before the nutritional labeling regulations were adopted. Likewise, we added fat source labeling long before FDA proposed such labeling requirements. We have also included source labeling for starch when we use a modified food starch. Because of expressed concerns over complex chemical names of some food additives, we have attempted to explain the function of many additives in our ingredient lines. When the quantity of sugar in presweetened cereals became an issue, we provided the amount of sugar per serving on our cereal labels.

One of the specific ways in which General Foods tries to make nutritional information generally available is through the distribution of a booklet entitled "Nutrition Information Can Work For You." This booklet contains a simple explanation of the importance of nutrition, a description of the key nutrients and their function, an explanation of U.S. RDA's, information on how to utilize nutrition labeling, and nutritive value charts for all General Foods' products which are nutritionally labeled. The booklet is revised annually and provided free of charge to any interested person, including consumers, educators, students, health professionals, and communicators. We ask that this booklet be included with this testimony for the record.

The present inquiry both by the Legislative and Executive branches of Government to determine what information consumers want on their food labels is, we believe, commendable. However, we suggest that a label cannot be all things to all people. Therefore, we propose certain general criteria against which labeling needs should be assessed:

1. Significance--As a general principle, everyone faced with a decision is in favor of more information to help in making that decision. But every proposed additional labeling requirement should have a clearly stated objective and there should be a strong conviction that the additional information is absolutely essential in view of that objective.

2. Editorializing--Research data exists showing that consumers want to make their own decision based on facts rather than on judgments about the product made by others. Symbols, of course, involve a judgment by others as to the appropriateness of the products. We believe it makes more sense to provide factual information to consumers who must possess the requisite level of nutrition knowledge and thereby make their judgments as to the products appropriateness vis-a-vis their own particular dietary needs.
3. Space--Available space on labels is finite. While larger packages of food may still have plenty of space for additional information, many small packages are already "bursting at the seams" with present labeling information. Limited label space could, of course, be supplemented by package inserts. However, this would begin to impact seriously on the issue of cost.
4. Clutter--Many consumers are already complaining that there is so much information on the label that it is confusing. What they want is a simpler, more understandable label. Each additional proposed labeling requirement should weigh the perceived benefit against the risk of increasing the complexity of the label.
5. Repetition--In a universe as cluttered or potentially cluttered as the food label, it would seem that once is enough. If information is already provided on the information panel, it should not be required elsewhere on the label.
6. Cost--Every label change involves cost. This cost can vary from the miniscule to the very significant depending on how often the changes must be made and what kind of a follow-up program is necessary by the processor or packer to support the accuracy of the label claim. Needless to say, all such additional costs are ultimately reflected in the price consumers pay for such label changes and the programs to support them. But cost factors are not limited strictly to consumer prices. They may also be reflected

in increased expense to the regulatory agency in the setting of tolerances, monitoring the label claims, and, where necessary, taking regulatory action.

With these general criteria in mind then, we offer the following comments on certain of the specific issues raised by S. 1652.

INGREDIENT LABELING

Recently there has been a considerable amount of discussion involving "full ingredient" labeling. While not always carefully defined in these discussions, full ingredient labeling usually revolves around two separate provisions of the law.

The first concerns standards of identity. Under the FD&C Act, products for which there are standards of identity need not disclose on their label the mandatory ingredients contained in the product. Such labels need only disclose any optional ingredients permitted by the standard. General Foods questions whether such an exemption from ingredient listing is appropriate today, and we support S. 1652's elimination of the exemption. Of course, foods not covered by standards have always been subject to full ingredient labeling.

The other area of the law involved is the section which permits spices, colors and flavors to be labeled as such without identifying the specific ingredients in those classes. Advocates of full ingredient labeling argue that each individual constituent in these classes should be listed on the label. Most of these substances are present in foods in minute quantities ranging from, roughly, one-tenth of one percent to less than one-thousandth of one percent. If each constituent of these substances had to be listed, any change--even one representing a thousandth of one percent or less of the total product--would require a label change.

S. 1652 would retain the exemption for listing of flavors but would require that colors and spices be listed specifically by name. General Foods believes there is merit in retaining the exemption as well for colors and spices. With one exception, we do not believe this information would be meaningful to consumers. We recognize that some consumers have a concern over the presence of these constituents. However, this concern is usually with regard to the class of ingredients, not to the specific components of the class. And the labeling of spices and colors as such provides them with the desired information. The exception to which we referred would apply when

one of the constituents of the class is identified clearly by appropriate scientific tests as an allergen to a significant segment of the population. We agree that it is then appropriate to label that specific color or spice or flavor. For example, FDA has identified the color FD&C Yellow No. 5 as an allergen and has promulgated a regulation to list it specifically. We are in agreement with that proposal, and General Foods is already in the process of changing its labels to identify Yellow No. 5 by name in those products which contain this particular color.

In short, we believe that the current laws and regulations regarding ingredient labeling are serving the consumer well. We do not believe there is a need for major changes except in the elimination of the standards of identity exemption as discussed above.

DECLARATION THAT INGREDIENTS ARE LISTED IN DESCENDING ORDER

S. 1652 also would require a food label declaration that ingredients are listed in descending order of predominance by weight. Such a label declaration simply means less space flexibility for manufacturers to display other information that could prove more responsive to consumers' needs. Additionally, this requirement appears totally inconsistent with another provision of S. 1652 which states that ingredients comprising five percent or less of a food product need not be listed in order of predominance. Consumers' understanding of ingredient labeling is not advanced by these inconsistent provisions.

NUTRITIONAL LABELING AND OTHER DIETARY INFORMATION

Nutritional labeling was introduced in the hope that it would aid consumers to prepare nutritionally sound meals. Data suggests that it has not succeeded in that objective. We believe there are two principal reasons for this lack of success. First, voluntary nutrition labeling was developed originally as an informational tool, and from the outset there was recognition that education would be required to make such labeling useful to the consumer. However, until very recently, there has been little focus on nutrition education--only periodic complaints about the adequacies of nutrition labeling. Until there is adequate progress on nutrition education, attempts to modify consumption behavior by revised nutrition labeling requirements have little chance of success. Second, nutrition labeling has remained voluntary because the cost of such labeling--including its related quality control procedures--has been exorbitant, particularly for smaller producers. We support with

certain modifications discussed below, the provisions of S. 1652 requiring mandatory labeling of calories and macronutrients provided it is tied in with the permitted use of nutritional data bases referred to on page 6, lines 9 through 13, of S. 1652.

We suggest the following modifications in the proposed nutritional labeling provisions.

1. Calories Supplied by Protein, Fats, and Carbohydrates. Lines 23 and 24 on page 5 would require that the amount per serving of protein, fat, and carbohydrates be expressed in terms of calorie content. While we agree that consumers have a strong interest in the total number of calories per serving, we see no evidence that there is any appreciable consumer interest in how much of these total calories are supplied per serving by protein, fats, and carbohydrates. We believe the present method of declaring grams per serving has become reasonably understood by consumers and that this method should be retained.
2. Use of Symbols. On page 6, lines 22 to 24 and page 7, lines 1 and 2, there is broad authorization provided for "symbols, figures, and other devices." We believe this constitutes editorializing by suggesting to consumers what is or is not good for them. We do not believe such an approach is desirable. Consumers themselves, and not others attempting to represent them, should be equipped with the knowledge and facts to make these choices based on their individual dietary preferences and requirements. We believe that factual information regarding nutrient content can best be communicated to the consumer in the form of grams per serving or other common household measure.

   It has been suggested that a pie chart format might be used to provide objective nutrition information. We have no reason to believe that such a format would convey nutrition

information more effectively to consumers than does the current nutrition labeling system. Indeed, this new approach could tend more to confuse than to clarify. We are convinced that such devices should not be relied upon without thorough testing to determine whether or not they are readily understandable and truly responsive to consumers' needs. Therefore, we suggest including such an approach in the bill, if at all, only under Section 5, Demonstrations and Evaluations, as a subject which might be worthy of testing.

3. Foods That Are Not Consumed For Nutritional Purposes. Prior to the adoption of the nutritional labeling regulations by FDA, General Foods had adopted the policy of labeling its directly-consumed products (as opposed to such recipe products as baking powder) with the number of calories per serving. When the nutritional labeling regulations were promulgated, we made the decision that all our products which could be considered meaningful sources of nutrition would carry nutritional labeling. However, we recognized that certain foods are not consumed for nutritional purposes and provide little or no nutrients. Our policy therefore did not extend to products such as regular coffee, syrups, and recipe-type products such as coconut, baking chocolate and pectins. On some of these products, we still wished to provide calorie information. However, under the nutritional labeling regulations, we were required to include all of the specified nutritional labeling information or none of it.

In 1973, we petitioned FDA to permit limited nutritional information. Our specific proposal was to permit just the calorie information plus a statement such as "not a meaningful source of nutrients." This proposal was rejected. As a result, certain General Foods' products have no information with regard to nutrition or calories.

S. 1652 would require all human food products to bear nutritional information. Paragraph (4) on page 6 of S. 1652, lines 18-21, does permit exemptions where it is "impractical or not necessary to provide health information to consumers." While this exemption provision is probably broad enough to cover situations such as we have described above, we believe the exemption should be clarified and strengthened with additional criteria, and we suggest the following specific language changes:

> (4) To the extent that compliance with the requirements of paragraph (1) is impractical or not necessary to provide health information to consumers, the Secretary may, on his initiative or pursuant to a proposal contained in a petition, prescribe exemptions from such requirements. In prescribing such exemption, the Secretary shall take into consideration the intended use of the products and whether any part of such required information would have practical meaning to consumers.

4. Labeling of Cholesterol. This bill requires labeling of the amount of cholesterol per serving unless the Secretary determines it is not necessary. We have a basic philosophic disagreement with mandatory labeling of cholesterol because, in our judgment and that of many nutrition experts, the cholesterol issue is still a scientific hypothesis. However, if mandatory cholesterol labeling is retained as part of this legislation, we do not believe it should be applicable across the board for all products.

Cholesterol is typically found in certain types of products, such as dairy products, meats, and shellfish, and may be totally absent from a wide variety of other products. While cholesterol information may be important in certain instances, it seems unnecessary to burden products which have no cholesterol or only insignificant levels with mandatory cholesterol labeling. Therefore, we recommend specific language changes that would leave to the Secretary

the determination of what cholesterol level is significant enough to require cholesterol labeling of food products.

5. Nutrition Data Bases. We regard the language on page 6 dealing with nutritional data bases to be so essential--particularly for smaller manufacturers--that the effective date for these reform measures should be scheduled to coincide with the time nutrition data bases are ready to utilized.

PREEMPTION

The preemption language in Section 4 of the bill should not exempt from its reach state and local efforts to prescribe open dating--particularly of food products having a longer shelf life. Regarding open dating, General Foods believes that federal standards are essential for determining uniformly the manner of open dating of perishable and semi-perishable retail food products, i.e., products with a shelf life of less than 90 days and 12 months, respectively. Further, we believe that there is no legitimate basis upon which to mandate the open dating of nonperishable products, a position that more recently has been supported by an August, 1979 OTA report dealing with this subject. Not to include open dating in this proposed preemption clause means the possibility of a multiplicity of label formats and, in turn, increased consumer confusion, higher costs due to lost efficiencies in food distribution and additional pressures on food prices.

MISCELLANEOUS COMMENTS

We have not commented on the specific language in Section 6 of the bill. As implied in comments made earlier in this testimony, General Foods strongly supports the concept of nutrition education and would hope to be able to support this Section of S. 1652 when rewritten.

Also, it is our opinion that Section 7 of S. 1652 must be eliminated in its entirety. We regard this bill as dealing with food labeling and with nutrition education largely in the context of food labeling. We see Section 7 as unrelated to this focus. It would remain inappropriate, we believe, regardless of how revised since the Federal Trade Commission's authority to regulate advertising is confined to that which is either "deceptive", "misleading" or "unfair" within the meaning of the Federal Trade Commission Act. Even amending the Federal Trade Commission Act to empower the Commission

to require that otherwise accurate advertising also carry specific nutrition information would appear to raise significant constitutional issues.

Finally, one provision which is not included in S. 1652 is a provision related to criminal penalties. Since this bill would require mandatory nutritional labeling and would permit labeling information derived from a data bank, we feel it would be appropriate to exempt this aspect of labeling from the criminal liability provisions of the Federal Food, Drug, and Cosmetic Act.

Again, we wish to express our appreciation for this opportunity to present our points of view concerning S. 1652. While we have reservations about some provisions of the bill, these largely relate to mechanics rather than objectives. I feel certain that by continuing our constructive relationships with you and the staffs involved, we can achieve final results that will benefit and be supported by consumers and industry.

Senator SCHWEIKER. Thank you. Mr. Schulze.

Mr. SCHULZE. Thank you, Mr. Senator.

I am a group vice president for consumer foods with General Mills. I would like to take the opportunity to thank you for inviting us to participate, and also to congratulate the subcommittee and especially Senator McGovern for what we would regard as a very thoughtful approach to a somewhat complex subject.

As I've mentioned earlier in response to questions, we agree with the major premises of this legislation, that the consumer should be provided with useful and usable nutrition information.

We believe that this bill, along with the other, represents a constructive attempt to achieve these goals, and although we do see some problems in the bill as now drafted, certainly our overall posture here is one of support.

I mentioned earlier also that the proposed legislation is in the main really quite consistent with what we are already doing with respect to nutritional labeling at General Mills.

We adopted nutritional labeling not because of pressure from regulatory agencies, but primarily because we found from our consumer research that consumers wanted this data.

We are in communication via mail or telephone, sometimes personal interviews, with approximately 8,000 consumers every week, and since food is essential life and a subject of great interest to everyone, I would say that they do not hesitate in any way to tell us what they like about our products, the packaging or the labeling, and in turn what they may dislike.

It's impossible to summarize accurately in a few words what consumers think about foods or labeling, but I think if I had to, I would make just a few points.

One is that most consumers today are aware that food consumption is an important factor in the general quality of their health.

Our research would indicate that nutrition, and of course taste is important here, cost, ease of preparation are critical factors which determine consumers choices.

Second, I would observe that consumers concerns over nutrition center about avoidance of certain foods or food ingredients. This is the major use which consumers are making today of food labeling.

For example, we know from research that something over half the population, adult population, is watching its weight at any given time, and since most people are quite aware of the relationship between excessive caloric intake and weight problems, the number of calories listed per serving on a food label provides an extremely important function.

In addition, our research indicates that next to calories, information on salt, sugar, and fat is of interest to consumers; and it is therefore not surprising that roughly 55 percent of consumers do look at the ingredient listing on food packages in deciding what to buy, and a slightly lower number, 45 percent, look at the nutritional information.

I don't think I'll spend a great deal of time on what we've done as a company regarding nutritional labeling or nutrition education. We've also worked in one case with the Department of Agriculture. We also have had nutritional information programs of our own involving labels, package labels involving television shows that we have produced and that have been running on a substantial number of stations in many markets.

Let me list very briefly the provisions of the bill with which we agree. I won't provide any support for why we agree, but when we get down to those that we disagree with, I'll try to elaborate in some more detail.

One, we are in agreement that the distinction between standardized and unstandardized foods for purposes of labeling should be eliminated.

Second, we support the use of common or usual name in labeling of food and ingredients.

I might note at this point that we have in the past received letters from children asking why we were poisoning our food with nitrates, by the addition of thiamin mononitrate. That is the chemical name for vitamin B_1. So there is some potential confusion when common names are not used.

We support the idea of the order of ingredients declaration. We suggested that this approach be adopted in the hearings of 1978 and we continue to support that provision.

We support enthusiastically the exemption of less than 5 percent on that subject.

In terms of sodium, we have instituted a corporate policy whereby all of our products include the labeling of sodium, and we are therefore supportive of sodium labeling.

We would regard a dual declaration, and I won't get into the details of that, which has been recommended, I believe, at times——

Senator SCHWEIKER. No, I'd be interested in that part. Go ahead.

Mr. SCHULZE. Well, we are currently required to list sodium in milligrams per serving as well as milligrams per 100 grams; and I think one of the problems that we have, Senator, and I'll skip to the last page of my testimony without reading it.

One of the suggestions that we would make that we think would be helpful in this regard would be—and again, we're adding a little

more clutter to what is already perhaps a cluttered side panel to the package. But we think a simple statement that says, "1 ounce equals 28.3 grams," would be useful to consumers, because we're adopting the metric system as a nation and yet many people simply do not understand that idea.

We state in terms of—all of our nutritional labeling information is stated in grams, and since most consumers, I believe, do not know that there are 28 grams in an ounce, I think this would be helpful.

Now if you did that, and in fact if you wanted to list everything in grams, you would get an idea of the relative importance of the individual ingredient in the product; and that's simply the reason of that. But in effect, we request that something else be done to simplify the problem.

In terms of calories, obviously, we do support labeling calories per serving.

Much has been said on the topic of preemption of State legislation in terms of open dating, and I agree with everything that has been said here by Dr. Bauman and Mr. Schroder.

I'm also going to skip the comments that I have, and you have them in detail, on the nutrient data base, because I think we've covered that in great detail and you know where we stand on that.

Senator SCHWEIKER. All right, and you concur with the other testimony?

Mr. SCHULZE. Yes, I do.

Now we get into some areas where we have some concern. One is the alternative source labeling of fats and oils.

We certainly support the concept of labeling by common or usual name of ingredients, as we indicated previously, but we do believe that food processors should continue to be permitted to declare alternate sources of fats and oils when they are not the predominant ingredient.

Requiring a specific declaration of the source of fats and oils would result in higher costs by reducing our flexibility. Given the volatility of the fats and oils markets, we believe that the cost in this case is not worth the benefit.

I think it's also interesting to note that the FDA's research indicated that 1 percent of the people were interested in that.

They are interested in type of fat, whether it's vegetable or animal, but in general, they are not interested in a difference in more detail than that.

In terms of colors, flavors and spices, we do support the concept of disclosure of colors, flavors and spices where there has been a determination by the agency through a proper hearing that a health problem exists. I won't comment any more on that.

There are a few provisions of the bill we simply cannot support. One is the idea of percent labeling.

We believe that it is important for a consumer who may be watching his or her intake of a specific ingredient, whether it be sodium or sugar, to know the precise amount of sugar or salt or fat, whatever, contained in a serving. We think that is extremely important.

Food is consumed in amounts. It is not consumed in percentages, and percentage labeling, in our judgment, is potentially misleading.

Let me just show you a little chart that we had made for this particular hearing, and I've listed three products, A, B and C, and I've listed on the top the percent of sugar included in those products.

If a consumer were trying to avoid sugar and we're looking at percentage labeling, obviously you would avoid product C first and then product B and then product A because the percentages are higher.

In fact, in terms of amount consumed, the reverse would be the case in that the product that has the highest percentage in terms of sugar content in fact has the lowest number of grams of sugar.

Senator SCHWEIKER. Now why is that?

Mr. SCHULZE. Well, it's because frankly in most of these products—and the middle one is a banana—because of the water content. The one on the right is a ready-to-eat cereal.

Senator SCHWEIKER. What are the three products?

Mr. SCHULZE. The one on the right is a ready-to-eat cereal. Product C is a ready-to-eat cereal, presweetened ready-to-eat cereal. The one in the middle, B, is a banana. The one on the left is a soft drink.

If you remove the water from all of them, you would have a rather different situation.

Senator SCHWEIKER. So the products that have the higher water would be what, then?

Mr. SCHULZE. Yes. The reason the percent sugar in product A——

Senator SCHWEIKER. Because of the water.

Mr. SCHULZE [continuing]. Because there's a lot of water in the product.

Senator SCHWEIKER. Well, what would your response be to using a calorie system?

Mr. SCHULZE. In terms of calories, we're against that, also, because——

Senator SCHWEIKER. Why are you against that? The calorie system does solve that problem. Do you have another——

Mr. SCHULZE. A little bit, but the consumer is really interested, and all of this research seems to indicate that—not only our research, but the FDA research—a very neat, quite simple way of communicating this data.

The consumer is very much interested in the calories per serving. The consumer is not much interested in where those calories come from.

The consumer is very much interested in the number of grams of sugar, salt, fat in the product, and I think if you start going combination, you're going to find confusion.

In fact, a study was done that showed both percentage and grams, and that could be an argument; why doesn't it show both? A study was conducted that indicated both the percentage and the number of grams, and the consumers, as it turned out, were misled more by that than by any other system. Showing both was more confusing.

You've mentioned the graphic symbol approach earlier. I was listening when you questioned the Food and Drug Administration representative.

We're very leery of that because it usually involves some kind of judgment. We're leery of it for the same reason that I just mentioned here.

I really think what we have now is pretty good where you list the number of calories, list the number of grams of fat, protein, carbohydrates, sugar and salt. It's a very clear way for the consumer to understand what's in the product, and also it facilitates communication. That is to say that the consumer at the point of purchase can compare what's in one product with what's in another product.

I'm not opposed, incidentally, to experimenting with some of these things. I just think it's going to be difficult to do anything better than the numbers.

Senator SCHWEIKER. I'm not quite clear. Why don't you like the graphics approach?

Mr. SCHULZE. Frankly, I don't think it will be as good as what we have now. In the past we have seen the graphic approach. We have experimented with it some ourselves, and usually they end up being more difficult.

If it's a little pie chart, it's hard to see the numbers in the pie chart given the space available on the panel; and if it gets into judgmental factors; that is, this product is good or this is bad, consumers have told us they'd like to make those decisions themselves.

Let me go fast here and take cholesterol. I'm going to dwell on that because I thought you made quite a point of that with the FDA.

We disagree with mandatory labeling of cholesterol on all products, as proposed in the legislation, and I'll tell you why.

If you'll look, I brought a list with me of products that are generally high in cholesterol, and I think you'd find it very difficult to label those products.

The highest, of course, is egg. Dried egg on this chart is the highest, but eggs are high.

Senator SCHWEIKER. Milk is high unless you get skimmed milk.

Mr. SCHULZE. Brains are the highest on this list. Oysters and other shellfish, organ meat. I think, and I'm not a medical authority, but it is not strictly the consumption of cholesterol that alone may lead to some possible form of heart disease. It is the consumption of fat, saturated fat.

I think where we are today is most of the processed food industry does, to the extent possible, list the number of grams of fat. I know at General Mills we do.

Here again you get into this problem of how are you going to handle what is the major source of fat consumption in the country, which is, frankly, fresh meats.

Senator SCHWEIKER. As soon as you have a heart attack, the doctor puts you on a low cholesterol diet. How do you explain what you just told me and that rather important medical fact?

Mr. SCHULZE. Well, I think——

Senator SCHWEIKER. There may be some controversy, but if you've been through the situation in terms of a heart attack, and I haven't, but the first thing they tell you is to cut it down. So why wouldn't that be something?

Mr. SCHULZE. Well, I think the reason for that is at the point that you suffered the heart attack, if it's due to that reason, is that your cholesterol has already risen to exceedingly high levels.

I'm saying that at least there's some medical testimony or evidence that says the way that you get there, get to those high levels, may be through lack of exercise or through heavy consumption of saturated fats.

Frankly, you're right. At that point it is too late, but it is not, at least as I understand it. There are better experts by far than me on this subject. It's not strictly the consumption of cholesterol that's important; it's probably more so the consumption of saturated fat.

Frankly, to list on products—what would happen, I think, if we had mandatory cholesterol labeling, is that a company like General Mills, we would be able to put it on the label and there would be a very, very small amount in some of our products; but the products that have the most cholesterol would probably not be ready to be labeled at this point in time.

So in effect, I think it might be misleading.

I think at this point, given all the questions, I've probably used up more than my share and I'll defer now to the Senator.

Senator SCHWEIKER. Mr. Bauman, at the November 15, 1978 nutritional labeling and information hearings before the Senate Agricultural Subcommittee, there was some discussion about the cost of changing labels as well as the cost of analytical work to insure that labels are correct.

At that time I believe you said it costs between $500 and $1,500 to change one label, and that your company had 1,300 labels.

Have your cost estimates changed in view of inflation or are they still pretty solid?

Dr. BAUMAN. You are probably referring to me. I think I made that——

Senator SCHWEIKER. It was your testimony.

Dr. BAUMAN [continuing]. In my testimony. We are developing much more detailed information on this. The figures that we have now out of our general procurement area, for instance, just for plate changes and things that are necessary, would indicate that with the number of labels we currently have with Green Giant and all, which is about 2,000, it would cost us approximately $5,640,000 to make a change in all of those labels at any one time.

Some are less, some are more, but that's a pretty good average of what it would cost us to change 2,000 labels.

That's only the plate costs. When we get into the analytical effort that's necessary, just the manpower time alone to take care of those changes would range from $3.5 million to $3.2 million; and we have a range because it's kind of difficult to estimate whether it's 3, 4, or 5 percent of the persons' times.

That's a second factor. The third factor is the analytical costs of developing the information that you need.

I cited the one example of the line of 19 pizzas produced in three different plants that would cost us approximately $600,000.

That's only one line of products, and if we consider all of the lines, such as Pillsbury, Green Giant alone have, and add all the others, we're talking many millions of dollars.

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Senator SCHWEIKER. Getting back to this other argument you were making that the data base saves money, would the saving from that offset this or not?

Dr. BAUMAN. Well, it would completely offset it, as far as I'm concerned, because right now, for example, and I'll be a little bit more specific, just taking one pizza in one plant that we have now.

To do a minimal number of analyses to insure that we're somewhere within the ballpark and can meet the requirements, we have to pull together and composite and end up with 19 different samples; and it costs us approximately $262—this is internal cost; probably three times that much externally—to analyze each of those 19.

That's something on the order of $40,000.

We multiply that again by 19 different products which have to be done the same way times three different plants, because the plants all vary. Then we've reached an astronomical figure of analysis.

Let's say that all pizza manufacturers begin to pool their data and we have data on pepperonies, we have data on the various flours in the data bank, we have data on the tomato pastes that are being used, and so on.

It's simply a matter of feeding your formula in and getting the data back from the data base, and then instead of running 19 samples to verify this, we just run a composite, say, stretching over a week's time, and one or two analyses could tell us whether we're in the ballpark or not.

If we're out of it, then we know we have to look for some problem that may exist; but it can simplify it tremendously, I think.

Senator SCHWEIKER. Mr. Schroder, in your testimony you indicated that the FDA rejected your proposal to modify nutritional labeling requirements when the products in question were not a meaningful source of nutrition, but you still desired to give the consumer information on calorie content.

What reason did the FDA give for rejecting that proposal?

Mr. SCHRODER. We could very easily check our files on this, Senator, if you would have an interest, and provide you with exactly what that communication flow was.

My recollection is this, that we began to provide calorie declarations on our products back in the mid-1960's. So we had, then, the voluntary nutritional labeling program begin in 1973, and at that point what we wanted to do for those products which were not principal sources of nutrition, such as coffee, for example, we wanted to continue providing calorie information.

My understanding is that the FDA, getting into this voluntary nutritional labeling program for the first time in 1973, really was just not prepared to grant any exemptions to requiring that all of the nutritional data to be required if you wanted to make any nutritional claim or provide any nutritional information.

So in effect, their policy was, "it's all or it's nothing." In effect, we just simply could not reach agreement on that point, and so therefore for those products not a source of nutrition and not consumed for that purpose, we had no choice but to also omit the calorie declaration that we would have liked to continue to provide.

Senator SCHWEIKER. Do I understand from your previous testimony of the cost impact on your company of this bill, that you would agree it's a net plus, along the line of what Dr. Bauman said, or do you have a different——

Mr. SCHRODER. I would not be in a position to give you a definite answer to that now.

What I would say, as I indicated earlier with some specific numbers, is no doubt we're going to save funds as a result of not having to do the nutritional analytical work that we're doing now on the assumption that we do get into a data base concept.

It sounds to me that Pillsbury has come a little bit further than we have so far in terms of being able to assess specifically what the dollar significance is of making label changes.

We've done some rough work on that, and again it would seem that if we had to redo all of our labels in the United States on all of our domestic packages, that we'd be talking—again this is rough—about a number somewhere between $5 and $6 million.

So there would be some offset of that kind of cost were we to have a nutritional data base to rely on so we didn't have to do the analytical text work on the other side.

We're just not simply far enough along at this stage to know whether we've got a net plus or a net minus. We just don't know.

Senator SCHWEIKER. Mr. Schulze, do you have any other response to that same question?

Mr. SCHULZE. No, we have not updated our data for several years. My recollection is that 4 or 5 years ago the costs were in the neighborhood of $3 million, and I would assume that given inflation——

Senator SCHWEIKER. At the tripartite agency hearings earlier this month on food labeling, General Mills stated that they believe consumers want a statement that ingredients are listed in descending order.

I just wonder what you based this on and what kind of consumer studies you might have done that might be helpful to us?

Mr. SCHULZE. Yes; we have learned that from a number of interviews over the past 3 or 4 years. The fact is that they are listed in that order and I see no reason why the consumer shouldn't be entitled to that information.

Senator SCHWEIKER. Who do we owe thanks to for the cookies?

Mr. SCHULZE. Composite.

Senator SCHWEIKER. I hope they are low sodium; that's all I can say.

We thank you very much for your testimony and appreciate your participation here today. Thanks a lot.

[The prepared statement of Mr. Schulze follows:]

TESTIMONY BY ARTHUR R. SCHULZE
GROUP VICE PRESIDENT
GENERAL MILLS, INC.

re

U.S. SENATE BILLS 1651 and 1652

before the

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

of the

COMMITTEE ON LABOR AND HUMAN RESOURCES

U.S. SENATE

WASHINGTON, D.C.

March 19, 1980

GENERAL MILLS TESTIMONY RE U.S. SENATE BILLS 1651-2

My name is Arthur Schulze, and I am a Group Vice President for Consumer Foods with General Mills, Inc. On behalf of General Mills I would like to thank the subcommittee for extending to us the opportunity to be heard on this very important matter of food labeling.

My testimony this morning will include three major points. First, we support the effort to improve food labeling and, in general, are supportive of most of the provisions of these bills. Secondly, nearly all of General Mills' products are currently carrying nutrition labeling, in response to what we have perceived to be a real consumer need. In this connection, I hope that our experience on nutrition labeling will enable us to make suggestions and comments that will be useful to the subcommittee. Third, we are concerned about, and in some cases opposed to, some features of the bill. I will offer specific reasons for our objections.

Let me start by congratulating the subcommittee and especially Senator McGovern for the thoughtful approach that he has taken to what may be considered a technically complex subject. As I mentioned at the outset, we agree with the major premises of this legislation: that the consumer should be provided with useful and usable nutrition information. The two bills, S1651 and S1652, we think represent a constructive attempt to achieve these goals and while we will address several of the problems that we see in the bills as now drafted, our overall posture is one of support for the subcommittee's efforts and objectives.

The proposed legislation is, in the main quite consistent with the current labeling practices of General Mills, which in turn have been based on what our market research has told us about consumer's needs for informative labeling. At this point I should like to add that we are in communication, via mail, telephone or personal interviews with approximately 8,000 consumers per week. And since food, which is essential to life, is a subject of very great interest to everyone, consumers do not hesitate to tell us what they like, or dislike about our products, packages, labeling, or advertising.

And while it is impossible to summarize accurately in a few words the results of what we have learned about consumer food needs, I think it would be useful to offer these conclusions:

1) Most consumers are aware that food consumption is an important factor in the general quality of their health. Our research indicates nutrition, along with taste, cost and ease of preparation, are the four most critical factors which determine consumers' food choices.

2) Consumers' nutrition concerns center about avoidance of certain foods or food ingredients. This is the major use which consumers make of labeling. For example, approximately half the population is watching its weight at any given time. Since most people are aware of the relationship between excessive caloric intake and obesity, listing the number of calories per serving on a food label serves an extremely important function.

3) General Mills' consumer research indicates that, in addition to calories, information on salt, sugar and fat is of interest to many consumers. It is not surprising then that 55% of consumers look at the ingredient listing on food packages in deciding what to buy, while a slightly lower number, 45%, look at the nutritional information. Incidentally, these statistics have not changed much in the past year and a half. It is clear that both ingredient and nutrition labeling is currently being used by significant numbers of consumers and that the current labeling format is quite useful. This is underscored, I believe, by the results of a 1979 national study of 1,374 consumers conducted by Response Analysis Corporation and sponsored by the Food and Drug Administration. The study indicated that only 8 percent of consumers interviewed had specific problems with current food labeling compared to 59% who said they were "completely satisfied." Approximately 33% did see a need for some improvement in food labeling.

I don't want to spend a great deal of time on what General Mills as a company has done regarding nutritional labeling. I believe our record speaks for itself. We have, for example, been nutrition labeling our cereal products since 1941. The voluntary nutritional labeling currently prescribed by FDA has been on virtually all of our products since 1974. In addition, in 1978 we began to include sodium content in our labels, and, in

the case of breakfast cereals, began to provide sugar content as well. Over the years we have supported numerous nutrition education programs, including one highly successful program for pre-school children developed in cooperation with USDA.

At this point, let me proceed to those provisions of the bill with which we agree.

1) Standardize v. Unstandardized Foods. As in the past, we support the elimination of the distinction between standardized and unstandardized foods for purposes of labeling.

2) Common Name Labeling. We support the use of a common or usual name in labeling of food. We also support the common or usual name labeling of ingredients. In this connection, we would like to see that carried one step further so that names like pyridoxine hydrochloride be labeled as Vitamin B_6. The currently required use of chemical names does little to inform the consumer. For example, General Mills has received letters from children in a California school asking why we were poisoning our food with nitrates by the addition of thiamin mononitrate. Thiamin mononitrate is the chemical name for Vitamin B_1. Apparently the teacher who sponsored the letter writing project confused thiamin mononitrate with the use of nitrates as preservatives.

3) Order of Ingredients Declaration. We suggested during the regulatory agency hearings of 1978 that a statement should be made indicating that ingredients are listed in descending order by weight. We continue to support this provision.

Our current plans are to have our nutritional information panels carry such a statement in the near future.

4) Ingredients of less than 5%. We support enthusiastically an exemption from the order of predominance labeling those ingredients individually comprising less than 5% of a product.

5) Sodium. As I mentioned, we have instituted a corporate policy whereby all of our products include the labeling of sodium and we are therefore supportive of sodium labeling. In this regard, however, we are currently required to list sodium in milligrams per serving as well as milligrams per hundred grams of the product. Frankly, we regard this dual declaration system as being unnecessary, and would recommend listing sodium only in milligrams or grams per serving.

6) Calories. We support labeling calories per serving.

7) State Preemption. We wholeheartedly endorse and support the preemptive aspects of the two bills. You are probably aware that the State of Massachusetts has promulgated open dating regulations for non-perishable products, the only jurisdiction--state or federal--to do so. Our perishable products already carry an open date. Compliance with the Massachusetts legislation will require a rather substantial investment in equipment, and also increase our operating costs--cost increases which do not appear to produce a tangible consumer benefit. Without going into the details, let me just add that the Federal Government's own Office of Technology recently has studied this issue and agrees that there is no justification or rationale to support open code dating of non-perishables.

The following additional provisions we support in concept and compliment the subcommittee for considering them:

8) Nutrient Data Base. We support the implementation of a data base or source of information for use in nutrition labeling of commodities. Nutrition labeling based on analyses of each food company's products may be appropriate for certain categories of formulated foods, but for many fruits, vegetables, meat, fish and similar products, that requirement is an unduly burdensome and costly process. Yet, nutrition labeling of these commodity-type products is crucial if complete labeling information is to be provided to the consumer. For instance, concern exists about fat labeling on processed foods, yet a third of the fat in the American diet comes from meat, poultry and fish, for which essentially no labeling is available.

We thus suggest, as we did before the joint FDA, USDA and FTC labeling hearings in San Francisco in 1978, that a data base be compiled for the labeling of commodity-type foods. This data base should be developed from representative nutritional values for specific categories of products. Nutrition labeling could then be based on these representative values.

Let me cite an example. Fish products are extremely difficult to label nutritionally because of the variation in nutritional value of the various fish species. An average for, say, codfish, obtained from a data base such as Handbook 8 could be used for the purposes of establishing the nutritional value of fish products. Thus, a manufacturer would not have to analyze each

and every lot of raw fish used and would not have to change cartons with every new lot. The establishment of a data base along the lines suggested is essential for implementation of a complete nutritional labeling program, which would include nutrition labeling of such items as meats, fruits, and vegetables.

A key to the success of a nutrient data base is to simplify and reduce the cost of developing data. In addition, it is just as critical to keep compliance simple if industry is to expand labeling without incurring new and significant costs. Nutrition labeling does not need to be more precise than the variability of human nutrient needs or the normal nutrient variability of foods. Use of a nutrient data bank should be consistent with this variability as well as the recognized need for consumers to eat a variety of foods.

9) Alternative Sources of Fats and Oils. While we support the concept of labeling by common or usual name of ingredients, as we indicated previously, we believe that food processors should continue to be permitted to declare alternative sources of fats and oils when they are not the predominant ingredient. Requiring a specific declaration would result in higher costs by severely reducing the flexibility of the processor. With the volatility of today's fats and oils markets, it is essential the current labeling alternatives be continued.

10) Colors, Flavors and Spices. We support in concept the disclosure of color, flavor and spices where there has been a

determination by the agency through a proper hearing that a significant health problem does exist with regard to the ingredient. A recent example is FD&C Yellow No. 5, which FDA will require to be labeled specifically beginning July, 1981. We believe that it is better to handle these problems on a case by case basis rather than by broadsweeping legislation.

Let us turn now to those provisions of the bill that we cannot support.

1) Percent Labeling. First, we oppose a declaration of ingredients or characterizing ingredients by percentages. We believe that consumers ought to know the precise amount of sugar or salt or fat contained in a serving in order to facilitate comparisons with alternate products. Food is consumed in amounts, not percentages; thus percentage labeling is potentially misleading. For example, here are three food products commonly consumed in American households (read from chart):

	PRODUCT A	PRODUCT B	PRODUCT C
%Sugar	11%	17%	39%
Amount of Sugar	37 grams/ serving	20 grams/ serving	11 grams/ serving

As you can see, the percentages bear no relation to the actual amount of sugar contained in a serving of each product. This is because other ingredients which are inherently present in many products (such as water), and which have no bearing on nutritional value, are factors in percentage calculations.

As you can see, this can lead the consumer to a false conclusion as to which products contain the most sugar. For these reasons we remain opposed to percentage labeling in any form.

2) Nutrition Disclosures in Advertising. We also oppose strongly the provisions in the two bills which would empower the Secretaries of HEW and Agriculture with authority to recommend to the Federal Trade Commission the inclusion of nutritional information in food advertising. Quite apart from the legal questions that can be raised about FTC authority in this regard, the requiring of nutritional information in advertising also fails on its merits alone. The primary purpose of advertising is to call attention to those distinguishing characteristics or attributes which are likely to be of primary and significant interest to the consumer. With some products, a specific nutritional feature may well be of important interest to the consumer and this is likely to be stressed. On the other hand, there are many, many products in which the consumer has no genuine interest in nutrition. In such cases, it does not make sense to require the communication of information which the Secretary may find of interest but is of no interest whatsoever to the consumer, particularly given the limits and constraints inherent in a 30-second television commercial.

In addition, the meaningful communication of numerical nutritional data is not facilitated well through the television media. It seems highly unlikely that the average consumer could absorb,

let alone comprehend fully, the series of numbers involved in communicating, for instance, the number of calories, the number of grams of protein, carbohydrate and fat and the percent of U.S. Recommended Daily Allowances of several vitamins for an individual serving of an individual product. Further, if only one or two of the nutritional components are selected for mention, the net effect is that the consumer may be misled into thinking they they are the only nutrients available or significant in the product. It would seem, therefore, that nutritional information can be best communicated through package labeling at the point of purchase. This enables the consumer to make nutritional comparisons of one food product versus another and to make an informed choice based on those comparisons.

3) Use of Graphic Symbols. The legislation invests the respective secretaries of HEW and USDA with authority to prescribe labeling systems which employ graphic symbols. We urge that this be pursued with a great deal of caution. We have yet to see graphic symbols for use in nutrition labeling which do not editorialize. Research by the Food Marketing Institute as well as our own communications with consumers make it very clear that the public does not want nutrition labeling to editorialize. As elected public officials, I am sure you are sensitive to the considerable resentment among the American people to being told by the government--or anyone else, for that matter--what to do, including what foods to eat. Consumers want labeling information, but they want it presented to them in a straightforward fashion. They know better than does anyone else their own budget limitations, family tastes and lifestyle patterns.

4) Cholesterol. We disagree with mandatory labeling of cholesterol on all products as proposed in this legislation. Cholesterol is significantly present in a relatively few number of food categories, namely meats, shellfish and dairy products. It does not make sense to label for cholesterol the great number of food products which do not contain any cholesterol or which contain only insignificant amounts.

5) Calories Supplied by Proteins, Fats and Carbohydrates. We strongly object to the approach suggested in the bills that protein, fat and carbohydrate be listed in terms of caloric content. We prefer the current listing of protein, fat and carbohydrate in grams per serving. This is the most meaningful way to communicate this information to the consumer. This was the conclusion of the FDA when the original food labeling regulations were published in 1974, and we are aware of no consumer research since that time that indicates there should be a change. In fact, a study on sugar labeling by the research firm Market Facts, Inc., demonstrated that consumers accurately identified the relative sugar content of different foods most often when the sugar content was shown in grams per serving, compared to when it was shown as a percentage by weight.

6) Authorities Vested in the Secretaries. We are somewhat concerned about the broad powers which might be vested in the Secretaries of Agriculture and Health, Education and Welfare should this legislation be enacted. There currently exist procedures

and mechanisms which enable all interested parties (processors, regulators, consumers) to offer comments prior to the adoption of specific requirements, including labeling or, for that matter, other regulations. The vesting of undue powers in individual secretaries would constitute a major deviation from current policy. At this point in time we see dangers in this deviation, and respectfully submit that the current system, which begins with the proposing of a rule, followed by comments and careful evaluation, is a much more systematic, fair procedure which helps, to the extent possible, to ensure due process.

We also request that any legislation that is adopted be very specific in nature so that USDA and FDA are not in a position to exercise broad discretion in creating new labeling requirements based on their own subjective beliefs as to what the consumer wants. Like you, we have an interest in knowing what the consumer wants. We must be careful, however, to distinguish between what the majority of consumers want and what you or I or any government agency thinks the consumer needs. The value judgment must remain with the consumer.

Conclusion.

Let me conclude by offering one suggestion and one observation. First the suggestion. I believe that it would be informative and useful to consumers to add the simple statement "28.3 grams = 1 oz." on all food product labels. Our own experience is that this fact is not commonly known or understood by many consumers

because of unfamiliarity with the metric system. Since, as a nation, we are committed to a metric system it makes sense to continue to provide nutrient information in grams per serving. The inclusion of this simple statement on food product labels would improve the usefulness of nutritional labeling systems.

And now the observation. It would seem to me that the success of any labeling information system, whether it be to provide information about foods which some consumers may wish to avoid or whether to provide information genuinely needed for functional nutritional reasons, depends largely and most importantly on information being available on all foods. It is of little use for a weight-conscious consumer to know that there are 110 calories in a bowl of Cheerios or Wheaties, which provide the consumer with about 6% of his daily caloric needs, but not to know the numbers of calories present in meat or poultry, which represent approximately 20% of calories consumed. Similarily, it would seem quite important that a consumer wishing to avoid fat would be able to determine, at point of purchase, the approximate number of grams per serving in hamburger, steak, or chicken. I recognize that there are practical limitations on the ability of meat packersand food processors to provide this information in an accurate and inexpensive manner. However, until such time that this is made possible, any system of nutritional labeling will be at best incomplete.

Thank you very much.

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Senator SCHWEIKER. We've got to give credit. The staff did the cookies, but it was a Pillsbury cookbook recipe, so we have appropriate credits.

Our next panel includes Ellen Haas, director, Consumer Division, Community Nutrition Institute; Dr. Richard Hagen, Washington Laboratory, National Food Processors Association; Robert W. Bracken, president, Morton Frozen Foods, representing the American Frozen Food Institute; Karen Brown, vice president, Food Marketing Institute.

Now, I'll let you proceed in that order unless you have some other order you'd like to proceed in.

STATEMENT OF ELLEN HAAS, DIRECTOR, CONSUMER DIVISION, COMMUNITY NUTRITION INSTITUTE; RICHARD HAGEN, PH. D., VICE PRESIDENT, EASTERN RESEARCH LABORATORY, NATIONAL FOOD PROCESSORS ASSOCIATION; ROBERT W. BRACKEN, PRESIDENT, MORTON FROZEN FOODS, REPRESENTING AMERICAN FROZEN FOOD INSTITUTE; AND KAREN BROWN, VICE PRESIDENT, FOOD MARKETING INSTITUTE, A PANEL

Ms. HAAS. Thank you very much, Senator Schweiker.

I'm Ellen Haas, director of the Consumer Division of the Community Nutrition Institute, and I'd like to ask that my complete statement be in the record and I will summarize my comments this morning.

Senator SCHWEIKER. Very good.

Ms. HAAS. Also, let me say that consumer advocates also eat cookies. When I'm completed, I will indulge.

It is indeed a pleasure to be here today to testify in very strong support of S. 1652, and it's very encouraging for me having heard the testimony that preceded us to be very encouraged to how far we've come in the food system, to hear how food manufacturers certainly have responded very responsively and enthusiastically to what I believe is very significant legislation.

We believe that the development of food labeling policy refocused to meet the health and economic needs of the American people is and ought to be a national priority, and S. 1652 should provide an appropriate legal framework that we've been wanting for so long for food labeling in the 1980's.

In hearings of this committee in June 1978, and again in hearings before this committee several weeks ago, the relationship of diet and health have been closely examined.

It has been clearly stated many times over this past year that the shift in dietary patterns over the past many years have left in their wake health problems which are the leading causes of death today: Heart disease, stroke, cancer, obesity, and hypertension.

These conditions place a tremendous strain on society and one that we should be cognizant of in these troubling inflation times; that is, elevated medical costs, human disability, premature deaths, and decreased human potential during most of life.

There is only one approach that we believe that will be truly worthwhile, and that is efforts that must be stepped up to insure the prevention of these dietary disabilities.

As Senator Kennedy has stated earlier in this committee, "The consumer's ability to select a better diet is a critical factor in preventing disease and promoting health."

In the few short years since the Senate Select Committee on Nutrition and Human Needs published its findings on the link between diet and disease, there truly has been a growing concensus of scientific thought.

Just this year in the published Surgeon General's report on health promotion and disease prevention and the publication of the dietary guidelines by USDA and HEW, these two policy approaches have made landmark contributions to the evolution of rational scientific thinking.

So, too, in the past year we've had unprecedented consumer and consumer organizational participation in the food labeling hearings before the three-agency food labeling task force, and they have made it clear that they are concerned about the relationship of diet to health and that they need more, different, and better information on the foods available in grocery stores and elsewhere.

May I also say that that represented the participation of hundreds of consumer representatives and consumer organizations in those hearings, and at the recent annual meeting of Consumer Federation of America, the Nation's largest consumer organization representing more than 200 organizations and which I've just concluded my second term as president, I must say that we passed a unanimous resolution in support of mandatory nutrition labeling, as is in this bill, S. 1652.

For consumers the label is a critically important tool for making food decisions. The sponsors of this legislation have undertaken the very important objective of bringing our Nation's laws up-to-date with today's needs; and I must say, as was said earlier this morning, in a commonsense approach.

S. 1652 derives its vitality and significance from numerous features. I will only briefly touch on four that we believe are highly important.

First, mandatory nutrition labeling: CNI fully supports this. Unless uniformly available, many of the most important applications of such labeling will be precluded, especially the most important, comparison shopping; and I believe that the approach that's taken is truly one that meets the needs of both industry and consumers, and that is that such information be based on nutrient data bank analysis provided by the Federal Government cooperatively with the industry.

It is fair to say that consumers, industry, and regulators share equally the view that nutrition information must be provided at the lowest possible cost.

It's widely recognized that by adopting the representative value approach utilizing the nutrient data bank, the legislation assures that labels will display the essential information at minimum cost.

Equally important, though, and one that we must not forget, is the axiom that nutrition information itself is anti-inflationary.

Mandatory nutrition information will allow each and every consumer in waging his personal war on food inflation to get more bang for his buck. When food prices rise faster than personal income, families make inevitable nutritional and health compro-

mises, but mandatory nutrition information will permit a new type of food shopping to occur.

Mandatory nutrition information will make the traditional cost comparisons of consumers more meaningful by allowing nutrition to be factored into the product's price and value so that appropriate substitutions can be made where necessary.

The second point of concern to us is percentage ingredient labeling, which we believe is vitally important for making economic and nutritional value comparisons in a meaningful way.

How much beef in beef stew is very important to consumers in making their decisions when food prices rise more than 10 percent each year in the past 3 years.

However, we feel that S. 1652's treatment of percentage ingredient labeling is too limited. Quantitative declarations of some health-related, noncharacterizing ingredients would not only be helpful to some consumers, but it would also be essential to most.

The nutrition labeling framework envisioned by S. 1652 provides only for information on total carbohydrates, fat and salt, yet the thrust of the dietary guidelines is that intake of too much sugar, fats and salt should be reduced.

For this reason, consumers of such foods as canned fruit or celery in cream sauce need to know the quantity of added sugar or sodium; therefore, percentage ingredient labeling is very important, not only for characterizing ingredients, but for those ingredients that have an accumulative effect and those that relate to our health, such as sugar, fats, and salts.

Senator SCHWEIKER. Let me ask a question. We just saw that chart, of course, where a soft drink came out looking like the good guy in the white hat and a lot of people would say it's the bad guy in the black hat. How do you respond to that?

Ms. HAAS. Sitting there, I wanted to respond to that very much.

First of all, consumers do not make their comparisons between whether they will buy sugared cereals, bananas and soft drinks.

You buy a comparison between soft drinks and other soft drinks, and the concern is what you add to the product. You can't avoid what is already inherently in a product, such as fruit, the sugar that's inherently in it; but you can avoid adding to products, and labeling gives an incentive to processors to reduce that added sugar or that added salt, because it's going to be information that's on the label for the consumer.

I felt that it was somewhat misleading to compare in discussing percentage ingredient labeling packages of products that we don't comparison shop in the supermarket.

Senator SCHWEIKER. Let's take your analogy and let's compare soft drinks. It seems to me as I read that chart, there's an incentive to put more water in my soft drink so that my percentage of sugar looks lower than yours as a competitor.

I mean, if somebody has a 12 percent of sugar, all they have to do is add more water, and they only have 10 percent sugar. That's quite an incentive to water down your food.

Ms. HAAS. Well, perhaps, it may be an incentive to water it down, but at the same time you might be getting more nutrition from your soft drink than you would if you had all that high sugar content in it.

Senator SCHWEIKER. It depends on what kind of water it was.

Ms. HAAS. If it was sugar water, you'd have a problem.

But I think that's a good case in point. Perhaps diluting the heavy concentration within the Coke or Pepsi or whatever it is might be something that we want to encourage.

Again, I think that this is essential information and one that relates our health concerns to our label.

If I can go back, I think that we have many examples of foods that contain noncharacterizing ingredients, for example, of sugar, such as peanut butter, salad dressing, catsup, unsweetened cereals, mayonnaise and nondairy creamers.

Consumers need to know the percentages of sugar in those kinds of products as well.

One area that I'll just touch on briefly is the requirement that a declaration of fats, carbohydrates, sodium and cholesterol be made.

We feel that this is vital information and it responds very positively to the dietary guidelines and the Surgeon General's report.

Something that I find very interesting in this legislation that perhaps gives food labeling a tremendous chance of success without costing the industry unnecessarily in changing the label again in 5 years.

This legislation provides for a 2-year period of pilot programs or demonstration projects on the labeling. We've heard discussion this morning about the use of graphics, changing the format. Through this 2-year period, we will, through a tested period of time, we will know what works and what does not work.

Senator SCHWEIKER. How do you feel about graphics?

Ms. HAAS. I personally believe that this format needs to change and I think that a format based on graphics would be useful to consumers; but some of the ones that have been available, like the pie shape, have certain problems with them in consumer understanding, and I'd like to see it evaluated.

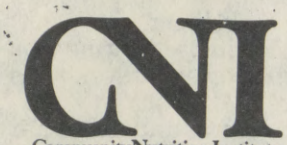
I've not seen a decent evaluation of it up to this point.

In conclusion, let me say that we think that this bill through all of this period of time to determine where the industry sits on it, where the consumer sits on it, where the regulators sit on it is a bill whose time has come.

During these trying times of double-digit food inflation and increasing knowledge about the links between diet and disease, S. 1652 would provide consumers with the long-needed tools to arm themselves in today's complex marketplace without presenting unnecessary financial burdens on industry. We don't have those opportunities too many times.

We support S. 1652 as an effective, inflation-fighting, health-enhancing, protective measure for the consumer of tomorrow.

[The prepared statement of Ms. Haas follows:]



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Statement of Ellen Haas
COMMUNITY NUTRITION INSTITUTE
Before the
Senate Human Resources Subcommittee on Health
Regarding the Nutrition Labeling and
Information Amendments: S.1652

The Community Nutrition Institute is a non-profit public interest organization that supports the development of a national food and nutrition policy serving consumer needs at the community level. We publish a weekly newsletter (CNI Weekly Report) on food and nutrition issues and we provide training and technical assistance services as well as sponsoring workshops and conferences on public policy issues in food and nutrition.

BACKGROUND

It is indeed a pleasure for me to present the views of CNI on the important recent developments in food labeling. We have long been very deeply involved in efforts to reform the presently inadequate legal framework for food labeling in order that the American consumer might have access to the information they need and want.

We believe the development of a new food label, refocused to meet the health and economic needs of the American people, is and ought to be a national priority. We testify here today in support of S.1652 which will provide, for the most part, an appropriate legal framework for food labeling in the 80's.

During hearings of this committee, in June, 1978, on the need for comprehensive nutrition information and food labeling, I spoke on the long-evolving approach toward diet and health throughout this century.

As you will recall, with the discovery of vitamins over 75 years ago, nutrient deficiencies became the focus of the science of nutrition. With the growth of technology and a changing demand of a more affluent society, our diets shifted from basic and traditional foods to more highly processed foods. Seeking to avoid nutrient deficiencies, we ate more: more meat, eggs, cheese, fruit, vegetables, and cereal. In their processed forms they contained invisibly large quantities of fat, salt, sugar and other highly refined carbohydrates. In addition, as a result of that processing, many nutrients were lost; only some to be replaced by set quantities of specific nutrients.

These and other dietary developments have left in their wake an epidemic of health problems which are the leading causes of death today: heart disease, stroke, cancer, obesity and hypertension. These conditions place a tremendous strain on society--in elevated medical costs, human disability, premature death, and decreased human potential during much of life. These

are diseases which often cannot be adequately treated after diagnosis; the societal loss cannot be regained on the surgical table or over the counter. There is only one approach that will be truly worthwhile--efforts must be stepped up to ensure the prevention of these dietary disabilities. As Senator Kennedy has stated, "the consumer's ability to select a better diet is a critical factor in preventing disease and promoting health."

RECENT DEVELOPMENTS

In the few short years since the Senate Select Committee on Nutrition and Human Needs published its findings on the links between diet and disease, the evolution of which I spoke earlier, has changed course dramatically. We have since seen numerous "fronts" open up in our overall effort to provide American consumers with an opportunity to obtain a nutritious health-supporting diet at affordable prices. The Surgeon General's Report on Health Promotion and Disease Prevention and the publication of the Dietary Guidelines by USDA and HEW have both made landmark contributions to the evolution of rational policy and reflect the emerging scientific concensus to which officials of both Departments refer, on the relationship between diet and health.

Consumers, through their unprecedented level of participation in the food labeling hearings before the three agency Food Labeling Task Force have made it clear that they are concerned about the relationship of diet to health and that

they need more, different and better information on the foods available in grocery stores and elsewhere. Survey after survey reveals that consumers are becoming more knowledgeable about the advantages and disadvantages of certain dietary components and patterns but that they aren't getting the kind of information they need to make the right food choices.

For consumers, the label is a critically important tool for making food decisions. Essentially, it links knowledge on nutrition to voluntary modifications in diet and food purchasing patterns. The information consumers seek is not something which can be intuited or committed to memory. Nor is it reasonable to expect them to write food manufacturers for data which survey after survey reveals is so basic that it would be used routinely by large numbers at point of purchase.

The Food Labeling Task Force (of FDA, USDA and FTC) has responded in an appropriate fashion to the outpouring of consumer interest in a refocused food label. The three agencies have conducted the most comprehensive review of food labeling ever undertaken. The voluminous product of their labors is something which contributes greatly to the literature and will serve as the foundation for all future discussions on food labeling, both in the agencies and inside Congress.

In the Senate, the response has been equally gratifying to consumers. In furtherance of their commitment to progressive national food and nutrition policies, the sponsors of the legislation have undertaken the very important objective of

bringing our nation's laws up-to-date by offering two major bills that would largely provide the needed legal framework for refocusing the food label.

The role of this committee and its staff as well as Senator McGovern's Nutrition Committee and its staff has been decisive in identifying the degree to which industry, consumer, and regulator perspectives are compatible and this alone has been the single most important factor in the success you have had in obtaining the broad support of so many parties interested in food labeling.

ANALYSIS OF LEGISLATION

In general CNI has allocated a high priority to passage of legislation of the type now before this committee. S.1652 derives its vitality and significance from numerous features, four of which I will briefly address specifically.

1. Mandatory Nutrition Labeling

CNI fully supports mandatory nutrition information labeling. Unless uniformly available, many of the most important applications of such labeling will be precluded, especially comparison shopping to ascertain, for example, the degree of processing that may have altered the nutrient composition of the food as compared with its traditional counterpart or other analogous processed alternatives.

It is fully appropriate that such information be based on nutrient data bank analysis, provided by the federal government cooperatively with industry. Consumers, industry and regulators

share equally the view that nutrition information must be provided at the lowest possible cost. It is widely recognized that by adopting the representative value approach, utilizing the nutrient data bank, the legislation assures that labels will display the essential information at minimum cost. Equally important, though, is the axiom that nutrition information is anti-inflationary in itself. Mandatory nutrition information will allow each and every consumer, in waging his war on food inflation, to get more "bang" for his buck. When food prices rise faster than personal income, families make inevitable nutritional and health compromises. Mandatory nutrition information will permit a new type of food shopping to occur. Mandatory nutrition information will make the consumer's traditional cost comparison more meaningful by allowing nutrition to be factored into the product's price and value so that appropriate substitutions can be made, where necessary.

2. Percentage Ingredient Labeling

Existing food labeling laws and regulations serve the consumer well in guaranteeing that beef stew contains some beef and that mushroom soup contains some mushrooms. It is time however, to move ahead. Today's consumer wants to know how much beef and mushrooms are in the respective containers. Just as today's food shoppers require nutritional information for shopping, they also need percentage ingredient labeling to make economic and nutritional value comparisons in a meaningful way.

(7)

S.1652's treatment of percentage ingredient labeling is an area which we believe should be subjected to re-examination. CNI recognizes that percentage ingredient labeling of some non-characterizing ingredients might be inappropriate. Nonetheless, a quantitative declaration of some non-characterizing ingredients would not only be helpful to some consumers but would be essential to most.

It is known that the human body cannot distinguish natural sugars, sodium and fats from added sugar, sodium and fats. In fact, the nutrition labeling framework envisioned by S.1652 provides only for information on total carbohydrates, fats and salt. Yet the thrust of the Dietary Guidelines is that intake of sugar, fats and salt should be reduced and that this reduction should take place through the consumer choosing between different brands of similar products which contain the ingredients and among different prepared products using similar basic foods. For this reason consumers of such foods as canned fruit or celery in cream sauce need to know the quantity of added sugar or sodium. To only require nutrition labeling of the total amount of such ingredients would tend to over-emphasize the importance of naturally-occurring (and uncontrollable) sources of these components and under-emphasize the importance of deliberate (and fully controllable) processing techniques.

Consumers need percentage labeling for ingredients which, although not characterizing, have an accumulative effect in sugar, fat and salt. Examples of foods that contain non-characterizing quantities of sugar might include peanut butter

ketchup, salad dressing, unsweetened cereals, mayonnaise, and non-dairy creamers. For these foods and others, consumers need specific data on added sugar, fat and salt.

3. Protein, Fats, Carbohydrates, Sodium, and Cholesterol Declarations

The third particular provision which gives life to this legislation is the requirement that a declaration of fats, carbohydrates, sodium and cholesterol be made. We at CNI believe that this provision is vital to achieve the overall goal of the legislation preventing disease and promoting health. Without these declarations, Americans, who wish to utilize the Surgeon General's recommendations and the Dietary Guidelines by exercising control over their diet will be hamstrung by the unavailability of essential data.

4. Format and Consumer Education

A failure of the fourth and final aspect that I will discuss today will diminish the possible success of years of cautious and carefully planned work to refocus the food label. This is the transition management: designing the label format and consumer education.

Redesigning the format of the label as a key issue in this important project. By allowing the respective Departments two years to supervise the demonstration and evaluation of new methods to convey the required information, the opportunity for success is multiplied.

Without a full commitment to comprehensive consumer education on the refocused food label, the public's ability

to utilize the refocused food label will necessarily suffer from dietary myopia. Just as uncorrected visual myopia impairs our ability to navigate our car through a crowded metropolis, dietary myopia impairs our ability to navigate through the food labels to select the most prudent diet, no less complex a process. A thorough and meaningful program to educate consumers in the use of the refocused label will be as useful to the consumer in selecting foods as providing spectacles to a myopic driver. The benefits will be just as great to the navigator and to the society of pedestrians which pays the medical cost arising from poor diet.

In conclusion, we urge prompt consideration of this important piece of health promotion legislation. During these trying times of double digit food inflation and increasing knowledge about the links between diet and disease, S.1652 would provide consumers with the long needed tools to aim themselves in today's complex market place. We support S.1652 as an effective, inflation fighting, health enhancing protective measure for the future.

Senator SCHWEIKER. All right, thank you. Dr. Hagen.

I would appreciate it if you all would summarize your statements, and we'll put them all in the record, of course.

Dr. HAGEN. Thank you, Mr. Chairman. We have done that, and you will have a full copy of our detailed statement for the record.

I am pleased to testify on S. 1652 as the spokesman for the National Food Processors Association.

NFPA represents processors of more than 90 percent of the national production of canned fruits, vegetables, meats, seafoods, and specialty products.

Labeling is vitally important to all food processors, Mr. Chairman, and we urge this subcommittee to look at this legislation in terms of the additional regulatory burdens it would impose, especially on small processors, and I'll have more to say on that in just a moment.

We also want this to be considered in terms of the cost to the consumers. This has been discussed at length by a number of people.

Now, on small food processors I want to point out that many small food processors pack private label product or label for the buyer, and they may have—in addition to their own house labels,

they may have thousands, up to 15,000 labels in some instances that they have to inventory.

So this burden of labeling becomes quite onerous for many of these smaller packers.

Mr. Chairman, the food processing industry and the National Food Processors Association have for many decades been in the forefront of providing label information to the consumer.

I have a copy here, Mr. Chairman, of our labeling manual which has been revised seven times. We have often recommended putting information on the label before it was actually required by the Government. I think that's an important point.

It's also important to recognize that in our industry we are concerned about consumers, and we must on a daily basis be responsive to their genuine needs and their desires, in order to stay in business.

Recently, in recognizing that the current nutrition labeling program had not accomplished its intended goals, we offered a document entitled a proposal for a realistic improvement in the labeling of processed foods, and copies were provided to this subcommittee. We call this the blue book, Mr. Chairman, and we detail the program which we believe is the most effective.

Many of the points covered in our proposal are also contained in this legislation. Thus we agree that any new labeling program must be designed to reduce the cost and increase the flexibility for industry.

It should also simplify label information and make it more meaningful to consumers; and most importantly, it must eliminate declarations on the label that are not meaningful to consumers.

Regarding requirements of this bill, we have long endorsed full ingredient labeling in descending order of predominance, a step which we have supported as a proper response to the consumer's desire to know what is in the food being consumed.

So we do support the full ingredient label.

We cannot agree, however, to the listing of all colors and spices by specific names. Doing so will only confuse many consumers by presenting them with unfamiliar names that many will not understand or even be able to use.

We strongly oppose quantitative or percentage ingredient labeling. There simply is no great consumer demand for it, as FDA's own 1978 food labeling survey shows.

That requirement will only add to label clutter and to cost and we've heard several other witnesses this morning demonstrate the problems inherent in percentage labeling.

Now our primary difference between the NFPA labeling proposal and S. 1652 is that we believe nutrition labeling should be voluntary, while this bill would make it mandatory, thus eliminating the flexibility we think is so important to its success.

In the current FDA regulation, nutrition labeling declarations are voluntary, but when a processor decides to make a nutrition claim, he must follow a rigid prescribed format which many times makes no sense to the consumer; and again, the labeling survey bears this out.

Industry has gone along with the FDA regulation and at considerable expense.

Some 2 years ago a survey showed that over 60 percent of the processed foods carried nutrition information, and many more do so since that time, but we seriously doubt that consumers understand much of what processors are required to declare.

If NFPA's voluntary proposal were implemented, current obstacles to nutrition labeling would be alleviated, thus inviting wider participation in the program. Our proposal would allow processors to declare calories and appropriate macronutrients, as many have discussed this morning.

It would eliminate unnecessary declarations required by rigid mandatory format which adds to confusion, label clutter and cost.

We have long supported use of the nutrient data bank, Mr. Chairman, as this bill would allow. However, the current language of this bill will not accomplish this intended effect, and this is a most important point I'd like to make: that the current bill as written leaves the judgment as to whether or not a data base can be used to the discretion of the agency.

Furthermore, the whole question of compliance and the accuracy of any label declaration is not addressed by this bill, and we have serious concerns about those two points.

We support the enactment of a Federal preemption clause to the Food, Drug and Cosmetic Act, but the provision in S. 1652 must be greatly strengthened if it is to be effective.

We agree with the sponsor of this bill, Senator McGovern, that criminal liability for labeling violations should be eliminated.

Mr. Chairman, this is only an outline of some of our views on S. 1652, and as I mentioned earlier, we have provided full written comments for the record.

In conclusion, we support the goals of this legislation, but are convinced that these goals cannot be achieved as the bill is currently drafted.

NFPA therefore opposes the legislation as presently written, and we have identified those principles which we think are essential.

At this time of fiscal austerity, with the Congress and the President moving toward a balanced budget in an effort to control inflation, we seriously question whether this is the time to add costly new mandatory requirements that have no material public health significance.

We are proud of our positive record of responding to consumer needs and will continue to look for ways of doing even better.

[The prepared statement of Dr. Hagen follows:]

TESTIMONY
BY
DR. RICHARD HAGEN
VICE PRESIDENT, EASTERN RESEARCH LABORATORY
NATIONAL FOOD PROCESSORS ASSOCIATION
BEFORE THE
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
MARCH 19, 1980

Mr. Chairman, on behalf of the National Food Processors Association (NFPA), I am pleased to testify on S. 1652, the Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug and Cosmetic Act.

The National Food Processors Association, formerly the National Canners Association (NCA), represents firms that process more than 90% of the national production of canned fruits, vegetables, meats, fish, and specialty products.

Mr. Chairman, food labeling is vitally important to food processors and to those who buy their products. It is with that compelling reason in mind that we are testifying on this legislation today.

The food processing industry recognizes the consumer interest in informative labeling, including nutritional labeling. Over the years, the industry has responded effectively and responsibly to genuine consumer interests. There has been constant recognition of the need to avoid label clutter and resultant confusion, and to maintain an appropriate balance between the desirability of communicating adequate information for informed purchasing decisions and keeping costs under control.

Today's consumer has available a large number of products. In order to provide the wide selection of products, virtually every food processor must maintain a wide variety and a large inventory of labels. The designing and printing of new labels are expensive, and so is the sample analysis for nutrition labeling if it is provided. Government-imposed changes including percentage ingredient labeling and listing of colors and spices could add substantially to consumer cost. It is important that new label requirements be designed for cost-effectiveness.

The label is an important marketing factor, especially for small food processors that typically do not have a large advertising budget. We must bear this important fact in mind, together with its implication for maintaining strong competition in the industry, as we consider new label proposals.

History of NFPA Labeling Advances: In recognition of the importance of the label, NFPA has actively worked for many decades to improve food labeling. In 1934, the Association began its Descriptive

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Labeling Program which first proposed and implemented a system for uniform descriptive terms to describe product attributes. Declaration of mandatory labeling information in standardized form on a principal display panel of each container and voluntary placement of recommended desirable information on an equally prominent side panel were proposed in 1939. These recommendations have been widely adopted by the industry, in advance of any governmental requirements.

In 1940, our Association published and made available to every canner a comprehensive labeling manual, Modern Labels for Canned Foods. This manual is periodically revised, with the latest 7th edition published in June, 1977. The labeling manual covers in complete detail all federal and state requirements, along with NFPA's recommended additional descriptive labeling terminology.

In 1941, the NFPA Labeling Committee developed for wide public dissemination its basic pamphlet, Canned Food Labels That Meet Consumer Needs. This pamphlet recommended to our members information that should be placed on the label for guidance and protection of consumers.

In 1953, the Association published its comprehensive bulletin on Dietetic Canned Foods. The bulletin includes specific recommendations on labeling of dietetic canned foods. The publication was reviewed and approved by the Council of Foods and Nutrition of the American Medical Association.

In 1965, the Association recommended to the industry that "added salt" be stated on the label, even though that requirement did not exist for the bulk of the products then standardized.

Most recently, in June, 1979, the Association published its Proposal For A Realistic Improvement In The Labeling Of Processed Foods. We have submitted this proposal to FDA, USDA and to the appropriate committees and subcommittees of Congress including this subcommittee.

That proposal recognizes that the current labeling program should be improved, because the present system of nutrition labeling is too complex and confusing. An improved labeling program must achieve simplicity and avoid the confusion of label clutter. Our proposal is based on the concept of voluntary labeling which has worked successfully for many years, and could be accomplished without legislative changes.

Goals of Legislation: The NFPA labeling proposal has many points in common with this legislation, and while we agree generally with the goals of the legislation, we have many concerns and reservations about the specific provisions.

The bill states, "a more nutritious diet is a critical factor in preventing disease and promoting health." As an industry, we are proud of the broad range of nutritious and reasonably priced processed foods we provide to consumers. While we recognize that health may be influenced by diet, we believe it is inappropriate

to expect mandatory labeling to have a major impact on "preventing disease" or raising consumer interest in nutrition. This more logically should be left to consumer education and the health-care profession.

We agree that "special attention must be placed on improving labeling formats to convey more effectively needed information in a readily understandable fashion to the average consumer". Our proposal is intended to do just that.

Cost of New Requirements: Unquestionably, regulations carry a cost with then, both to the government and to industry. There is no doubt that the full cost of regulations ultimately is borne by the consumer. It's encouraging to know that Congress and government agencies are becoming increasingly aware of this.

With Congress and the President trying to control inflation and achieve a balanced budget, we seriously question whether this is the time to add costly new mandatory requirements that have no material public health significance.

We are prepared to cooperate in the development of needed regulations. But in the public interest, in this time of fiscal austerity, we must continue to resist what we believe to be unnecessary regulations.

This legislation cannot be considered alone but must be considered in the context of the numerous additional potential requirements that FDA, USDA and FTC proposed on December 21, 1979. In trying to develop a simple, straightforward, uncluttered label that will present salient information to consumers, we must bear in mind that the new requirements proposed in this legislation are in addition to other requirements the agencies have said they will propose under existing authority. We cannot expect to achieve the goals of this legislation, and respond to the desires of the public if we attempt to answer all questions about diet and nutrition on the label. Also, the cost of changing labels is a large enough factor in food costs that good conscience and practicality dictate that changes not be made in a piecemeal fashion.

Basis for Changes: To determine what consumers want and need from label statements, the three agencies -- FDA, USDA, and FTC -- conducted a series of hearings in 1978. We believe Congress should guard against giving an undue weight to these hearings. As stated in the Federal Register, "the agencies recognize that the testimony received at the hearings and the written comments do not represent a random sample of the American public's views." Those who testified or commented clearly had a particular motivation. The aggregate result, if translated into label declarations, would require almost encyclopedic information on food labels. This is not physically possible, or even desirable, because the volume of information would be overwhelming and confusing. After a detailed examination of the hearing record, we conclude that the hearing results are

virtually meaningless as a basis for making policy because they could be used to justify almost any conceivable label declaration.

The FDA 1978 Consumer Food Labeling Survey is much more realistic and significant because it was conducted according to scientific principles, and much more accurately reflects what the public thinks about the food label.

This FDA survey revealed that about three shoppers in five (59 percent) are satisfied with current food labeling. Only one shopper in twelve (8 percent) is unhappy enough with food labeling to name this as a major problem with food these days; another twenty-five percent express lesser degrees of dissatisfaction. The survey showed that only 2.9 percent of canned food buyers consider label deficiencies a major problem. In short, consumers do not have an overwhelming desire for drastic label revisions, and there is no widespread public demand for new mandatory labeling requirements.

We believe that several important improvements must be made in the legislation if it is to accomplish what is intended. We would like to share our specific recommendations on the provisions of the bill, under the categories of ingredient labeling, nutrition labeling and administrative provisions.

I. INGREDIENT LABELING

Full Ingredient Labeling: The first significant provision of this legislation is to require "the common or usual name" of each ingredient in the descending order of its predominance by weight, except that any ingredients that individually comprise 5% or less of a food need not be listed in such order but shall be named at the end of the ingredient list.

The National Food Processors Association has supported full ingredient labeling on all foods for the past fifteen years or more, but with spices, flavors, and colors designated as such rather than by name. NFPA members have cooperated with this program by voluntarily listing all ingredients, including mandatory ingredients, on foods having a standard of identity.

We support the proviso that ingredients comprising 5% or less of a food need not be listed in descending order of predominance but shall be named at the end of the ingredient list.

Labeling of Colors and Spices: NFPA supports the present method of declaring colors, spices, and flavors.

This bill, if enacted, would change that policy. It would require that colors and spices be declared on the label by "common or usual name".

Ironically this would have the very effect FDA and USDA are trying to avoid. It would present the consumer a wide variety of

often exotic, unfamiliar identifications, which would increase consumer confusion, not reduce it.

The declaration of colors and spices by specific name would detract from the label identification of key food ingredients. There would be an increase in food costs for consumers as a result of such a requirement. For example, it would reduce the opportunity to modify these essentially condimental minor ingredients. It is in the best interest of consumers to have the flexibility to modify the color and spice formulation, in order to adjust to changing tastes or to use similar but less expensive colors and spices.

The declaration of colors and spices by specific name would make it more difficult to protect formulations. This is especially important to small processors, many of whom are competitive because they have a specific recipe that others have not been able to imitate.

The argument in support of the declaration of colors and spices by specific name implies that consumers think some ingredients are unsafe. Consumer concern about the safety of food additives could be better addressed by an educational program on FDA's approval process for food additives rather than by confusing consumers with a list of technical names on the ingredient statement.

Quantitative Ingredient Labeling: This bill would give FDA discretionary authority to require "a declaration of the quantity or percentage" of any specified ingredient (other than a flavoring) or class of ingredients if the agency determines that an ingredient "has a significant bearing on the quality, consumer acceptability, or cost of food or food of its class." FDA indicated in its recent proposal that it intends to use this authority broadly, if enacted, to require overall mandatory percentage ingredient labeling.

NFPA understands that it may be necessary to state the percentage of an essential characterizing ingredient for a few fabricated products when there is a clearly demonstrated need as in the case of shrimp in shrimp cocktail, mixtures containing maple syrup, or perhaps olive oil in combination with other oils. In such cases, that demonstrated need should be addressed in a specific labeling regulation applicable to the particular product, as has been done in a few instances under existing statutory authority. But, there is no need for broad sweeping authority for percentage ingredient labeling, as evidenced by marginal consumer interest in the declaration of percentage ingredient labeling. In the FDA Consumer Food Labeling Survey, only 3.8 percent of those questioned wanted to see the label changed by quantifying the ingredient list. In another line of questioning, 3.9 percent said the ingredient list should be quantified to give desired additional information. Of these, 2.6 percent would do so by stating percentages. Such small numbers cannot be interpreted as a compelling consumer interest and definitely fail to support the FDA conclusion that, "There is

rather widespread desire for such other changes as: quantification of the ingredient list (preferably in percentage) . . . ."

For the vast majority of consumers, the present ingredient statement, stated in order of predominance, appears adequate. Percentage ingredient labeling often would make batch type products more costly because, while the percentages of ingredients in the batch are known, the exact percentages in each container may vary somewhat.

Declaration of percentage ingredient labeling will make it more difficult to protect specific recipes and product formulations. Disclosure of percentage or quantitative ingredients would, in many cases reveal information that cannot be determined by any form of analysis. In addition, FDA intends to seek authority giving its inspectors access to a company's product formulas, quality control records, and related records in order to ensure that such expanded quantitative ingredient labeling is "truthful and accurate." Giving FDA inspectors access to a company's product formulas will further endanger proprietary information, and is certainly not justified by any consumer demand.

Descending Order Statement: The bill requires a statement on every label that "ingredients are listed in the descending order of predominance by weight." The stated purpose for this additional requirement is that a large number of consumers apparently do not know that ingredients are, and for the past forty years have been, listed in descending order of predominance.

The objection to putting such a statement on the label is simply that it takes up precious space. On smaller labels, such as those on small convenience products, it takes up a sizable portion of a very limited label space. The statement would add to label clutter, which many consumers say needs to be reduced.

The information that ingredients are listed by descending order of predominance is an appropriate subject for consumer education programs initiated under this legislation and otherwise by the government.

II. NUTRITION LABELING

Mr. Chairman, a major portion of this legislation is on nutrition labeling. If enacted, the bill would require declaration of certain nutrition information on all processed foods. It would give FDA authority to permit use of a nutrient data base as the source of nutrition information but only if FDA elects to do so.

We agree fully with the goals of the legislation in the area of nutrition labeling. The primary goals, as we understand, are to provide "objective and useful nutrition information" for consumers, and at the same time "to reduce, if not eliminate, the economic and regulatory burdens" of nutrition labeling. The proposal is intended to meet "the food industry's need for greater flexibility

and full participation in the development process." The approach is to redirect "the focus toward the vital information function of nutrition and ingredient labeling instead of "the classic compliance aspect of food regulation."

The goals are entirely consistent with NFPA's goals, and we support them.

We firmly believe, however, that the legislation must be changed in several important respects in order to meet these goals.

The NFPA voluntary nutrition labeling proposal has been put forward by the food processing industry as the best approach to achieving these goals. The primary difference between the NFPA proposal and this legislation is that nutrition labeling should be voluntary, not mandatory.

We recognize that the current voluntary nutrition labeling program is not adequate, because the format, which is mandatory, is confusing and in many cases does not provide relevant information to consumers. We can see clearly that a totally mandatory program covering the broad range of food products would be far worse, resulting in expenditure of huge amounts of time and money with small benefit for consumers. As we contemplate changes in the existing program, we should keep in mind this experience. The program should be voluntary to lessen the impact of unforeseen problems and costs.

A great merit of a voluntary labeling system, as NFPA has proposed, is that it allows market pressures to operate to the consumer's best advantage. It also permits flexibility to adjust the label for new or different information as more is learned about nutrition.

Given our limited knowledge of the relationship of any specific nutrient to health, it is not surprising that certain nutrients tend to be in or out of vogue, depending on the contemporary state of the science.

For example, at the outset of the current nutrition labeling program, providing accurate label information on the micronutrients--the vitamins and minerals presently required in nutrition labeling--was considered an absolute necessity to the success of the program.

Now, as Senator McGovern had indicated, micronutrients are of less interest than macronutrients. As evidenced by the 1978 FDA Food Labeling Survey and other surveys, very few people understand or use the micronutrient information. This earlier postulated interest in micronutrients has resulted in a significant amount of added expense without corresponding benefit to consumers. Let's not repeat this by a broad-based mandatory program without a demonstrated need.

Currently, some nutrients are the subjects of concern. These include cholesterol, sodium, fat, sugar and calories. Some people have medical reasons to be concerned about certain nutrients but we question whether this is reason enough to impose the extra financial burden on all consumers that a mandatory labeling program would bring. According to most nutritionists, those people who for medical reasons need to control the intake of certain nutrients should do so under the care of a physician and should not depend on a label to tell them what, and what not to eat. There are many special dietary products available on the market.

In addition, Mr. Chairman, we need a nutrition labeling program that is flexible enough to allow for the addition of new information as it develops, and it surely will because all is not yet known about the effect of foods we eat on our physical well-being. A program based on legislated mandatory requirements does not provide this flexibility.

Indeed Mr. Chairman, we do not understand why processed foods are singled out for so much attention in this legislation. This bill, S. 1652, requires mandatory nutrition labeling solely for processed and packaged foods. Yet the average American spends about 40 percent of the food dollar on food away from home that bears no nutrition labeling. Also, a substantial portion of our food is consumed fresh, again without nutrition labeling. If, as some have suggested, posters in supermarkets are adequate to inform consumers about nutrition values of these products, why shouldn't they also be adequate for food placed in a package or other container? Certainly the idea suggested in the FDA proposal, of a booklet containing nutrition information, available in the supermarket, ought to be comparably adequate for packaged foods.

We suggest it makes no sense to require mandatory nutrition labeling for processed foods when there is no nutrition labeling for the vast bulk of food that is consumed fresh or away from home. All the nutrition labeling imaginable for processed foods would still leave the consumer uninformed about nutrient content of most food.

Need for Industry Innovation: The current FDA nutrition labeling program is limited by a mandatory format. If a food processor voluntarily uses a nutrition label, or makes a nutrition claim, he must follow a prescribed format with a required set of complicated declarations, many of which are unnecessary and meaningless. This format thwarts innovation and initiative in finding better ways to convey nutrition information on the label.

The food processing industry tries continually to learn what consumers want and how to provide its customers with a high quality, cost-effective product. There is a clear understanding throughout our industry that "the consumer is boss." The key to success in the food industry is, and has been, the ability to provide a superior

product to consumers. The recognition of this fact, coupled with ingenuity, has given the American consumer the best food supply for the lowest cost, of any in the world.

NFPA's nutrition labeling proposal would allow the industry to apply its ingenuity and research toward creating a nutrition label that is both responsive and understandable to consumers.

The current nutrition labeling program, with all its limitations, clearly demonstrates one fact: a voluntary program can effectively make nutrition information available to the public whether they use it or not. More than 60 percent of processed foods are presently nutrition labeled, including virtually every kind of product. If industry flexibility is maximized, and the use of data base information allowed, as we propose, nutrition labeling will become even more prevalent.

NPFA's Nutrition Labeling Proposal

NFPA's nutrition labeling proposal addresses each of the nutrient declarations required by this bill, as well as several nutrients not addressed in the legislation.

Calories: NFPA recommends that the voluntary declaration of the calorie content of a food, standing alone, should not require further nutrient declaration. This option would give processors flexibility to respond to a key consumer interest, and to the USDA's and HEW's "Dietary Guidelines for Americans," without being required to make other nutrient declarations that in many instances are not needed or are meaningless to the consumer.

Protein, Fats and Carbohydrates: S. 1652 would require declaration of "the amount per serving of protein, fats, carbohydrates in terms of caloric content." This format is potentially misleading. If consumers don't understand nutrition labeling, they will be further confused by this format of caloric density.

NFPA recommends that the label statement of protein be made in grams per serving. This will allow for comparisons, about all we can reasonably expect consumers to do with this kind of information.

The same is true for fat. However, for some foods there may be voluntarily added a further statement of saturated and polyunsaturated fats.

The declaration of total "carbohydrates" may, where appropriate, be accompanied by an additional statement in grams of the amount of "sugars" (meaning mono- and di-saccharides) and "other carbohydrates." This option is responsive to the interest some consumers have shown in sugar.

Sodium : S. 1652, if enacted, would require declaration of "the amount per serving of sodium unless the Secretary determines

that providing such information is not necessary to provide health information to consumers." In effect, this is mandatory labeling, because FDA has already stated its intent to require sodium labeling if this legislation is enacted.

NFPA opposes mandatory sodium labeling. The NFPA labeling proposal for sodium labeling is a practical alternative that is responsive to demonstrated public health and consumer needs.

In addition to the ingredient declaration when salt is added, NFPA's proposal calls for amendment of FDA/USDA labeling regulations to allow voluntary quantitative declaration of sodium, either in combination with full nutritional labeling or on labels which do not contain nutritional labeling.

For consumers with a real or perceived health problem due to excessive sodium intake, there is a broad range of dietetic low-sodium products currently available and fully labeled. A long list of these products has been compiled and published by the American Heart Association. The wide selection shown by that list well demonstrates how the industry has voluntarily responded to the consumer need and desire for low-sodium products.

Mandatory sodium labeling is not justified for several reasons:

1. Consumer need has not been demonstrated. Only one percent of respondents in the 1978 FDA Food Labeling Survey expressed concern over salt labeling. This was true in both the open-ended and the semi-direct questions which specifically asked what additional label information consumers want.

2. Data is lacking to show that consumers can effectively understand and use quantitative sodium labeling. The agency's Labeling Background Papers (p. 48) state that:

> "Evidence also indicates that educational efforts will be required to help consumers use sodium information on the label; most consumers do not understand the difference between salt and sodium. Whether consumers use the information will depend upon how well they understand it, as well as the interest they have in it." (Emphasis provided.)

3. Hard facts are missing to support the implied assumption that mandatory provision of sodium information would provide a demonstrable health benefit either to hypertensive-prone people or to the vast majority of Americans who are not susceptible to hypertension. Most authorities recognize that current studies do not show that sodium consumption is a causative factor in hypertension. Data presented to the Select Committee on GRAS Substances (SCOGS) emphasized that benefits from reduced sodium intake accruing to

hypertensives could be demostrated only when daily sodium intake levels approached 1 gram or less (NaCL equivalent). Since SCOGS also concluded that the naturally-occurring or background salt equivalent in American food intake is approximately three grams, it is extremely difficult to conclude that quantitative sodium labeling, either alone or coupled with a massive education program, could have a significant health impact.

Some experts contend that excessive sodium in the diet comes mainly from salt added at the table or in home cooking to suit individual tastes. Again, according to the SCOGS report, up to 50 percent of the average daily intake is added in this way. The solution to that is nutrition education. Addition of salt at the table will not be resolved by any form of sodium declaration on food labels. If that is the main problem, as it appears to be, then mandatory sodium labeling is unnecessary and unjustified.

The daily need for salt clearly varies on an individual basis. Persons who engage in heavy physical excertion or are active in hot weather need more salt than those who do not. There is no question that overzealous reduction of salt from the diet of these individuals presents a health risk.

A more detailed discussion of sodium in the diet is contained in the article entitled "Dietary Salt", prepared by the Institute of Food Technologists' Expert Panel on Food Safety and Nutrition and the Committee on Public Information. We would be happy to provide this article to the subcommittee.

4. Sodium analysis requires relatively sophisticated and costly flame-emission equipment and skilled technicians to operate it. There is a well-recognized variability in the natural sodium content of foods. High-precision metering equipment for adding salt used in processing is necessary to allow sodium labeling under existing compliance procedures. Due to these factors, mandatory sodium labeling as proposed in S. 1652 would be costly and burdensome, especially for small food processors.

A voluntary approach avoids the problems of a mandatory declaration, yet is responsive to demonstrated consumer needs.

Cholesterol: S. 1652 would require a label statement of "the amount per serving of cholesterol unless the Secretary determines that providing such information is not necessary to provide health information to consumers."

Many of the same arguments regarding sodium can be made for cholesterol.

NFPA recommends that where fat is labeled, with or without an additional declaration of saturated or polyunsatruated fats, cholesterol content may be declared. Such a statement should be voluntary and

not required.

A voluntary label statement of cholesterol responds to prevailing consumer interest. A voluntary program would ensure availability of cholesterol labeling on foods where appropriate, yet not require such labeling on foods where the statement would be superfluous.

Micronutrients: The legislation does not require labeling of micronutrients (vitamins and minerals) but leaves FDA the option to do so. Previous statements by Senator McGovern have suggested that micronutrient labeling should be optional.

NFPA recommends that declaration of a full range of macronutrients (calories, protein, fats, carbohydrates, sodium and cholesterol) should not result in mandatory labeling of micronutrients. Micronutrient declaration should be voluntary.

As previously mentioned, current micronutrient labeling is not understood by consumers. The presence of such a statement may simply add to label clutter and confusion.

If consumer interest in micronutrients becomes keener, then the voluntary program would allow them to be declared.

Nutrient Data Base: NFPA long has advocated use of nutrient data bases and supports them now. However, there exist several problems and unanswered questions with the provision in S. 1652, which states that FDA "shall allow, to the maximum extent feasible and appropriate the use of nutrition data bases that indicate representative (weighted) nutritional value at the point of purchase."

The purpose of the nutrient data base is two-fold.

First, it would reduce the cost of nutrition labeling by reducing or eliminating the cost of nutrition analysis.

Second, it would provide nutrient information that has "a degree of accuracy that satisfies the public health concern." The data base would contain representative nutrient values that may not be precise for a given container of product or a given lot, due to wide natural variations, but is representative of the nutrition consumed over a period of time.

We believe that the data base is a good approach, and that if it can be implemented, it will lead to nutrition labeling on a much wider basis. We are concerned about increased costs because ultimately they are borne by the consumers in their direct food spending or as taxpayers.

We do not know how much it would cost the industry to participate in the data base. However, we do know that nutrition analyses are expensive, especially for micronuttients. Eighty percent of the analytical cost of the mandatory nutrients in the current FDA

nutrition labeling format is for vitamins and minerals (micronutrients). The cost to small processors and to the industry as a whole is a major concern. FDA recently estimated that the cost of the nutrient data base could be in excess of $100 million, although careful cost analysis has not been done. A thorough cost analysis should be made by FDA.

We recommend the program be voluntary and not mandatory since the cost will not be truly apparent until the agencies begin to implement the program.

Ultimately, accuracy becomes an issue in compliance, and compliance may be the key to the success or failure of the nutrient data base. The use of data bases and the enforcement mechanism for nutrition labeling are discretionary for FDA in S. 1652. In the FDA-FTC-USDA proposal, FDA's position is that it will not allow use of a nutrient data base without strict compliance requirements, but the current compliance program for nutrition statements is totally unrealistic. As Senator McGovern has said, "(We) have overregulated this matter - overemphasizing the classic compliance aspect of food regulations." However, this bill does not address the compliance issue.

The data base concept takes into account natural variations by providing a representative value that is accurate over a period of time. Inherently, the nutrient content in a given lot must vary from the representative value. The question is whether the compliance requirements will be realistic in terms of natural variation and if not, what sanctions will be applied. FDA says the manufacturer is responsible for "assuring that a product meets its labeled nutrient content within established limits." This statement suggests FDA may continue the same rigid, unrealistic compliance program.

An unrealistic compliance program, rigidly enforced, would be disastrous for the entire industry, and especially for small processors. Small processors simply cannot afford to have products placed on hold or penalized due to an arbitrary compliance standard unrelated to the reality of natural variations.

Currently, a food processor who voluntarily nutrition labels will declare nutrient values high or low, depending on whether FDA views the nutrient as "bad" or "good", in order to ensure that the statement will be in compliance. Consequently, the FDA compliance program produces an inaccurate label. We believe the obligation for FDA to implement the data bank concept in a reasonable manner should be more strongly stated.

Senator McGovern, FDA and USDA have said that nutrition labeling should remain voluntary until the data for a given product is available through the data base. Such an approach is inadequate. It should continue to be voluntary after the data base is set up, because a small processor could still be faced with unforeseen costs or compliance problems under mandatory labeling.

Label format: This bill gives the FDA discretionary authority to "prescribe a system of symbols, figures, or other devices" to convey nutrition information.

Use of graphic methods to convey nutrition information can be misleading to consumers. Use of such a format should be preceded by extensive market testing and careful analysis. This provision is unnecessary, in view of the authority in Section 5 allowing FDA to conduct demonstrations and evaluations on new label formats.

III. ADMINISTRATIVE PROVISIONS

Federal Preemption: We are encouraged by the legislation's federal preemption clause.

NFPA did not request legislation, and we do not feel it is necessary for improved labeling. However, we have long supported the addition of a strong food labeling preemption provision to the Federal Food, Drug and Cosmetic Act, consistent with the Wholesome Meat Act and the Poultry Inspection Act. Unfortunately, the federal preemption provision in this bill has several serious weaknesses and must be improved.

Senator McGovern indicated at the outset of his efforts to improve the labeling laws that several differences exist between the labeling programs of FDA and USDA "which should be resolved in order to reduce public confusion, and to enhance the development of a comprehensive nutrition labeling and information system."

The absence of a federal preemption clause in the Food, Drug and Cosmetic Act (FD&CA) is one of those differences. The preemption for the FD&CA should be equal to that in the statutes governing USDA.

The quest for a comprehensive and consistent food labeling strategy is futile when, as now, individual states are free to impose differing and varied food labeling requirements. These impose economic barriers to interstate commerce and cause consumer confusion. Disadvantages to consumers from the cost of compliance with multiple inconsistent state food labeling requirements overshadows any improvements that could be accomplished by a comprehensive federal food labeling policy without effective federal preemption.

The absence of a strong federal preemption clause invites a hodgepodge of differing and possibly conflicting state laws. American consumers and industry alike need protection from this very undesirable situation.

We recognize the issue of states rights, and respect the authority of states to govern matters solely within their jurisdiction. However, every conceivable new label requirement could become a burden to interstate commerce. Virtually every food processor operates in more than one state, usually on a regional or national basis. So,

any state or local label requirement has consequences that extend to other jurisdictions. This regulation of interstate commerce should be at the federal level.

There are three difficulties with the federal preemption in S. 1652:

First, it pertains only to nutrition and ingredient labeling. There are many label declarations beside nutrition and ingredient labeling. Separate state and local requirements in those areas can be equally as burdensome as those in nutrition and ingredient labeling. The preemption clause should pertain to the entire label.

Second, a state or local jurisdiction may require a different label statement "if the Secretary determines that the requirement is required by compelling local conditions". This proviso defeats the entire purpose of the premption.

As we have explained, any different standard will have a bearing on interstate commerce. If conditions in one area suggest a new label requirement, then it should be considered at the federal level. We have seen no state or local label issue that has not been addressed at the federal level. We do not believe that elimination of the above stated exemption will cause injury to any state or local jurisdiction. The USDA preemtion contains no such exemption, and in order to achieve consistency, neither should the preemption in the FD&CA.

Third, the bill provides that a separate "sell or use date" requirement may be established or continued by any state or local jurisdiction. The issue of sell or use date labeling is addressed in the joint FDA-USDA-FTC labeling proposal. There need not be a separate exemption for date labeling because it already is being addressed at the federal level. This provision would exempt the sell or use date program in Massachusetts. The Massachusetts program is a prominent example of why a strong federal preemption clause is needed. Specifically, the recently enacted Massachusetts open date labeling requirement for nonperishable food compels out-of-state producers to choose among (1) eliminating sales to Massachusetts, (2) maintaining separate product inventories for Massachusetts and the remainder of the country or (3) converting their entire national production to meet the Massachusetts requirement. In the first two instances, Massachusetts consumers are denied an optimum range of products or forced to pay a premium for separate product inventories for Massachusetts. In the last instance, consumers throughout the country are compelled to pay for label information mandated only by Massachusetts. If other states impose requirements differing from those of Massachusetts, the problems would become insurmountable.

We urge that the state sell or use date exemption be eliminated.

Criminal Liability : Senator McGovern stated upon introducing S. 1652 that elimination of criminal penalties for labeling violations is a key step in addressing "the problem of inappropriate regulation

by redirecting the focus toward the vital information function of nutrition and ingredient labeling".

This is reflected in S. 1651, the companion bill dealing with USDA, but it is absent from this bill, S. 1652.

A stated goal of this legislation is to achieve a consistent labeling program between FDA and USDA. It is a very worthy goal and we support it.

Yet there cannot be consistent labeling programs when the basic statutes for FDA and USDA are different in critical ways.

Individual food producers are now subject to absolute criminal liability for violations of the FD&CA. This rule of vicarious criminal liability, affirmed by the Supreme Court in United States v. Park, 421 U.S. 658 (1975), is outmoded, patently inequitable and unnecessary for consumer protection.

In recognition of the fundamental unfairness of this strict criminal liability rule, the Consumer Food Act of 1975 (S. 641), passed by the Senate in the 94th Congress, as well as the virtually identical food surveillance bill (S. 2540) considered in the Senate in the last Congress, would have amended the FD&CA to overrule United States v. Park, to eliminate the absolute criminal liability rule for individuals with respect to food violations and to replace it with a standard of due care.

The Drug Regulation Reform Act of 1979, S. 1075, similarly would eliminate absolute criminal liability of individuals for drug violations.

We urge the subcommittee to add a provision to this bill to reverse the "Park Doctrine" and eliminate absolute criminal liability for food violations.

Nutrition Information in Advertising: This bill provides in Section 7 that FDA shall recommend to the Federal Trade Commission (FTC) which nutrition information, if any, should be required to be included in advertising a food product.

Mr. Chairman, this provision has a most objectionable implication and the entire Section 7 should be deleted.

The implication suggests one or both of two possibilities: (1) that consumers cannot evaluate what is of interest to them in food advertising, and therefore must be provided a comprehensive message prescribed in part by the federal government, and/or (2) that food processors do not know what real consumer intersts are and therefore must be instructed by the federal government. Neither is true.

Food advertising today is done in the context of an abundant food supply that is safe, wholesome and nutritious. The cardinal

consumer interests are price, quality and convenience. Success in the highly competitive food processing industry hinges on being able to attract the consumer's attention in these areas. At the same time, the consumer's attention is being occupied by an endless number of other matters.

Advertising time and space is severely limited by cost and its effectiveness by the public's attention span. To burden food advertising with government-imposed nutrition information could have a disastrous impact on the competitive status of many companies, especially smaller companies with limited advertising budgets.

The FDA Consumer Food Labeling Survey indicates that the vast majority of consumers are not presently dissatisfied with current nutrition information. Forcing nutrition information into food advertising is therefore unwarranted.

In fact, nutrition information already is used in food advertising, to the extent that limited advertising time and space permit. The government already has authority to demand that nutrition claims in advertising are not false or misleading, a power that is adequate to protect consumer interests .

If the NFPA voluntary nutrition labeling proposal is adopted, more nutrition information will be provided in advertising. That will happen because under the voluntary proposal, nutrition labeling will be available on more products and will be more relevant and usable to consumers. This will stimulate greater consumer interest in nutrition information, which will in turn result in food processors competing in the marketplace on the basis of levels of nutrients in their products.

We understand that Senator McGovern, the sponsor of S. 1652, now advocates the elimination of Section 7 as presently worded. We concur.

Demonstrations and Evaluations: NFPA does not object to a program of demonstrations and evaluations. Whether such a program will be of consequence depends on how it is carried out. We suggest that an advisory panel be appointed to guide and counsel development of such a program.

The provision for a demonstration and evaluation program further precludes the need for a mandatory nutrition labeling program. The stated objective is to find more effective methods to convey nutrition information. If more effective methods are found, it would entail label changes. Under a mandatory program, label changes could result in major costs and disruptions in the food marketing chain.

The most effective research and testing of methods to convey information can be carried out by industry. Under the NFPA voluntary nutrition labeling proposal, industry would be encouraged to undertake what this provision of S. 1652 proposes to have government do.

Consumer Label Education: NFPA has long supported better nutrition education for consumers, and that includes education on nutrition labeling.

Conceptually, it is easy to agree that everyone should know more about nutrition and about what they eat. Disagreement usually arises over the nutrition education message.

In responding to the Dietary Goals published by the former Senate Select Committee on Nutrition, and on other occasions, consumers make it abundantly clear they do not want to be told what to eat. Instead, they want to have the best information available, in the most cost-effective way, so that they can use the information if they choose. Beyond that, consumers have asserted their right to eat foods of their choice.

We recommend provision be made for establishment of an independent advisory panel to include food industry executives. The requirement should be written into this legislation that the Secretary of HEW make a good faith effort to incorporate recommendations of this panel into the consumer label education program. The food industry is in direct daily contact with consumers about their attitudes toward food and food labels. A relevant and meaningful program is much more likely with food industry input.

In conjunction with an education program on nutrition labels and labeling, there must be greater emphasis on nutrition education. Nutrition labeling is only beneficial to consumers if they know how to apply the information. Knowledge and understanding of nutrition among consumers today is woefully lacking, in part because nutrition science itself is in the developmental stages.

Mandatory nutrition labeling is inappropriate in the absence of a better public understanding of nutrition. This is one reason why NFPA's voluntary labeling proposal should be adopted, for it allows a degree of nutrition labeling that is commensurate with consumer interest and understanding.

In conclusion, we support the goals of this legislation but are convinced that those goals cannot be achieved as the bill is currently drafted. NFPA opposes the legislation as presently written and we have identified the principles we think are essential.

We believe that the goals outlined for S. 1652 could best be achieved through adoption of the NFPA voluntary labeling proposal and we urge the subcommittee to endorse the voluntary concept.

Senator SCHWEIKER. All right. Next, Mr. Bracken.

Mr. BRACKEN. Thank you, Senator.

I am Robert Bracken, president of Morton Frozen Foods and a member of the board of directors of the American Frozen Food Institute.

I will also briefly summarize my written statement which I ask be placed in full on the record.

Senator SCHWEIKER. We will without objection.

Mr. BRACKEN. We at the American Frozen Food Institute also support the basic aims of this legislation. We feel the consumer has the right to accurate, objective, and easily understandable nutrition and ingredient information.

However, we believe the bill could be improved in several areas.

The legislation would require manufacturers to list on their labels all the spices and colors they use. AFFI opposes this requirement for the following reasons:

First, the listing of the names of those ingredients, which are used in very small amounts in most foods, would unduly lengthen ingredient statements with long chemical names having no meaning to consumers.

Second, the combinations of flavors, colors, and spices used by manufacturers constitute in many cases important trade secrets which ought not to be sacrificed without some compelling reason.

This bill already provides that flavorings need not be disclosed unless deemed necessary for the purpose of providing health information to consumers.

This limitation should also apply to colors and spices.

We would eliminate the requirement that every food label bear the statement that ingredients are used in the descending order of predominance by weight.

In a significant respect, that label statement would be inaccurate, since this legislation also provides that ingredients comprising less than 5 percent of a food need not be listed in the descending order of predominance by weight.

We believe that consumer education, not the food label, is the appropriate vehicle for advising the public that the format of the ingredients statement is in the order of predominance.

As for nutrition information, we believe that a shortened format, wherein only macronutrient information would be required, would adequately serve the consumer need to know while at the same time encouraging industry to voluntarily label an increased number of foods.

We do urge, however, that except where nutrition claims are made for a food or where nutrients are added to a food, that nutrition labeling remain voluntary.

The approach we favor, which is reflected in part in this bill, is to have the FDA and the USDA with the help of industry develop an approved nutrition data base.

Industry could then use it as a standard reference in its voluntary labeling programs.

AFFI is, however, seriously concerned about that portion of the legislation directing the utilization of a nutrition data base which indicates representative nutritional value at point of purchase.

This point of purchase requirement would cause substantial problems to our industry because the nutritional information that we have already developed is based on point of pack, not on point of purchase.

Moreover, handling conditions over which the processor has little or no control vary widely throughout the food distribution chain.

AFFI wholeheartedly supports any legislative effort to achieve national uniformity for all food labels. In point of fact, we would go beyond the proposed legislation and ask that it be revised to encompass preemptive authority for all food labeling requirements.

We think that conflicting State and local laws concerning food labeling constitute a serious problem for consumers and manufacturers alike.

Such conflicting requirements, which have been brought up by many of the witnesses this morning, reduce efficiency and ultimately increase the cost to the consumer.

As Senator McGovern testified this morning, the labeling provisions of this bill would apply to food introduced into or delivered for introduction into interstate commerce 2 years after enactment.

This provision is unrealistic because of the leadtime required for the promulgation of implementing regulations. We therefore suggest, as did Senator McGovern, that compliance be required only after a period of time following promulgation of implementing regulations.

We also share his concern about criminal liability. We believe that any proposed legislation, including S. 1652, seeking to amend the Federal Food, Drug and Cosmetic Act, must contain a provision mitigating the strict, vicarious individual criminal liability standard of the present law.

In conclusion, I want to reaffirm the commitment of AFFI and its members to work with you and your committee in improving our food labeling laws, to the end that the consumer is provided with relevant, understandable information at a reasonable cost.

Thank you, sir.

[The prepared statement of Mr. Bracken follows:]

TESTIMONY OF ROBERT W. BRACKEN

ON BEHALF OF

THE AMERICAN FROZEN FOOD INSTITUTE

ON S.1652

"NUTRITION LABELING AND INFORMATION AMENDMENTS

OF 1979 TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT"

MARCH 19, 1980

Good morning. I am Robert W. Bracken, President of Morton Frozen Foods of Charlottesville, Virginia and a member of the Board of Directors of the American Frozen Food Institute ("AFFI"). I am here today to testify on behalf of AFFI which is a non-profit, national trade association of processors and packers of frozen foods. AFFI's members number in excess of 400 companies which account for approximately 90 percent of the country's total production of frozen fruits and vegetables, and a substantial portion of the production of other frozen food products.

AFFI and I appreciate this opportunity to share with you our views concerning S.1652 - the "Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug, and Cosmetic Act."

We support the basic aims of this legislation. We feel the consumer has the right to "accurate, objective, and easily understandable nutrition and ingredient information." In many respects, we think this bill represents a major step forward in food labeling. However, we believe the bill could be improved in several areas, and my brief comments will focus on these suggestions.

Labeling of Colors and Spices

This legislation would require manufacturers to list on their labels all the spices and colors they use. AFFI opposes this requirement for the following reasons:

First, the listing of the names of these ingredients (which are used in very small amounts in most foods) would unduly lengthen ingredient statements with long chemical names having no

meaning to consumers. Second, the combinations of flavors, colors and spices used by manufacturers constitute, in many cases, important trade secrets, which ought not to be sacrificed without some compelling reason. This bill already provides that flavorings need not be disclosed unless deemed necessary for the purpose of providing health information to consumers. AFFI believes that this limitation should also apply to colors and spices.

Order of Predominance Statement

We would eliminate the requirement that every food label bear the statement that "ingredients are listed in the descending order of predominance by weight." In a significant respect, that label statement would be inaccurate, since this legislation also provides that ingredients comprising less than five percent of a food need not be listed in descending order of predominance by weight. We believe that consumer education is the appropriate vehicle for advising the public that the format of the ingredient statement is in order of predominance. The food label is not the proper place in which to convey this information.

Nutrition Information

AFFI applauds that portion of the proposed legislation which addresses the basic nutrition information of importance to consumers. We believe that a "shortened format" - wherein only macronutrient information would be required - would adequately serve the consumer's "need to know" while at the same time

encouraging industry to voluntarily label an increased number of foods.

We do urge, however, that except where nutrition claims are made for a food or where nutrients are added to a food, that nutrition labeling remain voluntary.

The approach we favor which is reflected in part in this bill, is to have the FDA and the USDA, with the help of industry, develop an approved nutrition data base. Industry could then use it as a standard reference in its voluntary labeling programs. We are confident that as a result of the development of such a data base nutritional labeling would appear on virtually every food product, even if it were not mandated.

AFFI is, however, seriously concerned about that portion of the legislation directing the utilization of a nutrition data base which indicates "respresentative (weighted) nutritional value at point of purchase". This point of purchase requirement will cause substantial problems to our industry because the nutritional information that we have already is based on point of pack, not point of purchase. Moreover, handling conditions, over which the processor has little or no control, vary widely throughout the food distribution chain.

Preemption and Open-Dating

AFFI wholeheartedly supports any legislative effort to achieve national uniformity for all food labels. In point of fact, we would go beyond the proposed legislation and ask that it be revised to encompass preemptive authority for all food labeling requirements.

We think that conflicting state and local laws concerning food labeling constitute a serious problem for consumers and manufacturers alike. Such conflicting requirements reduce efficiency and ultimately increase costs to the consumer.

This problem is intensified where the states impose conflicting labeling requirements in areas where there is no adequate foundation regarding the need for such labeling. For example, Massachusetts has recently promulgated an open-dating regulation which is being challenged in Federal Court. Other states are also actively considering the implementation of conflicting labeling requirements. A recent Office of Technology Assessment Report finds that "there is little evidence to support or to negate the contention that there is a direct relationship between open shelf-life dating and the actual freshness of food products when they are sold." Yet, Massachusetts, at least, has not been dissuaded from taking action. This type of ill-advised state activity burdens interstate commerce, and needlessly increases food costs. It is for precisely these reasons that national uniformity is required.

Effective Date

The labeling provisions of this bill would apply to food introduced into or delivered for introduction into interstate commerce two years after enactment. This provision is unrealistic because of the lead time required for the promulgation of implementing regulations. We, therefore, suggest that the precedent established by the Fair Packaging and Labeling Act be

applied here. This would require compliance only after a period of time following promulgation of implementing regulations.

Criminal Liability

We believe that any proposed legislation, including S.1652, seeking to amend the Federal Food, Drug, and Cosmetic Act, must contain a provision mitigating the strict, vicarious individual criminal liability standard of the present law.

Conclusion

In conclusion, I want to reaffirm the commitment of AFFI and its members to work with you in improving our food labeling laws, to the end that the consumer is provided with relevant, understandable information at a reasonable cost.

Senator SCHWEIKER. Thank you. Karen Brown.

Ms. BROWN. Mr. Chairman, my name is Karen Brown. I am vice president of consumer affairs for the Food Marketing Institute, which is an international nonprofit trade association representing approximately 1,000 food retailers and wholesalers located throughout the United States and in 30 foreign countries.

Stores operated by our combined membership numbered about 24,000 and did approximately $90 billion in sales in 1978, which is the last year we have the data for, which represents more than 50 percent of all food store sales in the United States.

We appreciate the opportunity to testify today on S. 1652. FMI and its members strongly believe in the consumer's right to freedom of choice and the grocer's responsibility to assist in providing enough meaningful information to consumers so they can make an informed choice.

Our own consumer research on labeling, the results of which are attached for the record, clearly indicate that consumers want food labels with understandable nutrition and ingredient information that will help them in their purchasing decisions and in planning a varied, healthy, balanced, and nutritious diet for themselves and their families.

At the same time, as purchasing agents for the consumer, we are particularly concerned about costs that will add to the price of food.

It is important to understand that the FMI labeling research did not analyze any cost considerations involved in suggested label formats.

Any changes in label format must take cost/benefit factors into account. We believe an economic impact study should be done of proposed labeling changes and that the results should be an important factor in deciding what will finally be included in labeling revision.

The following provisions we feel are imperative in any food labeling legislation supported by FMI:

One, Federal preemption over State and local labeling laws and regulations. We feel the language providing preemption in S. 1652 needs to be improved and would suggest language similar to that contained in the Federal Meat and Poultry Products Inspection Act.

We strongly oppose exempting certain specific labeling, such as open dating, from preemption requirements.

Moreover, we are concerned with that portion of the bill which authorizes the Secretary of Health, Education, and Welfare to make exceptions from the basic rule of preemption if a State or political subdivision can show that their separate requirement is necessitated by compelling local conditions.

This is especially troublesome because this legislation does not specify what these conditions might be.

This serves as a major impediment to the need for a coordinated, consistent, and practical labeling revision process and could significantly increase the cost of food labeling.

Two, the inclusion of a provision to limit criminal liability under the Federal Food, Drug and Cosmetic Act. Since S. 1652 seeks to amend the Federal Food, Drug and Cosmetic Act, violation of its provisions would subject the offender to all the sanctions available to the FDA under that statute, including criminal penalties.

We therefore strongly recommend that this bill be amended to contain a provision mitigating the strict individual criminal liability standard of *United States* v. *Park.*

FMI would like to work with the subcommittee regarding such amendatory language to be included in S. 1652.

Three, provision for the use of nutrient data bases that indicate representative values. Before any expansion of nutritional labeling can be accomplished, a nutritional data bank must be developed.

We propose the utilization of revised Agriculture Handbook No. 8 and similar bases which would alleviate the necessity for the manufacturer having to do extensive analyses to verify specific nutrient information with regard to specific products.

We believe the consumer can be adequately informed concerning nutrition using standard reference values.

Such an approach would preclude costly verification by manufacturers which costs, again, would ultimately be borne by the consumer.

We support this provision in S. 1652 but we seriously question the practicability of providing meaningful nutrient data based on point of purchase values, since most all labeling regulations have been promulgated on the processing/distribution sampling.

To require point of purchase data would essentially be starting over.

Point of purchase data should only be used on products offered as fresh.

Four, provision for marketplace experimentation of proposed labeling formats before they are mandated. FMI has consistently supported and encouraged voluntary experimentation with mechanisms by which nutrition information can be conveyed on the label.

We strongly endorse the provision contained in S. 1652 for this type of experimentation.

Our research clearly demonstrates a need to evolve a better organized format for presenting label information.

Further, we strongly urge that any nutrition labeling format be subjected to extensive tests in the marketplace before being adopted as a mandatory requirement.

I would like to comment briefly here on graphics. We have done some research in this area, the results of which are attached to our statement on S. 1652.

We feel that further research should be done in this area, but we feel that our research pointed out two problems which need to be addressed with graphics.

One is that they tend to editorialize about food, and this is further complicated by vitamin fortification. We feel that there could be some problems with a horsepower race on vitamin fortification in order to bring products up to a positive nutrient level for representation on a graphic label, and so that must be kept in mind as we approach this area.

We will briefly comment on the specific labeling requirements proposed in S. 1652.

Our research indicates that the prime concern of consumers is the ingredient content of foods. FMI supports ingredient disclosure for all food products, including those for which there is already an established standard of identity.

FMI supports the goal of the proposal for an ingredient order of predominance statement. Our research showed a surprising number of individuals were not aware that ingredients are presently listed in order of predominance by weight. We feel that further research is necessary to determine the best way to communicate this information to consumers, by the label or by other information and education vehicles.

We believe that the total amount per serving of sugars, sodium, potassium, fatty acids, and cholesterol should be considered for declaration on product labels if necessary to provide health information to consumers.

However, such labeling cannot be mandatory until adequate nutrient data bases are developed.

FMI does not oppose granting the FDA discretionary authority to require label declarations of specific colors, spices, and flavors if necessary to provide important health information to consumers.

We underscore the need for a finding of a public health informational need before mandating disclosure of such ingredients, because of the label clutter problem which will invariably result from disclosure, and because such declarations might invade the sanctity of proprietary formulations.

Our research demonstrates that while consumers may be interested in knowing the percentage of ingredients in the foods they buy, that interest is limited to characterizing ingredients in main meal items.

They do not seem to be interested in knowing the percentages of ingredients which constitute less than 5 percent of the total product.

Therefore we support that provision of the proposed legislation limiting disclosure to those characterizing ingredients which compose greater than 5 percent of the food, except where it might be

determined the absence of such declaration is likely to result in deception or confusion.

The ingredient and nutrition labeling provisions of the proposal would apply to food introduced or delivered for introduction into interstate commerce 2 years after enactment.

It is not unlikely that it would take this long for the FDA to do the preliminary work leading to final regulations. We therefore urge that this measure be made applicable to a period of time following the date implementing regulations have been promulgated.

We appreciate the opportunity to appear here today to comment on S. 1652. We would like to continue to work with the subcommittee as you continue your deliberations on labeling issues.

It is important that label revision be accomplished in a coordinated, consistent, and practical manner, and we recognize that the proposed legislation attempts to meet this need.

Thank you.

[The prepared statement of Ms. Brown and additional material supplied for the record follow:]

Testimony of

Food Marketing Institute

before the

Subcommittee on Health and Scientific Research

of the

Senate Committee on Labor and Human Resources

regarding S. 1652

March 19, 1980

My name is Karen Brown. I am Vice President, Consumer Affairs, for the Food Marketing Institute (FMI). FMI is an international non-profit trade association representing approximately 1,000 food retailers and wholesalers located throughout the United States and in 30 foreign countries. One-third of our members are single-store operators. Another 40 percent operate 10 stores or less. Most large food chains are members of FMI. The composite of these firms do business in every state and in nearly every county in the nation. Stores operated by our combined membership numbered about 24,000 and did approximately $90 billion in sales in 1978, representing more than 50 percent of all food store sales in the United States.

FMI appreciates the opportunity to testify on S. 1652, "Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug and Cosmetic Act."

FMI and its members believe strongly in the consumer's right to freedom of choice and the grocer's responsibility to assist in providing enough meaningful information to consumers so they can make an informed choice. Our own consumer research in labeling (results attached for the record) clearly indicates that consumers want simple food labels with understandable nutrition and ingredient information that will help them in their purchasing decisions and in planning a varied, healthy, balanced and nutritious diet for themselves and their families.

At the same time, as purchasing agents for the consumer, we are particularly concerned about costs that will add to the price of food. It is important to understand that the FMI labeling research did not analyze any cost considerations involved in suggested label changes. Any changes in label format must take cost/benefit factors into account. If food manufacturers revise their label format pursuant to government directives without compelling reason, it will be the consumer who ultimately pays the bill. We believe an economic impact study should be done of proposed labeling changes and that the results should be an important factor in deciding what will finally be included in labeling revision.

The following provisions we feel are imperative in any food labeling legislation supported by FMI:

1. Federal preemption over state and local labeling laws and regulations. We feel the language providing preemption in S. 1652 needs to be improved and would suggest language similar to that contained in the Federal Meat and Poultry Products Inspection Acts. We strongly oppose exempting certain specific labeling, such as open dating, from preemption requirements. Moreover, we are concerned with that portion of the bill which authorizes the Secretary of HEW to make exceptions from the basic rule of preemption if a State or political subdivision can show that their separate requirement is necessitated by "compelling local conditions." This is especially troublesome because this legislation does not specify what these "conditions" might be. This serves as a major impediment to the need for a coordinated,

consistent and practical labeling revision process and could significantly increase the cost of food labeling.

2. Inclusion of a provision to limit criminal liability under the Federal Food, Drug and Cosmetic Act. Since S. 1652 seeks to amend the Federal Food, Drug and Cosmetic Act, violation of its provisions would subject the offender to all the sanctions available to the FDA under that statute, including criminal penalties. We, therefore, strongly recommend that this bill be amended to contain a provision mitigating the strict individual criminal liability standard of U.S. vs. Park. FMI would like to work with the Subcommittee regarding such amendatory language to be included in S. 1652.

3. Provision for the use of nutrient data bases that indicate representative values. Before any expansion of nutritional labeling can be accomplished, a nutritional data bank must be developed. We propose the utilization of revised Agriculture Handbook Number 8 and similar bases which would alleviate the necessity for the manufacturer having to do extensive analyses to verify specific nutrient information with regard to specific products. We believe the consumer can be adequately informed concerning nutrition using standard reference values. Such an approach would preclude costly verification by manufacturers which costs would, again, be ultimately borne by the consumer. We support this provision in S. 1652 but we seriously question the practicability of providing meaningful nutrient data based in point of purchase values since most all labeling regulations have been promulgated on processing/distribution sampling. To

require point of purchase data would be essentially starting over. Point of purchase data should only be used on products offered as fresh.

4. Provision for marketplace experimentation of proposed labeling formats before they are mandated. FMI has consistently supported and encouraged voluntary experimentation with mechanisms by which nutrition information can be conveyed on the label. We strongly endorse the provision contained in S. 1652 for this type of experimentation. Our research clearly demonstrates a need to evolve a better organized format for presenting label information. Further, we strongly urge that any nutrition labeling format be subjected to extensive tests in the marketplace before being adopted as a mandatory requirement.

We will comment briefly on the specific labeling requirements proposed in S. 1652.

1. FMI research indicates that the prime concern of consumers' is the ingredient content of food products. FMI supports ingredient disclosure for all food products, including those for which there is already an established standard of identity.

2. FMI supports the goal of the proposal for an ingredient order of predominance statement. Our research showed a surprising number of individuals were not aware that ingredients are presently listed in order or predominance by weight. We feel that further research is necessary to determine the best way to communicate this information to the consumer -- by the label or by other information and education vehicles.

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3. We believe that the total amount per serving of sugars, sodium, potassium, fatty acids and cholesterol should be considered for declaration on product labels if necessary to provide health information to consumers. However, such labeling cannot be made mandatory until adequate nutrient data bases are developed.

4. FMI does not oppose granting the FDA discretionary authority to require label declarations of specific colors, spices and flavors if necessary to provide important health information to consumers. We underscore the need for a finding of a public health informational need before mandating disclosure of such ingredients, because of the label clutter problem which will invariably result from disclosure, and because such declarations might invade the sanctity of proprietary formulations.

5. FMI research demonstrates that while consumers may be interest in knowing the percentage of ingredients in the foods they buy, that interest is limited to characterizing ingredients in main-meal items. They do not seem to be interested in knowing the percentages of ingredients which constitute less than 5% of the total product. Therefore, we support that provision of the proposed legislation limiting disclosure to those characterizing ingredients which compose greater than 5% of the food (except where it is determined the absence of such declaration is likely to result in deception of confusion).

6. The ingredient and nutrition labeling provisions of the proposal would apply to food introduced or delivered for introduction into interstate commerce two years after enactment. It is not unlikely that it would take this long for the FDA to do the preliminary work leading to final regulations. We, therefore, urge that this measure be made applicable to a period of time following the date implementing regulations have been promulgated.

We appreciate the opportunity to appear here today to comment on S. 1652. We would like to continue to work with the Subcommittee as you continue your deliberations on labeling issues. It is important that label revision be accomplished in a coordinated, consistent and practical manner. We recognize that the proposed legislation attempts to meet this need.

FOOD MARKETING INSTITUTE
NUTRITION RESEARCH

AN ATTACHMENT TO TESTIMONY

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

OF THE

SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

REGARDING S.1652

March 19, 1980

FOOD MARKETING INSTITUTE
NUTRITION RESEARCH
DR. TIM HAMMONDS
AUGUST 9, 1978

FMI first became involved in the nutrition issue two years ago when our ongoing consumer research indentified this as a major area of concern for our customers. At about that same time, our good friends frc Family Circle Magazine in the person of John Pfriender came to us with their identification of the same emerging issue. From these initial discussions came the first jointly sponsored national nutrition conference held last year and a statement from our Board of Directors targeting nutrition as a major concern for FMI.

The feedback from our first conference convinced us that more than opinion would be needed, even expert opinion, if the growing debates over nutrition policy and nutrition information were to produce meaningful results. FMI decided it was time to find out what our customers' interests and concerns were relative to nutrition. We undertook an exploratory project on the presentation of nutrition information to discover what the public really wants to know and how that information might be made more readily understandable.

To guide us in our project design we sought the input of representatives from many interest groups including the U.S. Department of Agriculture, the professional nutrition community, food retailers, and consumer organizations. These groups told us one of the major gaps in nutrition research and education was that no recent studies had brought the talents of communications professionals to bear on the development of nutrition information programs.

Dr. Hammonds is Sr. Vice President at the Food Marketing Institute, 1750 K Street, NW, Washington, DC 20006. FMI is a trade association for food wholesalers and retailers.

With this in mind, we selected as our prime contractor on this research, the firm of Kelly Nason, Inc. Kelly Nason is a group of professionals located in New York City whose speciality is the development of advertising and communication strategies. The unique strength of this group is that all concepts are developed directly from original consumer research. They observe actual consumer behavior through a series of shopper interrupts and focus groups to determine information needs and to test the concepts developed to fill those needs.

The objective of this phase of our research was to develop a readily understandable nutrition indicator or set of nutrition indicators which would be meaningful to the general public in their food purchase decisions. We had no preconceived notions as to the final delivery system which would be most appropriate. We felt the final product or products might be useful in school educational programs, in point-of-purchase displays, on product labels, in media programs aimed at adults, or in a variety of other delivery formats.

The focus groups for this phase of the research consisted of 10 panels geographically dispersed from New York to California and assembled during the months of March through May of 1978. The groups were held in metropolitan areas and consisted primarily of women between 20 and 45 years of age with at least 2 children living at home, representative of an appropriate ethnic mix for the region, and having middle to low-middle income and educational levels.

Because Kelly Nason's process is creative, employing qualitative research to observe actual behavior, we felt it was important to cross-check the key hypotheses and assumptions through quantitative research where possible. For this purpose we relied on specific directed ques-

tions administered to a representative and projectable national sample of food shoppers by Yankelovich, Skelly and White, Inc. of New York. Part of this quantitative research was drawn from our regular yearly sample of consumer attitudes and behavior, and part from special studies. We would be happy to supply copies of the Yankelovich studies to those of you who are interested. Now to the research itself.

As to where nutrition information should be provided, our research (all references are drawn from the Kelly, Nason studies unless otherwise specified) shows that no single source will be sufficient. Nutrition information and education are complex issues with no "quick fix" solution. A variety of information sources which reinforce each other will be needed.

At this point in time, people want nutrition information relevant for their purchases but they do not want to become "professional nutritionists". That is, people are interested in information which will improve their shopping and meal planning but have no desire to become scientists in the process. The quantitative Yankelovich research supports this with the finding that currently only 15 percent of the shoppers feel "strongly" about "eating only what is good for them," while 60 percent "try for a balanced diet but don't make a big deal of it," and 17 percent "eat what they like and don't worry about it." But there is no doubt the level of interest is growing. The Yankelovich survey finds 77 percent of the population "more interested in nutrition than a few years ago."

We also learned that the new interest in nutrition is primarily because of the broader interest in the United States in health, physical fitness, and staying thin. Consumers use the word nutrition as an umbrella term covering eating habits, health, and lifestyle in a context much broader than the meaning of the word within the professional nutrition community.

Our qualitative research picked up something else very important. Even though shoppers are interested in nutrition information from a variety of sources, their prime concern right now is that they do not think they really know what is in the products they buy. Since this type of evolutionary creative research must move in the direction established by the consumer focus groups, Kelly Nason arrived very quickly at the product label as the focal point. The panels told us they do not pay much attention to current nutritional labeling because it is not useful to them. Broader education is of interest but labeling should be tackled first.

The quantitative Yankelovich research confirmed this finding. Approximately 75 percent of the shoppers say they use current nutritional labeling "some" or "not at all." Even the 25 percent who say they use it "a lot" would seem to use only part of the label based on our experience in the focus groups. When presented with a variety of products and asked to comment on them, our focus group label readers spent little time with the actual nutritional information. Instead, they moved very quickly to the list of ingredients. They seemed to be especially sensitive to additives and ingredients which might impact special dietary sensitivities. We learned quickly that a surprisingly high percentage of people in the United States have diet problems or allergies which require them to pay special attention to the ingredient list. Our Yankelovich survey confirmed this with the finding that 51 percent of the families identifying someone in the family as having allergies or health problems requiring special diet information.

We will use sample hot dog labels to illustrate this presentation. Many products were tested but we will have time to talk about only one

in today's short discussion. The hot dog was selected because it is a popular product which fits the category of food people are most interested in from a nutrition information perspective: processed main meal, main item foods.

It should be emphasized that our research was at least as important for our findings as to what consumers did not like as for our findings concerning what they did like.

Since the list of ingredients seemed to be of primary importance, we experimented with a variety of alternative presentations. In each case focus group participants were shown large mock-ups where explanations were needed but were then given actual label size mock-ups for comment and behavior observation.

Here is an example of what might be a current hot dog label (Exhibit A). Since graphic labels are currently the topic of so much discussion in Washington, we started with a variety of graphics. Sample bar graphs (Exhibit B) and pie charts (Exhibit C) were used for openers.

Typical reactions were negative with comments like: "This makes it hard to see the small (percentage) ingredients"; "It takes me back to school"; "Don't treat us like babies." And the very important observati "It would make me lazy." That is, this type of graphic creates a tendency to look at the main ingredient only. Remember, these were observations from medium-to-low income and medium-to-low education level individuals. The level of sophistication of nutritional information and knowledge is higher than anticipated at the beginning of this project.

It soon became clear that people wanted more than a mere presentation of ingredients. It was a mistake to assume that because people

concentrated on current ingredient lists, this was their only interest. They would like more information but pay little attention to current labels because they are poorly organized and difficult to use.

With this in mind, we broadened our scope to include nutritional information. There is now in use in the Netherlands a graphic label popularly called the Albert Heijn label or the Dutch label (Exhibit D). In preparation for testing of this version we presented an extensive explanation which I do not have time to repeat here. Put very simply this graphic represents the nutritional content (density) of products by depicting the relationship between nutrients and calories. The top half of the large circle contains a wedge representing nutrient content with the bottom half wedge representing total calories.

We found that while this label may work well in the Netherlands, and may be the subject of much discussion over here, it was a disaster in our focus groups. This was a major surprise to us since we hypothesized this format would be very well received.

The typical reaction was: "My God, it looks like a test." Other initial reactions indicated there was no obvious entry point, the format was too complex, and the organization was a barrier to use. This was true in spite of the explanations given prior to exposure.

Beyond the initial reactions, a significant secondary reaction was common to our focus groups and was one of the most important findings of this project. Almost everyone wanted to know how the size of the nutrient content wedge was calculated. The people in our focus groups were very suspicious of any graphic which reduced nutrient information to a simple form because they feared the method used would not reflect their own values and opinions.

As a further exploration of graphics, we tried a new system designed to incorporate many of the comments we were hearing (Exhibit E). There were many, many problems with this one. People simply did not relate well to it. One problem was the tendency to translate recommended daily amounts as upper limits. For example, sample products high in protein compared to the recommended daily amount tended to cause concern that other high protein products should not be eaten in the same day.

But there was a more fundamental concern with the portion of the label indicating actual recommended daily limits. There is considerable mistrust of "experts" who recommend actual product choice decisions or trade-offs instead of leaving these to the public. It is one thing to present a variety of recommendations from independent sources subject to public judgment, quite another to institutionalize one particular set of judgments on the label.

It was through this line of reasoning that the basic problem with graphics finally came out. Graphics tend to editorialize. That is, by their nature the design tends to predispose some products to look good and others to look bad. This is particularly significant since different consumers in our focus groups clearly used different judgment criteria in their own product decisions.

The mood in our sample of consumers was definitely one of "don't editorialize." The public told us loud and clear they would prefer to make their own judgments based on basic product information because they know their own budget limitations, their own family's tastes, and their own lifestyle patterns. Our Yankelovich research found the most important factor in deciding what people eat is still "balancing the budget" at 41 percent of the sample. There was also considerable concern that fun foods would not survive a new label format, particularly a

graphic label; and that selective fortification could make almost any product look good under an oversimplified display system.

Not being quite ready to give up on systems which simplify information, we tried a currently available non-graphic nutritional indicator: Dr. Michael Jacobson's nutritional scoreboard approach. This again was a system requiring considerable explanation before its actual exposure. We used copy taken from Dr. Jacobson's writings (Exhibits F and G), a sample advertisement showing how comparative information might be presented (Exhibit H), and our researchers interpretation of the actual label format itself (Exhibit I).

For some this may be an excellent system, but not for the general population as represented by our focus groups. Comments included: "We would all have to be re-educated"; "This editorializes, we can decide for ourselves"; and "What is the basis for this?"

What had we learned to this point in the research? First, that people are not looking for oversimplification; they recognize the complexity of nutrition issues and the trade-offs versus their own budgets and lifestyles. Second, better organization of the information currently available on the label is needed. Third, the approach most favored seems to be the presentation of basic information leaving actual product choice decisions to the individual.

It is easy to see why better organization is important to people. We have been dealing with a reasonably simple product in our illustrations but consider another product we also tested, frozen waffles. (Exhibit J). Notice how long and how confusing this list of ingredients is. Notice also we have listed functional properties for the less well known ingredients. Our focus group panels liked this very much for they tend to shy away from ingredients which are difficult to pronounce and

serve no obvious purpose. Functional property listing helps them to understand what is in a product and why it is in there. Ascorbic acid for example sounds much less threatening when shoppers can immediately see that it is Vitamin C. Even with a simpler product such as hot dogs (Exhibit K) people ask how the information may be sorted into meaningful categories.

When we explored basic information needs more thoroughly, we found three basic categories which appear to be generally useful. First, a list of characterizing ingredients which our focus group panels felt would include percentages by weight. Second, a list of additives and artificial flavoring or coloring agents. The presence or absence of these agents seemed to be sufficient for those concerned with this category. Percentages were not found to be a useful supplement. Third, a list of nutrient facts which seem to be most usefully presented in grams.

In addition we found that people preferred the total list of ingredients to be as complete as possible. One woman gave the example of corn syrup. She was allergic to this particular ingredient and her doctor had told her not to buy any product which merely listed "other sweeteners" without spelling out what these were.

Observing how people tend to use labels and how they think about nutritional information led our Kelly Nason researchers to evolve the format which I call the Organized Label (Exhibit L).

As you can see, it is easy to use and proceeds in a logical order. Major ingredients are listed by percentage content and minor contents are named even though not listed by percentage. Additives, coloring agents, and flavoring agents are highlighted separately.

Nutritional information follows on the organized label highlighting the items of most interest to our population sample: calories, protein, carbohydrates, fat, total sweeteners, and cholesterol.

Our groups were not interested in food composition data. Taking water in a stew product as an example, people seemed interested in knowing how much water was added but not how much water naturally occurred in the vegetables contained in that product.

This label format was consistently well received by every focus group exposed to it regardless of the order in which it was presented.

Vitamins and minerals would appear to be best treated separately at some other position on the label. Although people seem to like the idea that this information is available, most pay little attention to it and it is certainly of less importance than the information already highlighted. As you can see (Exhibit M), vitamins and minerals appear as they do in current label formats except that protein has been moved to the nutritional information part of the organized format. This was done because including it with vitamins and minerals tended to lead people to think Vitamin A or B was equally important as protein.

Summary

We have presented an organized label format which evolved from stated consumer preferences and observed consumer behavior. This has not been tested for technical or economic feasibility. We are not preaching this as a final solution by any means.

This is a well-received format, but we clearly need further discussion about where to go from here. We welcome the input of this conference, and we welcome the cooperation of grocery manufacturers. Our research is a solid beginning to discussion, not the end of debate.

We feel the key points of this research are:

First, people do not need a radically different or exotic label. Graphic formats in particular did not seem to be well received;

Second, any new system must leave room for fun foods. One of the greatest concerns was that any new system would force products off the market place or price them out of reach;

Third, people are concerned about making their own decisions based on the type of information shown here. They want facts, not editorials or opinions; and

Fourth, it is a mistake to think legislating someone's concept of "bad" foods out of existence will automatically improve everyone's diet. People want to make their own tradeoffs within their own budgets and lifestyles. Time and time again we heard the phrase: "I don't want the Government telling me what to eat."

One woman illustrated this last point by using the example of fruit drink versus fruit juice. She said she knew drinks were much higher in water content than were juices. But with a large family, when her children came in from play and wanted something besides water she just could not afford to give them juice.

A final point in conclusion. Information overload is already upon us. Our sample of consumers was already confused by conflicting claims and counterclaims about foods and nutrition. A few more major reversals of what have been recently presented as "facts" could turn the public away from this issue altogether. All of us including the Government, the media, the nutrition professionals, and especially the non-professionals, must be very careful to avoid unsubstantiated claims concerning the health or safety of particular foods. Now is the time to tread carefully in our public pronouncements.

THE FOLLOWING TABLES ARE EXAMPLES OF LABEL FORMATS TESTED AND ARE NOT TO BE TAKEN AS FINAL RECOMMENDATIONS. THESE ARE NOT TO BE REPRODUCED WITHOUT THE SPECIFIC WRITTEN PERMISSION OF THE FOOD MARKETING INSTITUTE.

THESE ILLUSTRATIONS ARE NOT MEANT TO BE REPRESENTATIVE OF ANY INDIVIDUAL MANUFACTURER AND THE INGREDIENT CONTENT DATA HAVE BEEN ALTERED SLIGHTLY TO PREVENT ANY INADVERTENT SIMILARITY TO AN ACTUAL PRODUCT.

(EXHIBIT A)

HOT DOG

Company Name, City

INGREDIENTS: Beef and Pork, Water, Salt, Corn syrup, Flavoring, Dextrose, Sodium ascorbate, Sodium nitrite

CALORIES	140	FAT (PERCENT OF CALORIES: 70%)	13g.
PROTEIN	5g.	POLYUNSATURATED	1g.
CARBOHYDRATE	2g.	SATURATE	12g.
		CHOLESTEROL*	100mg
		SODIUM	900mg

PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCES (U.S. RDA's)

	%		%
PROTEIN	10	CALCIUM	0
VITAMIN A	0	IRON	2
VITAMIN C	15	VITAMIN B_6	2
THIAMINE	2	VITAMIN B_{12}	8
RIBOFLAVIN	2	PHOSPHORUS	4
NIACIN	6	ZINC	6

* Information on fat and cholesterol content is provided for individuals who, on the advice of a physician, are modifying their dietary intake of fat and cholesterol.

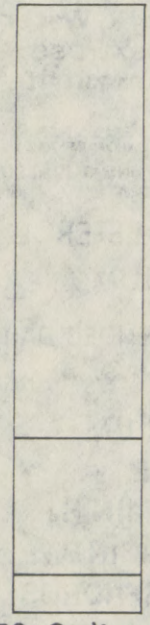
61-331 O - 80 - 33

(EXHIBIT B)

HOT DOG

Company Name, City

Ingredients (one link)



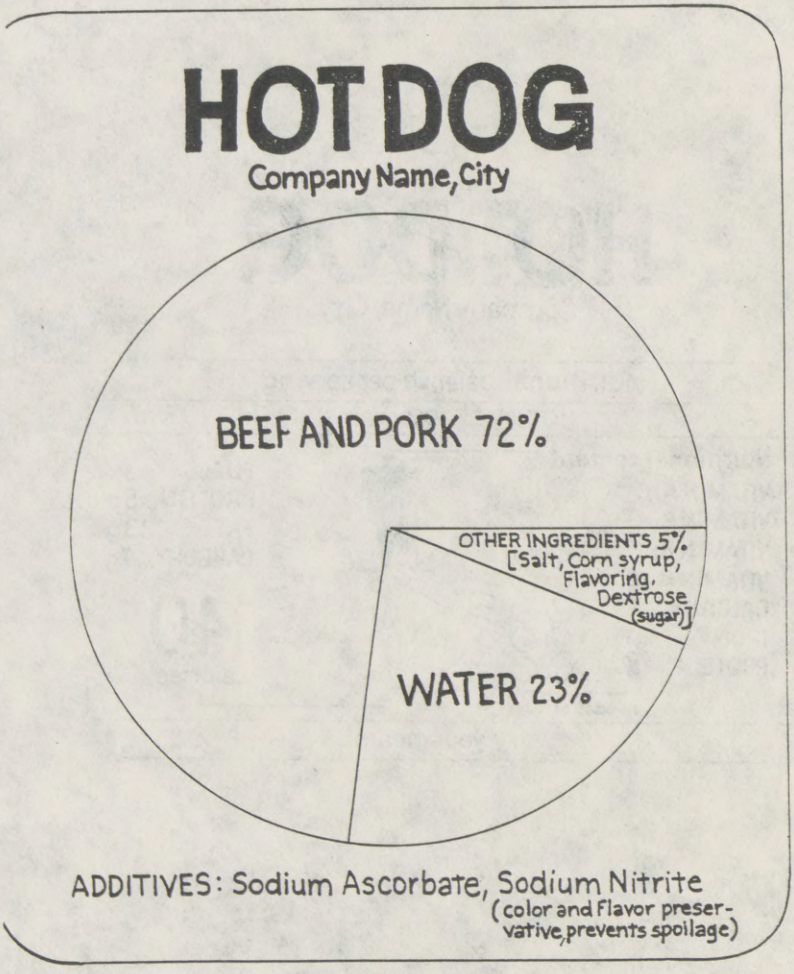
Beef and Pork 72%

Water 23%

Other Ingredients 5%
[SALT, CORN SYRUP, FLAVORING, DEXTROSE (SUGAR)]

ADDITIVES: Sodium Ascorbate, Sodium Nitrite
(color and flavor preservative, prevents spoilage)

(EXHIBIT C)


HOT DOG
Company Name, City
BEEF AND PORK 72%
OTHER INGREDIENTS 5%
[Salt, Corn syrup, Flavoring, Dextrose (sugar)]
WATER 23%
ADDITIVES: Sodium Ascorbate, Sodium Nitrite
(color and flavor preservative, prevents spoilage)

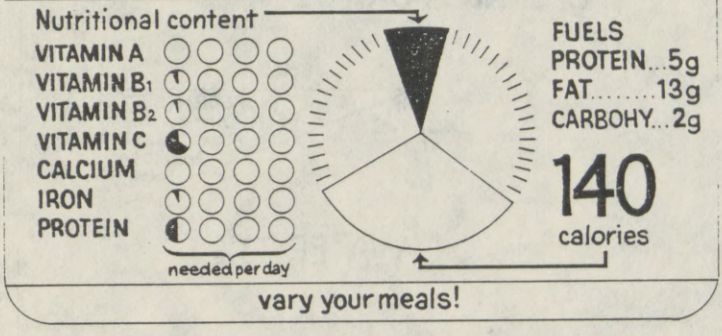
(EXHIBIT D)

HOT DOG

Company Name, City

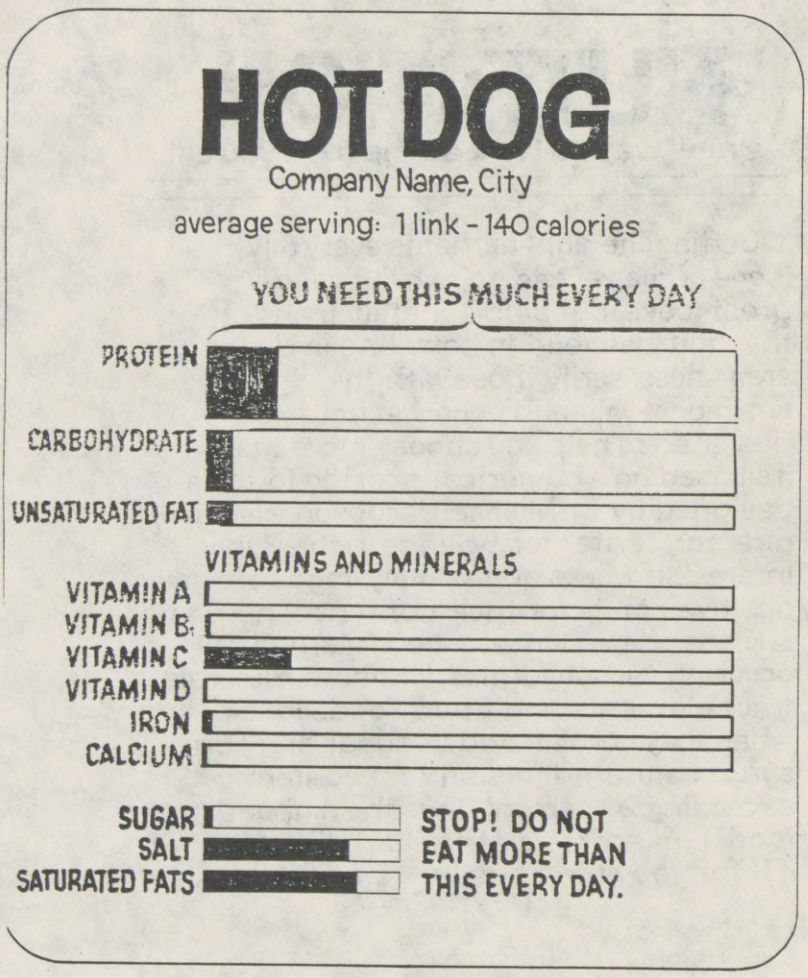
nutritional balance per serving

HOT DOG: 100 grams



vary your meals!

(EXHIBIT E)


HOT DOG
Company Name, City
average serving: 1 link - 140 calories
YOU NEED THIS MUCH EVERY DAY
PROTEIN
CARBOHYDRATE
UNSATURATED FAT
VITAMINS AND MINERALS
VITAMIN A
VITAMIN B
VITAMIN C
VITAMIN D
IRON
CALCIUM
SUGAR
SALT
SATURATED FATS
STOP! DO NOT EAT MORE THAN THIS EVERY DAY.

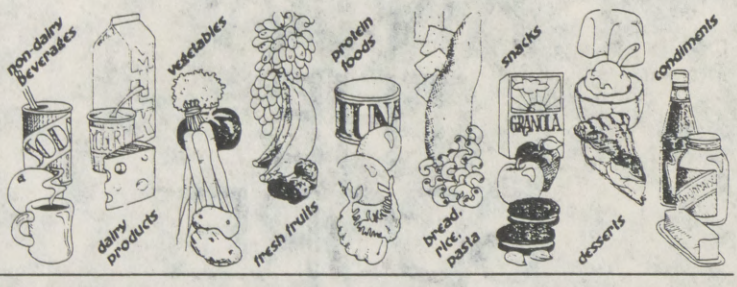
(EXHIBIT F)

NUTRITION

a new way to look at the food you eat.

Getting the right nutrients every day is one of the keys to good health and great looks, but unfortunately, many of the foods we tend to consume in quantity aren't necessarily those with the highest nutritional value. The chart at right was designed to help you choose more wisely. It's based on a numerical-scoring formula designed by Dr. Michael Jacobson, executive director, center for Science in the Public Interest. It works quite simply. Foods are given positive points for their content of nutrients such as protein, unsaturated fats, naturally-occuring carbohydrates, vitamins, minerals, trace elements and fiber. Foods lose points when they contain added sugar and corn syrup, saturated fats and fat content exceeding 20 percent. Thus the higher a food item scores on the chart, the better it is for you nutritionally.

(EXHIBIT G)



high-scoring foods

orange juice 62	skim milk 49	frozen collard greens 126	cantaloupe 99	beef liver 172	rye bread 29	granola and milk 45	cantaloupe w/ice cream 90	wheat germ, 1 T. 10
V-8 juice 40	buttermilk 45	frozen chopped spinach 91	water-melon 74	chicken liver 158	enriched egg noodles 28	sunflower seeds 44	water-melon 74	catsup, 1 T. 2
tomato juice 37	plain low-fat yogurt 44	raw tomato 69	orange 68	chicken breast 62	whole wheat bread 26	almonds 31	peach 29	cream, ¼ oz. 1
Tang (fortified) 30	Swiss cheese 43	canned carrots 59	honeydew melon 59	tunafish in oil 55	enriched spaghetti 26	cashews 24	apple-sauce 9	margarine, 1 pat −1
apple juice 7	whole milk 39	asparagus 49	straw-berries 50	lean pork chop 47	enriched white bread 22	raisins 13	angel food cake −15	butter, 1 pat −3
coffee w/cream 1	cheddar cheese 38	baked potato 32	grapefruit 45	cooked soybeans 41	brown rice 22	apple 12	ice cream −18	salad dressing, 1 T. −4
coffee or tea 0	creamed cottage cheese 34	romaine lettuce 28	diced pineapple 35	two eggs 36	enriched white rice 16	potato chips 8	apple pie −40	mayon-naise, 1 T. −7
artificially sweetened soda* 0	American cheese 32	iceberg lettuce 10	banana 26	shrimp 24	enriched instant rice 14	sandwich cookie −7	gelatin dessert −45	jelly, 1 T. −9
coffee w/sugar −9	butter −3	celery 7	grapes 12	pure beef hot dog 6	white bread 12	milk chocolate −27	chocolate cake −52	sugar, 1 T. −27
soda pop −92	ice cream −18	onion 6	plum 9	bacon 4	crackers 8	brownie −30	frozen coconut cream pie −62	syrup, 1 T. −34

(EXHIBIT H)

KNOW THE SCORE.

The nutrition scoreboard takes the mystery out of nutrition.

Now there's a simple way to know which foods are the most healthful. Just look at the Nutrition Scoreboard on the back of labels.

Example: .a hamburger (without roll) scores +34
.a Product X candy bar scores -33
.a portion of brocolli scores +116

The higher the score, the better. And so the hamburger is better for your family's health than the candy bar.

Look at the chart on the side

It shows how too many minus (-) nutrients add up to a very low score for the candy bar.

In the hamburger, everything scores pretty well, except for fat.

You can see how we add up the scores for the food item's nutrients, to get its total score.

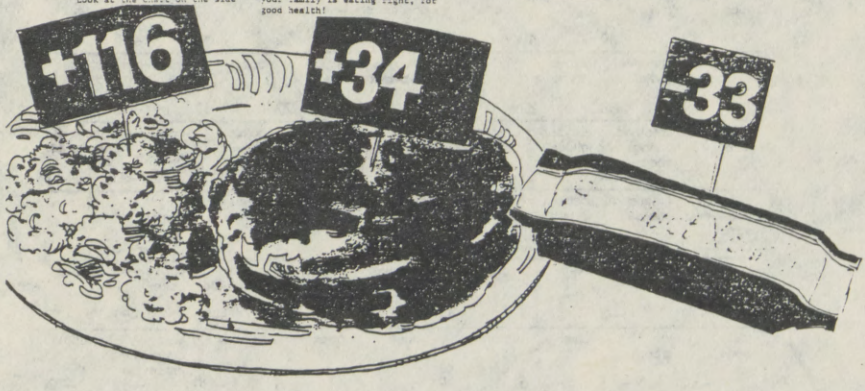
When you shop, look for our Nutrition Scoreboards on the back of many food labels.

Plan your meals with lots of high scoring foods.

And then you'll be sure that your family is eating right, for good health!

Hamburger	
Protein	20
Carbohydrate	0
Fat quantity	-8.4
Fat quality	-4.7
Vitamins: A	0.3
B1	2.3
B2	5.3
B3	11.5
C	0
Minerals: iron	15
calcium	-0.6
Nutritional value rating	34.3
Additives	none

Product X Candy Bar	
Protein	3.1
Carbohydrate, natural	2.5
added sugar (corn syrup	-47.5
Fat: quantity	0
Fat quality	-3.4
Vitamins: A	1.3
B1	1
B2	4
B3	0
C	0.5
Minerals: iron	1
calcium	-4.5
Nutritional value rating	-33.2
Additives	sodium sorbate



(EXHIBIT I)

NUTRITION SCOREBOARD

HOT DOG

Company Name, City

PROTEIN		5
CARBOHYDRATE		1
FAT QUANTITY		-3.5
VITAMINS:	A	1
	B_1	2
	B_2	2.5
	B_3	0
	C	1
MINERALS:	IRON	1.2
	CALCIUM	0.5

NUTRITIONAL VALUE RATING ..... +6

TOTAL CALORIES 140

(EXHIBIT J)

FROZEN WAFFLES

COMPANY NAME, CITY

Ingredients: enriched flour (flour, niacin, reduced iron, thiamine mononitrate, riboflavin), whey, water, corn flour, partially saturated soybean oil (with citric acid added to preserve freshness), sugar, whole eggs, soy flour, salt, monocalcium phosphate (a leavening agent), monosodium glutamate (a flavor enhancer), ferrous fumarate (an iron source), artificial coloring, niacin pyridoxine hydrochloride (one of the B vitamins), riboflavin, thiamine mononitrate, vitamin B_{12}

(EXHIBIT K)

HOT DOG

Company Name, City

Ingredients:

Beef and Pork,
Water, Salt,
Corn syrup,
Flavoring, Dextrose,
Sodium ascorbate,
Sodium nitrite

(EXHIBIT L)

HOT DOG

Company Name, City

- **Ingredients:**
  - Beef and Pork 72%
  - Water 23%
  - Other ingredients 5%

  [LESS THAN 2% EACH: SALT, CORN SYRUP, FLAVORING, DEXTROSE (SUGAR)]
- **Additives:**

  Sodium Ascorbate, Sodium Nitrite } (COLOR AND PRESERVATIVE, PREVENTS SPOILAGE)
- **Artificial Flavoring/Color:**

  none
- **Nutritive Facts (single serving link):**
  - Calories 140
  - Protein ..... (10% of USRDA) 5 grams
  - Carbohydrates ..... 2 grams
  - Fat ..... 13 grams
  - Total sweeteners ..... 1 gram
  - Cholesterol ..... 100 milligrams
- **Net Weight: 16 oz.**
- **Open date: 12-8-78**

(EXHIBIT M)

VITAMINS & MINERALS

(PER SERVING)
SERVING SIZE: 1 LINK

PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCES (U.S. RDA's)

	%		%
VITAMIN A	0	IRON	2
VITAMIN C	15	VITAMIN B_6	2
THIAMINE	2	VITAMIN B_{12}	8
RIBOFLAVIN	2	PHOSPHORUS	4
NIACIN	6	ZINC	6
CALCIUM	0		

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1055 Thomas Jefferson Street, N.W.
Washington, D. C. 20007

(202) 337-6000

MEMORANDUM

April 8, 1980

TO: FOOD MARKETING INSTITUTE

FROM: JAMES F. RILL

RE: APPROPRIATE STANDARD OF INDIVIDUAL CRIMINAL LIABILITY FOR FOOD-RELATED OFFENSES UNDER THE FOOD DRUG AND COSMETIC ACT.

Pursuant to your request, this memorandum will briefly address the issue of individual criminal liability for food-related offenses under the Food Drug and Cosmetic Act ("FDCA"). 21 U.S.C. §301, et seq. The current state of the law is such that food company executives and other supervisory employees work under a severe risk that they will be held to a standard of absolute liability for such offenses when committed by their company, regardless of the absence of their own relationship to the offense. This standard has evolved from certain language in the Supreme Court's United States v. Park, 421 U.S. 658 (1975), decision and some questionable interpretations thereof by the U.S. Court of Appeals for the Ninth Circuit. United States v. Starr, 535 F.2d 512 (9th Cir. 1976); United States v. Hata, 535 F.2d 508 (9th Cir.), cert. denied, 429 U.S. 828 (1976).

In our opinion, such a standard is fundamentally unfair, contrary to the standards set forth in current federal legislation dealing with health-and-safety-related offenses, and potentially damaging to individual incentive to participate directly in undertaking the elimination of adulterated and insanitary conditions affecting foods. It would be appropriate and consistent with the objectives underlying the FDCA for Congress to establish a rule under which an individual's criminal liability would depend on his not satisfying a standard of conduct which could reasonably be expected of him.

I. Absolute Liability For Individuals Under The FDCA Is Unfair And Inconsistent With Basic Notions Of Criminal Justice.

It is a fundamental precept of criminal justice in the United States that an individual should not be subject to prosecution without some act or omission on his part which is related to the offense. This principle can be derived from certain aspects of the Supreme Court majority's reasoning in the Park case, supra, 421 U.S. 658, although the result of that decision appears to endorse absolute vicarious liability. Nevertheless, the Court emphasized that the FDCA " . . . does not require that which is objectively impossible." Id. at 673. Moreover, the decision refers to a standard culpability under which an individual must be found to have had " . . . responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained

of, and that he failed to do so." Id. at 674. It is the fact that Park endorsed a District Court construction which imposed absolute liability and the subsequent narrow construction of the decision, see United States v. Starr, supra, 535 F.2d 512 and United States v. Hata, supra, 535 F.2d 508 which give rise to an improper standard, in spite of the above quoted excerpts from the Court's opinion.

The Senate Commerce and Public Works Committees also reached the conclusion that an individual should not be prosecuted for a food related offense under the FDCA unless he committed that offense knowingly, willfully or negligently. In 1976, these Committees endorsed an amendment to the FDCA which would have permitted prosecution of an individual under the Act only for violations knowingly, willfully or negligently committed. In doing so the Committees explained, "[n]egligence includes both actions of commission and actions of omission, and thus the failure to take appropriate action to avoid a violation of section 301 [of FDCA] is a negligent act." S. Rept. No. 94-684, 94th Cong., 2d Sess. at 31 (1976).

Finally, even the FDA recognizes that a strict construction of the Park standard under which individuals are absolutely liable for corporate offenses is inappropriate.

Though it opposed the Commerce and Public Works Committees' amendment to the Act, FDA did conclude that the law does not and should not " . . . permit imposition of criminal penalties on an executive officer for the actions or omissions of others. It is the officer's personal neglect that is punishable." Id. at 79. Thus a revision of the statute which would codify a negligence standard would not be inconsistent with either a fair (but not universal) reading of the Park decision or statements by the FDA.

II. Absolute Liability For Individuals Is Inconsistent With Current Federal Health And Safety Related Legislation.

No other comparable federal regulatory statute allows criminal liability under the absolute standard of culpability currently applicable to food and drug violations. The most common standard of individual criminal liability under the federal regulatory statutes concerned with health and safety issues limits liability to willful or knowing violations. For example, the Clean Air Act of 1970, the Consumer Product Safety Act, the Occupational Safety and Health Act, the Ports and Waterways Programs and the Toxic Substances Control Act all limit criminal liability to knowing or willful violations.

Section 113(c) of the Clean Air Act of 1970, 42 U.S.C. §7413, provides criminal sanctions for those who "knowingly" violate the requirements of an applicable

plan, or who "knowingly" fail or refuse to comply with an order of the administrator.

Section 21 of the Consumer Products Safety Act, 15 U.S.C. §2070, provides criminal penalties for any violator who acts "knowingly and willfully . . . after having received notice of non-compliance from the Commission . . . ."

Section 17(e) of the Occupational Safety and Health Act, 21 U.S.C. §666(e), limits criminal penalties to an "employer who willfully violates any standard, rule, or order . . . and that violation caused death to any employee . . . ."

Section 107 of the Ports and Waterways Safety Program, 33 U.S.C. §1277, provides criminal penalties for "[w]homever willfully violates a regulation issued under this Chapter."

Finally, §16(b) of the Toxic Substances Control Act, 15 U.S.C. §261(b), enacted in October 1976, provides that "any person who knowingly or willfully violates . . ." shall be liable to criminal penalties.

The "willful" standard has been defined by a long line of cases to mean "consciously and intentionally." See, e.g., United States v. Consolidation Coal Co., 504 F.2d 1330, 1334 (6th Cir. 1974); St. Louis & S.F. R.R. v. United States, 169 F. 69 (8th Cir. 1909). Accordingly, liability under this standard would be limited to those individuals who, proceeding from a conscious notion of the will and intending

the result which comes to pass, act or fail to act in violation of the FDCA.

The Federal Water Pollution Control Act provides criminal penalties for negligent as well as willful violations. Section 309(c), 33 U.S.C. §1319(c), of the FWPCA extends criminal liability to "any person who willfully or negligently violates" specified sections of that Act.

These standards are common to provisions contained in comparable regulatory statutes. The courts have considerable expertise in applying these standards and potential defendants would have a more precise idea of the standard of care against which they must guide their actions.

The "prudent man" standard which appears in the Senate-passed Drug Regulation Reform Act was drawn from section 404(a)(1)(B) of Public Law 93-406, the Employee Retirement Income Security Act (hereinafter "ERISA") and would extend liability to an individual:

> . . . acting without the care, skill, prudence, or diligence, under the circumstances then prevailing, that a prudent person would use if acting in a like capacity and familiar with the matters with which a prudent person in like capacity would be familiar. [125 Cong. Rec. S13483 (daily ed. September 26, 1979)].

We are not aware of any analog in criminal law for this standard. The floor debate on which it was adopted indicated it was intended to be a stricter standard than ordinary criminal negligence, but a more lenient standard than strict liability.

The fact that the "prudent man" rule is drawn from ERISA only obscures and confuses the standard intended. The rule of a prudent man standard in ERISA is insofar as we are aware the first occasion when such a standard has been incorporated in a federal statute. A Harvard Law Review note discussing the "prudent man" standard observes:

> Neither the Act nor its legislative history, however, clearly indicates how any of these more general fiduciary standards is to be interpreted. [Note: Fiduciary Standards and the Prudent Man Rule Under the Employment Retirement Income Security Act of 1974, 88 Harv. L. Rev. 960 at 964 (1975)].

Thus a standard calling for criminal punishment in those circumstances where the defendant acts willfully or is guilty of simple negligence is better rooted in both legislative and judicial precedent than is a "prudent man" standard of criminal responsibility.

III. Absolute Individual Criminal Liability Is At Least Potentially Inconsistent With The Objectives of FDCA.

Obviously, the FDCA seeks to assure the safety and sanitation of the nation's food supply and processing and storage facilities. This goal is best achieved through the direct participation of top-level executives in the food industry in sanitation and similar programs. Cf. S. Rept. No.

94-684, supra, 79 (Comments of FDA).* Under a system of absolute liability, where a company official could be prosecuted regardless of his diligence or care, the motivation to establish comprehensive and competent systems and procedures designed to prevent violation could be undermined. Since, as FDA recognizes, some errors are inevitable, an official might be more inclined to remove himself from the line of responsibility rather than to involve himself intimately with the development and implementation of necessary safeguards. A legal system which creates such an incentive for avoidance of responsibility is at best counterproductive and at worst perverse.

IV. An Appropriate Standard Of Individual Criminal Liability Under The Act Would Comprehend The Element of Negligence.

As the U.S. Court of Appeals for the Fourth Circuit in its Park decision observed "[a]s a general proposition, some act of commission or omission is an essential element of every crime." United States v. Park, 499 F.2d 839, 841 (4th Cir. 1974), rev'd, 421 U.S. 658 (1975). Although the Supreme Court disagreed with the Fourth Circuit's application

* In its memorandum on S.641, FDA made the following observation:

> "If the executive does his job properly, he will have established a elaborate system of checks and double checks which will practically preclude failure by subordinates . . . Of course, we recognize that no system is fool-proof and that some types of occasional isolated mistakes are inevitable." Id.

of this statement to the trial court's jury instruction, it did not under a fair reading of its decision disagree with the Court of Appeals' statement of general principle. It is necessary to codify this principle to avoid uncertainty of the law's application and to encourage responsible employee conduct. Thus, it is submitted that a "willful and negligent" standard endorsed by the Senate Commerce and Public Works Committees would be appropriate. Such a standard would incorporate not solely a standard of deliberate and intentional wrongdoing, but one involving the failure to take reasonable steps in order to avoid the offense. Under such a standard, an individual would be held to a higher duty of care than merely the avoidance of reckless conduct; however, this standard would not be so uncertain and potentially absolute as the "prudent man" test proposed in the Drug Regulation Reform Act.

Senator SCHWEIKER. Thank you very much.

First, I have a question from Senator Metzenbaum, who would like to have this asked of Dr. Hagen.

The NFPA argues that sodium labeling should be voluntary. They believe a variety of special diet products are readily available.

However, the Surgeon General says that everyone should avoid too much sodium, not just people on special diets.

Why shouldn't there be sodium labeling to help consumers make healthful food choices?

Dr. HAGEN. Senator, there are two parts of that question which I think are important, the first part being that the GRAS, generally recognized as safe committee, stated in their statistics in their research that up to 50 percent of the sodium in the diet of Americans comes from sources other than processed foods.

Now it varied all the way from 30 percent up to 50 percent. The saltshaker, in other words, on the table is a leading problem.

There's also that portion of the food supply, daily intake of food, which comes from restaurants, and that's not labeled for sodium.

Finally, and this is the second major point, this bill only provides for mandatory sodium labeling for processed foods. These other foods are not included in this segment, nor can we control table salt.

So I think that's the most compelling argument there.

The problem from a food processor's standpoint is cost of analysis and the metering equipment in the plant and so on.

Senator SCHWEIKER. Doctor, my own question. In hearing the other panel, the larger companies indicated they felt that the data base economically would be a net plus for them in most cases, but they did say at that point that one of the difficulties would be with smaller companies.

I would assume that your association would have a number of small companies and, therefore, whatever negative economic impact there is would probably fall on your membership.

No. 1, is that correct? No. 2, how might we adjust this bill to that problem relating to the small manufacturers and producers and suppliers?

Dr. HAGEN. Well, our program, of course, calls for voluntary nutrition labeling and that has been successful.

Senator SCHWEIKER. Well, is it true that many of your members are quite small or not?

Dr. HAGEN. Well, members both large and small are engaged in the current voluntary program. We believe it should be kept that way because particularly with the use of the data bank as we proposed in our blue book, this would encourage more members to come into the program.

In some cases, for example with canned foods, up to 90 percent of the product on the market is nutrition labeled already. So we don't believe that the program needs to be mandatory to accomplish desired public health or other consumer information effects.

The other part of the——

Senator SCHWEIKER. When you say 90 percent, is that of the total products your association manufactures?

Dr. HAGEN. No. The best statistics we have are from the food and drug survey, and they say overall processed foods—that was a

couple of years ago before some major product lines came on stream—they said that 60 percent were nutrition labeled; but we know, for example, within certain of the canned fruits and vegetables that the numbers are way up there.

It's very hard to find certain of the canned fruits and vegetables that are not nutrition labeled.

I think at the heart of this economic issue that I've raised is the compliance aspect of nutrition labeling. We favor the concept of a data bank. We propose it in the blue book, but what has not been addressed by this bill is the question of compliance.

The Food and Drug Administration has said on repeated occasions and in their current policy which is set forth in their December 21 Federal Register document that they still want the food processor to assure that his product falls within some undefined limit.

Now, a prudent food processor would still be forced to monitor his food, monitor his product, and make sure he's within certain limits and that is not addressed by the bill.

We think that should be addressed by any data bank proposal.

Senator SCHWEIKER. Do you see a significant differential impact between your large and small members or not? I don't know; I'm just asking you.

Dr. HAGEN. I have no way of judging all the details. Some of the small processors certainly have very specialized formulations. They've carved out a niche in the market and to get involved in mandatory nutrition labeling could be very difficult; but in terms of quantitative aspects, we're still engaged in our research on the economic impacts of these and the FDA proposals, and as that information becomes available, we'll be happy to make it available to the committee or subcommittee.

Senator SCHWEIKER. All right. I think we'd appreciate having that.

Karen Brown, you recommend that an economic impact study should be done on proposed labeling changes and the results should be an important factor in deciding what will finally be included.

Have you made this recommendation to the FDA or USDA and if so, has there been any reaction?

Ms. BROWN. We did make that recommendation in our testimony before the tripartite hearings on March 4 and we have not received a specific reaction to that from the agencies.

Senator SCHWEIKER. Unfortunately, I have a meeting I have to go to at this time, too, so I'm going to have to cut the questions short, but we will keep the record open in case there are some additional questions we might send the panel.

At this point I order printed all statements of those who could not attend and other pertinent material submitted for the record.

[The material referred to follows:]

TESTIMONY OF THE RETAIL BAKERS OF AMERICA BEFORE
THE FOOD AND DRUG ADMINISTRATION
ON TENTATIVE LABELING PROPOSALS
Washington, D.C.: March 5, 1980

My name is Gerard P. Panaro*. I am General Counsel to the Retail Bakers of America. On behalf of the nation's retail baking industry and its 20,000 or more members, I thank you for allowing us to be heard.

My testimony will address the tentative position of the Food and Drug Administration on:

1. Requiring specific declaration of colors, spices and flavorings;
2. Requiring quantitative ingredient labeling on more foods;
3. Requiring naming specific sources of fats or oils when they equal 10% or more of the food;
4. Requiring nutrition labeling on all foods, even those for which no nutritional claims are made or to which no nutrients have been added;
5. Requiring quantitative labeling of sugars; and
6. Requiring open dating.

Our concern here is that were these amendments to existing laws and regulations made to apply even to foods in intra-state commerce, then retail establishments would have to be exempted. Otherwise, retail bakeries, related lines of commerce and consumers will be adversely affected:

1. Compliance will be virtually impossible in retail bakeries;

*With the law firm of Jenkins, Nystrom & Sterlacci, P.C., Washington, D.C.

2. Compliance will destroy the retail baker's most important characteristic--the creation of hundreds of varieties of fresh, hand-made, fancy and unique bakery foods;
3. Compliance will not afford consumers any greater protection or information;
4. Substantial weakening or elimination of the retail baking industry will lessen competition, reduce consumers' freedom of choice, and impact on farmers, suppliers and related businesses;
5. Compliance would increase costs of bakery foods to consumers by as much as 20 or 25%.

To understand the reasons for our concern, it is first necessary to understand our industry. Retail baking is different from the wholesale baking industry, the biscuit and cracker manufacturing industry, and from other kinds of food processing generally.

Retail bakeries are not huge food "factories". They do not mass-produce millions of identical products using the technology and methodology of the assembly-line. Retail baking is largely a hand-craft operation. Literally hundreds of different products are made each day and in the course of the year.

Ingredients in a retail bakery are measured and combined in a far more approximate way than is the case with mass-produced baked goods. Quantities of each ingredient are not automatically dispensed in predetermined units as raw materials move along a conveyor belt. In retail baking, the ingredients are weighed by the baker using his personal judgment. This, of course, does not mean that goods produced in a retail bakery are inferior to those produced by machine, any more than a hand-built Rolls Royce automobile is inferior to an

assembly-line passenger car. But it does mean that no two finished products will be exactly alike.

Baking is done fresh every day in a retail bakery. Depending on the product, the season, the weather, the locale, customer preference and even the time of day, a baker will produce from several hundred to a few score to only one or two of each item he bakes that day. Unlike wholesale bakery plants which box, pack and distribute their products to a multitude of re-sellers in a several-state area, the great majority of retail bakers produce only for their own outlets. They carefully estimate their day's run so as not to have anything left over at the end of the day. There are exceptions, of course, since some retail bakeries also do a certain amount of wholesale business.

Retail bakeries do not prepackage most of the foods they make and sell. Most products are carried on trays directly from the oven to display cases in the retail portion of the bakery, where they are offered for sale unwrapped. Some items, such as brownies or breads, may be wrapped in plain shrink-wrap for display on top of the counter. The same holds for "multi-unit" operators--bakers who own two or more retail outlets--who usually do all their baking at a central location and deliver the finished foods unwrapped in boxes or trays, to each of their outlets.

Retail bakeries sell directly to the ultimate consumer. Most retail bakeries do a wholly intra-state business in a market often no wider than the neighborhood, the city or the area within a few miles' radius of the bakery. Bakeries located near state borders may do a negligible amount of "interstate" business. Most bakery foods are bagged or boxed only after sale to the consumer.

Retail bakers plan the next day's product mix the night before. They buy supplies only a few weeks or perhaps a month ahead of actual use and in relatively small quantities. They have little storage capacity. They buy from a variety of suppliers, depending on price, availability and other factors, such as strikes or special needs or opportunities. Even the same ingredient--flour, for example, or fruits for toppings--will have different compositions if from different suppliers. Virtually all baking done in a retail shop--75 to 90% or more--is done "from scratch"--that is, combining the ingredients according to the baker's own formula or recipe. Several such formulas are appended to my statement.

In short, were we to seek a model for the typical retail bakery, we could almost compare it to one's own kitchen at home. Retail bakeries are engaged in a commercial enterprise, to be sure, but the typical one is a small, family-owned business in which the owner and his spouse and relatives work side by side with the other employees. Most retail bakeries have between five and twenty employees only and have from $250,000 to $500,000 dollars gross sales per year. It is in this sense that we liken the retail bakery to a big home kitchen.

Perhaps it will now be obvious why we believe it is unnecessary, impractical or impossible to apply many of these proposals to the retail baking industry.

Requiring us to provide quantitative ingredient and sugar labeling, to specifically identify sources of fats and oils, and to provide nutrition labeling for everything we sell regardless of whether the foods are packaged or not, moved in interstate commerce or not, or the subject of nutritional claims or not, would force many retail bakeries right out of business. This is because most of them cannot

afford to pay the hundreds of thousands of dollars it will cost to have everything they make analyzed for nutrition and/or ingredient information. On the other hand, were they to stop making all but a relatively few kinds of basic, standard foods, they would lose the very thing--a marvelous variety of freshly-made, one-of-a-kind creations--which sets them apart as retail bakers. At the same time, putting the baker to such choices will add nothing toward further protecting the retail bakery customer's health or right to know.

Laboratory analysis of a sample product to determine nutrient information alone is quite expensive. Such an analysis, depending on the number of nutrients tested and the methodology used, could cost several hundred or a thousand dollars and might take three or four weeks to do. At an average cost of $600 per sample, it would cost a retail bakery $120,000 to have 200 products analyzed and close to $200,000 to have 300 products analyzed. Nor would this be a one-time cost only, since the analysis will have to be repeated regularly and performed initially with new recipes. To a baker doing only a half a million dollars of business a year, the one figure is as unaffordable as the other. Where will the money come from? The government has already said it will not foot the bill.

Aside from cost, there are other inherent limitations in laboratory analysis which make us question whether even this much could satisfy FDA:

1. The baker must still do the necessary calculations to determine the percentage of each ingredient in his product. He could have the lab do this as well, but that would cost perhaps a few hundred dollars more <u>per product</u>. Figuring the percentage of ingredients involves not only calculating

their proportions from a formula, but also weighing the raw mass before and after baking to determine moisture loss, then multiplying this factor by the original proportions obtained in order to get the percentage for the finished food. But the typical retail baker cannot do these things--he is too busy, baking!

2. Moreover, the analysis would still fall short in certain respects. For example, such analysis can distinguish coconut oil from lard, but might not be able to determine very well the percentage of oil and the percentage of lard.
3. Results of a sample analysis will not necessarily apply to other pieces of the same product. If the dough out of which a sample bun was cut, for example, was worked or allowed to stand for a shorter period than other dough out of which other buns were made, the composition of each would differ. This is because as dough is kneaded or let stand, the yeast in it burns sugar and this changes the character of the dough. The longer the dough stands, the more sugar is consumed by the yeast.
4. The baker frequently must substitute one ingredient for another in the same product. A fruit-topped danish, for example, may be topped with strawberry, lemon, apple or some other kind of fruit. Which topping is chosen and exactly how much is put on by hand will of course affect not only the ingredient list but also the ingredient percentage of every single piece of danish. The baker may spontaneously decide to substitute lemon for apple topping in the middle of doing a single batch. He may do so for

variety, color, taste, an unexpected exhaustion of his apple topping supply--and may put a few more grams or less on each danish. If the baker has only labels listing apple topping and he puts them on lemon-topped danish, he is guilty of misbranding. Requiring percentage ingredient labeling in situations like these is equivalent to requiring Detroit to paint cars only one color or to ordering utility companies to ration water by the drop.

5. Requiring a laboratory analysis of every product will slow the introduction of new ones and increase the losses on those which fail. As we have seen, the retail baker produces day to day; competition from wholesalers, grocery stores and supermarkets is intense. Ninety percent of consumers now buy their bakery foods from supermarkets. The retail baker survives and maintains his distinctive advantage against other competitors chiefly through his ability to offer a wide variety of custom-made products. Part of this capacity comes from the ability to test new product ideas right away, and either capitalize on a success immediately or cut a loss quickly if the product fails. Having to wait weeks for an analysis will deprive the retail baker of this advantage.

For these same reasons, we believe that requiring retail bakeries to declare specific colors, spices and flavoring, to declare specific sources of fats and oils and to provide quantitative sugar labeling is equally impractical, burdensome and unnecessary. Such requirements would virtually eliminate entirely the flexibility the retail baker, perhaps more than any other food processor, must have to vary

ingredient amounts and to substitute one ingredient for another, depending on price, availability and supplier. And here too, we submit, such penalty would be exacted of the baker without conferring any corresponding benefit on the consumer.

The retail bakery customer is always able to ask the man who made the product himself--the baker--about what is or is not in any item in the bakery. If the baker is not immediately available on site, he is at most a telephone call away. Or, the information can be obtained from his formula book by one of the sales clerks. What can elaborate labeling regulations, in truth intended for a wholly other kind of large-scale commercial enterprise, add to this? How can such a regulatory system improve on it?

Do small quantities of a huge number of products made, sold and usually eaten all on the same day need to be labeled with a "use" or "sell" or "not good after" date?

If there be any consumers for whom the lack of printed labels on a food is a fatal flaw, such people need not buy their bakery foods from a retail shop. But if there be consumers for whom the thought and taste, sight and smell of so many home-made, freshly baked delicacies, each a special creation, have no substitutes, and if you take away <u>their</u> prime source of satisfaction--the retail bakery--then to whom shall these consumers go and who will there be to protect <u>their</u> right to choose and <u>their</u> right to have expectations fulfilled?

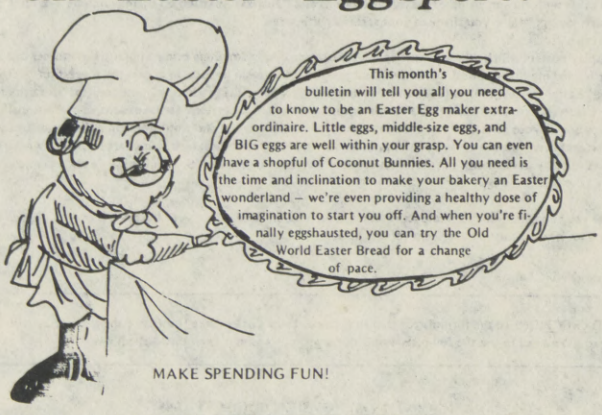
On these grounds, we respectfully, but forcefully, urge you not to try to make these proposals applicable to the retail bakers of America.

(301) 277-0990

RESEARCH ... MERCHANDISING BULLETIN

March, 1980

Be an Easter Eggspert!



MAKE SPENDING FUN!

Easter can be one of the happiest holidays of the year: Winter is over (hopefully). Spring is on its way. The Easter Bunny delights children without bringing out the "gimme" syndrome of Santa Claus. Spring flowers and fresh spring breezes help everyone shake off the winter blahs. Capitalize on the rejuvenating effects of spring by making a visit to your bakery a bright spot in your customer's day.

In these days of rising prices and omnipresent inflation, no one likes spending money, and few people are in a position to spend without thinking. However, everyone has to purchase food, and you can attract and keep more customers by making their purchases at your store enjoyable. Of course, your bakery must be spotlessly clean, but it needn't look antiseptic and dull.

A cheerful decor with bright colors and attractive displays won't compensate for poor quality products. However, high-quality products in lack-lustre surroundings won't bring in customers either. Do yourself and your customers a favor by displaying quality merchandise in a quality style.

Faded, raggedy display items do more harm than good sometimes. A customer can be forgiven for thinking that the bakery foods are in no better condition than the display surrounding them. Likewise, a shiny-fresh display unconsciously suggests that the items in it are equally fresh and tasty. If you use artificial flowers, make sure they are always dust-free.

61-331 O - 80 - 35

Easter and spring lend themselves very nicely to theme decorating which is both eye-catching, cheerful, and relatively inexpensive. With the Easter Egg Cakes and Novelties in this bulletin, you can decorate your store with your products to a large extent. A window display of bunnies in various sizes is sure to make some little boy drag his mommy into the store. Likewise, you can catch the adult's eye with a bunny and egg display and a poster which asks: "Which came first, the bunny or the egg?"

Plan to rearrange your displays weekly, at least a little. Move a display from one spot to another. Change a few items around. Replace sold merchandise with slightly different items. You're not in the redecorating business, but you are in a selling business, and you're customers will notice a new touch here and there and come in to investigate. You might find it effective to have a small display area which is completely changed every week; use it to feature new items or specials. Customers will become accustomed to "just stopping by" to check it out and staying to purchase something.

Make a major decor overhaul for new seasons or holidays – Mother's Day, Memorial Day, Father's Day, Fourth of July, Labor Day, summer and fall. Check your Fresh Baked for lesser-known holidays which could suggest a small special display, such as National Secretaries Week, April 20-26 (Secretaries Day is the 23rd). Small cakes with flowers or other pretty decorations and "Thanks!" written on them would be a natural. Put up a sign saying: "Have you thanked your secretary this week?"

Display posters which ask questions or tell a customer to do something bring a potential customer one step closer by making him respond. An automatic answer will trigger an impulse to act on the suggestion. A sign saying "Easter is April 6th" is functional but dull. A sign saying "Bring a bunny home tonight!" is far more liable to attract attention and bring a customer into the store. Posters need not be expensive professional jobs. Perhaps one of your sales staff has a hidden talent for casual lettering and would welcome the opportunity to be a bit creative. You can't lose by asking. Consider supplying your local high school art class with a cake or cookies one day in exchange for posters (you offer wording suggestions). Some of those "kids" may be pretty talented.

Use your imagination and whatever resources you have on hand. Make your bakery a place people will enjoy coming to, if you want to have them coming back.

CORRECTION: In the formula for Danish Caramel Twist Coffee Cake (January), the last line should read: "You can re-use the foil pans 4 or 5 times without washing, then throw them away."

SCINTILLATING SIGN SUGGESTIONS

St. Patrick's Day, March 17

- Take some green home tonight.
- Make someone's Irish eyes smile today.
- Bring home a treat for the "Little People" at your house.

April Fool's Day (All Fools' Day), April 1

- Don't fool around! Buy fresh-baked for your family.
- Feeling foolish? Giggle over our goodies today.
- Don't be fooled! Bakery-fresh is best.

Easter, April 6

- You're nobunny till somebunny loves you!"
- Everybunny loves somebunny sometime.
- Have an eggciting Easter!
- Try our eggceptional Easter basket!
- Give a bunny a home.
- Plan an eggsclusive Easter party with out help.
- Hop on in for some of our Easter specialties.

Secretaries Week, April 20–26
Secretaries Day, April 23

- Have you thanked your secretary today (this week)?
- Surprise your secretary!
- Brighten your secretary's coffee break!

OLD WORLD EASTER BREAD

Mix well in clean bowl:

15 lbs.		Bread Flour
7 lbs.		Water (variable)
	2½ ozs.	Salt
1 lb.		Yeast
3 lbs.		Sugar
1 lb.		Powdered Milk
2 lbs.		Shortening
1 lb.	12 ozs.	Whole Eggs

Add and mix smooth:

3 lbs.		Currents or Raisins (washed and drained)
1 lb.	8 ozs.	Diced Fruit
	2 ozs.	Vanilla

Fermentation time – 1 hour of full rise.

Scale weight 1 lb. 2 ozs. Round and put 4 staggered on a bun pan.

Proof ¾. Cut a cross on top. Put sanding sugar in cut on top.

Bake at 360° F for about 35 minutes. Glaze when hot out of oven. Ice around cut after bread has cooled.



Test-baked by: PETER VANDER MEER
Vander Meer Bakery, Inc.
33 Central Avenue N.W.
LeMars, Iowa 51031
(712) 546-5211

EASTER CAKE NOVELTIES

EASTER EGG CAKE

Mix on low speed, adding water slowly:

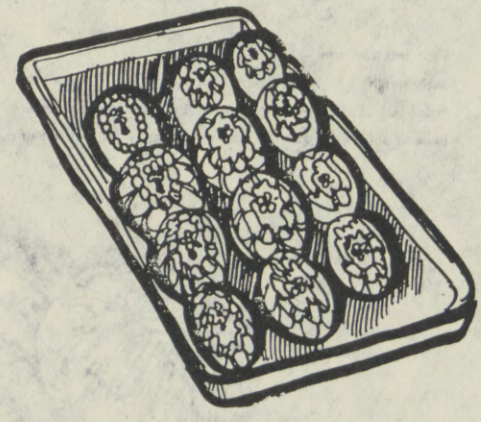
5 lbs.		Cake Flour
	1½ ozs.	Salt
	3 ozs.	Baking Powder
5 lbs.	12 ozs.	Sugar
	5 ozs.	Milk Powder
3 lbs.		Cake Shortening
2 lbs.	4 ozs.	Cold Water
	1 oz.	Vanilla

After all of water is added, mix at low speed for 5 minutes.

Add in 3 parts:

4 lbs.	8 ozs.	Eggs

Mix 5 minutes at low speed.



EASTER EGG CHOCOLATE FROSTING

Melt together and set aside:

1 lb.	Cookie Shortening
2 lbs.	Bitter Chocolate

Heat to 180° F:

1 lb.	4 ozs.	Water
1 lb.		Corn Syrup

Mix with part of water/syrup to form a paste:

5 lbs.		Powdered Sugar
	¼ oz.	Salt
	1 oz.	Vanilla

Add chocolate mixture to paste and mix.

Add the rest of the water/syrup and mix smooth.

SYRUP FOR THINNING EGG ICING

Bring to a boil:

8 lbs.	Granulated Sugar
8 lbs.	Corn Syrup
8 lbs.	Water

(ASSEMBLY AND DECORATION INFORMATION ON BACK.)

For Small Chocolate-Coated Eggs (1½" x 2½"):

Fill bottom half of mold using a large pastry bag. Clip on top. Bake at 370° F for 14 minutes. Remove from mold while hot. Cool. Trim.

Dip in heated chocolate egg icing. Use syrup if it needs to be thinned.

Sell these plain (coating only) or decorated. These can be attractively (and inexpensively) displayed on Easter basket "grass" with bunnies (cardboard or stuffed) set here and there. Place something under eggs to keep them from sticking to cellophane. Make up some complete baskets with bows on the handle, jelly beans and a small toy bunny or chick. Suggest them to parents as an alternative to the usual basket of cavity-encouraging candy.

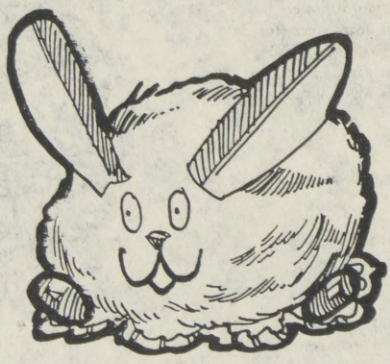
For Decorated Eggs and Coconut Bunnies:

Use 2½" x 3½" or 3½" x 5" easter egg molds. Fill half-full of Easter Egg Cake batter. Bake at 360° F. Cool.

Dip in chocolate icing and decorate as eggs. Be as fanciful as you like, with little flowers, swirls, rosettes, stars, etc.

Ice bunnies with white buttercream frosting. Roll in flake coconut. Leave white or spray with pastel colors. Cut ears out of grease-proof board trays and place on small end. Bag buttercream tail on large end. Use a small plain tube and any color buttercream for eyes and mouth. You might leave some bunnies without coconut for those children who like bunnies but don't like coconut.

These can be promoted as a cupcake substitute for birthday or school parties.



Test-baked by: PETER VANDER MEER
Vander Meer Bakery, Inc.
33 Central Avenue N.W.
LeMars, Iowa 51031
(712) 546-5211

LARGE EASTER EGG CAKES

Scale 1 lb. yellow cake or pound cake in each mold, using the large 3-strap egg frame (approximately 8¼" long x 5¼" wide x 2¼" deep).

Bake at 350° F. Dump on sheet pans, put in freezer to cool.

Remove from freezer. Put two half-eggs together with buttercream icing.

Place on sheet pan; you should get 9 eggs per sheet pan. Return to freezer. (By putting the eggs together and letting them set, you get a small flat surface on the bottom of the egg as it settles down.)

Icing the eggs – Hold the egg in your hand with the flat part facing up. Ice this half first and place the iced side down on board. Finish icing the rest of the egg. You can pre-ice many eggs at one time. Ice some in all colors plus chocolate.

Decorating – This is where decorators can use their imagination. All colors work together at Easter. First, put a border where the two halves join together. Add different designs and flowers. This is a good time to try out those tubes you've never used before and don't know what they'll look like. Here are some suggestions:

(1) Bunny House Egg: Draw doors and windows on both sides of egg. Put a chimney on top. Use lots of colors – red doors, purple windows, orange chimney and all colors of flowers. Ice the front of the board green (for grass). Put Easter picks, small candy eggs, jelly beans, etc. around the house, stick a chick, duck or rabbit on top of house.



(2) Make a cross on top of egg. Decorate with small flowers.

(3) Make a nest on top of egg (using green icing and leaf tube). Fill nest with cookies, candy eggs, and Easter picks.

(4) Put lots of assorted flowers on top and border, using different colors and designs.



NOTE: Make sure you use different borders and colors of flowers on the same cake. Use lots of Easter picks and Easter candy. Display in volume.

This is a good time to break in a new decorator, because every design and color goes well at this time of year.

Submitted by: EUGENE WILSON
Cakes, Cakes, Cakes, Inc.
d/b/a Harvey's Bakery
Castle Park Shopping Center
Valdosta, Georgia 31601
(912) 242-6142



INDEPENDENT BAKERS ASSOCIATION

March 25, 1980

Mr. Lawrence Horowitz
Majority Staff
Subcommittee on Health and Scientific Research
Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Horowitz:

William Botty, President of the Independent Bakers Association (IBA) prepared the enclosed testimony on S 1652 for the March 19, 1980 hearings.

IBA tried to have Mr. Botty give the statement in person but the limited one day hearing precluded his appearance. Nevertheless, IBA is deeply concerned with this legislation and would like you to place his statement in your hearing record so that our position is properly recorded.

Our membership is generally favorably inclined toward the goals of S. 1652, but we need help in several specific areas as detailed in the enclosed statement.

If we can answer any questions regarding the statement please feel free to call.

Sincerely,

Robert N. Pyle
Executive Director

PS: Would you please confirm in writing that the statement has been included in the hearing record.

RNP

P.O. Box 3731 · Washington, D.C. 20007 · (202) 223-2325

Fort Lauderdale, Florida Office: (305) 742-5457

March 19, 1980

STATEMENT BY WILLIAM G. BOTTY
OF THE INDEPENDENT BAKERS ASSOCIATION

BEFORE THE

SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

ON

S. 1652

"INGREDIENT AND NUTRITION LABELING BILL"

Mr. Chairman, I appear before you today as a representative of the Independent Bakers Association (IBA), a trade association comprised of over 300 small and medium sized wholesale bakers. Collectively we produce over half the nation's bakery supplies and represent virtually every state in the United States. Our association also includes many of the allied trades of the bakery industry, who share common interests on labeling issues and policies with their bakery clients.

You will be pleased to know, Mr. Chairman, that our membership is generally favorably inclined toward the overall goals of S. 1652 despite reservations, which I will detail later. Certainly, S. 1652 is better than the food labeling overhaul recently announced by the Food & Drug Administration (FDA), U.S. Department of Agriculture (USDA) and Federal Trade Commission (FTC).

Its dual goals of providing simple labeling information that the consumers will understand and simplifying the labeling

requirements, so that bakers and other food processors will have less expense in providing information is commendable and refreshing.

And in achieving its goals, S. 1652 has gone a long way in dispelling three myths:

1. that consumer oriented legislation necessarily means increased government regulation;
2. that less regulation of industry leads to an atmosphere less responsive to consumers; and
3. that industry interests and consumer interests can never go hand in hand.

In our view, S. 1652, does, however, fail to show a conscious understanding of the needs of the many small businesses that comprise an important part of the food industry. It is as if the legislation was written solely for the industry giants.

This shortcoming, unfortunately, is nothing new. Since enactment of the Federal Food, Drug and Comestic Act of 1938 (FD & C Act), the first law setting broad authority for FDA labeling requirements, the outgrowth of government regulation in the food industry has shown a remarkable lack of sensitivity toward small and medium sized businesses.

By promoting consumerism through arbitrary and unbending dictums of ever increasing expensive and baffling regulations, Congress and the regulatory agencies have threatened the very existence of many small business food concerns.

Nowhere else perhaps has the impact of this costly regulatory burden been more acute than among independent bakers. Independent bakers are becoming an endangered species due in large part to increased government regulation. Insensitive regulation makes the small business less able to compete with the giant conglomerates, who can more easily absorb the regulatory impact.

Our industry figures certainly support this statement. In 1939, a year after the first labeling law, there were 10,000 independent bakers in the United States. In 1964, the number was down to 5,000. In 1980, just 16 years later, there are fewer than 1,000 independents.

Admittedly, some of this decline can be traced to wide fluctuations in commodity prices and continued lax enforcement of anti-trust laws. Government tax laws, which tilt in favor of large chains and national bakers, haven't helped. There is little doubt, however, that over regulation has been the major cause in the demise of many independent bakers.

The long range result of this continuing trend is obvious. The country will have fewer bakers, less competition, higher bakery prices and accompanying excessive profits for the few giants that will survive.

The small-to-medium independent wholesale baker is also the leading developer and innovator of new and improved bakery foods. These are to the consumers' advantage in providing a greater

variety of nutritious foods at economical prices.

Let me make it clear that we are not asking that the health of Americans become secondary to our industrial survival. To the contrary, our industry has a spotless and responsive record of consumerism and food safety. When the Russo Subcommittee in the House held hearings on small baker problems with the 1978 bread labeling regulations of FDA, a panel of five FDA leaders could not recall a single case of harm or ill health to the American public from improper bread labels. That is an impressive record, Mr. Chairman, and our industry is proud of that record with our 220 million customers, who every day vote on our products.

Indeed, independent bakers are anxious to give consumers all the detailed information about ingredients they may require, consistent with high quality products at a fair price.

IBA simply advocates that new regulations and legislation, in this case, S. 1652, cast a more compassionate eye toward the independent bakery, which because of its size, doesn't always need the heavy handed regulatory guidance that has been propagated far too often.

Isn't it,after all, the policy of the Congress and the President to encourage the survival of small businesses, and in the interest of the public to do so?

Accordingly, I hope you will weigh our recommendations and objections to parts of S. 1652 with this thought in mind.

Basically, our reservations concerning new food labeling

requirements in the past have come down to the lack of flexibility shown for labeling relief in (1) certain emergency situations involving non-characterizing ingredients; (2) certain process changes; (3) new product testing and (4) ingredient changes.

An example of the structural flexibility that any food labeling bill needs, particularly in regard to small businesses, is a procedure which our industry has arbitrated with the Food and Drug Administration to provide labeling relief in emergency situations when the effect on the consumer was absolutely negligible. An example of such a situation would be if a baker producing bread using a sponge dough, which requires a two-stage mixing, had his plant's power turned off as a result of a heavy thunderstorm. When the power returns, some 24,000 pounds of dough, $2,000.00 in value had been over-fermented. In order to save the dough, the formula would have to be adjusted with sodium stearoyl-2-lactylate, yeast, and yeast nutrient and reworked.

Currently FDA would allow the baker temporary labeling relief since the effect on the product was negligible and the cost involved significant. It is this sort of recognition small business needs in S. 1652.

Another consideration important to our industry, and representative of the special circumstances involved in small business, are those instances in which the baker wishes to make

a process change, such as changing from a sponge dough to a liquid ferment process. While labels must be prepared simultaneously, it may not be until the initial run is made that the baker is able to adjust his new formula with changes in minor ingredients to produce a quality product. FDA currently allows a brief period of labeling relief to allow new, correct labels to be obtained from the label supplier, if because of a last minute change, certain minor ingredient amounts were changed slightly.

Would S. 1652 grant this kind of flexibility?

Another problem now encountered by the independent baker because of inflexible labeling requirements occurs when a manufacturer has because of cost considerations, or performance factors, the need to replace an ingredient, major or minor. The greatest problem in this area is when the various labels for a complete line of products have differing inventory supplies, in which case the labels for all the products will not be used up at the same time. The economics of certain ingredients may for example, necessitate a switch from palm shortening to soybean shortening. While there will be no discernable difference in product quality using either shortening, the baker would not be able to take advantage of certain market price changes if labeling requirements were such that the specific type of shortening would have to be identified. At present, the FDA permits a company, in the case of shortening, to list on the ingredient labeling that the product contains one of the following: palm,

soybean and or palm kernel. This allows the small and medium sized baker to take advantage of market fluctuations in that market. The consumer has the advantage of reduced product cost.

Our paramount concern with S. 1652, however, is that it should address more specifically the problems of the small and medium sized companies which comprise the overwhelming proportion of the bakery industry. We feel that S. 1652 should be amended to include a small business impact statement or that language be adopted specifically stating and allowing the amount of flexibility we need to operate and survive.

We also have a number of other related concerns.

First, with regard to the additional ingredient information which is required in the bill -- the need to identify spices and colors by name and to state that the ingredient listing is in decending order -- will require significantly more space for the ingredient listing.

For example,if a product contains three spices and three colors, there could be as many as three additional lines of text required on the ingredient listing.

The requirements for the nutritional information are even more lengthy and also cannot be placed on existing small labels which our industry uses. Indeed, it is probable that in some cases, such as snack cakes, where the product is relatively small, that it would not even be possible to put the specifically required nutritional information on pre-printed film.

Though to the layman, this may seem a rather mundane and insignificant point, in terms of cost to our industry, it is not. As you are aware, many bakers are using relatively small labels on single serving cakes and are having a very difficult time in locating all the text which is presently required to be on the label. Additional information would be impossible to add to the labels which the majority of our members use.

To give you an idea of the cost factor, changing the size of the labels would require a significant capital investment for each labeling machine, and even a small baker may have a large number. In any event, in some cases, the product can not take a larger label as it is too small. Anyone looking for an obvious example of this need only look at the packaged wafer or bread sticks commonly given out by the airlines. The present government required ingredient labeling nearly obliterates the product.

Complying with a labeling requirement on single serving packages would mean the use of wrapping film printed with the label information. This is more expensive on a per unit basis and necessitates the use of electric eyes to locate the printing in the proper place on the product. As you may know, these devices are notoriously unreliable and the increase in damaged product and rewraps would impose a further cost burden.

IBA requests that this bill be changed to grant an exemption from these requirements for single serving food products. I might note that, at the present time, S. 1652 does provide for exemptions

from the nutritional information requirements, at the discretion of the HEW Secretary. Our experience, nevertheless, has been that the regulatory agency is not sympathetic to the views of industry representatives, however costly and impractical the requirement might be, until mountains of testimony are available as to the need for an administrative exemption. By this time the country is usually littered with the remains of companies unable to comply.

Providing the public with more detailed ingredient labeling on single serving food products is, we believe, way out of line in cost and for a benefit that is negligible.

Second, we are generally concerned as small bakers over the continued "life and death" power that remains in the hands of the personnel at every level of FDA under S. 1652. Small bakers can't know every minor detail of every FDA rule and regulation under which they must operate and they count on the local inspectors to keep them informed.

In most cases the inspectors and their supervisors ask for more than is required, often at great expense to individual plants.

Therefore, we hope the Committee will write language into the law that guards against the "over zealous" inspector.

Third, our analysis and comments on other sections of S. 1652 are as follows (in numerical order):

Sec. 3 (Nutrition Information and other labeling requirements) (A) the common or usual name of each such ingredient ... This would include spices and colors. Spices are the last remaining

ingredient which allows any degree of proprietary secrecy of recipes. The disclosure of blends of seasonings ought not to be required. Individual spices, colors or flavoring components should require declaration only if there is a proven specific health concern (as with FD and C yellow #5).

Sec. 3 (C) a declaration of the quantity ... if the Secretary determines that such ingredient ... has a significant bearing ... IBA feels that this section should stress that this should only be for characterizing ingredients present in excess of 5% of the total product weight.

Sec. 3 Q (I) (B) the amount per serving of protein, fats, and carbohydrates in terms of caloric content (at the Secretary's option) ... the amount of these nutrients ought to be expressed in grams per serving as currently practiced. The nutrition information should be restricted to the above three macronutrients and calories.

The FDA's own recent surveys (Federal Register, Vol. 44, #247, Page 75995) of those family members, who are primarily food shoppers, indicated little concern for micronutrients and sugar in food products as follows:

1. A near majority of those surveyed by the agencies, 49 percent, reported no problem, other than price when asked about particular problems or difficulties with food;

2. Only 1 percent of the total surveyed appeared concerned with the nutritional value of food;

3. Only 8 percent expressed concern about food labeling;

4. 59 percent said they were "completely satisfied" with the kind or amount of information available on food packages and cans;

5. 27 percent said they found one or more sources of confusion on labels.

6. Only 25 percent said they want more information than is now available on food labels.

7. A relatively small 10 percent were "seriously" critical of current food labels.

8. Less than 5% are worried about preservatives.

9. Only 4% were concerned about additives.

10. Less than 3% were upset at the sugar content of food.

11. Slightly more than 1% mentioned "artificial colors."

12. Salt was a matter of concern to less than 1%.

13. About 1.5% mentioned artificial flavors.

Specific detailed information on micronutrients and sugars could be available from the manufacturers.

Sec. 3 (d) The amendment ... shall only apply with respect to food that is introduced ... two years after the date of enactment ... IBA believes the effective date must be delayed until 2 years after FDA's recognition of a standard data base.

Sec. 4 (Preemption) (a) ... no State or political subdivision of a State may establish or continue in effect a label ... IBA strongly endorses this section and feels it ought to apply to net weight rules too.

Sec. 4 (c) Subsection (a) does not prohibit a State or political subdivision of a State from ... continuing ... the sell or use date ...

We are opposed to state by state by state passage. We encourage Federal Preemption at least of the format -- even if not mandated.

Sec. 6 (Consumer Education Program on the Use of Labels and Labeling) ... IBA encourages this effort and trusts that similar funds already allocated for such efforts to USDA will also be applied. We believe a review of past educational efforts in labeling deserves a thorough review for continued justification, because of a noticable lack of success to date. IBA points our that a successful educational program would inform the consumer that ingredients are listed in order of predominance, so that the statement required under Section 3 (b) (1) (B) would not be required.

Finally, Sec. 7: (Notification to and Report by the Federal Trade Commission) ... IBA would like to encourage further consideration which will promote uniformity in requirements between USDA/FDA and FTC. Advertised disclosure ought not to differ from labeling, and advertising ought not to have to repeat label information,

In conclusion, Mr. Chairman, I will state again that our Association finds that S. 1652 presents a positive framework in which our members can work. We do, however, regard its ommission of any language related to providing flexibility or review for the small business, whether intended or not, a major flaw.

We hope your committee will see fit to address this issue via an impact statement requirement for small businesses, conciliatory language or specific language stating when and where exceptions may be made. We also urge, among other things, that single products be

exempted and language be written into the law guarding against "over zealous" FDA personnel.

We feel these changes will not only allow our industry members to survive but will allow them to continue to provide the type of innovativeness, and consumer products which make the baking industry more competitive and responsive.

Mr. Chairman, we appreciate this opportunity to make our views known on S. 1652. Thank you!

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Independent Bakers Association
Contact: Robert N. Pyle, Executive Director
P. O. Box 3731
Washington, D. C. 20007
Telephone (202) 223-2325



AMERICAN BAKERS ASSOCIATION

March 31, 1980

Honorable Edward M. Kennedy
Chairman
Subcommittee on Health & Scientific Research
Labor and Human Resources
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Enclosed is a statement of the American Bakers Association on S. 1652. Please include it in the printed record of the hearings.

Sincerely,

Robert J. Wager

Robert J. Wager
President

RJW/kak

enclosures (3)

2020 K STREET, N.W. • WASHINGTON, D.C. 20006 • 202/296-5800

STATEMENT OF ROBERT J. WAGFR,
PRESIDENT, AMERICAN BAKERS ASSOCIATION,
ON S. 1652

The American Bakers Association ("ABA") is a trade association representing over 200 baker members who produce 80 percent of this country's bakery foods in some 1,000 plants. We appreciate the opportunity to be heard on S. 1652.

ABA believes that S. 1652 makes many useful changes in food labeling requirements. In particular, ABA endorses the following features of the bill:

(1) The bill recognizes that consumers need nutrition and ingredient information that is not only accurate and objective, but also "easily understandable" so that they can "choose healthier diets at a reasonable cost." (Sec. 2(1).) This finding is supported by the results of FDA's recently-completed survey of food shoppers, which disclosed that consumers' "major criticism" of current food labeling is "complexity" of the ingredient statement -- particularly "the use of chemical and technical terminology." (FDA 1978 Consumer Food Labeling Survey

at 17.) ABA, therefore, endorses the bill's declaration that, "[i]n altering labeling requirements, special attention must be placed on improving labeling formats to convey more effectively needed information in a readily understandable fashion to the average consumer." (Sec. 2(5).) We urge this Committee to consider an even more explicit direction to FDA to emphasize simplicity in ingredient declaration, even at the risk of loss of some specificity. */

*/ Representative Charles W. Whalen, a strong supporter of consumer interests, has noted some areas where at least bakery products labeling could be simplified:

> "I certainly agree with baking industry spokesmen that all ingredients not be listed as complicated chemical names. For example, iron could be listed simply as iron, and not as ferrous sulfate. Baking powder might be listed as such, and not by its chemical name, sodium aluminum pyrophosphate. Monocalcium phosphate and potassium iodate might be better listed as yeast nutrients. Vitamin B_1 is a term more familiar to consumers than thiamine hyrdochloride."

H. Rep. 95-1272, Food and Drug Administration's Food Labeling Regulation: Its Effect on Small Business, 95th Cong., 2d Sess. at 20-21 (1978).

Another way to promote "easily understandable" labeling is to coin shorter names for ingredients. In 1976, ABA submitted a petition to FDA seeking shorter names for a number of common ingredients that would be easier to remember and more indicative of the identity of the ingredient than the chemical name, but would not compromise the consumers' "right to know." For example, under the

[Footnote continued on next page]

(2) ABA also endorses the bill's recognition that problems in the American diet cannot be corrected by restructuring the labeling regulations to require additional disclosures. Rather, as the bill notes in Sec. 2(b), benefits from label modifications can be maximized only if consumers are educated on the use of the information that is provided. To date, the educational effort needed to prepare the consumer to utilize basic label information intelligently has not been forthcoming, and the ordinary consumer remains ill-equipped to evaluate the data that

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[Footnote continued from preceding page]
ABA proposal, "baking soda" would be recognized as the common and usual name for sodium bicarbonate, while the term "monoglycerides" could be used to denote both mono- and diglycerides of edible fats. Although FDA denied the petition, we believe that passage of S. 1652 would require FDA to reverse its position.

Passage of S. 1652 would also make it clear that food producers can use the familiar term "niacin" in providing ingredient information, rather than an unfamiliar, technical name like nicotinic acid. Although the name "niacin" was coined to avoid consumer confusion as to the source of nicotinic acid, and is used as an ingredient name in FDA's own regulations (see, e.g., 21 C.F.R. §§ 137.165, 182.5530), FDA has recently taken the position that the form of niacin used in a bakery product -- niacinamide or nicotinic acid -- should be declared in the ingredient statement. It is hard to imagine a step more inconsistent with S. 1652's goal of providing information in an "easily understandable" way.

currently appears on food labels. It is, however, our hope that the initiatives in consumer education which S. 1652 contemplates will go a long way toward remedying these deficiencies.

(3) The bill properly recognizes that labeling rules must allow "appropriate flexibility on the part of producers . . . ." (Sec. 2(7).) Neither consumer nor industry is served by rigid adherence to an abstract right to know where the information required is costly to industry but is neither useful to nor desired by the consumer.

(4) The bill encourages the use of nutrition data bases "to the maximum extent feasible and appropriate . . . ." (Sec. 3(c).) Particularly if mandatory nutrition labeling were to be imposed on the food industry, a manufacturer's good faith attempt to declare nutrient content in accordance with a composite data base, with reasonable variances, must be recognized as the only practical approach to nutrition labeling.

(5) The bill would permit a waiver of order of predominance listing for ingredients present in the

finished food at levels of 5 percent or less. (Sec. 3(b).) This provision would restore some of the labeling flexibility which bakers lost when the rules which had governed bakery products for nearly forty years changed in July of 1978. */

(6) The bill preempts conflicting state and municipal ingredient and nutrition labeling requirements.

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*/ In the Federal Register of April 7, 1978 (see 43 Fed. Reg. 14,677), FDA published a proposed rule waiving the order of predominance requirement for low level ingredients in bakery foods. That proposal was based upon petitions submitted by ABA and the Independent Bakers Association which demonstrated that, absent the requested waiver, bakers could not react to seasonal and raw material changes by making minor formula adjustments -- e.g., increasing or decreasing levels of dough conditioners or enzymes. FDA has not yet acted on the proposal, although only thirteen letters of comment have been received on the proposed rule, all but one favorable.

Waiver of the order of predominance requirement for non-characterizing functional ingredients present at low levels in all foods was requested in a joint petition filed on June 8, 1978 by a number of trade associations, including ABA. That petition also proposed an amendment to 21 C.F.R. § 101.4 which would permit listing of these ingredients -- identified through use of the "and/or" labeling format -- if they are sometimes present in the product. FDA has not yet acted on either of these proposals. We believe that it would be appropriate to incorporate a provision for the listing of alternative ingredients in the proposed legislation.

Labeling requirements now differ from jurisdiction to jurisdiction, and this variation is costly for manufacturers and confusing for consumers. Therefore, to the extent that S. 1652 promotes uniformity in approach to food labeling, it performs an important service for industry and consumers alike. ABA urges that uniformity in labeling achieved by preemption extend to open date labeling as well.

For all these reasons, ABA regards S. 1652 as a constructive step toward bringing food labeling rules into line with modern realities. We believe, however, that certain additional provisions and changes are required.

1. The 1978 bakery labeling experience illustrates the importance of simplicity and flexibility in future labeling changes.

Our concerns with S. 1652 rest heavily on the baking industry's recent experience in redesigning all its labels in response to new FDA rules effective July 1, 1978. That experience demonstrated that even simple labeling rules carry significant hidden costs in terms of (i) a loss of flexibility to deal with unexpected raw material variations; (ii) barriers to

new product development; and (iii) a diminution of competition among suppliers. Moreover, these costs hurt the smallest firms the most. (A fuller description of the problems which arose out of the 1978 labeling changes is attached hereto as Appendix A.)

FDA has taken regulatory action to ameliorate certain of these effects. It has issued new regulations permitting "may contain" labeling for dough conditioners, yeast foods, and leavening (21 C.F.R. § 101.4(b)(16)-(18)); it issued a proposed regulation (discussed above at p. 5 n.*/) permitting ingredients in bakery foods present at levels of 2 percent or less to be listed other than in order of predominance; and it has invited bakers to confer with FDA officials as specific new problems occur under the regulations. ABA welcomed these steps.*/ We urge

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*/ At the same time, we want to make it clear that, in our view, FDA has not gone far enough. For example, the labeling relief granted would not protect a baker who is required to reformulate a product (i) because of the unexpected unavailability of a noncharacterizing functional ingredient (e.g., because of a strike at his supplier's plant) or (ii) to accommodate natural variations in agricultural ingredients used in the food that could not reasonably have been anticipated in time to use up the existing inventory of labels. Accordingly, ABA and IBA filed a petition on March 23, 1978 proposing a regulation which would permit ingredient statements

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the Committee to make clear that these FDA initiatives are fully consistent with the bill's intent to preserve "appropriate flexibility on the part of producers." (Sec. 2(7).)

2. Nutrition labeling should be voluntary and flexible.

Our second area of concern is the proposal to make nutrition labeling mandatory. (Sec. 3(c).) We believe that the aims set forth in the preamble would be best served by leaving nutrition labeling a voluntary program. We fear that a mandatory program would lead to complex data, often of limited value, at significant cost.

a. Costs. The direct costs of changing labels to add nutrition information would be substantial. There is little justification for imposing such costs on the many foods which are eaten solely for personal

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[Footnote continued from preceding page]
on bakery foods to remain unchanged for a limited period of time when such emergency reformulations were necessary. By letter of October 31, 1978, FDA denied that petition. We believe that it would be appropriate to incorporate a provision governing such emergency reformulations in the proposed legislation.

satisfaction. Moreover, nutrition labeling will tend to lock firms into existing suppliers whenever a change in ingredients could affect by even a few percentage points ingredients which must be shown on the nutrition panel. The bakers' 1978 experience shows that these burdens affect small bakers disproportionately. Smaller firms do not have management personnel or sophisticated systems to redesign labels and plan ahead to minimize waste in label change-overs.

b. Data Base. ABA supports the use of data bases for voluntary nutrition labeling. We caution, however, againt viewing a data base as a cure-all. The costs and difficulties of such an effort are likely to be far greater than now appear. In particular, troublesome questions about acceptable tolerances are likely to arise.

Moreover, the timing set out in the statute could cause problems. The effective date of mandatory nutrition labeling should be postponed until a reasonable time after data base information, with reasonable tolerances, becomes available for each specific food.

c. Lack of Consumer Interest in Mandatory Nutrition Labeling. FDA's random sample survey showed that only 1 percent of the population is in favor of "nutrition information on all products." 44 Fed. Reg. at 75,995, Table B.

3. There is no need for a statement that ingredients are listed in descending order of predominance. (Sec. 3(a)(1)(b)(1).)

Ingredients have been so listed for decades; if consumers do not know that by now, the fault -- and the remedy -- lies in consumer education. There is no need for every food label in the country to be redone.

4. The present rules on labeling colors and spices are adequate.

Current rules permit FDA to require the declaration of specific colors and spices where there is a proven need for such information. Thus, because some consumers are allergic to FD&C Yellow No. 5, that ingredient must be specifically disclosed. But, where there is no need for the specific information, manufacturers should retain the flexibility of declaring colors and spices as such. (Sec. 3(a)(1)(b)(1).)

5. Repetitive label changes should be avoided.

It makes no sense to require food manufacturers to revise all their labels every few years. The costs are inevitably passed through to the consumer, and the management burden falls more heavily on the smaller firms that cannot spread the costs over as many units.

Unfortunately, the combination of proposed legislative and regulatory action threatens bakers with repeated label redesign. All bakery foods were redone in 1978 at FDA's behest. Bakers were advised in December 1979 that FDA may soon issue more new rules requiring all bakery labels to be redone again. On top of that, S. 1652 would, two years from enactment, require substantial further revision of the labels. Moreover, the bill would permit the nutrition labeling format to be completely revised, once again requiring new labels for every product. Thus, if both this bill and the current FDA proposals are implemented without coordination, bakers could be faced with four or more government mandated

label changes in five years. */ Such a course would confuse consumers and drive bakers to distraction. If mandatory changes are to be imposed, Congress and FDA should make all those changes effective at the same time, so only a single label redesign is needed.

6. Other issues.

There are a number of other matters in S. 1652 -- some technical and some substantive -- which require review. Attached hereto are lists of (a) some additional food industry concerns about S. 1652 (Appendix B); and (b) current food labeling problems not addressed by S. 1652 (Appendix C).

We present these lists because this legislation affords a unique opportunity to "rationalize" labeling rules. To the extent we are critical of certain of the bill's provisions, it is only because we fear that, as drafted, they fall short of the aims set forth in the legislative declarations.

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*/ The first change of all labels came from FDA rules effective July 1, 1978. A second change is threatened by FDA's pending labeling proposals. A third change would come from enactment of S. 1652, with a fourth change flowing from the revision in the nutrition panel contemplated by that bill.

61-331 O - 80 - 37

National Center: 7320 Greenville Avenue, Dallas, Texas 75231 214/ 750-5339

American Heart Association
WE'RE FIGHTING FOR YOUR LIFE

April 15, 1980

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Mr. Robert Wenger
Counsel
Subcommittee on Health and Scientific Research
310B Senate Courts Annex
120 C Street, N.E.
Washington, D.C. 20510

Dear Mr. Wenger:

Enclosed are ten (10) copies of written testimony on behalf of the American Heart Association. We respectfully request that this testimony be a part of the hearings that were held regarding S. 1652.

If you have any questions , or if we can be of any assistance, please do not hesitate to call upon me.

Sincerely yours,

Dawn Bryan
Director of Public Affairs

/m
Enclosures (10)

TESTIMONY

of the

AMERICAN HEART ASSOCIATION

before the

UNITED STATES SENATE
Subcommittee on Health and Scientific Research

of the

COMMITTEE ON LABOR AND HUMAN RESOURCES

APRIL, 1980

The American Heart Association commends the Congress for helping the consumer choose healthier diets through proper nutrition and ingredient labeling and appreciates the opportunity to comment on the Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug, and Cosmetic Act (S.1652).

Food labels should supply the purchaser with information that (a) has a real use, (b) is presented in an intelligible manner, (c) has a cost commensurate with its benefit. Re-examination of labeling regulations to determine how well present practices are fulfilling these requirements is desirable.

The existing regulations and practices are useful to the consumer in selecting between brands of a particular food item; however, the consumer has not been successful in applying this information in the formulation of a total diet. Accomplishing this is simply not a matter of selecting between brands, but rather of developing a diet pattern that encompasses several days. The intake of an individual nutrient is not determined by a single food item, nor is it determined by the foods eaten at one meal, or even within a single day. Rather, it is the total balance of nutrients that is realized over a period of several days. Admittedly, labeling alone cannot fill this need; it is only one of many sources of information that the American consumer uses in formulating the total diet. However, in developing regulations it should be recognized that dietary goals of the purchaser need to be related to several days' intake and not to the relative nutrient content of a single food item. Consequently, each section of the bill and the resulting regulations need careful consideration as to whether that proposal will meet the consumer requirement to develop a total balanced diet.

The information that is conveyed (Sec. 5:a) and the aim of consumer education (Sec. 6:a) should have , as their goal, the dissemination of information that will allow the consumer to develop a total satisfactory diet and not simply to select among brands. Only information that is needed by and is useful to the purchaser should be a part of the label. Too much information can discourage the use of labels by the consumer. We do, therefore, support the demonstrations and evaluations as described (Sec. 5:a(1) and (2)).

Ingredient function (Sec 5:a(2)) is the type of information that will be of use to the consumer, only if the function of an ingredient affects the health. In this respect, (Sec. 5:a(2)) labeling protein, fat, carbohydrate, sodium and cholesterol will be of potential benefit to the population in aiding the selection of dietary constitutents consistent with the American Heart Association diet recommendations which are designed to reduce one of the risks of coronary heart disease.

Nutrient content of a food is expressed quantitatively on the label. This is an appropriate method for the presentation of such information. However, advertising is not an appropriate method for conveying the considerable amount of information that is needed for meaningful evaluation of a food (Sec. 7(a)). On the other hand, advertising can have an important role in supplying more generalized nutrition information. By contrast, this type information would not be appropriate to a food label. Thus we encourage the use of both labeling and advertising for conveying appropriate nutrition information to the American public.

We are most grateful for your interest and the time you have given us to comment on this very important subject. We respectfully urge you to take our recommendations under careful advisement.

tc-1201*
4/15/80

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WRITER'S DIRECT DIAL NUMBER

457-0913

March 28, 1980

The Honorable Edward M. Kennedy
Chairman
Subcommittee on Health and Scientific
Research
Room 308C
Senate Courts Annex
120 C Street, N. E.
Washington, D. C. 20510

Dear Chairman Kennedy:

Enclosed are three copies of Tuna Research Foundation's written statement on S. 1652. We ask that this statement be made a part of the public record.

Sincerely,

Robert A. Hazel

Robert A. Hazel
Counsel for Tuna Research
Foundation

RAH/sjb
Enclosure

STATEMENT OF
TUNA RESEARCH FOUNDATION
BEFORE THE
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
ON S. 1652

This statement is submitted by the Tuna Research Foundation (TRF), a non-profit association whose members pack over 90 percent of the canned tuna processed in the United States, its territories, and possessions.

TRF favors improvements in the current food labeling program, but opposes the particular mandatory label declarations required by S. 1652 on the following grounds: (1) The food processing industry has voluntarily provided food labeling information that is more responsive to consumer interests than that required by S. 1652; (2) consumers have indicated that they are not interested in obtaining the additional information the Bill would require; (3) the additional costs of mandatory nutrition and percentage ingredient labeling will have an adverse impact on the food processing industry and ultimately on food prices; (4) some of the labeling requirements are potentially misleading and confusing; and (5) the food labeling issue should not be resolved in a piecemeal manner.

TRF agrees with the declarations and findings contained in Section 2 of the Bill, including the finding that "a more nutritious diet is a critical factor in preventing disease and promoting health." However, TRF suggests that it is unrealistic to expect mandatory labeling

to have a significant impact on the prevention of disease. To accomplish this, other methods of educating consumers about the benefits of a nutritious diet must be employed.

In 1978, the FDA conducted a Consumer Food Labeling Survey. The results indicated that 59 percent of shoppers were satisfied with current food labeling, while only 8 percent of shoppers considered food labeling to be a major problem with food. Among canned food buyers, only a miniscule 2.9 percent considered labeling deficiencies a major problem. As canners, the members of TRF question the necessity for imposing additional mandatory labeling requirements on an industry that is voluntarily providing the information that consumers want.

On December 21, 1979, the FDA, USDA, and FTC issued an advance notice of rulemaking, which set out tentative positions of the three agencies on food labeling. Thus, this Subcommittee must realize that food labeling will not be governed by the provisions of S. 1652 alone. The food industry will be asked to meet the requirements of S. 1652, its companion bill -- S. 1651 -- and the myriad of regulations that will result from the tri-agency rulemaking. Not only is the enactment of this set of food-labeling laws unncesssary, but the piecemeal approach employed will result in not one, but a series of expensive labeling changes over the next several years.

TRF's comments on specific provisions of the Bill are set forth below:

Ingredient Labeling

The Bill requires that each ingredient be listed under its "common or usual name" in the descending order of its predominance by weight. Ingredients that individually comprise 5 percent or less of a food, however, may be named in any order at the end of the ingredient list.

TRF supports these provisions of S. 1652 and notes that its members are already in compliance with them.

Flavorings

Under S. 1652, as proposed, the Secretary of Agriculture may require that the common or usual name of flavorings be provided on the label.

TRF supports the present method of labeling flavors as "artificial" or "natural" for the following reasons: (1) The declaration of flavorings by specific name will present consumers with very technical, unfamiliar identifications, which may prove confusing. (2) The declaration of flavorings by specific name will reduce the flexibility of manufacturers to substitute and modify flavorings since they will have to change labels whenever they make a change

in the flavorings used. (3) The declaration of flavorings by specific name will make it easier for the competition to imitate successful products. (4) FDA's process of approving food additives is the appropriate forum for deciding on the safety of food additives. There is no need to confuse consumers with a meaningless list of technical names on a product label.

Percentage Labeling

Section 3(b)(1) of the Bill permits the Secretary of Agriculture to require a declaration of the quantity or percentage of any specified ingredient or class of ingredients if the Secretary determines that such ingredient has a significant bearing on the quality, consumer acceptability, or cost of such packaged food.

TRF takes the position that it may be necessary to state the percentage of an essential ingredient for a few products, e.g., the percentage of maple syrup in pancake syrup. For these few products, specific regulations should be promulgated. However, there is no need to provide broad authority for percentage labeling.

In the 1978 FDA Consumer Food Labeling Survey, only 3.8 percent of respondents said that labels should be changed by specifying the quantity or percentage of each ingredient on the list of ingredients. Also, a

declaration of ingredient percentages, like a declaration of specific flavorings, will make it significantly more difficult to protect specific recipes and product formulations against imitation by competitors.

Descending Order Statement

Section 3(b)(2) of the Bill requires "a declaration that ingredients are listed in the descending order of predominance by weight." Our objection to this requirement is based simply on label clutter since, especially on smaller products, the required declaration would take up precious space better devoted to other uses. A consumer education program is a more appropriate method of informing consumers of this long-standing labeling practice.

Nutrient Labeling

S. 1652 requires that all packaged foods must bear a declaration of (a) the total number of calories per serving, (b) the amount per serving of protein, fats, and carbohydrates in caloric terms, and (c) the amount per serving of sodium and cholesterol.

TRF believes that these requirements are unnecessary and expensive, and that a voluntary labeling system, such as that proposed by the National Food Processors

Association, is better suited to providing consumers with the information they want.

TRF wishes to point out that the vast majority of its members already provide the following information on their consumer products: calories per can; the grams per serving of protein, carbohydrates, and fat; and quantitative information for more than a dozen vitamins and minerals.

Under the present regulatory scheme, the decision to provide nutritional labeling is a purely voluntary one, but once a canner decides to provide some nutritional labeling, it must provide all of the information listed above. While more than 60 percent of processed foods are currently nutritionally labeled, it is safe to assume that the adoption of less rigid requirements for nutritional labeling would make such labeling even more prevalent.

The particular nutrients attracting consumer interest have varied widely over the last several years. For this reason, a program is needed that is flexible enough to allow for the listing of new information as it develops, and for the removal of old information that is no longer of interest to consumers. The existing labeling requirements for processors who voluntarily decide to provide nutritional information are already too rigid to permit the food processing industry to adapt

to the changing nutritional interests of consumers; the mandatory labeling provisions of S. 1652 will make it even more difficult for the food processing industry to respond to consumers' interests in labeling.

Comments on Specific Nutrients

S. 1652 requires a declaration of the amount per serving of protein, fats, and carbohydrates "in terms of caloric content." It is less confusing if this information is presented simply in terms of grams per serving, which is the format TRF members presently use.

Both cholesterol and sodium declarations would be required by S. 1652, yet there has been no general consumer interest demonstrated in obtaining this information. For example, in the 1978 FDA Consumer Food Labeling Survey, only one percent of respondents expressed concern over the need for salt-content labeling. Voluntary cholesterol and sodium declarations are already made on particular foods where there is strong consumer interest and, in fact, particular segments of the dietetic food market serve consumers who need to limit their intake of these two substances.

In addition, mandatory sodium labeling is unwise because consumers generally do not understand the difference between salt and sodium, and because individuals

trying to reduce sodium intake to control hypertension will usually find that even naturally-occurring salt in foods far exceeds the level to which their intake must be reduced. Sodium analysis also requires sophisticated equipment and is expensive.

S. 1652 leaves the FDA the option of requiring labeling of vitamins and minerals. TRF recommends that such labeling be provided on a voluntary basis only since it is not understood by consumers, adds to label clutter, and is expensive to provide. In specific instances where there is strong consumer interest, vitamin and mineral labeling will be provided by the food industry.

Compliance

S. 1652 encourages the use of nutrition data bases, which serve two purposes: (1) to reduce the cost of nutritional labeling by reducing the cost of analysis, and (2) to provide accurate nutrient information.

Because a data base provides a representative value that is accurate over a period of time, the nutrient content in any given lot of food products will differ from the value in the data base. Thus, from lot to lot, realistic levels of variance from the data bank value must be permitted. TRF asks that the Subcommittee address

the issue of reasonable variance from the data base value since the FDA has indicated its intent to continue a rigid and somewhat unrealistic compliance program.

Demonstrations and Evaluations

Most of the provisions of S. 1652 become effective two years after enactment. Upon enactment, the Secretary is to approve testing to ascertain the most effective methods of organizing food labels and of conveying to consumers the information that is or may be required to be placed on labels. While TRF stronly supports food labeling testing, it sees no point in legislating food labeling requirements before the test results are known.

TRF believes that nutritional labeling should remain voluntary in accordance with a scheme such as that proposed by the National Food Processors Association. In the alternative, however, the requirements of S. 1652 should remain voluntary at least until more is known about consumer interest in labeling and consumer ability to comprehend labeling information.

John P. Mulligan
President
Tuna Research Foundation, Inc.
1101 Seventeenth Street, N. W.
Suite 607
Washington, D. C. 20036

GENERAL FOODS CORPORATION / *250 North Street, White Plains, N.Y. 10625*

ANDREW J. SCHRODER III
VICE PRESIDENT, PUBLIC AFFAIRS

March 27, 1980

The Honorable Richard S. Schweiker
United States Senate
Washington, D. C. 20510

Dear Senator Schweiker:

Thank you for the opportunity to submit additional data regarding the preemption issue of S.1652 to the Senate Subcommittee on Health and Scientific Research.

As you may recall, my remarks to the Subcommittee on March 19 indicated General Foods strong conviction that Federal standards are essential in the area of food labeling. Without it, conflicting and contradictory state and local efforts will lead to a multiplicity of label formats occasioning considerable cost to the consumer without corresponding benefits.

Regarding the open-dating question specifically, we call your attention and that of the Subcommittee staff to the attached chart which graphically reflects the appropriateness of this concern. The chart summarizes thirteen of the open-dating bills and one regulation, all of which were numbered among the many date labeling proposals advanced in the states during 1979.

One can observe from a rapid review of the columns "Products Covered", Type of Date Required" and "Manner of Disclosure" that local jurisdictions readily place their own personal touch on the open-dating issue. We submit that such often conflicting distinctions would have disastrous consequences on the attempt to efficiently distribute food products nationwide.

We would be pleased to provide further assistance to you or members of the staff regarding this issue and the particular problems occasioned by the lack of a comprehensive Federal preemption policy on food labeling.

Thank you again for your interest in our opinion in this matter.

Very truly yours,

AJS:ds

61-331 O - 80 - 38

1979 OPEN DATING BILLS

STATE	PRODUCTS COVERED	TYPE OF DATE REQUIRED	MANNER OF DISCLOSURE	STATUS
MI BH4224	Canned Foods & specified perishables	Recommended Last Date of Sale	Requires label to include recommended last date of sale (to be one year from first offer of sale for canned foods)	In Original Committee
CA AB 34	Foods that are processed, packaged or manufactured (but not canned)	Pack or Pull Date	On the label in a manner that is plain, legible, conspicuous & readily understood by the general public	Dead
NY A379/ S385	Frozen Desserts & frozen foods	Freshness Date plus "Best if Used By"	Must show first month, then year. Month must be shown by letters that clearly identify month or by digits 1-12. Digits for month must be separated from digits for the year by a space, a dash, an asterisk or other symbol. Letters at least ¼" in height on outside wrapper.	Tabled
NY AB3047	Perishables (Long list of bakery, dairy & other goods)	Pull Date plus statement as indicated by commissioner	Same as above	In Original Committee
NY A274/ S252	Packaged Goods, including hermetically sealed, frozen, fresh produce, poultry & meat products	-"Sell By" (if under 60 days) -"Best When Used By" (if over 60 days)	Date of the month and year conspicuously place on outside container or wrapper	Passed Assembly 3/10/80
NY AB1020	Frozen Foods	Freezing & Packaging Date	On container in letters ¼" in height	In Original Committee
NY A6700/ S4036	Frozen Foods	Freshness Date--must say "Best if Used By"	Conspicuous manner on outside wrapper ¼" in height	" "

STATE	PRODUCTS COVERED	TYPE OF DATE REQUIRED	MANNER OF DISCLOSURE	STATUS
CT SB116	Perishables	Dated to determine freshness	--------	Dead
CT HB7103	Canned & Jarred	Date to show when nutritional value of such food may decrease	--------	Dead
PA SB 30	Perishables (produce, dairy, poultry, meat & seafood)	Date of Packaging	Main label, date of packaging in type not less than eight points, brevier caps, in size and position plainly seen & read by the purchaser	In Original Committee
PA SB 459	Same	Same	Same	Same
TN A847/ S1141	Foods which become unfit within 90 days of sale	Perishable Date (date product not fit for human consumption)	Perishable date shall be marked on or attached to each unit of food sold	Dead
MO SB 206	Perishable or Semi-perishable (spoilage, loss of value, or loss of palatability within 60 days of packaging) excluding meats & produce	Pull date (last date commodity should be sold without significant risk of spoilage, value, palatability)	Date must show first the month, then day of month, followed by year. Month must be shown by letters that clearly identify the month or by using digits 1-12. Day of month shall be shown by digits 1-31. Digits for month must be separated from digits for date within the month by a space, a dash, an asterisk or other symbol.	Dead
GA Dept. of Agriculture Amendment Regulation	Packaged Foods-voluntarily labeled	Pull date--month & year by which product is to be sold-may be prefixed by "sell by," "not to be sold after," "best if used by" or "expiration"	Combination of letters for month or numbers for date of month, year may be stated by last digit of year. Prominently & conspicuously placed on label.	In effect 4/1/79

3/17/80

COMMENTS OF THE INTERNATIONAL FOODSERVICE MANUFACTURERS ASSOCIATION ON S. 1652, THE NUTRITIONAL LABELING AND INFORMATION AMENDMENTS OF 1979

March 31, 1980

International Foodservice
Manufacturers Association
875 N. Michigan Avenue
Chicago, Illinois 60611

Introduction

The International Foodservice Manufacturers Association ("IFMA") submits these comments on S.1652, the Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug and Cosmetic Act. We take a position on this legislation for several quite specific reasons:

. IFMA represents a particular segment of the foodservice industry and wishes to bring that focus to bear on the goals of the proposed legislation.

. Certain of the legislative sections specifically exhibit requirements or omissions that indicate an inadequate awareness of the special concerns of foodservice.

. Certain provisions of the legislation represent potential problems to member companies and therefore require comment even at this early stage of these proceedings.

A brief description of the Association will help place these general statements in proper perspective. The International Foodservice Manufacturers Association represents some 300 of the nation's leading companies engaged in the manufacture and distribution of food, equipment and supplies to the institutional, away-from-home market. IFMA members, often divisions of major companies, sell, customarily in bulk or case packages, to schools, airlines, hospitals, restaurants. The market for a member company's products, and the "consumer" of those products is a very different market and individual from those related to the purchase of food for preparation and use at home. That consumer almost never comes in contact with our products, and would derive no benefit from percentage or ingredient labeling on institutional

packages. The institutional consumer, on the other hand, applies to his purchasing decisions the specific requirements of his particular setting (the hospital cafeteria, the school purchasing program, etc.) and a professional background that often includes some training in nutrition or food technology. He brings a degree of sophistication to his food purchases that the typical retail customer lacks; indeed, this lack is one of the reasons behind the current labeling initiatives. Frequently, as we indicated in our appearance before the tri-agency hearings, it is the IFMA customer who asks for and gets the technical and nutritional information he requires about his food purchases. In a highly competitive foodservice market it does not require federal initiatives to produce the information consumers want; if a consumer does not receive what he wants from a foodservice supplier there is another and competitive supplier who will readily produce it.

The Foodservice Perspective

Given the nature of the foodservice market, foodservice companies have, under current regulations, been able to avoid costly and extraneous nutrition labeling that consumers never see simply by not choosing the option of making voluntary nutritional claims; or, where such claims are made, by providing such information directly on a current basis to foodservice purchasers.

This sensible pattern is open to the foodservice sector because current regulations of the Food and Drug Administration

recognize the logic of exempting foodservice companies from nutritional labeling requirements. Present regulations require nutritional labeling if a company makes nutritional claims or fortifies a food product. However, the regulations exempt "food products containing an added vitamin, mineral, or protein, or for which a nutritional claim is made on the label or in labeling or in advertising, which are supplied for institutional use only." (emphasis added) 21 C.F.R. §191.9(h)(9). The exemption requires only that the manufacturer or distributor provide the nutritional information to institutions on a current basis.

At the time this exemption was written into the regulations, the FDA Commissioner explained its inclusion by the recognition:

> "that many products are manufactured only for use in institutional feeding, and that under these circumstances the ultimate consumer would not have an opportunity to see the label. In certain instances, e.g., hospitals and school lunch programs, the persons responsible for planning menus and purchasing food may have special training and be aware of the nutritional qualities of the foods, or may even establish nutrition specifications for certain food products being purchased. 38 Fed. Reg. 6951, 6957-6958 (March 19, 1973).

We feel that an institutional or foodservice exemption is reasonable and deserves to be retained. We continue to believe it would be illogical and costly to impose nutritional labeling requirements on institutional products in packages which are never seen by the final consumer. This is even more true given our current inflationary crisis and intense national concern with the economic impact of incremental government regulation.

While the cost analysis presented at the March 19 hearing was preliminary and applies to product analysis for the consumer

market, it is still worth noting the magnitude of the figures. One witness, the Pillsbury Co., noted that the company now has 1,300 labels and estimates that simply to change all the printing plates one time would cost $5,640,000. This does not cover analytical costs to determine nutritional data nor man hours involved in either of these tasks. Pillsburg also estimated analytical costs of $600,000 for its voluntary nutritional labeling effort, plus additional annual costs of $300,000 to maintain the voluntary program.

Almost all the cost data presented on March 19 represented costs for work done internally at major corporations. Almost every industry witness commented that the costs associated with nutritional labeling would be much greater for smaller companies without internal capabilities, and that the nutritional labeling proposals could have significant cost implications for such smaller companies.

It is worth noting that Dun and Bradstreet lists almost 3,000 companies under the category of Standard Industrial Code 20, "Food and Kindred Products." The firms are broken down by net worth into two sets, one of companies in the $500,000-$1 million range, the other over $1 million. Close to twenty-five percent of the firms fall in the former category, well under conventional Small Business Administration definitions of small business. As legislation such as S.1652 is being shaped it is important to weigh its impact on small business, especially as government increases its awareness of the need to reduce the regulatory burden

on this important sector of our economy. While the nutrient data base concept reduces the cost of nutritional labeling, the cost implications still should make the framers of the legislation concerned not to extend unnecessarily the reach of government regulation beyond its original scope. IFMA urges that the framers of S.1652, as well as its companion bill, S.1651 (on which we will comment at a later time), take into account the specific character of the away-from-home market and the realities of foodservice distribution as the legislation is refined, and that the FDA retain the existing foodservice exemption.

Special Foodservice Concerns

Obviously the legislation is not yet responsive to the voluminous data and testimony that is accruing from the legislative hearings and, more especially, from the record of the tri-agency hearings on these issues March 4-5 and what is likely to be extensive written comment on the tri-agency position paper published in the Federal Register December 21. IFMA wishes to ensure the consideration of several issues that seem not to have occurred to the drafters of the legislation, omissions which to some extent reflect an inadequate awareness of the special concerns of this segment of the industry.

1. The portion control market - For example, one type of foodservice product does reach consumers in the package in which the manufacturer packs it: the foods in the rapidly growing

"portion control" market. Portion control products are familiar to virtually every consumer; they are the ketchup, salt, pepper, jellies or coffee creamer which come in small packages containing an individual serving. We believe that while, in theory, it might be desirable to require these products to bear nutritional labeling, in practice the small size of the package creates a physical barrier to meaningful nutritional labeling.

As we understand it at the present time, the problem relates not only to the small area available even for the presently required label information but also to the almost hand-crafted and costly nature of the machinery for making these packages. If additional nutritional information were to be required, it should be possible to provide it on or in the shipping container.

2. The rapidly changing technology of foodservice - The arguments many food groups have put forward for the retention of a voluntary nutritional labeling program are supported, to some extent, by the very nature of foodservice. A mandatory system, with a structure of requirements and specific exemptions, is by its nature less flexible than the industry it attempts to regulate. Portion control, referred to above, for instance, represents an estimated $150 million foodservice market, yet was of only minimal importance as little as 10 years ago. Frozen foods are marking their fiftieth year in the marketplace, yet accustomed as we are to that aspect of the foodservice market, the language of S.1652 at §403(2) requiring that labeling shall

define nutritional value at point of purchase ignores some of the difficulties affecting processors of frozen food, whose product is more vulnerable than most to distribution and point of sale handling problems and is more often guaranteed at point of pack.

As this legislation is being developed, so are new foods, packaging processes, distribution methods and marketing concepts. IFMA urges the labeling legislation to embody the greatest possible flexibility to accomodate the rapidly changing foodservice industry to the degree such flexibility is consonant with the bill's goals and objectives. The Association reserves the right to comment on additional foodservice specifics should legislative developments require it.

Areas of Potential Concern to Foodservice

Whether because of the special nature of foodservice, or because foodservice companies share or support certain approaches as part of the total food sector, IFMA would like to voice its support--or opposition--to certain specific provisions of the legislation.

1. Declarations and Findings - Point (7) under this section represents an approach IFMA supports:

> Nutritional labeling should be approached as an information function that allows appropriate flexibility on the part of producers, while also protecting and enhancing the consumers' right to know what is in the food they select so that they can make informed choices.

For that reason IFMA has shared the industry's efforts to provide consumers with a safe and dependable diet and has participated in many hearings and programs whose objective is a food label that provides appropriate food information for the consumer.

2. Mandatory percentage labeling - IFMA opposes this proposal as it applies to predominant ingredients and particularly to the listing of specific spices and colorings and to the quantitative percentage labeling of certain foods. The physical limits of the label and the restraint on manufacturer flexibility argue against the provisions. More important, such requirements potentially encroach upon proprietary formulations and trade secrets and should not be required of manufacturers in a highly competitive market.

Additionally it is our understanding that FDA intends to seek authority to give its inspectors access to a company's records of product formulations, quality control and other related materials to determine conformity and compliance with nutritional labeling requirements. Associate FDA Commissioner Mark Novitch argued forcefully in these hearings that the Agency's authority be broadened to support factory inspections with records inspections. This can only be read as an additional threat to the sanctity of proprietary information; IFMA wishes to go on record early in opposition to such an approach.

3. Specific source labeling for fats and oils - IFMA opposes this provision, as have most company and association witnesses. Since the availability and cost of these commodities are particularly volatile, specific label requirements would have serious cost implications for manufacturers. Processors would have to maintain a standing library of label inventories for each product, given the uncertainties regarding the availability and cost of different sources of fat and oil. The current "and/or" declaration is responsive to health concerns; additionally, as a witness from The Frito-Lay Company testified on March 4, an exhaustive computerized search of the medical literature has revealed no substantiated health problems linked to edible fats and oils.

4. Federal preemption - Today almost all the various sectors of the food economy are interstate in nature, and the preemption clause in the legislation recognizes that fact. Industry has pressed for a broad federal preemption measure for a number of years and IFMA adds its enthusiastic support to Section 412(a). We may, however, be confronted with the legislature taking away with one hand what it has given with the other. Section 412(b) exempts from preemption any "label or labeling requirement of any such State or political subdivision if the Secretary determines that the requirement is required by compelling local conditions ..." Section 412(c) further emasculates the force of the preemption by exempting "a label or labeling requirement respecting the sell or use date of food."

The matter of "sell or use date of food," or open dating, has been and continues to be a plaguing problem for the industry. While the preemption proposal has the potential for relieving some food processors of duplication and burdensome state requirements, it leaves open the interpretation of indefinite phraseology ("compelling conditions") and the possibility of two, a dozen, or fifty sets of state open dating regulations to complicate what could--and should--have been a straightforward preemption provision.

5. Demonstration projects - IFMA supports the authorization in Section 5 of demonstrations and evaluations to determine the best label formats, and how best to convey to consumers whatever information finally is required by Section 3 of the bill. Speaking from our particular perspective, and notwithstanding the foodservice exemption, we would urge that advisory boards be set up to develop, cooperate with, and monitor, such demonstrations and that the foodservice perspective be represented in such efforts.

6. Criminal penalties - IFMA would add its support to the testimony of the Committee's lead-off witness, Senator George McGovern, who urged that S.1652 be improved by dropping the criminal penalties for mislabeling. These presently are derived from the Food, Drug and Cosmetic Act to which S.1652 stands in amendment. S.1651, the companion bill, does not contain criminal

penalties for mislabeling; S.1652 should not. Mislabeling does not require the same level of punitiveness as do matters of food safety. IFMA agrees with Senator McGovern that nutritional labeling, to the extent it is reasonable and responsive to realities, should move away from punitive measures and compliance procedures toward the cooperative provision of information to the extent consumers require it.

7. Industry cooperation and the public interest - The wide-ranging proceedings to date exemplify a high degree of industry-government-consumer cooperation. IFMA is pleased to be a participant in this process and would certainly respond to any additional requests for foodservice data.

national association of margarine manufacturers

SUITE 1202 • 1725 K STREET, N.W. • WASHINGTON, D. C. 20006 • TELEPHONE: (202) 785-3232

Siert F. Riepma
President

March 12, 1980

Honorable Edward M. Kennedy
Chairman
Subcommittee on Health & Scientific Research
United States Senate
Washington, D. C. 20510

Dear Chairman Kennedy:

As previously discussed with the Committee Staff, I respectfully ask that your proposal S. 1651 include language that will usefully modernize Sec. 407 of the Food, Drug, and Cosmetic Act with no lessening of consumer protection.

These changes are to modernize parts of that Section. They have been discussed before and do not appear to be controversial. Indeed, it is believed the Food and Drug Administration has no objection to them. Since 1970 bills have been introduced in both houses to effect similar or identical changes. Currently, Sen. Hollings' S. 416 is such a bill. I believe it is before your Committee.

The language I am now suggesting departs from S. 416 in some respects, while not making any substantive change from the thrust of that bill.

The amendatory language I suggest for Sec. 407 is as follows:

(1) Subsection (b)(3), delete "in type or lettering as large as any other type or lettering on such label", to bring margarine product name labeling under the regular provisions of the Act, along with other foods. 21 CFR 101.3, especially (d), regulates placement and visibility of product names on the label and already applies to margarine. Sec. (b)(3)(A) is therefore redundant.

This amendment is proposed in S. 416. A letter from then Secretary Califano, Department of Health, Education, and Welfare, to Chariman Harrison A. Williams, Jr., of the Committee on Commerce, Labor and Human Resources, July 31, 1979, makes no objection to this provision as it appears identically in S. 416.

(2) Clarify Sec. 407(b)(4) by adding the language, "Each such part or inner unit shall be labeled as an inner unit under the regulations of the Food and Drug Administration and the Department of Agriculture". This puts margarine inner units in the same position as those of other foods in respect of labeling, and meets the proposal of the Department of Health, Education and Welfare in its letter to Chairman Williams cited above.

(3) Repeal Sec. 407 (c and d) has to do with the notice to be given consumers when colored margarine is served in public eating places. The enforcement agency, the Food and Drug Administration, for many years has not enforced this complex and unique requirement, which amounts to a discriminatory restraint on trade.

S. 416 would reduce the double notice requirement to a single requirement. In the letter to Chairman Williams cited above, the Department of Health, Education and Welfare proposes somewhat different language to clarify the forms of notice.

However, in testimony to the House Appropriations Committee in 1978, Commissioner of Food and Drugs Kennedy, responding to a question, made it clear that "It is our view that menus, labeling or other restaurant customer notification regarding margarine use can more effectively be enforced by state and local inspection agencies....their handling of this responsibility is much more cost effective".

All states have provisions in their food laws covering the proper identification of foods in public eating places. Many states have specific provisions regarding margarine notification.

Therefore the proposal to repeal Sec. 407 (c and d) is in line with the thinking of the enforcement agency and recognizes that the latter is not enforcing the provision.

* * *

Thank you for your consideration of this simple, but useful, updating of Sec. 407 of the Act.

Sincerely,

S. F. Riepma
President

SFR:ch
cc: Robert M. Wenger, Esq.

national association of margarine manufacturers

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Siert F. Riepma
President

April 3, 1980

Senator Edward M. Kennedy, Chairman
Subcommittee on Health and Scientific
Research
Senate Committee on Labor and Human Resources
Dirksen Senate Office Building, Room 4220
Washington, D.C. 20510

Re: S. 1652

Dear Mr. Chairman:

The comments following are submitted on behalf of the National Association of Margarine Manufacturers (NAMM), the national trade association representing the manufacturers of the preponderant amount of margarine consumed. We appreciate this opportunity to share with the Subcommittee our views concerning S. 1652 - "The Nutrition Labeling and Information Amendments of 1979 to the Food and Cosmetic Act".

We support the general intent of S. 1652 which is to provide consumers with accurate and easily understandable nutrition and ingredient information for foods. We however respectfully state our belief that a number of the provisions of S. 1652 will needlessly complicate the food label, require processors to disclose trade secrets, discourage cost-effect utilization of ingredients, and unnecessarily raise labeling costs without providing a corresponding benefit.

Sec. 407 Amendments Proposed

Section 407 of the Food, Drug, and Costmetic Act was enacted at the time the old federal taxes on the food were repealed by Congress. We ask the Subcommittee to approve amendments to this Section that will place the federal regulation of margarine more fully in the regular provisions of the Food, Drug and Cosmetic Act, along with other foods. S. 1652 is an excellent opportunity to modernize this section. We therefore ask the Subcommittee to adopt the following amendments. They would accomplish substantially the same purpose as S. 416, by Senator Hollings, but represent later thinking as to the best procedure for improving Section 407.

61-331 O - 80 - 39

(1) Subsection (b)(3) - delete "in type or lettering as large as any other type or lettering on such label", to bring margarine product name labeling under the same provisions as all other FDA regulated foods. Currently, the FDA regulations specify required placement and type size for product names. 21 C.F.R. Section 101.3(d). Accordingly, Section 407(b)(3)(A) is slightly different from the general FDA labeling requirements, partially redundant, and should be amended.

This amendment is proposed in S. 416. A letter from former Secretary Joseph Califano, Department of Health, Education and Welfare, to Senator Harrison A. Williams, Jr., Chairman of the Committee on Commerce, Labor and Human Resources, dated July 31, 1979, indicates FDA's support for this provision. (See Attachment B).

(2) Clarify subsection 407(b)(4) by adding the language, "each such part on inner unit shall be labeled as an inner unit under the regulations of the Food and Drug Administration and the Department of Agriculture". This places margarine inner units in the same position as those of other foods with respect to labeling and is consistent with the proposals and recommendations of HEW as expressed in the July 31st letter.

(3) Repeal subsections 407(c) and (d) relating to the mandatory notice requirements in public eating places when colored margarine is served.

This requirement, unique to margarine, has not been enforced by FDA for many years. The provisions of S. 416 would reduce the double notice requirement to a single requirement. In the letter to Chairman Williams cited above, the Department of Health, Education and Welfare proposed similar language in order to clarify the notice requirements. In testimony to the House Appropriations Committee in 1978, former FDA Commissioner Donald Kennedy, responding to a question, made it clear that "it is our view that menus, labeling or other restaurant customer notification regarding margarine can more effectively be enforced by state and local inspection agencies.....for handling of this responsibility is much more cost-effective".

All states have provisions in their food laws covering the proper identification of foods in public eating places. Many states have specific provisions regarding margarine notification. Accordingly, NAMM believes that repeal of subsections 407(c) and (d) is consistent with the thinking of FDA and its current enforcement activities.

Comments on Labeling Provisions of S. 1652

A. Total Food Label

All producers and consumers have an interest in providing label information in a cost-effective manner. We urge the Subcommittee to weigh the potential benefits of mandating new labeling information against the cost, which would have to be borne by consumers.

We note that the Food and Drug Administration's 1978 "Consumer Food Labeling Survey" demonstrates less than compelling need or desire for food labeling changes. Food safety, not labeling, is of real concern to consumers. Nearly 50% of those surveyed had no problem at all with food. One-third were concerned about quality, while only 8% expressed any dissatisfaction with labeling. Of the 8% concerned with labeling, the most commonly cited problem involved the ingredient list, with the major criticism being its complexity.

Implementation of many of the provisions contained in S. 1652 would further complicate the label by requiring the listing of lengthy technical names for colors, spices, and possibly flavors to appear in the ingredient labeling and by requiring a large amount of new information as part of the nutrition label. To require all this information is to go counter to consumer concern about overly complicated, technical food labels.

B. Order of Predominance Labeling

We support proposed Section 3(b)(1), which would require all ingredients be listed in descending order of predominance by weight, "except .... any ingredients that individually comprise 5% or less of a food ...." This provision would provide margarine processors with necessary flexibility to utilize slightly different amounts of truly minor ingredients.

In this connection, we ask the Subcommittee to recognize the importance of having all fats/oils ingredients in margarine listed together. Under strict order of predominance labeling, it is conceivable that certain minor fats/oils would be used in amounts less than water, salt, or other minor ingredients. To list all fats and oils together would help those consumers interested in the fats in their diet.

As for the requirement of a statement "ingredients are listed in descending order of predominance" on the label, we believe the current regulatory requirements, that ingredients be listed in descending order of predominance, makes such an extra statement unnecessary.

C. Spices, Colors and Flavors

The proposed legislation would require manufacturers to list specific spices, colors, and in some instances flavors. We point out that to mandate the listing of specific colors, spices, and flavors will further complicate the already lengthy ingredient list and in some instances may disclose trade secrets information. NAMM believes specific listing of these ingredients should be required only where the Secretary demonstrates through rulemaking that such information is of public health significance to consumers.

D. Quantitative or Percentage Ingredients Labeling

The concept of "characterizing ingredient" does not seem to be applicable to margarine, which is simply a companion food consisting of 80% fat, milk and/or water, and other ingredients. Federal regulation has long required the minimum fat content of standard margarine be 80%.

To require the specific percent of product weight of each fat or oil ingredient in margarine would impose a genuine burden and undoubtedly increase consumer costs, since the fats and oils are often interchangeable (in the interest of consumer cost) and percentage labeling would require frequent new packaging. This problem of interchangeability in relation to labeling has been amply reviewed before the Food and Drug Administration; it affects many food products besides margarine.

E. National Uniformity

Section 4(a) of the bill would add a new Section 412 to the Food, Drug, and Cosmetic Act providing for uniform federal, state and local food labeling requirements for nutrition and ingredient information. We endorse this provision and urge the Subcommittee to delete proposed Section 412(c) which would permit unique and inconsistent open-date labeling requirements to be promulgated by the states (Attachment C is included for your information).

F. Criminal Liability

We urge the Subcommittee to include a provision in S. 1652 to limit the current strict and vicarious individual criminal liability standard to the present law. U.S. vs. Park 421 U.S. 658 (1975). In general, criminal liability is imposed

on corporate officers only for those illegal acts in which they personally participate. Several recently enacted federal statutes concerning environmental and safety matters, in thus dealing with public welfare, provide a much more reasonable standard of executive liability than does the Food and Drug Act. These include the Clean Air Act of 1970, the Consumer Product Safety Act, the Occupational Safety and Health Act and the Toxic Substance Control Act. In each of these cases, liability is limited to situations wherein the alleged violator has acted knowingly or willfully. We urge the Subcommittee to amend Sec. 303 of the Food and Drug Act to provide a similar standard.

Conclusion

NAMM and its members support the efforts of the Subcommittee to improve the food label. The Committee is urged to act cautiously and to consider all alternatives prior to mandating new and potentially costly labeling requirements.

Sincerely,

S. F. Riepma
President

SFR:ch
Attachments

ATTACHMENT A

96TH CONGRESS
1ST SESSION

S. 416

To make uniform with the general requirements of the Federal Food, Drug, and Cosmetic Act certain provisions relating to the labeling and notification of colored margarine and colored oleomargarine.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 9 (legislative day, JANUARY 15), 1979

Mr. HOLLINGS introduced the following bill; which was read twice and referred to the Committee on Human Resources

---

A BILL

To make uniform with the general requirements of the Federal Food, Drug, and Cosmetic Act certain provisions relating to the labeling and notification of colored margarine and colored oleomargarine.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 407 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 347) is amended by—

(1) deleting "in type or lettering at least as large as any other type or letter on such label" in subsection (b)(3) thereof,

(2) deleting "in a wrapper which bears the word 'oleomargarine' or 'margarine' in type or lettering not smaller than twenty-point type" in subsection (b)(4) thereof, and inserting in lieu thereof "in a separate wrapper", and

(3) amending subsection (c) thereof to read as follows:

"(c) No person shall serve colored margarine or colored oleomargarine at a public eating place, whether or not any charge is made therefor, unless a suitable notice or identification that such colored margarine or colored oleomargarine is served is prominently and conspicuously displayed or labeled in such manner as to render it likely to be read and understood by the ordinary individual being served in such eating place.".

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

ATTACHMENT B

JUL 31 1979

The Honorable Harrison A. Williams, Jr.
Chairman, Committee on Labor and
Human Resources
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This responds to your request for a report on S. 416, a bill "To make uniform with the general requirements of the Federal Food, Drug and Cosmetic Act certain provisions relating to the labeling and notification of colored margarine and colored oleomargarine."

In summary, the Department supports most of the changes recommended by this legislation.

S. 416 would amend section 407(b)(3) of the Federal Food, Drug, and Cosmetic Act to eliminate the present requirement that package labels of oleomargarine or margarine bear the word "oleomargarine" or "margarine" "in type or lettering at least as large as any other type or letter on such label." Further, S. 416 would delete the part of section 407(b)(4) of the Act which requires the wrapper on each part of the content of the package of margarine or oleomargarine to bear "the word 'oleomargarine' or 'margarine' in type or lettering not smaller than 20-point type."

Current law requires that public eating places possessing colored margarine in a form ready for serving advise patrons through signs or menu notices that margarine is served and that such separate serving is either triangular in shape or bears or is accompanied by labeling identifying it as margarine. S. 416 proposes to eliminate this "double notice" requirement by providing that public eating places

must give "suitable notice or identification" which is "prominently and conspicuously displayed or labeled in such a manner as to render it likely to be read and understood by the ordinary individual being served in such eating place."

The Department agrees that current requirements of the Act are unnecessarily burdensome and that the changes included in S. 416 would check consumer deception. We suggest, however, that the following language be substituted for the proposed amendment to section 407(c) of the Act, in order to indicate more clearly the forms of notice which would satisfy the requirement as it would be amended by the proposal:

> "(c) No person shall serve colored margarine or colored oleomargarine at a public eating place, whether or not any charge is made therefor, unless --
>
> (1) a suitable written notice that such colored margarine or colored oleomargarine is served prominently and conspicuously displayed therein; or
>
> (2) each separate serving of colored margarine of colored oleomargarine is triangular in shape or is identified by labeling,
>
> in such a manner so as to render it likely to give notice which will be understood by individuals being served in suc eating place."

In addition, we suggest that the requirement for labeling separate wrappers within a package not be repealed altogether. Frequently consumers will buy only a portion of a package or margarine, leaving the other quarters behind for someone else. If the remaining quarters are not labeled as "margarine" or "oleomargarine" consumers will not know what they are buying.

Therefore, we recommend that section 407(b)(4) be amended to read:

> "(4) each part of the contents of the package is contained in a separate wrapper which bears the word "oleomargarine" or margarine."

We recommend that the bill, with the modifications proposed above, be favorably considered.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

/s/ Joseph A. Califano, Jr.

Secretary

ATTACHMENT C

Food Labeling— The Case for National Uniformity

By RICHARD L. FRANK

Mr. Frank Is an Attorney With Collier, Shannon, Rill, Edwards & Scott.

FOOD COMPANIES, distributing or selling products in more than one state or jurisdiction, have an obvious interest that labeling, packaging, notice and ingredient requirements be as uniform as possible. The consumer interest in uniformity is more subtle but equally important. Differing state labeling requirements wastefully burden interstate commerce, aggravate food price inflation, and tend to confuse and mislead the general public.

The additional costs imposed by differing food labeling requirements, all of which must be borne by consumers in the form of higher food prices, are literally incalculable. To the extent that two or more jurisdictions require different labels, there are the direct costs of printing the additional labels. But the indirect costs of maintaining two or more separate product and label inventories, imposing separate distribution and recordkeeping requirements and the necessity for entirely different advertising, to name just a few, are far greater. Each minor label change in the future means, as a practical matter, multiple changes in all of the labels required to be used in each of the various jurisdictions involved. Thus, consumers are paying millions of dollars each year, in the form of higher food prices, as the direct and immediate result of different food label requirements.

Permitting individual states to impose labeling requirements that differ would not only have an adverse impact on the free-flow of goods in interstate commerce, but would also dramatically alter and complicate the regulatory responsibilities of the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA). Since processors would be required to meet a variety of

state labeling standards, federal Food and Drug investigators may be required to monitor the labeling of thousands of additional packages to ensure they conform with each relevant state standard and are not misbranded within the meaning of those standards. Similarly, under Section 7 of the Federal Meat Inspection Act, as amended,[1] Department of Agriculture officials would be obligated to review and approve, in advance of their use, all labels required for all meat and poultry products. This program would be greatly complicated if packages contained new and different material required by any state electing to fashion its own regulatory plan.[2] In essence, the federal government would be expending its major efforts administering a wide variety of state requirements rather than enforcing its own uniform and pervasive regulatory framework.

In 1973, the Assistant Secretary of Agriculture responsible for supervising meat and poultry inspection testified before the House Committee on Agriculture on the problem of inconsistent label requirements imposed by the states:

> Just looking at labels alone and ignoring all the other six areas, we processed about 181,000 labels this last fiscal year at a cost of something over $400,000, an average of a little better than $2 per label. If the interstate meatpacking firms had to process label changes every time a State changed its label regulations, this 181,000 would end up being many, many hundreds of thousands, depending on the number of States that had regulations that were different from the Federal. Of course, it would have an obvious impact on our processing of all those label changes as well as premises, equipment, and so on. The cost to the Federal meat inspection program is inestimable, but is bound to be a very significant factor, and we think it is totally unjustified. It obviously serves as a trade barrier too.[3]

The need for and benefits of uniformity in food labeling regulation have been stressed by virtually every organization which has examined the problem. In 1966, the National Commission on Food Marketing urged that "a concerted effort should be made to effect uniformity among state regulations that obstruct trade in foods across the state lines."[4] Similarly, the 1969 White House Conference on Food, Nutrition and Health urged "uniform application of all regulatory

[1] 21 U. S. C. Sec. 607.

[2] 9 CFR Sec. 317.4 (1978). It is unclear whether USDA would approve a label which contains information "in addition to and different than" that required under the Wholesome Meat Act.

[3] Hearings on H. R. 1752 Before the Subcommittee on Livestock and Grains of the House Committee on Agriculture, 93rd Cong., 1st Session at 10, 11 (1973).

[4] *Food from Farmer to Consumer: Report on the National Commission on Food Marketing*, p. 112 (1966).

requirements throughout the nation, enforceable by federal, state and local officials."[5]

The Association of Food and Drug Officials (AFDOUS), whose membership includes regulatory officials from all of the states and a large number of local jurisdictions, has consistently decried the lack of regulatory uniformity. In 1941, for example, the Association's president criticized "trade barriers that force many producers and manufacturers to live under the virtual dictatorship of localized bureaucracy" and urged state food officials to "[d]iscourage the enactment of laws that make it impossible for legitimate industry of one state to engage in trade in another under conditions which are fair and equitable."[6] That year, the Association's members adopted a resolution expressing "disapproval of the tendency toward the enactment of legislation which constitutes definite barriers to Commerce between the states . . . ."[7] Since 1941, the Association has repeatedly adopted resolutions urging enactment of uniform food and drug legislation.[8] Nonetheless, as recently as 1973, the Association's members passed a resolution acknowledging (and disapproving) "a growing trend that . . . some States and local agencies are passing laws, regulations, or ordinances which are inconsistent with the principle of uniformity to which AFDOUS is committed . . . ."[9]

Federal Statutory Provisions

As to food products regulated by federal statutes, uniformity of labeling and packaging requirements among the states and local jurisdictions may be achieved through inclusion of express preemptive language in those statutes. Even where a federal statute includes no explicit preemptive language, it will nevertheless preempt state and/or local requirements in each of the following instances: (1) federal regulation is so pervasive so as to preclude state action; (2) the nature of the subject matter demands national uniformity of regulation; (3) a direct conflict exists between state and federal regulation; and (4) the state requirements stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.[10]

The Supreme Court has specifically ruled that the area of "readying foodstuffs for market has always been deemed a matter of peculiarly

[5] 1969 White House Conference on Food, Nutrition and Health, *Final Report*, Recommendation 8, p. 117.

[6] 5 AFDOUS Quart. Bull. 2 (1941).

[7] 5 AFDOUS Quart. Bull. 8 (1941).

[8] *See, e.g.*, 31 AFDOUS Quart. Bull. 73 (1967) and 33 AFDOUS Quart. Bull. 46-47 (1969).

[9] 37 AFDOUS Quart. Bull. 19 (1973).

[10] *See De Canas v. Bica*, 424 U. S. 351 (1976); *Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U. S. 132 (1963); *Campbell v. Hussey*, 368 U. S. 297 (1961); *Hines v. Davidowitz*, 312 U. S. 52, 67 (1941); *McDermott v. Wisconsin*, 228 U. S. 115 (1913).

local concern" and that the "[S]tates have always possessed a legitimate interest in the protection of [their] people against fraud and deception in the sale of food products at retail markets within their borders."[11] Compliance with a state regulation is not required however, where "compliance with both federal and state regulation is a physical impossibility for one engaged in interstate commerce."[12]

Currently, the Federal Meat Inspection Act ("Meat Act"),[13] the Poultry Products Inspection Act ("Poultry Act"),[14] and the Egg Products Inspection Act ("Egg Act"),[15] contain explicit preemption provisions which in essence prohibit any state or local jurisdiction from imposing a labeling, packaging, notice or ingredient requirement "in addition to or different than" those under the federal statute. The Fair Packaging and Labeling Act contains an extremely narrow provision that preempts state net weight laws "which are less stringent than or require information different from the requirements" of that Act.[16] The Federal Food, Drug, and Cosmetic Act ("FD&C Act") contains no preemptive language, and therefore, preemption under that statute is governed by the principles enunciated in *Hines v. Davidowitz, supra,* and *Florida Lime and Avocado Growers v. Paul, supra.*

The recent decision of the Supreme Court in *Jones v. Rath Packing Co.*[17] contains an analysis of the express preemptive provisions of the Meat Act and the Fair Packaging and Labeling Act and implied preemption under the FD&C Act and provides valuable guidance as to the effect given to the wording of statutory provisions relating to the uniformity of federal and state requirements for products distributed in interstate commerce. In *Rath Packing,* the Supreme Court reviewed two decisions of the Ninth Circuit Court of Appeals holding that California's net weight labeling enforcement program was preempted, as it applied to bacon, by the Meat Act[18] and as it applied to flour, by the Fair Packaging and Labeling Act.[19]

The Supreme Court unanimously accepted the reasoning of the Ninth Circuit, that the language of the Meat Act clearly and explicitly preempted additional or different net weight requirements imposed by California on bacon, a federally inspected meat product.[20]

[11] *Florida Lime and Avocado Growers, Inc. v. Paul,* 373 U. S. 132, 144 (1963).
[12] *Id.* at 142-143.
[13] 21 U. S. C. Sec. 678.
[14] 21 U. S. C. Sec. 467e.
[15] 21 U. S. C. Sec. 1052.
[16] 15 U. S. C. Sec. 1461.
[17] 430 U. S. 519, 97 S. Ct. 13 (1977).
[18] *Rath Packing Co. v. Becker,* 530 F. 2d 1295 (CA-9 1975).
[19] *General Mills, Inc. v. Jones,* 530 F. 2d 1317 (CA-9 1975).
[20] Since the preemptive language of the Poultry Act, 21 U. S. C. 476e, is nearly identical to that used in the Meat Act,
(Continued on the next page.)

Earlier, in *Armour & Co. v. Ball,*[21] the Sixth Circuit, interpreting the preemptive language of the Meat Act, held that a Michigan ingredient requirement for sausage was preempted because it established a standard for sausage different from that established by USDA. In both *Rath Packing* and *Armour* the state requirement was "different from or in addition to" an existing federal requirement.[22]

It could be argued that other language in the Meat Act would permit requirements "in addition to" federal standards:

> . . . but any State . . . may, consistent with the requirements under this chapter, exercise *concurrent jurisdiction* with the Secretary . . . for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded . . . This chapter shall not preclude any state . . . from making requirement or taking other action with respect to other matters regulated under this chapter.[23]

In *Armour* however, the court fully analyzed the effect of this language which permits "concurrent" state actions with respect to "other matters regulated under this chapter." The court held:

> By permitting state action "with respect to any other matters regulated under this chapter," Congress is unmistakably ordaining that a state may not take action with reference to "marking, labeling . . . or ingredient requirements in addition to, or different than, *those made under this chapter* . . ."
> [I]n view of its unambiguous language, Section 408 [21 U. S. C. § 678] reflects unequivocal legislative purpose to make the Federal Act preemptive [with respect to *all* labeling.][24]

The *Armour* decision clearly demonstrates that the "in addition to" language preempts state regulations which are over and above existing federal requirements in a particular area. It casts some doubt however, as to whether the "in addition to" language preempts state regulations in areas subject to federal regulation, but where the federal government has failed to act. It could be argued under Section

(Footnote 20—continued)
the rationale of the *Rath Packing* decision is equally applicable to poultry products.

[21] 468 F. 2d 76 (CA-6 1972); *cert. den,* 411 U. S. 981 (1973).

[22] The exact meaning of "in addition to" is unclear. Three distinct possibilities exist. First, "in addition to" could refer to a labeling requirement over and above an existing labeling requirement. For example, a hypothetical federal regulation requires non-perishable food products to bear the day and month the product was packed while a hypothetical state regulation requires the year packed as well. A second possible meaning of "in addition to" would be a state requirement in an area not yet directly regulated by the federal government but within the statutory authority of the federal government to regulate. Continuing with the open-date labeling example, the federal government has no open-date requirements while a state requires a pack date. The third possible meaning would be to apply to both of these interpretations.

[23] Emphasis supplied) 21 U. S. C. Sec. 678.

[24] (Emphasis supplied) *Armour & Co. v. Ball, supra* at 84-85.

408 to the Meat Act and *Armour* that federal preemption extends only to state requirements in addition to or different than ". . . those *made* under this chapter."[25] While attractive on its face, this interpretation ignores the expressed intention of Congress to establish a uniform and consistent labeling system. The legislative record is replete with statements clearly demonstrating that Congress intended to create a uniform national system of labeling. For example, the House Subcommittee Report on H. R. 12144 (which ultimately became the Wholesome Meat Act) summarizing Section 408, provides in part:

"States would be prohibited from regulating federally inspected plants whose operations are governed by Title I. Any recordkeeping and related requirements proposed by States for federally inspected plants must be in conformance with the Federal Meat Inspection Act. *States could not impose marking, labeling, packaging, or ingredient requirements in addition to or different from Federal requirements for products prepared under Federal inspection.*" (Emphasis supplied.)[26]

Similarly, the Senate Report provides that:

"Section 408 would exclude States, territories, and the District of Columbia from . . . imposing marking, labeling, packaging, or ingredient requirements in addition to or different than those under the Federal Meat Inspection Act for articles prepared under inspection in accordance with Title I of the Act, *but would permit them to impose recordkeeping and related requirements with respect to such plants if consistent with the Federal requirements* and to impose requirements consistent with the Federal provisions as to other matters regulated under the act."[27]

Thus, Congress made its intent clear to limit state regulation in this area to record keeping requirements and only where they are consistent with federal requirements. To permit states to construct unique labeling requirements in areas where the federal government has authority, but has failed to act, would clearly frustrate Congressional intent and stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Further, unique state labeling requirements for meat and poultry products could make compliance with both federal and state requirements impossible even where the federal government has failed to act. All USDA inspected products must be labeled in accordance with applicable USDA regulations.[28] No label may be used on any meat or poultry product until it has been approved by USDA.[29] Thus, in cases where a state regulation requires a label statement not required by USDA, it is unclear whether the label would be approved.

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[25] *See, e.g. Corn Products Refining Co. v. Eddy*, 249 U. S. 472 (1919).

[26] (Emphasis supplied) H. R. Rep. No. 653, 90th Cong., 1st Sess. at 7 (1967).

[27] (Emphasis supplied) S. Rep. No. 799, 90th Cong., 1st Sess. at 22 (1967).

[28] 9 CFR Parts 316 and 317 (meat) and 9 CFR Part 381 Subpart N (poultry).

[29] 9 CFR Secs. 317.4 and 381.132.

The Supreme Court in *Rath Packing* also sustained the Ninth Circuit's holding that the application of California's statute to flour was preempted by federal law, but rejected the Court of Appeals' reasoning. The Ninth Circuit, although recognizing that the Fair Packaging and Labeling Act grants greater labeling flexibility to states and local jurisdictions than does the Meat Act, concluded that the California net weight statute was preempted because it was "less stringent" than applicable federal requirements. The Supreme Court, in rejecting this analysis, concluded:

> The meaning of the statutory preemption of laws that require "information different from" the federal net weight labeling provisions, like the meaning of the phrase "less stringent," is unclear.... *The legislative history, however, suggests that the statute expressly preempts as requiring "different information" only state laws governing net quantity labeling which impose requirements inconsistent with those imposed by federal law.* Since it would be possible to comply with the state law without triggering federal enforcement action, we conclude that the state requirement is not inconsistent with federal law.[30]

The Supreme Court did find preemption, however, after determining that the California net weight statute would frustrate the accomplishment and execution of the purposes and objectives underlying the Fair Packaging and Labeling Act—to facilitate value comparisons among similar products.

As pointed out by the dissent, the scope and general application of the Supreme Court's decision regarding General Mills' flour and other food products subject to the Fair Packaging and Labeling Act and FD&C Act is far from clear.[31] What is made clear, however, is that the FD&C Act contains no preemptive language and that uniformity under the Fair Packaging and Labeling Act appears to be limited to net weight requirements, assuring only that state and/or local requirements are not inconsistent with federal requirements.

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[30] (Emphasis supplied) *Jones v. Rath Packing Co.*, 430 U. S. —, 97 S. Ct. at 1316. The language of Sec. 1461 as adopted was originally contained in the House bill. The Senate bill, by contrast, provided for preemption of state and local requirements which "differ from" those under the Fair Packaging and Labeling Act. S. Rep. No. 1186, 89th Cong., 2d Sess. 38 (1966). The conference committee accepted the House language and the House committee's explanation that "preemption would take place to the extent that State laws or State regulations with respect to the labeling of net quantity of contents of packages impose inconsistent or less stringent requirements than those imposed under Section 4 of this legislation." H. R. Rep. No. 2286, 89th Cong., 2d Sess. 11 (1966).

[31] Justice Rehnquist joined by Justice Stewart remarked "(I) am unable to agree, however, with the implicit preemption the Court finds with respect to flour. The latter preemption is founded on unwarranted speculations that hardly rise to that clear demonstration of conflict that must exist before the mere existence of a federal law may be said to preempt state law operating in the same field." 430 U. S. —, 97 S. Ct. at 1318.

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Implied Preemption

In the most recent interpretation of implied preemption under the FD&C Act, the Eighth Circuit in *Cosmetic, Toiletry and Fragrance Association, Inc. v. Minnesota,*[32] affirmed "on the basis of the district court's well-reasoned opinion" the issuance of a preliminary injunction against the enforcement of a Minnesota statute requiring a chlorofluorocarbon warning label. The district court held there was a substantial likelihood of success on the issue of preemption based on several grounds.[33]

In *CTFA* a non-profit trade association for the cosmetic industry and three cosmetic manufacturers, sought to enjoin the enforcement of a Minnesota statute governing display of warning labels on pressurized containers employing a saturated chlorofluorocarbon propellant. Plaintiffs argued that although the warnings required by the FDA and the Minnesota statute were identical in content, they differed in terms of the placement on the label of the warning. The FDA regulation required the warning to "appear on an appropriate panel with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase."[34] The Minnesota statute required the warning to appear on the front panel.

The court in *CTFA* articulated four key factors to be considered in determining whether preemption of a particular area of regulation has occurred:

(1) intent of Congress to occupy the field;

(2) pervasiveness of the federal regulatory scheme;

(3) the nature of the subject matter regulated and whether it is one which demands exclusive federal regulation in order to achieve uniformity vital to national interests; and

(4) whether the particular state or local law stands as an obstacle to the full purposes and objectives of Congress.[35]

Concerning the first factor, the district court noted that the FD&C Act contained neither express preemptive language, nor at the time of enactment, preemptive intent. The court noted, however, that all recent federal consumer labeling legislation included express preemption language.[36] The court suggested that this pattern would be fol-

[32] 575 F. 2d 1256 (CA-8 1978).

[33] *Cosmetic, Toiletry and Fragrance Association v. Minnesota, supra* at 1220. F. Supp. 1216 (D. Minn. 1977).

[34] 42 *F. R.* 22033 (April 26, 1977).

[35] *Cosmetic, Toiletry and Fragrance Association v. Minnesota, supra,* at 1220.

[36] *Id.* at 1221-22. *See.* the Federal Hazardous Substances Act, 15 U. S. C.

(Continued on the next page.)

lowed today with respect to preemption under the FD&C Act if Congress were "to legislate with regard to food, drug and cosmetic products."[37] On this basis the court found that Congressional preemptive intent exists at the present time with respect to labeling under the FD&C Act:

> Thus, although these [federal labeling] statutes [containing preemption procedures] are by no means controlling, they weigh heavily in the court's analysis of the preemption question.[38]

As to the other three factors, the court concluded that federal regulation appears to have occupied the field since three federal agencies coordinated their efforts in arriving at the regulatory action. The court also noted that given the national distribution of consumer products, the nature of consumer product labeling requires national uniformity "once the federal government has acted with regard to the interest sought to be furthered by the [state]."[39] Finally, the court found the Minnesota statute to be an obstacle to achieving the "national goal of the most effective warning at the least possible cost." Thus, although the court seemed to acknowledge that the Minnesota statute would merely be supplementary to, and not in direct conflict with, the federal regulation, its extra cost and deviation from the federal goal of purchase awareness and its frustration of the federal goal of the most effective warning at the least possible cost, rendered it "an obstacle to full effectuation of the federal purpose."[40]

The district court in *CTFA* distinguished an earlier Supreme Court case which addressed the preemption question in the context of the

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(Footnote 36—continued)
Sec. 1261 *et seq.* (1970) and the Consumer Product Safety Act, 15 U. S. C. Sec. 2051 *et seq.* (1972). Under both statutes, state regulations which are in addition to or different than federal requirements are permitted if the responsible federal agency determines that the state regulation offers a greater degree of protection at a reasonable cost which is not unduly burdensome on interstate commerce.

[37] *Id.* at 1222. *See also,* H. R. 10358 (95th Congress); S. 2540 (95th Congress).

[38] *Id.*

[39] *Id.* at 1223-24. Relying on statements made by the Commissioner of FDA, the court concluded:

> These statements supported the common sense notion that in an economy where goods are distributed on a national level, a subordinate unit of government should not be able to require that an interstate producer create special packaging or manufacture a special product for a limited distribution area once the federal government has acted with regard to the interest sought to be furthered by the subordinate entity's action. That is, the benefit to be derived from the subordinate's regulation is minimal relative to the costs of segregating and specially treating products bound for the limited geographical area. *Id.*

This statement however, tends to further support the argument that there would be no preemption in areas where the federal government has failed to act.

[40] *Id.* at 1224.

1906 Food and Drugs Act.[41] *Corn Products Refining Co. v. Eddy, supra* involved a challenge to a Kansas Board of Health regulation requiring all proprietary foods to bear percentage ingredient labeling. The Supreme Court held that the regulations were not preempted because Congress had not required any specific form of ingredient labeling, thus leaving it to the states. The district court distinguished *Corn Products*, concluding that the FDA had acted with respect to the problem of ozone deterioration.

The arguments which the district court found persuasive in concluding that there was a "substantial likelihood of success" on the issue of preemption necessary to sustain the preliminary injunction against enforcement of the Minnesota chlorofluorocarbon labeling requirement in *CTFA*, should be equally helpful in challenging state and local labeling requirements which differ from federal requirements under the FD&C Act. For example, the court held that although the FD&C Act contained no express preemptive language, Congressional preemptive intent existed with respect to consumer labeling, since most recent federal statutes contain express preemptive language. Similarly, nearly all federal statutes which pertain to food labeling enacted after the FD&C Act contain express preemptive language. Further, legislation introduced during the 94th and 95th Congress would have amended the FD&C Act to provide for national uniformity.[42]

The Court in *CTFA* also noted that federal action with regard to chlorofluorocarbon labeling had occupied the field since the federal regulation was the product of three agencies' concerted action in exercising their concurrent jurisdiction in this area. Federal regulation of food labeling is equally pervasive. Both FDA and USDA have jurisdiction with respect to food labeling and Federal Trade Commission (FTC) has jurisdiction with respect to advertising.

The provisions of the FD&C Act together with the voluminous and detailed labeling regulations promulgated and administered by the FDA to enforce that statute, constitute a nationally-applicable body of food labeling standards so pervasive as to preclude additional or different regulations by state and/or local government. Recently, the FDA, USDA, and the FTC held five hearings focusing on seven current issues involving food labeling.[43] The avowed purpose of the hear-

[41] *Corn Products Refining Co. v. Eddy*, 249 U. S. 427 (1919).

[42] S. 641 (94th Congress), H. R. 10358 (95th Congress), and S. 2540 (95th Congress).

[43] *See* 43 *F. R.* 25296 (June 9, 1978).

ings was to obtain public opinion and views on these issues which "will in turn provide a basis for development of a comprehensive strategy aimed at providing consumers with useful nutrition-oriented information on the labels of all food products."[44] It can be argued that such concerted action by three federal agencies and the already pervasive and comprehensive nature of federal regulation of food labeling has "occupied the field" and excludes any state action in this area.

In both *Rath Packing* and *CTFA* the courts sustained preemption theories under the FD&C Act in the absence of express preemptive language or a direct conflict in implementing or enforcing both the federal and state requirements on the basis that the state regulation was an obstacle to Congressional purposes and objectives. These decisions appear to indicate a willingness on the part of at least two courts to find that preemption exists when confronted by demonstrable economic loss or inconvenience in compliance for those affected by both a federal and state regulatory scheme, particularly where the state has had difficulty demonstrating that significant advantages result from its regulatory system. In both of these cases, however, the preempted state regulation addressed matters covered directly by federal regulations. The state regulations were an obstacle to the effectuation of an express Congressional purpose in precisely the same area. As discussed previously, it is unclear how the courts would view a state regulation in an area not addressed by the federal agency.

Although recent cases establish that state and/or local labeling regulations may be challenged as impliedly preempted under the FD&C Act, the absence of express preemptive language should be remedied. The proliferation of unique state labeling requirements continues. For example, the Commonwealth of Massachusetts recently enacted an open-date labeling regulation applicable to *all* perishable, frozen, and non-perishable foods.[45] To date, there are no federal open-dating requirements for frozen or non-perishable foods. Similarly, the State of Wisconsin has sought to impose labeling requirements for foods containing cheese substitutes which differ from federal requirements.[46]

[44] *Id.*

[45] Section 101.19 of the Massachusetts Department of Public Health Labeling Regulations. This regulation is being challenged in the Massachusetts Supreme Judicial Court by the Grocery Manufacturers of America, the American Frozen Food Institute and ten companies doing business in Massachusetts. *Grocery Manufacturers of America, et al. v. Massachusetts Department of Public Health* (Civil Action No. 73-180).

[46] *See, Anthony J. Pizza Food Corp. v. Wisconsin Department of Agriculture,* (W. D. Wisc. Civil Action No. 77C101).

Recent Efforts to Provide National Uniformity Under the FD&C Act

S. 641, the "Food Surveillance" legislation passed by the Senate but not the House during the 94th Congress, contained a provision which would have preempted state and local labeling requirements "in addition to, or different from," information required under the labeling provisions of the FD&C Act. The S. 641 preemption provision contained an exception allowing states to promulgate additional or different labeling requirements by applying to the Secretary of HEW and demonstrating that the additional or different law or regulation involved would promote the interests of consumers in the applicant's state. Applications for exemptions would have been published for comment in the *Federal Register* pursuant to the notice and comment procedures of 5 U. S. C. Sec. 553, and the Secretary would have been required to grant proposed exemptions if he found that the law or regulation involved would likely promote the interests of consumers within the applicant's jurisdiction without unduly burdening interstate commerce or otherwise adversely affecting the interests of all consumers.

The preemptive language contained in S. 641 is consistent with other recent Congressional enactments. Although this type of statute does not provide for the broad and predictable uniformity available under the Meat and Poultry statutes, it is more extensive and predictable than the uniformity provided by the preemptive language of the Fair Packaging and Labeling Act.

S. 2540, which is virtually identical to S. 641, was introduced by Senator Donald Riegel (D. Mich.) during the 95th Congress. Like its predecessor, S. 2540 would have amended the FD&C Act to prohibit all labeling requirements enacted by state and/or local jurisdictions which are "in addition to or different than" applicable labeling requirements promulgated under the misbranding provisions of the FD&C Act. This bill was never actively considered by the Senate.

In the House, former Congressman Paul Rogers (D. Fla.) introduced H. R. 10358 which would have amended the FD&C Act to preempt state and/or local labeling requirements "different from or in addition to" applicable labeling requirements under the FD&C Act. Following extensive hearings, during which industry groups uniformly endorsed the proposed preemption provision, the House Health and Environment Subcommittee approved a substantially revised preemptive provision.[47] The marked-up bill would have rendered nugatory

[47] *See* H. R. 13967 (95th Congress).

the federal preemption provision in H. R. 10358 by adding a provision authorizing the states, upon application to the FDA, to impose "experimental" food labeling requirements for a period of up to three years, regardless of their justification, cost, or impact on interstate commerce. Moreover, the states would be specifically authorized to establish or continue in effect open-date labeling requirements until the FDA promulgates such a regulation. This provision would have encouraged, rather than deterred, nonuniform labeling requirements.

Conclusion

In the wake of the Supreme Court's *Rath Packing* decision, it is clear that food processors who are interested in uniformity among the states cannot rely on the implicit preemptive effect of the Food, Drug, and Cosmetic Act or the specific, but equivocal preemptive language of the Fair Packaging and Labeling Act. The Federal Meat Inspection Act's and Poultry Products Inspection Act's preemption of additional or different requirements provides a degree of predictable uniformity among the states, but this uniformity does not necessarily extend to every detail of state enforcement programs. The preemptive provisions of newer statutes such as the Consumer Products Safety Act (as amended), may provide a lesser degree of uniformity than the Meat and Poultry Inspection Acts, since the administering agency can allow exceptions to uniform national requirements. However, these statutes do provide a high degree of certainty and predictability regarding the extent of uniformity among the states, since any exceptions are a matter of federal public record, permitting interested persons the opportunity to comment.

The need for national uniformity under the FD&C Act is widely recognized and long overdue. Legal challenges to the myriad of unique state and local labeling, ingredient, notice and packaging requirements do not represent a realistic approach to the problem. Federal legislation correcting this obvious deficiency in the FD&C Act is sorely needed.

[The End]



VEGETARIAN INFORMATION SERVICE, INC.
P.O. BOX 5888, WASHINGTON, D.C. 20014

LABELING REQUIREMENTS FOR ANIMAL PRODUCTS

Testimony Submitted To The Subcommittee on Health and Scientific Research, Committee on Labor and Human Resources, U.S. Senate

by Alex Hershaft, Ph.D., President
Vegetarian Information Service, Inc.

Washington, DC -- 18 March 1980

My name is Alex Hershaft, and I am President of the Vegetarian Information Service, Inc., a non-profit, public interest organization formed to advise the American public on the merits of reducing the consumption of meat and other animal products. I hold a Ph.D. in chemistry, have been engaged in nutrition education activities for the past five yars, and am currently employed as a senior environmental scientist by a local consulting firm. I appreciate this opportunity to present our views on labeling requirements of animal products.

According to our best estimate, based on a recent Roper poll (see enclosed summary report), nearly ten million Americans have effectively given up the consumption of meat, while another 50 million are careful about how much meat they consume. What's more, nearly one half of the American population believes that a vegetarian diet is better for one's health. Beyond vegetarianism, several million Orthodox Jews, Muslims, and members of other religious denominations observe special restrictions on their intake of animal products. A large number of people are allergic to certain animal proteins and fats. Certainly, all American consumers are vitally concerned with ingredients in meat and other animal products that may be hazardous to their health.

Under current FDA regulations, food manufacturers are permitted in most cases to list all fats and oils of both animal and vegetable origin that may be present, rather than only those that are. There is no requirement for identifying any other animal ingredients. This situation denies to millions of consumers the freedom to avoid all food products containing any ingredients of animal origin without unduly restricting their available choices. To correct this problem, we request that the proposed actions on fats and oils be expanded to require that food manufacturers identify clearly any ingredients of animal origin, regardless of the amount present.

Current FDA regulations permit the voluntary inclusion of fatty acid and cholesterol content as part of nutrition information. This is not sufficient to protect the health of the informed consumer from the many additional hazardous ingredients contained in meat and other animal products. These include heavy metal, pesticide, hormone, and drug residues, pathogenic organisms, nitrites and other carcinogens formed on heating of animal fat, and metabolic waste products that place an added burden on the consumer's liver and kidneys. Accordingly, we request that labeling of fatty acid and cholesterol content be expanded to encompass additional ingredients that have been implicated in the incidence of cancer and other chronic diseases.

Such a move would at least provide the consumer with a fair warning during the customarily lengthy period of negotiations before a hazardous ingredient can be banned under the Delaney or other clause of the Food, Drug, and Cosmetic Act. The federal government's responsibility to protect the public health requires nothing less.

Alex Hershaft

AMERICAN MEDICAL ASSOCIATION
535 NORTH DEARBORN STREET • CHICAGO, ILLINOIS 60610 • PHONE (312) 751-6000 • TWX 910-221-0300

JAMES H. SAMMONS, M.D.
Executive Vice President
(751-6200)

March 6, 1980

The Honorable Edward M. Kennedy
Chairman
Subcommittee on Health and
Scientific Research
Committee on Labor and Human Resources
4230 Dirksen Senate Office Building
Washington, D. C. 20510

Re: S. 1651 and S. 1652 --
Food Labeling Legislation

Dear Chairman Kennedy:

The American Medical Association takes this opportunity to submit its statement for the record of hearings held recently on the captioned bills, the "Department of Agriculture Nutrition Labeling and Information Act of 1979" and the "Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug, and Cosmetic Act." These bills would clarify and expand the authority of the Food and Drug Administration (FDA) and the U. S. Department of Agriculture (USDA), working in concert with the Federal Trade Commission (FTC), to require nutrition and ingredient labeling for foods under the jurisdiction of each agency.

We would suggest that the Subcommittee not go forward with this legislation at this time. We believe that it would be preferable for the Subcommittee to wait for the specific requests for legislation from FDA, USDA and FTC that the agencies have announced will be forthcoming very soon. These agencies have been engaged in a thorough analysis of current and proposed food labeling requirements for almost two years. To a great extent the agencies have conducted their inquiries and analyses in public forums and have had the benefit of literally thousands of public comments in shaping their tentative plans. These plans, announced in the Federal Register of December 21, 1979, and the subject of public discussion at March 4 - 5, 1980, hearings called by the three agencies, include the development of agency requests for authorizing legislation in a number of areas. We believe the Subcommittee should suspend activity on S. 1651 and S. 1652 until it has the benefit of the proposals from each of these agencies as to what each believes is essential legislation. In this regard, we note that the agencies do not intend to address these issues in the same manner as do these bills.

We have enclosed for the Subcommittee's consideration a copy of AMA's full statement of March 5, 1980 presented at the administrative hearing on the food labeling issues under discussion. We trust that the Subcommittee shares our concern that Congress and the agencies should act in concert in revising and updating the food labeling laws. Such cooperative action can better assure that consumers are presented food label modications and education programs that will enhance their ability to make intelligent and, in some cases, medically necessary food selections from among the vast variety of foods available today.

Sincerely,

James H. Sammons

James H. Sammons, M.D.
Executive Vice President

Enclosure

Statement
of the
American Medical Association

to the

U.S. Food and Drug Administration
Federal Trade Commission
U.S. Department of Agriculture

Re: Food Labeling

Presented by: Philip L. White, Sc. D.

March 5, 1980

American Medical Association
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Chicago, Illinois 60610

Legislative Department
Public Affairs Division
(312) 751-6513

Comments

of the

AMERICAN MEDICAL ASSOCIATION

to the

U.S. Food and Drug Administration
Federal Trade Commission
U.S. Department of Agriculture

Re: Food Labeling

March 5, 1980

The American Medical Association is pleased to submit its comments concerning issues relating to food labeling in response to the captioned agencies' notice requesting comments from the public in the December 21, 1979 Federal Register (44 F.R. 75990). AMA's comments will address the following subjects:

-- Ingredient labeling;

-- Nutrition labeling;

-- Composite data base for use in nutrition labeling;

-- Labeling of sugars;

-- Sodium and potassium labeling;

-- Fatty acid and cholesterol labeling;

-- Fiber labeling;

-- Food fortification; and

-- Use of the terms "natural" and "organic" in food labeling claims.

Information contained in food labeling can be a valuable aid to physicians who prescribe, and to patients who must adhere to, a medical regimen that restricts, eliminates or enhances the consumption of certain substances found in foods. Food labeling information has become especially important since the contents of modern prepared foods may vary significantly from traditional recipes. The AMA is, therefore, pleased to cooperate in this important endeavor to review and revise the food labeling laws and regulations of the Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA) and the Federal Trade Commission (FTC).

INGREDIENT LABELING

Labeling of Ingredients in Foods Having a "Standard of Identity"*

FDA has stated that it will seek legislation to amend the Federal Food, Drug, and Cosmetic Act (the Act) to require that ingredients that must be included in foods for which there is a "Standard of Identity" be declared on product labels. (USDA regulations already require such declarations.) Pending such a change in the Act, FDA will revise pending Standards of Identity to require the declaration on a label of all optional ingredients, including the form of the mandatory ingredients where more than one form is available for use.

The AMA believes that the ingredients in standardized foods should be disclosed on the label and supports the efforts of the FDA in this regard. There are well documented reports of metabolic or allergic intolerances to specific food constituents. Ingredient disclosure on food labels is important for persons who have such intolerances.

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* FDA has, by regulation, established "recipes" for certain common food products (i.e. ice cream) that dictate what primary ingredients or characteristics a food must have to be marketed under the common name.

Label Identification of Colors, Flavors and Spices

The agencies have announced that they will seek authority to require that all colors and spices be declared by their common names on food labels. Although the incidence of intolerance to specific minor components of food such as colors, flavors or spices appears to be less well documented at this time than the incidence of intolerance to other components of food products, the frequency and, in some instances, the nature of reported intolerance to such minor ingredients indicates the need for continued research and monitoring in this area. On a more practical level, we believe that the identification of colors added to food products should be encouraged because of the relatively small number of food colors in use. Where statutory exemptions now exist (i.e. exempting a food product from a requirement to identify an added color), they should be repealed.

Natural spices and flavors, and many of their artificial counterparts, on the other hand, consist of a large number of flavor substances. Ingredient labeling that would require separate listings of individual flavor components would, therefore, be impractical. Where there is an identified intolerance to a flavor component (including a spice) that has occurred among a significant number of consumers, we would agree that identification of the substance on the product label is important.

We note that in this regard our concerns are similar to those expressed by the regulatory agencies. We concur in their view that it would be difficult and impractical to require identification of all flavors fully on food labels. We also concur, however, in the view that flavor substances known to cause health problems should be declared on food labels. We look forward to assisting in the task of identifying and evaluating health problems that may be associated with the consumption of flavoring substances.

Quantitative Ingredient Labeling

The agencies have stated that they will continue their efforts to encourage or require the use of quantitative ingredient labeling on foods. Specific proposals include:

--expansion of the use of "percentage labeling" (listing of valuable and characterizing ingredients in terms of percent of the whole) for both standardized and non-standardized foods;

--publication of guidelines for voluntary quantitative ingredient labeling; and

--support for legislation that would authorize the agencies to require quantitative ingredient labeling and give them access to a company's product formulas, quality control records and related documents to assure that quantitative ingredient labeling is accurate and truthful.

We believe that listing of primary ingredients in foods in descending order of predominance provides useful information to consumers. We do not, however, believe that it is necessary to require labeling to reflect the percentages of ingredients contained in a food product. Listing of ingredients present in small quantities as percentages of the whole would result in a long and confusing label that would convey little useable information to consumers. Moreover, such labeling would give the consumer no information about the actual amount of a substance consumed per serving.

In addition, "percentage labeling" of ingredients for products that are to be combined with other foods would provide no quantitative information about the actual amount of ingredients consumed per final serving. Thus, any requirement to provide quantitative information for the product as purchased would provide little meaningful information to consumers about the product as consumed.

There is another potential problem that may be anticipated with the use of "percentage labeling." Processed products can have the same nutrient content, but significantly different composition. In such a case, quantitative labeling of ingredients for two differently manufactured products could lead to incorrect inferences being drawn by consumers (i.e. that one product is superior to another) when such is not the case.

The purpose of current efforts to revise food labeling requirments is to encourage the conveying of nutrition information in terms useful for consumers' purposes. Any mandatory information that is potentially misleading, such as "percentage labeling," should not be required.

In our view, when the agencies' published "decision matrix" is used to evaluate the desirability of quantitative ingredient labeling, only one (of more than thirty) criteria may be said to justify an affirmative decision by the agencies to require such labeling--namely, that there may be a segment of the public that will find such labeling desirable. Other criteria (i.e. health implications, industry acceptability, legal considerations, economic implications, and probable effectiveness) would probably mandate that such a labeling requirement not be promulgated.

Statutory authority to require the "percentage labeling" of ingredients should not be sought unless information derived from carefully conducted studies demonstrates that such labeling serves an identifiable health purpose, or other compelling need, and that no deception of consumers or unreasonable increases in food prices would result.

Listing Ingredients by Order of Predominance

FDA and the USDA have announced that they will propose amendments to their current regulations to require that food labels bear a statement to the effect that ingredients are listed in descending order of predominance. We agree that all label declarations, whether for standardized or non-standardized foods, should be required to list ingredients in the descending order of predominance. Where practical, a readily understandable prefatory statement to the effect that foods are so listed could be a useful adjunct to the reading of food labels. We do recommend consumer testing of various alternative label statements, such as, "Ingredients are listed by weight from most to least." This alternative to the FDA's phrase, "Foods are listed in descending order of predominance," might be more readily understood by consumers. In cases where exemption to such ingredient labeling or labeling format would be permitted, such exemptions should be authorized only for minor ingredients and not for those ingredients that are major components of a food product.

Use of "And/Or" Labeling to Declare the Source of Fats and Oils

FDA and the USDA have announced that they will also propose amendments to their current regulations to require that foods containing 10% or more total fat on a dry weight basis declare on their labels the specific source of the fat or oil (e.g., "vegetable oil (may contain cottonseed oil, soybean oil and/or palm oil")). The agencies base this policy, in part, on the current regulation that prescribes voluntary fatty acid and cholesterol labeling for foods that contain 10% or more fat on a dry weight basis and at least 2 grams (g) fat per serving.

We are familiar with the history of the "10% dry weight basis" standard for fatty acid labeling. The use of this threshold permits the physician to guide the food choices of his patient and enables the patient to make intelligent selections from among those foods that supply the bulk of dietary fat. The consumer's ability to make such informed selections is of particular importance since the success of a fat-modified diet requires modification of the entire diet as well as control of the primary sources of dietary fat and cholesterol. We believe that this standard may serve better than the "2 g fat per serving" standard as an appropriate threshold for requiring label declaration of a specific source of a food's fat or oil.

Although we appreciate the agencies' concerns in this matter, we believe that no change from the current standard should be made until appropriate studies have confirmed that the level of 10% fat on a dry weight basis is as appropriate for specific source oil labeling as it is for fatty acid and cholesterol labeling.

Functions and Names of Ingredients

The agencies have stated that they will explore the feasibility of creating an "ingredient dictionary" for the public. We commend the agencies for adopting this innovative idea. It could prove to be a practical solution to the problem of providing general ingredient information via a common vocabulary to the industry, the agencies and the consuming public.

NUTRITION LABELING

Label information reflecting the nutrient content of food can assist consumers in making meaningful and medically necessary food selections. In

devising regulations regarding the declaration of certain nutrient information, the agencies must be careful to ensure that the required information is presented in an understandable and useful manner to the consumer. We believe that the use of simple language, clearly presented, can help assure that information provided on food labels is useful. Consumer education programs can also enhance the effectiveness of such labeling.

Mandatory Versus Discretionary or Voluntary Nutrition Labeling

The agencies have stated that they will seek legislation clarifying their authority to require nutrition labeling for all foods. USDA has also announced that it will propose regulations that would require nutrition labeling where nutrition claims are made for a product or where certain nutrients have been added to a product, thereby making USDA regulations on mandatory nutrition labeling similar to the current regulations of the FDA.

The agencies have also indicated that they plan to form a task group to develop criteria to determine which foods should bear nutrition labeling. The primary agency criteria developed to date would require consideration of the importance of the food in the diet, the potential for misleading the public when a food does not have nutrition labeling, and other matters of public health significance and consumer concern.

The AMA has supported, and continues to support, voluntary efforts to increase public awareness of the composition and nutritional value of foods. We agree that legislation to clarify the agencies' authority to require nutrition labeling for all foods is desirable. In the interim, we believe

that the decision of the agencies to design their nutrition labeling regulations to be more uniform is a wise one. Uniformity of label information presented is helpful if consumers are to become knowledgeable about nutrition labeling and routinely use the label information to make informed purchases.

Nutrition Labeling Format

The agencies propose to retain the present nutrition labeling system pending the outcome of research to be undertaken to determine what label format consumers find most useful and convenient and to determine what changes in current requirements, if any, are appropriate. The agencies plan to establish a task force to work with industry and consumers to develop proper experimental designs for these studies and appropriate criteria for evaluating the data generated by these inquiries. We look forward to working closely with the task group that will be convened to develop the experimental protocols and the criteria for evaluating this necessary research.

Among the label formats that should be tested is a simplified nutrition label that lists information needed to make medically important food selection decisions. A sample label reflecting a simplified format recommended by AMA is attached.

In most instances, the information needed to make important nutritional distinctions can be provided by combining ingredient listings and certain information regarding the nutrient composition of the product. For example, a food label should include:

1. serving size;
2. servings per container;

3. calories per serving;
4. carbohydrates (g/serving);
5. protein (g/serving);
6. fats (g/serving);
7. fatty acid content per serving (g-polyunsaturated fatty acid, g-saturated fatty acid);
8. cholesterol (mg/serving); and
9. sodium and potassium (mg/serving).

The above information in combination with ingredient declarations would provide consumers a sound basis for both medically necessary food purchase selections and those decisions motivated by personal dietary preferences. We urge that such a format be given priority examination by the agencies.

Mandatory Information for Nutrition Labeling

The agencies propose to continue their current policies regarding declaring nutrients that must be included on certain food labels, i.e., protein, carbohydrates, fat, certain vitamins and minerals, calories and information pertaining to serving size and servings per container. (USDA will continue to permit the use of an abbreviated format consisting of carbohydrates, protein, fat and other information deemed essential to consumers.) USDA has also announced that it will propose nutrition labeling regulations that would be the basis for providing information on calories, carbohydrates, protein, fat, sugars, cholesterol, sodium and other nutrients of public health concern.

The AMA is vitally interested in the nature of the information that agencies currently require as part of their nutrition labeling programs.

We have indicated above the information that we consider important. We have also previously indicated that within that framework other information, too, could be included that would serve consumers well. On the other hand, some information (i.e., declaration of vitamin/mineral content) may not be as necessary or useful. We suggest, therefore, that when no nutrition-related claims are made on a food label and no vitamins and minerals have been added to that food, a simplified nutritional label format should be evaluated. Such a label could include only:

-- serving size;

-- servings per container;

-- calories per serving;

-- protein (g/serving);

-- fat (g/serving);

-- carbohydrates (g/serving); and

-- sodium and potassium (mg/serving).

COMPOSITE DATA BASE FOR USE IN NUTRITION LABELING

FDA and the USDA propose to maintain their current policy that requires products to be labeled to reflect their composition and that places on the manufacturer responsibility for assuring the validity of nutrient claims on a food's label. The agencies have gone further in this notice and have included a statement of policy concerning the use of nutrient data bases. The effect of this statement is to preclude, for the time being, any experimentation with established (analytical) data base information on the nutrient content of food products.

AMA's interest in this area, i.e., with respect to the type of analysis used and degree of accuracy required for nutrition information, extends over

many years. In 1972, for example, the AMA recommended to FDA that:

> "...average values for labeling purposes be derived for each natural product (e.g., an updated USDA Handbook 8), under conditions of minimal processing, i.e., canning or freezing. The agreed upon average values would be used for nutritional labeling."

We further stated at that time:

> "...for commodity-type products which are not fortified and are not promoted for any special nutritional qualities, adequate compliance could be assured with an average value supported by adequate analyses over a period of more than one season."

Thus, in AMA comments on earlier FDA proposals concerning the nutrition labeling of foods, we have urged the agencies to consider the use of years of experience and accumulated data about food composition for the purpose of providing label information. We note with interest that although previous documents have not encouraged discussion of these concerns, such concerns have been raised by other commentors. We believe our earlier recommendations merit active consideration by the agencies at this time.

Consideration must be given to determining what methods are appropriate for obtaining the information to be used to label nutrients. The present nutrition labeling regulations require repetitive and costly analytical confirmation to assure that the amounts of nutrients stated on the label are present, with minimal variation from stated values permitted. These costs are, of course, being passed on to the consumer. In our view, the current requirements may be unnecessary and undesirable in that they deter some in the food industry from undertaking nutrition labeling.

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For years, health professionals have confidently calculated the nutrional value of diets using published statistical data (i.e., mean values). Variations between published values and actual analytical values are not considered to be significant to health professionals because serving sizes also vary. With the variety of foods in the average diet, nutritional deficiencies or imbalances resulting from minor error in the estimation of the nutrient content of any one food item are highly unlikely to develop.

We recommend that, prior to the agencies establishing any mandates regarding nutrient labeling, consideration be given to the following concerns:

1. the need by health professionals and consumers for the precise data on nutrient content in food labeling that is currently required;
2. the need for extensive, repetitive and costly nutrient analyses as is currently required to validate food labeling claims; and
3. the practical value to consumers of precise information on the nutrient content of a product as compared to label information that reflects the average amounts of nutrients likely to be encountered in a product.

To help reduce the costs of nutrient labeling, consideration should be given to the use of mean values for nutrients in those food commodities and food products that receive minimal processing and are not fortified (since they should not deviate significantly in nutritional composition). It should be possible to establish mean values for these minimally processed products or product classes as an alternative to existing procedures. For fortified foods or formulated foods that are subject to significant changes in formulation, current requirements may still be appropriate.

This suggested "mean value" or composite data base system for the labeling of nutrient content would provide consumer information regarding the approximate values for nutrients that he or she is likely to encounter in a given product. For example, under present regulations (21 CFR§101.9(3)), should calories, carbohydrate or fat be declared, the label may state an amount that is larger than the amount actually present in the product as determined by analysis. It is likely, therefore, that foods only occasionally contain the precise amount of a substance stated on the label. Would it not be desirable instead that the label state the amount likely to be encountered by the consumer, i.e., the mean value of a nutrient in any such product? Furthermore, existing good manufacturing practice regulations, quality control procedures and appropriate periodic analyses can assure that products are labeled in compliance with our suggested "mean value" labeling.

We consider it imperative that the agencies incorporate research into the use of composite data base information for nutritional labeling as a part of their new food labeling initiatives. Moreover, differing types of composite data base information systems must be evaluated. Certainly, the use of composite data base information compiled by an individual processor on its own products should be evaluated as a base for that firm's food labeling claims.

Serving Sizes

FDA proposes to publish final serving size regulations for some beverage products, cereal products and meal replacements. The agencies will propose regulations to establish serving sizes for additional product classes and/or types of food on an "as needed" basis. We agree that serving size information is important in conveying nutrition information to consumers and that a reason-

able and uniform serving size for labeling purposes can be established for many product classes.

Labeling of Sugars

FDA and the USDA have stated that they will propose amendments to the existing nutrition labeling regulations to require quantitative declaration of total sugars as part of nutrition labeling. The agencies are also seeking information on the amount of sugars (in terms of grams per serving or percentage by weight) that warrants such a label declaration. They have established a task group to develop criteria for determining the level of sugars that should require a label statement. USDA and FDA further propose to seek legislation providing them explicit discretionary authority to require quantitative labeling of sugars on the basis of public health concerns (i.e., the contribution of sugar to dental decay). The agencies also intend to conduct an education program to increase consumers' understanding of how sugars are declared on food labels.

The debate about whether, and how, to appropriately label simple sugars in food products is complex. It involves not only documented public health concerns, but also the perceived dietary concerns about sugar in the mind of the public.

In our view, it is, therefore, premature for the agencies to speculate as to what level of sugar in a food should "trigger" a label declaration of sugar content, public health concerns notwithstanding. We believe the agencies must first show that there is a level of sugar in the diet that, irrespective of other variables, impacts on a person's health. Then the agencies can properly seek the discretionary authority they desire and properly invoke the demonstrated public health concerns.

The AMA is not, however, opposed to optional listing of a food's carbohydrate contents, either in terms of total carbohydrates, total simple sugars, or total complex carbohydrate. We agree with the agencies' view that a declaration of sugar content should be based on the total amount, rather than the added amount, of sugar. A label statement reflecting only added sugar would not provide adequate information to consumers on the total content of all sugars in a food--a matter of some importance since the body cannot differentiate between indigenous and added sugars.

We recommend, therefore, that the multi-agency task force first establish whether there are characteristics of a food that can be used to predict its cariogenicity. We further recommend that dental health professionals should serve as public advisors to this interagency task force.

Sodium and Potassium Labeling

FDA has announced its intention to propose amendments to its nutrition labeling regulations to require the declaration of total sodium and potassium content of foods. The USDA has also announced its intention to require sodium labeling as part of nutrition labeling and is considering including potassium labeling in its proposal.

The AMA is pleased to note the agencies' intentions regarding labeling to indicate the sodium and potassium content of foods. The medical profession has had long-standing concerns in this regard. Many patients on restricted sodium intake diets currently have difficulty making informed purchases since label information rarely reflects the sodium content of foods. Standard diet therapy for the restriction of sodium often involves limiting sodium intake to 1000 to 2000 milligrams a day. Clinical conditions that require control of dietary sodium also frequently require control of potassium content in one's diet as well (e.g., for patients who are taking certain diuretics). Consequently,

labeling that states the amount of total sodium and potassium present in a food would be useful in guiding consumers on a special medical regimen.

We support the agencies' efforts to obtain explicit statutory authority to require quantitative labeling of total sodium and potassium content for foods. We submit for the agencies' consideration an AMA draft bill (attached) that would accomplish this end.

Fatty Acid and Cholesterol Labeling

FDA proposes to continue requiring that the cholesterol or fatty acid content of a food be included in nutrition labeling when any claim about these substances is made. FDA also proposes to amend the fatty acid/cholesterol regulation to require (1) fatty acid labeling whenever cholesterol is declared and (2) cholesterol labeling whenever fatty acids are declared. Finally, FDA will propose a regulation to define the terms "low cholesterol," "reduced cholesterol," and "cholesterol free," and will consider promulgating regulations to govern label claims regarding fatty acid content.

USDA will propose regulations to require cholesterol labeling as part of nutrition labeling, and both FDA and the USDA will seek legislation to provide them explicit discretionary authority to require cholesterol/fatty acid content labeling as needed to respond to public health concerns.

The AMA has long been interested in the accurate labeling of the fatty acid content of foods. The AMA's interest in labeling that provides information on the fat, fatty acids and cholesterol content of foods arises from the need for such information in the medical management of those patients who must make dietary modifications because they have, or are at risk of developing, coronary heart disease. In response to a 1965 proposal by the FDA to label the fatty

acid content of foods, the AMA's Council on Foods and Nutrition offered to carry out a study in order to assist in the preparation of more meaningful regulations. FDA accepted the proposal and endorsed the objective of the study. After receipt of the results of this AMA study in May 1967, FDA re-published its proposal and adopted the AMA recommendation that labels of foods that contain 10% or more of the dry weight as fat be permitted to state the fatty acid composition of the contained fat. In addition, AMA urged FDA to eliminate any unnecessary restrictions on the sale of alternative food products that could replace products high in saturated fat content.

We support the agencies' decision to continue to require that the cholesterol or fatty acid content of a food be included in nutrition labeling when claims about these substances are made. Furthermore, we support FDA's announced intention to require fatty acid labeling when cholesterol is declared and to require cholesterol labeling when fatty acid is declared. We note FDA's expressed intent to attempt to define the terms "low cholesterol," "reduced cholesterol," and "cholesterol free," and we look forward to working with the agency to assure that any proposed definitions are meaningful and useful.

Fiber Labeling

The agencies have stated that they do not plan to require fiber content labeling as a part of nutrition labeling until: (1) there is a clearer consensus on a definition of dietary fiber; (2) methods of analysis are developed; and (3) the significance of fiber in the diet is better understood.

We concur in the agencies' view in this matter. We recommend that nutrition label statements reflecting fiber content of food items remain optional until the questions discussed above have been resolved.

Disease-Related Claims on Food Labels

FDA and the USDA propose to maintain their present policy of not allowing claims in labeling that a food is effective for the prevention, cure, mitigation or treatment of a disease or symptom. We concur in this decision. We also endorse the Federal Trade Commission policy of challenging such claims in food advertising.

FDA has stated, however, that it will promulgate regulations covering "medical foods" (i.e., foods for use under medical supervision), thereby permitting the use of appropriate therapeutic claims for such foods in the labeling. The AMA has, for some time, been interested in specialized products for use under medical supervision that can be of assistance in the management of medical conditions, such as defined-formula diets or foods used in the management of phenylketonuria. For this reason, we look forward to working with FDA in developing appropriate "medical foods" regulations.

Food Fortification

FDA and the USDA have stated that they intend to seek legislation giving them explicit discretionary authority to control the fortification of a food when exercise of such control is deemed necessary for public health reasons. FDA has already published a policy statement on food fortification.

The AMA has provided leadership in food fortification activities for many years. Working with FDA, we have succeeded in developing a significant level of national interest in, and public awareness of, this subject. We continue to be actively involved in this ongoing discussion and believe that:

-- mechanisms need to be established so that food fortification can be used to remedy nutritional deficiencies in well-defined populations;

-- certain nutrients should not be added to certain foods when the food in question is not an appropriate vehicle for such additions;

-- nutrients lost in storage, processing or handling of foods should be restored when such losses result in a significant alteration of the original nutrient profile of the food item;

-- foods that replace other foods in the diet should be adequate replacements, both functionally (e.g., an entree for another entree) and nutritionally;

-- formulated meal replacers should have a balanced nutrient content and caloric content suitable to the intended conditions of use (e.g., a product used for weight control); and

-- any false or misleading promotion of foods, including fortified foods, does not benefit the public.

The American Medical Association is actively participating in discussions that center on these, and the many other concerns, surrounding food fortification. We would be pleased to assist FDA, the USDA and the FTC in developing updated policies on nutrient restoration and fortification practices.

Label Identification of Manufacturer, Packer or Distributor

FDA and the USDA have stated that they will continue their present policy of requiring declaration of the name and address of the manufacturer, packer, or distributor on food labels. The agencies have indicated that the potential cost of a change in this labeling policy would outweigh the projected benefits to consumers.

We concur generally in this view, but would point out a potential problem when a food's label bears only the distributor's name. In some instances, a

consumer may need to know specific ingredient information--information that in all likelihood a distributor does not have readily available (i.e., in order to manage a problem of intolerance to a food component). We are hopeful that efforts underway to expand label declarations for foods' ingredients will satisfy such consumer need for ingredient information where it does not now exist and that current requirements regarding the identification on a label of the manufacturer or packer will not need to be changed.

Natural and Organic Claims

FDA and the USDA have stated that, for the present, they will continue their respective policies for regulating claims of "natural" or "organic" contents--pending further evaluation of the FTC's rulemaking efforts related to the use of such claims in advertising. We perceive that all three agencies agree that because it is false and misleading to claim that foods described as natural or organic are inherently superior in nutrient content or safety, such claims should be prohibited.

In our view, there are many difficulties inherent in the use of the terms "natural" or "organic" in food labeling. The terms are used arbitrarily. Their meaning to a consumer is influenced by factors that the government cannot control. Hence, efforts by government agencies to try to appropriately define such terms, and then limit their use in advertising or label claims only to those products that meet that definition, will do little to resolve the problems and confusion caused by use of these terms. Moreover, for the government to sanction the use of these terms would only serve to perpetuate the myths surrounding these words when they are used to describe foods. Such government action would only divert attention from the basic truth--namely, that the words "natural" and "organic" have no meaning that relates to a food's nutrient content or safety. In our opinion, they should not be granted official recognition because scientific support for their use is lacking and their connotation to lay persons is so widely divergent.

SAMPLE

NUTRITION INFORMATION PER SERVING

Serving Size	2 ounces (approx. 2 slices
Servings per package	10
	Per 2 oz. serving
Calories	150
Protein	5 grams
Carbohydrates	27 grams
Fat	2 grams
Polyunsaturated	
Saturated	
Cholesterol	less than 5 milligrams
Sodium	
Potassium	

INGREDIENTS: *(listed in descending order from most to least)*
Enriched flour (barley malt, ferrous sulfate (iron), niacin (a "B" vitamin), thiamine monitrate (B_1), riboflavin (B_2), water, corn syrup, lard, yeast, salt, soy flour, calcium sulfate, sodium steroyl-2-lactylate, mono- and di-glycerides, whey, monocalcium phosphate, calcium carbonate, polyglycerate 60 (ethoxylated mono- and di-glycerides), hydroxlated lecithin, soy and whey protein, potassium bromate, calcium propionate (to retard spoilage).

96th Congress
2nd Session

Attachment A
DRAFT

BILL No. _____

IN THE (SENATE) (HOUSE) OF THE UNITED STATES

Date _____

_____ of _____ introduced the following bill,
which was read twice and referred
to the _____ Committee

A BILL

To amend Section 403 of the Federal Food, Drug, and Cosmetic Act, as amended, to require that foods for human consumption be labeled to show the amount of sodium and potassium in mgs. per average serving.

Be it enacted by the Senate and House of Representatives of the United States in Congress assembled,

Section 1. Section 403 is amended by adding at the end thereof the following new subsection as follows:

"(q) If it is a food for human consumption and in package form, unless its label bears information showing the total amount of sodium and potassium in milligrams per serving: *Provided, however,* That those foods subject to this subsection shall not be required to bear the label information specified herein upon a determination by the Secretary that--

(A) a food or class of foods does not contain sodium or potassium; or

(B) the public would be appropriately informed concerning a food or class of foods total sodium or potassium content by the posting of a notice in close proximity to the point of final sale of such food that contains the information specified in this subsection."

Section 2. The Secretary of Health, Education and Welfare shall promulgate and publish regulations to implement the foregoing provisions within (6) months after they become law, which regulations shall not be of the order currently required for nutrition labeling (i.e., 21 C.F.R. § 101.9), but shall be of the order requiring the evaluation and creation of a system that is both cost effective and responsive to the needs of the public, such as one permitting the use of "mean values" for a food or class of foods that may be maintained in and obtained from an officially sanctioned data bank.

SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

HEARINGS ON S. 1652

STATEMENT OF DAVE T. AJAY
PRESIDENT, NATIONAL NUTRITIONAL FOODS ASSOCIATION

March 19, 1980

Mr. Chairman:

My name is Dave T. Ajay . . . I am President of the National Nutritional Foods Association . . . otherwise known as NNFA . . . and I reside at 1118 Seventh Street, Sacramento, California.

NNFA is a trade association composed of retailers, manufacturers/distributors and wholesalers/jobbers in the nutritional foods industry . . . known to the general public as the health foods industry . . . and we do wish to express our sincere thanks for this opportunity to make known our views on S. 1652.

We wholeheartedly support the concept of full disclosure of every ingredient in any food product, for we believe the consumer has the right to know and should know what is in the foods that are being sold to him. We support the efforts of this Committee and the sponsors of S. 1632 to achieve this goal.

We advocate the full identification of all colors, spices, and flavors, and we cannot see any good reason why any standardized food product should be exempt from making a 100% revelation of its complete ingredient content:

There is one particular item which has received relatively little attention but which we think is of particular importance, i.e., the amount and exact kind of sugar in all foods. We believe that this is just as important as specific labeling with respect to sodium and fats. Also, we suggest that in addition to identifying the specific type of sugar in any product . . . such as dextrose, glucose, etc. . . . that when honey is the source of the sweetener, the kind of honey being used should be identified . . . with a statement whether it is pure liquid honey or powdered honey. Further, if it is powdered honey, we suggest that the carrier base be identified so as to identify any type of refined sugar being used. Doing this is certainly in the best interest of giving complete information to the consumer public.

We also suggest that the term, "no sugar" be disallowed . . . where the list of ingredients includes such terms as "fructose", "sucrose", "dextrose" and "glucose", for it is an established fact these are types of sugar, and the term "no sugar" would be misleading.

In addition, we believe that the term, "natural sweetener", should be disallowed for an ingredient such as sucrose which is a highly refined white sugar! The Federal Trade Commission's proposed definition for the word "natural" should be applied in this instance. Where pure liquid honey is the sweetening ingredient, a factual statement that the product contains "no refined sugar" may be appropriate . . . provided, of course, that the ingredient is identified as liquid honey.

We support the idea of an ingredient dictionary . . . and we pledge our support in aiding the dissemination of such information to the public.

And further, we would support the concept of a simplified, yet fully informative listing of ingredients by descending order of predominance -- with the addition of required listing of sugar by percent of weight; sodium by milligrams; and caffeine by milligrams.

We believe that the overconsumption of these three items by the youth of our country will lead to even greater problems . . . generation by generation. And now is the time to at least give proper information to allow the young mother to more wisely educate her children to choose better nutrition. It should also be noted that it is equally important that those of our older generation who suffer maladies should have this information . . . to prevent the compounding of their suffering.

We support the proposal to require quantitative ingredient labeling as a part of the ingredient statement . . . whenever the tradename of the product uses the name of an ingredient as part of the name. For example; if the product name is "Orange Drink" or "Grapefruit Drink" . . . then the amount of orange or grapefruit juice in that drink should be accurately identified. And, if this is required . . . then there should be no exception for other similar concoctions!

We support the identification of all artificial colors and flavors, to the extent that . . . in the case of colors . . . we prefer the combination of identification such as the following . . . "artificial colors, FD&C yellow #5." And we support the comprehensive labeling of all flavor ingredients, regardless of whether or not the full complex chemical names would substantially expand the food label! This information is particularly valuable and should be mandatory . . . in order to help protect the hyperactive and hypertensive child! . . . of which we certainly have a great many today!

We support the concept of voluntary nutritional labeling . . . but, we question whether a product label should list any nutrient . . . if non-existent in the specific product. For example: a loaf of bread may list percentages of nutrients on the label such as "Vitamin A" followed by "0%": . . . This may be misleading, since the customer's eyes may see only that there is "Vitamin A" in the loaf without going any further to see that there is indeed no "Vitamin A" at all! However, we do support mandatory nutritional labeling whenever a food product purports to be fortified . . . or makes other nutritional claims on the label. This is essential in order to substantiate such claims.

We believe that dating represents an important concept for consumer information and protection . . . However, there must be different considerations for different kinds of products . . . unprocessed and unpackaged foods may require one kind of evaluation; processed and packaged goods another kind; and one kind of packaging may have to be evaluated differently from another.

In determining the need for open dating, consideration should also be given to the consumer's ability to inspect the food before purchase and the susceptability of the food product to realistic dating projections. I am thinking, particularly, about products such as fruits, vegetables, seeds, nuts, and grains. Product dating should not be based upon meaningless and unfair generalities which fail to take into consideration conditions relating to harvesting, transportation, storage, handling and packaging.

Individual product differences must also be carefully considered in evaluating the soundness of "pull-by" or "use-by" dating requirements, so as to avoid a mandatory removal from our shelves of absolutely sound products. In some instances "packed-on", with the date, may provide a reasonable alternative for providing information to the consumer.

In addition to the National Nutritional Data Base, we wish to go on record as favoring complete federal preemption with respect to food labeling. With the data base and the single national set of labeling standards, the small manufacturer . . . of which the health food industry has a multitude . . . should be able to cope with the new and better labeling requirements.

And we thank you for permitting us to express the views of an industry which has worked for better nutrition for more than fifty years.

STATEMENT

OF

GROCERY MANUFACTURERS OF AMERICA, INC.

BEFORE THE

HEALTH AND SCIENTIFIC RESEARCH SUBCOMMITTEE

OF THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

REGARDING

HEARING ON S1652

MARCH 19, 1980

The Grocery Manufacturers of America, Inc., (GMA) is the trade association of the nation's leading manufacturers of food and grocery products. Both S1652 and its counterpart, S1651, affect the majority of GMA's membership. GMA therefore appreciates the opportunity to review the nucleus of the proposed legislation with you: its provisions for mandatory nutrition labeling, and for the development and use of a nutrient data bank as a foundation for nutrition labeling.

First, we re-emphasize GMA's support for the conveyance of useful and meaningful information about foods to consumers. Labeling can be a valuable adjunct to food and nutrition education.

Indeed, informative food labeling can be as valuable to industry as it is to consumers. Recognizing this, GMA has supported full ingredient labeling for seven years and helped FDA develop and implement its current voluntary nutrition labeling system. Moreover, GMA has been actively involved in the tri-agency (FDA, USDA, and FTC) review of federal food labeling policy initiated in 1978, most recently through testimony presented to the three agencies March 5, 1980.

The drafters of S1652 are to be commended for recognizing the urgent need for a nutrient data bank system. However, since the purpose of a nutrient data bank is to facilitate the provision of nutrient information to consumers through labeling, any legislation providing for the use of a data bank must also specify how it is to be implemented.

Without specific legislative guidance, the implementing agencies could easily frustrate the purpose of the program.

The agencies continue to ignore the fact that manufacturers could significantly reduce the cost of nutrition labeling if they were permitted to rely on existing common sources of quantitative nutrition information, such as U. S. Department of Agriculture Handbook 8.

According to the agency plan outlined in meetings with Congress and industry, companies wishing to use a data bank would be required to underwrite the bulk of its cost -- estimated to be $100 million -- by performing initial chemical analyses. Then, in order to be certified to use it, manufacturers would have to perform identical analyses to prove that each of their products falls within the data bank values. Recertification, dependent again upon the same expensive analyses, would be required on a yearly basis.

Thus, under the agency plan, a device originally intended to facilitate industry participation in voluntary nutrition labeling programs would become counterproductive. Industry costs would not be reduced but rather would be greatly increased without concurrent benefits. Discouraging the use of nutrient data banks discourages nutrition labeling.

Moreover, the tri-agency Tentative Positions document demonstrates that consumers do not want changes in the current food label, especially if such changes would increase the cost of the product. Only 8% of the respondents to FDA's 1978 Consumer Food Labeling Survey had problems with food

labeling.

However, the fact that consumers do not want any change in the current food label is not conclusive evidence that the current label cannot be improved. If consumer research ultimately justifies it, a comprehensive blueprint should be developed. Until that time, the current label format, including voluntary nutrition labeling, should be retained.

No need has been shown for mandatory nutrition labeling. In fact, a recent FDA study demonstrated that over 50% of all food products are now nutrition labeled, under the current voluntary system. Rather than increasing the costs of food labeling by making nutrition labeling mandatory, Congress and the federal agencies could significantly increase the number of nutrition labeled products by making nutrient data banks the foundation for nutrition labeling.

GMA does not support mandatory nutrition labeling, but GMA continues to support the current voluntary nutrition labeling system. GMA also supports the development and use of a nutrient data bank system making maximum use of existing data until it is replaced with improved data. Legislation providing for a nutrient data bank system should include appropriate guidance to the agencies. Use of a nutrient data bank system, including existing data, would increase participation in voluntary nutrition labeling.

Thank you for the opportunity to present our views.

The Sugar Association, Inc.

1511 K Street, N. W. Washington, D. C. 20005

J. W. Tatem, Jr.
President

April 2, 1980

The Honorable Edward M. Kennedy, Chairman
Subcommittee on Health and Scientific Research
Room 308C Senate Courts
United States Senate
Washington, D. C. 20510

Dear Senator Kennedy:

Please find enclosed written testimony of The Sugar Association, Inc. which we submit for the record being compiled for the hearing before the Subcommittee of Health and Scientific Research on Food Labeling S. 1652, March 19, 1980. Our statement is in two parts consisting first of comments on sugars and food labeling and an appendix discussing the specifics of the legislation.

Sincerely,

President

JWT:kcp

Enclosure

Telephone: Area Code (202) 628-0189

TESTIMONY OF J.W. TATEM, JR.

PRESIDENT

THE SUGAR ASSOCIATION, INC.

prepared for the

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

of the

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

WASHINGTON, D.C.

MARCH 19, 1980

INTRODUCTION

The Sugar Association believes the public is entitled to accurate and complete nutrition information. Nutrition disclosures made in a fair, objective as well as easily understandable manner enable the consumer to make intelligent food choices. We think consumers want facts on which to base their own decisions, not predetermined value judgments about "good" or "bad" foods, as individual foods cannot be termed "good" or "bad".

Food labeling is one means by which the consumer can have access to reliable information. In order to be truly informative, a label must be objective. We urge that every effort be made to insure that any new labeling scheme meets this goal.

Specifically, we recommend that each ingredient or nutrient in a product be declared on the label in a nondiscriminatory manner. No one element should be singled out for special mention, as this might give the consumer erroneous impressions about both the element and the product. The only exception would be in the case of foods for special dietary purposes. S. 1652 has been offered as one means of giving consumers objective and easily understandable nutrition and ingredient information on the foods they eat. Since sugar is an important constituent of many processed and unprocessed foods, The Sugar Association's comments on the proposed legislation are directed toward clarifying the food labeling issues that pertain to sugar.

SUGAR AND FOOD LABELING

Before proceeding with a discussion of sugar and food labeling, we should clarify what is meant by the word "sugar." "Sugar," to most people, is sucrose--the sweetener obtained from sugar cane and sugar beets and identifiable as the product found in the sugar bowl.

Sucrose is only one of many products currently used as a nutritive or caloric sweetener. Others include dextrose (corn sugar), fructose (fruit sugar), lactose (milk sugar), corn syrups, high fructose corn syrup (invert sugar), brown sugar, molasses, honey, maple syrup and sugar alcohols. These substances are collectively known as "sugars." In this paper, we shall use the term "sugars" to denote all caloric sweeteners while "sugar" shall refer to sucrose.

It is obvious that to be fully informative, any labeling plan must apply to all sugars. Furthermore, for maximum information, any quantitative labeling plan should indicate the total sugars content of a product, whether naturally occurring or added by the manufacturer.

The Sugar Association does not oppose the labeling of foods as to their sugars content. We do recommend that the information be presented in an objective, nondiscriminatory manner.

Sugars represent only one part of a properly balanced diet; food labels should be designed to reflect this fact. Thus, if the sugars content of a product is to be quantitatively declared, the

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disclosure should be made in the context of declaring all ingredients or nutrients in the product.

METHODS OF DECLARING SUGARS CONTENT

It is fair to say that the quantitative labeling of products as to sugars content is not a simple matter. There are many unresolved questions as to how to declare the sugars content of a product in a way that is meaningful and readily understandable.

If labeling is to be objective and informative, one question to be considered is whether disclosures should be made on an "as is" or "as used" basis. Many products, such as concentrated juices and soups, cake and dessert mixes, dry cereals and packaged dinners, are meant to be diluted or combined with other foods before they are consumed. We believe it makes sense and would be fairer and certainly more practical for the consumer if labeling for foods were made on an "as used" rather than an "as is" basis. Labeling on an "as used" basis is a more reasonable and understandable approach to nutrition information.

Proposed methods of labeling sugars content include declaring the amount of sugars in a product as in grams per serving, or using percentages on any basis which would have the result of showing only the relationship between sugars and other ingredients. It has also been suggested that the caloric contribution from each macronutrient (protein, fat, carbohydrate) be disclosed, giving the consumer additional information. In evaluating these methods and developing new possibilities Congress and the administrative agencies

should take into account the experience of food manufacturers who have been voluntarily declaring sugars and other ingredients and seek additional input from the food industry.

We stress the importance of insuring that labeling is objective. Each proposed method for declaring sugars content should be evaluated in terms of its possible potential for misinforming rather than informing the consumer.

WHY SUGARS LABELING?

Sugar is one of the substances most likely to be mentioned in any discussion of food labeling. Unfortunately, the issue of the role of sugars in the diet has been clouded by the misinformation and conflicting opinions appearing in many popular publications.

Moderation and balance are the cornerstones of good nutrition. But consumers have been encouraged instead to think that the declaration of one or more ingredients in a product will solve all nutritional problems.

Legislation and the ensuing administrative regulations should be based on facts not unsubstantiated opinions. If quantitative labeling of sugars is to be mandated, the reasons for such a step should be examined rationally and the expected benefits and problems should be clearly delineated.

Many of the frequently repeated reasons for mandating the quantitative labeling of sugars are based on unsubstantiated opinions or incomplete scientific hypotheses. The most frequently cited motives for desiring sugars labeling are:

1) consumption of sugars is linked to medical problems

2) sugars contribute to the formation of dental caries.

We would like to examine each of these issues and discuss the extent to which additional labeling can be expected to solve the problem.

As previously mentioned, as long as all nutrients are declared, we do not oppose quantitative sugars labeling. However, pleas for the labeling of sugars by themselves are so often accompanied by inaccurate statements about sugars that we would like to set the record straight.

1. Sugars and Medical Problems

It is hard to believe that sucrose, a safe substance that has been part of the food supply for thousands of years and occurs naturally in many fruits and vegetables, has been labeled as "dangerous" by a vocal minority.

It is gratifying to be able to report that there is no scientific substantiation for this accusation. Unfortunately, it is difficult to undo the damage that results from many years of repeating the same old myth. We are pleased to see that the perceptions of several government agencies regarding sugar have changed over the past few years to reflect awareness of the mounting scientific evidence on the safety of sucrose.

In December 1977, the Senate Select Committee on Nutrition and Human Needs issued "Dietary Goals," a widely circulated document that helped perpetuate the myths that sucrose contributes to diabetes and increases the body's need for nutrients.[1]

In February 1978, the staff of the Federal Trade Commission issued a report on children's advertising. Based on an incomplete review of the evidence, the FTC staff linked sucrose consumption to diabetes, heart disease, hypertension and other health problems.[2]

In December 1978, the Department of Agriculture, in a proposed regulation on the sale of competitive foods in the school lunch program, cited opinions that sugars might contribute to diabetes and heart disease.[3]

Since the issuance of "Dietary Goals," it has been increasingly realized that the scientific evidence does not support the opinions cited above.

In December 1979, the Food and Drug Administration, Department of Agriculture and Federal Trade Commission issued a statement on food labeling, agreeing that: "The only demonstrated hazard that sugars pose to the public health...remains their contribution to dental decay."[4]

The scientific evidence pertaining to the role of sugar in nutrition and health has been examined and reexamined.

In 1976, a Select Committee on GRAS (Generally Recognized as Safe) Substances of the Federation of American Societies for Experimental Biology reported its conclusions on the health aspects of sucrose consumption to FDA. The Committee concluded:

> "1. Reasonable evidence exists that sucrose is a contributor to the formation of dental caries when used at the levels that are now current and in the manner now practiced.
>
> "2. Other than the contribution made to dental caries, there is no clear evidence in the available information on sucrose that demonstrates a hazard to the public when used at

> the levels that are now current and in the manner now practiced. However, it is not possible to determine without additional data, whether an increase in sugar consumption--that would result if there were a significant increase in the total of sucrose, corn sugar, corn syrup, and invert sugar, added to foods--would constitute a dietary hazard."[5]

In August 1979, scientists participating in a Department of HEW sponsored conference on "Preventing Disease/Promoting Health" drafted the following statement:

"Patterns of dietary sugar consumption are associated with incidence of caries, but no consistent or independent relationship has been shown between heart disease or diabetes and sugar intake."[6]

Also in 1979, a panel of scientists of the American Society for Clinical Nutrition (ASCN) reviewed the subject of "Carbohydrates, Sucrose and Human Disease" and concluded that there is "little documentation that sugar consumption is associated with any health hazard except dental caries."[7]

The charge that calories from sugars are "empty calories" is really an empty complaint. The ASCN panel noted that simple sugars are rarely eaten alone but in combination with other foodstuffs. "There is no evidence that continuing to eat the present American diet will result in inadequate micronutrient nutrition," ASCN added.

The scientific evidence establishes that sugar is a safe food. While sugar does play a role in the development of dental caries, it is only one of many factors involved in this disease.

Using the argument that sugars contribute to health problems other than caries, as justification for requiring sugars labeling will only serve to perpetuate a myth.

2. Sugars and Dental Caries

It is generally agreed that sugars are involved in the development of dental caries. It is also generally agreed that dental caries is a multifactorial disease and the magnitude of the effect of sugars is uncertain.[8] Whether quantitative sugars labeling is a viable means of reducing sugar usage and dental caries has not been established. Current dental research does not support the conclusion that a reduction in the consumption of sugars will decrease the incidence of dental caries.[9]

A recent study by the Food and Nutrition Board of the National Academy of Sciences stated:

"Not only does dental caries occur in populations that have not consumed sugar, but the influence of sugar on the development of the disease depends on the form in which sugar is fed, the frequency of consumption, and the duration of exposure of the tooth surface. Sticky carbohydrates, in particular, promote dental caries...Although elimination of sugar from the diet greatly reduces the incidence of caries, it remains to be established whether moderate reduction in the proportion of sugar in the diet is an effective control measure."[10] Research is needed on this question, the Food and Nutrition Board said, as it is one of the many nutritional questions which needs to be answered before dietary guidelines can be established for the general population.

Quantitative sugars labeling has been offered as one means of informing the public so that consumption of certain products that may contribute to dental caries can be controlled. This approach is reasonable only if it is possible to predict the cariogenic potential

of a food.[11]

At the present time there are no universally accepted methods for determining the cariogenicity of foods. Indeed, dental researchers, scientific groups and the food industry are currently working cooperatively to gather data and produce research directed toward developing precise methods of predicting cariogenicity.

Dental researchers are in agreement that the amount of sugars in a product does not necessarily determine the product's cariogenic potential.[12,13] In other words, a product with a higher total sugars content is not necessarily more cariogenic than one containing less sugars.

It is possible that presenting a declaration of sugars content on the food label could mislead the consumer into making inaccurate judgments or comparisons concerning the relative cariogenicity of different food products even to the point of eliminating valuable foods from the diet. This problem underscores the fact that labeling cannot be expected to be the answer to all consumer questions regarding nutrition and health.

Quantitative sugars labeling is an indirect and possibly misleading method of protecting the public from dental caries.

We cannot help but add that there are more direct means of preventing tooth decay such as water fluoridation. Fluoridation has been shown to be a safe effective means of preventing caries at a most reasonable cost.[14]

CONCLUSION

Consumers have expressed an interest in being informed about the sugars content of processed foods. We conjecture that much of the consumer concern over sugars stems from the inaccurate perceptions relating to sugars and health that we discussed earlier.

As we also stated, we do believe the consumer is entitled to complete information, which would include sugars labeling. We must repeat our recommendation that any labeling plan accurately state all ingredients and thus avoid perpetuating the myth that sugars per se are harmful. We believe quantitative sugars information should be present on the label solely for the sake of completeness of nutrition information.

#

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APPENDIX TO THE SUGAR ASSOCIATION TESTIMONY

SPECIFIC COMMENTS ON S. 1652

We commend the sponsors of S. 1652 for seeking to provide consumers with objective, easily understandable nutrition information on the food label. The goal is a worthy one but nutrition is a complex subject. As we have pointed out, the food label cannot be expected to solve all problems.

The sponsors of S. 1652 have expressed their concern over the relationship of diet to health, suggesting that diet is a risk factor in six of the ten leading causes of death. Many in the scientific community take exception to this. We suggest that many complex questions in this area remain to be answered by further scientific research.

Consumers should not be frightened into using nutrition information. Therefore, we think Section 2 of the legislation should be rewritten to reflect the more immediate and more objective goal that the only purpose of food labeling is to provide information.

One of the most important goals of any new labeling plan should be objectivity. Consumers want and need information that will enable them to make food choices without undue influence from regulatory bodies. In this context, we express our concern about the broad powers S. 1652 would delegate to the Secretary. The delegation of extensive authority encourages a one-sided view of food labeling that could jeopardize objectivity. Section 3(C) of the proposed legislation is an example. It would provide discretionary authority to the Secretary for singling out individual ingredients for special labeling treatment.

We recommend that any legislation be more specific in nature with regard to delegation of powers, thus encouraging a balancing of all interests.

The delegation of authority to the Secretary to prescribe a labeling system employing graphic symbols could threaten the objectivity of nutrition information presented to consumers. By their very nature, pie charts and other "short cut" information devices are subjective and selective, emphasizing some dietary elements while deemphasizing others. We recommend that Section 403(r) be omitted.

Section 5 (Demonstrations and Evaluations) of the proposed legislation would allow the Secretary to approve demonstrations to ascertain the most effective methods of organizing the food label. Again, the delegation of this broad authority creates the possibility that one government agency could determine label requirements based on its own subjective beliefs as to what the consumer wants. In particular, we must note that the proposed nutrient density format is self-defeating and inappropriate for the nutritional evaluation of individual foods, though it may be useful for evaluating the total diet. As well, the proposed emphasis on individual dietary elements is definitely contradictory to the goal of providing objective nutrition information.

We recommend that an industry advisory panel be appointed to guide and counsel development of the Demonstrations and Evaluations program.

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PET FOOD INSTITUTE
1101 Connecticut Avenue, N.W., Washington, D.C. 20036 (202) 857-1120

April 2, 1980

Mr. Bob Wenger, Counsel
308 C Senate Court
120 C Street, N.E.
Washington, D.C.

Dear Mr. Wenger:

The Pet Food Institute appreciates the opportunity to submit comments for the hearing record on S.1652, entitled "Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug, and Cosmetic Act."

Because there are basic differences between pet foods and foods for human consumption, we recommend that the enclosed section 403(i) be revised. Enclosed is our suggested language. It is in the form of a new subparagraph 3 and a revision of existing subparagraph 3 which we have redesignated as 4.

The proposed language makes a distinction between pet food and food for humans, preserves a twenty year working relationship between industry and state regulators which has contributed in large measure to thorough nutrition labeling guidelines for pet food, and it provides pet food manufacturers with the option of using appropriate generic or collective terminology for ingredients related by type or function.

Should you have any questions about these recommendations, we welcome the opportunity to meet with you to discuss them.

Thank you for your thoughtful consideration of these suggested revisions.

Very truly yours,

Duane H. Ekedahl

Duane H. Ekedahl
Executive Director

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AMENDMENTS TO SECTION 403(i)
IN LIEU OF
LINES 9-13, PAGE 5 OF S.1652

(3) in the case of a food for consumption by animals other than man that is fabricated from two or more ingredients --

A. the common or usual name of each such ingredient except that (i) the Secretary shall provide for the use of appropriate generic or collective terminology for ingredients related by type or function; (ii) any flavoring shall be designated as artificial flavorings or natural flavorings, as the case may be, without naming each such flavoring.

B. a declaration of the quantity or percentage (as determined by the Secretary) of any characterizing ingredient (other than a flavoring) or class of ingredients if the Secretary determines that such ingredient or class of ingredients has a significant bearing on the quality, consumer acceptability, or cost of such food or foods of its class.

To the extent that compliance with the requirements of subparagraph (3) is impracticable or would result in deception or unfair competition, the Secretary shall prescribe exemptions from such requirements.

(4) The Secretary shall exempt from the provisions of this subsection any food that the Secretary determines is subject to comparable requirements established with respect to such food under any other Federal law or uniform pattern of state law.

Revised 4/1/80

WALNUT ACRES, INC.
PENNS CREEK, PA. 17862
NATURAL FOOD PRODUCTS BY MAIL
PAUL KEENE, President

28 March 1980

The Honorable Edward M. Kennedy
2241 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Kennedy:

Earlier we sent a paper entitled PLEASE LET US LIVE, which spoke to our acute concerns regarding mandatory nutrition labeling.

The enclosed is an expanded version of this, with Sections 2, 3, and 6 added. I think you will find these interesting.

We would be grateful if this could be included in the record wherever possible. Thank you.

Sincerely,

Paul Keene

Paul Keene

PLEASE LET US LIVE

RE: MANDATORY NUTRITION LABELING

The Concerns of One Small, Troubled Food Producer

Walnut Acres, Penns Creek, Pa. 17862

Rewritten and Amended - March 19, 1980

Parts 2, 3, 4 and 6 Added to the Original

SUMMARY

PART 1 - An American Saga — Pages 1 - 3
Background Material

PART 2 - The Government and We — Pages 4 - 6
Experiences to date

PART 3 - How Do Consumers Feel About Nutrition Labeling? — Pages 7 - 12
Results of a recent Bureau of Foods (FDA) Survey

PART 4 - Small Food Processor Impossibilities Under Mandatory Nutrition Labeling — Pages 13 - 15
The killing details

PART 5 - The Only Ways We Can Continue to Live — Pages 16 - 17
Life-saving suggestions

PART 6 - Observations and Conclusions — Pages 18 - 20
Is Mandatory Nutrition Labeling the best answer to national health improvement?

Prepared by: Paul Keene, President
Walnut Acres, Penns Creek, Pa. 17862
717/837 - 6635
Spring, 1980

Spring, 1980

Walnut Acres, Penns Creek, Pa. 17862

RE: Mandatory Nutrition Labeling

The Concerns of One Small, Troubled Food Producer

As Amended March 19, 1980 by addition of parts 3, 4, 6

*

PART 1 - AN AMERICAN SAGA

The year was 1946. Thirty four years ago Mrs. Keene and I moved onto our newly acquired farm, named Walnut Acres. We came out of a background of rural village living, and of teaching. My training was in Mathematics, Chemistry and Physics. For several years I was head of the Mathematics Department of a small college.

While teaching for several years in India, we had become deeply interested in the land and our relation to it. We felt we had to know more, so we decided to leave teaching altogether, to make our living and raise our family on a farm. For four more years we studied all branches of organic farming and living on the land in general, at two separate schools then in existence.

We had only two hundred dollars to start with, plus a fine team of horses, some old pieces of equipment, no tractor, and loads of university debt. We were able to borrow the money to buy our lovely farm, and with our small children we moved onto it. The going was not always easy, but in the best Mom-and-Pop tradition we were determined to make a 'go' of it in our great free-enterprise system. Nothing could stop us. We were moving against the tide by not using any synthetics or artificials, on either the soil or the plants, or in any products we prepared to sell. It is interesting now to note modern trends in this direction.

The years have gone by all too rapidly. Grandchildren now play around our knees. Yet we have remained true to our principles, and have shown many

fascinating things about insect and disease control, for example. We have seen great results in both soil and crops. We were among the pioneers in this field in modern times. We became one of the best-known and most-trusted sources for specially-grown-and-prepared foods. We have always tried to make small, fresh lots of our foods, and have watched a reputation for quality develop all about us.

We have not claimed our way to be a universal panacea, applicable in all circumstances. But we had the freedom to try out what we felt to be a valid approach Several giant companies offered to buy our business, but we were not interested. One of the wonders of being in business in this country, we soon learned, was the way in which little persons like ourselves could hold up our heads proudly, making our way among the giants of the food industry, setting and living up to such standards of integrity and unselfishness as we felt proper, and still succeeding. With us, all around quality of products has always come ahead of quantity and large incomes.

People soon began coming and writing from the cities for our products. They wanted us to ship by mail. Here they could contact directly the people who did it all, from the ground up. We could attempt to answer their questions about growing and processing methods, which even in those early days were of great interest to them. As they becaome more sophisticated in their requests, experience led us to know more of the answers. We had first one customer, then two - and then a hundred, a thousand. Now there are a number of thousands, all over the country and out of it.

Sales are still primarily by mail. We make no special claims for our products. We tell how we grow and process, people may come to see us at our work, and they decide if they want what we produce. We feel we offer a valid, important choice, and our customers keep pushing us continually for more products. Their sensing that we want only to supply what they desire, in friendship and honor, has caused a bond to be formed which ties us all together into one large, consumer-supplier 'family', where true concern for the other comes first.

We could not do it all alone, so we reached out to our neighborhood farm and rural-village people for help. Most of us are of hard-working, simple, frugal Pennsylvania-Dutch stock. our lives will be spent in this rather depressed Upper Appalachian mountain region. Here is our home. Overall incomes before taxes in our work average between eight and nine thousand dollars yearly. We are all shareholders who work and own the company in common. No stock is sold outside the company. No one may hold more than one hundred shares of ownership stock. No person or family holds a majority of the stock. It is really ours together. Our average net profit over the past five years has been 1.83%. We brought millions of dollars into our area, and have earned the high respect of many persons.

As normal, public-office-holding, community-serving farm persons, we've tried to conserve both the soil, and also all those special values inherent in rural community living. We borrowed money from the F.H.A. to build a lovely community center in our village. This is unique in the whole of central Pennsylvania. Its program reaches people for miles around, upbuilding, enlightening.

We've seen much joy and growth come as a fulfillment of earlier dreams. Only in this country could something so wonderful have developed. It is so typically American. We thank God every day for it.

Yet now, through ever-present tendencies to force all people into molds, this whole way of life is seriously threatened with complete extinction. If nutrition labeling is made mandatory, we are finished. But not we alone, for a host of other small food processors all over this great nation will suffer a similar fate. What a pity to see small things forced by law to die, that only the large might remain. We think of nature's attempts with the dinosaurs, and weep.

PART 2 - THE GOVERNMENT AND WE

We have numerous close ties with federal and state authorities. We keep in touch with things which affect us and our work. We come under F.D.A. and U.S.D.A. regulations and inspections, of course, and are basically happy that we live in a country where there are agencies of this nature, concerned with the public health. We have found their requirements and oversight reasonable, helpful, and possible. We would not want to live without the protection they afford in their monitoring of the safety and cleanliness of the food supply.

We have reason occasionally to write, telephone or visit legislators and regulatory agency persons about particular concerns. Over the years we have been impressed with the ability, sincerity and dedication to the public that we have sensed in these contacts. We have not felt harassed or put-upon. If we have shown deficiencies, we have received help and guidance, and have learned the best way, to our ultimate all-around benefit. It has been in most areas a happy relationship of mutual understanding, and, we think, of appreciation.

However, over the past eight to ten years we have become increasingly concerned with what seems to be a determination to force what is termed "mandatory nutrition labeling" upon every food processor who engages in interstate commerce. Occasionally over the years bills concerning nutrition labeling have come up. Some have passed into law, but up to this time it has been on a voluntary basis only.

In 1974 we were invited to comment at a sub-committee hearing on the Moss-Hart amendment proposal to S.2373. Under this proposal, nutrition labeling would have been made mandatory. After our presentation, we were told by committee members that they had never before known how damaging mandatory nutrition labeling would be to small food processors. Changes were made, and the plan to make nutrition labeling mandatory was dropped.

But since that time rumors of mandatory nutrition labeling have simmered under the surface quietly. This year our ever-present nagging fears seem to be coming to a head. So we begin all over to struggle for our life. Over the years it has taken countless hours of our time, plus many thousands of dollars in printing and postage, telephone calls, trips to Washington, in correspondence and in the making and writing of presentations, and in lost opportunities, to try to inform legislators, regulatory agencies, and public in general about the indisputable danger to the very existence of small food processors countrywide, of mandatory nutrition labeling. This is over and above the ever-present mental anguish that can be so debilitating. This time and money, both so precious, should have been going instead into the increasing of productivity, the lowering of prices. Now we start another round.

We were invited by the Chairman of a Senate subcommittee to attend a meeting in February of this year, in the Senate Office Building, to learn more about certain aspects of two companion nutrition bills that have been introduced. These are S.1651 and S.1652. We were grateful for this invitation, with its opportunities. Representatives from the F.D.A and the U.S.D.A. presented their views, and a general discussion followed. We were able to present our views.

We learned that attempts are under way in current proposals to soften the blow and ease the burden of mandatory nutrition labeling, but that the concept is still very much alive. We sensed a determination this time to push through some form of it to its final adoption.

The past ten years have seen the beginning of work on a "nutrition data bank" concept. Under this, a federal "bank" is established which contains basic nutrition data on a number of foods. The idea is to have collective analyses of five-to-six thousand food items in this bank, in about five more years. These will be the foods most commonly used in our country. These would have to be laboratory

analyzed annually by each food processor making any of them. Other less-used foods would never come under this plan. They would be exempt from mandatory labeling, since they would represent in total but a small percentage of all foods.

It is our hope that this paper will assist persons in seeing a side of the question which may not be commonly seen, so that small food processors may once more retire at night in peace.

It was T. S. Elliot who wrote:

"We shall not cease from exploring
And the end of all our exploring
Will be to arrive where we started
And know the place for the first time."

We small food processors would like very much to work with those who do not realize fully our plight, that we may continue to explore together.

PART 3 - HOW DO CONSUMERS FEEL ABOUT NUTRITION LABELING?

Will Rogers once said - "This country is where it is today on account of the real common sense of the big normal majority." Let us look at recent responses of a consumer cross-section to questions concerning food labeling, to learn the thinking of the people.

In the fall of 1978, the Consumer Research Staff, Division of Consumer Studies, Bureau of Foods, of the F.D.A., conducted the 1978 Consumer Food Labeling Survey. In May, 1979, an eleven-page Summary Report of the findings was published. Copies are available from the Bureau of Foods, F.D.A., 200 "C" Street S.W., Washington, D.C. 20204.

This study was done by a research firm chosen by the Bureau of Foods. It was based on personal interviews with a representative and nationally-projectible sample of "primary food shoppers." Presumably the hope was to learn with a fair degree of accuracy something of the thinking of the people at large on this subject. The method used here affords a wholesome balance to the holding of hearings, which often are attended primarily by persons representing strong personal or corporate points of view which may be in part biased.

One should read the whole report to get the full flavor. Here we quote points from it, in brackets, which impinge particularly upon our concern with mandatory nutrition labeling. These quotes are from pages 3, 4, 5 and 10 of said Survey.

QUOTE from Pages 3, 4, 5 of Survey - [SCOPE OF CONSUMER CONCERN WITH FOOD AND FOOD LABELING. The first question in the survey asked, "Aside from prices, please tell me about any particular problems, difficulties, or concerns which you have with food these days." In response to this question, about half of consumers (49%) reported no problem other than price. On the other hand, 47% did mention one or more specific problems. Most of the problems mentioned were with the food itself,

with 14% of consumers having generalized and rather undifferentiated concerns about product quality (feeling food is simply not as "good" as it might be), another 14% concerned with possible adverse health implications of the ingredients in their food, and 8% feeling that the food that they purchase is not as fresh as it should be. In addition to concerns about the food itself, 8% of respondents mentioned specific food labeling problems, and 3% mentioned problems dealing with such things as damaged containers, insufficient stock in the store, and other similar shopping concerns.

Looking in detail at the one person in seven who reported concern with the health implications of food, it appears that about a third of them (35%) (W.A. note - 5% of the total) are worried about preservatives, 29% (W.A. note - 4% of the total) are concerned about additives or chemicals in general, 20% (W.A. note - 3% of the total) are apprehensive about the sugar content of their food, 8% (W.A. note - 1% of the total) specifically mentioned artificial colors, 7% (W.A. note - 1% of the total) have concerns about salt content, and 4% (W.A. note - .5% of the total) worry about the use of artificial flavors. Only 8% of those concerned with the health implications of food (i.e., about 1% of the total population) mentioned any problem with the nutritional value of their food.

It is clear from this and from the other findings reported below that there is among American consumers some degree of fear of the food supply. Relatively few people question the nutritive value of their food, but large numbers express concern with what they see as a proliferation of substances with long-or-short-term adverse health effects. It is clear that most consumer advocacy of food label revision stems from this fear, rather than from desires to achieve a more nutritious diet, from economic concerns, or from a generalized "right to know" not attached to a specific need.

Turning to the one person in twelve who expressed some concern about food labeling, about a third (32%) (W.A. note - 2.5% of the total) of them mentioned the

ingredients list, a quarter (25%) (W.A. note - 2% of the total) mentioned freshness information, 19% (W.A. note - 1.5% of the total) had some concern with the information on the nutrition label (most of these discussed only calorie information) and one person in five (20%) (W.A. note - 1.5% of the total) expressed concerns about deceptive or inaccurate labeling.

In response to the question, "Are you satisfied with the kind of information available on food packages and cans?", 59% of consumers expressed themselves as fully satisfied. However, one person in three (33%) did see some need for improvement. The portion of the label most in need of improvement, according to these consumers, is the ingredients list - 19% of all consumers see need for improvement in this area. The most commonly expressed needs were: to list all ingredients, to simplify the language used in the list, to extend the ingredients list to all products, to make it more legible (most often, to use larger print), and finally to quantify the information on the ingredients list (preferably in percentages rather than in weights of each ingredient).

One person in twelve (8%) saw a need for improvement in the nutrition label, and 3% expressed a desire to extend open dating to more products. About 2% mentioned a need for drained or fill weight on canned goods, and fewer than 1% expressed a desire for information about the specific sources of fats and oils.] END OF QUOTE FROM PAGES 3, 4, & 5.

QUOTE from Pages 10 & 11 of Survey - [CONSUMER DESIRES FOR FOOD LABEL REVISION.

In addition to the questions already discussed as to ways in which the food label could be improved, and sources of confusion with the label, respondents were asked directly whether they would like to have more or less information than is currently available on food labels. Although 2% of respondents indicated that the label has too much information on it already, 25% indicated a desire for additional label information. Again, most comments dealt with the ingredients list. The most commonly cited additional information wanted is quantification of the ingredients

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list, followed by simplification of the ingredients list, and calorie information on all products. Other relatively high frequency requests included making the ingredients list more exhaustive, giving the amount of sugar, and extending open dating to more products. Finally, rather low levels of interest were expressed in the amount of salt, listing of all preservatives, extending vitamins/mineral information, extending the ingredients list to all products, and giving drained or fill weight.

In summary, it appears that about 10% of consumers are seriously critical of the food label and see strong need for revision. An additional 15% appear to be less concerned, but still express some desire for one or more changes in the food label. The other 75% of the population does not care much about the food label, is satisfied with it as it now stands, or is simply so confused as not to be able to express preference.] END OF QUOTE FROM 1978 CONSUMER FOOD LABELING SURVEY.

These findings from "the big normal majority" parallels our own experiences over the years. Consumers want to know what ingredients are in the foods, in toto. From our beginning we have attempted always to list on our labels every ingredient of every food, even where not required to do so. We think this is most important. The current voluntary nutrition labeling program has not satisfied the deep need for consumers to know exactly what they are putting into their bodies, and into those of their children. They would rather be free, it seems, to choose on the basis of ingredients than on that of analysis. Perhaps their common sense leads them to want to know the whole picture rather than little bits here and there.

We have a very close, first-hand, mail-order relationship with our customers, who are generally highly inquisitive, highly knowledgeable persons who ask endless questions. We answer thousands of letters, and thus gain a rather good picture of what they want to know, which is everything! We probably have more real, first-hand information on this than most businesses have, and perhaps more than government agencies.

Basically, people contacting us want to know what is in the food and what has been taken out; how much is real food and how much, if any, is synthetic or artificial; exactly how the food is raised and prepared; if poisonous sprays can drift onto our farms from our neighbors; how fresh and whole the products are; how dried foods are dehydrated and at what temperatures; at what temperatures honey is bottled, and how the bees are treated; how products are peeled and blanched; and so on. They want to know not only what we do not use on the soil, but also how we feed and care for the soil and the plants; how we handle insect and disease problems; at what temperatures we dry grains if we have to, and so on. They come from all over the country to see for themselves what we do and how we do it.

In light of the Consumer Survey quoted above, and our own experiences, it would seem that mandatory nutrition labeling may be barking up the wrong tree. We calculate that we have filled in the last 34 years over one million mail orders. We cannot honestly recall more than an infinitesimal number of questions coming to us with these orders which would have been answered had all our foods been labeled nurtitionally. In our unique situation, this tells us a lot.

Times are changing. More and more the real concerns of consumers are not answered by nutrition labeling. The public is not greatly concerned over it. It seems not to be as much an answer to the health needs of the nation as it was hoped to be. Nowadays those persons most concerned about foods and health know to a sufficient degree of refinement to please themselves much of what nutrition labeling reveals. For them it is largely redundant.

Based on the Consumer Survey, one would expect a lessening of emphasis on requiring nutrition labeling, instead of the opposite. A number of questions arise at this point, among which are the following:

(1) Is it wise and proper for government (particularly in times such as these when frugality is of the essence) to mandate the costly giving of label information which a large percentage of consumers does not want and/or will not use?

(2) Is a small label the best place to educate the public in nutritional matters, when those who use the label information are so few?

(3) How may it be assumed that more consumers will read and profit by label nutrition information in the future than do so now?

(4) Is it logical and just to force upon all food processors steps which will invariably increase overall food costs to consumers, directly through increased costs and indirectly through costly bureaucratic programs, which will not be used to any significant extent, and which may put out of business many sound, contributing companies which cannot possibly meet the costs and conditions involved?

(5) If nutrition labeling were to be made mandatory, based on analytical factors deemed currently important, what guarantee is there that in a few years the thinking might not change dramatically, but too late to resuscitate the host of small food processors who have in the meantime succumbed? Even now there is disenchantment with the nutrition labeling information being placed voluntarily on some food containers, with calls for change after just a few years of use.

(6) Can it truly be said that mandatory nutrition will lead to a significant bettering of the public health?

PART 4 - SMALL FOOD PROCESSOR IMPOSSIBILITIES UNDER MANDATORY NUTRITION LABELING

There are two chief "impossibilities" for small food processors under mandatory nutrition labeling plans, as we see them. Granted that our case may have unusual features under which we would be subjected to manyfold overkill, the same principle applies to small food processors in general, most of whom would stand to suffer from the same "impossibilities", perhaps to a lesser extent but enough to do them in.

IMPOSSIBILITY NUMBER ONE - ANNUAL LABORATORY TESTING

Current discussion centers around the ultimate possibility of a food processor being required to have analytical laboratory tests run annually of many of his food products. Small companies, not having their own laboratories, would have to send away samples to an outside commercial laboratory. Recently we received an advertisement from one such, showing the minimum fee for analysis of one sample of one product, providing current nutrition labeling data, as being $250.00. The literature from this company suggests that one sample would not be sufficient.

We package at present four hundred and forty items. One must think of the cost of products shipped for testing, of shipping charges, of the additional staff required to handle the day-to-day collecting, cataloging, shipping of samples. Also for the receipt of the reports, the filing, collating, checking old labels and destroying those which will have to be changed, ordering new labels, holding up manufacture until new labels arrived, and on and on.

For the actual testing of only one sample of each product the cost for all items could run well over one hundred thousand dollars. If more than one test of each product annually were to be required, this amount would grow accordingly. Add in costs for other items above, and it could easily reach 50% to 100% additional to testing costs themselves. If only 75% of our products were finally listed in the nutrition data bank, costs would still be incredibly beyond us. We could try to raise prices by about 10%, but then we would be priced out of this growingly

competitive market. This does not speak to the incredible complexities and hopeless, never-ending muddles that would ensue. Actual out-of-pocket costs would be at least several times our present average net profit. There have been suggestions that a way may be found to allow the government to subsidize at least a part of the costs of such a program for small processors. Considering all the difficulties involved in this testing program, the real possibilities of the government supporting the program in sufficient amount seem rather remote.

IMPOSSIBILITY NUMBER TWO - ACTUAL LABELING LOGISTICS

Suppose in our case we do not consider the labeling logistics with the two hundred of our products which we do not pack in paper bags. That leaves two hundred forty products that we now pack in paper bags, in three to four different sizes. The minimum economical order is twenty-five thousand bags of each size. At present, that many bags of any one size might last us two to three months, since they can be used for all 240 items. We stamp the various product names on the bags.

But if we had to use a separate bag for each size of each item, each with its own appropriate nutrition labeling on it, we could need at the most up to one hundred thousand bags for each product, or at the outside about twenty million bags. The estimated maximum of two million dollars for bag inventory alone would then be several times our present total inventory for all our foods and packaging materials together. Obviously we would not be required to have printed separate bags for such items as would not be listed in the data bank, and this may seem like exaggeration for emphasis, but the principle and impossibility remain clear.

For slower moving products, our bag inventory could last us five years or more. Many, many would end up being discarded. Formula imporvements would be almost impossible. The bags would keep us tied forever to the original formula. If one ingredient became unavailable, we'd have to discard untold numbers of bags. If due to soil, crop variety, weather conditions, etc., an analysis would change, more bags would have to be discarded. There could be ultimately up to eight hundred

different bags. We are overwhelmed by thoughts of storage, of deteriorating bags, of the terrible logistics of handling. As we make very small lots, we are daily in the two-to-three hundred bag range. Simply impossible.

PART 5 - THE ONLY WAYS WE CAN CONTINUE TO LIVE

We think of nutrition labeling as proposed as being a most costly exercise, which cannot do what is hoped. We regret feeling we must write this, knowing the calibers of those persons who have spent so many years in deep involvement in the health problems of our people. The sincerity of these persons, the depth of their concerns, cannot be questioned. If the time were to come, however, when it was felt good to mandate nutrition labeling as discussed earlier, we see the following as being the only situation with which the majority of small food processors could possibly remain vital.

In what follows we refer to certain exemptions. As pointed out earlier, under the data bank program, exemptions are permitted for lesser-consumed foods. Likewise exemptions could apply as well to small producers, whose total production of data bank foods would be of very little significance in comparison to the production of large companies, whose products would presumably be nutrition labeled.

WAY NUMBER ONE - Let Nutrition Labeling Remain Voluntary

It is not true that we and others like us oppose mandatory nutrition labeling because we want to market cheapened, inferior products. We merely beg for the right to continue to exist. If nutrition labeling is so necessary, so desirable, so universally sought after, then surely non-nutrition-labeled foods would fade away, unable to compete. Those consumers who felt concern for nutritional information would simply cease purchasing the non-nutrition labeled products. We'd take our chance on that.

WAY NUMBER TWO - Let Nutrition Labeling Be Made Mandatory Only For -

any product of any processor who manufactures and sells over five hundred thousand dollars ($500,000.00) worth of that product per calendar year. The processor should be able to afford the program for products selling more than this.

WAY NUMBER THREE - Allow The Use of a Disclaimer

In either of the above two WAYS, require processors who do not use nutrition labeling to print on the label or package some kind of disclaimer - for example - "The food in this container has not been tested for nutrition labeling purposes." Precedents for this sort of thing may be shown in numerous areas. Cigarette manufacturers, purveying a product generally accepted as being harmful to health, may still sell their product by placing a disclaimer on the package. In clothing and bedding, flammable materials are marked as such, and are sold to consumers without further ado. The consumers make up their own minds, make their choices on the basis of their own wishes.

PART 6 - OBSERVATIONS AND CONCLUSIONS

If, regarding matters of nutrition and health, the public has been miseducated, undereducated, or simply mesmerized by the siren song of the hucksters, after all the noble efforts of so many persons working in these fields for so long a time, it seems sanguine indeed to expect a series of small labels, containing a table of sterile figures, to come to the rescue and remedy the defect. The nutrition label will never win the battle against the overwhelmingly-appealing product-promotion tide which beats against our senses everywhere, all the time.

We read recently that a mixture of shoeleather and glue, plus a few synthetic additives, could be made to yield a very appealing nutrition label - low in sodium and cholesterol, in sugar and salt, high in protein, and in other good things. Let not the sow's ear of mediocre foods be made in any manner, through either clever promotion or infinitely-detailed analyses or both, to appear as a silk purse of wholesomeness.

When even the saddest "food" product, of little hope or promise, can gleam forth enveloped in the very best four-color Madison Avenue aura, given seeming respectability, and perhaps even in some perverse way government endorsement itself, what hope is there for any significant impact from this "nutrition" information?

There must be a better way. Study should look in other directions, perhaps, to the curtailment of over-enthusiastic inferences or blandishments which may be deceptive, and which may even work against the health of the people.

If the public will not read, interpret and apply nutritional label information, and if too much of certain elements (sugar, salt, fat, etc.) may have harmful effects, then let food processors be restricted in some manner in the amounts of these dubious elements which may be placed in a product. Let such food elements be simply unavailable in concentrations dangerous to health when appearing in combination with other foods - sugar in children's cereal, for example.

Some persons hope that the annual testing of nutrition-data-bank foods will keep food processors on their toes, almost shamed out of cheapening a product too much. The same result might be obtained by requiring processors, in each combination of foods, to list every ingredient by name, and also to show the percentages of such ingredients as are considered 'harmful'. Should the amounts of 'harmful' ingredients in a food product be higher than a certain specified percentage, perhaps a warning message stating that it may be harmful to health could be placed on the label.

On our price list we even now show the percentage of sugar in a number of items. If a product contains any one of a number of ingredients (including sugar) which we know some of our customers wish to avoid, we mark this product in a special manner, calling attention to this fact.

On can and bottle labels, this information could be printed when the labels are printed, usually in very small quantities for the small processor. For those bagged items of ours which contain a mixture of foods, we have printed, or print for ourselves on a small machine, small quantities of labels telling all the product ingredients. These labels are then stuck to the bags. It would be easy on such labels to include the percentages referred to above, assuming that label and type sizes, plus location on the bag, made for clear, easy reading. This method of labeling lends itself to small amounts of information on relatively few products. It would not be workable for extensive analysis information on a large number of items.

If followed, these methods would avoid the overwhelming cost and cumbersomeness of mandatory nutrition labeling. Processors, government agencies, and the public in general would be saved millions of dollars each year, an appealing prospect. In the overall health picture, this could be more promising than nutrition labeling, and help fulfill the needs most indicated in the Consumer Survey.

Emerson once spoke of the real value of "common sense and plain dealing." The small food processor needs and uses a lot of both. This paper is a plea for allowing folks like us to continue building on these as a basis for a sound, enduring, and contributing way of life. We feel we are struggling against mighty odds. In this time of national election campaigns, and deep international concerns, there is a great danger that something truly harmful to our society and its future, at the grass roots level, will be rushed through without sufficient study.

As so often happens when something small comes up against something much larger and more powerful, it becomes a matter of life and death for the small. Most large food companies started small. If smallness in the food field can no longer exist because of government edict, how can any new food businesses arise with full vigor, inventiveness and competitiveness? What a tragedy for our national life, when young enthusiastic persons are no longer able to dream big dreams, and hope to see them fulfilled!

We would like to sit down on a one-to-one basis with anyone, to give more details on the plight of the small food processor in this matter. We will go anywhere, at any time that we can. We would like to speak in hearings. We feel that we are literally fighting for our lives, as well as for those of a multitude of small food processors all over our country. We beg for the privilege of presenting our case. We understand something of the problems of legislators and consumers, as well as our own, and those of many fellow processors.

In all our work here, we ask only to be free to experience in the future the joy of living that the years past have brought to us in this great venture. George Bernard Shaw was speaking for us when he wrote -

> "This is the true joy in life, the being used for a purpose recognized by yourself as a mighty one; the being thoroughly worn out before you are thrown on the scrap heap; the being a force of nature instead of a feverish selfish little clod of ailments and grievances, complaining that the world will not devote itself to making you happy."

Paul Keene, Walnut Acres
Penns Creek, Pa. 17862

THE PILLSBURY COMPANY
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HOWARD E. BAUMAN, PH.D.
VICE PRESIDENT OF SCIENCE AND TECHNOLOGY

PHONE (612) 330-4676

May 1, 1980

Subcommittee on Health and
Scientific Research
310B Senate Courts Annex
Washington, D.C. 20510

ATTENTION: Robert Wenger

Dear Mr. Wenger:

Enclosed is a copy of The Pillsbury Company's response to the food labeling tentative position proposals published by FDA, USDA and FTC in the December 21, 1979 Edition of the Federal Register.

I had promised in my testimony that I would forward this information as soon as it was completed. The cost information was specifically requested, and most of this will be found on pages four and five.

If there is any additional information that we can supply you, please don't hesitate to contact me.

Sincerely,

Howard E. Bauman

HEB:sc
Enclosure

THE PILLSBURY COMPANY
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HOWARD E. BAUMAN, PH.D.
VICE PRESIDENT OF SCIENCE AND TECHNOLOGY

PHONE (612) 330-4676

April 18, 1980

Mr. Gary Dykstra
Regulatory Operations Staff (HFC 22)
Office of Regulatory Affairs
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20857

SUBJECT: Food Labeling; Tentative Positions of Three Agencies: Food and Drug Administration; Department of Agriculture; and Federal Trade Commission Published for Comment in December 21, 1979 Edition of Federal Register

Dear Mr. Dykstra:

On behalf of The Pillsbury Company, I wish to submit these comments in response to the tri-agency proposal above.

I. SUMMARY

Compliance with present nutrition labeling requirements and virtually any change in labeling is exceedingly costly to the manufacturer and ultimately to the consumer. Accordingly, industry and public resistance to current nutrition guidelines and the tri-agency labeling proposals above could be mollified substantially by incorporating cost effective analysis in any labeling proposal. Further, industry use of nutrition labeling would greatly increase,

and costs associated therewith would greatly decrease, if manufacturers would be permitted the use of a composite data base in lieu of individual product analyses and the omission of micronutrient information from nutrition labeling.

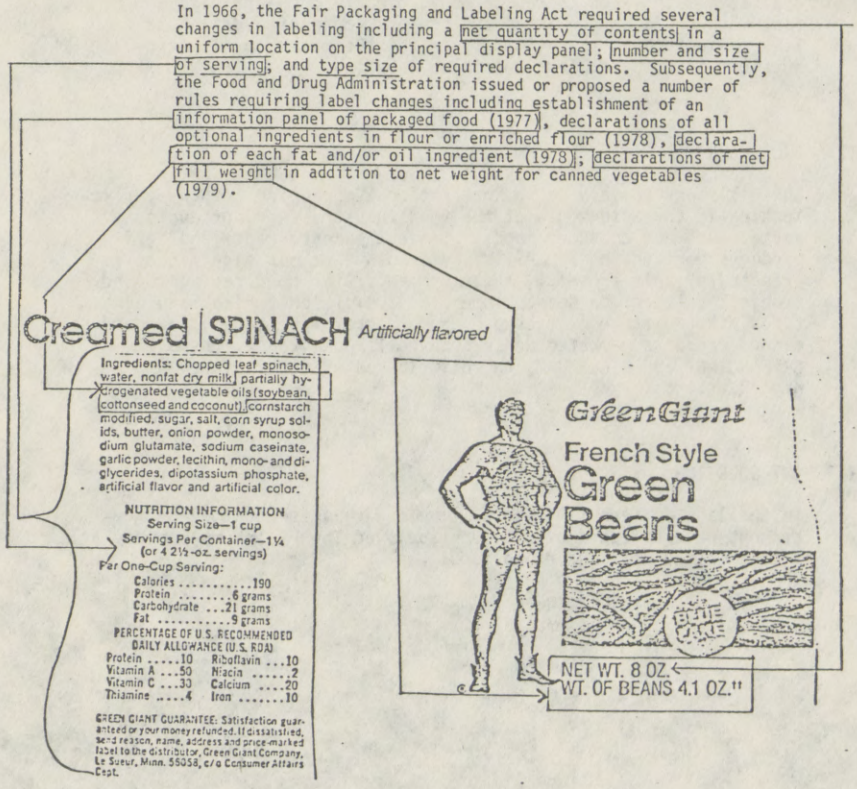
II. BACKGROUND

The Pillsbury Company is an international marketing company participating in three segments of the food industry: Agri-products, restaurants and consumer foods. Since the restaurants and agri-products portions of The Pillsbury Company are not significantly affected by this proposal, these comments will be directed to the proposal's impact on the consumer foods division, which manufactures a broad range of packaged grocery, refrigerated, frozen and canned products marketed under such well known trademarks as GREEN GIANT and PILLSBURY, and distributed at retail through grocery stores.

III. INTRODUCTION

In the last fifteen (15) years, labeling changes mandated by government have affected over 2,000 labels of The Pillsbury Company at a cost in the millions of dollars.

In 1966, the Fair Packaging and Labeling Act required several changes in labeling including a net quantity of contents in a uniform location on the principal display panel; number and size of serving; and type size of required declarations. Subsequently, the Food and Drug Administration issued or proposed a number of rules requiring label changes including establishment of an information panel of packaged food (1977), declarations of all optional ingredients in flour or enriched flour (1978), declaration of each fat and/or oil ingredient (1978); declarations of net fill weight in addition to net weight for canned vegetables (1979).



This list is far from exhaustive and does not include individual state and local labeling requirements which, for national distributors of food, such as The Pillsbury Company, are tantamount to federal law. For example, the recently upheld Massachusetts open dating regulation forces Pillsbury to open date several products (not otherwise dated) in an effort to avoid the necessity of separate inventories. While none of the requirements above places unmanageable burdens on the manufacturer, each does force a change (deletion, addition, etc.) on the label, which change many times extends to a label redesign.

Any change is expensive. To the extent that these changes force label redesign and/or new labeling regulations are implemented over a period of time rather than all at once, these costs are exaggerated. (In this regard, we urge that all agency proposals aim for a common effective date to reduce the cost impact of staggered implementation cited above.) To illustrate: Any change on a label generates a color separation and press plate cost. Present costs vary according to the extent of the change and the complexity of the label (number of colors, quality of paper, size, shape of label, etc.). In the table below, The Pillsbury Company has established a range of costs per label from the least expensive to generally the most expensive.

RANGE OF COST PER LABEL CHANGE

Costs	Low	High
1. Color Separation	$400	$1,000
2. Press Plate Change	$360	$ 900
TOTAL	$760	$1,900

Labeling changes, however slight, affecting all or substantially all of our more than 2,000 labels would result in added costs ranging from a low of $1.5 Million to a high of $3.8 Million. Moreover, this calculation is simply an estimate of Pillsbury's

out-of-pocket expense and does not include an appropriate allocation of staff services such as marketing, procurement, research and legal department necessary to assure compliance. Interviews with individuals involved in these changes resulted in time estimates that translated into costs currently ranging from $1 Million to $1.8 Million per year. It must be kept in mind that the dollar costs of personnel time is not the only factor involved, since this diversion results in a substantial loss of productive effort by scarce resources such as nutritionists. Finally, it is important to distinguish one-time costs from continuing costs resulting from labeling proposals. In the Chart entitled "Type Of Costs Associated With FDA/FTC/USDA Proposal" attached hereto as Exhibit A, a disportionate number of these proposals impose on the manufacturer and ultimately the consumer "continuing" costs which become a permanent part of the product's cost of production.

The most costly recent government regulation has been the Food & Drug Administration (FDA) nutrition labeling guidelines of 1973 which, although voluntary with the manufacturer, once used, forces upon the manufacturer substantial costs in compliance. For example, in 1973 and continuing to the present date, Pillsbury's wholly owned subsidiary, Green Giant Company, nutrition labeled its vegetable products incurring an annual out-of-pocket expense in excess of $300,000 resulting solely from product analyses required under the guidelines. Yet, these costs are relatively small when compared to costs of nutrition labeling prescribed by the U. S. Department of Agriculture which has jurisdiction over all food products containing meat. If, for example, Pillsbury were to nutrition label just its 19 different pizzas, marketed under the Totino's brand, Pillsbury would incur in excess of $600,000 in out-of-pocket expenses annually. Clearly such costs are extraordinary and provide ample reason for manufacturers' reluctance to voluntarily nutrition label meat products.

Throughout the discussion, it is important to keep in mind that these costs do virtually nothing to enhance product profitability, i.e., they must be passed on to the consumer.

In summary, label changes and present nutrition guidelines are costly. If manufacturers are to control costs yet meet public demands for more labeling information, the government must reduce their cost of compliance to the manufacturer to encourage industry acceptance and use.

IV. RESPONSE TO TRI-AGENCY PROPOSAL

Although this omnibus tri-agency proposal touches on a number of subjects, it is not the only food labeling matter before the public. Comprehensive legislation sponsored by Senator McGovern is presently before Congress, which addresses many of the same issues raised in this regulatory proposal.

To properly assess the impact of these proposals, and at the same time provide Congress and the Regulatory agencies a consistent and coordinated response, The Pillsbury Company has compiled a summary chart of, and its position on, each Legislative and agency proposal, which summary is attached to this comment as Exhibit B.

A. WITH TWO EXCEPTIONS NOTED, PILLSBURY OPPOSES COMPREHENSIVE QUANTITATIVE INGREDIENT LABELING AS CONFUSING AND MISLEADING.

Pillsbury opposes any across-the-board requirement for quantitative ingredient labeling as part of the ingredient statement for all foods. With respect to non-characterizing or functional ingredients, this proposal is particularly inappropriate. To require the percentage declaration of such ingredients would, in many instances, inhibit the flexibility of manufacturers to make minor alterations in the composition of products without changing labels. Moreover, mandatory quantitative ingredient labeling would subject manufacturers to extensive and costly verification analyses. It would also result in increased label clutter by needlessly lengthening the ingredient statement and in the divulging of proprietary trade secret information without any commensurate benefit to the consumer. Moreover, virtually every food label with which we are familiar includes a vignette of the food product which by law must be accurate and not "misleading in any particular." Therefore, such a requirement is both costly and unnecessary from both the industry and consumer perspectives.

When dealing with low percentages of functional or non-characterizing ingredients, there is no valid consumer interest in determining whether one ingredient is present at levels slightly more or less than another. The cost saving realized by eliminating the need for label changes under these circumstances would be substantial. Pillsbury doubts that the

declaration of percentages of characterizing or valuable ingredients will serve the purpose intended, i.e., enabling more accurate value judgments to be made by consumers. The presence of more of a characterizing or valuable ingredient (e.g., beef in a pot pie) does not necessarily mean a better pie from the sensory viewpoint or a markedly superior pie in terms of nutrition. Quality rather than quantity of ingredients is generally the most important factor in determining the quality of the foods. The emphasis on quantity will also detract from developing the technological skills (in blending and combining ingredients, in creating desirable textures and other sensory characteristics) needed to improve the sensory quality of products.

Two instances in which quantitative ingredient labeling are appropriate are as follows: If a product contains a combination of a valuable characterizing ingredient, and a dramatically less valuable substitute for said characterizing ingredient, and the proportion of each ingredient is not visibly discernible, manufacturers should disclose the percentage or specific quantity of the valuable, characterizing ingredient. An example is table syrup containing maple syrup. Since maple syrup is clearly more clostly than sugar syrup and the amount of maple syrup in the combination product is not ascertainable on inspection, the quantity of maple syrup should be disclosed.

The second instance in which we would support and do, in fact, use quantitative ingredient labeling is when an ingredient is not normally consumed but included nonetheless in calculating the net weight of the product. Example: canned vegetables. Each of our canned vegetables declares the weight of vegetables only at the time of packaging ("fill weight") together with the "net weight" which is the sum of the fill weight and packing medium.

Except in the two instances above, percentage ingredient labeling of all ingredients mistakenly directs consumer focus to the quantity of an ingredient and away from its nutritive value, the far more important consideration in food.

In summary, quantitative ingredient labeling should be used only on a limited basis.

B. FDA MUST RETAIN ITS USE OF "AND/OR" LABELING TO DECLARE THE SOURCE OF FATS AND OILS.

FDA must retain its present "and/or" labeling format. This is necessary in order to provide manufacturers with the flexibility which they require in order to utilize the most readily available and lowest-cost ingredients, thus maintaining retail food prices at the lowest possible level. In this connection, we are attaching as Exhibit C a portion of a memorandum prepared by Pillsbury's purchasing department substantiating the need for flexibility which if absent results in significant costs to the manufacturers. Additionally, there is a further adverse cost implication in restricting the flexibility of co-packers or suppliers of ingredients should they not be permitted to continue to use "and/or" labeling. Pillsbury, therefore, urges retention of the present format, and suggests that this approach should be expanded to include non-characterizing functional ingredients including stabilizers and emulsifiers.

Pillsbury is also concerned about the utilization of dry weight basis for determining percentages of fat. We question the relevance of a dry weight basis when, in fact, food is not consumed in this manner. We therefore believe it ought to be fat "as eaten" and not on a dry weight basis.

C. PILLSBURY SUPPORTS MANDATORY NUTRITION LABELING PROVIDED MANUFACTURERS ARE PERMITTED THE USE OF A COMPOSITE DATA BASE AND THE OMISSION OF MICRO-NUTRIENTS.

Pillsbury supports mandatory nutrition labeling provided that micro-nutrients may be omitted from the nutrition declaration and a national composite nutrition data base is established and used in lieu of extensive individual manufacturer's analyses. Such a data base offers a substantial opportunity for cost effectiveness because it eliminates the costly and unnecessary current practices cited above which require every

manufacturer to establish the variability or standard deviation for each of its ingredients and/or food products. This current practice is duplicious and wasteful of scarce technical resources. Exhibit D demonstrates the feasibility and increased accuracy over present methods of such a data base. The number of samples used in the analyses to establish the variability of nutrients in food products will largely determine the accuracy of the information that appears on the nutrition information panel. The fewer the number of samples used to establish the variability, the greater the standard deviation or the variability between products. The larger the number of samples the narrower this difference becomes.

Under current law, each manufacturer must establish his own data base. Consequently manufacturers are operating on a very wide variability which results in the necessity to "round down" the declared nutrient levels and to "round up" items such as calories and sodium. At the same time, the manufacturer is incurring substantial costs cited above. Depending on sample size, many labels are inaccurate by as much as 20%. A nutrition data base that is established through the pooling of many samples can result in extremely accurate nutrition information that will include varietal and regional differences in food items, as well as manufacturing variations that may occur. With the variability established from this large increased number of samples, the manufacturer has only to composite a number of samples to determine whether or not his product falls within the range of the data base. Of course, variations will occur from lot to lot or even from day to day; however, over a period of time, the nutrition information provided through this method will be far more accurate than under the present system. A company's compliance could be measured by its records which it would be required to maintain against the national sampling. These records would be available for inspection and evaluation by the Food and Drug Administration or the Department of Agriculture.

Nutrition information is perhaps the most important information about the food product. To the extent that government regulations inhibit (as do current FDA regulations through burdensome testing for compliance procedures) or prohibit (as does current USDA policies which sampling and testing requirements are extraordinarily expensive) manufacturer nutrition labeling, government is doing a great disservice to the consuming public.

D. THERE MUST BE NATIONAL UNIFORMITY IN LABELING LAWS AND REGULATIONS.

Finally, while not specifically addressed in the food labeling proposal, Pillsbury supports any effect on the part of the agencies and Congress to seek legislation designed to achieve national uniformity for all food labeling requirements. Disparate labeling requirements from state to state are causing ever increasing burdens on interstate commerce resulting in increased food costs with no commensurate benefit to the consumer.

SUMMARY:

Pillsbury supports meaningful information disclosure to the consumer including in particular, nutrition information labeling. At the same time, Pillsbury advocates agency recognition of the burdensome costs its regulations often impose on manufacturers and ultimately the consumer. To the extent that industry and government can identify, prioritize and eliminate burdensome regulations, the consumer will ultimately benefit.

Sincerely,

Howard E. Bauman

HEB:gfh

EXHIBIT A

TYPE OF COSTS

ASSOCIATED WITH FDA/FTC/USDA PROPOSAL

Issue	ONE-TIME	CONTINUING				
	Adding Print to Label	Additional Step(s) in Processing (Identify)	Additional Testing	Additional Inventory of Labels, Ingredients	Locked in to Fewer Suppliers	Additional Warra
I. INGREDIENT LABELING						
A. Labeling all Ingredients:						
- in standardized foods	x					
- including foods which use standarized foods as an ingredient, e.g., cheese in pizza or entrees	x	x (maintaining order of predominance)		x (standardized foods use different optional ingredients and in different quantities)	x	
B. Label Declaration of colors, spices and flavors	x	x (maintaining order of predominance)		x		
C. Quantitative Ingredient labeling	x	x (maintaining fill charts)	x	x (where percentages vary from product to product)		x
D. Ingredient Order of Predominance Statement	x					
E. Use of and/or Labeling to Declare Sources of Fats and Oils	x					
F. Functionality and Names of Ingredients -No additional cost						
G. Labeling of Fresh Fruits and Vegetables -N/A						
H. Ingredient Labeling for Restaurant Served Foods -N/A						
I. Incidental/Secondary Ingredients-no change in policy -No additional cost						

ASSOCIATED WITH FDA/FTC/USDA PROPOSAL

Issue	ONE-TIME	CONTINUING				
	Adding Print to Label	Additional Step(s) in Processing (Identify)	Additional Testing	Additional Inventory of Labels, Ingredients	Locked in to Fewer Suppliers	Additional Warr
II. NUTRITION LABELING						
A. Mandatory	x	x	x			x
Voluntary	x	x	x			x
B. Nutrition Labeling Format	x					
C. Mandatory Information for Nutrition Labeling	x					x
D. Composite Data Base for Use in Nutrition Labeling		Eliminates costs and risks associated with warranty, processing, testing and compliance.				
E. Serving Sizes	x					
F. Quantitative Sugar Labeling	x	x	x			
G. Quantitative Sodium and Potassium Labeling	x	x	x			
H. Fatty Acid and Cholesterol Labeling	x					
I. Fiber Labeling -no change						
J. Disease-Related Claims on Food Labels	x					
II. OPEN DATE LABELING	x	x (Adding date to package)	x	x		x

ASSOCIATED WITH FDA/FTC/USDA PROPOSAL

Issue	ONE-TIME	CONTINUING				
	Adding Print to Label	Additional Step(s) in Processing (Identify)	Additional Testing	Additional Inventory of Labels, Ingredients	Locked in to Fewer Suppliers	Addtio War
IV. IMITATION/SUBSTITUTE Food labeling-no change						
V. FOOD FORTIFICATION No added cost						
VI. SAFE & SUITABLE INGREDIENTS AND FOOD STANDARDS No added cost						
II. MISCELLANEOUS						
A. Label declaration of country of origin -no change						
B. Label declaration of name of manufacturer, packer or distributor -no change						
C. Natural and organic claims -no change						
D. Quantity of content declaration Drained weight Fill weight (present practice)		x	x			
E. Federal Preemption	Precludes state/local government from establishing different standards eliminating duplicate label inventories, differing processing methods, etc.					

April 18, 1980

SUMMARY OF TRI-AGENCY FOOD LABELING POSITIONS AND McGOVERN BILL PROVISIONS

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
I. INGREDIENT LABELING			
A. Labeling of Mandatory Ingredients in Standarized Foods	Will seek, support legislation to amend FD&C Act to Require mandatory ingredients in standarized foods be declared on product labels. FDA will expedite revision of standards of identity to require declaration of all optional ingredients including mandatory ingredients where more than one form is available for use. (97-98% ingredients in standarized foods will be required to be declared within one year.) USDA regulations already require such declarations.	S1652 (FDA Bill) would require labeling of all ingredients in the food whether standarized or not.	Pillsbury supports a requirement that the ingredients of standarized food products be listed on the label in a manner consistent with current FDA regulations for nonstandarized products to the extent that the packaging, labeling and manufacturing characteristics of the product permit. However, where the standarized food is itself an ingredient in a food product then only the standarized name be required in the ingredient listing or in the alternative composite labeling of such ingredients.
B. Colors, Flavors and Spices	FDA will seek or support legislation to require that all colors and spices be declared on food labels by their specific names. USDA believes it has such authority but will support legislation providing more explicit authority.	S1651 and S1652 would require labeling of colors and spices in descending order of predominance by weight, with ingredients comprising 5% or less of the food being named at the end of the ingredient list.	Pillsbury supports revising federal food labeling authority of FDA and USDA to require disclosure of individual colors flavors and spices only on an FDA finding that failure to disclose such an ingredient would pose a significant public health problem.

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
B. Colors, Flavors and Spices (continued).	FDA will seek or support legislation to provide it with discretionary authority to require label declaration of a flavor when necessary to provide important health information. USDA believes it has such authority.	Would require flavorings used as ingredients to be designated artificial or natural flavorings unless the common or usual name is required to provide health information.	The Pillsbury Company strongly supports the McGovern proposal permitting the listing of any ingredient present in the product 5% or less in any order at the end of the ingredient statement.
C. Exemption of Butter, Cheese and Ice Cream from Artificial Color Labeling	FDA will seek or support legislation to eliminate the statutory exemption.	S1652 would eliminate exemption	The Pillsbury Company supports such elimination as consistent with other Pillsbury Company proposals eliminating similar statutory exemptions.
D. Quantitative Ingredient Labeling	FDA will: (1) expand the use of percentage ingredient labeling for characterizing ingredients as part of the name of the food; (2) publish guidelines for voluntary quantitative ingredient listing as part of the ingredient statement;	S1651 and S1652 would authorize the labeling of the quantity or percentage of any specified ingredient (not a flavoring) having significant bearing on quality, consumer acceptability, or cost. Exemptions permitted for ingredients present in quantities of 5% or less, unless it results in consumer deception or confusion.	Pillsbury supports quantitative ingredien labeling for: 1. Those products which authority have already been upheld by the courts; a 2. Only those products which include ingredients not normally consumed (e.g., canned vegetables and mushroo

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
D. Quantitative Ingredient Labeling (continued).	(3) seek or support legislation giving FDA explicit authority to require quantitative ingredient labeling as part of the ingredient statement; and (4) seek or support legislation giving FDA records and reports authority, and access to companies' product formula records and quality control records. USDA will propose regulations to provide for more quantitative ingredient labeling.		In the absense of (1) and (2) above, percentage quantitative ingredient labeling directs consumer focus away fr more important nutrition label information.
E. Listing of Ingredients in Descending Order of Predominance (1) Listing	Current FDA regulations require ingredient listing in descending order of predominance.	Exemptions permitted for ingredients present in quantities less than 5% unless it results in consumer deception or confusion.	Pillsbury supports a petition requestin or enactment of the McGovern provision requiring the Food and Drug Administrati to revise and simplify its food labelin requirements so that ingredients which compose less than five percent of the weight of a product would not be requir to be listed in descending order of predominance.

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
E. Listing of Ingredients in Descending Order of Predominance (continued). (2) Statement	FDA and USDA will amend their current regulations to require that food labels bear a statement that ingredients are listed in descending order of predominance.	S1651 and S1652 would require a label declaration that ingredients are listed in descending order of predominance.	Pillsbury supports a listing of major ingredients in order of predominance and minor ingredients (5% or less) in any order. Such a listing would be headed "major ingredients" followed by a listing in order; "ingredients present 5% or less" followed by a listing in any order.
F. Use of "and/or" Labeling to Declare the Source of Fats and Oils	FDA and USDA will amend current regulations to require that foods containing 10% or more total fat on a dry weight basis declare the specific source of the fat or oil. Foods containing less than 10% may use the "and/or" approach.	S1651 and S1652 would require the listing of each ingredient by common or usual name.	Pillsbury strongly disagrees with FDA/USDA proposal as extremely costly and without scientific basis. 10% level is arbitrary.
G. Functions and Names of Ingredients	The agencies will explore the feasibility of an "Ingredient Dictionary."	No provision.	Pillsbury supports establishment and maintenance of an "Ingredient Dictionary."

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
H. Labeling of Fresh Fruits and Vegetables	FDA will continue to encourage compliance with the requirements of federal law that the presence of colors, preservatives and waxes be declared on placards and leaflets at the point of sale. FDA will not seek the statutory authority to impose similar requirements for pesticides and fertilizers.	No provision.	Pillsbury supports FDA policy.
I. Ingredient Labeling for Restaurant-Served Foods	The agencies will not at this time initiate any action to require that ingredients in restaurant-served foods be declared. This policy will be reexamined in the future as necessary.	No provision.	Pillsbury supports current agency posture.
J. Incidental/ Secondary Ingredients	The current policy of not requiring the declaration of incidental/secondary ingredients will be continued. "This policy will be reexamined in the future as found necessary."	No provision.	Pillsbury strongly supports current policy as cost-effective.

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
NUTRITION LABELING			
A. Mandatory, Discretionary or Voluntary Labeling	FDA and USDA will seek or support legislation to clarify their authority to require nutrition labeling of all foods. USDA will propose regulations requiring nutrition labeling where nutrition claims are made or a product is fortified (i.e., to be equivalent to current FDA regulations.) The three agencies are forming a task group to develop criteria for determining which additional foods should bear nutrition labeling and specifically ask for public comment on criteria.	S1651 and S1652 make nutrition labeling mandatory on human food (FDA) and packaged meat and poultry products (USDA).	Pillsbury supports revising the federal nutrition food labeling authority of FDA and USDA to require nutrition labeling provided: 1. Manufacturers may use a composite data base in lieu of individual on-going analytical procedures. 2. Manufacturers may omit micro-nutrient declarations. 3. Manufacturers may list calories without triggering nutrient labeling.

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
B. Nutrition Labeling Format	The agencies propose to retain the present nutrition labeling system pending the outcome of research to determine which format consumers find most useful and convenient and what changes, if any, are appropriate. The agencies will encourage and facilitate voluntary experimentation by industry, with graphic and other formats that are consistent with the principles of the current quantitative system, or with new concepts this research produces. FDA studies are to be carried out in conjunction with USDA and FDA.	S1651 and S1652 permit conveyance of information through symbols, figures or other devices. S1651 and S1652 provide for demonstrations to ascertain the most effective methods of organizing labels and conveying information to consumers, emphasizing: (1) nutrient density, (2) serviing size, (3) ingredient function, (4) conveyance of the following information: (a) protein, fats, carbohydrates, (b) sodium, (c) vitamins and minerals, (d) dietary fiber. Products subject to approved demonstrations are exempted from nutrition labeling requirements.	Pillsbury supports the mandatory declaration and prominent labeling of available nutrients based on typical values. (See above for detail). Pillsbury supports the McGovern provision.

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ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
C. Mandatory Information for Nutrition Labeling (serving size, calories, macro and micro nutrients	The agencies request information to: (1) whether they should retain the present mandatory listing or expand it; (2) make it more flexible; (3) whether a nutrient should be mentioned when a serving of the food provides less than 2% of a USDA requirement.	S1651 and S1652 retain the current mandatory listing and add to it.	(1) Pillsbury supports a listing of macro-nutrients without the listing of micro-nutrients. (2) Calories should be permitted to be listed without triggering full nutrition labeling requirements. (3) Nutrients present in amounts less than 2% should be exempted from nutrition labeling requirements.
D. Composite Data Base for use in Nutrition Labeling	FDA and USDA will maintain for now the current policy that products be labeled according to composition and that the manufacturer is responsible for insuring the validity of nutrient content expressed on the food label. FDA and USDA encourage industry to develop and maintain meaningful data bases and encourage their submission for evaluation, but such submission will not exempt manufacturers from assuring that a product meets its labeled nutrient content within established limits.	S1651 and S1652 permit the use of nutrition data bases indicating representative nutritional value at point of purchase. S1651 (USDA) authorizes $1 Million for FY80, $2 Million for FY81 and $1 Million for FY82 for the development and publishing of a standardized reference on the nutrient composition of all foods.	Pillsbury supports revision of the federal food labeling authority of FDA and USDA provided the bill proposal permits manufacturers to use nutrition data bases for labeling their products without the regulatory burden of costly on-going analytical procedures to demonstrate compliance.

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
E. Serving Sizes	FDA will publish final serving size regulations for some beverage products, cereal and meal replacements. FDA and USDA will propose regulations to establish serving sizes for additional product classes and/or types of foods.	No provision.	No position.
F. Labeling of Sugars	FDA will propose to amend the nutrition labeling regulations to require quantitative declaration of total sugars as part of nutrition labeling. USDA will propose regulations to require quantitative declaration of total sugars as part of nutrition labeling.	S1651 and S1652 would require the labeling of carbohydrates in terms of caloric content as part of nutrition labeling. Note: Leaves form of sugar labeling to agency discretion.	Pillsbury supports FDA and opposes USDA proposal.
G. Sodium and Potassium Labeling	FDA will propose to amend its nutrition labeling regulations to require the declaration of sodium and potassium content as part of nutrition labeling. USDA will propose regulations that would require sodium labeling as a part of nutrition labeling and it will consider including potassium labeling in this proposal.	S1651 and S1652 would require the labeling of sodium as part of nutrition labeling.	Pillsbury supports FDA/USDA proposal for sodium and potassium labeling.

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
H. Fatty Acid and Cholesterol Labeling	FDA will continue to require that the cholesterol or fatty acid content of a food be included on nutrient labeling when claims about these substances are made. FDA will propose to amend the fatty acid/cholesterol regulation to require fatty acid labeling whenever cholesterol is declared and cholesterol labeling whenever fatty acids are declared. FDA will propose to amend the present fatty acid/cholesterol regulation to eliminate the requirement for the statement "Information on fat (and/or cholesterol as appropriate) content is provided for individuals who, on the advice of a physician, are modifying their dietary intake of fat (and/or cholesterol as appropriate). FDA will propose a regulation to define the terms "low cholesterol," "reduced cholesterol" and "cholesterol free." FDA will also consider proposing regulations to govern claims about fatty acid content.	S1651 and S1652 would provide authority for cholesterol labeling as a part of nutrition labeling unless it is determined to be unnecessary health information.	Pillsbury supports FDA position.

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROPOSAL	THE PILLSBURY COMPANY POSITION
H. Fatty Acid and Cholesterol Labeling (continued).	FDA will seek or support legislation to provide it with explicit discretionary authority to require cholesterol/fatty acid content labeling on the basis of significance to public health. USDA believes it has such authority but will support legislation to provide more explicit authority for both agencies. USDA will propose regulations to require cholesterol labeling as a part of nutrition labeling.		Pillsbury opposes mandatory requirements for nondiscretionary cholesterol labeling.
I. Fiber Labeling	FDA and USDA will not require dietary fiber labeling as part of nutrition labeling until there is a clearer consensus on a definition of dietary fiber, until methods of analysis are developed, and until its significance in the diet is better understood.	S1651 (USDA) lists dietary fiber as one of the elements which should be included in demonstrations.	Pillsbury supports current FDA/USDA policy.

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
J. Disease-Related Claims on Food Labels	FDA and USDA will maintain the present policy of not allowing disease-related claims on the labeling of conventional foods products.	No provision.	Pillsbury supports current FDA/USDA policy.
OPEN DATE LABELING	FDA will seek or support legislation to provide it with explicit discretionary authority to require open dating on classes of foods as is found necessary. USDA believes it not has such authority but will support legislation to provide more explicit authority for both agencies. USDA will propose regulations to require open dating on perishable and semiperishable foods to the extent that authority under current law permits.	While there is no explicit open dating requirement in the bills, S1652 (FDA) preempts state labeling requirements with the exception of state requirements for a sell or use date.	Pillsbury supports open dating of products provided such a requirement: (1) totally preempts state, county and city requirements, (2) uses a pull date or expiration date defined as recommended last date of sale or use, (3) permits sale of past-date foods if fit for human consumption and separated from foods whose pull dates have not passed.

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
1. IMITATION SUBSTITUTE FOODS	The agencies are soliciting comments on the following five options: (1) Maintain the existing policy. Foods which are not nutritionally inferior to foods for which they substitute need not be labeled imitation but can be given new names which are not misleading. (2) Expand the use of imitation labeling. Any food which resembles and is intended to replace a traditional or standardized food regardless of its nutrient content or other characteristics would be called "imitation" or, alternatively, there must be established for this food a common or usual name or a standard of identity. (3) Expand use of imitation labeling but add to the "imitation" designation a common or usual name that explains what the product is.	No provision.	Pillsbury supports the following: (1) Only those "new foods" that are "nutritionally inferior" to traditional foods they resemble should be required to be called "imitation." (2) New foods that are "nutritionally equivalent" to foods they resemble and foods that do not resemble traditional foods should be permitted to be identified by descriptive names. (3) The further use of descriptive terminology should be encouraged wherever possible. (4) Nutritional equivalence of "new" and traditional foods should be based upon nutrient contents; the concept of "nutritional difference" should be developed.

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
IV. IMITATION SUBSTITUTE FOODS (continued).	(4) Expand use of imitation labeling but add to the "imitation" designation an explanation of how the substitute product differs from the traditional food. (5) Establish a policy based on the proportion and type of characterizing or valuable ingredients.		
V. FOOD FORTIFICATION	FDA and USDA will seek or support legislation giving them explicit discretionary authority to control the fortification of food when exercising this control is deemed of public health significance. In the interim, FDA will publish guidelines on food fortification and encourage manufacturers to adhere to them.	No provision.	Pillsbury supports, if shown to be necessary, the adoption of a statement of general principles regarding food fortification.

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
VI. SAFE AND SUITABLE INGREDIENTS AND FOOD STANDARDS	The agencies will propose the following modifications to the current policy and request public comment on the revised policy: (1) The new policy would apply only to optional, functional ingredients used in quantities of less than 5%. Functional ingredients (for this purpose) would be defined as ingredients which do not alter the basic characteristics of the food. (2) Label declaration of ingredients that the products contain would be required. (3) The descriptive phrase "safe and suitable" would be changed to one such as "permitted functional ingredient" that is less confusing and which more accurately describes this concept.	No provision.	Pillsbury supports present policy and approves agency proposal in the absense of demonstrated benefit.

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY POSITION
VII. MISCELLANEOUS ISSUES			
A. Label Declaration of Country of Origin.	USDA and FDA will continue the present policy requiring that the country of origin be declared on the label for foods imported in packages and sold in such packages at retail.	No provision.	Pillsbury supports current regulation.
B. Label Declaration of Name and Address of Manufacturer, Packer or Distributor	USDA and FDA will continue the present policy of requiring declaration of the name and address of the manufacturer, packer or distributor.	No provision.	Pillsbury supports current regulation.
C. Quantity of Contents Declaration	FDA is now evaluating comments on its fill weight/drained weight labeling regulations for the canning industry. USDA requires the net weight of canned products to reflect the solid weight only, unless the packing medium has nutritive value.	No provision.	Pillsbury supports fill weight (not drained weight) labeling regulations as only economically feasible method. Pillsbury supports (a) the "averaging" principle in the determination of the compliance of packages with net weight/net contents declarations and (b) existing federal regulation allowing for variations caused by ordinary exposure during good distribution practices.

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
II. THE TOTAL FOOD LABEL	FDA will conduct a research program, supported by USDA, to help decide what labeling format is the most comprehensible to the consumer. Nutrition labeling and ingredient labeling will be the primary focal point for this research.	No provision.	No position.
IX. UNIFORMITY	No discussion	S1652 (FDA) preempts all state labeling requirements with the exception of state requirements for a sell or use date.	Pillsbury supports federal preemption of state and local labeling laws.
X. CONSUMER EDUCATION	No discussion.	S1652 (FDA) provides for pilot testing and implementation of a program of consumer education on how to use nutrition labels effectively. $4 Million authorized and appropriated for FY80, $6 Million for FY81 and $8 Million for FY82. (USDA already has a consumer education fund.)	Pillsbury supports McGovern proposal.

ISSUE	FDA/USDA/FTC POSITION	McGOVERN BILL PROVISION	THE PILLSBURY COMPANY POSITION
XI. FTC REPORTING REQUIREMENTS	No discussion.	S1652 and S1652 require the secretaries of the respective agencies to notify the FTC of nutrition information to be used on food labels and recommend which should be required in advertising. FTC Chairman is to report to Congress on recommendations and subsequent actions taken biennially.	Pillsbury opposes any bill proposal containing any of the following: Mandatory reports to the FTC by USDA and HEW detailing what nutrition information will be required on product labels and recommending what nutrition information will be required on product labels and recommending what nutrition information would be included in advertising.
XII. CRIMINAL LIABILITY	No discussion.	No provision.	Pillsbury supports modification of the absolute criminal liability of individuals for their vicarious association with violations of law.

EXHIBIT C
FEB 29 1980

General Procurement
M. VanderSloot - 1111
February 19, 1980

Alastair D. Morton 9000

cc: W. A. Malkerson 1111
H. Bauman 9000

FDA LABELING PROPOSALS

The FDA labeling proposal to eliminate the "and/or" fat labeling presently allowed would be a significant penalty to The Pillsbury Company. On some shortening specifications, we have the option of either lard and/or tallow base shortening which allows the supplier to bid on the least cost shortening. With several other shortening applications, we have alternate specifications written utilizing different base fats which allow us to order the least cost shortening specification. The price spread between the base fats (lard, tallow, soybean oil) varies very sharply at times. Because the price spreads are often limited time periods, it is very important that we be able to make changes in base fats very quickly so that we can take advantage of attractive prices and therefore hold our costs and selling prices down.

Normally the following price relations exist in the shortening market:

1. Historically, lard will be at a premium price relative to tallow. I would estimate this exists 70% of the time with an average spread of 50¢/cwt. However on occasion this relation reverses itself. Also the spread can be as great as several dollars per cwt.

2. Soybean oil, almost without exception, is normally at a significant premium to lard and/or tallow - with a normal $1-$3/cwt. price spread. Because of higher refining costs of soybean oil versus animal fats, the actual premium for refined soybean oil is normally $3-$5/cwt. over animal fats. It would be highly unusual therefore that the market would ever provide an opportunity that we would switch from animal fats to soybean oil.

Our cost reduction efforts normally are concentrated in switching from vegetable oils to animal fats or vegetable/animal fat blends. The necessary leadtime to implement such changes would be lengthened significantly (8-10 weeks minimum) if the labels would have to be specific to the individual fats because of new label leadtimes. We would also be confronted with significant label obsolescence costs because of the large quantity manufacturing runs. The change-off to obsolescence labels would be either much higher labor cost for small manufacturing runs or even further time delays in implementing alternate shortenings. It would virtually eliminate the opportunity of switching base fats provided by unusual short term price spreads in the market.

APPENDIX I

EXHIBIT D

NATIONAL NUTRITIONAL DATA BASE

The National Nutritional Data Base would be an accurate and cost-effective method of providing nutritional information to a manufacturer for nutritional labeling. The National Data Base would reflect the benefit and accuracy derived from utilization of a very large number of samples.

In determining nutritional values for products, a manufacturer in the first instance must establish the variability of these nutrient values for a wide range of product samples (by plant, region, etc.). The larger the number of samples in this initial phase the more accurate is the data. However, the larger the number of samples the greater the number of analyses that have to be carried out and hence the greater cost.

The second phase, the monitoring phase, may be carried out after the nutrient data variability is established in order that the manufacturer can confirm that he is running within the values determined initially. This would not involve a great number of samples and consequently would be less expensive.

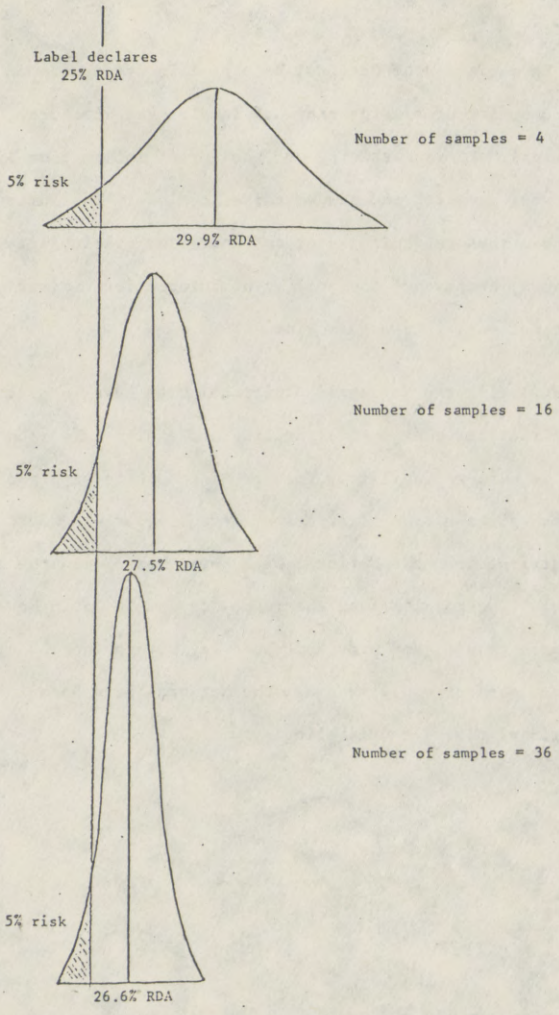
Figure 1 shows the benefits and merits of a national nutritional data base over one established by each manufacturer. Referring to the upper curve, the manufacturer who used 4 samples to establish his variability would have to add 20% more nutrient than he can actually declare (that is, 29.9% compared with 25%).

The lower curve conversely illustrates that with 36 samples, the actual nutritional value (26.6%) approaches very closely to the declared value of 25%.

The merit of the National Data Base is predicated on the basis that it is a composite of a large range of samples (manufacturer, region, plants, varieties). It is a sharing and pooling of information by the food industry, government agencies and academic institutions. The National Nutritional Data Base thus tends to cancel out individual variability, and for given nutrients, because of the pooling of information, is truly more representative of the national intake over time.

Utilizing the National Nutritional Data Base in practice eliminates the initial large expensive sampling and analyses by each manufacturer to establish his variability. Instead, a composite sample of product is analyzed for each given nutrient criteria. Secondly, values would be derived for the nutrient from the National Data Base, based upon the components of the product. The results from the composite sample would be compared with the data base result, and provided these lay within the 95% confidence limit, the manufacturer would then use the National Data Base information for nutritional claims and labeling.

FIG. 1



The curves from top to bottom of mean value distribution indicate the effect of increasing sample size on the accuracy of actual and declared nutritional values. The shaded portions represent the risk that the nutritional mean value lies below the declared value.

Senator SCHWEIKER. We do appreciate very much you all coming to this hearing. The Health and Scientific Research Committee will stand in recess.

[Whereupon, at 12:35 p.m., the subcommittee was adjourned.]

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