IN THE MATTER OF

GENERAL NUTRITION, INC.

*Docket 9175. Initial Decision**, February 24, 1986

INITIAL DECISION BY

MONTGOMERY K. HYUN, ADMINISTRATIVE LAW JUDGE

FEBRUARY 24, 1986

PRELIMINARY STATEMENT

On March 20, 1984, the Federal Trade Commission ("Commission") issued an administrative complaint charging General Nutrition, Inc. ("General Nutrition") with unfair methods of competition and unfair or deceptive acts or practices in violation of Sections 5 and 12 of the Federal Trade Commission Act (15 U.S.C. 45, 52). Specifically, the complaint charged that General Nutrition made a number of misrepresentations in connection with its product "Healthy Greens," including (a) the representation that the findings of the National Research Council's Report *Diet, Nutrition and Cancer* support the claim that use of Healthy Greens tablets (and food supplements of dehydrated vegetables such as Healthy Greens) is associated with reduced incidence of certain cancers in humans, (b) the representation that research indicates that vitamin E plays an important role in reducing the risk of cancer, (c) the representation that the use of Healthy Greens is associated with a reduced incidence of certain cancers in humans, and (d) the **[2]** representation that vitamin E plays an important role in reducing the risk of cancer (Complaint ¶ 7). The complaint also charged that the representations listed in 7(a) and (b) are false (Complaint ¶¶ 8, 9). The complaint further charged that General Nutrition did not possess and rely on a reasonable basis for the claims listed in 7(c) and (d) (Complaint ¶ 10).

The case, initially assigned to Administrative Law Judge Thomas F. Howder, was reassigned to me on April 25, 1985. After conclusion of prehearing proceedings including discovery and filing of pre-trial memoranda, the hearing for the presentation of complaint counsel's case-in-chief was held from June 25, 1985 to July 17, 1985 and the

* Decision and Order issued February 2, 1989 (111 FTC 387).

defense hearing, from July 24, 1985 to August 1, 1985 and from September 3, 1985 to September 13, 1985. Complaint counsel called four expert witnesses, and about 100 documentary exhibits (CX's) were received in evidence in support of complaint counsel's case. Respondent called four expert witnesses, and some 50 defense exhibits (RX's) were received in evidence. The documentary exhibits in the record include extensive textual material and excerpts of epidemiological and biomedical literature relied on by respondent, including a substantial amount of post-claim substantiation material. Transcripts of hearing testimony amounts to about 3,200 pages.

The proposed findings and conclusions submitted by the parties and their arguments in support thereof have been given careful consideration by me and to the extent not adopted by this Initial Decision, in the form proposed or in substance, are rejected as not supported by the evidence or as immaterial. Any motion appearing on the record not heretofore or hereby specifically ruled upon either directly or by the necessary effect of the conclusions in this Initial Decision is hereby denied.

Upon consideration of the entire record in this proceeding and having considered the demeanor of the witnesses, I make the **[3]** following findings of fact and conclusions of law and order based on the record considered as a whole.[1]

FINDINGS OF FACT

I. RESPONDENT, JURISDICTION AND OTHER GENERAL FINDINGS

1. General Nutrition, Inc. (GNC) is a corporation organized, existing and doing business under and by virtue of the laws of the state of Pennsylvania with its offices and principal place of business located at

[1] By order of November 5, 1985, the Commission extended the due date of this Initial Decision to February 23, 1986.

For the purposes of this Initial Decision, the following abbreviations were used:

F.	—	Finding of Fact in this Decision
CPF	—	Complaint Counsel's Proposed Findings
RPF	—	Respondent's Proposed Findings
CR	—	Complaint Counsel's Reply
RR	—	Respondent's Reply
Tr.	—	Transcript of hearings, sometimes preceded by the name of the witness
CX	—	Complaint counsel's exhibit
JX	—	Joint exhibit of the parties
RX	—	Respondent's exhibit
Comp.	—	Complaint
Ans.	—	Answer

921 Pennsylvania Avenue, Pittsburgh, Pennsylvania (Answer of GNC, ¶1).

2. GNC is now and has been engaged in the distribution, advertising, offering for sale, and sale of nutritional supplements, including Healthy Greens (Answer of GNC, ¶2). In connection with the marketing of Healthy Greens, GNC has caused the dissemination, publication and distribution by mail and across state lines of advertisements and promotional material for the purpose of promoting the sale of Healthy Greens for human use (Answer of GNC, ¶3). As advertised, Healthy Greens is a "food" and a "drug" within the meaning of Section 12 of the Federal Trade Commission Act (CX 71E-F).

3. In the course and conduct of its business, GNC caused Healthy Greens, when sold, to be transported from its place of business to over 1,100 of its company-owned retail outlets located in 49 states of the United States and the District of **[4]** Columbia (CX 71B) and through the U.S. Mail to purchasers located in various states of the United States and the District of Columbia (CX 71C; JX 2C). GNC has maintained a substantial course of trade in these products, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act (F. 80-81, *infra*).

4. In the course and conduct of its business, GNC has disseminated and caused the dissemination of certain advertisements concerning Healthy Greens through the United States mails and by various means in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act (CX 71A-D).

5. Healthy Greens tablets are dietary supplements each consisting of the following nutrients and foods: 35% of the U.S. recommended daily allowance (U.S. RDA) of vitamin A, 15 mg. of beta-carotene, 300% of the U.S. RDA of vitamin C, 150% of the U.S. RDA of vitamin E, 50 microgram of selenium, 500 mg. of dehydrated cruciferous vegetables and 5 mg. of dehydrated spinach and carrots (CX 8). The label directions recommend that an individual consume one tablet each day (CX 8).

6. In 1980, the National Cancer Institute (NCI) concluded an evaluation process of the basis and feasibility of a large scale study of the field of diet and cancer and commissioned the National Research Council (NRC), the research arm of the National Academy of Sciences (NAS), to conduct a review of the available scientific information on the subject of diet, nutrition and cancer. The NAS-NRC formed the

Committee on Diet, Nutrition and Cancer (Committee), an *ad hoc* committee of experts on diet and cancer. The NRC charges to the Committee contained three components: (1) to "review...the state of knowledge and information pertinent to diet/nutrition and the incidence of cancer;" (2) to "develop a series of recommendations related to dietary components (nutrients and toxic contaminants) and nutritional factors which can be communicated to the public;" and (3) develop a series of research recommendations related to diet, based on the Committee's review described in (1) (JX 1, Preface at v).

7. In 1982, the NAS-NRC Committee made a report pursuant to the first and second components of its mandate. The Report, entitled "*Diet, Nutrition and Cancer*," was published by the National Academy Press (JX 1). Much of the testimony at trial involved the Report (frequently referred to as the "Green Book" or the "Report"). An "Executive Summary," which summarizes the most relevant scientific information on diet and cancer and recommends several interim dietary guidelines, is followed by individual chapters which discuss in detail the scientific information relating to various aspects of diet and cancer reviewed by the Committee. And, Dr. Clifford Grobstein, who **[5]** served as Chairman of the Committee, and Dr. T. Colin Campbell, who served as a member of the Committee, testified at trial as did Dr. Guy R. Newell, who participated in the NCI planning which led to the NCI request to the NAS-NRC to undertake the review in question.

8. Based upon its comprehensive review of the scientific literature on diet, various nutrients and minerals and cancer, the Committee concluded that the available evidence suggests that diet affects the incidence of cancer (JX 1, p. 14). It recommended six interim dietary guidelines that if followed the Committee believed to be likely to reduce the risk of various cancers in humans (JX 1, p. 14). Four of these are applicable to individuals: (1) reduce consumption of fat; (2) emphasize the importance of fruits, vegetables, and whole-grain cereals in the daily diet (this recommendation specifically does not apply to any nutrients found in these foods); (3) minimize salt-cured and smoked foods; and (4) consume alcohol only in moderation (JX 1, pp. 14-16). These guidelines were only interim in nature, and the Committee stressed that the current data is incomplete (JX 1, pp. 14-16). Further, these guidelines involve increasing some foods and decreasing others, and the Report emphasized that these guidelines were to be applied in their entirety to obtain maximum benefit (JX 1, p. 14).

9. In 1983, the Committee issued, pursuant to the third component of its mandate discussed hereinabove, a report entitled "*Diet, Nutrition and Cancer: Directions for Research*" (RX 45). Witnesses testified that several NCI-funded, controlled trials have since commenced as a follow-up to some of the recommendations contained in that report. *See* F. 244, *infra.*

10. Also in 1983, the NAS-NRC Committee staff compiled and published a comprehensive bibliography of scientific literature, entitled, "*Diet, Nutrition and Cancer—Bibliography 1969 to 1982,*" (RX 204) which assembled and listed what the Committee staff considered pertinent resource material that may be of use to scientists and others involved in a study of the relationship between diet, nutrition and cancer. *See* JX 1 at iii.

II. EXPERT WITNESSES WHO TESTIFIED AT THE HEARING

11. Complaint counsel presented the testimony of four expert witnesses. They are Dr. T. Colin Campbell, Dr. Clifford Grobstein, Dr. Theodore P. Labuza and Dr. Adrianne E. Rogers. Respondent presented the testimony of three expert witnesses. They are Dr. Paul Lachance, Dr. Guy R. Newell and Dr. Raymond J. Shamberger. In addition, Dr. Ronald W. Thompson, Director of Nutrition Education of respondent General Nutrition, Inc., testified regarding respondent's so-called substantiation **[6]** material and also gave his evaluation of pertinent scientific material discussed in the NAS-NRC Committee Report.

A. *Complaint Counsel's Witnesses*

T. Colin Campbell, Ph.D.

12. Dr. T. Colin Campbell is recognized as a leading scientist on the issue of diet, nutrition and cancer (CX 56; Newell, Tr. 2808; Rogers, Tr. 1388). He is the Jacob Gould Schurman Professor of Nutritional Biochemistry at Cornell University, Ithaca, New York (Campbell, Tr. 622). He is Director of the Nutrition and Cancer Program Project at Cornell. He is also the Senior Scientific Advisor to the American Institute for Cancer Research, Falls Church, Virginia (CX 56A). Dr. Campbell received both his Ph.D. and M.S. from Cornell in nutrition and his B.S. from Pennsylvania State University (Campbell, Tr. 627).

13. Currently, Dr. Campbell, in cooperation with the Peoples' Republic of China, is the director of the largest study ever undertaken in the area of diet and cancer (Campbell, Tr. 625). Dr. Campbell

directs graduate research at Cornell and teaches advanced nutritional biochemistry to undergraduate and graduate students. He also teaches classes in molecular toxicology, environmental toxicology, and international nutrition (Campbell, Tr. 623; CX 56P).

14. Dr. Campbell was a member of the National Academy of Sciences/National Research Council Committee on Diet, Nutrition and Cancer, the Report which is the focus of this litigation (Campbell, Tr. 632). In 1980, he was a member of the Food and Drug Administration Consultant Group on Risk Assessment, and in 1981, he was a consultant to Tufts University USDA Human Nutrition Research Center (CS 56P-Q). Dr. Campbell was co-chairman of the Federation of American Societies for Experimental Biology/Life Sciences Research Office Study Workshop on Nutrient Toxicities (FASEB/LSRO) in 1979-1980. He was also a member of the FASEB/LSRO Study Workshop Panel on Evaluation of Nutrient Safety from 1979-1980 (CX 56Q). Between 1978-1979, he was a member of the NAS Committee on Saccharin and Food Safety Policy (Campbell, Tr. 632-33).

15. Dr. Campbell has acted as consultant for several government and industry groups including the Food and Drug Administration, Federation of American Societies for Experimental Biology, National Institute of Health, National Aeronautical & Space Administration, M & M Mars, Inc., Chocolate Manufacturers Association, and the American Society of Pharmacology and Experimental Therapeutics. He is also a member of the Society of Toxicology (CX 56A; Campbell, Tr. 628). **[7]**

16. Dr. Campbell has authored or edited a number of books, including the NAS Report on *Diet, Nutrition and Cancer*, the NAS Report on Food Safety Regulations and Societal Impact and *Drugs and Nutrients, The Interactive Effects* (CX 56B). He has published about 150 research publications on the subject of diet and cancer, 100 to 110 of which were original research that appeared in peer-reviewed journals and included both epidemiological and experimental data (Campbell, Tr. 633). Dr. Campbell has been on the editorial board of a number of scientific journals including, *Journal of Nutrition, Drug-Nutrient Interactions, Nutrition Reviews, Journal of Environmental Health Sciences,* and *Journal of Toxicology and Environmental Health Services* (CX 56Q).

17. Dr. Campbell has received a number of awards including an NIH Cancer Development Award, an American Society for Clinical

Nutrition Visiting Professorship to the University of Maryland Medical School at Baltimore, and a National Cancer Institute Scholarship to the People's Republic of China (CX 56A).

18. Based on his training, experience, and familiarity with this area of research, Dr. Campbell is well-qualified as an expert in the area of nutrition with special expertise in the relationship between diet, nutrition and cancer.

Clifford Grobstein, Ph.D.

19. Dr. Clifford Grobstein is an internationally recognized scientist who was chosen to serve as Chairman of the Committee that wrote the Report. He has had long involvement with, and knowledge of, cancer research. Dr. Grobstein is currently Professor of Biological Sciences and Public Policy at University of California, San Diego (CX 55A). Previously, Dr. Grobstein was Vice-Chancellor of University Relations at the University of California, San Diego, from 1973-1977 (CX 55A). Between 1967-1973, he was Dean of the School of Medicine and Vice-Chancellor of Health Sciences at the University of California, San Diego (CX 55A). He was also Professor in the Department of Biology at the University of California, San Diego from 1965-1977 and was Department Chairman from 1965-1967 (CX 55A). From 1956-1965, he was Professor of Biology at Stanford University (CX 55A). Between 1946-1956, Dr. Grobstein worked at the National Cancer Institute as a research biologist (CX 55A).

20. Dr. Grobstein is a member of a number of professional societies including the National Academy of Sciences, the American Academy of Arts and Sciences and the Institute of Medicine (CX 55A). Dr. Grobstein's election to the National Academy of Sciences signifies that he has made an unusually significant contribution to science (Grobstein, Tr. 308). He is **[8]** past-president of both the American Society of Zoologists and the Society for the Study of Growth and Development (CX 55A). Dr. Grobstein has been recognized by the Belgian Royal Academy of Sciences, which awarded him the Brachet-laureate (Grobstein, Tr. 303; CX 55A).

21. Dr. Grobstein has served on numerous national committees. He is currently a member of the National Academy of Sciences/National Research Council Report Review Committee, which is the body responsible for reviewing all of the reports that are issued by the National Academy of Sciences (Grobstein, Tr. 308). He is a member of the Advisory Committee on Health Science Policy of the Institute of Medicine and the Committee on Science and Society of Sigma Xi (CX

55B). Dr. Grobstein also served on the Committee on Future Directions of the American Association for the Advancement of Science and on the Executive Committee of the American Institute of Biological Sciences (CX 55A).

22. Dr. Grobstein has been a member of several National Academy of Sciences/National Research Council committees including the *ad hoc* Committee on Policies and Procedures, the Committee on Laboratory Related Biohazards, the Committee on Saccharin and Food Studies, the Committee on National Needs for Biomedical and Behavioral Sciences Personnel and the Committee on Diet, Nutrition and Cancer (CX 55A). Dr. Grobstein also served on a National Institute of Health Study Section on Cell Biology and as Chairman of the National Institute of Child Health and Human Development's Consultant Study on Mental Retardation and Population Research Centers (CX 55B).

23. Dr. Grobstein has served on several National Science Foundation committees including the Advisory Panel on Developmental Biology, the Council on Science Information, the Advisory Committee on Planning and Institutional Affairs, the Advisory Committee to Science and the Citizen Program, the Advisory Committee to Education Directorate, and as Chairman of the Advisory Committee to Program on Science and Society (CX 55B). Dr. Grobstein was Chairman of the Advisory Committee to the Environmental Protection Agency, Division of Anticipatory Research on Risk Assessment (CX 55B). He was also Chairman of the Institute of Medicine Committee to review the national research plan of the National Institute of Neurological and Communicable Diseases and Stroke (CX 55B). Dr. Grobstein has also been a member of the Committee on Biological and Medical Science of the President's Science Advisory Council (CX 55B).

24. Dr. Grobstein is currently on the Editorial Board of the scientific journal, *Perspectives in Biology and Medicine.* He has previously served on the Editorial Board of *Science* (Grobstein, Tr. 303-04; CX 55B). Dr. Grobstein has published in excess of 100 scholarly publications in peer-reviewed journals and books (CX 55C-K). **[9]**

Based on his background, training, experience, and the fact that he was Chairman of the Committee on Diet, Nutrition and Cancer, Dr. Grobstein is well-qualified as an expert on issues relating to the Report on *Diet, Nutrition and Cancer.*

Theodore P. Labuza, Ph.D.

26. Dr. Theodore P. Labuza is recognized as an expert on the

subject of food science and technology. Dr. Labuza has been Professor of Food Science and Technology in the Department of Food Science and Nutrition at the University of Minnesota since 1973 (CX 57A). Previously, he was Associate Professor of Food Science at the University of Minnesota from 1971-1973 (CX 57A). Between 1966-1971, he held appointments first as Assistant and then as Associate Professor of Food Engineering at Massachusetts Institute of Technology (CX 57B). Dr. Labuza obtained his Ph.D. degree at Massachusetts Institute of Technology in 1965.

27. Dr. Labuza consults extensively and has his own consulting business, National Food and Nutrition Consultants (Labuza, Tr. 1128). He is currently a consultant for several major corporations (CX 57B). Dr. Labuza is a member of numerous professional societies including the Institute of Food Technologists, American Chemical Society, American Institute of Chemical Engineers, and the American Association of Cereal Chemists (CX 57B).

28. Dr. Labuza has been a member of many national and international committees. He was a member of the American Institute of Nutrition—United States Department of Agriculture Advisory Committee (CX 57C). He was also a member of the National Science Federation Food Engineering Committee (CX 57C). He was Chairman of the National Nutrition Consortium—Committee on Long-Range Effects of Food Regulations (CX 57C). He was a member of the Scientific Advisory Committee of the National Cancer Institute Diet and Nutrition Program (CX 57C). He was also a member of the American Dental Association Committee on Carcinogenicity of Foods (CX 57C). He was co-chairperson and co-organizer of the 2nd International Food Engineering Congress in Helsinki, Finland in 1979 (CX 57C). He was also co-chairperson and co-organizer of the International Conference on Browning of Foods in Goteborg, Sweden in 1979 (CX 57C). He was on the National Academy of Sciences Advisory Board on Military Personnel Supplies (CX 57C). Dr. Labuza was a member of the Food and Drug Administration International Subgroup on Evaluation of BHA (CX 57C). He was co-chairman of the Institute of Food Technology Symposium on Food Safety Risk Analysis in Anaheim, California in 1984 (CX 57C). **[10]**

29. Dr. Labuza has received many honors during his professional career (CX 57A). He received the Outstanding Teaching Award at Massachusetts Institute of Technology in 1970 and the William V. Cruess Institute of Food Technology Teaching Award in 1979. Dr.

Labuza received the Samuel Cate Prescott National Institute of Food Technology Research Award in 1972 (CX 57A). Dr. Labuza was named an Adjunct Professor of Food Law in Hamline Law School in St. Paul, Minnesota (CX 57A).

30. Dr. Labuza is on the editorial boards of several scientific journals including the *Journal of Food Processing and Preservation, Nutrition and Cancer,* and the *Journal of Food Additives and Contaminants* (CX 57D). He is also a peer-reviewer for numerous scientific and technical journals (CX 57F-G). He has published over 100 scientific articles in peer-reviewed journals (CX 57Z-10-Z-18), a number of textbooks in the area of foods and nutrition (CX 57Z-21), and over 40 book chapters and review articles (CX 57Z-22-Z-25).

31. Based on his background, training, experience, and familiarity with the literature, Dr. Labuza is well qualified as an expert in food technology with specialized expertise in food chemistry and food engineering.

Adrianne E. Rogers, M.D.

32. Dr. Adrianne E. Rogers is a leading expert in the field of diet and cancer. She is a physician and Professor of Pathology at Boston University School of Medicine, Boston, Massachusetts (CX 58A-B) and is the Associate Chairman of the Pathology Department (Rogers, Tr. 1330). She graduated from Radcliffe College and from Harvard Medical School (CX 58A-B). She is licensed to practice medicine in Massachusetts and is Board certified in both Anatomic Pathology and Toxicology. The major area of Dr. Rogers' research has been diet and cancer (Rogers, Tr. 1334; CX 58A). She also has an appointment as a Senior Research Scientist at Massachusetts Institute of Technology (CX 58B). Dr. Rogers spends 20% of her time as pathologist at Boston City Hospital and 80% researching and teaching, mainly in the area of diet and cancer (Rogers, Tr. 1339). Dr. Rogers has conducted research concerning the effect of dietary fat, B vitamins, vitamins A and E and selenium on cancer in laboratory animals (Rogers, Tr. 1339).

33. Dr. Rogers is a member of numerous professional societies including the American Institute of Nutrition, the American Association of Pathologists, the Society of Toxicology, the American Association for the Study of Liver Diseases and the New England Society of Pathologists (CX 58C). Dr. Rogers has been a member of a number of major scientific national committees **[11]** including the National Advisory Food Committee of the Food and Drug Administration (CX 58B). She served as a member of the Subcommittee on

Laboratory Animal Nutrition of the Committee on Animal Nutrition of the National Research Council and also for the Animal Resources Advisory Committee of the National Institute of Health (CX 58B), the World Health Organization Task Group on Environmental Health Criteria for Mycotoxins (CX 58B), and a National Institute of Health Study Section in Pathology charged with the responsibility of reviewing research grant applications to the NIH in the area of diet and cancer (Rogers 1346; CX 58B). She was a member of the National Academy of Sciences Panel in the Geochemistry of Fibrous Materials Related to Health Risks. Between 1980-1983, she was a member of the National Large Bowel Cancer Project (CX 58B).

34. Dr. Rogers is on the editorial boards of several scientific journals including *Nutrition and Cancer, Nutrition Research,* and the Franklin Institute Press that publishes books on cancer and nutrition research (CX 58C). She is also a peer-reviewer for *Cancer Research Journal of the National Cancer Institute* (Rogers, Tr. 1353). She has published over 50 peer-reviewed scientific articles mainly in the area of diet and cancer, and over 20 scientific review articles and book chapters in the same area (CX 58D-K).

35. Based upon her background, training and expertise in this area, Dr. Rogers is well-qualified as an expert on the subject of diet, nutrition and cancer with emphasis in the area of experimental carcinogenesis and diet.

B. *Respondent's Witnesses*

Paul Lachance, Ph.D.

36. Dr. Paul Lachance is a professor of nutrition and food science at Rutgers, the State University of New Jersey, and is a recognized expert on the subject of food science and nutrition. *See* RX 197. He has been involved in consultancies to the government, food and pharmaceutical companies, and also designed the nutritional regimen for the U.S. space program.

37. Dr. Lachance holds a Bachelor of Science degree in biology, received in 1955 from St. Michael's College in Vermont and in 1960, a Ph.D. in biology with an emphasis on nutrition from the University of Ottawa. Dr. Lachance also received an honorary degree of doctor of science from his alma mater St. Michael's College in 1982 (RX 197; Tr. 2924-25). Dr. Lachance's studies at Ottawa involved advanced study in the biological sciences, including anatomy, human anatomy, **[12]** physiology, histology, pathology, microbiology, biochemistry and endocrinology (Tr. 2925).

38. Upon completion of his doctorate, Dr. Lachance served in the U.S. Air Force at the Aerospace Medical Research Laboratories and specialized in the areas of nutrition and food, food science and nutrition, food technology and nutrition, and his work provided the basis for testing whether a man could eat under conditions of weightlessness in the space program's Project Mercury (Tr. 2926-28).

39. From 1963 to 1967, Dr. Lachance was the Flight Food and Nutrition Coordinator for NASA at the Manned Spacecraft Center in Houston, Texas. He was the first individual to hold this position and was responsible for establishing the Gemini/Apollo flight food systems. Dr. Lachance also designed the food systems for Skylab and the experiments for Skylab (Tr. 2929-33).

40. At Rutgers University, Dr. Lachance has taught a variety of nutrition and food science courses including "Food and Health;" "Food Science Principles;" "Food Science;" "Nutrition Aspects of Food Processing;" one of the first courses in the country to look at the effect of processing and the preparation of food on nutrient value; and "Nutrition Pathology," an advanced course which deals with pathology problems related to nutrition and the role of nutrition in disease conditions (Tr. 2946-49).

41. Dr. Lachance is a member of the American Institute of Nutrition, American Society for Clinical Nutrition, the leading society in the United States for clinical nutrition, and the American College of Nutrition, to which Dr. Lachance has recently been named a fellow (Tr. 2933-35). Dr. Lachance is also a fellow of the Institute of Food Technologists, an association of professionals concerned with the various phases of food technology, including food processing, food science, food packaging, food manufacturing and other concerns related to the production, manufacture, presentation, chemistry, biology, and physics of food. Dr. Lachance has served as chairman of that committee and was named a fellow in 1982 (Tr. 2934-35).

42. Dr. Lachance also is on the Editorial Board of the *Journal of Medical Consultation* and does peer review for the *American Journal of Clinical Nutrition; Food Technology* and the *Journal of Food Science* among others (Tr. 2939).

43. In 1984, Dr. Lachance was appointed by the U.S. Secretary of Agriculture to the Wheat Industry Council, as a representative of the American Institute of Nutrition. In addition, he serves as a consultant to several groups in the food industry (Tr. 2941-42). **[13]**

44. While he was with the Air Force and NASA, Dr. Lachance was a

liaison member for the NAS/NRC Food Nutrition Board, which periodically publishes the Recommended Dietary Allowances (RDAs) (Tr. 2944).

45. Dr. Lachance has published some eighty-six articles in the field of experimental nutrition and food science, including a chapter on the effects of processing and preparation on the nutritive value of food in "*Modern Nutrition and Health and Disease*," a nutrition textbook (Tr. 2952-54).

46. Some of Dr. Lachance's research and writing has dealt with the nutritional status of the American population, including an "Overview of Current Nutritional Status of the U.S. Population" which includes a summary of the nutritional implications of the food habits, as well as a review of nutrition surveys that have been conducted on a national scale (Tr. 2956-57).

47. On the basis of his education, training and experience, Dr. Lachance is well qualified as an expert in the field of nutrition and food science, with an emphasis on food technology.

Guy R. Newell, M.D.

48. Dr. Guy R. Newell is a physician and a leading cancer epidemiologist. *See* RX 195. From September 1973 until August 1979, he was Deputy Director of the National Cancer Institute and served as Acting Director of the NCI for about 10 months during 1976-1977. While at the National Cancer Institute, Dr. Newell was a strong supporter of the National Academy of Science program, which reviewed the epidemiological and experimental literature dealing with diet, nutrition and cancer and produced the Report "Diet, Nutrition and Cancer" in 1982. Dr. Newell is currently Chairman of the Department of Cancer Prevention and Professor of Epidemiology at the University of Texas System Cancer Center in Houston (Tr. 2618). Dr. Newell holds bachelor's degree and M.D. degrees from Tulane University and Masters of Science degree in Hygiene from Harvard University (RX 195).

49. Dr. Newell is certified by the American College of Preventive Medicine and the American College of Epidemiology. He is licensed to practice medicine in three states: Louisiana, Maryland, and Texas. He was also licensed to practice in Massachusetts during his residence there (Tr. 2623).

50. In his current position, Dr. Newell holds several titles. He is Chairman of the Department of Cancer Prevention (Tr. 2625) and is Professor of Epidemiology at the School of Public Health at the

University of Texas Health Science Center, **[14]** and Professor of Community Medicine in the Medical School of the University of Texas Health Science Center (Tr. 2626-27).

51. Dr. Newell has held a number of prior appointments, including an associate professorship on the faculty of Tulane University, Tulane Medical School and Tulane School of Public Health. While at the National Cancer Institute, Dr. Newell also held several visiting professorships, including the University of Kentucky, the northern California cancer program, the External Scientific Review Committee, Comprehensive Cancer Center in Florida, and the Scientific Review Committee at the Roswell Park Memorial Institute (Tr. 2628-29).

52. Dr. Newell returned to the NCI in 1973 as Deputy Director of the Institute and from 1976 to 1977 served as Acting Director. At the Institute, Dr. Newell directed the Cancer Control Program and also served on the American Cancer Society National Task Force on Uterine Cancer (Tr. 2632).

53. Dr. Newell was also involved in the agent orange issue in which the Texas Department of Health provided counselling along with the research provided by the University of Texas system. Dr. Newell served as chairman of the entire University of Texas System Agent Orange Advisory Committee on researching agent orange (Tr. 2632-33).

54. Dr. Newell represented the United States on a number of international committees, including Japan and the Soviet Union. Dr. Newell was chairman of the delegation which conducted an active program of research cooperation with researchers from Japan, and his counterpart was head of the National Cancer Center of Japan. In addition to these programs, Dr. Newell was active in other joint programs with the Soviet Union and with France (Tr. 2635-36). The U.S.-Japan program, Dr. Newell explained, was fairly heavily involved in nutrition research and drew upon the much more advanced research in Japan on the role of nutrition in human disease (Tr. 2637-38).

55. Dr. Newell is also a member of a number of editorial boards including *The Cancer Bulletin* and *The Texas Health Letter*, and serves as a peer reviewer, and a reviewer of grants while at the NCI (Tr. 2641-42).

56. Dr. Newell was the recipient of numerous awards, including the National Cancer Institute's Research Career Development Award, membership in the American Epidemiological Society, which is a highly prestigious professional society limited to 150 epidemiologists;

and an award from the disabled American veterans for his research on agent orange (Tr. 2643-46). Dr. Newell is program chairman of the American Society of Preventive Oncology, another limited group of 200 investigators who devote their careers solely to the study of preventing malignant diseases, *i.e.*, preventive oncology (Tr. 2646-47). **[15]**

57. With respect to his publications, Dr. Newell testified that all except two deal with the subject of cancer, and almost all deal with using epidemiological techniques to study the cancer problem. Dr. Newell's publications include papers on cancer in the *New England Journal of Medicine.* Some articles dealt with analyzing Hodgkins disease through epidemiological means which suggested that the etiology of the disease lay in a virus, like other diseases which exhibited similar epidemiological characteristics (Tr. 2649-50). Other papers concerned case-control studies on malignant diseases including Hodgkins disease. These case-control studies, Dr. Newell explained, were being used more and more to generate and test etiologic hypotheses for diseases. Others of his studies, Dr. Newell noted, utilized large, existing data bases to provide data for studies and thereby assign values of relative risk based upon already existing data which no one had examined (Tr. 2651-52).

58. Dr. Newell testified to his extensive work in nutrition and cancer, including initial leadership in the program on nutrition and cancer for the National Cancer Institute, which led to the NAS-NRC study and the Report (Tr. 2652-53). Dr. Newell also published numerous articles in peer-reviewed publications on nutrition and cancer, including some in co-authorship with Dr. Weisburger and Dr. Reddy of the Naylor-Dana Institute in New York (Tr. 2654). Much of his writing is aimed at providing practical information to practicing physicians for implementing preventive and therapeutic modes of medicine (Tr. 2655-56). In addition, Dr. Newell has published books and chapters in books on the etiology of cancer, its treatment, and its relationship to nutrition (Tr. 2656-57), including editing two volumes with Dr. Ellison on "Nutrition and Cancer," which gives a comprehensive overview of all aspects of the field. Dr. Newell also authored some of the chapters of those books (Tr. 2657-58).

59. Dr. Newell's responsibilities at the Preventive Medicine Clinic include seeing patients, which currently encompasses AIDS patients. Dr. Newell is also involved in a chemoprevention trial designed to prevent squamous metaplasia in which retinol (vitamin A) is being used (Tr. 2662-63).

60. Dr. Newell is a leading cancer epidemiologist with a strong interest in preventive oncology and is well qualified to interpret the Report of the Committee in terms of its findings and recommendations and to evaluate the evidence contained in the Report.

Raymond J. Shamberger, Ph.D.

61. Dr. Raymond J. Shamberger is a well-known research scientist on the subject of vitamins and cancer, and particularly **[16]** on selenium and vitamin E as antioxidants. *See* RX 196. His pioneering work on selenium in particular, but also vitamins A, C, and E, performed over the last two decades, was cited numerous times in the Report of the Committee as well as in the Bibliography (RX 204).

62. Dr. Shamberger is currently section head of enzymology at the Cleveland Clinic Foundation. His current work includes diagnostic work in enzymology as well as research on tumor markers and enzymes as antioxidants (Tr. 2189). His current work is based upon his earlier work with selenium and vitamin E and cancer (Tr. 2189).

63. Dr. Shamberger's research on vitamins and cancer began in 1964-1969, at the Roswell Park Memorial Institute in Buffalo, where he was a senior research scientist (Tr. 2191). At the time, he worked with antioxidants, including vitamin E and selenium, which appeared to markedly retard skin cancer induced by certain carcinogens (Tr. 2192). Dr. Shamberger described this work on selenium and vitamin E as "the pioneering effort" in relating these substances to cancer prevention (Tr. 2193). In addition to these nutrients, Dr. Shamberger also performed research on vitamin A which was successful in preventing skin cancer in mice (Tr. 2193). Dr. Shamberger also did work with vitamin C, and found that vitamin C too retarded the cancer process in animals (Tr. 2193). Other scientists have built on Dr. Shamberger's selenium research. According to Dr. Shamberger, there have been about 30 or 40 subsequent papers showing that dietary selenium prevented several different types of cancer induced in animals (Tr. 2194). He also published books on the biochemistry of selenium, and nutrition and cancer (Tr. 2199).

64. Dr. Shamberger currently teaches clinical chemistry and biochemistry at Cleveland State University as a professor and guides the research of graduate students (Tr. 2200).

65. Dr. Shamberger's professional activities include the American Institute of Biological Sciences (Tr. 2202) and the Federation of American Societies for Experimental Biology. Dr. Shamberger is also a member to the American College of Nutrition (Tr. 2205).

66. Dr. Shamberger is also a member in a number of professional organizations which are required for work in his area, including the National Registry in Clinical Chemistry, and the American Boards in Clinical Chemistry (Tr. 2213).

67. Dr Shamberger has acted as a peer-reviewer for *Cancer Research, Journal of the National Cancer Institute, Federation Proceedings, Nutrition and Cancer, American College of Nutrition,* as well as about 15 other individual journals over the years (Tr. 2208-09). **[17]**

68. Dr. Shamberger's publications include the field of diet and cancer, and span both experimental and human epidemiological studies, including studies on selenium, general diet, vitamin E, vitamins A and C, antioxidants, trace metals, the B vitamins, cadmium, zinc in carcinogenesis, chromosome breakage, peroxidation and other cancer-related phenomena. Some are publications which evolved out of meetings of national and international organizations to which Dr. Shamberger was invited to present his own work. Others review the work of other scientists as well (Tr. 2217-35).

69. Among Dr. Shamberger's presentations was his presentation at a conference in Helsinki on selenium demonstrating the relationship between low selenium levels and high heart disease and cancer death rate (Tr. 2229-30). In 1980, Dr. Shamberger was invited to give a presentation before the National Cancer Institute where he reviewed his findings on selenium and vitamin E and their relationship to cancer (Tr. 2230). In 1984, Dr. Shamberger was invited to a conference in Sweden to discuss his epidemiological work with selenium and cancer.

70. Dr. Shamberger's work is cited in the Report of the Committee (JX 1) six times in the section on minerals and two times in the section on vitamins, and in the Bibliography, six times in the mineral section and once in the vitamins section (Tr. 2236).

71. Dr. Shamberger is a qualified expert on the subjects of nutrition and cancer with specialized knowledge in selenium and vitamins.

Ronald W. Thompson, Ph.D.

72. Dr. Ronald W. Thompson is Director of Nutrition Education at General Nutrition Corporation. Dr. Thompson is a trained nutritionist. *See* RX 199. Dr. Thompson assumed his position at GNC in 1979 as consultant, scientist and nutrition expert who reviews information in the literature for translation and dissemination to the public, and who reviews product and product advertising (Tr. 1796). His CV is contained in RX 199.

73. Dr. Thompson received a Ph.D. degree in nutrition from Rutgers University in New Jersey, and his thesis subject studied zinc deficiency and skin and connective issue metabolism. In addition, Dr. Thompson has a Masters degree in animal science from Rutgers. Both the masters and Ph.D. programs encompassed courses in nutrition.

74. Dr. Thompson received from the University of Alabama School of Medicine a departmental fellowship in post-doctoral **[18]** research in nutritional biochemistry (Tr. 1803) and a post-doctoral fellowship from the Public Health Service Department of Digestive Metabolism.

75. Dr. Thompson also served as a consultant at the University of South Alabama School of Medicine, Department of Pediatrics, where he developed a clinical laboratory for nutritional assessment (Tr. 1805). Dr. Thompson also held a teaching position at the medical school of the University of Alabama at Birmingham and taught a section on the nutritional requirements of pregnancy, lactation and early childhood development (Tr. 1807). In addition, Dr. Thompson taught courses in nutrition at the School of Education in Birmingham and supervised graduate student research for master's degree dietician candidates.

76. Dr. Thompson has published a small number of scientific papers in the area of nutrition, including a study on protein intake and skin and muscle metabolism and a study on the role of zinc as a nutrient involved with connective tissue. In other studies, Dr. Thompson investigated folic acid and its pathways of use by the body in response to alteration in protein ingestion, one of which appeared in the *American Journal of Clinical Nutrition,* a peer-reviewed journal (Tr. 1810-11). Dr. Thompson also received a grant from the Department of Agriculture to produce a survey of vitamin content in foods which was reported in a Handbook published by the United States Department of Agriculture (Tr. 1812-13). Dr. Thompson has also presented papers at the "FASEB" Society of Experimental Biologists in the nutrition section (Tr. 1813).

77. Dr. Thompson keeps up to date on the scientific literature, and regularly reviews *Lancet, American Scientist,* and the *American Journal of Clinical Nutrition.* Dr. Thompson also searches for scientific articles of interest in a computer data base, and at the University of Pittsburgh medical library (Tr. 1819).

78. As respondent's resident expert on nutrition, Dr. Thompson gave testimony regarding the information and findings of the Report and the conclusions drawn therefrom with respect to the claims respondent made for Healthy Greens.

III. MARKETING AND ADVERTISING OF HEALTHY GREENS TABLETS

79. GNC, with 1983 sales of over $350 million (CX 71A), is a major seller of vitamins and food supplement products (*see* CX 54F-J). In that year, it operated over 1,100 company-owned stores in the United States and Canada through its "General Nutrition Centers" and other retail sales outlets (CX 71A). In **[19]** addition to its retail outlets, it also operated a mail order division (CX 71B).

80. GNC sold Healthy Greens tablets in stores throughout the United States and the District of Columbia from approximately June 1983 through January 1984, for a period of about six months. The total sales of the tablets were approximately 20,000 bottles through retail outlets and 4,000 bottles through mail order; the price ranged from $8.99 to $12.99 per bottle. Thus, sales were approximately $216,000-$312,000. Healthy Greens tablets were withdrawn from the market before the Commission began a formal complaint proceeding.

81. Advertising for Healthy Greens tablets was extensive until the product was withdrawn from the market between December 1983 and January 1984 (JX 2; Stipulations 6, 8, 9, 10 and 12).

82. Exhibits CX's 1-7 are copies of GNC's advertising and promotional material for Healthy Greens tablets (JX 2A, Stipulation 1). CX's 1-3 are ads for the tablets that ran in various magazines and newspapers throughout the United States in the summer of 1983 (CX 60A-B). CX 4 is a mail order catalog ad, and CX 5 is an ad which accompanied mail-order shipments of other products (CX 60A-B). CX 6 is a "store bag stuffer" pamphlet which was distributed by GNC to its 1,100 retail stores throughout the United States where it was distributed to customers (CX 60B; JX 2A-B, Stipulation 2). CX 7 is a point-of-purchase poster that was used in GNC's retail stores throughout the United States (CX 60B).

IV. MEANING OF HEALTHY GREENS ADVERTISEMENTS

A. *Standards For The Determination Of The Meaning Of Advertisements*

83. In determining whether an advertisement made a particular representation, the appropriate standard is whether, taking the advertisement as a whole, the representation constitutes a reasonable interpretation of the advertisement. The question is whether the representation at issue is a reasonable interpretation of the advertisement to which some consumers acting reasonably under the circum-

stances are likely to adhere to. Since more often than not several reasonable interpretations of a given advertisement are possible, it is not necessary that the claim which is found to have been made be the only or the most reasonable interpretation of the advertisement. *See Thompson Medical Company, Inc.*, 104 FTC 648, 788-89 (1984), *appeal filed*, 85-1047 (D.C. Cir. Jan. 18, 1985); FTC Enforcement Policy, Deceptive Acts and Practices, **[20]** 5 Trade Reg. Rep. (CCH) ¶ 50,455 at 56,074 ("FTC Enforcement Policy Statement").

84. The evidence with respect to the meaning of Healthy Greens advertisements in the record consists entirely of the advertisements themselves (CX's 1-7). The advertising claims alleged in the Complaint include both express and implied claims.

85. With respect to implied claims, they are not directly stated in the advertisement. In such cases, in the absence of extrinsic or secondary evidence, such as testimony of expert witnesses and consumer surveys, it is appropriate, based on the net impression of the advertisement as a whole, to conclude that it contains an implied claim after evaluating the content and layout of the advertisement and the circumstances surrounding it. Both express and implied claims are representations for which an advertiser is responsible and are subject to the same standards of accuracy and adequate substantiation. *See Thompson Medical Co.*, 104 FTC at 788-90; FTC Enforcement Policy Statement, 5 Trade Reg. Rep. at 56,074.

86. Elements of an advertisement that contribute to the net impression, and so to the representations conveyed, include the headline, general tone, the presence or absence of elements contradicting a general impression or tone, the interaction of all the different elements, and the juxtaposition of phrases within an advertisement. *See Thompson*, 104 FTC at 789, 793, 799-800; *Cliffdale Associates, Inc.*, 103 FTC 161, 176 *appeal dismissed sub nom. Koven v. FTC*, No. 84-5337 (11th Cir. Oct. 10, 1984). In cases where these elements of an advertisement are sufficiently clear to conclude with confidence that consumers acting reasonably under the circumstances are likely to interpret that advertisement to convey a particular claim, no evidence other than the advertisement itself is necessary in order to find as a matter of fact that that representation was made.

87. When an advertisement "conveys more than one meaning to reasonable consumers, one of which is false, the seller is liable for the misleading interpretation." FTC Enforcement Policy Statement, *supra*, at 56,074. Similarly, "[a] secondary message understood by reasonable consumers is actionable if deceptive." *Id.*, n. 21.

B. *Respondent Made The Representations Alleged In The Complaint*

88. Each of the representations set forth in the complaint is made by GNC in its advertising for Healthy Greens. The record evidence establishes clearly that each advertisement, when examined as a whole for its net impressions, conveys one or more **[21]** of the challenged representations to some consumers acting reasonably under the circumstances. *Thompson Medical Co.*, 104 FTC at 790 and 793, n. 17; *Bristol Myers*, 102 FTC 21, 320 (1983), *aff'd*, 738 F.2d 554 (2nd Cir. 1984), *cert. denied*, 105 S. Ct. 960 (1985).

(1) The representation that the findings of the National Research Council's *Diet, Nutrition and Cancer* Report support the claim that use of Healthy Greens, or food supplements of dehydrated vegetables such as Healthy Greens, is associated with a reduction in the incidence of certain cancers in humans (Complaint ¶ 7(a)).

89. General Nutrition has represented impliedly that the findings of the National Research Council (NRC) Report entitled "*Diet, Nutrition and Cancer*" support the proposition that use of Healthy Greens, or food supplements of dehydrated vegetables such as Healthy Greens, is associated with a reduction in the incidence of certain cancers in humans. Each and every one of the Healthy Greens advertisement, promotional letter and point of purchase literature in the record (CX's 1-7) conveys that net impression.

90. For example, CX 1 shows in the upper half of the page a picture of vegetables such as cabbages, carrots, cauliflower, brussels sprouts and some leafy greens. Above the picture, a question is printed in large letters:

What do these vegetables have to do with cancer?

The textual material printed in smaller letters in the lower half of the page states in part:

They may help reduce your risk of developing it, says the National Research Council. Their report on diet, nutrition and cancer, written by request of the American Cancer Society states "It should be made clear that the weight of evidence suggests that what we eat during our lifetime strongly influences the possibility of developing certain types of cancer."

The committee's dietary recommendations include increasing the amounts of green

cruciferous vegetables (broccoli, brussels sprouts, cabbage, cauliflower) and those rich **[22]** in beta-carotene (spinach and carrots) among other food items. These vegetables seem to contain nutritional factors that encourage and enhance our natural defenses against cancer.

Additionally, research is continuing into the benefits of reducing cancer risk with regular use of vitamins A, C, E and selenium with which Healthy Greens are fortified.

Then comes the following statement:

THE HEDGE AGAINST CANCER. Healthy Greens is brand new! And each tablet gives you exactly what the name implies—your daily dose of healthy greens! In convenient tablet form. And judging from the NRC study for the National Cancer Institute just possibly your best hedge against cancer. There is no guarantee against cancer...but it is foolish not to give your health every chance you can.

91. A clear net impression of CX 1 as a whole is that the National Research Council Report on diet, nutrition and cancer recommends increasing the amounts of green cruciferous vegetables (broccoli, brussels sprouts, cabbage, cauliflower) and those rich in beta-carotene (spinach and carrots) as a means of enhancing our defense against cancer, and that Healthy Greens gives us our daily dose of healthy greens in tablet form, and that according to the NRC study, Healthy Greens may be the best hedge against cancer.

92. Another clear net impression of CX 1 is the secondary message that Healthy Greens is better than eating vegetables because it is further "fortified" with vitamins A, C and E and a mineral which researchers are looking into for benefits of reducing cancer risk.

93. CX 2 is headlined by the following:

SPECIAL REPORT—CANCER

NEW STUDY REQUESTED BY THE AMERICAN CANCER SOCIETY REVEALS HOPE FOR PREVENTION OF CANCER! **[23]**

The ad goes on to state in part as follows:

Two years ago, when the National Research Council, at the request of the American Cancer Society, launched a study to see if a link existed between diet, nutrition and cancer, researchers had no idea what they would find. One of the most startling revelations in the report seemed to bear out the original theory of the diet-cancer link. The report states "It should be made clear that the weight of evidence suggests that what we eat during our lifetime strongly influences the possibility of developing certain types of cancer.

Researchers also found that some vegetables may be key weapons in the prevention

of cancer. The study indicates that two types of vegetables seem to enhance our natural defenses against cancer. They are cruciferous vegetables (cabbage, brussels sprouts, cauliflower, and broccoli) and vegetables that contain large amounts of beta-carotene (spinach, carrots).

The exciting news is that Healthy Greens (now available from General Nutrition) is made from these six important vegetables. Healthy Greens, which come in tablet form, are also fortified by vitamins A, C, and E, the mineral selenium, and they contain an extra portion of beta-carotene. Research is now under way to determine the full benefits of these nutritional factors. Although the final results are not in, early reports indicate they play important roles in reducing the risk of cancer.

The American Cancer Society estimates that cancer will strike one American in three. By taking Healthy Greens you may reduce your chances of getting cancer. There is no guarantee, of course, that any diet, even one including Healthy Greens, will eliminate all risk of cancer. But, the evidence is coming in, and all points to Healthy Greens as being an important ingredient to your well being, and that of your family and friends. **[24]**

94. The overall net impression of CX 2 is that an important government study requested by American Cancer Society found that some cruciferous vegetables (such as cabbage, brussels sprouts, cauliflower and broccoli) and vegetables that contain large amounts of beta-carotene (spinach and carrots), are key weapons in the prevention of cancer, that Healthy Greens tablets are made of these six important vegetables, and that by taking Healthy Greens tablets we can reduce chances of getting cancer, which will strike one American in three.

95. A secondary message conveyed by CX 2 is that Healthy Greens tablets are also fortified by vitamins A, C and E, a mineral selenium and extra beta-carotene, which early research indicates they play important roles in reducing the cancer risk in humans.

96. CX 3 poses the following question on the top of the ad in bold type:

> CAN THESE 60 TABLETS WITH 6 VEGETABLES AND 5 NUTRIENTS HELP REDUCE THE RISK OF CANCER?

The ad says:

> READ ON.... Maybe Mom was right after all...

The ad goes on to state in part as follows:

Well after two years an important government study has reported a series of recommendations that show strong evidence that what we eat during our lives does in

fact influence the chances of developing certain types of cancer. This important U.S. government study (requested by the National Cancer Institute) recommended we increase among other things our amounts of specific vegetables to help safeguard our bodies against the risk of certain forms of cancer. These vegetables recommended by the *National Cancer Institute* commissioned study are the ones we should increase cabbage, brussels sprouts, cauliflower, broccoli, carrots and spinach. Mom Was Right. Now you say that's great but just maybe I don't want to be a rabbit or maybe I don't like cabbage, cauliflower or spinach so what can I do? **[25]**

Research scientists and technicians at General Nutrition Labs realizing the importance of the research instantly went to work to harness all of the vegetables and combined all of them into a natural easy to take potent tablet. But wait, our scientists did not just stop there, they also fortified these tablets with vitamins C, E and A selenium and beta-carotene—the result is Healthy Greens a new potent breakthrough in nutrition that millions of people can now help safeguard their well-being with. The greens that the National Research Council recommends we eat more of. Naturally there is no guarantee against cancer and Healthy Greens is not a cancer cure but there is good sense in decreasing risks.

The above textual material is placed between what appears to be a drawing of carrots, cauliflower and some leafy vegetables and a picture of Healthy Greens bottle and some half a dozen loose tablets.

97. The clear net impression of CX 3 as a whole is that an important U.S. government study commissioned by the National Cancer Institute recommended that we increase cabbage, brussels sprouts, cauliflower, carrots and spinach in our diet, that General Nutrition Labs research scientists have harnessed all of these vegetables into tablets and fortified them with vitamins C, E and A, selenium and beta-carotene, and that by taking Healthy Greens we will be eating the greens that the National Research Council recommends we eat more of and thus be reducing the chances of developing certain types of cancer.

98. A secondary message of CX 3 is that Healthy Greens tablets are fortified with vitamins A, C and E, selenium and beta-carotene and as a result Healthy Greens is a new breakthrough in nutrition that everyone can take to decrease cancer risks.

99. CX 4 is very much like CX 3 in content and layout and conveys the same messages discussed in connection with CX 3.

100. CX 5, a promotional letter for Healthy Greens which accompanied mail-order shipments of other products, conveys the same messages as in CX's 2, 3 and 4. CX 5 states in part:

CAN OUR ALL NEW HEALTHY GREENS WITH SIX VEGETABLES AND FIVE NUTRIENTS HELP YOU REDUCE THE RISK OF CANCER.....READ ON. **[26]**

WELL, AFTER TWO YEARS...AN IMPORTANT GOVERNMENT STUDY HAS REPORTED A SERIES OF RECOMMENDATIONS THAT SHOW STRONG EVIDENCE, THAT WHAT WE EAT DURING OUR LIVES DOES IN FACT INFLUENCE THE CHANCES OF DEVELOPING CERTAIN TYPES OF CANCER. THIS IMPORTANT GOVERNMENT STUDY REQUESTED BY THE NATIONAL CANCER INSTITUTE SAID IT RECOMMENDS WE INCREASE AMONG OTHER THINGS OUR AMOUNTS OF SPECIFIC VEGETABLES TO HELP SAFEGUARD OUR BODIES AGAINST THE RISKS OF CERTAIN FORMS OF CANCER. THEY ARE CABBAGE, BRUSSELS SPROUTS, CAULIFLOWER, BROCCOLI, CARROTS, AND SPINACH.....MOM WAS RIGHT.

REALIZING THE IMPORTANCE OF THIS STUDY, WE TOOK ALL THESE VEGETABLES, AND COMBINED ALL OF THEM INTO POTENT EASY TO TAKE TABLETS CALLED HEALTHY GREENS. WE ALSO FORTIFIED THEM WITH VITAMINS C, E, AND A PLUS SELENIUM AND BETA-CAROTENE. ...HEALTHY GREENS IS THE EASY WAY TO GET THE GREENS YOU NEED. MOM SAID EAT YOUR VEGETABLES AND NOW SCIENCE HAS PROVEN HER RIGHT. ORDER YOUR HEALTHY GREENS NOW....

This letter as a whole clearly suggests that an important government study requested by the National Cancer Institute recommends we increase the amounts of cabbage, brussels sprouts, cauliflower, broccoli, carrots and spinach in our diet to help safeguard our bodies against the risks of certain cancers, that GNC combined all of them into Healthy Greens tablets, and that Healthy Greens is the easy way to get the greens we need to protect us from certain cancers.

101. CX 7 is a point of purchase literature and highlights an important government study which points the way to reduce cancer risk:

VITALLY IMPORTANT GOVERNMENT STUDY: DIET, NUTRITION AND CANCER points the way for you to reduce cancer risk.

This is followed later in the text by another equally bold headline:

ULTIMATE NUTRITION SUPPLEMENT—HEALTHY GREENS. [27]

It also suggests that Healthy Greens is an easy-to-take tablet which combines all the vegetables recommended by the government report and taking it is a convenient way of ingesting all the good vegetables and nutrients which scientists say can reduce cancer risks in humans.

102. CX 7 also contains a secondary message that Healthy Greens is not only made of all the vegetables recommended by the government report on diet, nutrition and cancer but also is a multi-

vitamin supplement which will provide greater protection than vegetables alone.

103. CX 6 contains almost identical textual matter as in CX 7 and conveys like messages as in CX 7.

104. Typically, a reader of these advertisements is told first that the National Research Council report on diet, nutrition and cancer recommends we eat more broccoli, brussels sprouts, cabbage, cauliflower, spinach and carrots to safeguard ourselves against the risk of certain cancers. The reader is then told that the General Nutrition scientists have successfully combined all of the vegetables into easy-to-take tablets and fortified them with vitamins C, E and A, selenium and beta-carotene. The reader is then told that by taking Healthy Greens tablets everyone can now protect one's health with the greens that the National Research Council recommends we eat more of. When viewed as a whole, the net impression of such an advertisement is clearly that the NRC report on diet, nutrition and cancer supports the use of Healthy Greens tablets, or any tablets of similar formulation, as a means of reducing the risk of certain cancers.

(2) The representation that the use of Healthy Greens is associated with a reduction in the incidence of certain cancers in humans (Complaint ¶ 7(c)).

105. General Nutrition has represented impliedly that the use of Healthy Greens is associated with a reduction in the incidence of certain cancers in humans in each of the Healthy Greens advertisement discussed in (1) hereinabove (F. 90-103, *supra*). The net impression of an advertisement which says that Healthy Greens tablets are made up with all the vegetables, which an important government report recommends we eat more of in order to safeguard our bodies against the risks of certain cancers, and is further fortified with vitamins and minerals, is clearly that taking Healthy Greens will help reduce the risks of certain cancers. Such advertisements include CX's 1-7. **[28]**

(3) The representation that research indicates that vitamin E plays an important role in reducing the risk of cancer (Complaint ¶ 7(b)).

106. General Nutrition has expressly represented in CX 2 that research indicates that vitamin E is one of the nutrients which play important roles in reducing the risk of cancer. CX 2, after referring to vitamins A, C and E, selenium and beta-carotene, further states:

Although the final results are not in, early reports indicate they play important roles in reducing the risk of cancer.

107. Respondent appears to contend that none of its Healthy Greens ad singled out vitamin E and said it plays an important role and that every single reference found in these ads was in a collective reference to vitamins A, C and E, a mineral selenium and beta-carotene. Respondent asserts that to interpret these collective references to mean what is alleged in Complaint Paragraph 7(b) is an unreasonable distortion of these ads (RPF at 15-18). The critical question, however, is whether the claim alleged in Complaint Paragraph 7(b) is *a* reasonable interpretation of CX 2 which some consumers acting reasonably are likely to form on the basis of their net impression. If it is, then the fact that the claim may not be the principal or focal point of the advertisement as a whole does not alter the ultimate conclusion that CX 2 did contain the alleged representation.

(4) The representation that vitamin E plays an important role in reducing the risk of cancer (Complaint ¶ 7(d)).

108. The express statement made in CX 2 and quoted in the preceding Finding also represents by implication that vitamin E plays an important role in reducing the risk of cancer as alleged in Complaint Paragraph 7(d).

109. Various references to research into the cancer-prevention benefits of certain vitamins, including vitamin E, are also contained in several other Healthy Greens advertisements. They include CX's 1, 4, 6 and 7. None of them, however, suggests that research indicates that vitamin E plays an important role (as alleged in Complaint Paragraph 7(b)) or that vitamin E plays an important role (as alleged in Complaint Paragraph 7(d)), in reducing the risk of cancer. It is not likely that any of CX's 1, 4, 6 or 7 will convey to a reasonable consumer the **[29]** impression that research indicates that vitamin E plays an important role. The most that can be said is that each of CX's 1, 4 and 6 conveys a net impression that research indicates vitamin E plays a role or some role in reducing the cancer risk.

(5) The claim that respondent processed and relied on a reasonable basis to substantiate the claims listed in Complaint Paragraphs 7(c) and (d) (Complaint ¶ 10).

110. When respondent made the product claims alleged in Complaint Paragraphs 7(c) and (d), respondent, by virtue of that fact and

as a matter of law, also represented that it possessed and relied upon a reasonable basis for these claims. *E.g., Thompson Medical Company, Inc.*, 104 FTC at 813, *appeal filed*, No. 85-1047 (D.C. Cir., January 18, 1985); *Porter and Dietsch, Inc.*, 90 FTC 770, 866 (1977), *aff'd*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980). And, the rationale for the reasonable basis requirement in advertising regulation is more compelling in cases where, as here, the claim involves important health issues. *Thompson, supra*, at 822. Here, respondent's claims involved reduction in risk of cancer, a chronic and dreaded disease.

111. It is well-established that when an advertiser implies in its ads that it has a certain level of support for its claims, it represents that its reasonable basis consists of that level of substantiation. *Thompson, supra*, at 813.

112. Healthy Greens advertisements prominently and conspicuously cite one scientific source for its claims and that source is the Report. It is referred to in numerous ways within each ad. It is called among other things: "the Committee's dietary recommendations" (CX 1), "the NRC study for the National Cancer Institute" (CX 1), an "important U.S. government study (requested by the National Cancer Institute)" (CX's 3-5), "the National Cancer Institute commissioned study" (CX 3), the "vitally important government study: Diet, Nutrition and Cancer" (CX's 6-7), "NRC Committee" (CX's 6-7), and the "recommended dietary guidelines of the National Research Council" (CX's 6-7).

113. Each Healthy Greens ad focuses on the Report and uses it as a means of bolstering the credibility of the claims being made for Healthy Greens tablets and, indeed, as the very reason for introducing Healthy Greens tablets. In these circumstances, a reasonable consumer cannot but conclude that GNC relies on the Report to substantiate its claims. Thus, the conclusion is inescapable that at least one net impression conveyed by Healthy Greens ads is that GNC's reasonable basis consists of the Report. **[30]**

114. The Healthy Greens ads also make a more general representation that the substantiation supporting the claims consists of competent and reliable scientific evidence generally accepted by the scientific community as proving the claims. *See Thompson, supra*, at 813-14. As was the case in *Thompson*, this representation flows from the ads' references to scientific reports and research that suggest that GNC's claims are supported by a certain level of scientific evidence which is generally accepted by the scientific community.

115. Specifically, GNC invoked the name of the American Cancer Society as the Report's sponsoring organization (CX's 1-2), the National Cancer Institute and the National Research Council (CX's 6-7). It has characterized the Report in terms such as a "vitally important government study" (CX's 6-7). In CX's 3-5, GNC itself vouches for the importance of the Report. (For instance, CX's 3-4 state that "Research scientists and technicians at General Nutrition Labs realiz[ed] the importance of [this] research.") And, GNC also has enhanced these references to the Report and prestigious scientific organizations and studies, with further references to additional scientific proof supporting the claims for the tablets. (For example, CX's 3-4 state that the tablets were developed by GNC research scientists.)

116. In short, through references to the Report, as well as to renowned scientific organizations and scientific research and studies, each ad represented that GNC possessed scientific evidence generally accepted by the scientific community as proving the claims.

V. THE CLAIMS IN COMPLAINT PARAGRAPHS 7(a) AND (b) ARE FALSE

A. *The Report Does Not Support The Use Of Healthy Greens*

117. The Healthy Greens tablets contain dehydrated vegetable matter along with the following nutrients: vitamins A, C, and E; beta-carotene; and the mineral selenium (CX 8). Neither the dehydrated vegetable content nor the nutrient content allows a claim that the Report supports the use of the tablets to reduce the risk of cancer in humans. Accordingly, the representation that the findings of the Report support the claim that the use of Healthy Greens, or food supplements like Healthy Greens, is associated with a reduction in the incidence of cancer in humans, is false. **[31]**

(1) The NRC Committee Report Does Not Support The Use Of Healthy Greens On The Basis Of The Inclusion In The Tablets Of Approximately 500 Mg. Of Dehydrated Vegetables In Its Formulation.

118. GNC sold Healthy Greens to the public as an "easy way" to consume the vegetables recommended by the Report in order to reduce the risk of cancer (*see, e.g.*, CX's 3-4). Thus, the ads clearly suggested that Healthy Greens' vegetable content rather than its nutrient content, was the source of the tablet's claimed benefits.

119. The evidence shows that the Healthy Greens tablet contains only about 500 mg. of dehydrated vegetable matter (CX 9), or $1/16$ of a serving of whole vegetables (Labuza, Tr. 1172, 1174-76). As one GNC company official admitted, such an amount is equivalent to only a "teaspoon" or "tablespoon" of vegetables (Thompson, Tr. 2122). In any event, it is only a negligible amount of dehydrated vegetable matter (Campbell, Tr. 571-72) and cannot be reasonably expected to offer any meaningful benefit as a component of cancer prevention diet. Indeed each Healthy Greens tablet contains only about two calories and is so insignificant as to have any effect on the diet (Campbell, Tr. 677). Respondent does not seriously dispute these conclusions. It did not offer any testimony to show that the amount of dehydrated vegetable matter is large enough to provide any significant benefits.

120. Furthermore, the small amount of vegetable matter found in the tablet is also structurally and chemically different from the same foods before dehydration or the same foods processed other ways (Labuza, Tr. 1214, 1224-25). This is important because the vegetable studies reviewed by the Committee did not involve dehydrated vegetables (*see* Campbell, Tr. 659; Grobstein, Tr. 523), and the vegetable matter in Healthy Greens was dehydrated using the air-dried process, which is said to be among the most destructive methods of processing foods (Labuza, Tr. 1224-25).

121. More specifically, there are thousands of chemical constituents in whole vegetables (Campbell, Tr. 662, 784; Rogers, Tr. 1393-94), many of which have not yet been identified (Lachance, Tr. 3000). Some of these unidentified constituents in the vegetables, individually or in conjunction with other constituents of vegetables, may account for the protective benefit associated with the consumption of vegetables. Since that is the case, and since dehydration significantly alters food, it is impossible at present to determine whether the constituents remain or retain their protective properties after dehydration (Labuza, Tr. 1228-30). Thus, the current scientific information does not support a claim that taking a tablet made of **[32]** dehydrated vegetables gives the same benefits that eating whole vegetables would.

122. Also, nowhere does the Report mention dehydrated vegetables as providing any benefits against cancer. And the studies cited in the Report do not deal with dehydrated vegetables (Campbell, Tr. 659). Therefore, the Report does not provide substantiation for the claim

that the minuscule amount of dehydrated vegetable matter incorporated into Healthy Greens tablets reduces risk of cancer. Thus, the dehydrated vegetable component of Healthy Greens has no bearing on any issues in this proceeding.

(a) The NRC Report Does Not Support The Use Of Healthy Greens Tablets As A Multivitamin Dietary Supplement

123. As determined in F. 104, *supra*, the principal message of Healthy Greens ads is the claim that Healthy Greens is a convenient or easy alternative to eating the recommended vegetables. However, these ads contained a secondary claim that Healthy Greens offered cancer prevention benefits because they were fortified with vitamins A, C, and E, beta-carotene and the mineral selenium in addition to the vegetable matter.

124. To the extent that the challenged claims were based on the role of the individual nutrients, however, the language of the Report clearly does not support the use of Healthy Greens on the basis of the varying amounts of vitamins A, C, E, beta-carotene and the mineral selenium.

125. Respondent's expert witnesses, Dr. Newell and Dr. Shamberger, testified that the Report did not mean to exclude supplements such as Healthy Greens or, alternatively, that the scientific evidence the Report reviewed in the body of the Report did not, in their view, justify exclusion of dietary supplements from the Report's recommendation (*see, e.g.*, RPF at 188-190). Neither view is supported by the Report. The Report is entirely unambiguous on this point. Nowhere does the Report recommend the use of dietary supplements of nutrients such as Healthy Greens. On the contrary, it specifically states that its recommendations apply only to foods and not to nutrients or supplements (JX 1, p. 15). Further, the Report concludes that there is insufficient evidence to state that nutrients will reduce the risk of cancer in humans (JX 1, p. 11).

126. The Report consists of several chapters discussing the evidence concerning various aspects of diet and cancer (JX 1). The Executive Summary is a condensation of the salient evidence and essential findings of the entire Report **[33]** (Campbell, Tr. 669). It summarizes the literature, draws conclusions about that literature and recommends interim dietary guidelines based on these conclusions.

127. In the section where its dietary recommendations relating to vegetables appear (the section which GNC repeatedly referred to in its advertisements), the Report states clearly and simply that:

These recommendations apply only to foods as sources of nutrients—not to dietary supplements of individual nutrients (JX 1, p. 15).

Respondent's witnesses characterized Healthy Greens as a multivitamin supplement or a dietary supplement of individual nutrients (Thompson, Tr. 2126; CX 8). Therefore, the Report's recommendations do not apply to Healthy Greens, and it is clear that the Report does not support the use of Healthy Greens (Campbell, Tr. 651-52; Rogers, Tr. 1400-01).

128. Further, the Report concluded that there is insufficient evidence that individual nutrients reduce the risk of cancer in humans (JX 1, p. 11; Campbell, Tr. 651-52). The literature examined by the Report focused on the consumption of *foods* and the incidence of cancer. The Report itself states, "there is very little information on the effects of various levels of individual nutrients on the risk of cancer in humans" (JX 1, pp. 11-15).

129. Respondent's witnesses, Dr. Newell and Dr. Shamberger, testified in effect that the NRC Committee's decision to exclude dietary supplements from its recommendations was not a scientific decision but a public policy decision stemming from its fear of toxicity problems resulting from indiscriminate overdosing of supplements by consumers and that this exclusion was not meant to apply, or should not apply, to Healthy Greens because the product involves dose levels which pose only minimal toxicity risks while offering demonstrated benefits (*See* RPF at 185-96). These arguments cannot be reconciled with the clear and straightforward statements of the Report excluding dietary supplements from its recommendations. Thus, any opinion testimony that the Report supports the use of supplements such as Healthy Greens is not persuasive.

130. The NRC Report did find that a number of non-nutritive and nutritive compounds present in vegetables appear to inhibit carcinogenesis in laboratory animals (JX 1, pp. 11, 366). However, the Report also states that such findings provide testable hypotheses regarding specific components of a diet in humans (JX 1, pp. 1-3), and an hypothesis requires further **[34]** research to be confirmed (Campbell, Tr. 665-66; Rogers, Tr. 1657-58).

131. The Report makes clear that the epidemiological data are not sufficient to permit a definition of the individual roles played by each of these putative inhibitors (JX 1, pp. 11, 366). Investigators have not yet established which, if any, of these compounds may be responsible

for the protective effect of vegetables and fruits observed in humans (JX 1, pp. 11, 15).

132. The Report notes that part of the difficulty in assessing the impact of individual dietary components of a food on carcinogenesis is that any protective benefit may be due to more than one component. Nutritive and non-nutritive components of foods may interact to exert effects on cancer incidence (JX 1, p. 3). The Report also states that the data with respect to cruciferous vegetables (*e.g.*, broccoli) underscore the fact that it will be difficult for epidemiologists to determine which specific nutrients in food affect cancer:

> For example, the constituents of cruciferae responsible for their apparent effect on the occurrence of cancer may be, as Chapter 15 suggests, indoles, isothiocyanates, or other non-nutritive substances demonstrated to affect carcinogenesis in the laboratory. But it is not yet possible to attribute the epidemiological associations to any such substances simply because of the simultaneous presence in these vegetables of such other constituents as fiber, beta-carotene, ascorbic acid, or calcium (JX 1, p. 62).

133. Dr. Shamberger, respondent's expert witness, agreed that nine or more constituents in foods might play a role in reducing cancer (Shamberger, Tr. 2486); that there may be unknown elements in food which reduce cancer risk (Shamberger, Tr. 2486, 2522-23); and that it "is very likely" that each of the constituents that might play a role in reducing cancer acts in a synergistic way with each other or other constituents in food (Shamberger, Tr. 2487).

134. Furthermore, the Report notes that the protective effects observed in human studies may not be related to any particular dietary component of vegetables. Instead, these benefits may occur because people who incorporate more vegetables into their diet may consume less of other foods which may be associated with cancer (JX 1, p. 62; *see also* Shamberger, Tr. 2342-43; Campbell, Tr. 656-58). **[35]**

135. As a result of these uncertainties, the NRC Committee Report states unequivocally that its recommendation applies only to foods and that it is "unable to predict the health effects" of "isolated nutrients consumed in the form of supplements" (JX 1, p. 15). Because the Report makes clear that its scientific review of the literature does not establish which, if any, nutrients account for the protective benefit observed in human studies, the Report does not support the use of Healthy Greens or any other supplement tablets to reduce the risk of cancer.

136. In conclusion, it is abundantly clear that the Report does not support the use of Healthy Greens tablets. This is apparent from the face of the Report itself. The testimony of Dr. Campbell and Dr. Rogers confirms that this interpretation of the Report is correct (Campbell, Tr. 676-78; Rogers, Tr. 1396). Dr. Shamberger also admitted that the Report did not support the use of dietary supplements (Shamberger, Tr. 2525-26). Therefore, GNC's claim that the Report supports the use of Healthy Greens tablets is false.

B. *The Claims That Research Indicates That Vitamin E Plays An Important Role In Reducing The Risk Of Human Cancer Is False*

137. Respondent's claim that research indicates that vitamin E plays an important role in reducing the risk of cancer is false. The documentary evidence and testimony convincingly show that this claim is false. In fact, research has not demonstrated that vitamin E (or any other nutrient) plays any role in reducing the risk of cancer in humans, much less an important role.

138. The Report itself succinctly states the facts regarding vitamin E:

> Because vitamin E is present in a variety of commonly consumed foods (particularly vegetable oils, whole grain cereal products, and eggs), it is difficult to identify population groups with substantially different levels of intake. Consequently, it is not surprising that there are no epidemiological reports concerning vitamin E intake and the risk of cancer.
>
> Vitamin E, like ascorbic acid, inhibits the formation of nitrosamines *in vivo* and *in vitro*. However, there are no reports about the effect of this vitamin on nitrosamine-induced neoplasia. Limited evidence from **[36]** studies in animals suggests that vitamin E may also inhibit the induction of tumorigenesis by other chemicals. The data are not sufficient to permit any firm conclusion to be drawn about the effect of vitamin E on cancer in humans (JX 1, pp. 8-9) (emphasis added).

139. Respondent produced no testimony or evidence to refute the Committee's conclusion. None of respondent's prior substantiation documents, including the Report, or the testimony of its witnesses, support its vitamin E claim. The NRC Committee's interim dietary guidelines do not recommend vitamin E as reducing the risk of cancer (JX 1, p. 15). And, the studies introduced at trial do not demonstrate that vitamin E plays an important role in reducing the risk of cancer. On the contrary, complaint counsel's expert, Dr. Rogers, testified that even in animal studies, vitamin E has not been shown to play an

important role in reducing cancer and that there are major findings showing that vitamin E has no effect (Rogers, Tr. 1748; *see also,* Report, JX 1, pp. 148-49).

140. Dr. Campbell and Dr. Rogers both testified that research does not indicate that vitamin E plays an important role in reducing cancer risk in humans (Campbell, Tr. 1083-84; Rogers, Tr. 1749). Also, respondent's own expert, Dr. Newell, testified that there is not enough evidence to say whether vitamin E reduces the risk of cancer (Newell, Tr. 2822-23). Thus, respondent's claim that research indicates that vitamin E plays an important role in reducing risk of cancer in humans is false.

VI. THE CLAIMS SET FORTH IN COMPLAINT PARAGRAPHS 7(c) AND (d) ARE UNSUBSTANTIATED

141. One reasonable interpretation of the Healthy Greens ads is that GNC relied on the NRC Report as the basis for its advertising claims, including those listed in Complaint Paragraphs 7(c) and (d). The Report, however, does not support either the use of Healthy Greens to reduce the risk of cancer or the claim that vitamin E plays an important role in reducing the risk of cancer. Therefore, GNC did not possess and rely on a reasonable basis for these claims.

142. As discussed in the preceding Section, the Report does not support the use of Healthy Greens or the nutrients it contains to reduce the risk of cancer. Nowhere does the Report state that nutrients reduce the risk of cancer. Indeed, the Report expressly states that its recommendations do not apply to individual nutrients (F. 123-26; JX 1, p. 15). It also states **[37]** unequivocally that there is insufficient evidence to conclude that nutrients (apart from foods) reduce the risk of cancer in humans (F. 128-36; JX 1, p. 11). Because it is clear from the language of the Report that it does not support either claim, GNC did not possess a reasonable basis for either claim.

143. When an ad represents to consumers that the advertiser has a certain type of support, "the advertiser must possess the amount and type of substantiation the ad actually communicates." FTC Policy Statement Regarding Advertising Substantiation Program, 104 FTC 839 (1984); *Thompson Medical Co., supra* at 813. In this case, since consumers were told the Report supports the advertising claims, only the Report will satisfy this standard. Strictly speaking, therefore, GNC cannot now rely on other documents or a particular expert's opinion to satisfy its evidentiary burden. In any event, leaving the

Report for a moment, respondent's so-called substantiation material is also insufficient to satisfy the reasonable basis requirement of the law because it does not constitute, either individually or collectively, competent and reliable scientific evidence generally accepted by the relevant scientific community.

A. *GNC Did Not Possess A Reasonable Basis Because Its Claims Are Not Supported By Competent And Reliable Scientific Evidence Generally Accepted By The Scientific Community As Proving The Claims*

(1) The Report's Evaluation Of Scientific Information Related To Diet, Nutrition And Cancer And The Reports Conclusions And Dietary Recommendations Based Thereon Are The Most Authoritative Evidence Of What The Scientific Community Accepts As Competent And Reliable Evidence Proving The Claims In Issue In This Case.

144. The relationship between diet, nutrition and cancer is a difficult and controversial subject which invites a multi-disciplinary investigation. It is also a relatively recent concern and as knowledge increases, so will scientific consensus on a wider range of questions regarding the subject of diet, nutrition and cancer.

145. For the purposes of this case, however, the NRC Committee's evaluation of the scientific information related to diet, nutrition and cancer and its conclusions and recommendations based on its review contained in "Diet, Nutrition and Cancer" (JX 1), are the most authoritative and best available evidence of what the scientific community generally accepts as competent and reliable evidence on the subject of diet, nutrition **[38]** and cancer, including the advertising claims in issue in this case.

146. The status of the Report as the most authoritative and best evidence of the scientific community's views on evidence concerning the relationship between diet, nutrition and cancer, is founded on the Report's history—the origin and purpose of the NRC Committee, its composition, and its exhaustive review of the evidence on this issue—and the procedures followed by the Committee in writing the Report. The Report is the most comprehensive analysis of the literature bearing on the subject of diet, nutrition and cancer ever conducted, and it represents the views of the leading scientists and institutions involved in cancer research (Grobstein, Tr. 342; Newell, Tr. 2807-12).

147. The purpose of the Report was to determine what could

reasonably be concluded from the literature on diet, nutrition and cancer (JX 1, p. v). Before the late 1970's the state of knowledge relating to diet and cancer was scattered across many different disciplines and had never been systematically analyzed (Grobstein, Tr. 312; Newell, Tr. 2666-67). The National Cancer Institute (NCI) saw a need for a thorough and exhaustive review of the scientific literature (JX 1, p. v). NCI commissioned the National Academy of Sciences (NAS) to comprehensively review the state of knowledge and information pertinent to diet, nutrition and the incidence of cancer and develop a series of recommendations related to dietary components and nutritional factors which could be communicated to the public (Grobstein, Tr. 312-14; JX 1, p. v). The NAS assigned this task to its research arm, the National Research Council (NRC), which in turn empaneled an *ad hoc* committee of experts to carry out this study (Grobstein, Tr. 312-13, 315-18).

148. The NRC Committee, known as the Diet, Nutrition and Cancer Committee, collected some 3,000 to 4,000 studies in the related areas (Grobstein, Tr. 337). It reviewed the entire body of literature dating back to the 1940's. Its study lasted two years and cost over $1 million (Grobstein, Tr. 314). After two years of study, the Committee published the Report. This Report is the first, and to date the only, comprehensive and authoritative analysis of the scientific literature relating to this subject (Grobstein, Tr. 342).

149. The relationship between diet, nutrition and cancer is a highly complex area of science requiring many different perspectives, methodologies and expertises (Grobstein, Tr. 336). When, as here, a particular issue in science involves questions that cut across various disciplines, a committee composed of leading scientists in the various relevant disciplines is the best way to the necessary expertise (Grobstein, Tr. 316). The Committee that drafted the Report clearly met this requirement. It was composed of 13 scientists (Grobstein, Tr. 318) and a special advisor **[39]** (Grobstein, Tr. 327-29). These scientists were chosen to represent the various disciplines involved in cancer/nutrition research and often had more than one area of expertise (Grobstein, Tr. 318). Examples of disciplines represented on the Committee included: biochemistry, microbiology, embryology, epidemiology, experimental oncology, internal medicine, microbial genetics, molecular biology, molecular genetics, nutrition, nutrition education, public health, toxicology and pathology (Grobstein, Tr. 318).

150. Each Committee member was selected from among the leading scientists in each field (Grobstein, Tr. 317; Newell, Tr. 2808). And the Committee was aided by extensive consultation with other scientists, through specially arranged technical conferences on specific subjects, and through a public meeting where the Committee received such additional information and advice as scientists and others wished to provide (JX 1, pp. v-vi; Grobstein, Tr. 328). This multi-disciplinary composition served to ensure comprehensive coverage of the scientific literature and to provide a broad and balanced perspective to the Committee's deliberations (JX 1, p. v; Grobstein, Tr. 327). Therefore, the Committee's findings and recommendations based on them are more representative of the general scientific community than the opinions of any one scientist specializing in a particular discipline.

151. Just as the Committee's composition and access to the general scientific community ensured that its conclusions and recommendations represent a broad and balanced perspective of that community, the procedures adopted by the Committee and the NAS further ensured that the Report's conclusions would be soundly based, well reasoned, and representative of the general scientific community. The final version of the Report was subject to the careful scrutiny of the NAS's established review procedures (Grobstein, Tr. 308, 350-51). Those procedures included review of the findings by other members of the relevant scientific community (Grobstein, Tr. 328). Furthermore, Committee members were advised at the beginning and thereafter, as NAS procedures require, that they had the option of preparing minority statements if they reached views that differed substantially from those of the majority (Grobstein, Tr. 363). No such statement or dissent was filed. Thus, all Committee members agreed on the contents of the Report (Grobstein, Tr. 364).

152. Dr. Newell, respondent's leading expert witness, agreed that the Committee was comprised of the best scientists in the areas of diet and cancer (Newell, Tr. 2807), that the Committee was unbiased and its Report was carefully written (Newell, Tr. 2807-09). Dr. Newell also agreed that the Report represented the majority view of the relevant scientific community and that its views carry great weight in the scientific **[40]** community and greater weight than the views of any individual scientists (Newell, Tr. 2809-12).

(2) The Report Demonstrates That Respondent's Substantiation Material Is Not Accepted By The Scientific Community As Adequate Substantiation For Respondent's Advertising Claims

153. After a comprehensive review of the scientific literature, the Report concluded that there was not enough evidence to determine what role, if any, individual nutrients have with respect to cancer in humans. And as discussed in F. 155-235, *infra*, respondent's other substantiation material contained few pertinent scientific documents and added little to the body of scientific literature reviewed by the Report. Since the Report's conclusions represent what is generally accepted by the scientific community, the Report's finding that it is not known whether nutrients affect cancer in humans demonstrates that GNC's substantiation material is not adequate to support the advertising claims in issue.

154. The Committee based its recommendations that diets include vegetables, fruits and whole grain cereal products on findings that the consumption of these foods had been shown in humans to be associated with a lower cancer risk (Campbell, Tr. 653-55; JX 1, p. 15). In this connection, the Committee specifically noted that it is not known which, if any, of the nutrients found in vegetables reduce the risk of cancer in humans because almost all of the human studies involve whole foods and not their constituent nutrients (JX 1, pp. 11, 15). And Dr. Campbell (who was a member of the Committee that wrote the Report) testified that the Committee's dietary recommendations apply only to food because it is not known which, if any, specific nutrient or nutrients account for the apparent anti-cancer effect of the recommended foods (Campbell, Tr. 681-82). Therefore, respondent's argument that the Report supports the use of Healthy Greens as a multi-vitamin supplement is not supportable. *See* F. 128-36, *supra.*

(3) GNC's Prior Substantiation For Claims 7(c) And (d) Does Not Meet The Standard Of Evidence Generally Accepted By The Scientific Community As Necessary To Support The Claims

155. Respondent's prior substantiation material for its advertising claims consists of the Report and a disparate group of documents that includes 12 articles from the popular press **[41]** (CX's 17, 19-20, 29-30, 35-36, 40-41, 43-44, 46); two pamphlets prepared and published by respondent (CX's 12, 14); three documents that consist of letters to professional journals (CX's 24, 34, 42); 10 miscellaneous documents (Cx's 27-28, 37-39, 45, 47, 49-50, 52); and a physician's manuscript for a book intended for lay readers (CX 53). Additionally, respondent included nine documents that could be classified as scientific review articles (CX's 13, 15-16, 18, 21, 25, 33, 48, 51); and two documents that report the results of original scientific research (CX's 22-23).

156. In any event, none of respondent's alleged substantiation material (including the Report) relates to testing or use of vitamin supplements in humans. And, respondent's few scientific documents contain very little on the issue of how nutrients might affect the risk of cancer in humans. What little there is on this issue merely speculates about the possible role of nutrients or is couched in cautionary terms suggesting the need for further research.

157. Most of respondent's substantiation material would not be considered reliable scientific evidence by scientists. Popular press articles are not considered reliable by scientists in terms of evaluating claims (Campbell, Tr. 685; *see also,* testimony of respondent's witness, Dr. Newell, Tr. 2797-98). The two documents prepared and published by respondent are merely self-serving pieces intended for the general public. They do not report the results of original research by respondent or anyone else, and cannot serve as independent substantiation for respondent's advertising claims. The three letters to professional journals contain the opinions of the writers and do not report scientific data that can be critically reviewed (Campbell, Tr. 685-86). An examination of each of the miscellaneous documents and the book manuscript, combined with the testimony about these documents by the experts demonstrate that these documents do not provide scientific support for respondent's claims.

158. Although there is testimony that lay (non-scientific) publications may contain accurate scientific information (Rogers, Tr. 1589-90) and opinions of experts given to laymen may be reliable and can serve as a guide to the general public (Rogers, Tr. 1617-18), no expert testified that scientific opinions reported in newspapers or lay publications constitute the scientific literature in the accepted sense.

159. Respondent's expert witnesses, Dr. Newell and Dr. Shamberger, did not testify that any of respondent's prior substantiation material (other than the Report) was sufficient to substantiate the claims, although they testified that a few among them provide some rational basis for including nutrients in Healthy Greens to reduce cancer risk (*see, e.g.,* Newell, Tr. 2801-02). **[42]**

160. The nine scientific review articles and two documents reporting original research submitted by respondent do not substantiate its advertising claims. These documents (together with the Report) are the only scientific, peer-reviewed documents relied upon by respondent. As is shown by the following findings on each of these documents, it is clear that they do not substantiate a claim that

respondent's tablets, or any of the vitamin or mineral ingredients found in the tablets, will reduce the risk of cancer in humans.

161. Thus, respondent's prior substantiation material, whether viewed individually or collectively, does not substantiate the claim that Healthy Greens is associated with a reduction in the incidence of cancer in humans or the claim that vitamin E plays an important role in reducing the risk of cancer in humans. This is shown by the cogent testimony of Dr. Campbell and Dr. Rogers as well as by the documents themselves (Rogers, Tr. 1469-70; Campbell, Tr. 680-81). A more detailed discussion of respondent's prior substantiation material follows (CX's 11-53).

CX 11

162. CX 11 is the NRC Committee's Report, received in evidence as JX 1. Earlier discussions of the Report show that the Committee Report does not substantiate the advertising claim that Healthy Greens is associated with a reduction in the incidence of cancer in humans or the claim that vitamin E plays an important role in reducing the risk of cancer.[2]

163. Dr. Thompson, GNC's Director of Nutrition Education, testified extensively regarding his company's prior substantiation material. The record shows that GNC first decided to market a product of its own to be positioned against "Daily Greens" tablets, which had been introduced into the market by another firm, and largely duplicated the ingredients listed on the Daily Greens label in Healthy Greens tablets. Dr. Thompson testified that subsequently he satisfied himself that each of the ingredients making up GNC's Healthy Greens tablets had a rational scientific basis for inclusion in a supplement being offered as a product associated with reduction of cancer risks. Dr. Thompson also stated that GNC's prior substantiation material under discussion here consists of newspaper clippings, articles he found in trade and professional magazines and a few scientific **[43]** studies coming to his attention and which have been kept in a file in his office. *See* Thompson, Tr. 1821, 1827-30, 1840-41, 1911-12, 2122-25). A review of these prior substantiation materials appears in F. 165-235, *infra.* The record does not show that GNC or Dr. Thompson engaged any expert in any of the relevant disciplines or conducted any scientific study in order to ensure that the advertising

[2] In the following findings discussing the remainder of respondent's prior substantiation material (CX's 12-53), the two advertising claims listed in Complaint Paragraphs 7(c) and (d) will be referred to as "the advertising claims" or "the claims."

claims being made for Healthy Greens had adequate scientific substantiation, until after the Commission's proceeding in this case began.

164. Respondent's expert witnesses, Dr. Newell and Dr. Shamberger did testify extensively at trial that the Report and the underlying studies the Committee reviewed provide sufficient scientific basis for offering a multi-vitamin supplement like Healthy Greens. Their testimony, for the most part, did not distinguish between prior substantiation material and post-claim evidence.

CX 12

165. Dr. Thompson, GNC's Director of Nutrition Education, described CX 12 as a nutritional educational pamphlet on the subject of selenium which was written on the basis of the scientific literature. In it he refers to the work of Dr. Raymond Shamberger and to other epidemiological and experimental research which showed that selenium reduced the risk of cancer. These were described as follows:

> There is suggestive evidence that Selenium may reduce the risk of getting cancer. In experimental animals that are prone to developing cancer and animals given cancer-causing agents, Selenium supplementation significantly reduced the incidence of cancer. Clinical studies in humans have only recently begun, so hard evidence that Selenium may protect people from getting cancer is not yet available. However, there is indirect evidence.
>
> Regional studies have estimated levels of Selenium in the diet and incidence of many types of cancer, such as colon, breast, prostate, lung and ovarian cancer. These studies produce a consistent finding of higher incidence of cancer in regions where less Selenium is consumed. Also, it has been reported that blood levels of selenium are low or in the low normal range in cancer patients. **[44]**

This brochure shows that Dr. Thompson was aware of the research on selenium. However, Dr. Thompson states the evidence is "suggestive" and "hard evidence that selenium may protect people from getting cancer is not yet available."

166. Furthermore, CX 12 is not a scientific article; it is a general article without references or scientific data (Rogers, Tr. 1402), and it is not a peer-reviewed article (Campbell, Tr. 682-84). Moreover, even the secondary reporting of information within the document is incorrect. Dr. Shamberger, respondent's own witness, testified that there is "no substantial amount of evidence" to support the statement on page CX 12C that "for optimum health, daily intake [of selenium] should be between 250 and 350 micrograms per day..." (Shamberger,

Tr. 2555-56), even though Dr. Shamberger is one of the two authorities cited on CX 12C as supporting the 250 to 350 micrograms daily intake level. Dr. Shamberger testified that, contrary to the statement in the document, he believes that there is little benefit in exceeding 200 micrograms per day (Shamberger, Tr. 2553).

CX 13

167. Dr. Thompson described CX 13 as a portion of a textbook by Ananda S. Prasad. It describes the activity of selenium as an antioxidant which is linked in theory to the suppression of cancer (Thompson, Tr. 1917, 1920-21). One of the ways selenium functions, Dr. Thompson testified, is in protecting the cells from breakdown due to peroxides which form from fats and from other environmental and organic carcinogenic compounds (Thompson, Tr. 1918-20). The document also refers to the sparing effect of vitamin E and selenium by which one nutrient will compensate in the body for lower levels of the other (Thompson, Tr. 1919). Finally, the document discusses the distribution of selenium in the environment and notes that soil content of selenium varies widely around the country. Dr. Thompson added that to his knowledge other studies correlated areas of low selenium soil and water content with a higher incidence of cancer than areas of higher selenium content (Thompson 1912, 1924-25). The document discusses the work of scientists such as Shamberger and others which showed low selenium in the blood of cancer patients in contrast to normal controls or patients with other diseases, and finally it discusses possible selenium deficiency in low selenium areas, as well as the increased selenium requirements of the body during periods of high protein intake (Thompson, Tr. 1925-26).

168. Respondent contends that CX 13, when combined with the information in CX 12 and CX 14, indicate: that mechanisms for selenium activity have been established which can reasonably account for its anti-cancer activity; that epidemiological studies have shown that the ingestion of higher amounts of **[45]** selenium is associated with a reduced incidence of cancer; that experiments in animals have shown a cancer-resistant effect of supplemental selenium; that selenium spares the body's need for vitamin E (another nutrient which has anti-cancer activity); that average selenium intake falls short of what some scientists consider optimal intakes; and finally that there is great variability in selenium content of soil, water and food across the country. Respondent urges that on the basis of CX's 12, 13 and 14, it

is rational to include selenium in a supplement to reduce cancer. *See* RPF at 76-77.

169. CX 13, however, does not constitute adequate substantiation for the claims (Rogers, Tr. 1402-03; Campbell, Tr. 687-88). CX 13 appears to be a chapter on the mineral selenium from a medical book which reviews the role of trace elements and iron in human metabolism. As such, it does not report original research and, therefore, it cannot be critically reviewed to determine if the conclusions stated in the book are accurate (Rogers, Tr. 1402-03; Campbell, Tr. 687-88). The chapter on selenium contains a substantial amount of bio-medical information regarding selenium, one of the ingredients in Healthy Greens. However, the only reference to cancer to be found is on page CX 13R, where there is a brief reference to epidemiological studies by Dr. Shamberger (Rogers, Tr. 1402-03). The document contains no information about any of the other nutrients found in Healthy Greens (Campbell, Tr. 687-88; CX 13S-T). And CX 13 does not discuss vitamin E and cancer.

CX 14

170. Dr. Thompson described this two-page brochure as an informational piece which reviewed information for dissemination to the public by GNC. It includes references to studies by scientists about selenium, including Drs. Shamberger, Willis and Schrauzer, and summarizes some of their results:

> Dr. G.N. Schrauzer and co-workers studied the relationship between cancer deaths and the amount of dietary selenium intake in 27 different countries and 19 different states in the United States. Many types of cancer such as colon, breast, prostate, lung and ovarian cancer were included in the study. These researchers found that higher selenium intake related to fewer cancer deaths.
>
> Drs. R.J. Shamberger and C. Willis also examined the relationship between selenium and cancer. They reported that for both the United States and Canada, the higher the soil **[46]** or crop level of selenium the lower the cancer death rate. In another study focusing on several American cities they found that the higher the average selenium blood levels in people, the lower the cancer death rate.
>
> Animal studies appear to support these observations. When animals that were prone to getting cancer or animals that were given cancer-causing agents were given additional selenium, fewer cancers were seen.

In addition, CX 14 addresses the question of dietary supplementation with selenium and notes Dr. Schrauzer's view on an appropriate level of intake:

The average American diet supplies between 50 and 160 micrograms of selenium, depending on where one lives. Since the majority of Americans do not live in the parts of the mid and Southwest where soil selenium is high, they would likely be at the lower end of the selenium intake range. Dr. Schrauser thinks that the average intake is only half that needed "for optimal protection against neoplastic disease (cancer)" and suggests that at least 300 micrograms of selenium per day is needed. But note also that selenium is not a "if a little is good, a lot must be better" nutrient. Selenium toxicity can occur with prolonged ingestion of about 2400 to 3000 micrograms per day.

171. CX 14, however, does not constitute adequate substantiation for the claims (Rogers, Tr. 1403-04; Campbell, Tr. 689). It is a two-page document prepared and published by respondent in which it is suggested that selenium plays a role in a number of human conditions and disorders including cancer, heart function, high blood pressure, arthritis, aging, and cataracts, plus animal reproduction. Furthermore, this document contains two statements that respondent's own witness testified are wrong. First, it states that for humans "at least 300 micrograms of selenium per day is needed" for protection against cancer; and secondly, it states that selenium toxicity occurs "with prolonged ingestion of about 2400 to 3000 micrograms per day." Respondent's own witness, Dr. Shamberger, disagreed with these statements and testified that there is little benefit in exceeding 200 micrograms per day (Shamberger, Tr. 2553) and that selenium is likely to be toxic at intakes of 1400 micrograms per day (Shamberger, Tr. 2556). And this document reports no **[47]** original scientific data (Campbell, Tr. 689-90). Finally, it does not discuss vitamin E.

CX 15

172. CX 15 appears to be excerpts of a book entitled "Cancer and Vitamin C" by Drs. Cameron and Pauling, and was cited by Dr. Thompson as substantiation for the vitamin C component of Healthy Greens (Thompson, Tr. 1927). Dr. Thompson testified that CX 15 describes the mechanism of action of vitamin C in the prevention and treatment of cancer, suggests that vitamin C acts by stimulating the body's own protective defense mechanisms and advocates supplementation with vitamin C as useful in the treatment of cancer (Thompson, Tr. 1927-28). Although Dr. Pauling's ideas are somewhat controversial, as a two-time Nobel Laureate he is a respected scientist whose ideas merit attention (Thompson, Tr. 1928).

173. CX 15, however, does not constitute adequate substantiation for the claims (Rogers, Tr. 1404-05; Campbell, Tr. 690). CX 15 is a

chapter from a book by Dr. Linus Pauling *et al.*, and, except for a short discussion, deals almost entirely with the *treatment* of cancer, not the prevention of cancer. It contains no original research (Rogers, Tr. 1404-05; Campbell, Tr. 690). And it does not discuss vitamin E.

CX 16

174. CX 16 entitled "Human Needs for Vitamin E," is a document published by General Mills and is a summary of animal studies on vitamin E. According to Dr. Thompson, the document generally describes the antioxidant effect of vitamin E (Thompson, Tr. 1929). In the first, two groups of mice were exposed to ultraviolet light, which typically causes skin carcinomas. One group was supplemented with an antioxidant combination of vitamins E and C. The review noted that "[a]t the end of 24 weeks, 24% of the animals fed the regular diet bore tumors that were classified as frank carcinomas confirmed by histopathological examinations. No tumors were present in any of the animals receiving the antioxidant supplemented diets" (*Id.* at 19).

175. The second reviewed study studied the effect of vitamin E on ozone, which is a potent oxidant in smog and is believed to be a pollutant. The experiment showed that dietary vitamin E "may cause a marked difference in the response of animal lungs to ozone exposure" (*Id.* at 19). **[48]**

176. Drs. Campbell and Rogers, complaint counsel's expert witnesses, testified that CX 16 does not support the claims made for Healthy Greens (Rogers, Tr. 1406-08; Campbell, Tr. 691). CX 16 is not peer-reviewed scientific literature (Campbell, Tr. 691). It is a summary of other articles with little information on methods and data and most of it has nothing to do with cancer (Rogers, Tr. 1407).

CX 17

177. CX 17 is a two-page medical news article from the *Journal of the American Medical Association* (JAMA). It is not a report of original research. It discusses vitamin E and cystic breast disease, not cancer (Campbell, Tr. 695-96). It simply involves some preliminary studies that indicate that women with this disease felt better (experienced less pain) after taking vitamin E (Rogers, Tr. 1408). It is not known if cystic breast disease relates to cancer (Campbell, Tr. 696). Dr. Thompson acknowledged that it would be speculative based on this document to say that vitamin E reduces the risk of breast cancer in women (Thompson, Tr. 2064). Moreover, it is noted in the

document that one researcher said that "vitamin E is not a benign vitamin that you can take like vitamin C if you think you're getting a cold. It is—and we need to stress this—a pharmacologic agent" (CX 17B). Drs. Campbell and Rogers testified that CX 17 does not support any of the ad claims in this proceeding (Rogers, Tr. 1408; Campbell, Tr. 695).

CX 18

178. CX 18, Cameron and Pauling, "On Cancer and Vitamin C" is a review article which appeared in *Executive Health* (Jan. 1980), intended for lay audience. It is a review of research in cancer and vitamin C and is concerned primarily with studies which show that high doses of vitamin C are effective in treatment of some cancer. The authors note that although vitamin C is "of definite value" in the treatment of the later stages of cancer, they believe it has "even greater value for the treatment of cancer patients with the disease in earlier stages and also for the prevention of cancer" (*Id.* at 000209). CX 18 is essentially the same as CX 15 and deals primarily with the *treatment* of cancer, not cancer prevention (Rogers, Tr. 1411-12; Campbell, Tr. 697). And it does not discuss vitamin E and the prevention of cancer. Complaint counsel's expert witnesses, Drs. Campbell and Rogers, testified that CX 18 does not support any ad claim in issue here (Rogers, Tr. 1411; Campbell, Tr. 696-97). **[49]**

CX 19

179. CX 19 is an article entitled "Vitamin C: Now It's Got Science on Its Side," which appeared in the *Executive Fitness Newsletter* (Sept. 19, 1981), and reviews a number of studies presented at a meeting in England on the issue of vitamin C and its importance in human health. The article noted, among other studies, that "J.W.T. Dickenson, Ph.D., Professor of Biochemistry at the University of Surrey in England, presented evidence that vitamin C may play an important role in resisting cancer both by bolstering the effectiveness of the immune system and also by strengthening cell walls and other tissue against deterioration that can allow cancer cells to spread." In addition, the paper reported on the work of Dr. H. Oshima of the International Agency for Research on Cancer, in France, on the inhibition of nitrosamine formation with vitamin C. These reports suggest that vitamin C may play an important role in human cancer. These and others suggest that vitamin C may play its anti-cancer role

at higher levels than those necessary merely to prevent deficiency. Dr. Albert Szent-Gyorgyi, the scientist who discovered vitamin C, is quoted in this exhibit explaining the new understanding of the functioning of vitamin C:

> The medical profession took a very narrow and very wrong view. Lack of ascorbic acid [vitamin C] caused scurvy, so if there was no scurvy there was no lack of ascorbic acid. The only trouble was that scurvy is not a first symptom...but a final collapse. There is a very wide gap between scurvy and full health—as indeed the past 20 years of vitamin C research has shown (emphasis added).

180. CX 19, however, does not substantiate the claims involved in this case (Rogers, Tr. 1412-13; Campbell, Tr. 697-98). It is a report which appeared in a lay publication and contains no original data (Rogers, Tr. 1412-13; Campbell, Tr. 697-98). The document reports no scientific data and merely states some opinions regarding vitamin C (Rogers, Tr. 1412) with very little discussion of vitamin C and cancer (Campbell, Tr. 697-98). And, the document does not discuss vitamin E and cancer.

CX 20

181. CX 20 is a newspaper article about Dr. London's study (which is CX 17) on vitamin E and pain relief for women suffering from cystic breast disease, not cancer (Rogers, Tr. 1413-14; **[50]** Campbell, Tr. 698). CX 20 does not substantiate the claims (Rogers, Tr. 1413-14; Campbell, Tr. 698).

CX 21

182. CX 21 is an article entitled "Vitamin A and Retinoids: From Nutrition to Pharmacotherapy in Dermatology and Oncology," by Bollag which appeared in *The Lancet* (April 16, 1983) 860. It is a review of the literature on vitamin A as well as the author's own research on retinoids, which, the author states, "showed a prophylactic effect of vitamin A in vivo on the induction of such precancerous conditions as benign epithelial tumors and metaplasias, as well as of carcinomas" (*Id.* at 861). In addition, he points out, "[v]itamin A in high doses is effective in the treatment of certain skin diseases in man and in the prevention of chemically induced tumors in animals." *Id.*

183. The author also noted that they involve levels of vitamin A which are above deficiency levels and noted, "it had to be designated as a substance possessing pharmacodynamic effects, since neither the

patients nor the animals that benefitted from vitamin A administration were vitamin A deficient." *Id.* According to Dr. Shamberger, CX 21 provides some basis for the inclusion of vitamin A in supplements to reduce cancer risk. The study shows that vitamin A added to premalignant metaplasia caused regression (Shamberger, Tr. 2438).

184. CX 21, however, does not substantiate any ad claim in issue here (Rogers, Tr. 1414; Campbell, Tr. 698-99). The article deals with the biological effects of vitamin A, and is not relevant to the issue of vitamin supplementation in humans to prevent cancer (Campbell, Tr. 892). A substantial portion of the article is devoted to a discussion of the development of a synthetic vitamin A that will not have the toxicity of natural vitamin A (Rogers, Tr. 1414-15). In fact, the article states that firm conclusions regarding vitamin A cannot be drawn (Rogers, Tr. 1415) and expresses doubt about the wisdom of using vitamin A (Campbell, Tr. 698). And the article does not discuss vitamin E.

CX 22

185. CX 22 (RX 139) is an article entitled Wald, *et al.*, "Low Serum Vitamin A and Subsequent Risk of Cancer," which appeared in *The Lancet* (Oct. 18, 1980) 813. It reports an epidemiological study on serum vitamin A levels and subsequent cancer incidence. This study also reviews the various kinds of studies, animal and epidemiological, which suggested vitamin A and retinoids to be inversely associated with the incidence of **[51]** cancer. CX 22 was a study of about 16,000 men in which serum samples were collected and stored. About five years later, 86 of these men had contracted cancer, whereupon their earlier blood serum vitamin A levels were compared to the levels of 172 controls who remained free of cancer. The study found that "low retinol levels were associated with an increased risk of cancer" (CX 22 at 813), and that persons in the lowest quintile for serum vitamin A had 2.2 times the risk of contracting cancer as those in the highest serum vitamin A quintile (Thompson, Tr. 1944).

186. Dr. Newell also testified that CX 22 supports the efficacy of vitamin A against cancer: "[t]he level of risk that was found was twofold; that is, men with the lung cancers had twice the risk if they were in the low range of the retinol concentration. That is, the higher the retinol levels, the less cancer developed. So higher retinol levels had exerted a protective effect against the development of cancers" (Newell, Tr. 2701). Dr. Newell testified that the study was noteworthy

in combining the advantages of both case control and prospective studies, and that it was "cited all the time in the literature" (Newell, Tr. 2702). Dr. Rogers similarly noted that this is a valid epidemiological study that shows that vitamin A tends to be lower in men who develop cancer. The methodology is valid, and the data supported the conclusions of the authors, she added (Rogers, Tr. 1594-95).

187. In the epidemiological study, reported in CX 22, men with lower blood serum levels had an increased risk of cancer, but the vitamin A serum levels of all of the subjects were within the normal, well-nourished range, and the actual differences between the low and high groups were slight (Rogers, Tr. 1417). In any event, CX 22 does not indicate that vitamin A consumed in the *diet* affected the risk of cancer of these subjects. In well-nourished subjects such as these, the amount of vitamin A in the blood is not reflective of the amount of vitamin A consumed (JX 1, p. 140; Campbell, Tr. 653-54; Newell, Tr. 2908). Since the subjects were well-nourished, ingestion of a vitamin A supplement by them would simply result in storage of vitamin A in the liver, not an increase in blood serum levels (Rogers, Tr. 1418).

188. The authors of CX 22 also stress that their findings are tentative (CX 22C). Moreover, this 1980 research was discussed by the Committee in writing the Report. The Committee stated that the implications of this study are unclear because of the static nature of vitamin A levels in the blood (*see*, JX 1, p. 140; Campbell, Tr. 706). There was also testimony that serum levels of vitamin A are determined by many factors other than dietary intake of that particular nutrient. For example, serum vitamin A levels can also be affected by dietary intake of protein (Campbell, Tr. 705). This study also points out that in cancer patients lower vitamin A serum levels may be the result of **[52]** the disease, not the cause of it (CX 22A). And, CX 22 does not discuss vitamin E.

CX 23

189. CX 23 (RX 12) is an epidemiological study entitled "Dietary Vitamin A and Risk of Cancer in the Western Electric Study," by Shekelle which appeared in *The Lancet* 1185 (Nov. 28, 1981). It is considered to be one of the seminal studies on the subject of vitamin A and cancer prevention. A prospective epidemiological study, it measured dietary intake of beta-carotene in over 3,000 test subjects with a follow-up 19 years later. After 19 years, the subjects were traced to determine which in the interim had suffered from cancer.

Correlating these results with the previous dietary histories, Dr. Shekelle and his co-investigators observed an inverse association between dietary beta-carotene and the subsequent incidence of lung cancer.

190. The study indicated that the relative risks among the test subjects varied greatly based upon beta-carotene intake. Those in the lowest quintile for beta-carotene intake, for example, had fully seven times the risk of developing cancer over the following 19 years as those in the highest quintile. Among men who smoked, the effect was more pronounced: lowest beta-carotene quintile subjects bore eight times the risk of developing lung cancer as smokers in the highest. The authors concluded: "These results support the hypothesis that dietary beta-carotene decreases the risk of lung cancer." CX 23B. The authors noted that beta-carotene was the only significant variable between the groups: "[t]here were no significant differences in mean intake of other nutrients by men in whom lung cancer developed and by those in whom it did not during 19 years of follow-up; this strengthens the view that the risk of lung cancer was specifically related to intake of carotene and not to some other variable associated with eating fruits and vegetables." *Id.* at D (Thompson, Tr. 1946). The authors also concluded that there was good reason for smokers who wished to reduce their risk of cancer to ingest higher amounts of beta-carotene:

> The consistency of the epidemiological evidence from diverse populations, the graded nature and temporal sequence of the association, its independence from cigarette smoking, and its coherence with the evidence from animals, all suggest that a diet relatively high in beta-carotene may reduce the risk of lung cancer even among persons who have smoked cigarettes for many years.

Id. at D. **[53]**

191. Dr. Thompson of GNC relied in part upon this study, and noted in his testimony, "[i]t is a very supportive article from a peer-review journal that has been frequently cited" (Thompson, Tr. 1946). Dr. Newell also noted its publication in *The Lancet* (Newell, Tr. 2691). The study, Dr. Newell testified, is "unique and important" because it is a prospective, cohort study of 1954 men performed in a 19 year time-frame (Newell, Tr. 2692). Dr. Newell noted the authors' statement that "[t]he results support the hypothesis that beta-carotene decreases the risk of lung cancer" (Shekelle, RX 12; CX 23 at 1185; Newell, Tr. 2692). Dr. Newell testified that this epidemiologi-

cal study is important because it was designed to test a specific hypothesis stated ahead of time, not developed after results were found (Newell, Tr. 2692).

192. Dr. Newell also noted the authors' view that the study implicated beta-carotene specifically, and not some other dietary constituent as effective against cancer:

> The results of our study support the hypothesis of Peto *et al.*, with respect to lung cancer; the dietary variable related to risk of lung cancer is beta-carotene, not retinol. There were no significant differences in mean intake of other nutrients by men in whom lung cancer developed and by those in whom it did not during 19 years of follow-up; this strengthens the view that the risk of lung cancer was specifically related to intake of carotene and not to some other variable associated with eating fruits and vegetables.

(CX 23D; RX 12 at 1188; Newell, Tr. 2693) (emphasis added). Dr. Newell also pointed to the authors' statement regarding the extraordinary length of time of the study: "The long period of follow-up indicates that below-average intake of carotene preceded the carcinoma and was not a consequence of it." *Id.*

193. According to Dr. Newell, the authors' recommendation in CX 23 supports ingesting higher amounts of beta-carotene as a matter of prudence, despite the fact that the relationship has not yet been conclusively proven, and pointed to the following passage in CX 23:

> Many questions remain to be answered, and further studies are required to determine whether increasing the intake of dietary beta-carotene will reduce the risk of lung cancer in man. However, it seems prudent to **[54]** emphasize that sound nutritional practice, at least for the general populations of countries such as the U.S.A., involves selecting foods from each of several major groups, including the vegetables and fruits that contain substantial amounts of beta-carotene. The consistency of the epidemiological evidence from diverse populations, the graded nature and temporal sequence of the association, its independence from cigarette smoking, and its coherence with the evidence from animals, all suggests that a diet relatively high in beta-carotene may reduce risk of lung cancer even among persons who have smoked cigarettes for many years (emphasis added).

(CX 23E; RX 12 at 1189; Newell, Tr. 2693).

194. Dr. Shamberger testified that this study is particularly advantageous because it is "blind"—it is random and eliminates the bias which can color conclusions from results which are already known (Shamberger, Tr. 2418-19). He further testified, "this would be a very important contribution and would shed light on the cancer question in

humans.... [P]rospective studies are about as good as one can do up to the point of a clinical trial" (Shamberger, Tr. 2419-20). Dr. Shamberger also noted (Tr. 2419-22) its high quality due to its long period of follow-up which eliminated any possible confounding results of persons who may have entered the study cancer. Dr. Shamberger also pointed to the same quotation given in the preceding Finding (Shamberger, Tr. 2422-23):

> ...nutritional practice, at least for the general population, of countries such as the U.S.A. involves selecting foods from several of the major groups, including the vegetables, and that contains substantial amounts of beta-carotene...a relatively high beta-carotene may reduce the risk of lung cancer even among persons who smoke cigarettes for many years.

Dr. Rogers, complaint counsel's expert witness, agreed that this study supports the hypothesis that dietary beta-carotene reduced the risk of lung cancer (Rogers, Tr. 1597-98).

195. CX 23 does not substantiate the advertising claims at issue in this case (Rogers, Tr. 1419-20; Campbell, Tr. 712). CX 23 was considered by the Committee before writing the Report (JX 1, p. 139; Campbell, Tr. 715). The research reported here involves a retrospective study where the researcher had existing **[55]** data on food intake for a group of people and on that basis attempted to estimate the intake of various constituents of that food such as beta-carotene (a nutrient in certain vegetables that converts to vitamin A). The authors themselves say this process may produce estimates which are unreliable (Campbell, Tr. 715-16; *see also,* JX 1, p. 139). The authors expressly state that:

> We believe that the correlation between our estimates of carotene intake and the true values, if they were known, would be moderate at best and that these results should be interpreted with considerable caution (CX 23E).

It is further noted that although the subjects who ate more foods containing beta-carotene developed fewer lung cancers, the same relationship did not apply to persons who ate foods containing vitamin A (Rogers, Tr. 1420).

196. Further, CX 23 involves the consumption of whole foods, not supplements. In fact, the authors state that in developing the dietary histories which served as the basis for this study, information on nutrient supplements was not recorded because they were used so seldom (CX 23E; Campbell, Tr. 712-15). Furthermore, the record

raises a real question as to whether studies, such as CX 23, involving foods are also applicable to nutrients, because whole foods, unlike nutrients, may affect cancer rates for the reason that they contain a variety of constituents which may reduce the risk of cancer (Rogers, Tr. 1598; Campbell, Tr. 656-57), or that these foods may cause *displacement* in the diet of foods that may promote cancer (Rogers, Tr. 1390; Campbell, Tr. 657-58; Shamberger, Tr. 2542-43). And, CX 23 does not discuss vitamin E.

CX 24

197. CX 24 consists of two letters to *Lancet* that do not contain original research (Campbell, Tr. 722-23). They are authors' comments on research concerning vitamin A blood serum levels and cancer. One letter deals primarily with the interactions of dietary zinc and vitamin A levels (Campbell, Tr. 722; Rogers, Tr. 1424-25). And, CX 24 does not discuss vitamin E. **[56]**

CX 25

198. CX 25 is an article entitled "The Cancer and Other Connections...If Any," by Gio Gori which appeared in *Nutrition Today.* It is a wide-ranging review of scientific information regarding an association between diet and cancer, including recommendations for the public. The review article focuses on the role of natural antioxidants in negatively affecting chemically-induced tumors in mice and other animals. Dr. Gori theorizes that the mechanism of action may be an indirect action on the expression of carcinogens, or a direct action in scavenging free radical carcinogens, thereby preventing transformation of cells into cancer cells (CX 25G). From this information, Dr. Gori further theorizes on a "possible preventive role of...vitamins A, C, and E, of selenium, and artificial antioxidants in the prevention of certain cancers" (CX 25H).

199. According to Dr. Shamberger, CX 25 notes that epidemiological findings in human populations with respect to various nutrients parallels experimental findings in animals. These experimental findings have shown, *inter alia,* that "natural antioxidants" such as selenium and vitamin E have negative effects on tumors in mice and animals. According to Dr. Shamberger, deficiencies, especially of trace elements, have been linked to cancer etiology (Shamberger, Tr. 2441).

200. CX 25 does not substantiate the advertising claims in issue

(Rogers, Tr. 1425-26; Campbell, Tr. 726-27). CX 25 is essentially an authoritative general review article in which epidemiological studies related to diet and cancer are summarized (Rogers, Tr. 1425-26; *see also,* Thompson, Tr. 2075-76). CX 25 also states that further research is needed (Rogers, Tr. 1426). And it makes no specific finding regarding vitamin E.

CX 26

201. CX 26 is a fund-raising letter from Dr. Linus Pauling. It is not a scientific document, and no scientific data or research are given to support the claims made for vitamin C (Campbell, Tr. 728-29). As Dr. Rogers testified, there is no research that would support the claim that vitamin C will reduce the risk of cancer in humans (Rogers, Tr. 1427). This document does not discuss vitamin E. CX 26 does not substantiate the ad claims in issue (Rogers, Tr. 1426-27; Campbell, Tr. 728-29). **[57]**

CX 27

202. CX 27 is a letter soliciting funds for investigating diet and cancer (Rogers, Tr. 1428). It is not a scientific document and it contains no original research (Rogers, Tr. 1427-28; Campbell, Tr. 729-30). The document primarily deals with the treatment of cancer, not its prevention. And, it does not discuss vitamin E. CX 27 does not substantiate the ad claims in issue (Rogers, Tr. 1427-28; Campbell, Tr. 729-30).

CX 28

203. CX 28 is a one-page news article for laymen discussing diet and cancer generally as well as mutagens and potential carcinogens in foods. The article does not report original research (Rogers, Tr. 1428-29; Campbell, Tr. 730). And it does not discuss vitamin E. CX 28 does not substantiate the ad claims in issue (Rogers, Tr. 1428-29; Campbell, Tr. 730).

CX 29

204. CX 29 is a news article that summarizes the interim guidelines published in the Report. On CX 29B, the authors note that "the Committee suggested very strongly that no one try to supplement his or her diet with these substances [vitamins A, C, beta-carotene and selenium] since high doses might have potentially serious side

effects." And CX 29 makes no statement that vitamin E reduces the risk of cancer. CX 29 does not substantiate the ad claims in issue (Rogers, Tr. 1429-30; Campbell, Tr. 731-33).

CX 30

205. CX 30 is a news article discussing the same research that is discussed in CX 23, discussed in F. 189-96, *supra.* The author of this document states that the research constitutes "very preliminary observations" (CX 30B). Moreover, the author notes that the research involved persons who consumed "dark green and deep yellow vegetables and fruits" (CX 30A). Thus, the research involved whole foods, not supplements. And CX 30 does not discuss vitamin E. CX 30 does not substantiate the ad claims in issue (Rogers, Tr. 1430-31; Campbell, Tr. 733). **[58]**

CX 31 and CX 32

206. CX 31 and CX 32 are 1984 newspaper articles which appeared after the publication of the advertisements and which respondent acknowledged at trial are not part of the prior substantiation (Rogers, Tr. 734-35). In any event, they contain no original research or other information which would support the ad claims in issue in this case.

CX 33

207. CX 33 is an article by Shekelle and Tangney entitled "On Dietary Vitamin A...Beta-Carotene...and Lung Cancer Prevention," which appeared in 19 *Executive Health* (Dec. 1982). It is a summary of the evidence associating vitamin A intake with the incidence of cancer, including Dr. Shekelle's own study on the subject. The article makes a number of points: first, it indicates that studies have shown that inadequate amounts of vitamin A may increase susceptibility to lung cancer. Other animal studies, as far back as 1967 demonstrated that oral vitamin A suppressed changes in the hamster respiratory tract after carcinogen exposure. The authors noted that "[e]xactly how vitamin A exerts this effect is still unknown. However, much further research with various animal models and other experimental systems has confirmed that vitamin A—and related substances collectively called retinoids—can suppress the progression of cellular changes from the normal to the cancerous state and the initial damage by the cancer-inhibiting agent has occurred" (emphasis in original) (CX 33C; Thompson, Tr. 1953). CX 33 further cites research by others

which show an association between vitamin A and the incidence of cancer, and also describes the study by Peto which links beta-carotene to cancer incidence. Dr. Thompson of GNC suggested that these studies are important in light of the authors' finding that it is "surprisingly common" for American adults to have vitamin A intakes below recommended levels (Thompson, Tr. 1955).

208. Dr. Shamberger testified that CX 33 is significant in providing a basis for vitamin A, because it shows that inadequate vitamin A or beta-carotene may markedly increase susceptibility to cancer (Shamberger, Tr. 2444-45). According to Dr. Shamberger, other scientists who have reported similar results are Saffioti, Sporn, Clark, Wald and Bjelke (*Id.*).

209. CX 33 is a review written by Dr. Shekelle *et al.*, of their own work discussed in CX 23, discussed in F. 189-96, *supra.* Complaint counsel's expert, Dr. Rogers, pointed out that this document states that there is no direct evidence to indicate whether increasing intake of beta-carotene would reduce the risk of cancer (Rogers, Tr. 1434; CX 33E). The study discusses **[59]** dietary vitamin A and beta-carotene (*i.e.*, foods that contain vitamin A and beta-carotene), not supplements (Rogers, Tr. 1434-35). And CX 33 does not discuss vitamin E and cancer. CX 33 does not substantiate the ad claims in issue in this case (Rogers, Tr. 1433-35; Campbell, Tr. 736).

CX 34

211. CX 34 is a one-page letter which appeared in *Lancet* and does not report original research (Campbell, Tr. 738). Dr. Rogers, complaint counsel's witness, pointed out that in human populations, malnutrition involves malnutrition with regard to many nutrients, and she notes that it is not possible to single out populations deficient in one single nutrient (Rogers, Tr. 1435-36). Further, the author points out that epidemiological data not only do not demonstrate a prophylactic effect of vitamin A on esophageal carcinogenesis, but that indeed an "enhancing action" of vitamin A on esophageal carcinogenesis is more consistent with the epidemiological and experimental findings (CX 34). CX 34 in fact suggests that vitamin A may promote cancer in some instances. And CX 34 does not discuss vitamin E. CX 34 does not substantiate the ad claims in issue in this case (Rogers, Tr. 1435-37; Campbell, Tr. 738).

CX 35

212. CX 35 is a newspaper article purporting to report on the

research of Dr. Lee Wattenberg, a member of the Committee (JX 1, Appendix A, p. 454). It therefore is not a scientific report of original research and is not peer-reviewed (Campbell, Tr. 740). Both complaint counsel's and respondent's witnesses testified that scientific conclusions cannot be drawn from newspaper articles such as CX 35 (Campbell, Tr. 740; Newell, Tr. 2797-98). And CX 35 does not discuss vitamin E. CX 35 does not substantiate the ad claims in issue in this case (Rogers, Tr. 1437-38; Campbell, Tr. 739-40).

CX 36

213. CX 36 is a *Wall Street Journal* article concerning the research of Dr. Michael B. Sporn on the possible role of nutrients in preventing cancer. The article itself states that "vitamin A by itself holds little promise as a human cancer inhibitor. For one thing, vitamin A concentrates in the liver and wouldn't reach those body tissues where most cancers arise" (CX 36A). The article goes on to state that: **[60]**

> Indeed, Dr. Sporn and others felt that publicity about their work may cause cancer-conscious Americans to go on expensive—and possibly dangerous—binges of vitamins and nutrients. 'I certainly don't recommend people medicate themselves... They can subject themselves to no benefit and definite risks' (CX 36A).

Thus, CX 36 clearly cautions against vitamin supplementation by consumers.

214. CX 36 also quotes an unnamed biochemist as saying that selenium, one of the ingredients of Healthy Greens, is "almost as toxic as arsenic" (CX 36B). The article goes on to note that "[e]ven if the theory (regarding selenium inhibiting cancer) proves true, scientists would face the problem of finding a dosage level for humans that lies on the razor's edge between a cancer inhibitor and a poison" (CX 36B).

215. With regard to vitamin E, CX 36 characterizes the research as only providing "hints" that vitamin E may block nitrosamine formation (CX 36B). As testified to by complaint counsel's experts, it has not been shown that nitrosamines cause cancer in humans (Rogers, Tr. 1579). Furthermore, experts for both complaint counsel and respondent stated that for vitamins to block nitrosamine formation, it is reasonable to believe that they must be in the stomach at the same time as the nitrites and amines (Shamberger, Tr. 2466; Rogers, Tr. 1383-84). Nitrites are most likely to be present in the stomach immediately after eating (Shamberger, Tr. 2466-67; Rogers,

Tr. 1383-84, 1498). However, respondent's expert, Dr. Shamberger, stated that the vitamins provided by a supplement such as Healthy Greens would remain in the stomach for only a short period of time. Therefore, since they should be taken only once each day, they would not necessarily be present when the nitrites and amines are present (Shamberger, Tr. 2466). CX 36 does not support any ad claim in issue here (Rogers, Tr. 1438-39; Campbell, Tr. 741).

CX 37

216. CX 37 is a one-page document of uncertain origin which discusses very general dietary guidelines to avoid cancer. For example, it suggests that raw or cooked vegetables and fruits be increased and fatty meats reduced; these are the same recommendations made in the Report. As Dr. Rogers testified, this document discusses whole foods (Rogers, Tr. 1442), not supplements. The document does not report original research (Campbell, Tr. 743). And it does not discuss vitamin E. CX 37 **[61]** does not substantiate the ad claims in issue in this case (Rogers, Tr. 1441-42; Campbell, Tr. 743).

CX 38

217. CX 38 is a two-page document apparently published or distributed by "Nutritional Specialty Products" of Annandale, Virginia. It is not a scientific paper and the assertions about the effect of nutrients are unsupported. This document is apparently a sales pamphlet. It contains no original research and its speculations are unsupported (Rogers, Tr. 1442-43). CX 38 does not substantiate the ad claims in issue in this case (Rogers, Tr. 1442-43; Campbell, Tr. 743).

CX 39

218. CX 39 is an article from *Prevention Magazine,* which contains information on a study in which a combination of vitamins C and B_{12} showed powerful effects against tumors in animals. However, it does not substantiate the ad claims in issue here (Rogers, Tr. 1443-44; Campbell, Tr. 744). The research discussed deals with transplanted tumors and, as Dr. Rogers testified, it is not related to reducing the risk of cancer in humans (Rogers, Tr. 1444). And CX 39 provides no support for respondent's vitamin E claims.

CX 40

219. CX 40 is a newspaper article entitled "Low-Fat Diet Is Called

A Cancer Preventive" in which Dr. Anthony B. Miller of the University of Toronto is quoted very generally regarding diet and cancer. For example, Dr. Miller (who was a member of the Committee, JX 1, Appendix A, p. 454) is quoted as advising that persons reduce fat intake and increase fresh fruit and vegetable consumption. These are the same recommendations made by the Committee. The brief statement regarding vitamins provides no new information and contains no scientific data.

CX 41

220. CX 41 is a brief newspaper article about the Committee's dietary guidelines and contains no original research (Campbell, Tr. 746; Rogers, Tr. 1448). The article very briefly discusses the apparent lower risk of stomach cancer associated with higher intake of vitamin C-rich foods, but goes on to point **[62]** out that the evidence is on whole foods, not on vitamin C supplements. In fact, the article quotes a Committee member as saying that the research "focused on populations that consumed lots of fresh citrus fruits." CX 41 does not discuss vitamin E.

CX 42

221. CX 42 is a three-paragraph letter appearing in *Lancet,* discussing beta-carotene, but it does not state that beta-carotene affects cancer in humans (Rogers, Tr. 1449). And this letter does not discuss vitamin E.

CX 43

222. CX 43 is a news report concerning the Committee's deliberations and the dietary guidelines contained in the Report. This article specifically notes that the Committee advised against supplements (CX 43A). And CX 43 contains no meaningful discussion of vitamin E and cancer.

CX 44

223. CX 44 is a document entitled "Carrots and Cancer" in which the possible role of foods containing beta-carotene in inhibiting some forms of cancer is discussed. CX 44 also repeats Dr. Sporn's statement in CX 36, discussed in F. 213, *supra,* that persons "not rush out and buy vitamin A in the hope of preventing cancer" (CX 44B). CX 44 also quotes Dr. Philip White, who is identified as Director

of the Department of Food and Nutrition of the American Medical Association, as saying that "it is premature to jump to the conclusion that increasing carotene consumption will prevent cancer" (CX 44B). The article goes on to say that Dr. White's statement "serves to underline others' belief that the pro-carotene evidence needs further substantiation" (CX 44B). Although offered by respondent as substantiation for its claims, respondent's employee, Dr. Thompson, testified that he does not agree with this statement (Thompson, Tr. 2085). And CX 44 does not discuss vitamin E. CX 44 does not substantiate the ad claims in issue here (Rogers, Tr. 1450-51; Campbell, Tr. 748-49).

CX 45

224. CX 45 is another news report that states that the consumption of foods rich in beta-carotene and not nutrient **[63]** supplements appear to reduce the risk of lung cancer. This report also refers to Dr. Sporn and to the search for non-toxic forms of vitamin A. It also notes that the research on vitamin A is merely suggestive and the need for further research (Rogers, Tr. 1452). And CX 45 provides no significant discussion of vitamin E. CX 45 does not substantiate the ad claims in issue here (Rogers, Tr. 1451-52; Campbell, Tr. 749).

CX 46

225. CX 46 is a newspaper article dealing with diet and cancer and purporting to quote complaint counsel's expert, Dr. Campbell. The testimony establishes that this article came from an interview given to a *Chicago Tribune* reporter by Dr. Campbell (Campbell, Tr. 931-32). The testimony regarding this document illustrates why non-peer-reviewed news articles are not reliable sources of scientific information. Dr. Campbell testified that the article may imply erroneously that he believes that individual nutrients, rather than whole foods, affect the risk of cancer in humans (Campbell, Tr. 929-32). In other respects this is simply a news article about the Report and Dr. Campbell's comments about the Report. CX 46 does not substantiate the ad claims in issue here (Rogers, Tr. 1452-54; Campbell, Tr. 749-50).

CX 47

226. CX 47 is an article entitled "Can Vitamins Cure Cancer?" The document contains no original research that can be critically reviewed

(Campbell, Tr. 750). In discussing the issue of vitamins and cancer, it states that "the whole issue has been mythologized by unscientific claims that 'megavitamin' therapy or pseudovitamins are effective cancer treatments" (CX 47A; Rogers, Tr. 1454). The article also discusses possible toxicity of vitamin A and the search for non-toxic forms of vitamin A (Rogers, Tr. 1454). Moreover, according to complaint counsel's expert, Dr. Rogers, the document raises "several cautionary statements about diet supplements as opposed to foods, food intake of nutrients" (Rogers, Tr. 1454). And CX 47 provides no significant discussion of vitamin E and cancer. CX 47 does not substantiate the ad claims in issue here (Rogers, Tr. 1453-54; Campbell, Tr. 750).

CX 48

227. CX 48 is an article entitled "Diet, Nutrition and Cancer," by Alcantara which appeared in **[64]** 29 *American Journal of Clinical Nutrition* 1035 (1976), a peer-reviewed journal. It does not substantiate the ad claims in issue here (Rogers, Tr. 1455-57; Campbell, Tr. 751). It is a 1976 review that summarizes some of the early studies reported up to that time and points out conflicting research on vitamin A (Rogers, Tr. 1456-57). The need for caution in extrapolating from animal research to humans is pointed out in the document (CX 48A). In any event, CX 48 also notes the potential toxicity of vitamin A and that much of the cancer research involving vitamin A has been at high doses (CX 48F).

228. CX 48 also stated that "Present evidence indicates that the overall consequences of diet and nutrition in cancer development will depend on the net physiological and metabolic effects of the various dietary components" (CX 48J). This latter statement is consistent with the view expressed in the Report that the perceived benefits to be derived from following the interim guidelines in the Report may result from interreactions of the dietary changes caused by eating vegetables (*see, e.g.,* Rogers, Tr. 1733; Campbell, Tr. 656-67).

CX 49

229. CX 49 is a brief article from the *Journal of the American Dietetic Association,* which summarizes a study published in the *Journal of the American Medical Association.* Dr. Thompson of GNC testified that he found particularly interesting that the article describes current work on tissue cultures which suggested that

vitamins C and E, which are believed to be antioxidants, used together may improve the management of some tumors by inhibiting cancer growth and enhancing the effects of chemotherapy. CX 49 notes that controlled trials are currently under way to confirm these effects in humans (Thompson, Tr. 1966-67). However, CX 49 does not substantiate the ad claims in issue here (Rogers, Tr. 1463-64; Campbell, Tr. 752). CX 49 also warns against supplementation with vitamin A, stating: "Vitamin-cancer researchers continue to caution against over-consumption of vitamin A by persons who might misinterpret results of research to date. Liver, spleen, and even brain damage may result" (CX 49) (emphasis added).

CX 50

230. CX 50 is a document produced by GNC in 1979 by its corporate vice president, and contains a general review of the subject of food nutrition and disease (Thompson, Tr. 1968-69). It includes a discussion of various mechanisms proposed to explain the observed effects of diet on cancer and refers to the role of antioxidants such as vitamin E in inhibiting cancer with **[65]** citations to the scientific research. In addition, it discusses the substantial research which has associated deficiencies in vitamins A, C and E with higher rates of cancer. The document concludes that "[b]ecause it is difficult to obtain all of the nutrients in proper proportions from our food, the use of a multivitamin and mineral supplement in addition to good dietary practices is indicated" (CX 50G). CX 50 does not substantiate the ad claims in issue here (Rogers, Tr. 1464-65; Campbell, Tr. 753-54). It contains no information identifying its source of publication or author(s) and which consists of brief review-type discussions under several different headings. It does not report original research (Campbell, Tr. 754). Large portions of the document have nothing to do with cancer. It contains brief reports regarding possible roles of diet with respect to cancer but only speculates about these roles.

CX 51

231. CX 51 is a review of obesity and cancer from *The Lancet.* The article suggests that oesophageal cancer may be associated with chronic vitamin A deficiency. CX 51 does not substantiate the ad claims in issue in this case (Rogers, Tr. 1465-66; Campbell, Tr. 754). It is a commentary with no original research (Campbell, Tr. 754). It does not state that nutrient supplements reduce the risk of cancer, but

instead describes how whole dietary intake was studied and talks about cancers in both malnourished and overfed populations (Rogers, Tr. 1466).

CX 52

232. CX 52 is a collection of abstracts published by the R.P. Scherer corporation and contains an abstract of a study by Peto in *Nature*. Dr. Thompson of GNC testified that the abstract contains information that various studies have shown that "retinoids and carotenoids can suppress, delay, prevent or cause regression of cancer under certain conditions" (CX 52A; Thompson, Tr. 1971). Dr. Rogers agreed that this is a "reasonable hypothesis" (Rogers, Tr. 1642). Dr. Thompson also testified that another abstract from the *Journal of Medical Hypotheses* given in CX 52 discusses supplementation and the opposition to it by some elements of the scientific community. The abstract states:

> Supplementation as a concept is opposed by some, according to this author, because it is assumed that from an evolutionary point of view, the existing diet must be the ideal one for survival and that supplementation of such **[66]** a diet would be superfluous. To this, he responds that our survival well past the reproductive age is in itself an evolutionary fluke, so that there is no reason to believe that the "natural" diet will provide protection from the diseases of aging. He estimates that constructing an optimal diet for the aging will require substantial manipulation and will require "the artifice of supplementation (CX 52 at p. 10; Thompson, Tr. 1972).

233. CX 52 does not substantiate the ad claims in issue here (Rogers, Tr. 1466-67; Campbell, Tr. 755). CX 52 notes that it is unknown whether vitamin A and dietary beta-carotene have a protective effect, or whether the protective effect is due to something else in vegetables or to a dietary pattern involving lower intakes of foods other than vegetables. CX 52 also contains a warning which states:

> CAUTION: Unwary readers (if such there are) should not take the accompanying article as a sign that the consumption of large quantities of carrots (or other major dietary sources of beta-carotene) is necessarily protective against cancer, and the correlation between blood retinol [vitamin A] and cancer avoidance is, for the time being, *sub judice* (CX 52B).

CX 52 in another abstract states:

> Low levels of nutrient intake may enhance the carcinogenic processes in the body, and high intakes of some nutrients may have the same effect (CX 52H).

The author estimates that for some nutrients, an excessive intake may be "only a few multiples of the recommended daily allowance. These include vitamin A, vitamin D, selenium, protein and linoleic acid" (CX 52H). CX 52 provides no substantive discussion of vitamin E.

CX 53

234. CX 53 is a manuscript of a book by Charles Simone, M.D., entitled *Cancer and Nutrition,* published in 1985. The **[67]** Simone manuscript discusses the research in the area of diet and cancer and sets out a program of dietary recommendations designed to implement the benefits of the available research. According to Dr. Thompson of GNC, the book indicated that "the extent of the literature was adequate to support a supplement for use in the prevention of cancer" (Thompson, Tr. 1973). The book based on CX 53 contains a Forward by Dr. Robert Good, a well respected cancer specialist and former President and Director of the Memorial Sloan-Kettering Cancer Hospital. In the Forward, Dr. Good stated in part "Dr. Simone summarizes current knowledge that promises prevention of many, if not most, cancers.... We must exercise regularly, eat a prudent diet, avoid known cancer-causing chemicals, and take rational amounts of certain vitamins and minerals." Dr. Good states his view that "[t]hese are simple means—all-but abundant experimental epidemiological and clinical evidence indicates that these relatively minor adjustments of life-style, initiated as early in life as possible, could reduce the frequency of cancer dramatically."

235. CX 53 contains no original data (Campbell, Tr. 756). Complaint counsel's expert, Dr. Campbell, testified that CX 53 is totally unreliable as far as nutrition and cancer is concerned (Campbell, Tr. 756). Dr. Campbell characterizes the book as basically a promotion for a dietary supplement called "Risk Modifier," which respondent GNC has sold (Campbell, Tr. 757; *see* CX 73). Dr. Campbell also testified that the document is an oversimplification with serious inconsistencies and misrepresentations of nutritional information (Campbell, Tr. 758-59). For example, Dr. Campbell testified that the RDAs are erroneously referred to as minimum nutrient levels needed to prevent obvious signs of vitamin deficiency (Campbell, Tr. 758-61). CX 53 does not contain anything which would show that the author is a recognized expert in the fields of cancer or nutrition. Dr. Rogers, who is a recognized expert in the field of nutrition and cancer, testified that the author of the manuscript is unknown to her (Rogers,

Tr. 1468-69). CX 53 does not substantiate the ad claims in issue in this case (Rogers, Tr. 1468-69; Campbell, Tr. 756).

(4) GNC's Prior Substantiation Material Does Not Constitute A Reasonable Basis For The Challenged Claims Under The Commission's Criteria

236. In the 1983 *FTC Policy Statement Regarding Advertising Substantiation,* the Commission summarized the factors, as developed by its prior cases, that Commission will weigh in determining the appropriate level of substantiation for both express and implied advertising claims as follows: **[68]**

> ...The Commission's determination of what constitutes a reasonable basis depends, as it does in an unfairness analysis, on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include: the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable....
>
> One issue the Commission examined was substantiation for implied claims. Although firms are unlikely to possess substantiation for implied claims they do not believe the ad makes, they should generally be aware of reasonable interpretations and will be expected to have prior substantiation for such claims....

104 FTC at 840.

237. First, regarding the type of product involved, respondent offered Healthy Greens essentially as a supplement product that will reduce the incidence of certain cancers in humans and also claimed that vitamin E, an ingredient of Healthy Greens, plays an important role in reducing the risk of cancer. In other words, Healthy Greens was offered as a cancer preventive.

238. Therefore, GNC should have possessed at least one well-controlled human test. Epidemiological and animal studies alone, however suggestive they may be, do not constitute adequate substantiation for a claim that a supplement product is a cancer preventive in humans. *See* F. 244-45, 270-71, 336-46, *infra.*

239. Regarding the type of claim involved in this case, the claims at issue are indisputably those whose truth or falsity would be difficult or impossible for consumers to evaluate by themselves. No one would seriously contend that consumers are, or may reasonably be expected to be, capable of evaluating the truth or falsity of a claim that a product or an ingredient therein is associated with a reduction in the incidence of cancer in humans or an ingredient in a product plays an

important role in reducing the risk of cancer in humans. Indeed, such a task would be a difficult one even for experts in the field of diet, nutrition and cancer. This fact is evident from the state of scientific knowledge, or the lack thereof, regarding the role, if any, of dietary components or nutritional factors in inhibiting the initiation or development of cancers in humans as revealed in this record. **[69]**

240. The third and fourth factors will be considered together. The third factor is the benefit of a truthful claim. The fourth factor is the ease of developing substantiation for the claim. As the Commission stated in *Thompson* (104 FTC 823), the Commission's concern in analyzing these two factors is "to ensure that the level of substantiation required is not likely to prevent consumers from being told potentially valuable information about product characteristics."

241. In this case, the benefit to consumers from the advertising claims at issue would be great indeed if Healthy Greens or vitamin E had the claimed benefits. However, the record in this case does not suggest that requiring controlled human trials going beyond animal studies and epidemiological information would significantly reduce the likelihood of consumers being told of effective cancer preventive agents. The market for such products is enormous beyond measure, in this country and abroad. It is safe to conclude that the total cost of complying with the reasonable basis requirement here would not deter the development or advertising of new cancer preventive agents or products. Rather, the record in this case clearly shows that GNC introduced Healthy Greens without conducting a single test of any kind and strongly suggests that GNC simply wanted to get on the band wagon to take advantage of the publication of a new, government-sponsored NAS-NRC Committee Report entitled *Diet, Nutrition and Cancer* in 1982. *See* Thompson, Tr. 1821, 2122-25.

242. The fifth factor is the consequences of a false claim. In this case, the principal injury is the economic harm to the consumer resulting from the repeated purchase of an ineffective product in the belief that daily use of Healthy Greens will reduce his or her cancer risk. However, Healthy Greens is not risk-free to consumers, for certain level of risk of vitamin toxicity or "overdosing" is inherent in any unsupervised use of vitamin supplements such as Healthy Greens. Respondent's experts, while characterizing such risk as at "minimal level," they did not disagree with the cautionary statements which appear in some of respondent's own prior substantiation material which speculated on potential benefits of vitamins A and E in humans.

243. The sixth and last factor is the amount of substantiation experts in the field would consider reasonable. This was a hotly contested issue at the hearing. Although respondent's expert witnesses urged that the available evidence offered some scientifically rational basis for the marketing of a supplement product such as Healthy Greens from a public policy or public health point of view ("it will do no harm and may do some good" or "until we learn more about diet, nutrition and cancer, there isn't anything better available"), their views, strictly speaking, do not address the issue of scientific substantiation **[70]** in the sense the term is used in the Commission's advertising substantiation cases or the 1983 *Policy Statement Regarding Advertising Substantiation. See, e.g.,* Newell, Tr. 2824-25, 2903-04.

244. The better view and the majority view of the scientific community with respect to the state of knowledge regarding the issues raised by the advertising claims alleged in Complaint Paragraphs 7(c) and (d) is that the available evidence suggests some promising hypotheses that merit further investigation but it is not sufficient to support those claims. The most telling evidence in this regard is the fact that a number of more focused studies including controlled human trials have been funded by the NCI and are in progress. *See* Newell, Tr. 2774-78, 2889-97; RX 55.

245. Therefore, it is determined that the amount of substantiation expert in the field would consider reasonable is clearly something more than the sum total of respondent's prior substantiation, including the NRC Committee Report, and that in the circumstances of this case, it is reasonable to require at least one well-controlled human trial demonstrating that the protective benefits suggested by animal studies and epidemiological data in fact exist for human subjects.

246. From the foregoing, it is found that respondent did not possess a reasonable basis before the advertising claims in dispute in this case were made.

VII. THE ADVERTISING CLAIMS AT ISSUE IN THIS CASE ARE MATERIAL REPRESENTATIONS

247. Each of GNC's advertising claims is material to consumers. A "material" representation is one that is likely to affect a consumer's choice of or conduct regarding a product. It is any information that is important to consumers in making a purchasing decision. *Thompson,*

104 FTC 816; *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 386-87 (1965); FTC Deception Enforcement Policy Statement, 5 Trade Reg. Rep. at 56,077-78. The Commission presumes the materiality of claims pertaining to the central characteristics of a product or service, such as those relating to purpose...[or] efficacy." *Thompson*, 104 FTC 60; FTC Deception Enforcement Policy Statement, 5 Trade Reg. Rep. at 56,078.

248. All of the advertising claims at issue in this case clearly are within these categories. Specifically, each of the advertising claims at issue relates to the possible benefits of Healthy Greens with respect to reducing the risks of cancer in humans. As such, these advertising claims are product purpose **[71]** and efficacy claims and are presumed material. Moreover, these claims are particularly important (and thus material) to consumers since they involve the vital health issue of reducing one's risk of cancer, a dreaded disease for which no effective cure is known to date.

249. It is also well-settled that advertising misrepresentation, express or implied, is material so long as it can induce a purchaser to buy the advertised product, *FTC v. Colgate-Palmolive Co.*, 380 U.S. at 386-87, and the Commission may infer materiality without further evidence. *Colgate-Palmolive Co.*, 380 U.S. at 392. For example, the reasonable basis claim in this case is material since it is well-established that the absence of support for claims that imply a reasonable basis is likely to mislead consumers and induce consumers to purchase a product. *See, generally, National Dynamics Corp.*, 82 FTC 488 (1973), *denied in part and remanded in part*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 409 U.S. 933 (1974), *reissued*, 85 FTC 391, *modified*, 85 FTC 1052 (1975).

250. In this case, respondent was promoting a tablet for its ability to reduce the risk of cancer. Indeed, the ability to reduce the risk of cancer was the *raison d'etre* for Healthy Greens tablets. Clearly the challenged advertising claims relating to the use and benefits of Healthy Greens tablets have the capacity to influence consumers to purchase the tablets. They are, therefore, material representations. *See National Dynamics Corp.*, 82 FTC 522.

VIII. SIGNIFICANCE OF POST-CLAIM EVIDENCE IN DETERMINING THE ADEQUACY OF RESPONDENT'S SUBSTANTIATION

251. Respondent introduced post-claim evidence (consisting of more recent literature bearing on anti-cancer effects of various nutrients)

and offered expert testimony regarding such materials. The post-claim material introduced by respondent is admittedly not a part of its prior substantiation material it possessed and relied upon for its advertising claims (JX 2B, Stipulation 4).

252. The complaint in paragraph 10 alleges that respondent failed to possess and rely upon a reasonable basis for its claims set forth in paragraphs 7(c) and (d) prior to their dissemination. Since the post-claim material is not part of respondent's prior substantiation material, they need not be considered in determining the issue of liability.

253. The law is clear that consumers are entitled to believe that advertisers have a basis for their advertising claims when they are made. *Porter & Dietsch,* **[72]** 90 FTC 865-66. Thus, in *Porter & Dietsch,* the Commission held that post-claim documents were irrelevant because they were not part of the prior-substantiation material. 90 FTC 868-69. The Commission's 1984 Statement Regarding Advertising Substantiation affirmed this doctrine: "we reaffirm our commitment to the underlying legal requirement of advertising substantiation—that advertisers...have a reasonable basis for advertising claims before they are disseminated." FTC Policy Statement Regarding Advertising Substantiation, 104 FTC 839. Thus, the Commission has reaffirmed its policy that it would generally not consider post-claim evidence in Section 5 proceedings.

254. The Commission's 1984 Statement did state that it would, in its discretion, consider post-claim evidence, not as a substitute for an advertiser's prior substantiation, but in the following circumstances:

a. When deciding, before issuance of a complaint, whether there is a public interest in proceeding against a firm;

b. When assessing the adequacy of the substantiation an advertiser possessed before a claim was made; and

c. When deciding the need for or appropriate scope of an order to enter against a firm that lacked a reasonable basis prior to disseminating an advertisement (104 FTC 841).

255. With respect to b. above, the Commission stated:

Second, post-claim evidence may indicate that apparent deficiencies in the pre-claim substantiation materials have no practical significance. In evaluating the adequacy of prior substantiation, the Commission will consider only post-claim substantiation that sheds light on pre-existing substantiation. Thus, advertisers will not be allowed to

create entirely new substantiation simply because their prior substantiation was inadequate (104 FTC 841).

256. It is thus clear that, in the circumstances of this case, the post-claim substantiation material can only be used to interpret or shed light on the prior substantiation material and **[73]** cannot be considered as independent substantiation. Thus, if the prior substantiation material is inadequate in light of the post-claim evidence, the claims remain unsubstantiated regardless of whether the post-claim material might independently substantiate the claims. That is to say, the so-called post-claim evidence cannot serve to save respondent from liability independently of its prior-substantiation material. This is such a case.

257. In this case, as discussed hereinafter in some detail (F. 280-346, *infra*), the post-claim material does not make the fundamental deficiencies of the prior substantiation material—*e.g.*, negative conclusions of the Report, the lack of evidence with respect to humans (other than epidemiological studies), the lack of any knowledge of doses that might or might not be effective in humans, etc.—of "no practical significance." Rather, these important deficiencies remain undiminished.

258. Respondent argues that the post-claim material "shed light" on the Report. However, the NAS-NRC Committee Report makes it abundantly clear that respondent's post-claim documents do not aid respondent to "interpret" the Report or any of its prior substantiation documents to reach a result different from the conclusions unequivocally stated in the Report.

259. Furthermore, the Commission has stressed that the post-claim material should only be used to interpret the prior substantiation material and that "advertisers will not be allowed to create entirely new substantiation simply because their prior substantiation was inadequate" (FTC Advertising Substantiation Policy Statement, 104 FTC 841; F. 254-56, *supra*). Therefore, the post-claim material must be so closely connected with the prior substantiation documents as to interpret these documents. Here the bulk of post-claim material is not connected with the prior substantiation material. With the exception of studies referred to in the Report, they consist of new studies or other documents that discuss data or opinions not part of the prior substantiation documents. Accordingly, under the Commission's Advertising Substantiation Policy Statement, they cannot be used to

extricate respondent from liability arising from the fundamental deficiencies in its prior substantiation.

260. Respondent offered testimony of three witnesses on the issue of the adequacy of its substantiation for the advertising claims at issue. They are Dr. Shamberger and Dr. Newell, and Dr. Thompson, an employee of respondent. Expert opinions, however well qualified the experts may be, cannot constitute substantiation apart from the scientific documents discussed at trial and cannot be a substitute for factual evidence as a basis for product claims. *Thompson,* 104 FTC 83.

261. In any event, neither Dr. Shamberger nor Dr. Newell was contacted prior to this litigation (CX 71F; Thompson, **[74]** Tr. 2129), and therefore, their opinions were not relied on by respondent prior to the dissemination of the advertisements (CX's 1-7). Nevertheless, their views on the prior substantiation material may be considered in interpreting the prior substantiation documents. However, their views on post-claim documents may be considered solely for the purpose of evaluating the significance of the post-claim material within the narrow confines of the limitations the Commission has placed upon the use of post-claim substantiation material discussed hereinabove.

262. In this connection, it is important to note that if post-claim material is to be considered at all with regard to the issue of substantiation, it is the scientific evidence *in the record as a whole.*

263. The Committee, after reviewing all the available scientific evidence, determined that it is not known whether nutrients affect cancer (JX 1, p. 11). It recommended vegetables and not nutrients because there was no evidence in humans that nutrients, as opposed to foods, affect cancer (JX 1, pp. 11, 15). Respondent's post-claim material is essentially the same type of evidence considered by the Committee, and many of respondent's post-claim documents were specifically considered by the Committee in reaching its conclusions.

264. The testimony of respondent's experts that, despite the Report's express exclusion of supplements from its recommendations, the NAS-NRC Committee Report did not mean to preclude the use of supplements such as Healthy Greens, which in their view will do no harm and may do some good, is hardly an adequate substantiation for a claim that the Report supports the use of Healthy Greens as a means of reducing the risk of cancer in humans.

265. As to the Report's expressed concern for the dangers of vitamin toxicity resulting from unsupervised consumer use of supple-

ments, the view of respondent's experts was that such risks are minimal as far as Healthy Greens tablets are concerned.

266. As to Dr. Thompson, GNC's Director of Nutrition Education, his testimony regarding respondent's prior-substantiation material is probative mainly of respondent's intent with respect to Healthy Greens advertisements (CX's 1-7) and secondarily of what Dr. Thompson thought of the newspaper clippings, articles from lay magazines, science news bulletins and few scientific review articles and letters published in reputable journals, together with the 1981 Simone manuscript (CX 53) and the NAS/NRC Committee Report itself, all of which he had accumulated in his so-called "substantiation file" maintained in his office. Although he was respondent's resident expert on nutrition, his qualifications as an expert in the evidentiary **[75]** sense in the field of diet, nutrition and cancer are not equal to those of the others who testified.

267. The NAS-NRC Committee was charged by NAS to determine among other things, the relationship between dietary elements such as nutrients and the risk of cancer (Grobstein, Tr. 310-14). The Report represents the majority view among scientists, and its views are therefore given greater weight in the scientific community than those of any one or two individual scientists (Newell, Tr. 2808-12). As further indication that the Report's conclusions are generally accepted by the scientific community, the National Cancer Institute agrees with the Report's conclusions that scientists do not know what role, if any, nutrients play with respect to cancer (Newell, Tr. 2805-07). Accordingly, the Report's conclusions are strong evidence that respondent's advertising claims remain unsubstantiated even when the post-claim material is taken into account when the record evidence *as a whole* is considered.

IX. Respondent's argument that evidence supports inclusion of individual nutrients in Healthy Greens

268. About half of respondent's proposed findings and supporting argument is devoted to two related propositions: (1) that the evidence supports inclusion of the individual nutrients and mineral (more specifically vitamins A, C and E and selenium) in Healthy Greens; and (2) that the use of a multi-vitamin supplement such as Healthy Greens is supported by the 1982 NAS-NRC Committee Report and more current scientific information (the so-called post-claim evidence). *See* RPF, pp. 106-94.

269. For the purposes of determining the issue of the Federal Trade Commission Act violation in this proceeding, however, it is important to keep these arguments in proper perspective. The central issue of liability to be determined *with respect to the advertising claims set forth in Paragraphs 7(c) and (d) of the Complaint* is whether respondent's prior substantiation material (including the Report (JX 1)) constitutes adequate substantiation for the two specific advertising claims. Neither of the two ad claims involve "inclusion of vitamins A, C and E or the mineral selenium in Healthy Greens" or the "sale or use of a multi-vitamin supplement such as Healthy Greens" in general terms. Therefore, to argue that the Report (or some epidemiological or animal studies referred to in the Report) offers sufficient scientific rationale for a product such as Healthy Greens, or to argue that, in the absence of any proven preventive or curative agent for human cancers, a risk-benefit type analysis or public health policy considerations favor the marketing and sale of Healthy Greens ("it will do no harm and may **[76]** do some good") is to obfuscate the central issues to be determined. These arguments do not aid respondent in establishing the adequacy of its prior substantiation for the specific advertising claims alleged in the Complaint and found to have been made in the earlier sections of Findings (F. 105-16, *supra*).

270. It is fair to conclude from this record that the sum total of scientific information (epidemiological and animal data and biological knowledge regarding certain nutritional factors) may suggest some rational and potentially useful hypotheses regarding diet, nutrition and cancer in humans which merit further, and more focused and rigorous, investigation including controlled human trials. *See, e.g.*, Rogers, Tr. 1460-63.

271. In fact, the record indicates that a number of such trials have been funded by the NCI and are in progress, largely along the lines of research directions recommended by the NAS-NRC Committee after a state-of-the-art appraisal of available scientific information related to dietary factors, nutritional components and the incidence of cancer. These studies have just begun and their outcome, one way or the other, will not be known for some years to come. *See* Newell, Tr. 2774-78, 2889-97; RX 55.

272. Against the background discussed in the preceding Findings, respondent's argument that the Commission should leave undisturbed the marketing of supplements such as Healthy Greens because the product will do no harm to consumers and may do some good is

tantamount to an assertion that the Commission should suspend its advertising substantiation requirement with respect to a class of products which are harmless and which can offer some scientific basis to hope that they might eventually turn out to have the promised benefits. Such an assertion is unacceptable as a matter of law and highly objectionable in this case where the promised benefit is reducing the risk of cancer in humans.

273. For example, Dr. Newell, respondent's expert witness, expressed his opinion on the public policy issue of the apparent risks versus benefits of nutrient supplements (*e.g.*, Newell, Tr. 2895-97; 2903-04) as well as his view that "political reality" and "public expectation" should be considered (Newell, Tr. 2824-26). Thus, Dr. Newell seemed to be testifying that nutrient supplements should not be banned from the market place. Since the issue at trial is not whether to ban the product but rather whether respondent's advertising claims are based on adequate scientific substantiation, his testimony in favor of nutrient supplement products does not for the most part address the issues raised in this case. *Also see* Thompson, Tr. 2046.

274. Dr. Newell did not dispute that, putting aside the public policy considerations of the risks versus benefits, it has not been demonstrated that nutrients or a supplement product such **[77]** as Healthy Greens affect cancer in humans. Also, he specifically agreed that there is not enough evidence to determine whether vitamin E or selenium reduce the risk of cancer in humans (Newell, Tr. 2821-26, 2838-39). He also agreed that in 1983, when the claims were disseminated, there were scant scientific data that vitamin C reduces the risk of cancer in humans (Newell, Tr. 2831-32). He also agreed with the National Cancer Institute that scientists cannot say what role vitamins and minerals, as opposed to foods, play with respect to cancer (Newell, Tr. 2805-07).

275. Dr. Lachance, another of respondent's experts, testified as to estimates of dietary intake of vitamins based on certain nutritional intake studies in the United States. Dr. Lachance also referred to a few scientific studies dealing with blood and liver nutrient levels. These studies, however, do not deal with the cause, prevention or treatment of cancer through the use of dietary supplements, and neither Dr. Lachance nor any other witness testified that they do.

276. Dr. Lachance's testimony concerning dietary intake of vitamins in the United States is not relevant to the issues in this case

because there has been no showing that deficiencies of specific nutrients are a significant cause of cancer. There is no showing that persons who are deficient in specific nutrients can reduce their risks of cancer by taking Healthy Greens or by taking vitamin supplements. Furthermore, the advertising claims at issue were not directed to persons deficient in nutrients but to the general public. In fact, respondent admitted that the ads were not limited to a certain group (CX 89I-J).

277. It is clear from respondent's proposed findings and argument contained in pages 106 through 184 that the main thrust of respondent's argument regarding substantiation is that the totality of the evidence it presented at the hearing—the prior substantiation documents (JX 1, CX's 12-53), certain designated portions of the post-claim documents (RX's 48, 50, 55-56, 60-61, 63, 66, 75, 78, 80, 85–87, 105, 107, 112-13, 118, 120, 132, 144, 149, 154, 156-57, 162, 164-65, 167, 170, 172, 175-76, 178, 180, 184, 187, 200, 203-04) which were received in evidence, the testimony of its expert witnesses regarding both the prior and post-claim documents in evidence—supports the proposition that there is sufficient scientific basis to show an association between the nutrients and mineral selenium included in Healthy Greens and a reduction in the risks of cancer in humans. *Also see* RRB at 23-40.

278. Respondent also argues that, although no single piece of evidence in the record shows conclusively that Healthy Greens or any nutrient included in Healthy Greens will reduce risk of cancer in humans, the convergence of evidence from epidemiological studies and animal studies all pointing to the **[78]** same direction of suggesting that there may be an association between the nutrients and mineral selenium included in Healthy Greens and a reduction in the incidence of cancer in humans, is sufficient substantiation which meets the Commission's reasonable basis requirement.

279. These arguments, however, are grounded upon an admixture of prior substantiation documents and post-claim documents as well as testimony regarding both, and it is difficult to sort out and evaluate them in light of the limitations placed upon the use of post-claim material by the Commission.

280. For the purposes of this case, it suffices to say that none of the post-claim documents or testimony discussing them is, individually or collectively, capable of making up for the fundamental deficiencies of respondent's prior substantiation or of demonstrating that these

deficiencies were of no practical significance. On the contrary, they serve to point out the basic limitations of epidemiological and animal studies and the need for further study of more animal models, culminating in controlled human trials. *See, e.g.,* F. 318, 320, *infra.*

281. For the sake of completeness, a brief discussion of respondent's post-claim documents is given in the following Section. It should be stressed here that respondent was permitted to offer designated portions of these documents for the limited purposes of "shedding light" on its prior substantiation documents and that, therefore, none of respondent's post-claim documents discussed hereinafter may be relied on as a basis for additional or independent substantiation for the purposes of this proceeding. *See* F. 253-56, *supra.*

X. RESPONDENT'S EXHIBITS THAT ARE NOT PRIOR SUBSTANTIATION

282. At trial GNC introduced through its expert witnesses various documents in addition to its prior substantiation documents (JX 1; CX's 12-53). These post-claim documents may be divided into two groups: those that were cited or discussed in the Report (JX 1) and those that were not.

A. *Post-claim Documents Which Are Cited In The NAS-NRC Committee Report (JX 1)*

283. Respondent was permitted to discuss 26 studies at the hearing that were cited or discussed in the Report. These included 14 animal studies (Rx's 60, 66, 118 (or RX 176), 120, 163-64, 167-68 (or RX 150), 170, 172, 175, 178, 180, 184), 11 **[79]** epidemiological studies (Rx's 56, 61, 103 (the same as CX 23), 112, 115, 139 (the same as CX 22), 149, 156-57, 165, 203) and one review article (RX 145).[4] These will be discussed below in numerical order.

284. RX 56 (also designated RX 111), Wassertheil—Smoller, *et al.*, "Dietary Vitamin C and Uterine Cervical Dysplasia," *American Journal of Epidemiology,* Volume 114, No. 5, 1981, is an epidemiological study of cervical dysplasia, and is cited in the Report on page 145. On the basis of a study of 169 women with cervical abnormali-

[4] Dr. Thompson, GNC's Director of Nutrition Education, also indicated his familiarity with the following studies in the Report, although he did not discuss all of them: Chapter 9, vitamins, Bjelke, 1975; 9-2, Gregor, *et al.,* 1980; Mettlin, *et al.,* 1979; Shekelle, *et al.,* 1981; Graham, *et al.,* 1981; Mettlin, *et al.,* 1979; Mettlin, 1981; p. 9-4, Crocker and Sanders; p. 9-5, Saffiotti, *et al.*; p. 9-6, Sporn and Newton, 1979. For vitamin C, p. 9-7, Haenszel and Correa, 1975; Kolonel, *et al.,* 1981; Mettlin, *et al.,* 1981; p. 9-8, Wassertheil-Smoller, *et al.,* 1981; Mirvish, *et al.,* 1975; Rustia, 1975; p. 9-9, Logue and Frommer; Reddy and Hirota, 1979; Kallistratos and Fasske, 1980; Logue and Frommer, 1980; Reddy and Hirota, 1979 (Thompson, Tr. 2042-44).

ties, identified through Pap smears, conducted to explore the relationship between nutritional intake and cervical dysplasia (nutritional intake being estimated from computer analysis of three-day food records and 24-hour recall of subjects), the authors concluded that there was a significant relationship between a low *dietary* intake of vitamin C and the presence of cervical dysplasia. The abstract of this article concludes by saying: "If other studies confirm these findings, it may be important to explore a possible protective role of supplementary vitamin C *for women at high risk of cervical cancer*" (emphasis added). RX 56 also notes that other studies (Bjelke, Cameron, Wattenberg and Miller) have indicated a need to evaluate *food sources* of vitamin C and of vitamin A or vitamin E, because the antioxidant theory "requires examination of all nutrients in *food* with potentially protective electron donor capacities" (at p. 723) (emphasis added).

285. The NRC Committee specifically considered RX 56, as it did all of the other RXs cited in the Report, before it reached its conclusion that it is not known what role, if any, nutrients have with respect to cancer in humans. Respondent's witness, Dr. Shamberger, agreed that RX 56 deals with people who ate *foods* containing vitamin C (Shamberger, Tr. 2335). Dr. Rogers pointed out that food intake recall methods such as those used in this study are not accurate in assessing dietary intake (Rogers, Tr. 1419-24). In fact, the authors of the study point out that "Assessment of the dietary vitamin C intake in each group is **[80]** difficult. Moreover, the intake estimates are subject to error due to the inherent difficulties in the technique of interviewing and the fact that no attempt was made to estimate destruction of vitamin C prior to consumption" (RX 56, p. 720). Dr. Newell agreed with the statement on page 723 of this article that "the case-control design of this study dictates caution in drawing conclusions with regard to causal relationship between low vitamin C intake and development of cervical dysplasia" (Newell, Tr. 2867). Also, this study dealt with cervical dysplasia, not cancer. Both Dr. Shamberger and Dr. Newell agreed with the statement in the paper on page 722 that: "These data do not establish a cause-effect relationship between lower vitamin C intake and the development of cervical cancer" (Shamberger, Tr. 2589; Newell, Tr. 2867).

286. RX 60, W.J. Mergens, J.J. Kamm and H.L. Newmark, W. Fiddler and J. Pensabene, "Alpha-Tocopherol Uses in Preventing Nitrosamine Formation," a paper from *Environmental Aspects of N-*

Nitroso Compounds, IARC Sci. Pub. No. 19, International Agency for Research on Cancer, Lyon, France, was cited at page 148 in the Report. It reports studies *in vitro* and in animals. The use of Alpha-Tocopheral (vitamin E) was shown to inhibit aminopyrene-nitrite induced hepatotoxicity in rats and to reduce the amount of NDMA formed in cigarette smoke (at p. 210). The authors also observed that the mechanism of protective effects of vitamin E is analogous to that previously reported for ascorbic acid (vitamin C) by Kamm, *et al.,* in 1973 and that their studies showed that tissue levels of vitamin E, unlike ascorbic acid can be raised in many organs of a rat by adding vitamin E to the diet. Dr. Shamberger expressed a view that this is likely to apply to humans. In any event, the NRC Committee considered RX 60 before it formed its conclusion with respect to vitamin E and stated that "although there is limited evidence suggesting that vitamin E may inhibit tumorigenesis in several [animal] model systems," the data "are not sufficient to permit any firm conclusion to be drawn about the effect of vitamin E on cancer in humans" (at 149).

287. RX 61, C. Mettlin, *et al.,* "Vitamin A and Lung Cancer" 62 *JNCI,* 1435-38 (1979), was cited in the Report at p. 139 and is an epidemiological study dealing with foods, not vitamin A supplementation. In this study, the authors gathered retrospective dietary and smoking data by interview of 292 male patients with lung cancer and 801 control patients with nonrespiratory, nonneoplastic diseases. The authors state that their findings on the interaction of *dietary* vitamin A and smoking in the study subjects "*suggests*" that vitamin A is associated with a lower relative risk of lung cancer in smokers (at 1435). The authors also note that recent findings "*suggests*" that vitamin supplements alone may influence cancer incidence, citing another epidemiological study by Smith and Jick, "Cancers among users of preparations containing vitamin A," (RX 115 **[81]** discussed in F. 292, *infra*). RX 61 was considered by the Committee in reaching its conclusions regarding dietary vitamin A.

288. RX 66, D. Medina and F. Shepard, "Selenium-Medicated Inhibition of Mouse Mammary Tumorigenesis," 8 *Cancer Letter* 241-45 (1980), was cited on Table 10-1 on page 166 of the Report. According to the authors, their study confirms earlier reports that selenium inhibits mammary tumorigenesis in breeding mice (at 244). Dr. Shamberger agrees that this study examined the effect on mammary tumors in mice which were given various amounts of

selenium in their drinking water (Shamberger, Tr. 2300). RX 66 was considered by the Committee in reaching its conclusions regarding selenium.

289. RX 103 is the same as CX 23, discussed in F. 189-96, *supra.*

290. RX 112, Graham, *et al.*, "Dietary Factors in the Epidemiology of Cancer of The Larynx," 113 *Am. Journal of Epidemiology,* 675-80 (1981), was summarized in the Report on page 139. The authors found, based on frequency of consumption data of select foods, that males ingesting low amounts of vitamins A and C in their diet had about twice the risk of developing cancer of the larynx as those ingesting large amounts. Dr. Newell agreed that this epidemiological study discusses the results of a dietary survey, not supplements, and that the results reported in this paper must be used with caution (Newell, Tr. 2854-56). The authors state as much at page 678 of the paper. Dr. Newell also agreed (Newell, Tr. 679) with the authors' statement:

> We stress the tentative nature of our findings, based on the crudeness of the data collection procedures and the comparatively few replications in the literature. The epidemiological evidence is sparse and we are convinced that the field is much more complex than it appears at this early stage of inquiry. All nutrients have not been examined as they relate to all cancers or other pathologies.... In addition, it is quite possible that nutrients found to inhibit certain pathologies could induce others. We conclude that further inquiry is needed on many facets of diet, not only as they are related to cancer of the larynx, but also cancer of other sites and other disorders. This may have potential for identifying elements which may reduce as well as enhance risk (at 679). **[82]**

291. The Committee considered RX 112 in reaching its conclusions regarding vitamin A that although the epidemiological evidence is sufficient to suggest that foods rich in carotenes or vitamin A are associated with a reduced risk of cancer, the toxicity of vitamin A in doses exceeding those required for optimum nutrition makes vitamin supplementation inadvisable (at 144). Dr. Shamberger does not agree with the Committee's conclusion regarding vitamin A supplementation.

292. RX 115, Smith and Jick, "Cancers Among Users of Preparations Containing Vitamin A," 42 *Cancer* 808-11 (1978), was discussed in the Report on page 139. This is a case-controlled epidemiological study in which regular users of vitamin A supplements were compared with non-users with respect to cancer development. The authors concluded there was no convincing evidence that regular

consumption of vitamin A supplements protected against cancer development. The abstract states in part that:

> overall, there was no convincing evidence that regular consumption of such preparations protected against the development of cancer.

The authors also state that (at 810):

> Overall, our findings are compatible with vitamin A exerting no protective effect against development of cancer.

The authors suggest further epidemiological studies of this issue.

293. RX 118, W. Benedict, *et al.* (RX 176), "Inhibition of Chemically Induced Morphological Transformation and Reversion of the Transformed Phenotype by Ascorbic Acid in $C_3H/10T1/2$ Cells," 40 *Cancer Research,* 2796-801 (1980), is a study of the effect of vitamin C on transformation of mouse cells and was summarized on page 146 of the Report. The authors studied effects of vitamin C on mouse embryo cells in culture and found that addition of ascorbic acid to the culture medium can prevent, morphological transformation of cells. The relevance of this study to human cancer is uncertain. In any event, the Committee Report considered this animal study in reaching its conclusion regarding vitamin C on page 147 of the Report.

294. RX 120, P. Cook and McNamara, "Effect of Dietary Vitamin E on Dimethehydrazine-Induced Colonic Tumors in Mice," 40 *Cancer Research,* 1329-31 (1980), was summarized and discussed in the Report on page 149. This animal study does not **[83]** substantiate the claims for Healthy Greens or the claim that vitamin E plays an important role in reducing the risk of cancer in humans.

295. RX 139 is the same as CX 22 and is discussed in F. 185-88, *supra.*

296. RX 149, A. Gregor, P.N. Lee, "Comparison of Dietary Histories in Lung Cancer Cases and Controls with Special Reference to Vitamin A," 2 *Nutrition and Cancer,* 93-97 (1980), was summarized and discussed in the Report at page 139. This case-controlled epidemiological study found that significantly less vitamin A had been consumed by male lung cancer cases than controls. The female cases who developed cancer in this study had consumed more vitamin A than the controls. This is stated in the Abstract on page 93 of the paper: "Twenty-two female cases took more, but not significantly more, vitamin A than did 63 female controls." The authors

state that: "The role of vitamin A in lung cancer etiology requires further investigation" (RX 149, p. 93).

297. RX 156, E. Bjelke, "Dietary Vitamin A and Human Lung Cancer," 15 *Int. J. Cancer* 561-65 (1975), was summarized and discussed in the Report on pages 138 and 139. Dr. Newell agreed that this epidemiological study involved food, not supplements, and that nowhere in this study is there a mention of supplements (Newell, Tr. 2854). Using frequency data collected by a questionnaire mailed to a cohort of Norwegian men, the author observed lower vitamin A values for lung cancer cases than for controls, after controlling for cigarette smoking.

298. RX 157, J, Kark, *et al.*, "Serum Vitamin A (Retinol) and Cancer Incidence In Evans County, Georgia," 66 *JNCI* 7-16 (1981), was cited and commented on in the Report on page 140. The authors reported, based on data from a cohort study of subjects from Evans County, Georgia, that there was an inverse relationship between serum levels of vitamin A and subsequent risk of cancer in general. The Committee Report observed that the "relationship between dietary intake of vitamin A and its level in serum (which is under homeostatic control) is not yet clear" in populations such as the cohort involved here, "which are generally not deficient in [vitamin A]" (at 140) (emphasis added).

299. Furthermore, the validity of RX 157 was cast into doubt by a follow-up study conducted by the same research group. This subsequent study (marked for identification as CX 96) failed to confirm the relationship between serum retinol (vitamin A) and cancer risk observed in RX 157 (CX 96; Newell, Tr. 2881). The authors stated that: "[I]n this new cohort of Evans County, we failed to confirm the strong inverse association between serum retinol and cancer reported in the previous study [RX 157]" (CX 96, p. 1457). Dr. Newell agreed with the statement **[84]** in CX 96 (at p. 1458) that the vitamin A relationship observed in RX 157 may have been an artefact resulting from thawing of serum (Newell, Tr. 2886-87).

300. CX 163, Thompson and Becci, "Selenium Inhibition of N-Methyl-N-nitrosourea-Induced Mammary Carcinogenesis in the Rat," 65 *JNCI* 1299-301 (1980), was cited on Table 10-1 in the Report on page 166. This is an animal (rats) study that was considered by the Committee. RX 163 reported inhibitory activity of selenium supplementation against MNU-induced mammary carcinogenesis in rats. As is true for all animal studies, it does not substantiate the role of

nutrients in reducing the risk of cancer in humans. Dr. Shamberger also criticized the methodology and conclusions of this study (Shamberger, Tr. 2307-14). Also see the next Finding with regard to the Committee's conclusion regarding selenium and cancer in humans.

301. RX 164, R. Shamberger, "Relationship of Selenium to Cancer: 1. Inhibitory Effect of Selenium on Carcinogenesis," 44 *JNCI* 931-36 (1970), is another study cited on Table 10-1 on page 166 of the Report. In this study of skin tumor induction in mice, Dr. Shamberger observed a significant reduction of induced tumors by either dietary or non-dietary application of selenium. Vitamin E was observed to have similar inhibitory effect. The Committee observed that although this and other studies cited in Table 10-1 on page 166 of the Report indicate that selenium has an antitumorigenetic effect, they provide no information on the mechanism of action or on the stage of tumor development during which selenium might exert its protective action in humans (at 167). The Report concluded that firm conclusions cannot be drawn on the basis of the present limited data reported in the epidemiological and laboratory studies and that selenium supplementation to achieve more than the RDA's upper range (200 micrograms per day) has not been shown to confer health benefits exceeding those derived from a balanced diet (at 168-69).

302. RX 165, R. Shamberger, "Antioxidants and Cancer: 1. Selenium in the Blood of Normals and Cancer Patients," 50 *JNCI* 863 (1973), was summarized and discussed in the Report on page 164. The Committee considered this epidemiological study and stated: "It is not clear from this study whether the observed difference in the selenium levels was the result or cause of the cancers."

303. RX 167, C. Ip, D. Sinha, "Enhancement of Mammary Tumorigenesis by Dietary Selenium Deficiency in Rats with High Polyunsaturated Fat Intake," 41 *Cancer Research* 31 (1981), was referred to in the Report on page 165. The Report ascribed "special nutritional importance" to the authors' finding that the incidence of tumors induced by DMBA was enhanced by diets high in polyunsaturated fatty acids and by dietary deficiency of selenium and noted that supplementation with *physiological* levels of **[85]** selenium (0.1 microgram per gram diet) resulted in protection against tumor formation (at 165). The NRC Committee considered this animal (rat) study in reaching its conclusion on selenium, which appears on pages 168-69 of the Report. *See* F. 301, *supra.*

304. RX 150 (also designated RX 168), Greeder and Milner,

"Factors Influencing the Inhibitory Effect of Selenium on Mice Innoculated with Ehrilch Ascites Tumor Cells," 205 *Science* 825-27 (1980), was cited in Table 10-1 on page 166 of the Report. Respondent's expert, Dr. Shamberger, stated that this animal study deals with the effect of selenium on established tumors (Shamberger, Tr. 2296-97). Thus, this paper deals with the *treatment* of cancer and its applicability to cancer *prevention* in mice is uncertain.

305. RX 170, U. Saffiotti, R. Montesano, *et al.*, "Experimental Cancer of the Lung," *Cancer* 857 (May 1967), was cited in the Report on page 142. This study which is 18 years old, was conducted on hamsters and was considered by the Committee. The authors demonstrated that a high intake of vitamin A protected against benzo(*a*)pyrene-induced metaplasia and squamous cell neoplasms of the tracheobronchial tree in hamsters. The authors stated on page 863 of the paper:

> It would be premature at the present time to speculate on the possible implications of our present studies for cancer prevention. They represent preliminary experimental observations; considerably more information is needed on dose and time requirements for vitamin A administration and on its possible long-term toxicity.

306. RX 172, C. Park, *et al.*, "Growth Suppression of Human Leukemic Cells *in vitro* by L-Ascorbic Acid," 40 *Cancer Research* 1062 (1980), was discussed in the Report on page 146. In this study of effects of ascorbic acid on human leukemia cells in culture, low concentrations of ascorbic acid were found to suppress growth of human leukemia cells from patients with acute nonlymphocytic leukemia under conditions in which growth of normal myeloid colonies were not suppressed. This study was considered by the Committee in reaching its conclusion regarding ascorbic acid, given on page 147 of the Report:

> The limited evidence suggests that vitamin C can inhibit the formation of some carcinogens and that the consumption of vitamin C-containing food is associated with a lower risk of cancers of the stomach and eosophagus (emphasis added). **[86]**

307. RX 175, T. Crocker, L. Sanders, "Influence of Vitamin A and 3,7-Dimethyl-2,6-octadienal (citrate) on the Effect of Benzo(*a*)pyrene on Hamster Trachea in Organ Culture," 30 *Cancer Research* 1312 (1970), was discussed in the Report on page 141. In this study of organ cultures of hamster tracheas, vitamin A inhibited the induction of squamous cell metaplasia and proliferative epithelial lesions by

benzo(*a*)pyrene. The Committee considered this study and reached its conclusion stated on page 144 of the Report regarding vitamin A's protective effects shown in most, but not all, animal models.

308. RX 178, B. Reddy, N. Hirota, "Effect of Dietary Ascorbic Acid on 1,2-Dimethylhydrazine-Induced Colon Cancer in Rats," *Nutrition and Cancer* 714 (Abstract 2565) (1979), is another animal study (rats) considered by the Committee on page 146 of the Report. RX 178 was one of the two abstracts which reported inhibition of carcinogenesis in the large bowel tissue by dietary sodium ascorbate. The Committee commented that since they are reported only in abstract form, their results warranted further investigation. In any event, the Report considered this abstract in reaching conclusion on vitamin A, given on page 147.

309. RX 180, G. Kallistratos, E. Fasske, "Inhibition of Benzo(*a*)pyrene Carcinogenesis in Rats with Vitamin C," 97 *J. Cancer Res. Clin. Oncol.* 91 (1980), was also cited in the Report at page 146. This study conducted on 10 rats reported that a high dose of ascorbic acid in the diet of rats inhibited the induction of sarcoma by benzo(*a*)pyrene in the 10 rats studied. Dr. Shamberger stated that a prophylactic dose is one that inhibits cancer, and that the prophylactic dose specified by the authors to inhibit cancer is speculative (Shamberger, Tr. 2355-57). Dr. Shamberger's testimony also showed that this study is based on very high doses of vitamin C given to the rats (Shamberger, Tr. 2459). They consumed vitamin C equal to 40% of their body weight over the course of the 180-day study (Shamberger, Tr. 2479-82). Dr. Shamberger testified that he would not make a comparison between rats and humans based on this study of a small number of rats (Shamberger, Tr. 2461). The Report appears to share that view (at 146).

310. RX 184, P. Nettesheim, M. Williams, "The Influence of Vitamin A on the Susceptibility of the Rat Lung to 3-Methylcholanthrene, 17 *Int. J. Cancer* 351-57 (1976), was summarized on page 141 of the Report. The authors reported that the induction of neoplastic lesions of the lungs by the chemical carcinogen 3-Methylcholanthrene was enhanced in rats deprived of vitamin A intake. This conclusion was based on observations of squamous nodules in the lungs, which have been demonstrated to be precursors of squamous cell carcinomas. The authors noted that this and earlier studies they published "are consistent with the interpretation that the growth of carcinogen-induced lung lesions accelerated in rats maintained on

suboptimal vitamin A levels (even if these rats are not vitamin A deficient)" (at 356). **[87]** However, they also note that it is possible that "different species and tumor systems respond differently to excess levels of retinoids" and the "fact that some investigators have even reported enhancement of tumor responses by vitamin analogous [citation] indicates that more carefully controlled studies are needed before any final conclusions can be drawn" (*Id.*) In any event, the Committee considered this and other studies cited in the Report in reaching the conclusion stated on page 144 of the Report with respect to vitamin A.

311. RX 203, Kolonel, *et al.*, "Association of diet and place of birth with stomach cancer incidence in Hawaii Japanese and Caucasians," 34 *The American Journal of Clinical Nutrition,* 2478 (1981), was cited in the Report's vitamin C section on page 144. This epidemiological study compared stomach cancer incidence among four population groups (Japanese in Japan, Japanese in Hawaii, Caucasians in Hawaii, and all American whites), and observed the highest rates occurred in Japan Japanese, followed by Hawaii Japanese. When the Japanese and Caucasians in Hawaii were divided by place of birth, the Japanese migrants to Hawaii had higher incidence rates than the Japanese born in Hawaii, while Caucasian migrants had lower rates than the Caucasians born in Hawaii. An examination of dietary data in relation to the place-of-birth-specific incidence rates showed a positive association of stomach cancer with consumption of rice, pickled vegetables and dried/salted fish, and a negative association with vitamin C intake. The Report states that these observations "are consistent with the hypothesis that vitamin C protects against gastric cancer by blocking the reaction of secondary and higher amines with nitrate to form nitrosamines." However, this study states that for vitamin C to block nitrosamine formation, it must be in the stomach at the same time that nitrosamines are produced (Shamberger, Tr. 2590-91). Dr. Kolonel, the lead author, was a member of the Committee (Report, Appendix A) and concurred in the statement in the Report that it has not been determined what effect, if any, nutrients have on cancer (JX 1, p. 11).

B. *Respondent's Exhibits Not Cited In The Report*

312. Respondent was permitted to designate portions of 17 documents which were not cited or discussed in the Report, as respondent's post-claim documents. These included three animal

studies (RX's 63, 162, 187); three epidemiological studies (RX's 87, 113, 144); and 11 documents, including letters, reviews, and reports (RX's 48, 50, 55, 75-76, 78, 80, 86, 105, 107, 154). A brief discussion of them in numerical order follows.

313. RX 48, E.L. Wynder, *et al.*, "Nutrition and Metabolic Epidemiology of Cancers of the Oral Cavity, Esophagus, Colon, **[88]** Breast, Prostate, and Stomach," in Newell and Ellison, Eds., *Nutrition and Cancer, Etiology and Treatment,* Raven Press (1981), is a 37-page review article. Although it appeared to be an informative and comprehensive review of relevant epidemiological studies, it does not contain original data that can be critically reviewed by peers. Therefore, the reliability of the review depends mainly on the reputation of the reviewers and the material that is reviewed. The authors of this review article are respected scientists. However, RX 48 does not state that the nutrients contained in Healthy Greens reduce the risk of cancer in humans.

314. To this reader, RX 48 appears to cover an area considerably narrower than that of the NAS-NRC Committee Report in terms of specific cancer sites, although both appear to discuss animal and epidemiological studies published in or before 1981. RX 48, however, organized the underlying studies according to sites, while the Report is organized mainly by dietary components and nutrients and discusses specific cancer sites involved in relation to the main dietary or nutrient topics under discussion. Another difference may be that the Committee Report appears to focus on food and dietary modifications while RX 48 pays more attention to the etiology of cancers under review and speculates on possible origins of carcinogenesis in some human cancers. In any event, RX 48 appears to confirm the Report's conclusions regarding the various micronutrients as well as the scientific basis of the Report's dietary recommendations for the purposes of this case.

315. RX 50, T.J. Slaga, "Potential for Preventing Cancer by Chemical Inhibitors," *The Cancer Bulletin,* Volume 36, No. 1, 1984, is a short review article. It was published in 1984 long after the advertisements for Healthy Greens were written, and it contains nothing that substantiates the advertising claims at issue here.

316. RX 55, "Preface," to National Cancer Program, 1981 Director's Report and Annual Plan, FY 1983-1987, May 1982, is a preface to the 1982 National Cancer Institute Report by V.C. DeVita, Director. Dr. Newell agreed with the statement on page v of RX 55:

It is important to determine whether the lower cancer incidence is due to dietary vitamin A (beta-carotene) or its metabolic products, retinal and retinol, or to other constituents of vegetables" (emphasis added).

(Newell, Tr. 2873) Thus, RX 55 shows a keen awareness of the fact that it is not known what in vegetables reduces cancer risk at the present time. **[89]**

317. RX 63, D.B. Menzel, "Nutritional Needs in Environmental Intoxication: Vitamin E and Air Pollution, an Example," 29 *Environmental Health Perspectives,* 105-14 (1979), is an animal study and does not substantiate the advertising claims made for Healthy Greens or for vitamin E. Respondent's witness, Dr. Lachance, agreed that RX 63 is generally concerned with the effect of airborne toxicants on human lungs, and he agreed that the author was merely speculating that vitamin E may play some protective role in that regard (Lachance, Tr. 3098).

318. RX 75, G. Block and A.M. Hartman, "Understanding the Results of Epidemiological Studies," 10 *Seminars in Oncology,* 257-63 (September 1983), is a general discussion of epidemiological studies and techniques. Although it is informative, it contains nothing that would substantiate the claims made for Healthy Greens or for vitamin E. In fact, the authors make a strong case that only human studies can provide evidence of whether or not a particular nutrient can affect humans. It is stated:

While laboratory experiments can elucidate mechanisms and animal studies can demonstrate effects in animals, only studies in human populations address the health question of interest: Does it work that way in humans? Is the relationship found in the laboratory both real and strong enough to be observed in a human population?

Dr. Newell agreed with this statement (Newell, Tr. 2866).

319. RX 75 also points out the uncertainty associated with determining dietary information in epidemiological studies. On page 259, it is stated:

An important problem in prospective as well as retrospective studies of diet is the adequacy of the dietary assessment instrument. Some type of assessment are inappropriate for classifying individuals with respect to their usual intake. For example, the variability (particularly for micronutrient intake) of an individual's diet from day to day makes the use of a single 24-hour recall questionable for prospective or retrospective studies in which individuals will be classified with respect to dietary exposure. **[90]**

320. RX 75 also points out at page 261:

> It is important to bear in mind, for all of the types of studies discussed above, that although a relationship may have been shown, causality has not. It is possible, for instance, that another factor associated with vitamin A intake is in fact the cause of the observed association with lung cancer. Careful analysis of as many other factors as possible may minimize, but does not eliminate this possibility. Thus, the final step in evaluation of a hypothesis is often the controlled clinical trial.

321. RX 76 is a letter written by J.H. Weisburger to the Editor of *Lancet* and was published in the September 17, 1977 issue under the heading "Vitamin C and Prevention of Nitrosamine Formation." In this letter, Dr. Weisburger emphasizes the importance of foods: "Thus, a simple way to prevent the formation of nitrosamines and nitrosamides is a year-round intake of foods containing adequate supplies of vitamin C." He also emphasizes the need for continuous ingestion of green vegetables and other sources of vitamin C because "seasonal exposure to nitrosamines or nitrosamides in the winter, a time when fresh vegetables are not readily available, may be sufficient for the development of cancer." He also states: "Encouraging consumption of salads, greens and vegetables with main meals will anyway help people stay healthy." Thus, Dr. Weisburger's view is in accord with the Report's dietary guidelines.

322. RX 78, T.J. Slaga, "Cancer: Etiology, Mechanisms and Prevention—a Summary," 5 *Carcinogenesis*, 243-63, Raven Press (1980), is a summary chapter of a publication edited by T.J. Slaga and appears to be a general review section of a book series. Here, the author appears to suggest a unified, multidisciplinary perspective across the questions of cancer etiology, mechanisms and prevention, and points to the need to look beyond epidemiological data and to understand better the processes involved in chemical carcinogenesis, modifiers of chemical carcinogenesis, tumor initiation and promotion, eventually leading to an understanding of the role of human diet, nutrition and life style in cancer prevention. In so doing, the author appears to be optimistic about identification of chemopreventive agents specific to different cancer sites and life styles. For the purposes of this case, it suffices to note that the author's discussions regarding the inhibitory effects of selenium and vitamins C and E are based on animal studies and epidemiological data. *See, e.g.*, 254-55. The author also states, with regard to Table 11, *Inhibitors of tumor initiation* that some of the agents listed on that table have been

shown to **[91]** inhibit carcinogenesis in a number of tissue cultures, "indicating that they may be unique agents in chemoprevention of cancer in man" (at 255) (emphasis added).

323. RX 80, N.M. Ellison and H. Londer, "Vitamins E and C and Their Relationship to Cancer," *Nutrition and Cancer: Etiology and Treatment*, 233-41, G.R. Newell and N.M. Ellison (editors) Raven Press (1981), is a 9-page article from a book series and reviews what the authors call the "substantial scientific data on the relationship" between vitamins E and C and cancer. The authors summary on the relevant scientific data appears on pages 239-40:

> Vitamin E functions as an antioxidant and has the ability to inhibit free radical-induced lipid peroxidation. It has been shown to protect against certain carcinogens in animal systems, and, in some test situations, to protect against radiation-induced damage. Vitamin E eases the cardiac toxicity of adriamycin in several animal systems, apparently without interfering with the antineoplastic activity of the drug. Although many of these observations are quite provocative, virtually all have dealt with specific experimental animal systems, and any potential relevance to human carcinogenesis or cancer therapy remains conjectural.
>
> Vitamin C probably possesses significant activity as a carcinogen inhibitor in some animal models. By extrapolating these data to man, one can conclude that it would be advisable to ingest vitamin C in its natural or supplemental form daily throughout the year, especially when eating nitrate- or nitrite-containing foods. There are no convincing data that vitamin C is effective in the treatment of already diagnosed cancer.

324. RX 80 is thus in accord with the NRC Committee Report's summary conclusions concerning vitamin C (JX 1 at 147) and vitamin E (JX 1 at 149). RX 80's suggestion, based on extrapolation of animal data, that daily ingestion of vitamin C "in its natural or supplemental form" would be advisable, especially when eating nitrate or nitrite-containing foods is contrary to the weight of the record evidence showing that, in order to obtain the supposed benefits from vitamin C's antioxidant effect, vitamin C in any form must be consumed with every meal, a condition Healthy Greens does not meet. RX 80 in fact states (at 237): **[92]**

> This protective action by vitamin C has been postulated to account for the decreased incidence of gastric carcinoma that has been observed in populations that frequently consume fruits and vegetables with high vitamin C content.

RX 80 further points out that "To date, no studies have examined any potential relationship of vitamin E to human carcinogenesis" (at 234)

and that any potential relevance of vitamin E to human carcinogenesis "remains conjectural" (at 239).

325. RX 86, T. Kummet, E. Moon and F.L. Meyskens, Jr., "Vitamin A: Evidence for its Preventive Role in Human Cancer," 5 *Nutrition and Cancer*, 96-106 (1983), is a review article. The abstract of the 11-page review states:

> Both the provitamin beta-carotene and natural vitamin A and its derivatives (the retinoids) are being proposed as potential chemopreventive agents. The biochemistry and pharmacology of vitamin A suggest a number of mechanisms whereby carcinogenesis can be affected. Epidemiologic studies have consistently demonstrated an increased relative risk of cancer for people with low vitamin A intake or low-to-normal serum retinol values. Chemoprevention trials in humans are only now beginning. In the interim, daily consumption of vitamin-A-containing foods may be a "prescription" worth following (emphasis added).

Thus, the tenor of this article is in accord with the Report's observations and interim dietary guidelines.

326. RX 87, Willet, *et al.*, "Prediagnostic Serum Selenium and Risk of Cancer," *The Lancet*, July 16, 1983, pp. 130-34, is an interesting epidemiological study which examined blood selenium levels. The authors found that the risk of cancer for subjects with low selenium levels was generally higher than that for the control group. However, Dr. Shamberger testified that no one has done studies to relate selenium levels in the diet to selenium levels in the blood (Shamberger, Tr. 2293). He also testified that it is very difficult to correlate different selenium levels in the blood with different dietary intakes of selenium (Shamberger, Tr. 2273-74). Thus, RX 87 does not support selenium supplementation by the use of Healthy Greens. *Also see* Shamberger, Tr. 2568-69. Furthermore, this paper was published in 1983, after the advertisements for Healthy Greens were **[93]** written. Dr. Newell testified that at the time the Report was published, there were virtually no epidemiological studies with respect to selenium and human cancer risk (Newell, Tr. 2785).

327. RX 105, J. Weisburger, *et al.*, "Inhibition of Carcinogenesis: Vitamin C and the Prevention of Gastric Cancer: 9 *Preventive Medicine* 352-61 (1980), is a report of an animal (rats) study which looked into the possible role of vitamin C in the prevention of gastric cancers in rats. Different types of fresh, frozen and canned fish were fed to rats and rat stomach tissue were compared for evidence of mutagenic activity. According to the authors, the formation of mutagens could be completely blocked by adding vitamin C to the

reaction mixture, and a diet regimen simulating migration from a high-risk to a low-risk country led to induction of tumors in the glandular stomach and some precancerous lesions instead of cancers. Dr. Newell designated certain portions of RX 105 for this case and discussed them. Authors conclude that the combined results suggest that the risk for gastric cancer in man may be lowered by ensuring the intake of foods containing vitamin C on a year-round basis and by reducing the consumption of pickled foods (at 359). In this connection, the authors also note that vitamin E can inhibit nitrosation reactions and is lipid soluble and because some nitrosated substrates are lipid soluble, it may offer certain advantages as an inhibitor in these conditions (at 353).

328. RX 105's conclusion given on page 359 is in accord with the observations of the Report regarding potential benefits of vitamin C as well as the Report's dietary recommendations against consumption of pickled foods and for adequate intake of fruits and vegetables. However, RX 105 also recommends "adequate consumption of foods containing vitamin C or vitamin E with every meal for the prevention of gastric cancers in humans. RX 105's inclusion of vitamin E-containing foods, however, does not aid respondent's position favoring the use of vitamins in supplements or its claim that vitamin E plays an important role in reducing the risk of cancer in humans.

329. The possible benefits of vitamins C and E as preventive agents in humans suggested in RX 105 are speculative only. Furthermore, Dr. Newell testified that the authors stated that vitamin C is active in the stomach for only several minutes to one hour (Newell, Tr. 2746). Thus, the authors recommend ingestion of vitamin C with every meal to obtain the supposed benefits. Clearly, ingestion of one Healthy Greens tablet per day does not conform to this recommendation. Therefore, it is unlikely that taking Healthy Greens would have any effect because the vitamin C contained in the Healthy Greens tablet would remain in the stomach for only a short time. As noted hereinabove, the authors of RX 105 recommend "intake of foods containing vitamin C or E with every meal" (at 359) (emphasis added). **[94]**

330. RX 107, J. Weisburger, *et al.*, "Nutrition and Cancer—On the Mechanisms Bearing on Causes of Cancer of the Colon, Breast, Prostate, and Stomach," 56 *Bull. N.Y. Acad. Med.* 673-96 (Oct. 1980), is a 33-page review article, some portions of which (pp. 687-92) were designated by respondent. RX 107 expands on the

proposition discussed in RX 105 and covers additional cancer sites. Authors suggest that the mechanisms of induction and enhancement of gastric cancer on the one hand and cancer induction and development of colon, breast and prostate on the other hand are different and that the risk of gastric cancer can be reduced by assuring appropriate amount of vitamins C and E with each meal on a year-round basis (at 691) assuming that the animal experiments reported in RX 105 hereinabove and other animal (rat) studies "can be transferred directly to the human situation" (at 690). In the authors' opinion, this is a justifiable extrapolation (*Id.*). RX 107 also essentially repeats the same cautions given in RX 105. RX 107 states "It is important to note that foods containing vitamins C and E must be consumed at the same time as food containing salt and nitrite because these vitamins do not remain in the stomach long enough to react with the nitrite ingested with food, or stemming from the oral cavity, or produced *in situ* under certain conditions of pH" (at 689).

331. RX 113, B. Underwood, H. Siegel, *et al.*, "Liver Stores of Vitamin A In a Normal Population Dying Suddenly or Rapidly from Unnatural Causes in New York City," *Am. Journal of Clinical Nutrition*, No. 8, August 1970, pp. 1037-42, is a paper on liver levels of vitamin A in people in New York City who died suddenly or rapidly from unnatural causes such as bullet wounds, stab wounds or heroin overdoses. The relevance of this study to cancer prevention in the general population is not clear. Dr. Lachance agreed that the data for a second group of accidental death victims (*e.g.*, victims of car accidents) was more representative of the general population (Lachance, Tr. 3076). The latter group had a mean liver content of vitamin A of 167 mg/g, which is well above the cut-off point of 30-40 mg/g that Dr. Lachance considers borderline (Lachance, Tr. 3064-66).

332. RX 144, J.V. Schlegel, "Proposed Uses of Ascorbic Acid In Prevention of Bladder Carcinoma," *Annals N.Y. Academy of Sciences*, is an undated paper which reviewed certain studies reported during the 1947-1973 period regarding oxidation-inhibiting effects of ascorbic acid (vitamin C) and suggested ascorbic acid may have beneficial effects in preventing tumor formation in the bladder. The study states at p. 434:

> The finding that ascorbic acid lowers urinary chemiluminescence of normal subjects does not prove that administration of ascorbic acid [vitamin C] could reduce the incidence of bladder cancer. It is stressed that no case **[95]** has been made out for the routine administration of ascorbic acid, either to smokers or the patients with bladder

cancer. There may be a case for a carefully controlled clinical trial of ascorbic acid, and it is hoped to embark on this in the future.

Dr. Newell also agreed with the following statement (Newell, Tr. 2869) on page 435:

From the experimental data available, there is no clear-cut evidence that an oxygen scavenger such as ascorbic acid, if present in the urine in concentrations such as would be achievable by the administration of ascorbic acid in the form of orange juice or as the pure chemical product, would indeed prevent the existence or formation of urinary carcinogens.

333. RX 154, T.K. Basu, M.S.C., Ph.D., "Vitamin A and Cancer of Epithelial Origin," *Nutrition and Cancer*, Volume 4, 33 *Journal of Human Nutrition*, 24-31 (1979), is a review article. An abstract of the article states:

Animal studies have shown, a) an association between vitamin A and cancers of epithelial origin, and b) that vitamin A and its analogues delay tumour appearance, retard tumour growth and regress tumours induced by carcinogenic polycyclic aromatic hydrocarbons. Human epidemiological and biochemical studies suggest that cancers of epithelial origin may be associated with vitamin A deficiency. Vitamin A and its analogues may have a prophylactic and a therapeutic role in cancers of epithelial origin.

This review speculates that high doses of vitamin A analogues may play a prophylactic and therapeutic role in human cancers of epithelial origin, including cancers of bronchi, trachea, stomach, intestine, uterus, kidney, bladder, testis, prostate, pancreatic duct and skin. This sweeping speculation is based on what he calls "some interesting leads" shown in animal studies in terms of vitamin A and its association with certain cancers and epidemiological and biochemical studies. However, the author notes the real difficulty in using large doses of vitamin A in clinical studies because of "its intrinsic toxicity." *See* p. 29. **[96]**

334. RX 162, R. Arensman, C. Stolar, "Vitamin A Effect on Tumor Angiogenesis" 14 *J. Ped. Surg.* 809-13 (Dec. 1979), is an animal study. The abstract states:

The inhibitory effect of vitamin A on tumor establishment and growth has been studied in two animal models. The C57L/J hepatoma, when placed in C57L/J mice receiving inoculations of vitamin A, showed slow growth and the hosts had significantly prolonged survival over untreated mice. The V-2 carcinoma, when implanted in the corneas of New Zealand white rabbits receiving injections of vitamin

A, showed decreased vascular response in the limbic vessels. The absence of an induced vascular response prevents vascularization of the tumor and subsequent tumor growth. The evidence suggests that vitamin A may exert its inhibitory effect by modifying the normal vascular response to neoplastic tissue.

The study looked at the effect of vitamin A on established tumors and does not deal with the issue of cancer prevention. Moreover, on page 356 it is stated that: "the fact that some investigators have even reported enhancement of tumor response by vitamin A analogues (Smith, et al., 1972, 1973) indicates that more carefully controlled studies are needed before any final conclusions can be drawn." Dr. Newell, agreed with this statement (Newell, Tr. 2858-59).

335. RX 187, G. Shklar, "Oral Mucosal Carcinogenesis in Hamster: Inhibition by Vitamin E," 68 *JNCI* 791 (1982), is an animal study where 80 hamsters were divided in four equal groups and observed the tumor formation in oral mucosa to see if vitamin E in diet made any difference. The author, a dentist, suggests possible mechanisms of action for the inhibitory effect of vitamin E observed in the hamster study. It offers no data regarding humans and expresses no opinion regarding any benefits of vitamin E in preventing cancer in humans. The author notes, however, that the average vitamin E intake in the United States is 7-9 mg/day, slightly less than the RDA of 8-10 mg/day. The author also states that the minimum nutritional requirement of vitamin E for adult humans appears to be in the 5-7 mg/day range, citing M.K. Horwitt, "Therapeutic uses of vitamin E in medicine," 38 *Nutr. Rev.* 105-13 (1980). Thus, RX 187 does not substantiate the advertising claim that vitamin E plays an important role in reducing the risk of cancers in humans. RX 187 is thus consistent with the Report's conclusion with respect to vitamin E. *See* JX 1 at 149. **[97]**

C. *The Post-Claim Documents Do Not Support The Advertising Claims*

336. The great majority of the epidemiological studies introduced by respondent as post-claim documents discussed hereinabove tested the possible relationship between diet and cancer in humans. Typically such studies estimated the diets of a group of people over time and attempted to determine whether anything in the diets had a relationship with cancer. These studies do not show either that the deficiencies in respondent's prior substantiation are without practical significance or that the claims made for Healthy Greens or for the

vitamin E component of Healthy Greens were based on a reasonable basis.

337. The epidemiological studies discussed hereinabove were studies of food intakes, not of individual nutrients. Foods are comprised of an almost infinite number of constituents including nutrients and non-nutrients and one cannot tell from epidemiological studies of food intake which specific nutrients, if any, might reduce the risk of cancer (Campbell, Tr. 657). This is why the Report and NCI recommended foods such as vegetables and not nutrients and why these authorities concluded it is not known what role, if any, nutrients have with respect to cancer (JX 1, pp. 11, 15; Newell, Tr. 2805-07).

338. The epidemiological studies that look at the relationship between diet and cancer in humans do not deal with dehydrated vegetables. Therefore, their applicability to dehydrated vegetables is unknown (Campbell, Tr. 659). Furthermore, the protective effect of vegetable consumption suggested by the epidemiological studies may result from the fact that the vegetables displace the consumption of animal products high in fat that may increase cancer risk (Campbell, Tr. 656-57; Rogers, Tr. 1466-67). Obviously, a Healthy Greens tablet does not have such displacement value (Campbell, Tr. 677-78).

339. Both Dr. Newell and Dr. LaChance also agreed that there were significant problems of accuracy inherent in dietary recall methods used in epidemiological studies to estimate diets, and that one should be cautious in drawing conclusions from such studies (Newell, Tr. 2833-35; LaChance, Tr. 3157-58). Dr. Newell agreed that 24-hour recall data systematically tend to underestimate consumption; many people do not consume certain food groups (such as vitamin A containing foods) on a daily basis, producing an erroneously high estimate of the prevalence of inadequate dietary intake (Newell, Tr. 2834-35). Furthermore, Dr. Newell also agreed that a person's diet 20 years ago is more relevant to cancer than his or her current diet and that there is no reliable way of estimating dietary intake of years long past (Newell, Tr. 2829-30, 2833-35). **[98]**

340. To compound these difficulties, there are significant losses of nutrients in various types of processing and cooking, and it is often impossible to determine what nutrients in what amounts were in the foods as eaten in these dietary intake studies.

341. Respondent's witnesses also discussed a number of epidemiological studies dealing with blood levels of different nutrients and their possible relationship to cancer (*e.g.*, RX 139/CX 22). These studies do

not substantiate the proposition that nutrient supplements affect cancer in humans because (1) the level of nutrients in the blood has not been shown to reflect the amount of nutrients consumed, and (2) the level of nutrients in the blood has not been shown to affect the risk of cancer.

342. When asked about the relevance of blood nutrient level studies, Dr. Campbell used vitamin A as an example and stated that vitamin A in blood, in general, does not reflect the amount of vitamin A consumed, at least in the normal range of intake. The amount of vitamin A in blood is fairly static and does not change except at extremes of intake (Campbell, Tr. 653-54). Both Dr. Newell and Dr. Lachance also agreed that there was a poor correlation between dietary intake of vitamin A and blood serum levels (Newell, Tr. 2908; Lachance, Tr. 3149). This poor correlation was also noted in the Report (JX 1, p. 140). Furthermore, the level of any nutrient in blood can be influenced by a great variety of other agents in the diet besides the nutrient (Campbell, Tr. 1027).

343. With respect to selenium, Dr. Shamberger testified that it is very difficult to translate the amount of selenium that is taken in the diet into the amount that is going to appear in the blood (Shamberger, Tr. 2274).

344. It is also well-recognized by the scientific community that animal studies cannot be extrapolated to humans to show that any nutrient reduces the risk of cancer in humans (Campbell, Tr. 661-64: Rogers, Tr. 1460-61: Newell, Tr. 2866-67). Dr. Campbell testified that these animal studies are narrowly focused to control for only one variable. However, humans are heterogeneous, their environments and diets vary substantially (Campbell, Tr. 659-62). Thus, the primary purpose of animal studies is to investigate various mechanisms of action of different agents and to obtain evidence that might be able to be used in human studies (Campbell, Tr. 661, 1443; JX 1, p. 3).

345. Also, Dr. Campbell noted that animals may react differently than humans to diet; for example, vitamin C is required by humans but it is not required in the diet of most animals (Campbell, Tr. 663-64). Further, some carcinogens are potent for some species but not in others (Campbell, Tr. 663). **[99]**

346. It is appropriate to note here that the NRC Committee also reviewed all scientific information available from epidemiological and animal studies in reaching the conclusions regarding vitamins A, C, E and selenium (JX 1 at 7-10, 139-49) as well as other inhibitors of carcinogenesis (JX 1, at 11, 358-66).

XI. INJURY

347. The deceptive claims disseminated by GNC are material for the reasons set forth in Findings 247-50. It follows from those findings of materiality that consumer injury is likely to exist. *Cliffdale,* 103 FTC at 165-66; Deception Statement, 5 Trade Reg. Rep. at 56,072, 56,078 and 56,079. Although it is well-established that actual injury or damage need not be shown, *see Cliffdale,* 103 FTC at 166 n. 11; *Resort Car Rental System, Inc. v. FTC,* 518 F.2d 962, 964 (9th Cir.), *cert. denied sub nom. MacKenzie v. United States,* 423 U.S. 827 (1975); Deception Statement, 5 Trade Reg. Rep. at 56,072, it is clear in this case that the injury to the consumer is significant. Because of the deceptive claims, consumers were induced to purchase Healthy Greens tablets and thereby suffered both economic injury and, for some purchasers, the further injury of losing the benefits to be derived from following the Committee's dietary recommendations by taking Healthy Greens tablets instead.

348. The record is clear that consumers who purchase and take the tablets as a partial or total substitute for the recommended vegetables may incur greater risks of cancer than consumers who eat the recommended vegetables. This is because vegetables have almost an infinite number of constituents, and only by eating vegetables can consumers expect to receive the benefits following the Committee's dietary guidelines (JX 1, pp. 11-15; Campbell, Tr. 656-58; Newell, Tr. 2842-43).

349. Another benefit of eating vegetables may result from the fact that consumption of vegetables causes one to consume less of other foods, including animal products or fats, which the Committee concluded should be reduced to minimize cancer risk (JX 1, pp. 14-15; Campbell, Tr. 656-57). Obviously, Healthy Greens tablets do not have such displacement value (Campbell, Tr. 677).

350. Also, there was testimony that even though ingestion of the tablets generally would be safe, vitamin A supplementation, a constituent of Healthy Greens, may cause toxicity problems for some individuals (Campbell, Tr. 797-99; Newell, Tr. 2838). With respect to selenium, another constituent of Healthy Greens, the Report cautions against high-dose supplementation, in part, because of its toxicity (JX 1, pp. 168-69). In fact, one of respondent's prior substantiation documents, CX 36, warns that selenium is almost as toxic as **[100]** arsenic. Although the selenium in the Healthy Greens tablets is well under toxic level, there is testimony that selenium in the diet is

ubiquitous and that the amount of selenium in the diet can vary widely. Therefore, there is a possibility that the selenium content of the tablets could contribute to toxicity problems for some consumers whose diet is already high in selenium (Rogers, Tr. 1379; Shamberger, Tr. 2557-59).

XII. SCOPE OF THE ORDER

A. *The Legal Standards*

351. The accompanying order would require respondent to cease and desist: (1) from misrepresenting the findings, results or conclusions of any test or research article in connection with the sale or distribution of any food/nutrient supplement product for its ability to prevent any disease in humans, and (2) from making representations concerning such product's ability to prevent or cure any disease in humans unless respondent possesses and relies upon reliable and scientific evidence that substantiates such representation, including at least one controlled clinical trial. Thus, the proposed order would restrict respondent's ability to advertise products other than Healthy Greens by fencing-in provisions.

352. The power of the Commission to issue orders containing fencing-in provisions is well-established. *See, e.g., FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952); *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 394-95 (1945). The Commission has wide discretion in fashioning orders to prevent resourceful respondents from a course of conduct similar to those found to have been unfair or deceptive in the past. However, the Commission's discretion is subject to two constraints: (1) the order must be clear and precise to be understood by the violator; and (2) the order must bear a reasonable relationship to the unlawful practice found to exist, citing *Colgate-Palmolive*, 380 at 392; *Jacob Siegel Co. v. United States*, 327 U.S. 608, 612-13 (1946). *Thompson Medical Co.*, 104 FTC at 832-33.

353. In *Thompson Medical, supra*, to ensure that a multiproduct fencing-in order bears a reasonable relationship to the unlawful practice found to exist, the Commission considered three factors. They were: (1) the seriousness and deliberateness of the present violation; (2) respondent's past history of violations; and (3) the transferability of the unlawful practices to other products. *Thompson*, 104 FTC at 833; *American Home Products v. FTC*, 695 F.2d 681, 706 (3rd Cir. 1982); *Sears, Roebuck and Co.*, 676 F.2d 385, 392 (9th Cir. 1982). Another factor considered in assessing the appropriateness of an order

is whether the subject matter of the **[101]** order involves serious health issues. Health issues may justify an order broader than that justified by other types of claims. *American Home Products*, 695 F.2d at 706.

B. *The Specific Circumstances Of This Case*

354. Although Healthy Greens has been withdrawn from the market by GNC, it is necessary and appropriate in this case to require respondent to refrain from making false and unsubstantiated advertising claims in the future with respect to any product marketed for its ability to prevent or reduce the risk of any disease in humans.

355. Respondent's claim that the findings of the Committee Report support the claim that use of Healthy Greens, or similar supplements containing dehydrated vegetables, is associated with a reduction in the incidence of certain cancers in humans was a clear case of false advertisement. So was the claim that research indicated that vitamin E plays an important role in reducing the risk of cancer. And the timing of these claims and the manner in which the Committee Report was headlined in the advertisements strongly suggest that they were deliberate and were calculated to take advantage of or exploit the attention-getting, trust-inspiring nature of the authoritative Report's publication.

356. GNC's violation in this case is a serious one. Cancer is a leading cause of death and is very costly to treat. The NAS-NRC Committee, after a thorough review of all scientific evidence available to it, concluded that persons can hope to reduce their risk of contracting this dreaded disease by following certain dietary guidelines, including increasing their intake of fruits and vegetables. Respondent falsely claimed that the Report supports taking Healthy Greens, or dehydrated vegetable supplements like Healthy Greens, as a means of increasing intake of recommended vegetables and fruits. Respondent also made unsubstantiated claims that by taking Healthy Greens, consumers could reduce the risk of cancers and that vitamin E plays an important role in reducing the risk of some cancers.

357. GNC's violations are also deliberate and GNC claimed its product was carefully developed and supported by scientifically-acceptable evidence when the facts in its possession demonstrated such was not the case. GNC allocated scant efforts to develop Healthy Greens. Desiring to market a product which will be positioned to compete with a supplement product being sold as "Daily Greens,"

GNC simply contracted with an independent supplier, Nutro-Labs, to copy Daily Greens (CX 71E-F). GNC reproduced Daily Greens, component for component, amount for amount (Thompson, Tr. 1821, 2124). GNC **[102]** could give no reason why particular amounts of nutrients were chosen other than that these levels were non-toxic and appeared in the same amounts in the Daily Greens tablet (Thompson, Tr. 1832-33, 2122, 2124). Dr. Thompson, the company official responsible for developing the product, testified that he did not know how the vegetable matter was processed (Thompson, Tr. 2124).

358. GNC did next to nothing to determine the effectiveness of Healthy Greens. It did not test the tablet or any of its individual components (Thompson, Tr. 2124-25; CX 71G). Neither did it consult with any expert in the field until after it was sued by the Commission (Thompson, Tr. 2129). The company simply relied upon the opinion of its Director of Nutrition Education, Dr. Thompson, that the product would work (Thompson, Tr. 2125). Dr. Thompson's expertise in the field of diet, nutrition and cancer, however, is minimal. And, the information respondent did have concerning the nutrients contained in Healthy Greens was enough to put the company on notice that its claims for the product with respect to human cancers were unsupported. GNC says it placed primary reliance on the Report (Thompson, Tr. 1912). Yet, the Report clearly states that its recommendations do not apply to supplements or individual nutrients (JX 1, p. 15) because scientists have not been able to identify which, if any, of the individual nutrients or other components in foods may be responsible for the protective effect noted in food studies and that there was some danger of toxicity in using supplements (*Id.* at 15; JX 1, p.11). Thus, GNC knew, or should have known, that the Report does not support the use of supplements just as it knew, or should have known, that the tablets contained a trivial amount of vegetable matter. Therefore, it knew that the use of Healthy Greens tablets was not supported by the Report or by the other prior substantiation documents in its possession.

359. Similarly, GNC's argument that the Report did not mean to preclude the use of supplements or that the Report's statements are inconsistent with the underlying literature contradicts GNC's own witness' statements (Thompson, Tr. 1912) and that of other witnesses that the Report is an excellent review of the literature (*e.g.*, Newell, Tr. 2807-11). Indeed, if GNC believed that the Report is wrong or is inconsistent as it now asserts, one wonders why it would offer it as substantiation for GNC's claims.

360. There is also reason to conclude that GNC's unconscionable, false and misleading advertising found in this case is not an isolated incident but in fact is a part of a continuing pattern. The record contains 14 consent agreements entered into by GNC with the U.S. Postal Service in 1985. In each of these, GNC entered into the agreement in order to settle allegations that it had engaged in false and deceptive advertising of its product (*see* CX's 72-85). GNC also entered into a consent agreement with the State of California regarding allegations of false advertising (CX 86). The products that are **[103]** the subjects of these orders are food supplements consisting of various combinations of vitamins, minerals and food extracts. In one instance, GNC entered into an agreement specifically prohibiting GNC from representing that "the ingestion of any food supplements was found by an NAS Study [the Report] to be effective in reducing the risk of cancer" (CX 73C). Moreover, GNC had previously entered into a consent agreement with the Commission to resolve allegations that it had falsely advertised. *General Nutrition Corp.*, 75 FTC 529 (1969), *mod.*, 77 FTC 1458 (1970). Although respondent did not admit a violation of any law, the sheer number of these consent orders suggests a pattern of questionable or deceptive advertising of food supplements by GNC. When viewed in this light, GNC's false and deceptive advertising in this case may be seen as an indication of GNC's propensity to employ false or misleading advertisements.

361. Also, the deceptive claims here can easily be transferred to other similar products. The deceptive claims involved misrepresenting the findings of the Report and misrepresenting the effect of Healthy Greens and vitamin E on cancer. Such claims are easily transferable to other supplement products. For example, GNC could easily misrepresent other scientific documents besides the Report. Claims that Healthy Greens reduces the risk of cancer could easily be transferred to another product and to another claim. Thus, a fencing-in provision to stop such transfers is clearly appropriate. The need for a fencing-in provision to guard against transferring these types of deceptive claims to other products is reinforced by the 14 consent agreements entered into by GNC with the Postal Service discussed hereinabove as well as the serious, deliberate and unconscionable nature of falsehoods and misrepresentations involved in this case (CX's 72-85).

362. Healthy Greens was marketed as a product that affects cancer risk in humans. Thus, the advertising claims involve potential health hazards and, accordingly, warrant an order adequate to cover all such products marketed by GNC. *See Thompson*, 104 FTC at 830, 832-37.

363. In sum, the record in this case clearly demonstrates a need for a fencing-in provision. Here, the violation found was deliberate and serious. The unlawful practices found are easily transferable to respondent's other products. Although the Commission determined in *Thompson* that these two negative factors warranted adoption of broad fencing-in provisions (104 FTC at 833), the evidence in this case also reveals a disturbingly long trail of consent orders involving changes of false and misleading advertising. Therefore, adoption of appropriate fencing-in provisions is imperative in the circumstances of this case. **[104]**

C. *The Specific Provisions Of The Order*

364. The circumstances surrounding GNC's violations justify the issuance of the accompanying order. Part I of the order prohibits several of the specific representations found to be false so long as those representations remain contrary to fact. This provision is necessary to prevent recurrence of the type of unlawful practices found in this case.

365. The product coverage of Parts II and III of the order to include other products is imperative. *See* F. 355-63, *supra.* Healthy Greens was advertised as a cancer-preventive and the Order coverage is limited to those products for which similar disease preventive claims are made.

366. Part II's fencing-in provisions are directly related to the violations established at trial. This provision prohibits GNC from misrepresenting the purpose, content, sample, reliability, results or conclusions of any scientific test, research opinion or data. As discussed above, this case concerns misrepresentation of a report prepared by the National Academy of Sciences. Part II is designed to prevent respondent from engaging in variations of the "same basic theme" in its future advertising. *Consumer Sales Corp.*, 198 F.2d 404 (2d Cir. 1952). *See, e.g., Litton Industries, Inc. v. FTC,* 676 F.2d 364, 373 (9th Cir. 1982); *Bristol Myers,* 102 FTC at 379 (1983). It is intended to ensure that future advertising claims will not mislead consumers into believing that a particular product attribute enjoys any greater support or authority within the scientific community than it enjoys in fact.

367. Part II's fencing-in provision is important. In Healthy Greens ads, consumers are offered "an easy to take," "no fuss" effective alternative to whole vegetables in order to reduce the risk of cancer. If

consumers understood the scientific basis of support that whole vegetables enjoy versus the lack of support for respondent's tablet, their purchase decision would clearly be affected. This provision will prevent a repetition of the same kinds of deceptive advertising techniques employed by GNC to market Healthy Greens.

368. Part III's fencing-in provision is carefully drawn and is justified by both the circumstances surrounding GNC's violation in this case and by the potential consequences of making disease prevention claims without a reasonable basis. Part III applies only to claims that a product can prevent or reduce the risk of disease. It is a carefully drawn provision directly related to the false and deceptive advertising proven against respondent in the instant case.

369. This provision is also important because it is directed to products that are marketed as disease preventives. Most **[105]** diseases are multifactorial in origin and the telltale symptoms do not immediately manifest themselves. These factors often make it impossible for consumers to determine whether the advertiser's claim is based on a reasonable basis. This can have serious and potentially hazardous consequences for consumers.

370. Part III requires respondent to possess competent and reliable scientific or medical evidence conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession or science to yield accurate and reliable results, including at least one adequate and well-controlled clinical study which conforms to acceptable designs and protocols when making disease prevention claims for any supplement product. Thus, the requirement in this case is less restrictive than that in the Commission's so-called *Analgesic Cases* or *Thompson Medical, supra,* but is more rigorous than the requirement in *Jay Noriss v. FTC,* 598 F.2d 1244, 1250 (2d Cir.), *cert. denied,* 444 U.S. 980 (1979). It is the firm view of the administrative law judge that a claim that a supplement product prevents, or reduces the risk of, a disease in humans should not be permitted without at least one adequate and well-controlled human clinical trial which supports such a claim. This is consistent with the NCI's funding of controlled clinical trials involving potential chemopreventive agents discussed in the NRC Committee Report. The Commission's standard of substantiation for disease prevention claims for a supplement product should not be less and should include at least one controlled clinical trial. *See* F. 238, 244-45, 270-71, 336-46, *supra.* **[106]**

DISCUSSION

The basic issues in this case, such as the meaning of respondent's advertisements, the falsity of advertising claims, the adequacy of substantiation and the scope of relief were discussed in the Findings. However, the central issue is the standard of substantiation, or the reasonable basis criteria, applicable to this case in determining the questions of liability and relief. The reasons for reaching the conclusions set forth in the Findings are discussed hereinabove. The question is a difficult one and may merit a brief discussion here.

First, the advertisements implied that the product "Healthy Greens" is a unique supplement which can reduce the incidence of cancer in humans, or that the product is a cancer preventive. Therefore, Healthy Greens was a "food" or "drug" within the meaning of Section 12 of the Federal Trade Commission Act.

Second, as to the standard of substantiation, the critical question is whether something less than a controlled human trial should be accepted as adequate substantiation for a claim that a supplement is a disease preventive. Complaint counsel would accept "reliable and competent scientific evidence" which means "those tests, analyses, research, studies, or other evidence conducted or evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession or science to yield accurate and reliable results" as adequate substantiation for a claim that a product can "cure, prevent or reduce the risk of diseases in humans."

The problem with complaint counsel's standard is twofold: it is vague; and it would apply equally to preventive claims and curative claims. It is vague because it is not quite clear whether a controlled human trial is required to substantiate a disease preventive or curative claim. The requirement does not in terms exclude a human trial or trials, and the "reliable and competent scientific evidence" may conceivably require a controlled human trial if and when a consensus of the relevant medical/scientific community would require one. And, it is equally conceivable that complaint counsel's standard will be met without a controlled human trial. Therefore, with respect to a supplement product such as Healthy Greens, the Order provision should specifically require at least one well-controlled human trial. On the other hand, it is inconceivable that anything less than two controlled human trials may be accepted as adequate substantiation for a curative or therapeutic claim for a product sold and advertised as "food" or "drug" within the meaning of the Federal Trade Commis-

sion Act. *Cf.*, *The Analgesic Cases* and *Thompson Medical Co.*, 104 FTC at 821-26. **[107]**

It is not the function of this case to provide answers to the current regulatory controversy regarding the broad issues of health claims for food. In this case, we are faced with a supplement product which was claimed to be a cancer preventive. Having weighed the six elements to determine what level of substantiation General Nutrition should have had for the cancer preventive claims it made for Healthy Greens tablets, I am convinced that adequate substantiation for such a claim should include at least one well-controlled human trial. *See* F. 236-46, 270-74, 344-45, *supra.* Dr. Campbell and Dr. Rogers supported this position. And the NAS-NRC Committee on Diet, Nutrition and Cancer as well as the National Cancer Institute appear to be of the same view.

Finally, nothing in the Order provisions is likely to hinder General Nutrition from communicating freely useful scientific information regarding its products to the consumer. All that is required of General Nutrition is that such scientific or medical information be accurate, that it does not misrepresent any test or study or opinion, and that its advertising does not imply that a product is a disease preventive unless it has at least one controlled human trial to substantiate the claim.

CONCLUSIONS OF LAW

1. The Federal Trade Commission has jurisdiction over the advertising of Healthy Greens under Sections 5 and 12 of the Federal Trade Commission Act.

2. Respondent's use of false, misleading and deceptive statements and representations as herein found has had the capacity and tendency to mislead members of the purchasing public into the erroneous and mistaken belief that said statements and representations were and are true and into the purchase of substantial quantities of Healthy Greens by reason of said erroneous and mistaken belief.

3. The acts and practices of respondent as herein found were and are all to the prejudice and injury of the public and of respondent's competitors and constituted and now constitute unfair methods of competition and unfair and deceptive acts and practices in commerce in violation of Sections 5 and 12 of the Federal Trade Commission Act.

4. The accompanying order is necessary and appropriate both under applicable legal precedent and the facts of this case. **[108]**

ORDER

I.

It is ordered, That respondent General Nutrition Incorporated, a corporation, its successors and assigns, and its officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacture, advertising, labeling, offering for sale, sale, or distribution of Healthy Greens, or any substantially similar product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, contrary to fact, that any finding of the National Research Council, National Cancer Institute, American Cancer Society, or U.S. Government, or any finding contained in the Report entitled *Diet, Nutrition, and Cancer,* supports the claim that use of such product is associated with a reduction in incidence of any type of cancer in humans.

II.

It is further ordered, That respondent, its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacture, advertising, labeling, offering for sale, sale, or distribution of any product marketed for its ability to cure, prevent or reduce the risk of any disease in humans, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from misrepresenting in any manner, directly or by implication, the purpose, content, sample, reliability, results or conclusions of any scientific test, research article, or any other scientific opinion or data, with respect to such product's ability to cure, prevent or reduce the risk of any disease in humans.

III.

It is further ordered, That respondent, its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, labeling, packaging, offering for sale,

sale, or distribution of any product marketed for its ability to prevent or reduce the risk of any disease in humans, in or affecting commerce, as "commerce" is **[109]** defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication, concerning such product's ability to prevent, or reduce the risk of, any disease in humans, unless at the time of such representation, respondent possesses and relies upon competent and reliable scientific or medical evidence. "Competent and reliable" shall mean those tests, analyses, research, studies, or other evidence conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession or science to yield accurate and reliable results. For a supplement product such evidence shall include at least one adequate and well-controlled, double-blinded clinical study which conforms to acceptable designs and protocols and is conducted by a person or persons who are qualified by training and experience to conduct such studies. *Provided however,* with respect to any representation covered by this part, if the Food and Drug Administration promulgates any final standard which establishes conditions under which such product is safe and effective or is not misbranded under the Food, Drug and Cosmetic Act, then in lieu of the above, respondent shall rely upon scientific evidence which fully conforms to such final standards as a reasonable basis for said representation.

IV.

It is further ordered, That respondent or its successors or assigns maintain accurate records:

1. Of all materials that were relied upon by respondent in disseminating any representation covered by this order.
2. Of all test reports, studies, surveys, demonstrations or other evidence in its possession or control that contradict, qualify, or call into question any representation made by respondent that is covered by this order.

Such records shall be retained by respondent or its successors or assigns for three years from the date that the representations to which they pertain are last disseminated. *It is further ordered,* That any such records shall be retained by respondent or its successors or assigns and that respondent or its successors or assigns shall make

such documents available to the Commission for inspection and copying upon request. **[110]**

V.

It is further ordered, That respondent notify the Commission at least thirty (30) days prior to any proposed change in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

VI.

It is further ordered, That respondent shall forthwith distribute a copy of this order to each of its operating divisions and to all distributors of products manufactured or marketed by respondent.

VII.

It is further ordered, That respondent shall within sixty (60) days after service of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this order.