

Chapter 3

Dietary Treatments

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A specified diet is the primary component of some unconventional cancer treatments. This chapter reviews three examples of unconventional treatments with dietary regimens as the primary or central component: the treatment regimen developed by the late Max Gerson, M. D., currently offered at a clinic in Tijuana, Mexico; the treatment regimen developed by William Kelley, D. D. S., and recently modified by Nicholas Gonzalez, M. D., who treats patients in New York; and the macrobiotic regimen, whose educational resources and specialized food products are widely available to patients in the United States. Coffee enemas, which are included in two of these regimens, are also discussed separately in box 3-B later.

In other chapters of this report, treatments are described that also include dietary elements, but in those cases, the diet may be one of several major elements in the approach, with a non-nutritional treatment usually considered primary in the regimen. In the Livingston-Wheeler regimen (described in ch. 5), e.g., dietary guidelines are specified, but the regimen is centered on its original anti-infective treatment. In addition, many of the clinics in the United States and Mexico that promote “metabolic” treatment for cancer specify particular foods to include or avoid as part of a regimen that also includes pharmacologic and biologic agents, exercise, and spiritual and psychological components (289).

Other dietary approaches used in unconventional cancer treatment for which more limited information is available are not covered in detail in this chapter. One of these is wheatgrass, a component of a regimen that has been available for several decades in the United States. Originally developed by Ann Wigmore, the wheatgrass regimen is advocated for prevention and treatment of a variety of conditions and for general health maintenance. Individuals attending one of three U.S. centers that offer instruction in following the wheatgrass regimen (289) are taught “an enlightened approach to the understanding of health and various cleansing and rebuilding techniques to restore and/or maintain a vigorous life” (198), according to promotional literature. One of the centers, the Hippocrates Health Institute in Florida, describes itself as a “health

resort” offering “a multi-dimensional program for the serious health seeker” (405). The wheatgrass diet is described as a “nutritional lifestyle that embraces an all natural way of eating” (405). Using books and products commonly available in health food stores and through mail order houses, patients can also follow the wheatgrass regimen on their own.

The wheatgrass regimen eliminates all meat, dairy products, and cooked foods from the diet, while emphasizing “live foods” (including uncooked sprouts, vegetables, fruits, nuts, and seeds), wheatgrass juice, “detoxification” (enemas and high colonies), enzyme supplements and chlorella (green algae tablets). Proponents believe that wheatgrass is the key element of the program and claim that it bolsters the immune system, kills harmful bacteria in the digestive system, and rids the body of waste matter and toxins (405,959). Anecdotal case reports of tumor regressions and life extension among cancer patients who followed the wheatgrass regimen have been published in the proponent literature (see, e.g., (344)), but thus far, no studies of its clinical role in the treatment of cancer have been reported.

GENERAL COMMENTS ABOUT UNCONVENTIONAL DIETARY APPROACHES COMPARED WITH OTHER FORMS OF NUTRITIONAL TREATMENTS

By relying for the most part on vegetarian, low-fat, high-fiber foods, the dietary regimens described in this chapter share certain characteristics with the kinds of foods currently recommended by mainstream groups for lowering the risk of developing cancer and heart disease. Recent American Cancer Society (ACS) guidelines for cancer prevention, e.g., suggest reducing the intake of fat, alcohol, and salt-cured and smoked foods, while increasing the intake of fruits, vegetables, and whole grains (681). One way they differ, however, is that the unconventional cancer treatment diets may emphasize a few particular foods and limit or totally eliminate others. The macrobiotic regimen, e.g., advises against consuming vegetables and fruits that

are not grown locally, such as bananas and other tropical fruit, and against certain types of vegetable, such as those in the nightshade family (including tomatoes, green peppers, eggplants, e.g.). The wheatgrass diet excludes all cooked vegetables and fruits in favor of raw foods exclusively. The Kelley regimen emphasizes certain categories of food, e.g., vegetables or red meat, over others, on an individual basis. (The Kelley diet does not necessarily conform to current mainstream dietary recommendations.) It has been noted that in some circumstances, cancer patients who follow overly restrictive diets of any kind, whether unconventional or not, maybe at risk for malnutrition and uncontrolled weight loss (8,84). It has also been noted that diets that may be useful in preventing cancer are not necessarily effective in treating cancer, since substances in food that may play a role in the initiation of cancer may be different from those that may contribute to tumor progression (84).

The goals of the unconventional dietary treatments also overlap with the goals of conventional nutritional support for cancer patients in that both try to counteract the metabolic and nutritional effects of the disease and of some forms of treatment. The unconventional treatments go beyond the conventional support measures, however, by claiming to reverse the course of the disease, to enhance host function, and to improve quality of life.

The fact that the unconventional treatments specify particular dietary regimens for cancer patients at all, regardless of their condition, stage of disease, or type of tumor, separates them from mainstream cancer treatment. Nutritional support has a well-established place in conventional cancer treatment, but generally does not include dietary recommendations for patients with cancer. At present, no diet is recommended publicly by NCI or ACS for use in cancer treatment. In practice, patients are not commonly given nutritional advice at the time of diagnosis or initiation of treatment by mainstream physicians. Nutritional support in mainstream oncology focuses instead on the provision of nutrients under special and usually more extreme circumstances. Nutritional support given in conjunction with conventional cancer treatment often involves the use of total parenteral nutrition (nutrient solutions given intravenously) or enteral nutrition (nutrient solutions provided (e.g., through a nasogastric

tube). These measures are normally limited to cachexic patients in advanced stages of disease, to patients who have particular cancer- or treatment-related nutritional problems that prohibit normal intake of food, or to malnourished patients undergoing major surgery (34,473,798).

It is well accepted that cancer and its treatment can cause malnutrition and that malnutrition itself predicts a poor outcome (253). A number of physiologic factors associated with cancer are believed to contribute to malnutrition, including the metabolic state of the tumor and its effects on the body's metabolism, catabolic effects of conventional treatment, and physiologic stress associated with rapid tissue growth and cell destruction (407), although the ways in which these factors influence nutritional status are still poorly understood. The issue of how to ensure that patients obtain an optimal daily intake of nutrients and calories in order to preserve lean body mass without stimulating tumor growth is considered unresolved (407). Total parenteral nutrition has been found to be of limited use, and in some cases even detrimental (798). In general, oral dietary treatments have not been evaluated for possible prevention of malnutrition or for possible effects on the course of the disease in cancer patients, although the initial stage of a multicenter study involving a low fat dietary intervention in patients with breast cancer was recently begun (35).

ADJUNCTIVE USE OF DIETARY APPROACHES IN CANCER TREATMENT¹

The unconventional dietary treatments for cancer described in this chapter are also distinct from the adjunctive use of dietary treatment in other contexts, e.g., in the more numerous and diverse practices where physicians and other practitioners offer what is often referred to as "alternative" or "holistic" health care. The issue of dietary treatment in conjunction with conventional treatment by these practitioners is commonly raised in the popular literature, but detailed information is scarce. The actual dietary regimens, their rationales, and the outcomes have not yet been reported, so the extent and nature of their use cannot be characterized precisely.

¹This section is based, in part, on a paper written by Keith I. Block and Charlotte Gyllenhaal, "Nutrition: *Unessential Tool* in Cancer Therapy (84)."

Box 3-A—An Example of an Adjunctive Nutritional Approach to Cancer Treatment

A program developed over the past 10 years by Keith I. Block M.D., illustrates one approach to nutritional treatment that can be used in conjunction with mainstream cancer care. The program, as described by its developer, is intended to be used adjunctively and not as a substitute for medical treatment. At present, it is used in Block's private medical practice in Evanston, Illinois, and at an independent medical center in Chicago.

According to Block's protocol, individualized dietary guidelines and nutritional treatment are used in combination with mainstream cancer treatment, exercise, and psychosocial support strategies for stress reduction. Overall dietary guidelines are made on the basis of nutritional assessments, including the use of body composition analysis, blood and laboratory studies, determinations of nitrogen balance, and other biochemical and clinical evaluations. Patients are given a range of food choices within an overall framework that covers five food groups (cereal grains, vegetables, fruits, fats, and proteins). Foods are divided into exchange lists so patients can select foods according to their tastes while still satisfying the overall nutritional requirements of the program.

The semivegetarian diet Block recommends consists of high-fiber, low-fat, protein-restricted foods along with specific items such as soybean products, shiitake mushrooms, and sea vegetables. In general, Block recommends that 50 to 60 percent of calories be derived from complex carbohydrates, 12 to 25 percent of calories from fat, and the remainder from protein sources. The diet, which is modified on an individual basis, emphasizes foods high in vitamins, trace minerals, and substances thought to reduce cancer risks. Developed in part from macrobiotic principles, the diet has been modified to incorporate information from other sources, primarily experimental data from the scientific literature on substances that maybe active in inhibiting tumor growth or stimulating immune responses. Nutritional analysis has reportedly shown Block's nutritional program to be nutritionally adequate; the Recommended Daily Allowances (RDAs) were met or exceeded for almost all nutrients for which RDAs have been established and for which nutrient analyses are available, and the diet reportedly exceeds requirements for vitamins A, C, and B12, calcium, iron, magnesium, and several other elements.

Block's use of an adjunctive dietary program for cancer patients has several goals, some of which he believes have been met in many cases, based on observations of patients treated with this regimen. One goal is to maintain adequate nutritional support through oral feeding as much as possible, in order to improve patients' quality of life and help them retain 'a sense of self-empowerment and clinical autonomy. "He notes that few of the cancer patients on his program experience weight loss, except those with anorexia in late stages of disease, or experience hair loss during chemotherapy. Another goal is to enhance patients' resistance to the disease by focusing on improving immune function and inhibiting tumor growth through the provision of a low-fat diet, which may decrease the intake of tumor-promoting substances. The high intake of vitamin A-containing vegetables in the diet is believed to enhance patients' responses to conventional cancer treatment. Overall, Block believes his program to be of benefit in diminishing the side-effects of conventional treatment and in improving patients' quality of life. The treatment protocol has been described in some detail in unpublished manuscripts (83,84), but thus far, it has not been studied systematically so that its effects on patients cannot be judged adequately.

One practitioner's approach that he uses currently as an adjunctive nutritional approach to cancer treatment is described in box 3-A. It is unknown how representative that example is of other efforts to use nutritional approaches adjunctively. In the judgment of some of the members of the Advisory Panel for this project, however, the adjunctive use of dietary interventions in cancer treatment is gradually becoming incorporated into conventional treatment and becoming accepted as a potentially valuable supportive measure (8). The stated aim of such adjunctive nutritional treatment is to maintain adequate levels of critical nutrients (assisted by close monitoring for deficiencies and abnormalities) in order to enhance the patient's natural resistance to the disease, to increase the ability to respond to

conventional treatment, to improve the patient's quality of life, and ultimately, to lengthen his or her survival time (84).

A number of factors maybe involved in stimulating efforts to combine nutritional intervention with cancer treatment before the development of overt deficiencies, metabolic abnormalities, and cachexia. One factor may be the public interest in self-help regimens and in health effects of diet, as shown by the wide range of books and articles in the popular literature concerning diet and cancer. This is paralleled by the large and expanding scientific literature on links between specific nutritional factors and cancer processes (361,660,661). Strong evidence is emerging from laboratory and population studies suggesting a substantial dietary contribution to a

large proportion of human cancers (866), though in some cases the data are not unequivocal and many specifics remain to be determined. Major efforts in this area at NCI are currently conducted in two research programs: the Chemoprevention Program, which focuses on the role of natural and synthetic micronutrients (e.g., beta carotene, vitamin A and related retinoids, vitamins C and E, and certain selenium compounds) in preventing or inhibiting cancer development; and the Diet, Nutrition, and Cancer Program, which focuses on macronutrient factors (e.g., fiber and fat) in cancer development (361).

THE GERSON TREATMENT

The Gerson treatment, consisting of a low sodium, high potassium, vegetarian diet, various pharmacologic agents, and coffee enemas, is one of the most widely known unconventional cancer treatments. As one of the first unconventional approaches now commonly referred to as “metabolic,”² it may have spawned the development of many other currently used unconventional dietary and pharmacologic approaches.

Max Gerson, M.D., a German-born physician, spent the last 23 years of his 50-year medical career in the United States. He died in 1959 leaving no apparent system in place to continue his treatment program. In 1977, Gerson’s daughter, Charlotte Gerson Straus, co-founded (with Norman Fritz) the Gerson Institute now based in Bonita, California. The Institute oversees a clinic in Tijuana, Mexico, where the Gerson treatment is offered. According to one outside report, that clinic treats approximately 600 patients per year (569).

Background and Early Use

Max Gerson was born in Germany in 1881 and graduated from the University of Freiburg medical school in 1907 (875). He practiced medicine in Germany, Austria, and France before emigrating to the United States in 1936. He received his New York medical license in 1938 and his U.S. citizenship in 1944 (875). He opened a private medical practice in New York City and in 1946 also began treating patients at nearby Gotham Hospital. Gerson was a member of the American Medical Association

(AMA), the New York State Medical Society, and the Medical Society of the County of New York (875).

In 1958, after a long investigation, the Medical Society of the County of New York suspended Gerson’s membership. The Society charged that Gerson’s participation in a 1946 radio broadcast, during which the show’s commentator, Raymond Gram Swing, described beneficial results of Gerson’s treatment for cancer, constituted personal advertising (387,465,956). Gerson reportedly also lost his hospital privileges and malpractice insurance (387,569), although no details of these actions are available.

In 1946, during a hearing on a proposed bill to authorize increased Federal support for cancer research in general, Gerson testified before a subcommittee of the Senate Committee on Foreign Relations. In his statement to the subcommittee, Gerson described his background, the development of his treatment for cancer, and submitted written case histories of 10 patients treated with his regimen, 5 of whom were questioned in person at the hearing (875). Gerson claimed that these patients were cured of advanced cancer as a result of his treatment.

Both Gerson’s testimony and radio appearance drew national attention. The same year, an editorial appeared in *The Journal of the American Medical Association* in response to numerous requests for information about Gerson. The editorial criticized Gerson and his sponsors at the Robinson Foundation, New York, for ‘promotion of an unestablished, somewhat questionable method of treating cancer. The editorial stated AMA’s view that Gerson had provided only “clinical impressions as to benefits secured but nothing resembling scientific evidence as to the actual merit of the method” (465). A 1949 report of the AMA Council on Pharmacy and chemistry reiterated AMA’s view of the Gerson treatment, concluding that “there is no scientific evidence whatsoever to indicate that modification in the dietary intake of food or other nutritional essentials are of any specific value in the control of cancer’ (39). The American Cancer Society’s Committee on Unproven Methods of Cancer Management published its first statement on the Gerson treatment in 1957 (90).

²In the unconventional cancer treatment literature, “metabolic” treatment generally refers to treatments intended to stimulate patients’ immunologic and biochemical processes to fight cancer. The term is used nonspecifically to refer to both particular treatments and to collections of unconventional treatments (e.g., combination pharmacologic and nutritional treatments).

While certain aspects of Gerson's regimen—e.g., the intake of fresh fruits and vegetables and the reduction or elimination of sodium and fat—are consistent with current knowledge about reducing the risk of contracting certain types of cancer and other illnesses, Gerson's thesis that regression of cancer can result from dietary treatment and 'detoxification' is unconfined.

Rationale for the Treatment

Gerson developed his dietary treatment over the course of several decades. His approach was largely empirical. By his own account, he tried variations and combinations of foods and other agents on his patients, noted the ones that reacted favorably, and adjusted subsequent patients' regimens accordingly (336). All along, he reasoned why some agents seemed to work while others did not and developed hypotheses to account for his observations. Gerson described the development of his treatment regimen and presented case histories of patients he believed were treated successfully in his 1958 book, *A Cancer Therapy: Results of Fifty Cases* (337), and in a number of published articles in German and in English (403). By the late 1950s, Gerson had produced an overall approach and rationale for treating cancer that diverged significantly from conventional medical thought and practice.

It is unknown whether Gerson's formal medical training included study of the therapeutic use of diet (939). Early on in his medical career, he devised a dietary regimen to treat his own severe migraine headaches. After reported success with his condition, he used his diet in the treatment of a variety of other disorders, including skin tuberculosis (*lupus vulgaris*), asthma, pulmonary tuberculosis, and arthritis (337). In 1928, he began treating cancer patients with the diet he used on tuberculosis, at the insistence of a patient with cancer of the bile duct, who reportedly recovered following Gerson's treatment (336). By the time he established his practice in New York in the mid-1940s, he concentrated on treating cancer patients. His first paper published in English³ on dietary treatment for cancer appeared in 1945 (331). In that paper, Gerson outlined his high potassium, low sodium, fatless diet regimen, which included foods, mineral and vitamin supplements, and crude liver injections (preparations of raw calves liver). He reported on 10 patients treated with the

regimen in whom he observed improvements in "general bodily health" and, in some cases, tumor reduction.

In a subsequent publication, "Gerson described other agents that he added to the regimen, including an iodine solution ('Lugol'), thyroid extract, potassium solution, pancreatic, and vitamin C (333). Gerson noted that in six additional patients his treatment appeared to reduce inflammation around tumors, relieve pain, improve psychological condition, and provide at least temporary tumor regressions (333). In the mid- 1950s, Gerson first published explanations of the components of his regimen and the rationale for their use, along with some of the clinical outcomes he observed.

Gerson described cancer as a "degenerative disease," fundamentally similar to many other disease states; he believed that an "impaired metabolism" was the underlying problem in degenerative disease and that proper liver function was critical to maintaining metabolic order (334). He believed that several physiologic functions were impaired in cancer patients, including the metabolism of fats, proteins, carbohydrates, vitamins, and minerals; the activity of oxidative enzymes; and the activity of intestinal bacteria (335). Gerson believed that the impairment in these functions created an internal climate favorable to the growth of malignant cells (334).

Gerson believed that his treatment regimen reversed the conditions he thought necessary to sustain the growth of malignant cells. He attached great importance to the elimination of 'toxins' from the body and to the role of a healthy liver in recovery. Gerson noted that if the liver were damaged, e.g., by cancer or cirrhosis, the patient had little chance of recovery on his treatment regimen (333,337). He observed that patients who died showed a marked degeneration of the liver, which he presumed was due to unspecified toxic factors released into the bloodstream by the process of tumor regression. He believed that these toxic tumor breakdown products poisoned the liver and other vital organs (229).

According to this view, Gerson believed that detoxification—preventing patients from dying of self-poisoning—was the most important first step in treatment (336). In support of detoxification, he cited a passage from Hippocrates that described

³Gerson published many articles in German before 1945 (see bibliography cited above).

drinking a “special soup” and administering enemas (336). Gerson prescribed coffee enemas, initially at the frequency of one every 3 or 4 hours, as part of his cancer treatment regimen. He maintained that the coffee enemas helped to stimulate the flow of bile (336), thereby increasing the rate of excretion of toxic products from the body.

Gerson believed that the need to detoxify resulted not only from the internal generation of poisonous substances but also from the external supply of toxins created by the use of insecticides and herbicides in commercial agriculture. Accordingly, his dietary regimen emphasized the use of food grown organically. He reasoned that treatment for cancer must replenish and detoxify the entire body to allow its innate healing mechanisms to be restored (337).

Another central component of Gerson’s approach concerned the balance of potassium and sodium in the body. An imbalance in the concentration of these substances contributes to the internal environment supporting the growth of tumors, Gerson believed. He sought to eliminate sodium in patients’ diets and to supplement with potassium (in the forms of potassium gluconate, potassium phosphate, and potassium acetate). Several papers published since Gerson’s death have elaborated on Gerson’s ideas regarding physiologic implications of the potassium-sodium balance in cancer states. Those papers suggest various biological and theoretical rationales for Gerson’s theory that potassium supplementation and sodium restriction act against tumor formation (229,551,590,991).

The role of oxidation in the treatment of cancer was another central element of Gerson’s theory. He believed that tumor cells thrive in an environment depleted of oxygen and can be destroyed when oxidative reactions occur. He believed it was essential to supply intact oxidative enzymes in the diet, in the form of vegetable and fruit juices prepared by a stainless steel grinder and press (rather than by centrifugal juicers or liquefiers, which he believed destroyed the foods’ oxidative enzymes) (336). He also recommended avoiding food that had been canned, processed, bottled, powdered, frozen, or cooked in aluminum pots (336).

The combined effect of these treatment components was intended to “normalize the biological function of damaged cells” (334). Gerson wrote:

... the end result is to return the body to its physiologic functions as they existed before the development of malignancies. In this state of the normal metabolism, abnormal cells are suppressed and harmless again. (334)

Current Gerson Treatment Regimen

Current patient literature from the Gerson clinic states that the treatment “restores the patient’s healing mechanism so that the body can heal itself and overcome degenerative disease.” In addition to treating patients with cancer, heart disease, diabetes, arthritis, multiple sclerosis, and other diseases, the clinic also treats “some people with no apparent serious disease [who] come to the Center simply to detoxify and build themselves up in order to feel good, to improve their health, and to prevent disease” (329).

The regimen is said to have two main components: 1) “an intensive detoxification program to help the body eliminate toxins and waste materials which interfere with healing and metabolism” and 2) “an intensive nutrition program which floods the body and its cells with easily assimilated nutrients needed for improving the metabolism and healing” (329). After a period of treatment at the clinic, each patient is instructed to continue the regimen at home for 1½ years or more “until the liver, pancreas, oxidation, immune and other systems have been restored sufficiently to prevent the recurrence of cancer and other degenerative diseases” (329).

At present, the dietary part of the Gerson treatment offered at the clinic consists of low-sodium, low-fat, low-animal protein and high-carbohydrate foods, with vitamin and mineral supplements. The diet relies on large amounts of fresh and raw fruits and vegetables. Until late 1989, raw fresh calves liver juice was included in the regimen (see discussion below). The current patient brochure lists the dietary components as: “13 glasses daily of various fresh raw juices prepared hourly from organically grown fruits and vegetables” and “three full vegetarian meals, freshly prepared from organically grown vegetables, fruits, and whole grains” (328).

The Gerson treatment also consists of a variety of other substances, including potassium supplements, thyroid hormone, Lugol’s solution (an inorganic solution of iodine plus potassium iodide), injectable crude liver extract with vitamin B 12, pancreatic

enzymes, and enemas of coffee or chamomile tea (317,328).

Other treatments, beyond the ones Gerson specified, have been added to the current protocol in recent years. According to materials distributed by the Gerson Institute, these substances include:

- ozone treatment (328) (given by enema (3 18) or via infusion in autologous, heparinized blood or directly into patients' blood vessels (401));
- hydrogen peroxide (topically, rectally, or orally) (328);
- intravenous "GKI drip" (glucose, potassium, and insulin solutions) (328);
- "live cell therapy" (328);
- castor oil (328);
- clay packs (328);
- Lincoln bacteriophage (a vaccine made from killed *Staphylococcus aureus* bacteria) and influenza virus vaccine, both reportedly to stimulate "allergic inflammation," a process Gerson believed contributed to healing (387); and
- laetrile (328,329).

The Gerson treatment is time-consuming and restrictive, and can be difficult to follow in areas where fresh fruits and vegetables are not widely available (530). To assist with the rigors of the treatment, the clinic advises patients to have a "helper," since patients "need time and energy and rest to heal and if they do the therapy alone it will reduce their chances of healing" (325).

Potential and Reported Adverse Effects

Two aspects of the Gerson treatment have attracted attention as possible causes of adverse effects—the use of raw calves liver juice, and coffee enemas.

Ingestion of raw calves liver juice has been associated with infection with *Campylobacter fetus* subspecies *fetus*, an organism that is carried in the intestinal tract of cattle and sheep. Infection with *C. fetus* subsp. *fetus* is treatable if detected early, but can lead to sepsis and death if undetected or inadequately treated (339).

An outbreak of *C. fetus* subsp. *fetus* infection among cancer patients, some of whom were thought to have been treated with the Gerson regimen, was reported in 1981 (339). Between January 1979 and March 1981, nine cancer patients and one lupus

patient with sepsis were reported to the San Diego County Department of Health Services. *C. fetus* subsp. *fetus* was isolated from blood cultures from nine patients and from peritoneal fluid from one patient. Upon admission to the hospital, five of the patients were comatose and all had severe electrolyte abnormalities. The nine cancer patients died shortly after admission (338).

After learning of the outbreak from a newspaper article, members of the Gerson staff contacted the San Diego Department of Health Services to discuss the problem, assuming from the description of treatments taken that at least some of the 10 patients had been treated at the Gerson clinic (401). Acknowledging the possible link between the raw liver juice and the *Campylobacter* infection in these patients, Gerson staff subsequently improved the handling and storage of the calves liver to reduce the likelihood of contamination and instituted routine tests for *C. fetus* among their patients at the first sign of infection; patients testing positive would then be treated with an appropriate antibiotic (e.g., erythromycin) (401). No further reports of this type of infection in Gerson patients have been published in the literature. The clinic discontinued the use of raw liver juice in late 1989, however, because of potential problems with infection (326).

Coffee enemas have been associated with serious fluid and electrolyte abnormalities, although none have been reported specifically in patients undergoing the Gerson regimen. One report in the literature noted the death of two Seattle women, one of whom had cancer, due to fluid and electrolyte abnormalities following coffee enemas (273). One of these women reportedly took 10 or 12 coffee enemas in one night, and continued at a rate of one per hour, while the other woman took them four times daily; in both cases, the enemas were taken much more frequently than is recommended in the Gerson treatment. Another report of serious adverse effects associated with coffee enemas cited three cases (579). The overall risk of fatal electrolyte disturbance associated with coffee enemas is unknown, and may depend to some extent on frequency and conditions of use (see also discussion in box 3-B).

Claims of Effectiveness

Gerson wrote (and rewrote, after the original was lost) *A Cancer Therapy: Results of Fifty Cases* to show that "there is an effective treatment of cancer,

even in advanced cases” (337). In testimony before a Subcommittee of the Senate Committee on Foreign Relations in 1946, Gerson estimated that about 30 percent of ‘hopeless cases’ of cancer he treated showed a favorable response (875). In a lecture Gerson gave in 1956 (published posthumously in 1978) (336), and in a paper published in 1954, he estimated that his treatment produced “positive results in about 50 percent of so-called generalized, regrowing or final cases” (334).

The current practitioners of the regimen also claim success with the treatment. Patient literature from the Gerson Institute claims:

... the Gerson Therapy is able to achieve almost routine recoveries in early to intermediate cancers. Even when the disease is advanced and incurable by conventional standards (i.e., involves the liver or pancreas or multiple internal sites) excellent results are possible. The Gerson Therapy has cured many cases of advanced cancer in man. (329) *Emphasis in original.*

Further, the patient literature states that even for patients with both cancer and other diseases (e.g., arthritis, heart disease, and diabetes), the Gerson treatment “usually heals the body of all diseases simultaneously” (329). This claim is reportedly based on Gerson’s belief that the body “will not heal cancer and yet leave arthritis or arteriosclerosis or diabetes unimproved” and that “when the body’s ability to heal is restored, the ‘physician within’ will set about to mend and restore the whole patient” (329).

The vice president of the Gerson Institute, Norman Fritz, republished a book by S.J. Haught (the pen name for Robert Lichello, a writer for the *National Enquirer* in the 1950s), which was originally titled *Has Dr. Max Gerson a True Cancer Cure?* (1962), renaming it *Cancer? Think Curable! The Gerson Therapy* (1983). In his introduction to the revised edition, Fritz claims that the Gerson treatment “can save about 50 percent or more of advanced ‘hopeless’ cancer patients’ and that “the percentage who recover can exceed 90 percent for early cancers and some ‘early terminal’ cancers. ” Fritz’s claims are apparently not made by others in the Gerson Institute, but the Haught book is still widely available to patients and is one of the most easily accessible sources of information about the treatment (401). The Gerson Institute’s newsletter often describes case histories of patients believed to

be cured through the Gerson treatment (see, e.g., a description of “cure of a partially removed, inoperable, radiation-resistant, adult astrocytoma through the Gerson Therapy” (327)).

Attempts at Evaluating the Gerson Treatment

Since the 1940s, there have been several attempts by a number of groups and individuals to assess the effects of Gerson’s regimen, and at least one attempt is currently in progress.

Gerson's Case Presentations

In 1947, Gerson submitted 10 case histories of cancer patients treated with his regimen to the National Cancer Institute (NCI) for review (332,822). The only available information about that review comes from a current NCI statement on the Gerson treatment, which states that the NCI review “found no convincing evidence of effectiveness, particularly since the patients were also receiving other anticancer treatments” (893). It was also noted that Gerson “was invited to submit additional data but did not do so.” Further information about the nature of the 1947 review is unavailable, since NCI cannot locate any records concerning it (766).

In 1959, NCI reviewed 50 case histories presented in Gerson’s book *A Cancer Therapy: Results of Fifty Cases*. NCI concluded that, in the majority of cases, the basic criteria for evaluating clinical benefit were not met. These criteria were the following:

- The patient must have histologic verification of the presence of a malignant neoplasm, and the diagnostic sections must be available for independent review to verify Gerson’s diagnosis.
- If the patient had surgical resection or other previous treatment for a proven malignant neoplasm, the presence of a recurrence or metastasis also must be verified histologically and the sections made available for review.
- If the patient had been previously treated, he must be completely reevaluated and observed for a long enough period of time to verify that this treatment was ineffective, and that the neoplasm is indeed advancing (60).

NCI concluded overall that Gerson’s data provided no demonstration of benefit (60,897). In an undated rebuttal, members of the Gerson Institute disputed NCI’s 1959 findings, taking issue with almost every case assessment and charging that NCI dismissed legitimate evidence on the basis of technicalities

(330). No independent assessment of the review has been made.

The Austrian Study

An exploratory study of the clinical effects of some components of the Gerson regimen is currently under way in Austria. According to an unpublished interim report (522), Peter Lechner, M.D., of the Second Department of Surgery of the Landeskrankenhaus in Graz, Austria, is conducting a study using a modified Gerson regimen as an adjunctive treatment. The modified regimen is described as a high fiber, low sodium, high iodine and potassium, lactovegetarian diet with regular coffee enemas. It reportedly omits certain elements of the original Gerson regimen, such as liver juice, thyroid supplements (unless the patient is hypothyroid), and niacin supplements. It also limits the number of coffee enemas to two per day; Lechner noted in previous experience with patients following the Gerson regimen that a higher frequency of enemas was associated with the development of colitis (inflammation of the large intestine, often leading to diarrhea) in some patients.

Twenty-nine patients who chose to follow the modified Gerson regimen were included in the study. An equal number of non-participating patients, matched for tumor type and stage of illness, were paired with the patients following the regimen. Nineteen pairs of patients with breast cancer, eight pairs with colorectal cancer, and four pairs with malignant melanoma were studied. All patients reportedly had previous mainstream treatment (surgery and possibly other treatments) and some of them were taking them concurrently (chemotherapy, radiation, or interferon). While some of the patients are described as having metastatic disease and in advanced stages of illness, the report does not indicate whether all patients had measurable disease at the start of the study or whether previous or concurrent treatment was considered to have had an antitumor effect in any of the patients.

Lechner reported that patients following the modified Gerson regimen showed no side-effects attributable to the treatment and did not become malnourished. One of the patients with inoperable liver metastasis who followed the Gerson treatment showed a temporary regression. In Lechner's opinion, there were subjective benefits from the modified Gerson regimen: patients needed less pain medication, were in better psychological condition, and

experienced less severe side-effects of chemotherapy than did the patients with whom they were compared. Without claiming definitive results, Lechner stated that the patients with breast and colon cancer with liver metastasis benefited more than others in the study. According to the report, those patients "seem to live longer, and their quality of life is apparently better" than patients with whom they were compared, although he noted that his conclusions were subjective and "of no statistical relevance at all.

Lechner's description indicates that the study was not designed to generate definitive conclusions about changes in survival or in quality of life among patients following the modified Gerson regimen. The fact that the patients following the regimen chose to undergo a relatively rigorous and demanding program suggests that there may well be differences between those patients and the ones who did not participate in the program. In this case, the comparison between participating and nonparticipating patients does not provide a legitimate basis for judging differences in tumor response, survival, or quality of life. In addition, based on the information provided in the report, it is impossible to separate the effects of the modified Gerson regimen from the effects of previous or concurrent treatments. The study does, however, provide preliminary qualitative information on the experiences of the 29 patients who followed a modified Gerson regimen along with conventional treatment. It is unclear from the report how much longer the study would continue or what endpoints were being measured.

The British Review

In 1989, three British researchers visited the Gerson Clinic on behalf of a British medical insurance company (805) "to assess its basis as a claimed dietary cure for cancer" (459). The investigators observed patients and their treatment freely and were offered information from the clinic's files on a group of patients considered by the Gerson staff to represent "best responses" to the Gerson treatment. They conducted two studies: the first was a review of the best responses, and the second was a psychological study of patients at the clinic at the time of the visit.

For the review, the investigators were presented with 149 cases from among all patients treated at the clinic since it opened in 1977. Of those, 27 were

alive and well and had sufficient documentation for assessment. Nearly all had had mainstream treatment of some kind before beginning the Gerson regimen, and a number continued to receive it in addition to the Gerson treatment.

The investigators reported that nine of the patients had melanomas, and the course of their disease “fell within what we would consider the limits of the ‘natural history’ of this disease.” Two patients reportedly had early stage prostate cancers which had been removed surgically, and their survival was also judged to be consistent with what would have been expected without further treatment. Another patient with prostate cancer having “clinically significant disease’ had survived beyond the expectation of the investigators, given his disease and prior treatment. Two patients with breast cancer and two with endometrial cancer were considered to have had disease courses consistent with their cancer and other treatment. A third patient with biopsy-proven endometrial cancer who had had no conventional treatment subsequently underwent a hysterectomy, at which time no evidence of malignancy remained, representing a case of tumor regression. One patient with non-Hodgkins lymphoma (NHL) had extensive radiation treatment, which could have accounted for a favorable outcome, and another had no followup scans, so tumor status could not be determined. In another patient with low-grade NHL, a biopsy-confirmed mass regressed with no other treatment. The remaining patients were described as having “slowly progressive disease.”

The investigators concluded:

Although several of these cases would have been expected to have a poor prognosis on the basis of their histology and stage . . . a proportion of poor prognosis patients do fare better than the average. Any large series of 6,000 poor prognosis patients treated conventionally would produce similar results.

A small number of the patients appear to have had disease regression that cannot be explained as being an extreme of the natural history of the disease. There may thus be a small antitumor effect in some patients. However, it must be stressed, if the anticancer effect of the Gerson Therapy was substantial, we would have expected to find evidence of a larger number of responses-if an effective new anti-cancer treatment had been given to 6,000 patients we would expect it to have been easier to find successful cases to present.

In the second study, 15 patients completed a questionnaire that elicited information about their background and disease history and their feelings about their physicians, their physical and mental health, the Gerson Clinic, and their interpersonal relationships. It was found that, in general, the patients had very positive feelings and experiences; they felt well supported by family and other patients at the clinic, had a ‘high degree of control over their health,” and had high “mood” and “confidence” scores. The investigators noted particularly that none of the patients was taking opiates for pain, though several had taken them previously, and they had low “pain” scores. The investigators concluded overall that there was a “significant subjective benefit” to patients and their families from the treatment:

The nature of the therapy requires a positive contribution to be made by the patient to his or her health and meets a need not satisfied by conventional therapy. There are therefore lessons for oncologists to learn in the management of desperate cancer patients and their families.

Gerson Institute Case Review

An effort to document possible tumor remissions among patients treated at the Gerson clinic in Tijuana is currently being conducted under the direction of Gar Hildenbrand of the Gerson Institute (402). Since 1987 (400), a “best case” review has been in progress to assemble relevant data from Gerson patients believed to have benefited from the treatment. As planned, the review would include patients who either had no previous treatment or who failed previous treatment, and would collect details from each patient’s medical records (including all cancer-related discharge summaries, pathology reports, slides, radiology summaries, films, laboratory reports, and surgery summaries). Provision was made for blind reevaluation of the pathology material by the U.S. Armed Forces Institute of Pathology and of the medical records by experts at the University of California at Los Angeles. Where necessary, followup evaluations on patients would be conducted (including scans or other evaluative procedures). The collected data would then be reviewed by an expert panel to determine whether objective responses to the treatment had been documented. As of August 1989, OTA had no further information on the status of the Institute’s review.

Box 3-B--Coffee Enemas

Several of the current unconventional cancer treatments, e.g., the Gerson treatment and the Kelley regimen, include a recommendation that patients take coffee enemas several times a day. Proponents believe that coffee enemas stimulate the secretion of bile and the action of the liver, helping to "detoxify" the body of waste products and poisons accumulated in the gastrointestinal tract (337,472). "Colonic irrigation" and "high colonies" are terms referring to a related procedure that involves flushing a larger portion of the colon with water. Colonic irrigation is used in the context of physical cleansing and general detoxification in many unconventional settings (450,959), but is usually distinct from the use of enemas in cancer treatment.

A few studies examining the theory of self-poisoning through the accumulation of toxins and waste products in the body were published in the 1920s (21,259) as a result of a belief common at the turn of the century that impacted feces in the colon produced pathogenic toxins. The specific causative toxins have apparently never been identified or measured and possible physiologic effects of the "detoxifying" enemas have not been studied systematically. In general, there is no scientific evidence to support the claim that coffee enemas detoxify the blood or liver. It has been suggested, however, that coffee taken by this route is a strong stimulant and can be at least as addictive as coffee taken regularly by mouth (947).

The occasional use of enemas, usually consisting of plain water, is conventional practice for a number of medical purposes, e.g., to prepare for x-rays of the intestines, surgery, or childbirth (649), or to relieve constipation (613c). The enema procedure is reportedly not without certain risks, however (970). Case reports of serious adverse effects associated with enemas used in conventional and unconventional treatment have appeared in the medical literature. Coffee enemas have been associated occasionally with fatal electrolyte imbalances. Transmission of enteric pathogens (835), fatal bowel perforation and necrosis (1%,454), and toxic colitis (478,727,793) have been associated with various other types of enema (soapsuds, water, barium, herbal, etc.). Colonic irrigation has been linked with fatal amebiasis resulting from contaminated equipment (450).

Proponents often point to the recommendation of coffee enemas in relatively recent editions of the *Merck Manual of Diagnosis and Therapy*, a general health care guide, as evidence of the medical appropriateness and conventionality of coffee enemas (355). Up to and including its 1972 edition, the *Merck Manual* did recommend coffee as one type of ingredient for occasional use as a retention enema, the purpose of which was to "soothe or lubricate rectal mucosa, to apply absorbable or local medications, or to soften feces" (613). No mention was made of the use of coffee enemas to remove toxins from the body. In addition to coffee, other agents mentioned for the same purposes were starch, olive oil, cottonseed oil, mineral oil, and whiskey in isotonic saline. Retention enemas using coffee or any of these other substances were not being recommended for frequent use, however (76), and coffee enemas were not recommended for use as a part of treatment for cancer or any other serious illness-only for temporary, specific problems such as constipation. In the 1977 and later editions of the *Merck Manual*, the mention of coffee enemas was dropped. In the three most recent editions, enemas using olive Oil, mineral oil, or, isotonic saline are recommended for constipation and fecal impaction (613a,613b,613c).

THE KELLEY REGIMEN

In the 1960s, William Donald Kelley, an orthodontist by training, developed and publicized a nutritional program for cancer patients based on dietary guidelines, vitamin and enzyme supplements, and computerized metabolic typing. The Kelley regimen became one of the most widely known unconventional cancer treatments. Although Kelley is no longer practicing his treatment, the regimen has been continued in a variety of forms by his followers. There are three distinct phases or interpretations of the Kelley program: the first, which Kelley described in his book *One Answer to Cancer*; the second, Fred Rohe's expansion and reinterpretation as published in his book *Metabolic*

Ecology; and the third, Nicholas Gonzalez's metabolic typology based on Kelley's ideas, which is currently being offered by Gonzalez in New York.

Background and Rationale

In 1964, Kelley was told he had metastatic pancreatic cancer, although he reported that the diagnosis was never confirmed by biopsy. Applying one of his own "biochemical tests" (one of which he called the "Protein Metabolism Evaluation Index," a test intended to diagnose cancer before it was clinically apparent), he concluded that he had had cancer for several months, if not years, and that his wife and two of his three children also had cancer (472). Kelley claims that his doctor told him he had

2 months to live and advised surgery, which Kelley refused. Based on his own experience, he felt that the wrong foods caused tumors to grow, while proper foods allowed the body to fight off the tumor. By trial and error, he regulated self-administered doses of various enzymes, vitamins, and minerals to achieve his recovery. He proceeded to apply his dietary program to his family and others, and eventually published his recommendations and the beliefs underlying them in a 1969 book entitled *One Answer to Cancer* (472), which achieved a wide distribution.

In his book, Kelley wrote that cancer represented “nothing more than a type of placenta growing at the wrong place and time in the body.” He characterized cancer as a deficiency disease—a deficiency of active pancreatic enzymes, in particular. He believed that an indication of inadequate protein metabolism signified early stages of cancer and that cancer could be controlled by supplying adequate doses of pancreatic enzymes, a key component of his “ecological” treatment (472). He claimed that this treatment could halt the growth of tumors from within 3 hours to 12 days of initiation. The difficult part, he concluded, was clearing the body of accumulated toxins and the toxic poisons that are released as the tumors are dissolved and excreted (472).

Development and Use of the Treatment

Kelley described his treatment as ecological since “the total person and his total environment must be considered in order to give proper treatment.” The program consisted of five components: taking sufficient nutritional supplements (vitamins, enzymes, minerals, etc.); detoxifying the body (purging, fasting, coffee enemas, colonic irrigations, cleansing the kidneys, the lungs, and the skin, and exercising); maintaining an adequate diet;⁴ providing proper neurological stimulation (e.g., osteopathic manipulation, chiropractic adjustments, ‘mandibular equilibration to re-shape the skull,’ or physiotherapy); and taking a positive spiritual attitude (“purifying the emotions and spirits”) (472).

The Kelley nutritional program gained popularity in the 1970s, when Kelley gave many interviews and made unequivocal claims that his program was regularly able to cure a wide range of cancers: “It is extremely effective and rather inexpensive. Those who are willing to faithfully and tediously follow it will be successful. Those who follow it in part or haphazardly will be completely unsuccessful” (472). He also developed a mail-order approach to nutritional-metabolic treatment in which he was able to use “technicians” who assisted patients in getting on and following his program. Specific recommendations for patients were generated by his computer system. In addition, Kelley developed his own supply houses for the supplements,⁵ water filtration systems, and even the coffee (“Kelley Koffee”). An updated and expanded version of his treatment was published in 1983 by Fred Rohe with Kelley’s input (761). Kelley endorsed Rohe’s book, stating that it represented his most up-to-date findings and recommendations.

In this second phase, Kelley’s spiritual philosophy had taken on a strong “New Age” tone. He wrote:

... there has to be some purpose to human life on this planet. That purpose seems to me to be the development of understanding and inner growth. I define inner growth as the expansion of our whole being, particularly our spirit, as we interact with each other and with the environment . . . This new positive foundation supports a new paradigm for the field of health care, allowing for the influx of great new streams of intelligence, experiences, and creativity. Millions of people who come along in future generations will be able to build and react upon this new paradigm. It is an ultra-holistic model with a completely realistic and scientific framework. We are moving from a left-brain dominant system to a left/right balanced brain system, with plenty of heart mixed in. I don’t know if I understand it all—I don’t think anybody can completely grasp such a comprehensive process of change. But it’s a beautiful thing to watch. (761)

According to Rohe, Kelley had noticed that not everyone he treated responded the same way, and modified his original idea of “one answer to

⁴This refers to a low protein diet and proper protein timing. Kelley claimed that “if people would not eat protein after 1:00 p.m., 83% of cancer in the United States could be eliminated” (472); no pasteurized milk, no peanuts, nothing cooked or processed, no white flour or white sugar, lots of vegetable and fruit @ices, plenty of raw almonds, fresh raw salads, whole grain cereals.

⁵Kelley believed that the supplements commercially available in health food stores and drug stores did not meet his standards of purity and potency, so he initiated a custom-made line of products made according to his specifications (353).

cancer. He came to believe that there was no single, perfect diet for all patients. To account for each individual's unique metabolic makeup, Kelley devised a system of metabolic typing or classifying each individual and coordinating a unique set of recommendations for each.

One of the elements of the Kelley program that evolved substantially from the first phase was his use of diagnostic tools. The "Kelley Enzyme Test," one of the many tests used in the program, was designed to provide a very early diagnosis—1 month to several years before clinical signs of cancer (761). The test consisted of taking ten "Ultra-zyme" tablets over a 4-week period. The presence or absence of cancer was indicated by the person's observation of whether they felt better, worse, or no different during this period. Feeling either better or worse indicated the presence of cancer, whereas feeling no different meant that the person was probably free of cancer (but in this case Kelley recommended that the test be repeated with a double dose of the enzyme tablets to be sure). The test was not intended to indicate the location of cancer in the body or the type of tumor (761).

According to Rohe, Kelley believed that environmental pollutants were being incorporated into our bodies and becoming internal toxins, and that exhaustion of the fertility of the Nation's farmlands was depleting our foods of nutritive value. All of this led, he reasoned, to pancreatic and immune system breakdowns, leading ultimately to cancer.

The diet recommended by Kelley as stated in the Rohe book outlines the following guidelines: restrict intake of meat (except liver); consume no protein after lunchtime; no refined foods, pasteurized milk, peanuts, tea (except herbal), coffee (except in enemas), soft drinks, tobacco, liquor, white rice, or fluoridated water. He recommended that patients eat fresh, raw salads, vegetable juices, whole grain cereals, raw liver (liver must be taken raw to preserve the "enzymes, amino acids, and other intrinsic factors science has not yet identified—which are destroyed when the liver is cooked"'), nuts and seeds, cultured milk products, eggs (preferably soft boiled or raw, except for certain types of cancers), beans, etc. In summary, the diet consisted of increasing one's consumption of raw foods, decreasing protein intake, and eliminating refined foods and additives.

The only classification system used by Kelley at the time of the Rohe book was a breakdown between "soft" and "hard" tumors. "Hard" tumors included all except leukemia, lymphomas, melanomas, and multiple myeloma, which were classified as "soft."

The nutritional supplementation recommended by Kelley consisted of 25 supplements (enzymes, vitamins, glands, minerals, hydrogen peroxide, aloe vera, bile salts, freeze-dried liver, etc.) that were to be taken for a 2-year period. In the standard protocols, patients were classified as "hard tumor" and "soft tumor" patients and were recommended the same list of supplements, although "soft tumor" patients were advised to take a few extra foods. Some patients were given specific recommendations tailored to them and in these, patients often were advised to take additional supplements beyond the 25 listed in the standard protocol. Patients were referred to Kelley's Nutritional Counseling Service in Texas for additional information.

These supplements were intended to stimulate the release of "wastes and debris" from the body. Ridding the body of these wastes through detoxification was advised as essential to the program's success. Kelley recommended that patients take at least one strong coffee enema each day, to clean out the liver and gallbladder and to rid the body of toxins produced during tumor digestion (see also discussion in box 3-B). In addition to coffee enemas, Kelley recommended regular purging, fasting, and colonic irrigation (high enemas, between 18 and 30 inches into the body). He also advised cleansing the kidneys, nostrils, lungs, and skin (761).

As in Kelley's original description, other components of the program as described by Rohe were neurological stimulation and spiritual growth. Kelley advised patients to "reactivate nerve function through structural alignment": osteopathic manipulation, chiropractic adjustments, cranial osteopathy, mandibular equilibration (to reshape the skull and take stresses from the brain), and reflexology.

Kelley considered matters of the spirit an integral part of his program: "Just as the body must be purged and cleansed, so must the emotions and mental attitudes be purified." He advised removing "all false teachings, false doctrines, fruitless activities, fears, and misunderstandings. Your spirit and very being hunger for truth—the truth that can be

found only in the proper understanding of the Word of God.” (761)

To support his program and make his teachings more widely known, Kelley created the International Health Institute in Dallas, consisting of a group of doctors, dentists, chiropractors, naturopaths, metabolic technicians (nutritional counselors certified by the institute), and attorneys. Under the umbrella of this institute, Kelley's Nutritional Counseling Service was developed, whereby patients attended workshops to find out about the Kelley program and then answer the 3,200-question Metabolic Evaluation Survey (which reportedly took about 8 hours to complete). This questionnaire, analyzed entirely by computer, formed the basis for the Kelley nutritional prescription, a program designed according to each patient's individual nutritional needs. Questions were answered on computer cards and sent to Kelley's headquarters. Kelley claimed that the cards gave him a detailed picture of the patient's metabolic type and of the efficiency of 50 physiological functions. In response to the questionnaire, patients received a lengthy, detailed computer printout of their metabolic status along with step-by-step instructions for following their particular version of the Kelley regimen--covering foods, supplements (in the range of 100 to 200 pills per day), detoxification techniques, psychological approaches, and lifestyle changes (341). With the cooperation of physicians unaffiliated with Kelley's institute, cancer patients were advised by Kelley to submit the questionnaire every 6 months until, according to Kelley, their nutrient levels reach normal ranges, and after that, about once a year.

For most early localized cancer, Kelley advised frequent oral doses of pancreatic enzymes taken between meals; the enzymes were said to destroy cancerous and other defective cells (353). Kelley maintained that patients with metastatic disease require prolonged therapy (1 to 2 years at least). In patients with very advanced malignancies involving many organs, Kelley did not claim that the tumors could necessarily be eliminated, only that the enzymes often shrink much of the tumor mass and could prevent the cancer from spreading further (353).

Kelley designed a mail-order form for an intensive nutritional-metabolic program for cancer that reached many patients who may not have had access to other unconventional treatments. The idea that cancer could occur as a result of inappropriate nutrition and could be treated with intensive nutritional supplementation and detoxification, as articulated in his book *One Answer to Cancer*, brought Kelley a great deal of attention from the public, the medical profession, and State medical examiners. In 1971, Kelley was issued a restraining order forbidding him from treating non-dental disease and was prohibited from distributing copies of his book. Gonzalez reported that following this restraining order, Kelley became more cautious in his claims and practice; he required all patients to sign a form acknowledging that he was a dentist, not a medical doctor and that his nutritional programs were intended for nutritional support, not as therapies for any disease (353).

Kelley's International Health Institute and his Computer Health Service (934) were closed in the mid-1980s. A computerized metabolic typing service similar to Kelley's is offered by Healthexcel in Winthrop, Washington, although Kelley is not identified as being directly involved in the service (390).

Current Applications of the Kelley Regimen

In recent years, Nicholas Gonzalez, M.D., has examined the Kelley regimen and has provided an additional analysis of Kelley's individual metabolic profiles. Since Kelley's ideas and results are known only from his 1969 book and the 1983 book by Rohe, it is not known whether Gonzalez's descriptions match Kelley's most recent interpretations of his program. However, Gonzalez is practicing this regimen in New York (354) and Kelley is apparently not, so Kelley's metabolic typology as interpreted by Gonzalez is presented herein summary (353).

According to Gonzalez, Kelley believed that human beings can be divided into three genetically based categories--'sympathetic dominants,' 'parasympathetic dominants,' and 'balanced types.'⁶ "Sympathetic dominants" will have highly efficient and developed sympathetic nervous systems. "In addition, the tissues, organs and glands nor-

⁶The autonomic nervous system, made up of the opposing sympathetic and parasympathetic nervous systems, innervates smooth and cardiac muscle and glandular tissues, governing actions that are more or less automatic, such as actions of the heart, secretion, constriction of blood vessels, and peristalsis. The parasympathetic nervous system tends to induce secretion, increase the tone and contractility of smooth muscle, and cause blood vessels to dilate. Effects of the sympathetic nervous system are opposite.

really stimulated by the sympathetic nerves—the heart for example—will be well developed. However, in this group the parasympathetic nervous system will be relatively inefficient, and all the tissues and organs normally activated by this system will be physiologically sluggish.” In “parasympathetic dominants,” the opposite is the case; and in “balanced types,” both branches of the nervous system and corresponding tissues, organs, and glands are equally developed.

Sympathetic dominants are hypothesized to have evolved in tropical and subtropical ecosystems on plant-based diets. Parasympathetic dominants evolved in colder regions on meat-based diets. The balanced types evolved in intermediate regions on mixed diets. While modern migrations have extensively mixed the three types, Kelley believes people tend to belong definitively to one of the three categories.

Kelley thus evolved a diet for each type based on its hypothesized historical origins. And he traced a characteristic path of “metabolic decline” for each group when they consume the wrong diet. He associates “hard tumors” with severely compromised sympathetic dominants, and ‘soft tumors’—cancers of the white blood cells and lymph system—with severely compromised parasympathetic dominants.

Gonzalez dispenses with the neurological stimulation and spiritual components of the original Kelley regimen, and now divides the Kelley therapy into several components. Gonzalez’s regimen consists of:

- An individualized diet, “as determined by an experimental blood test,’ that ranges in content from entirely vegetarian to entirely meat, with about 90 variations in between. Gonzalez stated in a recent interview that he has ‘patients who will not get well unless they eat fatty red meat three or four times a day” (356).
- Large doses of nutritional supplements, as many as 150 pills a day (356), including vitamins, digestive enzymes (e.g., pancreatic enzymes, pepsin, hydrochloric acid, bile), and concentrates in pill-form of beef organs and glands.
- Coffee enemas.

Attempts at Evaluating the Kelley Regimen

In his 1987 manuscript *One Man Alone: An Investigation of Nutrition, Cancer, and William Donald Kelley* (353), Gonzalez presents case histories of 50 patients he selected from Kelley’s files. This case series has been singled out by proponents as one of the most convincing in support of an unconventional treatment (530,596). As a means of finding out whether the evidence presented in these cases would be convincing to the medical community, OTA asked six physicians who are members of the Advisory Panel for this OTA study to each review a portion of Gonzalez’s case histories. Three of the physicians were supportive of some unconventional treatments (though none was associated particularly with Kelley or Gonzalez), and three were mainstream oncologists. (For convenience, these physicians are referred to, in this section, as “unconventional” and “mainstream.”) The three unconventional practitioners are not oncologists, though each treats some cancer patients.

Each of the 50 cases was assigned to one “unconventional” and one “mainstream” physician for review. Assignments were made randomly within each group of three physicians, so all possible pairings of reviewers could occur. The reviewers were asked to assume that Gonzalez’s reports were accurate, and then comment on whether the course of the disease described for each patient was beyond reasonable expectation, and whether attribution of benefit to the Kelley program appeared justified.

The cases include a variety of cancers: seven lymphomas (various types); six pancreatic; five prostate; four breast; four melanoma; three Hodgkins disease; three leukemia; two each of colon, lung, ovary, rectosigmoid, and testicular; and one each of bile duct, brain, cervix, metastatic liver (primary unknown) myeloma, kidney, stomach, and uterine.

Each case history consists of a narrative by Gonzalez and copies of some supporting medical records. The criteria for including cases were: they had to have been evaluated by “competent specialists” so that the diagnosis would not be in doubt; patients should have been given a prognosis of “poor” or ‘terminal’ and there had to be evidence of regression of disease or “long-term survival that might logically be attributed to the Kelley program.” The patients were chosen from more than

1,000 selected patient records that Gonzalez determined were “potentially suitable.” He contacted 455 of them, and 160 seemed to satisfy the stated criteria. For each of these, Gonzalez reports that he “obtained complete medical records,” and the 50 cases were then selected. Gonzalez refers to these cases as “representative” of Kelley’s patients, rather than his “most ‘impressive’ cases.”

In addition to making general comments (discussed below), five of the six reviewers responded with a narrative on each case; one categorized cases as “seem legitimate,” “suggestive but not definitive,” “somewhat suggestive,” and “definitely *not* convincing.” In all cases, however, documentation presented in the manuscript was inadequate to confirm critical details of the narrative, and in many cases, it appeared that critical pieces of information did not exist in the medical record at all (e.g., conflation of metastatic disease), mainly because the patients had not been followed up with tests and scans to determine the status of their disease.

Fifteen cases were judged by unconventional reviewers as definitely showing a positive effect of the Kelley program; the mainstream reviewer of each of these cases found 13 of them unconvincing and 2 unusual. Nine cases were judged unusual or suggestive by unconventional reviewers; the mainstream reviewers found these cases unconvincing. Fourteen cases were judged by unconventional reviewers as having been helped by a combination of mainstream plus Kelley treatment; the mainstream reviewers found 12 of these cases unconvincing and 2 unusual. Twelve cases were considered unconvincing to both the unconventional and mainstream reviewers.

Specified criticisms of the case presentations included the lack of histologic diagnosis in several cases, the assumption that disease was metastatic without biopsy, discrepancies between the narrative and the medical records (e.g., in one case, the surgical pathology report states that the tumor arose “in the colonic mucosa infiltrating into the wall,” Gonzalez describes the tumor as “growing through the wall,” which would have a much poorer prognosis), discounting the effects of prior mainstream treatment (e.g., hormonal treatment, which, unlike cytotoxic chemotherapy, may take months to take full effect), and the general lack of reassessment of patients’ conditions once begun on the Kelley treatment. Three illustrative cases are discussed below.

Discussion of Three Cases

In one case history, a woman in her early 40s was diagnosed with a 7-centimeter “infiltrating adenocarcinoma of the colon, intermediate differentiation with full thickness involvement of bowel wall but no evidence of regional lymph node metastasis.” It was removed surgically. She did well, except for chronic fatigue, until about a year and a half later, at which time she had a car accident and then developed severe abdominal pain with significant weight loss. Outpatient studies “revealed a large, restricting tumor in the remnant of her descending colon.” The narrative reports that the patient said her doctor told her that the cancer “had metastasized widely.” She refused recommended surgery. Shortly, she began the Kelley program, at a time when she appeared to be “critically ill.” Within a week, her bowel obstruction cleared and she improved gradually. “Eleven months after beginning her protocol, she reports passing a large globular mass of tissue which she and Dr. Kelley assume was the remnants of her tumor.” Seventeen years after diagnosis, she is alive and in “excellent health and apparently cured of her cancer.

The medical records accompanying this narrative include the discharge summary from the original surgery and corresponding radiology, surgery, and pathology report.

The mainstream physician who reviewed this case judged that this patient’s localized tumor was probably cured by the initial surgery. No documentation of the reported recurrence is supplied, and the cause of her later medical problems could not be determined. He commented that the globular mass of tissue, which was apparently seen only by the patient, was a unique but uninterpretable feature of this case.

The unconventional physician who reviewed this case noted that the recurrence was not confirmed by pathology, but felt that the Kelley program probably was instrumental in her survival.

In a second case, a man in his late 30s had an early stage (Clark’s level II) malignant melanoma removed from his back. A “livermass” was described in the hospital record as a “space occupying lesion inferior portion right lobe of liver,” but was not thought to represent metastatic disease. About 3 months later, he noticed a nodule under his left arm, which upon removal was found to be malignant.

Sixteen lymph nodes were subsequently removed, of which five were positive for melanoma. Four months later, he had another nodule near the previous one, and had it removed; it also was positive for melanoma. No other treatment was recommended. According to the narrative, the patient developed fatigue and anorexia. After another 6 months, he noted another nodule on his forehead, and shortly thereafter began the Kelley program. He gained weight and the forehead nodule regressed, disappearing after 6 months. At his last followup 2½ years later, he had no evidence of cancer and was in “excellent health.”

Supporting records for this case include the biopsy report from the first recurrence in the left axilla, a letter that appears to be from the treating oncologist to the patient’s personal physician written about 6 months after the forehead nodule was noticed (letter on plain paper, no letterhead), and a letter written about 6 months later from the same oncologist to what appears to be the patient’s insurance group discussing his history.

The unconventional reviewer found this narrative “highly suggestive” of benefit from the Kelley program, but that the absence of continued followup weakened the case. The mainstream reviewer commented that a waxing and waning course for malignant melanoma is not unusual, and mentioned a patient of his own with a similar history, whom he has followed for 10 years. He also commented that the cause of the fatigue was unclear, but could have been related to depression. In addition, the letter to the patient’s personal physician notes in relation to the forehead nodule that had disappeared, “this was not thought to be metastatic melanoma when he was examined by my colleague . . . at that time.”

In a third case, a man in his mid-60s was diagnosed with well-differentiated infiltrating adenocarcinoma of the prostate during a routine physical. An abnormality of the right eighth rib was noted on a bone scan, which the narrative notes was “initially believed consistent with metastatic disease.” On x-ray, an infiltrate was noted in the lower region of the left lung, which the narrative states “appeared to be an additional area of metastasis.” The patient refused further testing and treatment. During a hospitalization a little over a week later for removal of two superficial skin cancers, a chest x-ray showed some improvement in the lung infiltrate but the records stated that “the possibility of an

underlying neoplasm could not be excluded.” He began the Kelley program shortly after that. Nine years later, the patient, when contacted, said that his prostate was found to be completely normal on a recent physical examination. The narrative concludes that this was a “most remarkable patient,” and that “it seems reasonable to attribute . . . prolonged survival to the Kelley program.”

Supporting records for this case include the discharge summary and biopsy report from his original hospitalization.

Neither the unconventional nor the mainstream reviewer found this a case inconsistent with the expected course. Both commented that there was no real evidence of metastatic disease. The mainstream reviewer added, “The survival of nine years with localized adenocarcinoma is not at all unusual, and such cases are identified fairly frequently inpatients who seek medical attention for obstructive symptoms related to their associated benign prostatic hyperplasia” (271).

General Comments

The mainstream reviewers had similar general comments about the cases. A general theme in their remarks was that, based on the material presented, it was not possible to relate the reported results to the Kelley treatments. Nearly all the patients had had mainstream treatment, which, along with the natural variability of the disease, might also have been sufficient to account for the observed outcome. Two reviewer comments include:

My impression of these cases overall is that most of them represent better than average survival from their respective diseases, and to persons who are not familiar with the breadth of individual disease survival spectra they might seem unusual. For the most part, however, they are not and they do not as a group represent any basis for further pursuit of the Kelley treatment per se. (271)

Those of us who have worked over the years with cancer patients have come to respect the vagaries of human biology wherein there are cancer patients who for unclear reasons fare better than we would have expected. (544)

In several instances, reviewers commented that they had in their care patients whose courses are as exceptional, for reasons not immediately apparent, as the Kelley cases they reviewed.

Another common criticism was that comparing an individual patient's survival with average group statistics is misleading and an invalid use of the group data,

... it is an elementary statistical principal that retroactive or retrospective reviews of groups of patients such as that surveyed by Dr. Gonzalez of necessity are fraught with the bias imposed by the ways in which the patients selected themselves for referral to the Kelley program These patients can hardly be considered representative of the entire spectrum of cancer patients. Secondly, in critiquing the cases, Dr. Gonzalez is highly selective in marshalling references and supporting assertions which are limited and clearly chosen to support his point of view. His review of each case is not a neutral exercise, but is slanted to support his assertion that the Kelley program has had an impact on the outcomes of these patients. (544)

General comments of the unconventional reviewers were significantly different:

As an overall assessment, I would judge that the patients under my review appear probably, but not certainly, to have presented for the most part an unusual course, that the outcome exceeded normal expectancies with current contemporary conventional management and that the effect of the Kelley treatment contributed significantly, although not necessarily exclusively, to the outcome. (271)

I have . . . found 5 which seem legitimate; 5 suggestive but not definitive, 2 somewhat suggestive; 8 definitely not convincing. If we can extrapolate to the 50 cases there might be 12 which seem on the basis of the info presented, to represent genuine unexpected "cures" or remissions. Certainly, even 25% is striking. It obviously does not rule out expectancy and great motivation as the "cause" of the remission.

... in the cases I have marked legitimate, based upon the facts presented and beyond any reasonable medical doubt, it appears that totally unexpected remissions occurred. If there is such a thing as "best cases," these appear to fulfill that definition. It would be unscientific to ignore such data. (795)

Another comment had to do with the difficulty of assessing best cases attributable strictly to unconventional treatment, because patients so often use both mainstream and unconventional treatment (218).

This limited OTA review of Gonzalez's case histories suggests that physicians generally supportive of unconventional treatments found some of the

cases supportive of benefit from the Kelley regimen, whereas mainstream physicians did not find such suggestion of benefit, for several reasons. Key reasons appear to be lack of adequate documentation of the course of disease and reliance in most cases on unusually long survival rather than documented tumor remission. (See ch. 12 for a discussion of "best case" series, including discussion of medical documentation and endpoints.)

MACROBIOTIC DIETS

Macrobiotic diets, consisting largely of cooked vegetables and whole grains, are among the most popular unconventional approaches used by cancer patients (177,530,781). Books and magazines, special food items, macrobiotic cooking classes, and other macrobiotic products and services have, for the past decade or more, been easily accessible through local health food stores and regional macrobiotic teaching centers ("East-West Centers"). General bookstores are now also a common source of information about macrobiotic beliefs and practices, often carrying at least a few of the many available books by macrobiotic teachers and by individuals who initiated a macrobiotic regimen following diagnosis of disease. One recent example is a widely publicized book (777) (and excerpted magazine articles (634,635,776)) recounting a physician's personal use of a macrobiotic diet as an adjuvant treatment for prostate cancer.

During the past three or four decades in the United States, a small group of proponents has been active in developing and teaching macrobiotic beliefs and practices, drawing at first from elements of Japanese culture and Eastern philosophy. During this time, the dietary recommendations have been modified, and continue to evolve. One of the most prominent leaders in the macrobiotic movement is Michio Kushi, who, in 1978, founded the Kushi Institute near Boston, the aim of which is to "provide the education necessary to achieve our common goal of a healthy and peaceful world" (501). The overall goals of macrobiotic education include teaching people to take responsibility for their state of health and to develop natural, balanced ways of living seen as essential to recovery from disease. Kushi and his staff offer courses covering a diverse array of practical and theoretical issues, including physical and psychological health and well-being, environmental concerns, spiritual evolution, and international peace. Another prominent leader in the U.S.

macrobiotic movement is Herman Aihara, president of the California-based George Ohsawa Macrobiotic Foundation, a group whose aim is to spread the teachings of macrobiotics and its practical application in daily life. The Foundation publishes writing pertaining to macrobiotic principles and diet, along with a monthly magazine, and teaches macrobiotic cooking methods (16).

Macrobiotics is defined as the way of life according to the greatest or longest possible view (509). Kushi believes that through its practice, i.e., the “selection, preparation, and manner of eating of our daily food, as well as the orientation of consciousness,” it is possible to apply “the order of the universe, nature, and life” to our daily lives (507,509). According to Kushi, “macrobiotics is neither a treatment nor a therapy, but rather a common sense approach to daily living” (506) and a comprehensive approach to the maintenance of health (507).

The central and most prominent element of the macrobiotic belief system is its dietary practice. Most of the recent popular literature, including much of Kushi’s own writings, focuses on the use of macrobiotic diets not only to promote general health and well-being, but to relieve illnesses such as cancer (509) and AIDS (636). One effect of that literature is that many U.S. cancer patients initiate a macrobiotic regimen following a diagnosis of cancer and do so with the hope of obtaining direct health benefits related to their cancer; many who recover believe that their renewed health was a result of the macrobiotic diet they followed.

While the macrobiotic diets were not developed primarily as a treatment for cancer, they are, nevertheless, promoted actively and followed by many as a treatment for cancer. Accordingly, this section of the report focuses on current macrobiotic practices as applied to cancer treatment. The adoption of a macrobiotic regimen in other primary contexts, e.g., as a general lifestyle choice, as a preventive measure against cancer, or as treatment for conditions other than cancer, is not covered in this report.

Background and Philosophy

The introduction of macrobiotic practices into the United States is usually attributed to George Ohsawa (1893-1966), the pen name for Yukikazu Sakurazawa, a Japanese teacher who studied the writings of Sagen Ishizuka (1850-1910), a Japanese physi-

cian. Ohsawa is said to have cured himself of serious illness by changing from the modern refined diet then sweeping Japan to a simple diet of brown rice, miso soup, sea vegetables, and other traditional foods (509). He initiated the development of macrobiotic philosophy, reportedly integrating elements of Eastern and Western with ‘holistic’ perspectives on science and medicine (509). Ohsawa made his first of several visits to the United States in 1959.

Through his writings and teachings, Ohsawa combined elements of Zen Buddhist philosophy with macrobiotic principles. He popularized his approach through advocacy of the ‘Zen macrobiotic diet’—the diet from which the current (and different) macrobiotic regimen was developed. Ohsawa advocated simplicity in diet as a key to good health. He believed that personal happiness and health could be achieved by following a predominantly vegetarian dietary plan consisting of unprocessed, organically grown grain products, especially cereal grains (which he referred to as “principal food”), vegetables, beans, fruit, and seafood. In his 1965 book, *Zen Macrobiotics* (693), Ohsawa outlined 10 stages of diet (designated numbers -3 to +7), with diet -3 consisting of 10 percent cereals, 30 percent vegetables, 10 percent soups, 30 percent animal products, 15 percent salads and fruits, 5 percent desserts, and beverages ‘as little as possible.’ With each higher number diet, Ohsawa reduced the percentages of food from some of these categories or eliminated the category entirely and increased others, so that, e.g., in diet +3, 60 percent was cereals, 30 percent was vegetables, and 10 percent was soups. Ohsawa regarded diet +7, which consisted of 100 percent cereals, as the “highest” way of eating for treating illness, including cancer, or as a short-term exercise in dietary simplicity (592).

A 1971 report of the AMA Council on Foods and Nutrition noted various types of serious nutritional deficiencies, some of which were fatal, among individuals restricting themselves to Ohsawa’s +7 diet for extended periods of time. These included cases of scurvy, anemia, hypoproteinemia (low serum protein), hypocalcemia (low serum calcium), emaciation due to starvation, and loss of kidney function due to restricted fluid intake (43). Publicity surrounding these cases led to the development of a strongly negative stereotype of the macrobiotic regimen in the 1960s. The American Cancer Society Committee on Unproven Methods of Cancer Man-

agement published its first statement on macrobiotic diets in 1972 (90).

In the 1970s and 1980s, changes in the content and focus of the macrobiotic movement were led to a great extent by Michio Kushi, who had studied with Ohsawa, and who came to the United States from Japan in 1949 (499). Kushi, along with Herman Aihara and other leaders in the macrobiotic movement, preserved elements of Ohsawa's philosophy while incorporating a variety of broader and more complex components into macrobiotic philosophy and practice (16). Most notably, Ohsawa's 10-phase dietary levels were replaced with the general 'standard macrobiotic diet,' which Kushi described in detail in his 1983 book, *The Cancer Prevention Diet* (509). Aihara recommended his own macrobiotic dietary guidelines for cancer patients in his books *Basic Macrobiotics* (16) and *Acid and Alkaline* (15). Those books, along with Anthony Sattilaro's 1982 book, *Recalled by Life*, highlighted a new aspect of macrobiotic practice, at least from a public perspective, by asserting a fundamental relationship between current macrobiotic diets and cancer remission.

Rationale

Kushi and his associates have become prominent spokespersons for the ideas underlying macrobiotic practices and for the rationale for applying them to the treatment of cancer. From Kushi's perspective, the development of cancer is determined by dietary, environmental, social, and personal factors; by extension, existing cancers may be influenced by these same factors.

Kushi cites a number of specific factors he believes are linked fundamentally to the development of cancer, including patients' "overall blood quality," consumption of excess nutrients, exposure to toxic substances, "mentality and way of life," as well as more general factors, such as unfavorable trends in the food industry and our "increasingly unnatural and sedentary way of life. He emphasizes the role of personal behavior in the development of cancer: "cancer is not the result of some alien factor over which we have no control," he writes, but rather "the product of our own daily

behavior, including our thinking, lifestyle, and daily way of eating" (509).

The development of cancer is described as a long-term, multistep process that begins well in advance of actual tumor formation. Kushi writes:

Cancer is only the terminal stage of a long process. Cancer is the body's healthy attempt to isolate toxins ingested and accumulated through years of eating the modern unnatural diet and living in an artificial environment. (509)

He believes that these accumulated toxins result from overconsumption of milk, cheese, meat, eggs, and other fatty, oily, or greasy foods (509), and of foods with a cooling or freezing effect, such as ice cream, soft drinks, or orange juice (509). Depending on their location in the body, these accumulated toxins are manifested initially as, e.g., allergies, earaches, coughing and chest congestion, a "bulging abdomen," periodic swelling and weakness in the legs, dry skin, hardening of the breasts, prostate abnormalities, vaginal discharge, or ovarian cysts—problems Kushi believes are indications of potentially precancerous conditions (509). As he explains it:

As long as improper nourishment is taken in, the body will continue to isolate abnormal excess and toxins in specific areas, resulting in the continual growth of cancer. When a particular location can no longer absorb toxic excess, the body must search for another place to localize it, and so the cancer spreads. This process continues until the cancer metastasizes throughout the body and the person eventually dies. (509)

In Kushi's view, the central error in our behavior that leads directly to an imbalance and unnatural state in the body and thereby to cancer development, is the consumption of food that is overly expansive and contractile (509). He uses the traditional Oriental concepts of yin (expansive) and yang (contractile), described as antagonistic and complementary forces that create and balance all phenomena on earth (509), to devise a framework for explaining and formulating a set of dietary recommendations to treat each type of cancer.

⁷Kushi uses the traditional Oriental practice of "physiognomy" to diagnose cancer and to monitor its progress in individual patients. Correlations are made between external appearances (e.g., facial features, posture, and skin color) and disorders of specific organ systems, and particular attention is paid to certain markings in the eyes and to skin color, since a **greenish** skin color on certain areas of the body is **claimed** to indicate the existence of a tumor (509,776).

A macrobiotic approach to treating cancer would first classify each patient's illness⁷ as predominantly yin or yang, or sometimes as a combination of both, based in part on the location of the primary tumor in the body and the location of the tumor in the particular organ. In general, tumors in peripheral or upper parts of the body or in hollow, expanded organs are considered yin; examples include lymphoma, leukemia, Hodgkins disease, and tumors of the mouth (except tongue), esophagus, upper stomach, breast, skin, and outer regions of the brain. Tumors in lower or deeper parts of the body or in the more compact organs are considered yang, e.g., cancers of the colon, rectum, prostate, ovaries, bone, pancreas, and inner regions of the brain. Cancers thought to result from a combination of yin and yang forces include melanoma and cancers of the lung, bladder, kidney, lower stomach, uterus, spleen, liver, and tongue (509).

Macrobiotic dietary treatment would attempt to correct the perceived excess of yin, yang, or both tendencies. For cancers classified as predominantly yang, Kushi recommends the standard macrobiotic diet (explained below) with a slight emphasis on yin foods, and for cancers classified as predominantly yin, the same diet with a slight emphasis on yang foods. Patients with cancers classified as resulting from both yin and yang forces are advised to follow "a central way of eating," as suggested in the standard macrobiotic diet. Different cooking styles are also recommended based on this disease classification (509).

Beyond dietary guidelines, a number of additional recommendations are emphasized in the macrobiotic regimen, e.g., obtaining regular exercise, avoiding electromagnetic radiation, synthetic fabrics, and chemical fumes, and maintaining a good mental attitude. Kushi writes:

A person with cancer must understand that he or she was directly responsible for the development of the disease, through his or her daily diet, manner of thinking, and way of life. The patient should be encouraged to reflect deeply, to examine those aspects of modern mentality that have produced the problem of cancer and a host of other unhappy situations. These reflections should include a review of the rich heritage of traditional wisdom developed

by many cultures over thousands of years, an appreciation of the endless wonders of the natural world, including the body's marvelous self-protective and recuperative mechanisms, and a respect for the order of the universe that produces these phenomena. (509)

The overall purpose of these various changes in diet, exercise, attitude, and family interactions is reportedly to bring every aspect of the patient's life into balance. Macrobiotic philosophy teaches patients to be grateful and assume responsibility for everything in their lives, including their illness. By doing this, patients are encouraged to believe that since they had the power to create their illness, they must also have the capability to recover from it (667).

According to his 1983 book, Kushi does not encourage cancer patients to combine the macrobiotic diet with mainstream cancer treatment, except in immediately life-threatening circumstances, such as an inability to eat normally or an obstruction in the digestive system (509). Although he does encourage patients to keep their physicians informed of their macrobiotic practices and to have periodic medical checkups, he recommends in his book that patients gradually reduce their reliance on mainstream medicine as their health improves. He notes that patients who follow a macrobiotic diet while taking mainstream treatment might have a slower recovery than they would have with the macrobiotic approach alone. After an initial 1 to 4 months of both conventional and macrobiotic treatment, patients are advised to "reduce the frequency of outside treatment" (509). Kushi encourages patients to find physicians who are also trained in macrobiotic dietary practices and offers referrals to macrobiotic physicians through the Kushi Institute. According to information supplied to OTA by one of Kushi's associates, Kushi no longer recommends against cancer patients' combining the macrobiotic diet with mainstream treatment and encourages them to seek ongoing conventional care (652a).

In practice, there could be wide variation in patients' interpretations of Kushi's dietary guidelines, although no systematic information is available to document how patients are using macrobiotic

⁷Kushi uses the traditional Oriental practice of "physiognomy" to diagnose cancer and to monitor its progress in individual patients. Correlations are made between external appearances (e.g., facial features, posture, and skin color) and disorders of specific organ systems, and particular attention is paid to certain markings in the eyes and to skin color, since a greenish skin color on certain areas of the body is claimed to indicate the existence of a tumor (509,776).

diets in cancer treatment. In addition to consulting the Kushi Institute in Boston, local East-West Centers, or other national macrobiotics groups, a variety of approaches may be taken in following a macrobiotic regimen. For instance, patients may rely primarily on information obtained from books or magazines written by Kushi and others, with little or no guidance from physicians or macrobiotic counselors. They may receive instruction in cooking methods without more general guidance about the regimen. Patients may also be treated by physicians unaffiliated with the Kushi Institute who advocate an individualized version of the macrobiotic diet as an adjunctive approach to conventional treatment.

Macrobiotic Dietary Guidelines

The standard macrobiotic diet forms the basis for recommendations for individual patients and is adapted according to the individual's age, sex, level of activity, personal needs, and native climate. Kushi advises that such individual recommendations be made with the supervision of a qualified macrobiotics counselor and with a medical or nutritional professional although patients may devise their own dietary plans or modify the initial ones devised by a macrobiotics counselor. Kushi's 1983 book, *The Cancer Prevention Diet* describes specific dietary recommendations for most major types of cancer.

Kushi recommends a general dietary plan for cancer prevention and treatment in addition to guidelines for specific types of cancer. The standard macrobiotic diet emphasizes the intake of complex carbohydrates over simple sugars; high fiber foods over low fiber foods; unsaturated fats over saturated ones; sea salt over refined salt; natural vitamins and minerals found in food, rather than supplemental vitamins and minerals; natural, organically grown foods over chemically fertilized foods; whole, unrefined foods over processed foods, vegetable protein over animal protein, and foods cooked by gas and wood-burnin g stoves rather than by microwave ovens or electric stoves (507).

The standard macrobiotic diet is adjusted on a case-by-case basis, taking into account geographic, seasonal, and individual situations. The diet consists of the following types of food, identified as ones for regular or daily use, for occasional use, for infrequent use, and to avoid:

- . 50 to 60 percent by volume of daily food includes cooked, organically grown, whole cereal grains (e.g., brown rice, barley, millet, bulgur, oats, corn, rye, wheat, and buckwheat, with a small portion of whole wheat pasta, unyeasted whole grain breads, and other partially processed whole cereal grains) prepared in a variety of ways.
- . 5 to 10 percent soups (about 1 to 2 bowls per day), made with vegetables, seaweed, grains, or beans, seasoned with miso or tamari soy sauce.
- . 25 to 30 percent local, organically grown vegetables, which may include a small amount of raw vegetables and pickled vegetables. The diet specifies vegetables to be eaten frequently (e.g., green cabbage, kale, broccoli, cauliflower, collards, pumpkin, watercress, Chinese cabbage, bok choy, dandelion, mustard greens, daikon greens, scallion, onion, daikon, turnips, acorn squash, butternut squash, buttercup squash, burdock, and carrots, among others), ones "for occasional use" (e.g., celery, cucumber, iceberg lettuce, mushrooms, snow peas, and string beans), and ones to be avoided (e.g., potatoes, tomatoes, eggplant, peppers, asparagus, spinach, beets, zucchini, and avocado).
- 5 to 10 percent beans of various types (e.g., azuki beans, chickpeas, lentils), bean products (e.g., tofu, tempeh, and natto), and sea vegetables (e.g., wakame, hiziki, kombu, nori, arame, agar-agar, Irish moss).
- . Occasional foods 'if needed or desired' one to three times per week include a small amount of fresh whitemeat fish (e.g., flounder, haddock, herring, scrod, snapper, sole, cod, carp, halibut, or trout), locally and organically grown fruit, dried or cooked (individuals living in temperate climates are advised not to eat tropical or semitropical fruits); seeds and nuts, grain sweeteners, and vinegars.
- . Non-aromatic and non-stimulating teas, such as bancha twig tea, stem tea, roasted brown rice tea, or cereal grain coffee, or plain, non-iced water.
- Foods generally avoided on a macrobiotic diet include: meat and poultry; animal fat; eggs; dairy products; refined sugars; chocolate; molasses, honey, and refined sugar; tropical or semitropical fruits; soda; artificial drinks; aromatic or stimulating tea or coffee; all artificially colored, preserved, sprayed, or chemically treated foods; all refined and polished

grains and flours; canned, frozen, and irradiated foods; hot spices; and alcohol (500,505).

Kushi recommends that people with cancer, or with a "serious precancerous condition" emphasize certain types of food in the diet for an initial period "until vitality is restored" (509). In general, foods are identified as belonging on a scale from extremely yin (alcohol, tropical fruits, and dairy products) to the center (grains, beans, vegetables, and nuts), to extremely yang (fish, cheese, poultry, meat, and eggs). Patients with a tumor type categorized as predominantly yin would be advised to avoid, e.g., fruits, while occasional small amounts of white fish, a moderately yang food, would be encouraged. Patients with a yang cancer would be advised to avoid fish altogether, at least initially, but would be encouraged to eat small amounts of dried or cooked fruits, which are thought of as moderately yin foods. Foods categorized as extremely yin (e.g., sugar) or extremely yang (e.g., red meat) are considered inadvisable on a macrobiotic diet for patients with any type of cancer (509).

Possible Adverse Effects

The issue of possible adverse effects of the macrobiotic regimen has been a longstanding controversy in the medical and macrobiotic communities. Case reports of serious nutritional deficiencies and disorders resulting from extreme use of the Zen macrobiotic diet +7 and some types of vegetarian diets not specifically associated with macrobiotics have been published in the medical literature (267,760,797,799). The relevance of those case reports to currently recommended macrobiotic practices has been greatly reduced since the introduction of the general "standard macrobiotic diet" outlined above. Partly in response to the evidence of nutritional deficiencies, however, macrobiotic instructors reportedly adjusted some of the dietary recommendations (502,550). In current macrobiotic recommendations, for instance, small amounts of whitemeat fish and seafood are allowed a few times per week, although dairy products, eggs, poultry, and red meat are generally excluded (509). Vitamin and mineral supplements are not recommended in the macrobiotic regimen.

Advocates point out that a wide range of possible combinations of particular grains, beans, vegetables, fish, and fruit exist in individual macrobiotic diets, and that the standard macrobiotic diet is lower in fat and cholesterol and higher in fiber, complex carbohydrates, vitamins A and C, and beta carotene than a typical U.S. diet (504). It is also acknowledged, however, that macrobiotic guidelines can be interpreted too narrowly, resulting in overly restrictive food choices (276), and, in some individuals, possible deficiencies of certain nutrients (550). (These possibilities are not unique to macrobiotic diets, and apply equally to other diets.)

Although vegetarian diets similar to the macrobiotic diet have been acknowledged as potentially healthful and nutritionally adequate when appropriately planned (30,83), such diets are believed to carry a risk of nutritional deficiency under certain circumstances, notably in individuals with increased nutritional requirements (e.g., infants and children, pregnant and lactating women, and the seriously ill (95)) and in cases in which the diet is unplanned, unsupervised, or followed too restrictively (83,457). Critics of macrobiotics have suggested that seriously ill cancer patients, particularly those with cachexia,⁸ have special nutritional and caloric requirements that may not be met by a macrobiotic regimen and that may actually be exacerbated by it (30,53,95). Such effects have not been documented, however.

One possible adverse effect of an overly restrictive macrobiotic diet is a deficiency of vitamin B12, an essential nutrient normally supplied by meat, poultry, and other animal sources. Kushi maintains that his recommendation that a small amount of certain types of fish be included in the diet greatly reduces or eliminates this risk. In the dietary recommendations for certain tumor types (e.g., those he believes are caused by an excess consumption of animal products), fish is excluded, however, at least for an initial period in some cases (509). Kushi believes that vitamin B12 is supplied by other components of the macrobiotic diet, e.g., by sea vegetables and certain fermented foods (504). While the vitamin may be present in some sea vegetables (nori, seaweed, etc.) and in some fermented soya products (tempeh, tamari, rice miso, tofu, etc.) used in the diet, there is doubt about its availability in these foods in a form that the body can use (515).

⁸Cancer cachexia refers to general physical wasting and malnutrition often associated with advanced cancer.

Another possible adverse effect of a macrobiotic diet is a deficiency of vitamin D, which is essential for growth and development. Kushi acknowledges that an adequate supply of vitamin D might be a problem for some individuals, particularly young children, since most of the common sources of vitamin D-dairy products-are not included in the diet (924). A recent study of Dutch children fed with macrobiotic diets showed that growth curves for these children were below the Dutch standard after about 5 months of age and did not catch up later on in childhood (925). For children, Kushi advocates the addition of fish liver oils to the diet, other foods containing vitamins D and B 12, and exposure to sunlight. For adolescents and adults, he recommends adequate exposure to sunlight without supplemental vitamin D unless deficiencies develop (924). It is not yet known whether these measures, if followed, are successful in averting vitamin D deficiencies in individuals eating macrobiotically.

In its recent summary statement on macrobiotics, ACS noted that cancer patients following a macrobiotic regimen should take care to ensure adequate intakes of vitamins B 12 and D, but that with proper planning, the diet could provide sufficient nutrition (30). Another summary article also expressed concern about vitamins B 12 and D and about the adequacy of total calories and complete protein intake on the macrobiotic diet, and advised that cancer patients following Kushi's recommendations be medically supervised and monitored for potential nutritional deficiencies (95).

Claims of Effectiveness

In his book, *The Cancer Prevention Diet*, Kushi claims that macrobiotic diets have 'helped relieve' patients with a variety of tumor types, but notes that the "best responders" have been cancers of the breast, cervix, colon, pancreas, liver, bone, and skin (509). He believes that cancers of the lung, ovaries, and testes have responded poorly to the macrobiotic approach (509). Clinical data in support of these claims are not provided.

Kushi qualifies his claims of effectiveness by noting that certain conditions and personal attitudes must be present for a patient to recover while following a macrobiotic diet. These include: a spiritual awareness and an attitude of gratefulness for the illness and for the opportunity it affords to

correct previous errors in diet and lifestyle; an informed and careful interpretation of the macrobiotic dietary guidelines and cooking methods; a will and determination to overcome one's illness; support of family and friends; and maintenance of one's "natural healing ability" (509).

Attempts at Evaluating Macrobiotics in Cancer Treatment

OTA reviewed the available information concerning the efficacy of macrobiotic diets in cancer treatment. This information consists of retrospective case reviews and anecdotal reports, some of which come from the popular literature, and two unpublished retrospective studies. A number of individual accounts of patients who attributed their recovery from cancer to their adherence to a macrobiotic diet have been written in recent years (73,107,483,508, 686,777,782). Although these various accounts reflect the authors' beliefs that they were helped by following a macrobiotic diet, they are nevertheless inadequate to make an objective assessment of the efficacy of the diet in treating cancer.

In an unpublished study supplied to OTA by its authors, Carter and his colleagues discuss what they describe as "two retrospective studies," one of patients with primary pancreatic cancer, the other of patients with advanced prostate cancer (171). The stated purpose of the pancreatic cancer study was "to determine whether pancreatic cancer patients who adopted the macrobiotic dietary approach survived longer than those who did not."

Patients included in the pancreatic cancer study were those who had been counseled by a particular counselor about macrobiotics during the period January 1980 through June 1984, and who (or whose next-of-kin) reported having modified their diet for at least 3 months. Of 109 patients who had been counseled during the relevant period, 36 could be reached, and of those, 23 reported having modified their diets for at least 3 months. The mean survival (the average) and median survival (the point in time after diagnosis by which half the group had died) of these 23 patients was compared with the survival times of all pancreatic cancer patients diagnosed during that same period through the National Cancer Institute's Surveillance, Epidemiology, and End

Results (SEER) program.³ Statistical tests of significance were performed to determine whether the macrobiotic patients lived significantly longer.

The authors report that the mean survival for the 23 macrobiotic patients was 17.3 months, and for the SEER population, 6 months. Median survival was 13 months for the macrobiotic patients and 3 months for the SEER patients. They concluded from this comparison that the macrobiotic patients lived significantly longer.

Unfortunately, serious flaws in Carter's analysis make that conclusion unsupported and misleading. A comparison such as Carter makes between the length of survival of a selected group of patients and the length of survival among a national sample of patients would not indicate whether the selected group of patients lived longer than they would have had they not followed a macrobiotic diet. The analysis overlooks the fact that treatment with a macrobiotic diet was only one of numerous known and unknown differences between the groups that could have affected survival time. It is impossible to determine by their method whether it was, in fact, the diet, or whether other treatments or the patients' characteristics or a number of other possible factors contributed to their survival with pancreatic cancer. For this reason, comparisons between the survival times are uninformative in suggesting a possible treatment effect in the selected group of patients.

In addition, the way in which survival times are determined in Carter's study skews the results in favor of an effect of macrobiotics. According to the eligibility requirements, patients following a macrobiotic regimen had to survive for at least 3 months to be included in the study in the first place. The SEER patients, with whom the macrobiotic patients were compared, included all patients from the time they were diagnosed. For pancreatic cancer patients, this is an important difference, since the SEER statistics showed that 50 percent of this national population had died by 3 months after diagnosis.

In the second study described in Carter's paper, 11 patients with prostate cancer who followed a macrobiotic regimen along with conventional treatment were examined. No information is given about the way in which they were selected for inclusion in the study. The paper states that "length of survival

free-of-progression, overall median survival rates, and other characteristics of stage D2 prostate cancer patients, receiving conventional therapy and on a macrobiotic diet" were compared with stage D2 prostate cancer patients reported in the literature, and with "matched controls receiving conventional therapy and following a standard American diet." No other information is provided about these controls. The only comparison reported in the paper states that "the median survival of the macrobiotic group was 81 months, whereas those using the standard American diet had a median survival of 45 months.

It is impossible to interpret the results of the study, since details of the patients' selection factors are not reported in the manuscript. In general, however, conclusions in Carter's second study about survival time among prostate cancer patients following macrobiotic diets are subject to the same critical limitations as those in the study of pancreatic cancer patients described above. A randomized study, which could minimize differences between study and control populations, would be needed in the future to generate valid evidence on possible effects of macrobiotic diets on cancer patients' survival. Certain types of non-randomized studies could also be used to detect possible antitumor effects of the diets. (See ch. 12 for a discussion of such studies.)

In another unpublished manuscript (668), Newbold presents six case histories of patients with advanced cancer who adopted a macrobiotic diet in addition to using mainstream treatment. These cases are well described medically, including reference to appropriate diagnostic tests (all but one case was definitely biopsy-proven) and followup scans and tests.

At OTA's request, several physicians on the project Advisory Panel reviewed and commented on Newbold's cases. As was the case with the review of Kelley's cases, discussed earlier in this chapter, the reviews split along mainstream/unconventional lines. The three mainstream reviewers did not find these cases compelling, however they did not find them lacking in technical detail, as they did the Kelley cases. One reviewer suggested the need for a randomized trial of the diet before any conclusions could be drawn. He also commented that "restora-

³The SEER program covers about 10 percent of the U.S. population in various cities and States, and attempts to gather reports of all new cases of cancer diagnosed in those areas.

tion of harmony and balance to the lives of people with terminal illnesses and those without terminal illnesses is a reasonable goal," but he did not necessarily think that a diet could achieve this. The reasons given for skepticism about the cases were that the effects of mainstream treatment could not be ruled out as explanations for the observed effects; in one case, that there had been no scan to verify continued presence of disease before the patient adopted the macrobiotic diet; and in another case (an astrocytoma), the mainstream reviewers believed that the scans on which the reported regression rested could not have provided definitive evidence.

The two unconventional physicians were more positive about these cases. One concluded that five of the six cases (all except the one without biopsy-proven diagnosis) showed positive effects of the

macrobiotic diet. The other physician found two cases that seemed "legitimate," two "highly suggestive," one "suggestive," and one not convincing (a different one from the other physician).

If cases such as Newbold's were presented in the medical literature, it might help stimulate interest among clinical investigators in conducting controlled, prospective trials of macrobiotic regimens, which could provide valid data on effectiveness. It has also been suggested that improvements in recordkeeping and followup-e.g., monitoring compliance with dietary recommendations and health status among patients-could facilitate the funding and conduct of randomized clinical trials needed to study the efficacy of macrobiotic diets in cancer treatment (503).