

A Critique of the Kelley Nutritional-Metabolic Cancer Program

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Abstract

Introduction: Dr. Kelley developed the Kelley Nutritional-Metabolic Cancer Program in the 1960s which involves 4 major components: pancreatic enzymes, nutrition, detoxification and spirituality. The Kelley Program defines cancer according to Dr. Beard's theory that states that cancer is a normal, necessary part of life.

Components of the Kelley Program: The pancreatic enzymes are the anti-tumour element of the program. Studies conducted in animals demonstrated that enzyme treatment has an anti-tumour effect. Several case reports documented tumour regression and even remission in terminal cancer patients treated with pancreatic enzymes. Enzyme treatment in conjunction with conventional therapy has been shown to be beneficial. The diet and supplements are designed to provide a supportive role for the patient's body. One study demonstrated that the 5-year survival rates of those patients who employed the nutritional therapy and detoxification were considerably higher than those reported elsewhere. The patients perform detoxification with coffee enemas in order to eliminate toxic materials from the body and to alleviate pain. The Kelley Program prescribes having faith and encourages patients to pray. Many researchers have reported that religiosity and spirituality are associated with enhanced health and well-being as well as decreased mortality.

Conclusion: Many studies have shown that each component of the Kelley program has some effectiveness at treating cancer. There are also studies that support Beard's original theory of cancer. Therefore, further investigation of the Kelley program is definitely necessary to evaluate its effectiveness as a whole, which includes all 4 components, in order to properly prove or disprove this cancer treatment.

Introduction

Dr. William Donald Kelley, an orthodontist from Washington State, developed the Kelley Nutritional-Metabolic Cancer Program in the 1960s. In the 1960s Dr. Kelley was diagnosed with pancreatic cancer, he developed this

program, cured himself and is still alive today, forty years later. He then taught other cancer patients his program, which has had phenomenal results leading to complete cures in many cancer patients. In 1970, Dr. Kelley was convicted of practicing medicine without a license and in 1976 a court suspended his dental license for five years. Despite his hardships with conventional medicine, he continues to help cancer patients by teaching them his program.

The Kelley Program is a collaboration of various natural cancer treatments into one. It includes 4 major components: pancreatic enzymes, nutritional therapy, detoxification and spirituality. The program prescribes that all 4 components be employed by the client in order to achieve maximum benefit.

Cancer is a highly prevalent disease. In the United States each year over 1 million individuals learn for the first time that they have some type of cancer (Cotran *et al*, 1999). People living in the United States have about a one in five chance of dying of cancer. There were about 564,000 deaths from cancer in 1998 representing 23% of all mortality. Only cardiovascular diseases cause more deaths than cancer.

Cancer as Defined by Allopathic Medicine

In allopathic medicine, cancer is defined as a fast growing malignant tumour, which, if allowed to grow unchecked, will cause death. Cancer is a proliferation of cells, whereby there is a loss of normal control resulting in unregulated growth, lack of differentiation, local tissue invasion and metastasis. Cancer can develop in any tissue of any organ at any age. Generation time is the time it takes for cells to enter the cell cycle and give rise to two daughter cells. Malignant cells usually have a shorter cycle than non-malignant cells. As the tumour grows, nutrients are provided by direct diffusion from the circulation. Metastases develop when tumour cells adhere to vascular endothelium and penetrate into surrounding tissues, surviving and spawning independent tumours at distant sites (Beers and Berkow, 1999).

The allopathic medicine theory on cancer believes that mutations in genes are partially responsible for the growth or reproduction of malignant cells. These mutations alter the quantity or behaviour of the proteins encoded by growth-regulating genes and alter cell division (Beers and Berkow, 1999).

In most neoplasms (any abnormal growth of new tissue) the parenchymal cells bear a close resemblance to each other, as though they were all derived from a single cell. Infrequently, divergent differentiation of a single line of parenchymal cells creates what are called mixed tumours. The great majority of neoplasms, even mixed tumours, are composed of cells representative of a single germ layer (Cotran *et al*, 1999).

Cancer as Defined by the Kelley Program

The Kelley Program defines cancer according to Dr. Beard's cancer theory. Dr. John Beard (1858-1924), a Scottish embryologist, theorized that cancer is identical to the trophoblast. Cancer is an irresponsible trophoblast (Beard, 1905). In this respect cancer is a normal, necessary part of life (Beard, 1911).

In the first 5 days after fertilization in the formation of a human embryo, the growing mass of cells divides into two kinds of cells, an inner cell mass (embryoblasts), which becomes the embryo, the sexual generation, and an outer layer of cells called the trophoblast, the asexual generation, which later becomes the placenta. The trophoblast forms the primitive germ cell, which grows, doubling many times. After the cell mass attaches to the wall of the uterus, the trophoblasts invade the lining of the uterus, growing quickly and invasively. The trophoblast cells invade and digest a hole in the wall of the uterus and form a multinucleated mass with no cell boundaries. As the small blood vessels are invaded and digested by the invading trophoblasts, pools of blood form in the tissue, which nourishes the growing mass (Beard, 1911).

While the trophoblast cells are infiltrating the maternal tissue, the inner cell mass becomes three germ cell types; the ectoderm, the endoderm and the

mesoderm, which organize themselves to become the vast majority of cells of the body. The mesodermal cells are pluripotent, with a vast ability to become many different kinds of cells. Some of these cells remain "sleeping," dispersed throughout the tissues of the body (Kelley, 2000).

When these "sleeping" pluripotent cells are activated through genetic, environmental or nutritional factors, a tumour mass similar to the invasive trophoblast cell mass can begin to form (Kelley, 2000). The trophoblast cells (cancer cells) now trapped outside of the uterus, grow rapidly, trying to form a placenta (a malignant mass) (Beard, 1911). The trophoblast cells grow rapidly and uncontrollably, having the ability to invade (metastasize) the wall of the mother's uterus to form the cancer mass (placenta). This cancer mass first opens a blood supply to the embryo for nourishment and second, firmly attaches (metastasizes) the placenta (with its blood supply to the walls of the uterus) to protect the embryo from falling out of the uterus. Malignancy, therefore, is not normal tissue that has gone into wild proliferation, but rather normal trophoblastic tissue that is growing in the wrong place at the wrong time (Kelley, 2000).

Support for Beard's Cancer Theory

One critique of the Kelley program claims that Dr. Beard's theory on cancer is a turn-of-the-century (1900) idea that conflicts with established facts about cancer causation and etiology confirmed by research done over the past 50 years (Green, 1998). This is not the case, as there is recent scientific support for Dr. Beard's theory.

If, according to Beard, all human cancer is trophoblastic in origin, one might expect them to express human chorionic gonadotropin (hCG); hCG is the standard hormonal marker of pregnancy and the standard hormonal marker of germ cell tumours. In 1994, scientists showed that cancer cells express hCG in all its forms (Krichevsky *et al.*, 1994). Researchers showed that the "synthetic hCG...is a common biochemical denominator in cancer" (Acevedo *et al.*, 1995). It was demonstrated that there was the presence of hCG, its subunits, and/or fragments, in 85 different cancer cell lines. Acevedo consistently found hCG in human malignant tumour tissues. He concluded that hCG, the hormone of pregnancy and development that also has chemical and physiological properties of growth factors, is a common phenotypic characteristic of cancer. Acevedo stated that after a century,

"Beard has been proven to be conceptually correct" (Acevedo *et al.*, 1995).

Regelson (1995) wrote in an editorial that hCG defines the metastatic aggressiveness of the tumours in which it is found. Neither non-embryonic cells nor benign tumour cells express hCG, but hCG-beta is a defining phenotype statement of malignant transformation.

An oncologist wrote that pregnancy and cancer are the only two biologic conditions in which antigenic tissue is tolerated by a seemingly intact immune system. The trophoblastic tissue has all the characteristics of true cancer; it is deeply invasive, it is highly anaplastic in morphology, it has a high mitotic index, and it produces oncofetal antigens. In every respect, it behaves as a true cancer (Lentz, 1990).

In 1902, Beard described the role of "totipotent germ cells" in the development of cancer. In embryology, the word "totipotent" means a cell is capable of giving rise to all types of differentiated cells found in that organism. "Totipotent germ cells" are analogous to human embryonic stem cells (ESC), which were not isolated until 1998. Human ESCs are described as totipotent and in fact, they release hCG (Thomson *et al.*, 1998).

Allopathic medicine believes that cancer is caused by such things as viruses, X-rays, cigarette smoking chemicals, sunlight, and trauma (Cotran *et al.*, 1999). A number of cancer researchers believe that these factors, rather than causing cancer, are indirect stimulators of a normal trophoblast-like pluripotent cell (Kelley, 2000).

Components of the Kelley Program

1) Pancreatic Enzyme Treatment

The Kelley program prescribes that each patient take large amounts of pancreatic enzymes daily, taken with and away from meals and spread evenly throughout the day. The pancreatic enzymes are the anti-cancer element of the program. The idea of treating cancer with pancreatic enzymes was introduced by Dr. Beard.

In 1906, Dr. John Beard claimed that pancreatic proteolytic enzymes represent the body's main defence against cancer and would be useful as a cancer treatment. Continuing on Beard's trophoblast theory of cancer, he explained that what normally stops the trophoblast from being invasive is the presence of pancreatic enzymes of both the embryo and the mother. Pancreas functions throughout fetal life in a mammal though

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it has nothing to digest except the trophoblast. Nature itself has possibly provided a remedy for cancer through digestion of the trophoblast in the secretion of that important digestive gland, the pancreas (Beard, 1905).

These pancreatic enzymes travel to the tumour and only digest the cancer, without harming the person's body in which the cancer is growing. Beard explained that the secret to how the enzymes can tell the difference between self (healthy cells) and non-self (tumour cells) lies in the difference in left and right handed molecule configuration. It is known that trypsin acts on cooked left-handed proteins and living (non-cooked) right handed proteins. Proteins that we eat are broken down in the small intestine by trypsin that is released by the pancreas. Trypsin does not act on the organs of the human body because these are living, left-handed proteins. However, trypsin is very effective at breaking down living, right-handed proteins (Beard, 1911). The cancerous tumour is made up of living, right-handed proteins. The trypsin travels via the bloodstream to the tumour, and its action there is on the protein mass that makes up the tumour (Kelley, 2000). The cancerous tumour makes an enzyme that digests organs and tissues of the human body as its food. This tumour-made enzyme is called malignin, which is the mirror image of trypsin. Trypsin will only digest the protein of the tumour (Beard, 1911), the enzymes can then safely travel throughout the body (Kelley, 2000).

Beard believed that the enzymes had to be injected to prevent destruction by hydrochloric acid in the stomach (Beard, 1911). However, recent evidence demonstrates that orally ingested pancreatic proteolytic enzymes are acid stable (Moskvichyov, Komarov and Ivanova, 1986), pass intact into the small intestine and are absorbed through the intestinal mucosa into the bloodstream as part of an enteropancreatic recycling process (Gotze and Rothman, 1975, Liebow and Rothman, 1975).

Studies on Enzyme Treatment Effects

There are some studies that have examined the effects of enzyme treatment on cancer, as researchers understand it today. These studies demonstrate that enzyme treatment has an effect on cancer markers, antibody production and the immune system.

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The adhesion molecule CD44 and variants of the molecule on tumour cells are involved in the process of tumour progression and metastasis (Gebauer *et al*, 1997). One study investigated the effects of the proteases (bromelain, papain, trypsin, and chymotrypsin) on the density of CD44 molecules present on human leukemia Molt 4/8 cells (Harrach, 1994). The protease bromelain was found to be most active in reducing CD44 receptor density. These findings implicate the possibility of the anti-metastatic activity of orally administered bromelain with respect to CD44. Another study investigated the ability of several proteolytic enzymes to modulate the CD44 molecule on different tumour cell lines (Gebauer *et al*, 1997). They found that proteolytic enzymes like bromelain, papain, and chymotrypsin were able to modulate CD44 on cells of leukemic origin, as well as on melanoma and mammary carcinoma cell lines. These results imply that treatment with proteolytic enzymes might be useful in reducing the metastatic behaviour of malignant cells. Wald *et al* (2001) also found a correlation with a decreased expression of CD44 and CD54 molecules in tumours exposed to proteolytic enzymes *in vivo*.

In one study, the experimental group of Swiss mice had a 260% increase in antibody production with the addition of 2% pancreatin to the diet, which indicated an immune enhancement effect

for orally ingested pancreatin (King, 1965b). Another study on humans demonstrated that a proteolytic agent increased the T-cell counts significantly and this was most marked in older age groups and the patients with malignant disease (Holland *et al*, 1975), indicating that proteolytic enzymes may have an immune enhancing effect.

Animal Studies on Enzyme Treatment

Beard (1906) conducted research to determine the action of trypsin upon the living cells of Jensen's mouse-tumour. After 10 days, one trypsin mouse was found dead and post-mortem examination revealed no cause of death. The lab attendant thought the mouse got caught between the cage and the food vessel and caused its own death. The microscopic examination of the trypsin mouse demonstrated that every single cell of the tumour was in degeneration. After 22 days of treatment one of the control mice died of its tumour and the second trypsin mouse was killed for microscopic exam. Upon examination, the skin around the trypsin mouse's tumour was in necrosis. The tumour in the control mouse was as large as the terminal phalanx of a man's thumb, while in the second trypsin mouse the tumour was the size of a lentil and was in advanced degeneration (Beard, 1906).

Recent studies on animals with tumours treated with enzymes reveal similar results to Beard's studies, thus supporting Beard's theory on cancer.

In 1965, a researcher reported complete prevention of tumours in a group of C3H mice carrying Bittner's milk factor virus that received oral pancreatin compared with 100% tumour occurrence in the control group (King, 1965a).

In a study using C₅₇B₁₆ mice with the Lewis lung carcinoma, in the control group, which received no enzyme treatment, 90% of animals died of the metastatic spread of cancer by day 18. The treated groups A (received the enzymes from the time of primary tumour extirpation), B (received the enzymes from 6 days before primary tumour extirpation) and C (received the enzymes from 24 hours after intracutaneous tumour inoculation) showed survival rate 60%, 90% and 100% of animals, respectively, by 100 days (Wald *et al*, 1998a).

The influence of proteolytic enzyme mixture was tested on spontaneous lymphoblastic leukemia development in an *in vivo* experiment in rat species SD/Ipcv. In the group treated by a mixture of trypsin, chymotrypsin and papain a significantly lower rate of blast cells in the peripheral blood during disease development was noticed. The average survival time in the experimental group was 150 days (50% surviving until the end of the experiment, 366 days), while the control group was 43 days (none surviving until the end of the experiment) following the appearance of the first blast cells. The proteolytic enzyme mixture has also had a positive influence on the stable weight gain in animals in contrast to the weight loss of the control group in the terminal stage of the disease (Wald *et al*, 1998b).

This study investigated the effects of a mixture of proteolytic enzymes on C₅₇B₁₆ mice with syngeneic melanoma B16. The results show that administration of proteolytic enzymes to mice inhibited the growth of primary tumours, tumour recurrences were less numerous and metastasis was considerably curtailed both in the vicinity of the primary tumour and at distant locales. The results demonstrate that the enzyme mixture is capable of inhibiting B16 melanoma tumour growth and metastasis in mice (Wald *et al*, 2001).

This study investigated the influence of protease mixture in mice transplanted with human pancreatic carcinoma. The test group was administered a trypsin, chymotrypsin and papain solution, while the control group was administered saline. In the study, it was found that the protease mixture retards growth of human pancreatic adenocarcinoma in mice. These results confirm growth inhibition of primary tumour by trypsin, chymotrypsin and papain solution (Wald *et al*, 1999).

The thiolprotease bromelain, isolated from pineapple stem, was suggested for use in adjuvant tumour therapy. *In vitro* treatment of the melanoma cells with bromelain F9 and papain injected into mice prevented lung colonization. The proteases inhibited growth of the melanoma cells in a dose dependent manner. The proteases reduced the invasive capacity of the melanoma cells maximally by about 30%. Crude bromelain was most active in abolishing the CD44 re-expression after protease treatment (Grabowska *et al*, 1997).

Studies conducted on animals treated with enzymes revealed surprising results. The preceding studies demonstrated that enzyme treatment has an anti-tumour effect. It is important to



"Tell me doctor, doesn't the hospital know you're guaranteed privacy under the constitution?"

note that even though studies on animals are able to exemplify the potential benefits for humans, the results are never completely transferable to humans.

Case studies on Enzyme Treatment

Several case reports in the medical literature documented tumour regression and even remission in terminal cancer patients treated with pancreatic enzymes.

A 23-year-old woman was diagnosed with multiple fibrosarcoma of the tongue, and after multiple surgeries and reoccurrences of the tumours the case was considered practically a hopeless one. As a last resort the doctor decided to administer trypsin and pancreatic extract based on work he had read by Dr. Beard. Soon after the administration of trypsin and the pancreatic extract the tumours ceased to increase in size and after the doses increased, the tumours slowly began to decrease in size. The tumours were barely perceptible to the touch, the patient was able to speak distinctly for the first time, the patient's general health improved greatly, and she gained 11 pounds in weight. At this stage, at the patient's request, the treatments were discontinued. Upon examination three months later the growths had increased in size, the patient was depressed mentally and refused any further treatment (Wiggin, 1906).

A 56-year-old man was diagnosed with malignant disease involving the left tonsil, base of tongue and epiglottis, which was deemed inoperable. The patient was failing rapidly and nothing better could be suggested, so they decided to try trypsin injections. Upon starting the enzyme treatment, the submaxillary gland rapidly decreased in size. The patient was swallowing more comfortably, feeling much better and had gained 3 pounds. The patient says that he feels well and believes that he is cured. Unfortunately, in this case, the initial diagnosis was clinical only (Campbell, 1907).

A 65-year-old man had a rapidly growing abdominal tumour. He was told that nothing further could be done for him surgically. Cutfield treated this patient with injections of trypsin and amylopsin as recommended by Dr. Beard. The patient began to improve steadily. The vomiting, nausea and flatulence disappeared, his appetite improved, gradually the pain lessened, the swelling steadily diminished and his weight regularly increased. The only symptom left was some abdominal discomfort and occasional pain. He eats and sleeps well and attends to his business regularly and his weight is only a few pounds less than

it had been for many years. Cutfield does not claim that this patient was cured but does state that there is no doubt of the immense improvements, especially considering how rapidly the patient was deteriorating before the treatment commenced and how promptly and steadily the improvement took place after the treatment began (Cutfield, 1907). Cutfield wrote that, it is extremely difficult to believe that the trypsin was not the cause of that improvement.

Goeth wrote about 4 cases. In case 1 the patient was a man with a large vascular sarcoma on the side of the neck. The patient left Goeth's care in order to be operated on by another physician and died during surgery. In case 2 the patient was an elderly woman with cancer in both breasts and secondary cancers in glands on one side of her neck. She showed no improvement under the trypsin treatment and the treatment was discontinued for some time before her death. In case 3 the patient was a woman a little over 70 years old with cancer in the face, which had destroyed one eye. At first the trypsin treatment increased the lesion in her face. After a month, Goeth started alternating injections of amylase and trypsin and the patient

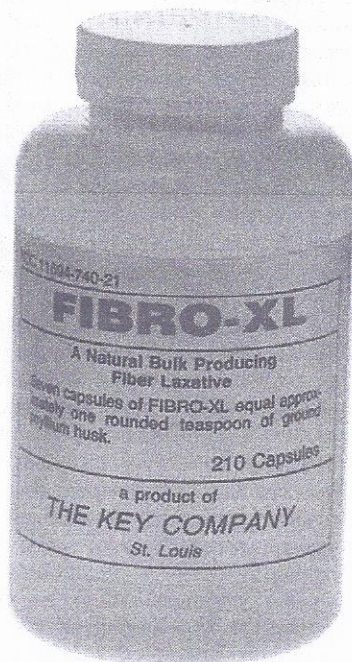
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began to improve at once, the lesion in the face began to heal rapidly until the eye cavity and the rest of the wound had a healthy skin over it. Also, her general health improved markedly and now she is able to do light housework. In case 4 the patient was a woman with cancer in one breast with secondary nodules in both axillae and around the diseased breast. At the start of the trypsin treatment every gland infected with cancer became inflamed and painful and the tumour mass was sloughing away rapidly. Goeth changed to alternating injections of amylase and trypsin and the pain was greatly reduced and her general health is improving daily. The microscopic findings revealed that the cancer cells were broken up so that it was difficult to find an entire cancer cell and the stroma of connective tissue was intact and uninjured. Therefore, Goeth concluded that the pancreatic treatment attacks the cancer cells only (Goeth, 1907).

Though case studies cannot, by themselves, prove that a method of treatment works, it does help to support



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the enzyme treatment for cancer, especially since different physicians observed results in cases that were treated in isolated situations.

Unfortunately, Beard's theory became largely forgotten in the medical community and further clinical studies were not conducted. This was largely due to the fact that other physicians were unable to consistently reproduce Beard's work. Though, Beard believed these failures were due to commercially available enzymes being variable in quality and inadequate doses being administered to patients. Due to the lack of reproducible results, interest in his ideas virtually disappeared.

Enzyme Treatment as Complementary Therapy

Recent articles have examined the effects of using enzyme treatment with the conventional cancer treatments of chemotherapy and radiation.

In this randomized prospective clinical trial, oral enzyme therapy was given additionally with radiation to abdominal cancer patients and compared with radiation only. The coupled oral enzyme therapy improved the tolerance of the radiation significantly. The enzyme-treated patients had less deterioration of the general condition and skin symptoms, fewer patients discontinued radiation and it reduced the number of drugs needed for the treatment of radiation adverse effects (Stauder *et al*, 1991).

The remission time of multiple myeloma patients after chemotherapy and after enzyme-chemotherapy were compared retrospectively. Enzyme-chemotherapy prolongs remission times in stage II multiple myeloma patients and reduces the concentration of progression markers, soluble TNF-receptors and $\beta 2$ -microglobulin (Desser *et al*, 1997).

Existing data was assessed on patients with multiple myeloma (stages I-III) treated with chemotherapy alone vs. chemotherapy and additional treatment with oral enzymes (OE). In the OE group all disease stages had longer median survival times. Response rates are higher and duration of remission is longer in the OE group. OE decreased the estimated mortality risk by 50% to 60% (Sakalová *et al*, 1998).

The results of these studies indicate the beneficial effects of using enzyme treatment in conjunction with

conventional therapy. This also exemplifies the need for further studies on treating patients with enzyme treatment only, in order to discover if the noted improvements were due to the enzyme treatment alone or enzyme treatment in combination with chemotherapy or radiation.

Nutritional Therapy

The Kelley program prescribes a diet that is tailored to each individual. In general the diet emphasizes fresh raw fruits, raw vegetables, and freshly made vegetable juices daily. The diet encourages plant-based protein sources such as cereals, nuts, seeds and whole-grain products. The diet allows one or two eggs daily, but forbids animal proteins, specifically red meats and poultry, processed foods, pesticide residues, milk, soy beans, peanuts, food concentrates, white sugar and white rice. The diet is designed to provide a concentrated supply of nutrients in their natural form with all the associated co-factors. The supplement regimen includes vitamins, minerals and trace elements. Organ, such as thymus and liver, derived from beef or lamb are also prescribed to provide a concentrated source of nutrients. The diet and supplements are designed to provide a supportive role for the patient's body.

In the 1930s, Dr. Max Gerson (1881-1959) designed a cancer treatment that includes nutritional therapy and detoxification using coffee enemas. The Kelley Program and the Gerson Program are very similar with respect to the nutritional therapy and detoxification, the one main exception is that the Kelley program includes the addition of pancreatic enzymes to the regimen. Therefore, examining the Gerson program provides a way to isolate and analyze the nutritional therapy and detoxification components of the Kelley Program.

The Gerson diet requires that patients eat mainly a raw vegetarian diet, drink freshly prepared vegetable and fruit juices and do coffee enemas. Other key elements of the diet include salt restriction, potassium supplementation, extreme fat restriction, temporary protein restriction, iodine and thyroid administration (Lerner, 1994). Gerson restricted calories while simultaneously increasing metabolism in an effort to emulate the anti-tumour effect of calorie restriction. Enhanced calorie utilization rates can alter tumour growth, whether metabolism is accelerated by iodine medication or exercise (Moreschi, 1909, Rous, 1914). Gerson's regimen also

included taking coffee enemas for detoxification. Gerson felt that in order for the body to heal itself, the body needs to be detoxified (Lerner, 1994). Enemas were taken as needed for their observed ability to alleviate pain and to improve nutritional conditions.

Studies on Gerson's Therapy

In a retrospective review of the 5 year survival rates of melanoma patients treated by Gerson's diet therapy, it was found that of the patients with stages I and II (localized) melanoma, 100% were alive at 5 years; of the patients with stage IIIA (regionally metastasized) melanoma, 82% were alive at 5 years; of the patients with combined stage IIIA and IIIB (regionally metastasized) melanoma, 70% were alive at 5 years and patients with stage IVA (distant lymph, skin, and subcutaneous tissue metastases), 39% were alive at 5 years (Hildenbrand *et al*, 1995a). The 5-year survival rates were considerably higher than those reported elsewhere.

One retrospective study found that survival rates were more than double for self-selected melanoma patients who employed surgery along with Gerson's diet therapy when compared with those who relied only on non-surgical treatment (Hildenbrand *et al*, 1995a). A critique of this study pointed out that the control group were matched patients who refused the therapy, which was basically a flawed control group (Lerner, 1994).

In another study, a research team visited Gerson's Clinic in 1989 and examined cases selected by the Gerson Institute (Weitzman, 1998). The researchers found little objective evidence of an anti-tumour effect. However, in a few patients, definite tumour regression was seen. There was subjective benefit to the patients and their families. The patients felt that they had control over their health, had high ratings for mood and confidence, with low pain scores and analgesic requirements, despite extensive metastatic disease.

Lechner and Kronberger (1990) have observed improved tolerance of aggressive conventional treatments in patients who employed Gerson's therapy at the same time. There is evidence that psychological well-being is associated with a better response to conventional therapy and the nature of the Gerson and other dietary therapies "require an active contribution by patient and family to his state of health and meets a need not satisfied by conventional therapy." (Reed *et al*, 1990) Pain control appeared to be better with Gerson's patients (Lerner, 1994). Gerson's patients lived longer,

were healthier, and had better responses to conventional therapies with fewer side effects, less pain and a better quality of life. It must be remembered, however, that the psychological characteristics of patients who will undertake and remain on this type of therapy may play a part in these results (Weitzman, 1998).

The evidence for the efficacy of the Gerson diet remains questionable and a review by an expert panel found the Gerson diet to be "ineffective in curing cancer" (American Cancer Society, 1990). It appears that the Gerson diet, by itself, does not result in cure for any type of cancer, but that the diet may act as an adjunct to conventional cancer treatment, allowing for greater well-being and quality of life (Weitzman, 1998).

In terms of the Kelley Program, it must be emphasized that the nutritional component of this regimen plays a supportive role for the body and is not believed to be the anti-tumour component of the program. Therefore, the studies that indicate that the Gerson diet alone does not cure cancer do not act to disprove the Kelley program.

Detoxification

The Kelley Program prescribes that patients perform detoxification with coffee enemas at least once a day. Coffee enemas have been discussed in the orthodox medical literature for the better part of this century (Gonzalez and Isaacs, 1999). Coffee enemas were prescribed for a variety of conditions, which proved to be effective after failure to improve following the usual forms of medical treatment (Snyder, 1939).

The reasoning behind conducting detoxification techniques is because the enzymes, in sufficient quantities, can begin to break down the cancerous tumour, and during this process some intermediate proteins are produced and abnormal molecules of the tumour waste are released into the blood, which can be quite toxic to the human body (Beard, 1911). These toxic substances must be eliminated and are done so by laxatives such as epsom salts and coffee enemas (Kelley, 2000). These toxic substances are filtered and detoxified by the liver. They are excreted through the bile ducts from the liver to the small intestine. The walls of the bile ducts are composed of smooth muscle that the caffeine in coffee causes to relax, causing the duct to open wide, allowing tumour toxins to pass into the small bowel. Research shows that the administration of coffee enemas does appear to cause biliary-duct dilatation and increased bile excretion (Lerner, 1994). The enemas act to lavage and thoroughly cleanse the walls, remove

abnormal mucus and also empty the bowel. The tone of the colonic muscles is improved and the blood supply augmented (Friedenwald and Morrison, 1935). By cleaning out the colon, the system is afforded relief from toxic products and an unnecessary burden is removed from metabolic processes (Marshall and Thompson, 1932). The coffee enemas have also been found by many patients to alleviate pain (Kelley, 2000).

Spirituality

The Kelley Program prescribes having a spiritual attitude and having faith. Mind/Body medicine attempts to use thought patterns to influence both the perceptions of health and the course of illness (Benson and Dusek, 1999). Many mind/body techniques, including progressive relaxation, autogenic training, Zen, yoga, meditation and some forms of prayer often elicit a physiological response termed the "relaxation response" (Benson *et al.*, 1974a). The relaxation response is characterized by decreased metabolism, heart and respiratory rate, responsivity to plasma norepinephrine, lowering of systolic and diastolic blood pressure and slowing of

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alpha, theta and delta brain waves (Benson *et al.* 1974b, Hoffman *et al.*, 1982, Morrell and Hollandsworth, 1986, Wallace *et al.*, 1971). Spiritual healing is one mind/body approach in widespread use by certain religious groups (Galanter 1997, Levin *et al.*, 1997, Roush, 1997) and may elicit the relaxation response through prayer (Benson, 1996).

Many have reported that religiosity and spirituality are associated with enhanced health and well-being (Ellison, 1991; Ellison and Levin, 1998; Koenig *et al.*, 1988, 1998; Idler and Kasi, 1997) as well as decreased mortality (Bryant and Rakowski, 1992; Goldman *et al.*, 1995; Oman and Reed, 1998; Schoenbach *et al.*, 1986; Seeman *et al.*, 1987). Others (Sloan *et al.*, 1999) however, assert these associations are not conclusive.

Gonzalez' Research

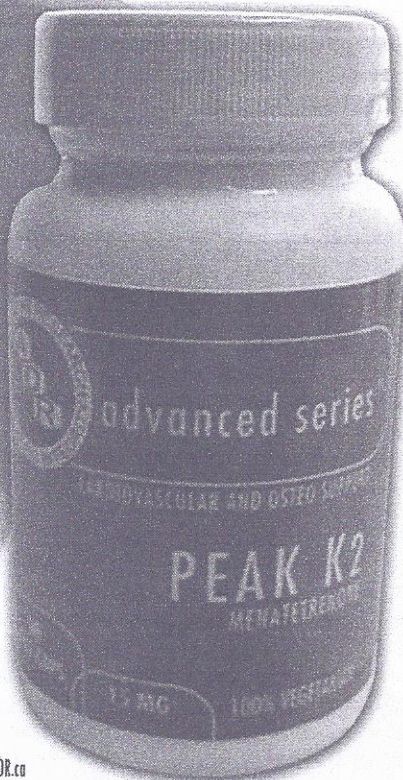
In 1981, Dr. Nicholas Gonzalez began researching the use of pancreatic proteolytic enzyme therapy as a treatment for cancer (Gonzalez and Isaacs, 1999). He conducted an intensive

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▶ retrospective review of 1306 patients who had been treated over a 20-year period by Dr. Kelley who used enzyme therapy, diet and nutritional support. This study included a review of pancreatic cancer patients, some of whom survived in excess of 5 years (unpublished).

Gonzalez concluded, "A study such as mine cannot, of course, prove conclusively that Kelley's treatment cures cancer, since the patients who were evaluated were not treated under controlled conditions. Nevertheless, significant number of patients with appropriate diagnosed terminal cancer enjoyed impressive regressions of the disease while on the Kelley regimen. This finding alone warrants a full, fair and unbiased investigation of Kelley's methods."

In June 1993, Gonzalez presented a selection of cases from his own practice at the National Cancer Institute (NCI) as part of an NCI effort to evaluate non-conventional cancer therapies. He was encouraged by the NCI to do further studies. In 1999, he published a 2 year, unblinded, 1 treatment arm, 10 patient, pilot prospective case study that was used to assess survival in patients suffering inoperable stage II-IV pancreatic adenocarcinoma treated with large doses of orally ingested pancreatic enzymes, nutritional supplements, detoxification procedures and an organic diet. After 1 year 81% had survived, 45% survived 2 years, and 36% survived for 3 years (Gonzalez and Isaacs, 1999). These results are far above the 25% survival at one year and 10% survival at two years for all stages of pancreatic adenocarcinoma reported in the National Cancer Data Base from 1995 (Niederhuber, Brennan and Menck, 1995). Following this publication, Gonzalez was given a grant of \$1.4 million from the National Cancer Institute for a larger prospectively randomized trial.

It must be noted that the Gonzalez program is very similar to the Kelley Program, but not identical. The Gonzalez program has dispensed with the spirituality component. The Gonzalez program also allows animal proteins in the initial stages of the program, whereas the Kelley program absolutely forbids animal proteins in the initial stages of the program. This is because Kelley believed that one of the contributing causes of the tumours are due to the decreased efficiency of the body to break down proteins. Therefore, the Kelley program prescribes that all allowed

proteins (grains, nuts, glandulars, eggs) be eaten before 1pm in order to give the body ample time to break down these proteins. Studies conducted on the Gonzalez program will give the scientific community insight into the efficacy of the Kelley program.

Discussion

Upon hearing about this program, some wonder if there exists an element of self-selection within the patient pool or if the patients are affected by individual motivation. It is important to understand that the Kelley program is not an easy program to follow. The Kelley program is a very comprehensive program and involves total commitment, active involvement by the patient and family, significant lifestyle changes, dedication and hard work. I would venture to say that there is definitely an element of self-selection and there is no doubt that this program involves individual motivation by the cancer patient. People would not commit to this program if they did not believe that it would work and if they did not have the drive to survive. The success of this program can be partly attributed to positive expectations, but it is probably not the only reason that this program works.

Some critics say that there is no proof that this program is any better than a placebo effect. Within the medical community the term 'placebo effect' has a very negative connotation. With the Kelley program the client has complete control over their health. The Kelley program is a self-empowerment program. It involves being taught the method to heal yourself. The program works to activate the healing powers within each client. Therefore, this program is not eliciting the placebo effect; in contrary, it is empowering the patient and giving them control over their healing.

The large number of required supplements vitamin/mineral may lead to toxicity and nutrient/nutrient interactions. Colonics and diuretics may cause an imbalance of the various nutrients in the body. Not enough information exists to prove that the cancer treatment program is safe or helpful (Biological Based Systems, 2002). Though this is a worthy caution, the last statement of this critique must be emphasized, because not enough information does exist to prove or disprove the program, but in most cases supplements of vitamins and minerals that act to support the body are more beneficial in comparison to numerous pharmaceutical drugs prescribed by allopathic medicine.

A critique of the Kelley Program states that "a review of all the material published by Kelley and Gonzalez shows neither to have had training in oncology or board certification in any medical specialty or to have performed or published experimental work verifying their conclusions about the cause of cancer or about their treatment" (Green, 1998). This statement has no bearing on the effectiveness of the program. This program is not designed to diagnose but rather to treat the cancer once it has been diagnosed. Patients that enter the program have been diagnosed by conventional physicians, who, in many cases, have told the patient that the cancer is untreatable by conventional approaches. Dr. Kelley does not advocate dismissing medical doctors, but rather encourages the patients to maintain regular visits, to trust and to work with their medical doctors. Additionally, Gonzalez is presently conducting a scientific study to verify his conclusions.

Green (1998) states in rebuttal to the Kelley program that, different cancers do not have identical causes, growth characteristics or response to treatment. Conventional medicine has yet to firmly establish any cause for cancer. According to conventional medicine, they do not know nor fully understand the cause of cancer therefore they cannot prove that different cancers do not have identical cause and growth characteristics. What they do understand of cancer still remains consistent with Beard's theory of cancer. Robbin's pathology textbook states that in most neoplasms (any abnormal growth of new tissue) the parenchymal cells bear a close resemblance to each other, as though they were all derived from a single cell (Cotran *et al*, 1999). This statement regarding cancer actually helps to confirm Beard's theory. The statement that different cancers have different response to treatment is obviously true and cannot be argued as every person is an individual and responds uniquely in different situations to varying stimuli.

Critics have mentioned that the Kelley program has no controlled studies. First, it must be mentioned that there are no controlled studies for human chemotherapy, radiation or surgery for cancer patients, as this is seen as unethical. Therefore the 'standard of care' used in allopathic medicine has yet to be scientifically proven. The study that Gonzalez is presently conducting on patients with pancreatic carcinoma does have a control group that receives conventional medicine treatment, which is 'state-of-the-art' chemotherapy. Having this control group is good for science but

not necessarily good for human life. Chemotherapy for pancreatic carcinoma has been shown to have no convincing improvement in median survival (Ahlgren, 1996). Therefore, being in the control group is equivalent to a death sentence. This is about human life and randomly assigning a person to this type of control group for the sake of "good science" is completely unethical and devalues human life.

The author believes that one can prove that this treatment is effective, meaning it has a strong claim for a causal relationship between the Kelly treatment and the various cure indicators, without having a control group, and the study can still be considered "good science." For example, the Kelley method can be studied using a quasi-experimental design, which does not involve random assignment to control groups, but does attempt to rule out threats to internal validity by collecting data that can be used to examine these threats (Shavelson, 1996). The time series design would probably be the most effective design, whereby multiple observations are taken before and after a treatment is administered. The multiple pre-treatment observations establish a control-group baseline and the multiple

post-treatment observations establish a consistent change in response. The dependent variables that can be physically measured include tumour size and serum cancer markers.

The standard of care in allopathic medicine to treat cancer is chemotherapy, radiation and surgery. Chemotherapy and radiation act to kill all fast growing cells. It may degenerate the tumour cells but it also damages the healthy cells, like cells responsible for hair growth, the cells lining the digestive tract, skin cells and most importantly, immune cells. Damaging the healthy cells makes it more difficult for the body to heal itself. Allopathic medicine fails to understand the enormous capacity that the body has to heal itself and instead are working against our natural healing powers, when it would be more worthwhile to work *with* the body. In many cases the conventional approach to treating cancer is causing the patient more harm than good. Chemotherapy does not treat the cause of the problem. Removing a tumour by methods such as chemotherapy, radiation or surgery, does not remove cancer *per se* because cancer is a process and therefore you need to stop the process. Additionally, allopathic medicine tends to treat the disease, not the person, when it should

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be the other way around. The allopathic method to treat cancer requires putting your life in the hands of a doctor whereby the patient plays a passive role. The author believes many of these factors contribute to the ill-success of the allopathic approach to cancer treatment.

There exists a major problem in the scientific model with regards to health. Human healing never happens in isolation. Therefore the scientific model is flawed and invalid when it comes to healing methods. Health cannot be defined by only one variable as it exists at 3 different dimensions; mind, body and spirit. Healing cannot be isolated, whereby all other variables are kept constant, as healing and achieving "health" is a multifactorial process. The scientific model also bases all conclusions on what they are able to see and what they can measure in the physical body. But in terms of health, people are more than physical beings. Nevertheless, the author does strongly encourage studies be done that test the Kelley program by using all the physical measures such as

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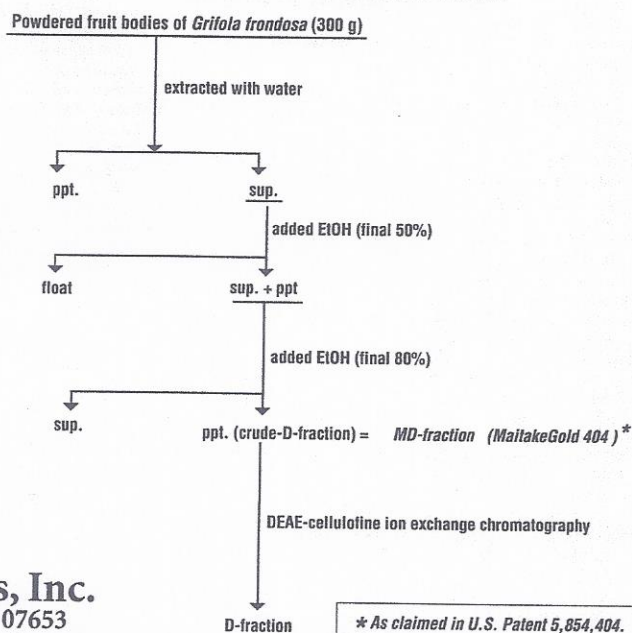
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*Source 1: Addition of Maitake D-fraction Reduces the Effective Dosage of Vancomycin for the Treatment of *Listeria*-infected Mice; H. Nanba, N. Kodama and M. Yamada, Jpn. J. Pharmacol. 87, 327-332 (2001).

*Source 2: Effects of Maitake (*Grifola frondosa*) Polysaccharide on Collagen-induced Arthritis in Mice; H. Nanba, K. Shigesue and N. Kodama, Jpn. J. Pharmacol. 293-300 (2000).

*Source 3: Activities of polysaccharides obtained from *Grifola frondosa* on insulin-dependent diabetes mellitus induced by streptozotocin in mice; H. Nanba, H. Kurushima and N. Kodama, Mycoscience 41: 473-480.

Extraction of D-fraction and MD-fraction



* As claimed in U.S. Patent 5,854,404.

Kelley Program

► tumour size, serum cancer markers, side effects, survival time and quality of life as its measurements of effectiveness.

The Kelley method for cancer treatment seems to have been completely overlooked by conventional medicine and deserves further investigation, as there is substantial research that does support its theory.

Conclusion

Many studies have shown that each component of the Kelley program shows some degree of effectiveness at treating cancer. There are also studies that support Beard's original theory of cancer. Therefore, further investigation of the Kelley program is definitely necessary to evaluate its effectiveness, which includes all 4 components, in order to properly prove or disprove this cancer treatment.

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