

THE MICRONUTRIENT BEST CASE CANCER SERIES

A COMPENDIUM OF MEDICAL PRESENTATIONS MADE AT CANCER
CONFERENCES BETWEEN 2000 AND 2004 DOCUMENTING
THAT THE QUALITY OF LIFE AND RESPONSE TO STANDARD TREATMENT
PROTOCOLS FOR MALIGNANCY IMPROVED WITH
DIETARY SUPPLEMENTATION

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Presented at: First International Conference
For Integrative Oncology 2004



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Forward

This publication is the information presented at:

1. The Comprehensive Cancer 2000 Conference held in Arlington, Virginia and sponsored by the Center for Mind Body Medicine, National Cancer Institute, National Center for Complementary and Alternative Medicine of the National Institutes of Health and Baylor School of Medicine.
2. The Comprehensive Cancer 2003 Conference held in Washington, D.C. and sponsored by the Center for Mind Body Medicine, National Cancer Institute, National Center for Complementary and Alternative Medicine of the National Institutes of Health.
3. First International Conference for Integrative Oncology held in New York City, NY, in November 2004 and sponsored by the National Center for Complementary and Alternative Medicine of the National Institutes of Health and the Society for Integrative Oncology.

This experience with the benefits of micronutrition (AKA dietary supplements, nutraceuticals, and functional foods) began in August 1985 when patients suffering from AIDS reported that drinking an aloe vera leaf gel beverage improved their health status and ability to function at work and in school. Eventually, analytical chemist Alexis Eberendu, Ph.D., demonstrated that the bioactive ingredient was chains of mannose sugars, polymannose. In three pilot studies involving 55 AIDS patients conducted under an individual physician exemption issued by the Food and Drug Administration (FDA) for human experimentation, the author observed that polymannose improved the clinical and objective laboratory parameters associated with this retroviral disease. In addition, a wide array of additional complications associated with AIDS ameliorated as the CD4 helper lymphocyte levels rose and viral loads dropped to a non-detectable level.

One of the more remarkable observations in the responding AIDS patients was the disappearance of Kaposi's sarcomas as the CD4 lymphocytes normalized, and shrinkage of lymphoma masses was also noted. This led to a pilot study in approximately 50 patients on hospice or sent home to die with advanced and non-responsive malignancies. Half of the patients reported significant improvements in quality of life, and in 25% of the patients, tumor masses ceased to grow and some had reduction of their tumor mass, and 25% experienced at least temporary disappearance of their massive load of tumor. This started a painful event repeated many times. The public is drug treatment and cure oriented, and when there is no evidence of a disease, the belief is that a cure has been accomplished. Over the past two decades it has been believed that nutrition does not cure cancer. The defense mechanisms that attack cancer cells are supported through enhanced nutrition in some fortunate individuals. If the improved nutrition is withdrawn, the malignant cells return. Apparently, a significant number of people need more micronutrients, respond to the improved supply, and will continue in good health only so long as the improved nutrition is maintained.

Two of the patients from the 1980s are presented in the Best Case Series that follows. They are currently alive, in good health with no evidence of malignancy, and have been visited in the last 4 months. One is patient WH with the mediastinal sarcoma, a type of malignant tumor that does not commonly respond to any treatment, and the other is BS that initially had over 100 adenocarcinoma metastatic nodules in his lungs and was dismissed to plan his funeral over a decade ago.

Appreciation is especially expressed to James Gordon, M.D., founder of the Center for Mind Body Medicine, who in 2000 gave major encouragement when the first cases were presented at the first cancer conference, listed above, that he organized. It was Dr. Gordon that informed the author of the Best Case Cancer Series being sponsored at the National Institutes of Health and introduced me to Jeffery White, M.D., NIH oncologist, who administers the program that searches for new potential therapies that will improve the quality of life and survivability of patients with malignant disease. The assistance and guidance of Dr. White and his staff has been most supportive of this effort, and their encouragement has been vital and for this gratitude is expressed. This group of patient records will be submitted to Dr. White in hopes that a major grant will result to conduct a prospective cancer study conducted in a formal environment. That is the necessary next step required to move forward toward professional acceptance and use of micronutrients in combination with standard treatment protocols for

various malignancies. Evidence based medicine required a strict discipline of study and proof that is well documented by qualified professionals. This collection of cases is not a basis for professional recommendations for cancer management or third party reimbursement for using the supplements. **Most importantly, the use of micronutrient dietary supplements is not a treatment for malignancy, and no one should consider supplements as a substitute for medical treatment.** One should note that all the patients documented in this series had standard medical management along with dietary supplements.

In 1982, having been a physician for 20 years, I was overwhelmed with a sense of inadequacy, if not guilt, for my medical profession. I was struck with how flimsy and weak the defense of having adhered to "a professional and accepted standard of practice" when patients died, often after a series of miserable and painful experiences absorbed in the name of "standard medical treatment" that failed. At the top of my list was what passed as cancer therapy, and this was followed by treatments for all autoimmune diseases. My feeling was, "If the disease did not kill the patient, the treatment, if continued long enough, was sure to accomplish the same end result."

One night at their regular monthly meeting I announced to the board of directors of Dallas-Ft. Worth Medical Center that I was establishing the Fisher Institute for Medical Research. The intent was stated to the group, "To improve the treatment of conditions for which medicine does not perform well." The chairman of the board, an older crusty buffalo of an attorney, in a bombastic voice with a touch of cynicism responded, "Haw! Haw! Haw! McDaniel, do you think you are going to find a cure for cancer?" Everyone had a good laugh as I sat silent and waited for the noise to die down. My retort was, "I do not know of any challenge in medicine where any less would have to be done to bring about a major improvement!" The reader holds in their hands 23 years of determination to put substance to that assertion.

The staff of Fisher Institute and MannaRelief Ministries has been invaluable in this effort that has required an incredible amount of time and attention to contacting patients, physicians and institutions. Most documentations and validations of patient medical records are done in one institution or city. Evaluation of cases in this series spans five nations and many dozens of potential patients. Numerous potential responses had to be eliminated due to incorrect initial reports of diagnosis, errors in responses, and/or inadequate or no records which could be obtained. The task was essentially refuting or validating rumors from a vast expanse of sources. One unexpected blind alley was discovering individuals that are still alive, and the institutions where their diagnosis and treatment was obtained claim no records exist for the patient. We were told with firm certainty that there are no survivors alive from that long ago in their tumor register. Such patients cannot be included due to lack of documentation, which is essential.

One wishes to express a sense of respect and admiration beyond words or earthly measure for expression to the patients recorded in this series. Most had to overcome criticism, condemnation, rejection, and often isolated abandonment when they decided to try dietary supplementation as part of their personal fight against cancer. Their physicians, family, mate and friends often ridiculed and belittled their determination to try to find something that might work to preserve their life when all else was failing or had failed. The confidence they gave me when there was little to provide to support the potential that optimizing nutrition might be of help in their challenges will never be forgotten or taken lightly. It is to the unconquerable spirit and will to live of these patients that trusted me that this effort is dedicated.

My prayer is that this simple nutritional technology that is as old as life itself will spread into the world for the benefit of persons these remarkable patients nor I will ever know. I pray that lives will be made better, and horizons and tomorrows that would not have been seen will now be seen, and achievements would not be lost that would have been lost, and happiness meant to be fulfilled as it was meant to be when each special human spirit was embodied. This is a gift, may all receive it with the hope and vision from which it comes and was given.

HRMcD 3/5/05

Publication of this material and ongoing research in this area are supported in part by a generous grant from the Gerrish Family Trust.

FISHER INSTITUTE PROFESSIONAL EDUCATION SYLLABUS

A Technical Syllabus Provided for Use by Health Care Professionals

PRESENTED AT:
**COMPREHENSIVE CANCER
CONFERENCE 2000**

The Center for Mind-Body Medicine
Washington, DC

June 9-11, 2000 • Hyatt Regency Crystal City • Arlington, Virginia

**Is There a Role for
Dietary Supplementation in Combination
With Standard Cancer Therapy**

Sponsors: The University of Texas-Houston Medical School
The National Cancer Institute
The National Center for Complementary and Alternative Medicine
OneBody.com

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Comprehensive Cancer Conference 2000:

Is There a Role for Dietary Supplementation in Combination with Standard Cancer Therapy

June 9-11, 2000

A Role for Glyconutrition in Combination with Standard Cancer Treatments?

H. Reg McDaniel, M.D.

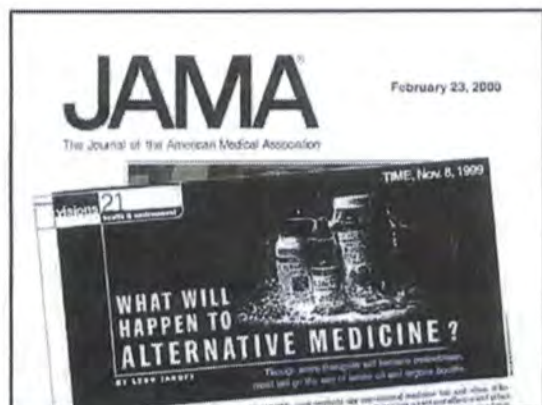
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Title: Is There a Role for Dietary Supplementation In Combination with Standard Cancer Therapy?

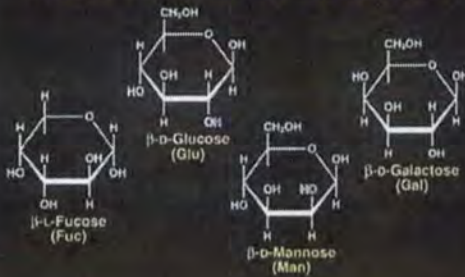
This presentation is not a report on a formal clinical study. It is a compilation of cases in which cancer patients self-administered modern dietary supplements in variable amounts, often guided by how they felt from day-to-day, while undergoing standard treatments or after having failed all therapy. This material is not represented to be formal science, a basis for public policy, or professional recommendation. It is presented before a "new ideas forum" to ask the question: Should nutraceutical dietary supplementation be examined in a critical clinical environment for whether micro-nutrient support has a potential to improve responses to established treatment and improve quality of life and survival of patients? Putative mechanisms of action will be shown that provide a potential scientific rationale for the patient responses shown. The developing basic science will be provided along with early clinical reports because professionals cannot condone or conduct their practice from a premise other than evidence-based medicine.

Slide 1

Time magazine had a special issue November 8, 1999. Authors were asked to predict what life would be like in the year 2025 compared to the start of the millennium. In this series of essays is evidence of the intense contempt many experts and well-meaning scientists have for the use of natural products and complementary/alternative medicine. It is believed that an article in this issue serves as a good starting point for this presentation for this conference designed to bring complementary and orthodox practitioners of medicine together to communicate in a constructive manner. A prevalent position and attitude is represented by a short essay by Leon Jaroff, founding editor of Discover magazine. He takes to task the current millions in our society using natural substances for their health and assailed the shift of approximately half the nation's citizens (NEJM 1999) in their choice for alternative medical management. His assertion is that the current wide usage of natural medical modalities is a foolish fad that will pass rapidly. This is because there is "no science or evidence to support the use of non-pharmaceuticals." Jaroff dismisses the dietary supplement industry and Dietary Supplement Health and Education Act of 1994 as being so much "baloney." Your guide for this lecture has had experiences starting in 1985 that suggest that Jaroff's position reflects the majority opinion of establishment scientists and medical leadership. This status requires acknowledgement and examination before a meaningful dialogue can develop between parties with great contrasts in experience, education, and orientation in the healing art. Jaroff's essay contrasts sharply with statements found in an interview with an established medical expert contained in the February 23, 2000, issue of the Journal of the American Medical Association. Steven Strauss, M.D., the recently chosen head of the Center for Complementary and Alternative Medicine at the National Institutes of Health is interviewed. Dr. Strauss expresses an attitude science should always adopt when evaluating a new idea or modality. It may be condensed to, "if valid data can be produced that shows value for a natural substance or alternative modality, it will be accepted as a new management for disease, if it improves patient care." Dr. Strauss described the status of contemporary non-standard modalities being used by some healers, professionals and the public as "Frontier Medicine." In the interview it is stated that anecdotal reports are not an acceptable basis for public use of unorthodox treatments, nor are many individual case reports sufficient for recommending an agent or method to the nation. Progressive steps of experimentation performed in an orderly, step-wise, objective scientific manner is required to gather sufficient data to judge whether an alternative treatment has value. This presentation is designed to take one through such a development and evaluation process that has been in progress for over 15 years. A great limitation for what is available to discuss has been due to an absolute minimum of research funding, all private in origin, that has been available.



Natural Dietary Monosaccharides (Sugars)



Slide 2

In the late 70s, the initial member of our research team, while a graduate student in pharmacology, began work to answer the question: "Why has aloe vera gel been used for over 5,000 years by every civilization on every continent for health its restoring properties?" The active principle was isolated and concentrated from the leaf gel and was eventually found to be beta 1-4 polymannose, a complex carbohydrate. Peer medical researchers were not impressed with the proposal that a plant polysaccharide had major physiological effects and it was difficult to get scientists to evaluate the material. It was found that in multiple countries and languages, all biological scientists are taught the same lesson. Simple sugars derived from complex carbohydrates are burned for energy to sustain animal life. Proteins and nucleic acids were an accepted dogma for possessing the capacity to initiate, conduct, and modulate the biological functions of life. Only with great difficulty was it possible to get capable scientists at credible institutions to perform some key evaluations with sophisticated instrumentation and in standard research models.

Slide 3

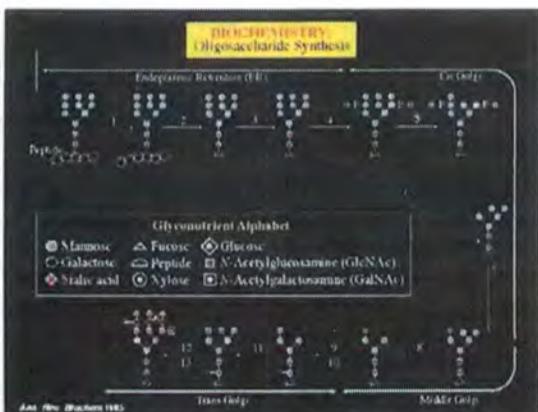
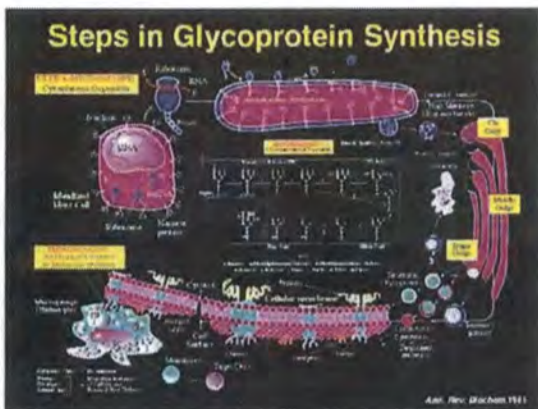
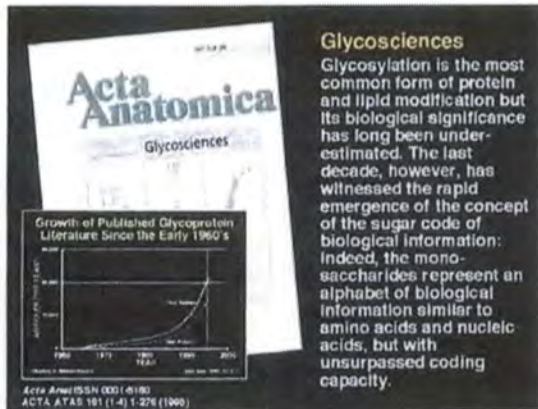
In regard to the newly recognized and expanded role played by carbohydrates in life processes, this is the cover of a special dedicated issue of *Acta Anatomica*, Vol 161, 1998. This theme issue focuses on a decade of discovery in glycoscience. A summary statement is on the issue's cover. The reader is informed of a revolution in biological knowledge that has been known only approximately 10 years. The interval of 1988 to 1998 has been witness to the discovery of the monosaccharide biological code. There is more information coded in sugars than nucleic acids (DNA and RNA) and amino acids in a human body. This is a revolutionary statement that has yet to make standard textbooks and contemporary lectures in medical training. In the late 70s and decade of the 80s, interest and cooperation with basic science researchers and clinicians needed for testing the active principle of aloe vera might have met less resistance if the scientific knowledge, not available until the decade of the 90s, had been known then. The 15 review articles in this journal establish the fact that sugar molecules attached to protein and lipid chains participate in a vitally important manner. Such activity ranges from the attraction and combination of the egg and sperm, through cell growth, differentiation, regulation, metabolism, repair, healing, cognition and memory. Anytime two or more cells are in contact, or when the trillions of cells in the human body interact or function in harmonious good health, monosaccharides, simple sugars that must be supplied in the diet, are essential to cell-to-cell communication.

Slide 4

We now shift from the newly discovered role sugars supplied in the diet play in the biochemistry of life processes. We have found that the clinical discovery of the power saccharides play in health and disease was being slowly developed in past decades by biochemists exploring intracellular biochemical pathways of glycoprotein and glycolipid synthesis. These two categories constitute the structure and function molecules of the body. A key article can be found in *Annual Reviews of Biochemistry* 1985 in a review by R. Kornfeld and S. Kornfeld. This schematic displays the ultra-structural organelles within an ideal cell and the biochemical steps in synthesis that are performed at each assembly step are in the center. Assembly of amino acids polymerized as dictated by mRNA occurs first in the free ribosomes to start protein synthesis.

Slide 5

In the endoplasmic reticulum, glycosylation, the next synthesis step, is initiated by the addition of 9 mannose sugars to peptide chains polymerized by the ribosomes. This complex is transferred to the final synthesis site, the golgi. In the golgi there is a reorganization of the three mannose sugar chains by the substitution and addition of up to 7 or more other sugar molecules that complete the very exquisite molecular structure of the structure/function compounds that are required for conducting life. Listed at the bottom is the "alphabet of biological information" expressed in monosaccharides referenced in *Acta Anatomica*. Membrane structures including the channels, pumps, adhesion receptor sites, and the antigenic statement of "self" is synthesized in this bio-assembly process. It was found that the mannose sugar is low or absent in the modern food chain and that providing a supply through nutrition had a remarkable restorative capacity to assist the body in achieving healing and homeostasis. This action was followed by going into nature and finding the additional natural dietary sugars of the "monosaccharide alphabet" and adding them to the diet. This enhanced the health pro-



moting activity previously observed. Host defense, regeneration of cells, repair, regulation, defense, and healing was improved by supplying the currently known glyconutrients by dietary supplementation.

Slide 6

At this point several anecdotal case presentations followed by basic science studies will be provided to inform you of the steps that have been followed since 1985. As in Dr. Strauss's interview we start with soft or anecdotal data typical of "frontier medicine." These cancer patients added to their diets as a supplement a natural source for glyconutrients, sugars that are low or absent from the modern urban diet.

Case W. H. # MCH 83-145,786

In August 1983, this 43 y/o male presented to a suburban hospital with acute chest pain. Emergency chest X-rays suggested an aortic aneurysm due to a widened mediastinum.

Slide 7

W.H. was transferred on an emergency basis to a major hospital where vascular studies with contrast media showed that a solid mass of an unknown, but not vascular, nature extended from the lower neck to the diaphragm, between the lungs and around the heart.

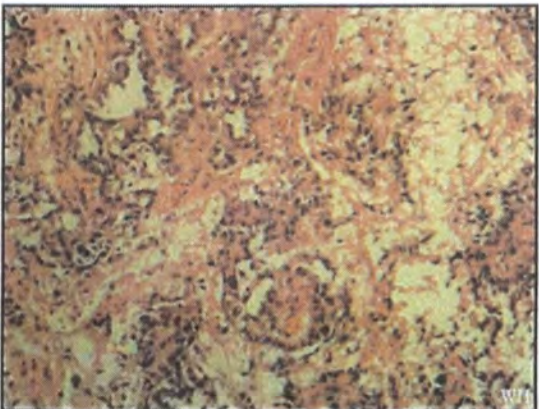
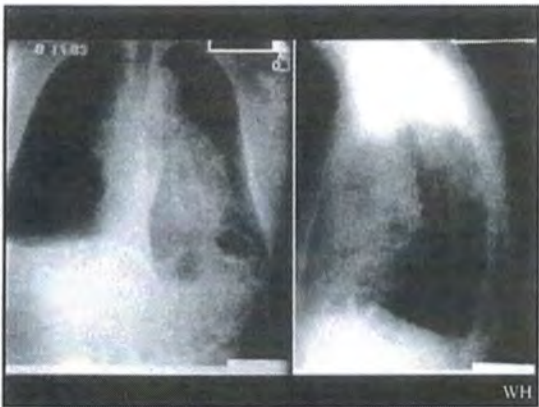
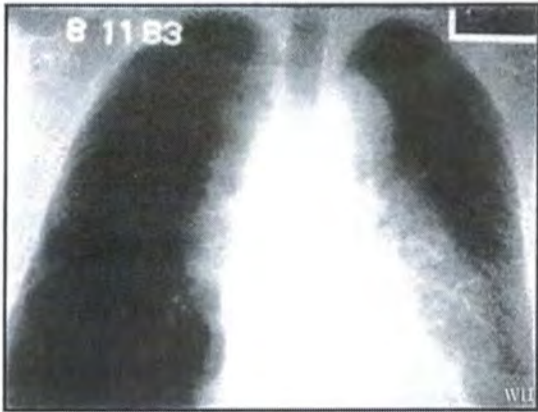
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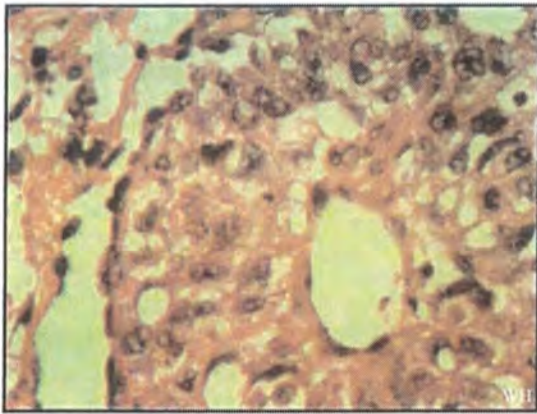
This set of X Rays shows the extent of the tumor obliterating the heart shadow and widening the mediastinum in the standard PA and lateral presentation. Note that on the lateral, no air-filled blackness is present above and anterior where the heart outline is obscured. This should be contrasted with an approaching post treatment PA and lateral.

Slide 9

A surgical biopsy was performed and the diagnosis was a malignant embryonal sinus tract tumor.

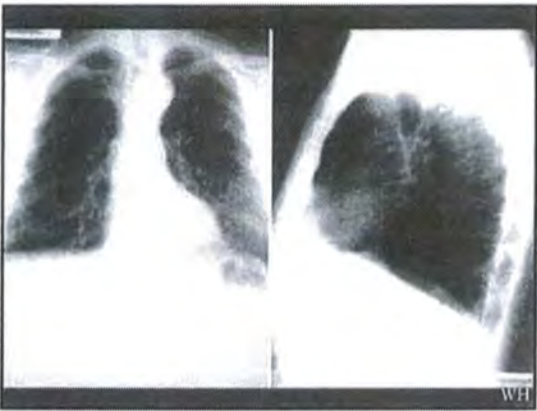
You may note that there are sheets of undifferentiated cells characteristic of the embryo in the disk stage of development with slits in the masses not unlike an amniotic sac.





Slide 10

This high power view shows the embryonal organization of cellular elements. This is a very malignant, rare tumor (a literature search providing no survivors beyond one year). Therapy administered was cytotoxic-chemotherapy with multiple agents on a sarcoma protocol. The patient is alive and well in 2000 having been interviewed in person on 8/9/2000, over 17 years after the initial clinical detection of his malignancy.



Slide 11

This is the normal chest film taken 10 years after diagnosis and treatment. One can see the sharp outlines of the heart and that air is now demonstrated in the lung segments by the black areas now anterior and superior to the heart.

Significant past history was that the patient had a long history of ulcerative colitis. He found that an aloe beverage controlled his symptoms. As previously stated, this natural product was eventually found to contain polymannose, the first generation glyconutrient vital for synthesis in the endoplasmic reticulum. W.H. self-administered the aloe drink while he underwent his chemotherapy for which he was informed would only be palliative. In 1987 the patient volunteered his story to a medical doctor stating his response "might be of interest to others." He is currently in an excellent state of health. From such a simple beginning, the responses of other patients that added glyconutrients to their diets, while undergoing standard cancer treatment, has grown.



Slide 12

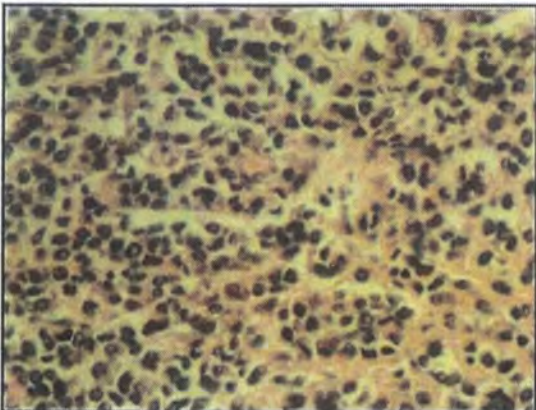
Case J.F. #89-13502

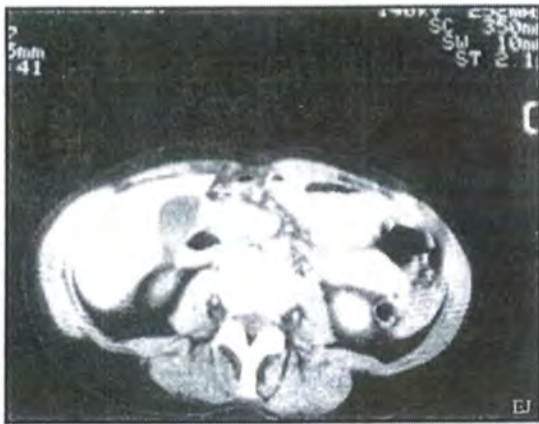
This young mother born in 1951 had an infiltrating duct cell carcinoma of less than 2 cm diameter at the age of 31 in 1982. A modified radical resection was performed and no lymph nodes were positive for tumor. Annual evaluations were negative for tumor for over five years. In 1988 a plastic reconstruction of her breast was performed.

In 1989 at the age of 38, approximately 10 lytic skeletal bone lesions were detected. As her condition rapidly progressed, a 5 cm lesion of the liver and ascites developed. An initial multiple agent cytotoxic chemotherapy induced no response. In March 1989 she presented herself looking 8 months pregnant with two small sons beside and requested that something be done to allow her to raise her two boys. Daily glyconutrients were added to her diet and she was referred to an oncologist to repeat the chemotherapy. Taking daily oral polymannose she received a repeat course of adriamycin, mutamycin, and carboplatinum in rotation. She swam daily, exercised, had no weight loss, and had little toxicity symptoms during the course of therapy. This was in stark contrast to her previous experience with chemotherapy.

Slide 13

A subcutaneous mass was excised from the lower neck prior to starting the final sequence of chemotherapy. This is a section of the undifferentiated tumor. Cytochemical stains were consistent with reactions of the original breast mass.

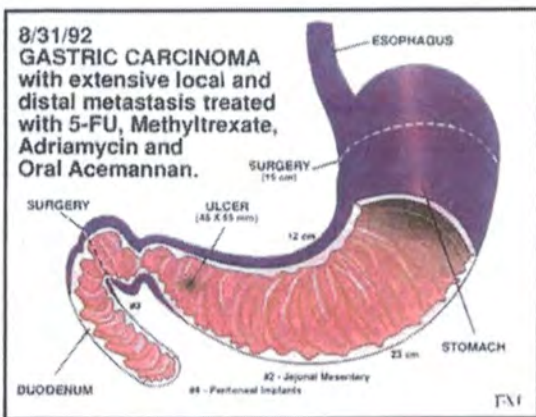




Slide 14

J. F. had little in the way of side effects of the chemotherapy given at the highest levels per kilogram other than hair loss. In four months the liver mass was less than 1 cm., all bone lesions were non-detectable, and the ascites had cleared. In 12 months no evidence of cancer was detected. You have been looking at a scan taken in March 1989 before her re-treatment when the patient appeared to be 8 months pregnant due to copious ascitic abdominal fluid. Note the fluid between the liver edge and the abdominal wall. The central tumor mass in the left lobe of the liver is apparent. The metastatic, lytic lesion in the centrum is typical of 10 such lesions in her skeleton. The red mark was put on the film by the radiologist. The liver now touches the body wall. The thorax and abdominal scan no longer had lytic bone lesions and she has remained in good health until the present date.

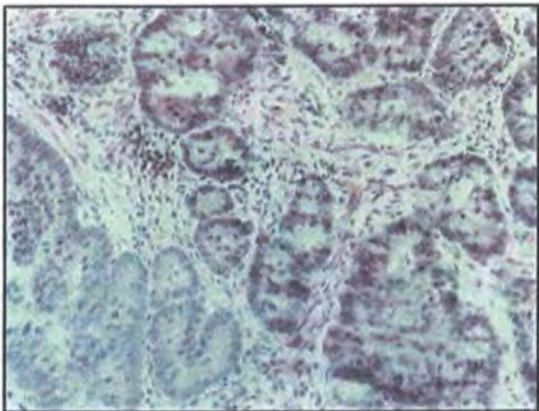
Energy and good health has continued until 1996 when her cancer returned despite continued supplementation with aloe polymannose. On demise she had survived approximately 7 years after being advised by her oncologist that she had less than 6 months to live.



Slide 15

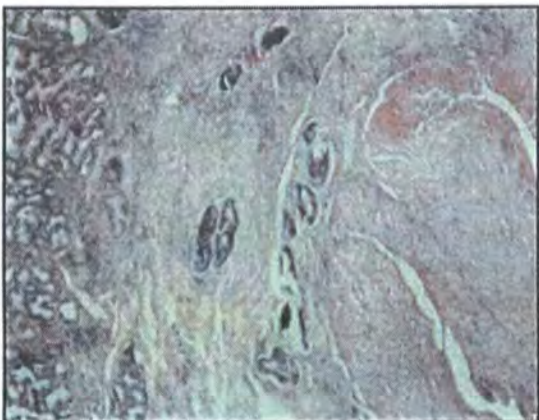
Case E.M. #92-14678

This 56 year old male developed upper abdominal pain with intermittent obstructive vomiting with minor amounts of blood. Occasional melana was noted in stools.



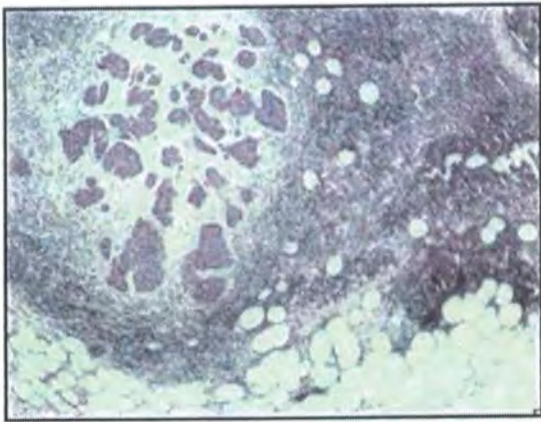
Slide 16

Gastroscopy revealed an antral ulcer and the biopsy diagnosis was adenocarcinoma.



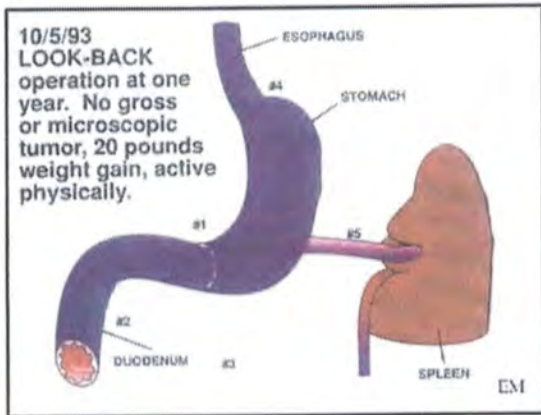
Slide 17

At surgery (8/31/92) wide spread tumor was diagnosed clinically, confirmed by frozen-sections that included lymph nodes and peritoneal implants.



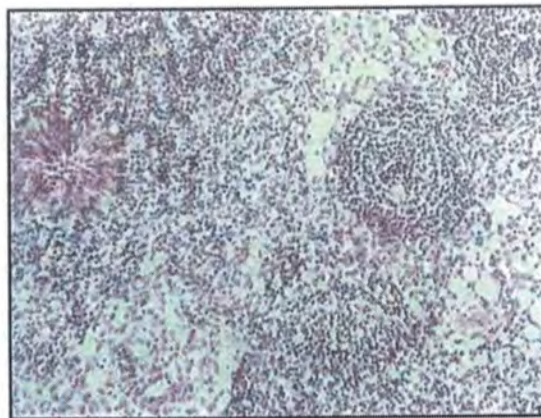
Slide 18

This is adenocarcinoma in a regional lymph node that drained lymph from the stomach tissues.



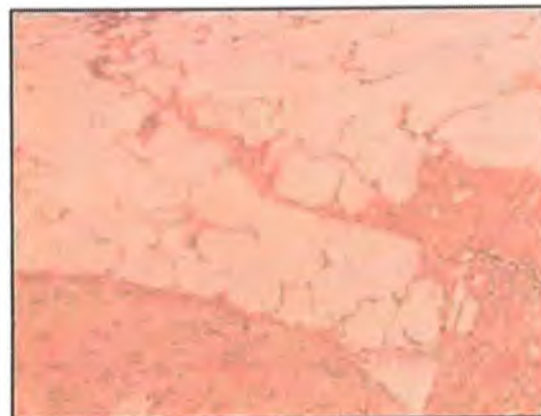
Slide 19

Due to the volume of the tumor and obstructive symptoms, a wide gastric de-bulking resection was performed. Permanent sections confirmed the wide spread of tumor into all margins of resection in the smooth muscle layers with extensive mesenteric implants. The patient received weekly infusions on a rotating basis of 5-FU, methyltrexate, and adriamycin with the fourth week off for one year. The patient's wife was a nurse and she added oral glyconutrition containing polymannose to the diet. E.M. gained weight while on chemotherapy, required one unit of packed-cells during the year without a break in his treatment schedule, had minimal side-effects from the infusions and his physical capacities were reduced approximately one day after each treatment due to fatigue and lack of appetite.



Slide 20

At one year a gastroscopy evaluation indicated that there was a healed gastric mucosa, with pliable, non-fixed, tissue in the area of reconstruction of the GI passage, and no evidence of tumor. A look-back surgery was scheduled in the 13th post-operative month. His hemoglobin, platelets, and leukocytes were within normal limits. Multiple biopsies were performed and the former implants were histiocytic and fibrous responses in lymph nodes that had formerly been enlarged with tumor and fibrous tissue on the mesenteric surface. There was no detectable tumor clinically or by biopsy. The patient stopped taking his dietary supplementation and died several years later from disseminated adenocarcinoma. This sequence has been observed a number of times. That is, complete and well documented inability to detect a formerly widely disseminated cancer that returns upon ceasing to take the nutraceutical dietary supplements. The patient also smoked tobacco and was a heavy daily drinker of alcohol throughout his treatment and temporary recovery.



Slide 21

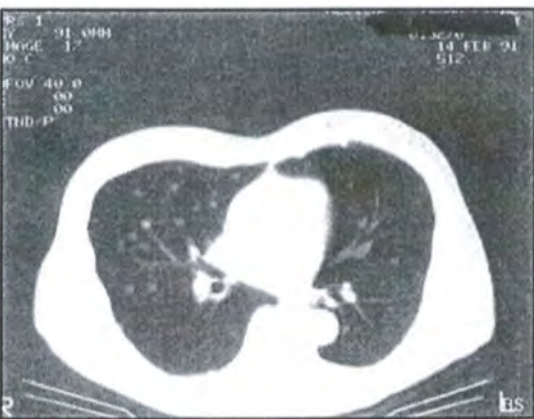
This histopath slide demonstrates a biopsy of the abdominal fat apron that contained grossly identified adenocarcinoma implants at the initial surgery. The tumor implant has been replaced by a fibrous scar and histiocytic cells. No residual tumor that was widely spread in the tissues was detected grossly or microscopically at the look-back operation.



Slide 22

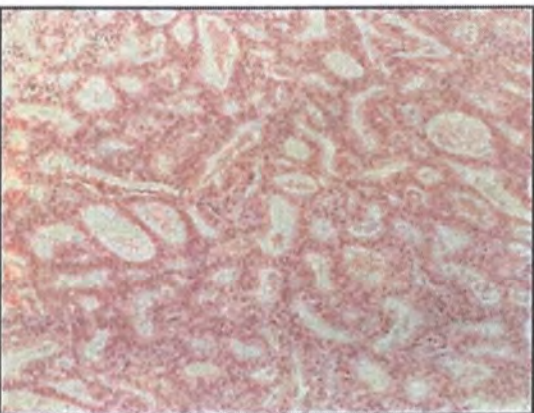
Case B.S. #91-7505

At the age of 68 this male developed obstructive urinary symptoms and was found to have an elevated PSA of 18. He had a radical surgical resection of the prostate. In the next year he experienced a slowly rising PSA without evidence of bone lesions. He underwent regional external radiation to the pelvis and lower back. His PSA declined and then began to rise again. Hormonal suppressive therapy was instituted which was ineffective and surgical castration was performed. In the fourth post-operative year at 72, he was found to have over 100 masses in the lungs.



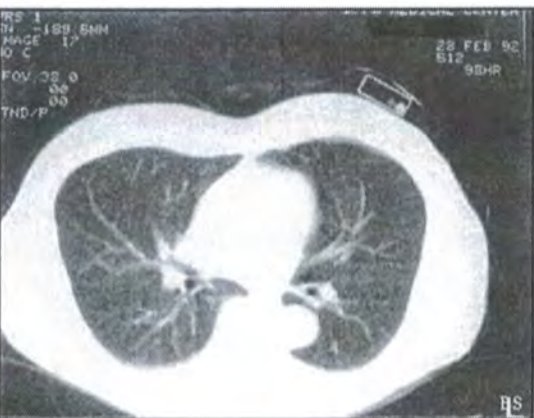
Slide 23

Here we see the many diffuse, small masses that are white in the black air containing lung tissue.



Slide 24

A biopsy was performed for possible tuberculosis and was found to be adenocarcinoma that cytochemically stained positive for the PSA antigen. He was dismissed in a debilitated and cachectic state to make his final plans. His brother was a physician and had knowledge of the prior anecdotal cases that led BS to use the glyconutritional aloe polymannose. In combination with glyconutrition, he received weekly doses of 5-FU, dicarbazine, and mutamycin.



Slide 25

At one year no lung masses were detected by lung scans, his weight was restored, and his significant athletic skills returned. He has continued his nutraceutical dietary supplementation.



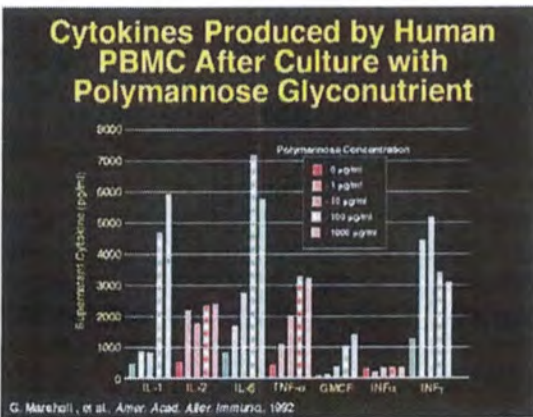
Slide 26

His chest studies have remained within normal limits for a man of this age.

In 1998 this patient won the state table tennis championship for his age bracket in Texas and competed in the nationals in Las Vegas. He has experienced the slow onset of hypoadrenalism thought to possibly be due to the past radiation. If he is alive in February 2001, it will be ten years since he was sent home to make funeral plans.

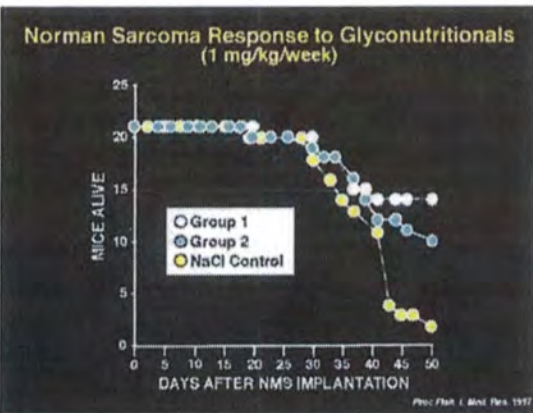
Slide 27

In a quest for a mechanism of action for the anti-tumor activity seen in humans and animals, multiple ELISA assays were performed to determine the effect of polymannose glyconutrient added to human mixed-leukocyte cultures. Polymannose was added to triplicate leukocyte cultures on a gradient basis. Pro-inflammatory cytokines were assayed and IL-1, IL-2, IL-6, TNF alpha, GMCSF, and INF gamma increases in production were initiated. INF alpha production was not supported by the addition of the glyconutrient (GD Marshal, 1993). One should recall that the Michaelis-Menten dynamics of substrate supply in cellular synthesis indicates that with an increase in supply of reactants, the velocity and amount of end-product production will be increased up to a limit. The addition of glyconutrients required for glycoprotein and glycolipid synthesis produced the predicted result. The results also suggest that the monosaccharide, mannose, was a rate limiting substrate when compared to control leukocyte cultures.



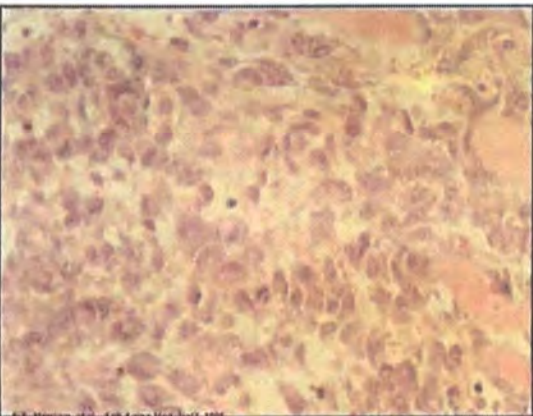
Slide 28

This is an example of a NCI murine tumor model used to search for antitumor activity of potential drugs. This is Norman sarcoma noted for its 100% death rate despite any intervention used. The graph shows the controls in the lower points, the response to the single glyconutrient polymannose in the middle points and to a complete glyconutrient formulation in the upper points. Administering the single glyconutrient resulted in about 48% survival of the target animals. The complete formula containing multiple monosaccharides required for glycoprotein and glycolipid synthesis, that includes anti-cancer substances, resulted in an average of 67% survival. The animals that lived had no evidence of residual tumor that was detectable.



Slide 29

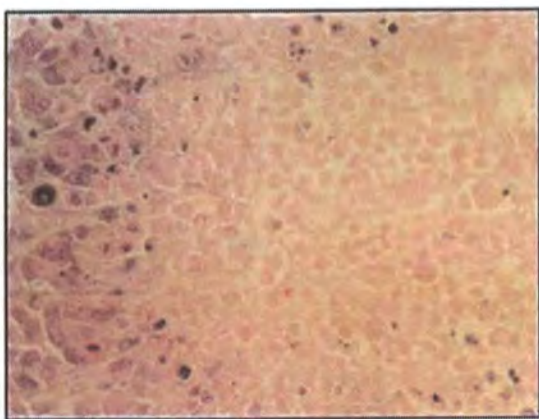
This slide shows the control Norman sarcoma tumor infiltrating the chest wall muscles. Note the numerous mitosis and anaplastic cytopathology.





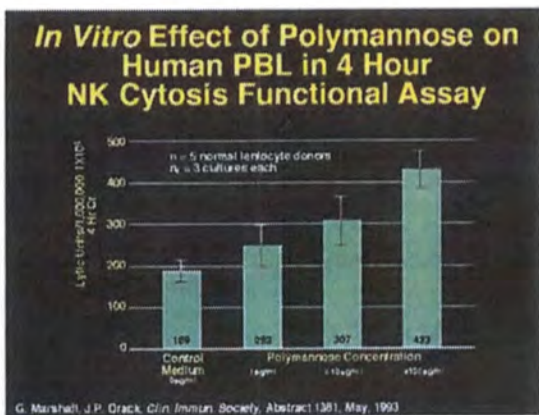
Slide 30

Here we see an early, but well-developing, stage of response that starts just beneath the skin and progresses toward the chest wall. Edema, congestion, polymorph infiltrate, followed by mononcytic infiltration and necrosis are the classical stages of progression for the general inflammatory process and it is demonstrated in the animal tissues. These stages are induced by bacterial, viral or other microorganism infections, physical trauma, autoimmunity attack of tissues, and the innate defense against malignant cells.



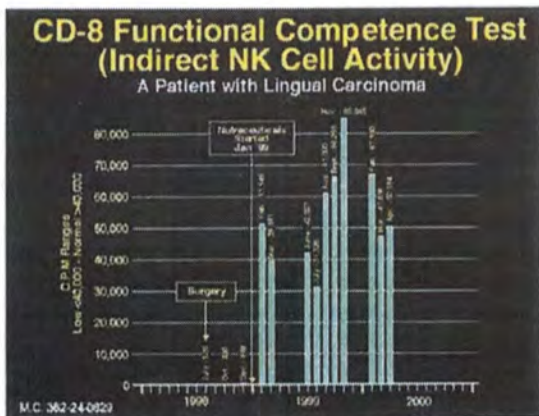
Slide 31

This is the end stage where coagulation necrosis is well developed. It has been demonstrated that cell-to-cell communication by cytokines, as cited above by G. Marshall's experiments, are the activating molecules, synthesized by cells, that conduct these stages of innate defense against any "non-self structure" detected by the immune system. Thus, the inflammatory process demonstrated initiates and sustains the defensive progress through the release of the cytokine, cell to cell communication, produced by the abundant supply of glyconutrients.



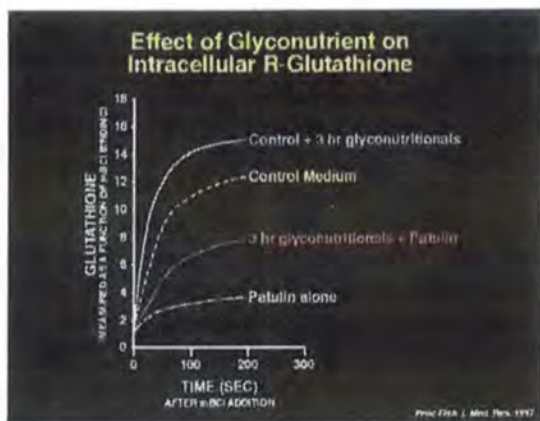
Slide 32

It is generally accepted that CD-8 lymphocyte pool by flow cytometry contains natural killer (NK) cells active in tumor cell destruction and lysis of virus infected cells. GD Marshall, et al., 1993, reported a dose-response activation of the 4 hour Chromium-release assay for human NK cells incubated with polymannose over night. The degree of cytolysis was found related to the availability of substrate on a concentration gradient basis.



Slide 33

In the current managed care environment and with the limit of funds for research on nutraceuticals, obtaining esoteric assays in cancer patients of a research nature is not possible. However, this doctor with a squamous cell carcinoma of the base of the tongue obtained serial indirect NK cell assays based of CD-8 competence. Note at surgery in July 1998 his assay was approximately 500 counts per minute and less, (normal >40,000) until January of 1999 when he added a glyconutrient dietary supplement containing multiple monosaccharides. All assays for competence have been normal or above and up to 2 X normal (>85,000) since this addition to his diet. There has been no evidence of return of the lingual cancer following the combination of radiation and dietary supplementation as of the last communication with the patient in June 2000.



Slide 34

Oncologists from various areas have reported the opinion that the combination of their standard treatment with nutraceutical dietary supplements appears to increase the susceptibility of tumor cells to therapy whether radiation or cytotoxic. In addition these same sources indicate that the normal cells are protected from damage. This is most apparent in the bone marrow elements, oral mucosa, and GI tract. Clinically less toxicity and fewer side effects are observed while the tumor shrinks at a remarkable rate, based on past experiences. An effort was made to determine if a rational scientific basis could be found for this putative desirable differential effect. The hypothesis was derived that normal cells conduct more cell maintenance of molecules in the G₀ phase of the cell-cycle. Malignant cells in the S₁ cell-phase direct more cellular resources, i.e. nutrient molecules used in synthesis, to production of DNA and the cell structure required for more malignant cells.

It is known that radiation and cytotoxic chemicals generate free-radicals and reactive oxygen pairs to kill cells. In the normal cell, in the G₀ phase, one might predict that molecules synthesized to protect cells from oxidative stress and maintain intracellular homeostasis have the potential to generate more protection if the molecules used for such synthesis were supplied through nutrition. In turn, malignant cells may not readily perform this task. The master antioxidant protective molecule in cells is reduced-glutathione. In these living liver cells in water soluble cytoplasm is reduced-glutathione that with the spectrophotometer a quantitative amount of the protective glutathione in 1,000 liver cells can be determined and graphed against time. The response of liver cells to dietary glyconutrient supplementation, as determined by a Meridian Laser Cell Analyzer, can be measured and has been published (R. Barhoumi, et al. 1997). The experiments reported were designed to determine if intracellular protection against oxidative stress is increased by increasing the supply of glyconutrient. The plot shows that in 300 seconds following the addition of polymannose to cultures, a 50% increase in intracellular oxidative stress protection is attained as evidenced by the amount of reduced-glutathione increase inside the cells. Patulin challenge, as an organic oxidizer to simulate free radical generation by radiation or chemotherapy, destroys all protection in normal complete medium. Over half the protection remains in glyconutrient-fed cells. This can explain the basis for the differential effect of a relatively enhanced destruction of malignant cells and protection of normal cells described by multiple oncologists.

**A Pilot Survey:
Standard Cancer Therapy Combined
with Nutraceutical Dietary
Supplementation Improves Treatment
Responses and Patient Quality of Life**

G. Hyland, M.D., D. Miller, M.T.
*Comprehensive Cancer Care II: Integrating Complementary and
Alternative Therapies, June 1999*

Nutraceutical Dietary Supplements:
In a prospective pilot of 100 patients treated by standard methods

- Do not inhibit tumor cell destruction by radiation and chemotherapy
- Do enhance tumor cell destruction
- Protect normal cells from radiation and cytotoxic damage
- Induce reductions in tumor masses in tumors resistant to all treatments
- Helped improve patient quality of life during and after treatment

Slide 35

At this conference one year ago a pilot study for combining standard radiation and chemotherapy with dietary supplementation in 100 cancer patients was reported by G. Hyland. You will note that the impression of benefit was remarkable and is in concert with many other oncologists that have seen the same benefits in fewer patients undergoing standard treatment. The differential effect of protection of normal cells and destruction of malignant cells is made possible due to the generation of intracellular antioxidant protective molecules related to the increase in intracellular reduced-glutathione.

INTRODUCTION TO FINAL CASE PRESENTATIONS

PANCREATIC CANCER

With the limited funds available for research in dietary substances, numerous skeptical oncologists have been asked what type of cancer would have to demonstrate a benefit for observers to consider anecdotal results warrant further evaluation? The uniform answer has been advanced, recurrent, or inoperable pancreatic cancer. We will share the anecdotal trail as one typically develops.

Word was sent over North America that there was a desire to collect documented, inoperable cases of pancreatic cancer, preferably with metastasis well demonstrated by scans, who had added nutraceutical dietary supplements to their diet and experienced a significant benefit. The first case received was from a physician regarding his wife. The case documentation is not currently available or may be lost, but the story exemplifies how and where the scientific process begins. A single, simple observation was made by one qualified person that had the insight to say, "This is different and just might be significant."

Case E.T. #97-14523

An 81-year-old physician's wife had a 20-year history of recurrent chronic pancreatitis with bouts of severe episodic pain and elevated amylase and lipase. In July 1998 she experienced a rapid weight loss of 135 down to 90 pounds in less than 6 months with constant back pain. This couple live in the northern region of British Columbia and the records and the patient travel great distances for medical diagnosis, and treatments. The medical file and studies are not available at this time. The husband is a physician and

he has reviewed all the records and studies with multiple specialists and has provided a signed statement. In July 1998 scans were done of the abdomen and several masses in the head of the pancreas and liver were demonstrated. The ductal system of the pancreas and liver was dilated and laboratory results reflected this status. Since she was not a surgical candidate her husband started her on Essiac tea and a dietary supplement regimen of glyconutrients, phytonutrients, and phytogenins. Her pain was slowly eliminated, weight was restored, fatigue reduced, appetite returned, and jaundice cleared. Her studies were repeated at 1-year post-diagnosis and the dilation of the ducts was gone, the pancreatic and liver masses non-detectable. This anecdotal story was the initial case that led to searching for other pancreatic cancers that will be presented. The greatest benefit claimed by this family is that the pain of pancreatitis has been gone for 2 years, for the first time in 20 years. The freedom from pain may be of significance in the difficult to manage condition of chronic pancreatitis. This is the 5th case reporting relief of pain in pancreatitis and further evaluation for this benefit may warrant a pilot study.

T. M. #E000386613



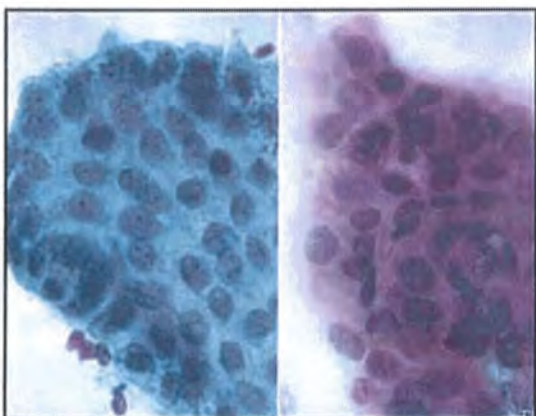
Slide 36

In 1997 this 80-year-old male developed jaundice, penetrating upper back pain, and overwhelming fatigue with rapid weight loss of 165 down to 125 pounds in 6 months. He presented to a large satellite regional hospital where abdominal scans with and without contrast media, and ultra sound were conducted. The common bile duct and hepatic ducts were well distended.



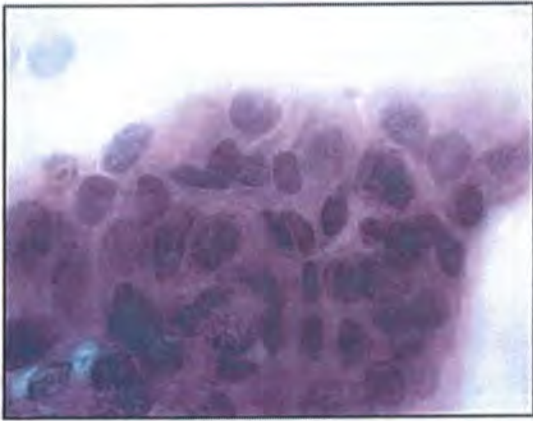
Slide 37

Multiple intra-hepatic masses were shown in the hilum of the liver and the pancreas head was enlarged in a manner typical of a pancreatic tumor.



Slide 38

A fiber-optic pancreatic cannulation was performed and cellular material was obtained for pathological examination. Normal, well-spaced, uniform ductal cell sheets are demonstrated on the left and on the same slide sheets of abnormal cells are on the right.

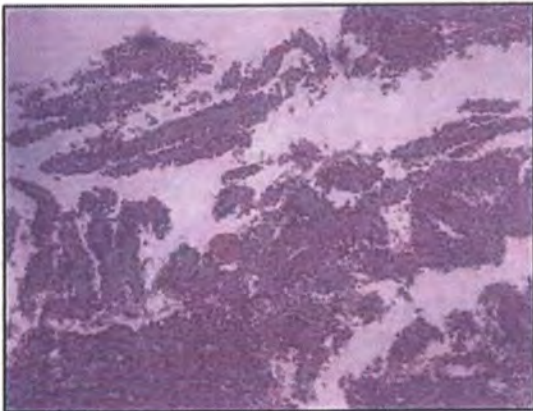


Slide 39

In this enlargement one can see numerous clusters of chromosomes in this single field. A tri-polar mitotic pattern is also demonstrated and the more aggressive pathologists diagnosed this as adenocarcinoma of the pancreas.

All pathologists interpreted the sheets of cells collected to contain abnormal clusters, with some suggesting diagnosis of "suspicious but not diagnostic of cancer." The patient was transferred to a major hospital and the radiological scans were repeated. All material was re-evaluated. He was informed that due to the cell clusters collected, clinical picture of weight loss, pain, jaundice, masses detected by scan, distention of the biliary tree and pancreatic duct system, masses of tumor in the central and right lobes of the liver, that he had inoperable pancreatic carcinoma.

The patient was sent home with a 6 month expected term of survival. He started large amounts of nutraceutical dietary supplements. His jaundice cleared, his energy returned, laboratory values consistent with bile duct distention normalized and his lost weight was regained. At 6 months his scans were repeated and no masses or ductal dilation were detected. He returned to his passion of fancy, ballroom dancing. As a bonus, he had had borderline compensated congestive heart failure with a pace-maker. His cardiac shadow is no longer dilated and his exercise capacity and endurance has been increased. He expresses pleasure with his third year of survival with a good quality of life, since being discharged as terminal. In April 2001, he expired from a cardiac arrhythmia, a condition he had the last few years of his life.



Slide 40

Case JH #E005233374

At the age of 39 this female oncology nurse presented with severe abdominal pain radiating into the upper back. Ultra-sound followed by MRI scanning disclosed an 8 cm. mass in the tail of the pancreas. She eventually underwent a Whipple resection and partial hepatic resection for metastatic nodules in the liver parenchyma in July 1994. A diagnosis of cystic papillary adenocarcinoma of the pancreas was made.



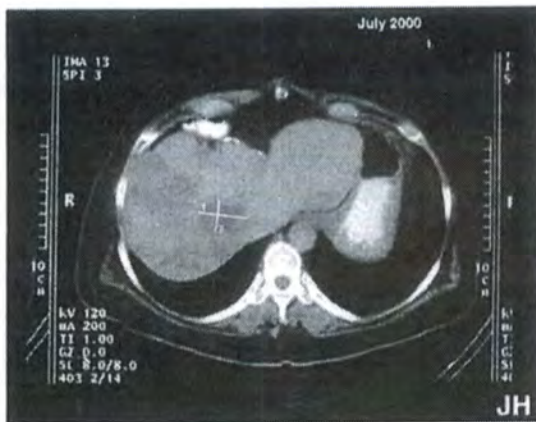
Slide 41

The masses removed from the liver had a similar pattern. In January 1995 at Sloan Kettering, a second hepatic resection was performed for additional liver masses of 8.7 and 4.2 cm. dia. In July 1996 she had recurrent liver metastases. In November 1997 vinyl alcohol embolism of the liver masses was performed. Her chronic problems became increasing pain, diarrhea, nausea, weight loss and jaundice. Her liver enzymes were minimally elevated and the CBC was within normal limits. Her progressive debilitation and multiple medications for pain led to hospice care being offered in July 1999. In the fall of 1999 she started on nutraceutical dietary supplementation containing glyconutrients, phytonutrients, and phytochemicals at the insistence of her elderly mother when she became too weak to move from her bed.



Slides 42

This patient's clinical status progressively improved and included reduction of pain and the need for narcotics, improved energy and endurance, elimination of jaundice and weight gain. This view shows a selected mass in July 1999. The two maximum diameters are 9 X 7 cm. The patient had various prior standard and unusual treatments including wedge resections of recurrent masses after the Whipple resection, followed by amyl alcohol catheter infusions into the additional recurrent masses. When on hospice and unable to leave her bed micro-nutrients were added to her feeding tube liquid diet. The shift in position and size of the liver makes comparative scan cuts difficult to select. However, note that metallic clips are present in the abdominal wall for orientation. The scan showing the largest diameter in the series was selected for each lesion in the sequences provided a year apart. Lesion 1 followed by the July 2000 scan is considered the most accurate demonstration of changes in the three areas in the liver selected.



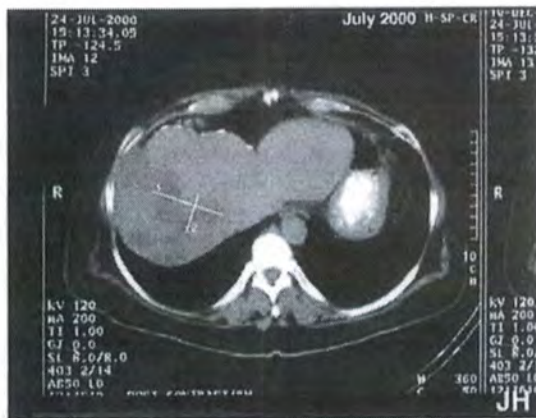
Slides 43

The addition of micro-nutrients to the diet included relatively large amounts of glyconutrients (8 table-spoons daily) intended to support optimal cytokine synthesis. Phytonutrients and phytogenins were also in the liquid formula. The maximum diameter of the liver mass was 5.5 X 4 cm. A crude estimate of the circumference of the mass was derived by taking an average of the two diameters, dividing by 2 to get the estimated average radius. The radius was squared and multiplied by the constant pi (3.14). Thus, the roughly estimated ave. circumference in July 2000 was 24 cm. The same treatment of the scan generated maximum diameters in 1999 led to an estimated 50 cm circumference. Thus, the estimated reduction in circumference of the tumor during a year of dietary supplementation was on the order of 50%. Quality of life experienced by the patient significantly exceeded this assessment.



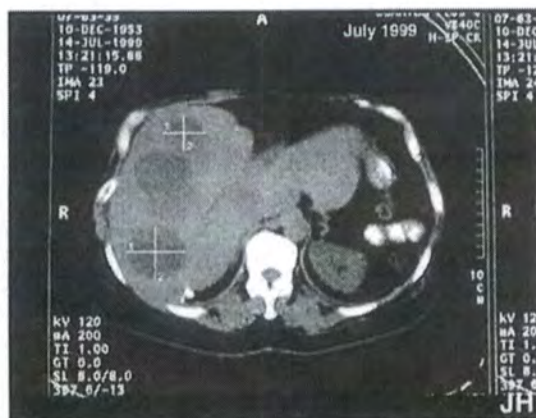
Slides 44

This MRI level of the liver demonstrates the largest conglomerate of metastatic pancreatic tumor. The maximum diameters were 8 X 10 cm. in July 1999. The roughly estimated circumference was 64 cm.



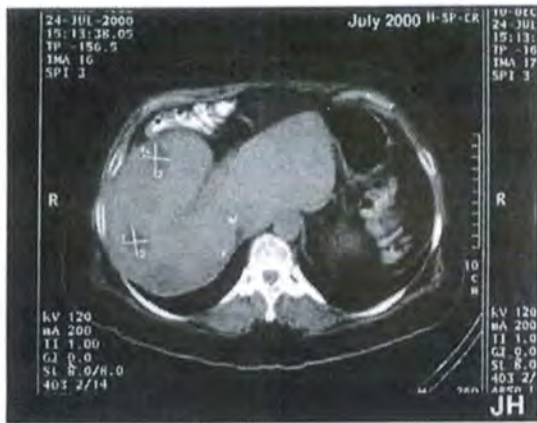
Slides 45

The July 2000 maximal diameter of the confluent masses was 7 X 4 cm. The estimated circumference of the mass, applied to all measurements in a consistent manner, was 24 cm. The circumference approached being 1/3 of the initial measurement estimate, 64 cm vs. 24 cm.



Slides 46

A series of multiple, smaller metastatic masses were demonstrated in the lateral right lobe of the liver in July 1999, as seen at this level of the serial scans. The most anterior tumor mass had estimated maximum diameters of 2.75 X 3.75 cm. The most posterior mass was 3.75 cm. X 3.75 cm. An estimated of the circumference was 8 and 11 cm respectively.



Slides 47

Serial cuts of the liver had shown 8 metastatic masses in 1999 at this level, but in July 2000 only 4 could be detected. The same presumed most anterior mass was now 3.0 cm X 1.5 cm, and the posterior mass was 2.5 cm X 3 cm. The estimated circumference of the two lesions were 4 and 6 cm. The reduction in this measurement again approached 50%. Because of a reduction in pain the patient stated that she was totally off narcotics in July of 2000 and had only required Tylenol II for two months to maintain an acceptable level of comfort.

Slides 48

Note that in the preamble to the Dietary Supplement Health and Education Act of 1994 that it is stated that science has shown a direct relationship between nutrition and health. The act goes even further to state that many chronic diseases can be prevented by nutrition and implies that restoration of health is supported by optimal nutrition. Only time will tell when the definitive studies can be conducted in a rigid scientific manner, whether the promise of dietary supplementation made widely available by this legislation will contribute significantly to the quality of health, while hopefully reducing health care costs.

Slides 49

One may be tempted to believe that the importance of nutrition and the role played by the newly recognized nutraceutical-containing dietary supplements is new science. Nothing could be further from the truth. Consider the words of those who have gone before us, giants in medical science.

Slide 50

One can only trust that the recipient of this knowledge recognizes the knowledge found in past words of wisdom. The discussion has been about lost ancient knowledge and not faddish, temporary style, or revolutionary new information. Nutrition has been essential to optimal health and healing since the beginning of life. However, in this scientific age, one must also recognize the need for the evaluation process described in the interview with Dr. Strauss cited at the start of this presentation. At the current stage in development, nutraceutical dietary supplementation in health and disease must be considered in the early, "Frontier Medicine" stage. It is hoped the case has been constructed that indicates further investigations are warranted in regard to combining standard cancer treatment with dietary supplementation. It has been demonstrated that rational mechanisms of biochemistry and immunology may be responsible for the encouraging anecdotal case reports. It is believed that investigator and grant support for basic science and clinical studies is warranted. The next step will be to assemble a "best case series" for NCI review. If the evidence warrants further experimentation, pilot studies to examine potential efficacy in various types and stages of single malignant conditions and then progress on to more stringent studies, if such steps are justified by preliminary results.

PUBLIC LAW 103-417-OCT. 25, 1994 108 STAT. 4325

(a) Short Title.—This Act may be cited as the "Dietary Supplement Health and Education Act of 1994".

Congress finds that—

- (1) improving the health status of US citizens ranks at the top of the national priorities of the Federal Government;
- (2) the importance of nutrition and benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;
- (3) (A) there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease and osteoporosis....

Sources of Wisdom and Insight

Hippocrates
"Let your food be your medicine and your medicine your food."

Paracelsus
"All that man needs for health and healing has been provided by God in Nature; the challenge of science is to find it."

Roger Williams, PhD
"The body heals itself and nutrition provides the resources to accomplish the task."
Nutrition Against Disease, pub. 1971.

The National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health

How to develop and evaluate alternative modalities?
Guided by anecdotal reports

1. Small preliminary studies designed to investigate potential benefits
2. Embark on larger studies, if indicated
3. Move to competent scientific studies

This program is "Frontier Medicine Research"

JAMA Feb. 23, 2000

The information that has been imparted is simple and in harmony with the processes and laws of nature that govern cellular biochemistry. It is believed that the promise of the DSHA and Center for Alternative and Complementary Medicine established by representative government will be fulfilled through use of nutraceutical containing dietary supplements that provide micro-nutrients no longer abundant in the modern urban food chain. Better health and more economical management of compromised health should be a reality through application of this knowledge.

Thank you for your time, attention, and interest.

HRMCD June 6, 2000.

Discussion:

Daniel Nixon, M.D., Professor of Medicine in the Department of Experimental Oncology, Medical University of South Carolina. Professor of Experimental Oncology, Hollings Cancer Center. Principle Investigator on the American Health Foundation Cancer Center Core Grant.

Susan Lord, M.D., Director Graduate of Western Reserve University School of Medicine, diplomat of the American Board of Family Practice, acting director of the Center for Mind Body Medicine and active in Professional Training, International program of the CMBM, developing a curriculum for teaching nutrition to medical professionals.

The following discussion was transcribed from an audio-tape recorded at the conference.

Dr. Lord- I believe the basic premise for what he have heard is that nutrient molecules low or absent in the modern diet are being supplied as dietary supplements. The supply of these molecules is important because molecules are used in cellular synthesis necessary for the integrity of cell-to-cell relationships and cell-to-cell communication. The communication is to convey information by way of complex molecules to operate the physiology of defense, repair, healing, intracellular/extracellular environment balance, regulation, and specifically in these presentations anticancer activity. That is why so many good clinical responses are possible through improved nutrition, even beyond cancer.

Dr. Nixon- This is a lot of material to absorb in a short period. I have an immediate question. What did you have the last two pancreatic cancer patients adding to their diets?

Dr. McDaniel- I was not in communication with these patients. They managed their own dietary supplementation and contacted me after their good fortune. I can claim no credit for the management of these patients or such benefits. I feel confident, based on many prior conversations with such patients, that the choice and amount varied greatly from day to day in what they consumed. However, for seriously ill patients we usually suggest that they add to their diet no less than 2 teaspoons, 3 times a day of the bulk glyconutrients that contains multiple saccharides. We suggest 1/2 to 1 teaspoon, 3 times a day the vegetable and fruit powder with the many free radical scavengers and antioxidant molecules of phytochemical origin. For endocrine nutritional support we suggest 1 to 2 tablets of the dioscorea plant sterol extract 3 times a day with vitamins and minerals. The oncology nurse with pancreatic cancer increased her glyconutrients until 6 tablespoons were taken each day. The range of intake people find necessary for benefit varies very widely. These dietary micro-nutrients provide molecules required in normal cellular synthesis that are used for establishing normal structure and function within the human body. These dietary supplements support the body's physiology and are not designed to treat, cure, or ameliorate a disease and are distributed with these limitations under the provisions of the Dietary Supplement Health and Education Act of 1994.

Nixon- There was a broad mixture in both cases of nutrients being taken and it was not just aloe powder. This brings the subject of "whole foods" into our discussion. This seems to be important. Since you quoted the Bible, let me add that after the flood, we hear God inform Noah, "I saved all these creatures and now you can add meat to your diet." He had been mad at Man and maybe this was a little more punishment? That may be where modern man has gone wrong in food choices by adding too much fat with not enough exercise and too many calories that lead to obesity and the complications we are seeing in deterioration of health with age. It sounds like a wide mixture of whole foods were added to the diet and that may be important to health. You mentioned that these nutrient molecules have shape and charge and are

complex. Increasingly, the use of isolated, purified nutrients and micro-nutrients may not be the best way to go for good health. Is that what you are saying?

McDaniel- I believe that is a good way to put the position. Roger Williams, Ph.D., in his book, *Nutrition Against Disease* published in 1971, has one illustration in the book. It is of a chain on a table top and it curls around to about 1/2 of a full circle and one end rises above the table top in the center like a snake about to strike. He informs us that each link in the chain is a nutrient or element required for the state of good health and well being that is symbolized by the elevated end stuck up in the air. He then informs the reader that if any nutrient is missing it becomes the last critical link on the table-top. If it is missing, the chain falls and we lose good health and well being. Dr. Williams goes further to state the chain is an example of how medicine has improperly looked at nutrition in research and in general found little evidence for the power of nutrition to support and restore health. The scientific model is to purify, isolate, and test a single substance, drug or nutrient, on the assumption that all else is equal in the research population's biochemistry. All the chain lengths, representing nutrients, are required for optimal health and healing. Your term "whole foods" is similar to this concept of supplying many natural nutrients, those known and unknown, and may be important in these cancer patients' responses. Our work and the growing literature supports a thesis that there are vitally important micro-nutrients that are not on the standard food pyramid we are all taught. Whole foods may supply more of these micro-nutrients that will be identified and their role defined in the future.

Nixon- I now want to address where you should go from here:

1. Glycoproteins have been recognized and studied for over a century. I recall seromucoid of Remington was discovered in cancer patient's serum in the 1920s. This material is immunosuppressive and it like other cancer cell produced compounds reduce the body's natural mechanisms to detect and destroy cancer cells. CEA is another glycoprotein along with others that may protect the cancer cells from defense mechanisms designed to destroy cancer cells before we have a detectable mass. It is generally accepted that we make cancer cells everyday and they are destroyed if the defense systems are working. It may be that supplying these saccharides and increasing the synthesis of cytokines, that was quite interesting data, may some how reverse the protection the cancer cell produced glycoproteins that provide possibly a coating over the membranes of the tumor and allow the cancer mass to grow undetected by normal defense mechanisms. I believe this can be tested in animals and should be done. What do you think?

McDaniel- I believe what you have described is an established fact. Macrophage inhibitory wandering factor produced by cancer cells is a well-established fact. This glycoprotein can be removed from essentially paralyzed leukocytes from a cancer patient and transferred to normal wandering leukocytes of a cancer-free patient and the normal functioning cells become unable to wander. This is believed to be a method to

protect cancer cells from detection and destruction. Cohen from NYU has spent a major portion of his life studying adeno virus mechanisms of infection and virulence. The adeno virus pirated cell sets up a series of defense mechanisms to prevent the defense systems from detecting that the virus had taken over the synthetic organelles of an infected cell. Viruses use a biochemical stealth mechanism to block the immune system's ability to destroy the virus-containing cell. In molecular biology, natural methods to block immune defenses are similar whether one looks at cancers blocking the defensive attack system or chronic viral tolerance.

Nixon- 2. The proper dose range is needed or an estimate of where to start is needed and must be determined.

3. You need to give these nutrients substances and determine the absorption levels, especially for the sugars. You need to know if normal volunteers and cancer patients have the same absorption levels.

McDaniel- The amount required for an activation of the anticancer activity varies at extreme levels. We have found a good place to start seems to be 2 tbs. bulk glyconutrients 3 times a day, 1/2 to 1 tbs. bulk fruit and vegetable phytochemicals 3 times a day, 1 or 2 tablets of the plant sterols 3 times a day, and one of the vitamins and minerals in the natural organic matrix 3 times a day. Many respond well on less and some take more. The oncology nurse in the final set of patients took up to 6 tablespoons a day of the glyconutrients alone.

Nixon- 4. The phenomenon of apoptosis, programmed cell death, needs to be evaluated for the influence of these nutrients. Cancer cells do not cycle and die right. Does this have an impact of apoptosis? That is a question worth of your attention. I believe you have a good shot at a NCI grant. They are always looking for innovative new ideas that need to be tested and you have a good basis for this approach. You are progressing in the right direction and I have just added a few details that those in cancer research are considering and will want to know how these molecules impact these

parameters involved in the process of cells becoming malignant and continuing to grow. You mentioned lycopene. It should be known that these are complex molecules and mixtures of molecules as they occur in nature or whole food. You may be able to construct a more effective mixture of these plant extracts if and when you know more about just what is in the food and what is producing the beneficial effect. You should look at less advanced cancer patients. Some that you have presented, it is asking too much to expect much benefit. Is there an effect in pre-malignant lesions?

McDaniel- We have seen anecdotal cases of reversal of tobacco induced leukoplakia in the mouth. Solar keratosis reversed due to sun damage in patients with histories of multiple skin cancers that have been removed. In women with abnormal pap smear, especially with HPV-induced dysplastic changes, the abnormal cells and even proliferating polyps reversed and eliminated. I want to add that I was taken aback to find with your positions and academic standing that you had been experimenting with raspberries in cancer patients. That does not make looking at aloe sound so wild or off the wall as peers have regarded my activity.

Nixon- Those are potentially important findings that need to be documented and moved beyond anecdotal report in regard to the early process of the development of malignant cells.

McDaniel- Thank you for your constructive suggestions. I believe the benefits of nutrition are as old as life and being a truth, it cannot be lost or suppressed forever. This knowledge is coming into its time and place in this modern era. The job of establishing more science and education lies before us. This must be done before the improvements in cancer treatment suggested by Dr. Hyland's 100 cancer patients who added dietary supplement to their diet, presented a year ago at this conference, can be realized in this world of great need as it is experienced by cancer patients, their families and friends.

Comprehensive Cancer Care 2000

Conference Sponsors: National Center for Alternative and Complementary Medicine of the NIH, National Cancer Institute, University of Texas HSC, Houston, Texas Center for Mind-Body Medicine. Hyatt Regency Crystal City, Arlington, Virginia, June 6, 2000

Abstract :

IS THERE A ROLE FOR DIETARY SUPPLEMENTATION IN STANDARD CANCER TREATMENT?

H. Reg McDaniel, M.D., Fisher Institute for Medical Research, Grand Prairie, Texas.

This scientific conference is regarded as an appropriate forum to review alternative ideas in cancer management to determine if there is a basis for further development. A challenge confronts participants of this forum. Each individual is presented with new vistas in intellectual pursuits that may one day be transformed into science through the experimental process. This activity constitutes a gauntlet to overcome due to the human proclivity to reject the new and unknown. Medical tradition expands this trait to limit revisionist thought and actions, maintain a revered status for fixed-orthodoxy, to have contempt for new diagnostic or therapeutic modalities, and to reject peers who venture into uncharted territory. This presentation is not represented to be formal science or designed to establish public policy or serve as a guide for professional recommendations or practice. Two series of anecdotal cases are presented. Set A contains extended survival of cases unresponsive to standard therapy or judged terminal in the mid-80s. Current cases in set B are pancreatic cancer patients with inoperable complications that are over 2 years post-diagnosis. Experiments that provide a scientific rationale for the clinical benefits observed include: the supply of glyconutrients to mixed-leukocyte cultures increases the synthesis of cytokines: (IL-1, IL-2, IL-6, TNF, GM-CSF, & g-interferon), on a dose-response basis (Marshall 1993). Similar cell cultures demonstrated an increase in NK lymphocyte 4-hour cytotoxicity of target cells on a glyconutrient concentration basis (Marshall 1993). Murine Norman sarcoma 100% fatality was reduced to 33% by a bi-weekly IP injection of glyconutrients (Campbell 1997). Feline leukemia had a 75% increase in expected survival and became negative for salivary and serum antigen following the receipt of glyconutrients (Sheets 1991). A medical researcher with lingual squamous carcinoma and an initial NK cell cytotoxicity ranging from 250 to 500 units rose to in excess of 80,500 units ($N > 40,000$) by the addition of a glyconutrient dietary supplement to his diet. No return of the cancer has occurred in 2 years. Anecdotal reports have been received and a series of 100 patients (Hyland 1999) were presented by an oncologist reporting a clinical impression that patients' malignant cells have an increased susceptibility to radiation or cytotoxic chemotherapy, while normal cells are protected from free-radical and reactive oxygen species damage. Protection was most noted in bone marrow elements. To explore this phenomenon, liver cells were scanned by a Meridian Cell Analyzer after the addition of 50 ug/dL of glyconutrient that resulted in a 50% increase in intracellular reduced-glutathione in 300 sec. This increase in intracellular oxidative stress protection combined with the biochemical activity of normal cells in the G1 and malignant cells in the S1 cell-cycle phase provides a plausible molecular mechanism for the clinically beneficial differential effects observed (Stockdale 1987). It is concluded that further investigation of the role dietary supplementation may provide in combination with standard medical treatment is warranted.

Provided by the Fisher Institute for Medical Research, P.O. Box 530689, Grand Prairie, Texas 75053 Email: helen@fisheri.org (972) 660-3219 FAX: (972) 660-1245

A PILOT SURVEY: STANDARD CANCER THERAPY COMBINED WITH NUTRACEUTICAL DIETARY SUPPLEMENTATION IMPROVES TREATMENT RESPONSES AND PATIENT QUALITY OF LIFE

G. Hyland, M.D., D. Miller, M.T., Medcenter One, Dept. Radiation Oncology, Bismarck, North Dakota

In thousands of cancer cases evaluated by H. Foster, 87% percent of those with "spontaneous remissions" had made major dietary changes prior to tumor regression. The Dietary Supplement Health Education Act of 1994 resulted in millions of US citizens adding a plethora of supplements to their diets. A favorable response by 5 patients that failed all cancer therapy was noted after treatment was stopped. We found that they had consumed glyconutrient, phytonutrient and phytogenin containing dietary supplements. A search revealed that Busbee et. al 1994 found a glyconutrient in these diet supplements increased IL-1, IL-6, INF and TNF production in monocyte cultures. See et. al 1999 reported enhanced NK lymphocyte cytolytic function in response to multiple glyconutrients. Barhomi et. al 1997 found glyconutrients increased intracellular reduced-glutathione protection 50% in liver cells. Such activity provides a potential differential effect for tumor cell destruction and normal cell protection. To increase our observations, patients with malignancies were solicited from a 3 state area and 127 volunteered to add nutraceuticals to their diet. 100 patients returned a quality of life survey focusing on weight loss, fatigue, nausea, vomiting, pain control, ability to complete treatments on schedule, physical activity and sense of well being. 40% of the group had failed standard therapy and were in a state of progressive disease. 60% were starting radiation or chemo-therapy. 85% reported improvements in the above clinical parameters. The phytogenin supplement contains plant sterols for nutrient based endocrine support. Ovarian, breast, uterine, and prostate malignancy patients were discouraged from taking this nutrient. Some elected to add the phytogenin to their diet and they reported the best preservation of appetite, muscle mass, and had the least side-effects during treatment. Patients with a diagnoses of ovarian carcinoma, astrocytoma grade IV, lymphoma with mild marrow suppression, a massive pelvic myxosarcoma, and colon adenocarcinoma with brain metastasis had unprecedented responses. Conclusions: Nutraceutical dietary supplements (1) do not inhibit tumor cell destruction by radiation and chemotherapy (2) enhance tumor cell destruction (3) protect normal cells from radiation and cytotoxic damage (4) induce reductions in tumor mass in malignancies resistant to all treatments (5) improve quality of life for patients by reducing treatment toxicity and side effects from radiation and chemotherapy. A formal, controlled clinical study is warranted to further evaluate the effects of nutraceutical dietary supplementation in combination with standard cancer therapy.



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**Glyconutrients Have a Long History of
Benefits in Cancer Patients that are Validated by
Modern Technology, Instrumentation, and Clinical Investigation**

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Glyconutrients Have a Long History of Benefits in Cancer Patients that are Validated by Modern Technology, Instrumentation, and Clinical Investigation

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ABSTRACT

War wounds in veterans that had febrile erysipelytic infections were reported to foster resolution of chronic osteomyelitis, non-union fractures, and cancer (H Fischer 1887). Prospective administration of bacterial products induced a febrile response and benefits for chronic disease including cancer, lymphomas, (P Bruns 1888) and sarcomas (W Coley 1892). Coley's Toxins were fractionated and lipopolysaccharide (LPS) was reported in mice to be the bioactive moiety in the above responses (MJ Shears 1943). Yeast cell wall LPS was found to be over 90% chains of mannose sugars that induced gamma interferon synthesis in monocytes (V Lackovic 1970). The bioactive component of aloe vera leaf gel used to promote health by humans for over 5,000 years was found to be chains of acetylated polymannose (APM) (A Eberendu 1988). APM induced a dose-response increase in innate antiviral and anticancer cytokine synthesis in mixed-leukocyte cultures assayed by ELISA (G Marshall 1993). These primed leukocytes added to the 4 hour NK-cytolytic assay caused release of Cr51 from pierced malignant cells proportional to the amount of APM supplied (G Marshall 1993). Norman sarcoma implanted mice with a history of resistance to any treatment modality when injected IP with APM destroyed all evidence of tumor in over 40% of subjects (D Busbee 1996). Cancer patients that had APM added to their diets while undergoing cancer therapy (n=100) were reported to have increased treatment efficacy and quality of life (G Hyland 1999). Intracellular reduced-glutathione synthesis was enhanced by APM (R Barhoumi 1997). This provides a basis for reduction of toxicity of radiation and cytotoxic agents. Molecular biology of gene mediated mechanisms for malignant cell surveillance and destruction will be presented that includes con-focal spectrometric microscopy and complementary nucleic acid array analysis to detect and quantify gene activation for synthesis of anticancer and antiviral cytokines. The Dietary Supplement Health & Education Act of 1994 led to patients with malignancies adding known glyconutrients to their diets while undergoing therapy. Former hospice cases will be presented that have no evidence of advanced metastatic disease for up to 19 years. Multiple pancreatic cancer and sarcoma cases that destroyed tumor mass and have extended survival will be presented. It is proposed that prospective clinical pilot studies are warranted.

OBJECTIVE

To improve the quality of life of patients undergoing standard radiation and cytotoxic chemotherapy through micronutrient dietary supplementation.

EXPERIMENTAL QUESTIONS

1. Is there a sufficient medical historical record to support the thesis that cell wall oligosaccharides (Glyconutrients) foster improvements in the response of the innate cancer defense mechanisms through dietary supplementation?
2. Do molecular biology assays provide a scientific rationale that supports clinical observations of an enhanced innate anti-cancer response by cancer patients who supplement their diet with plant source oligosaccharides?
3. Are there current responses to the use of dietary supplements taken in combination with standard cancer therapy sufficient to support a decision to conduct further investigations into the hypothesis that micronutrient dietary supplementation improves the quality of life during cancer therapy and enhances the response to such therapy?

HISTORY

In 1993, personal conversations with Helen Coley Nauts, daughter of William Coley, M.D., disclosed that, "In about 1885 a noted industrialist in New York City came to Dr. Coley and requested that he find a way to save the life of a dear friend with advanced breast cancer. Unlimited research funds were given to support research. The literature of Germany was surveyed and it was found that an orthopedic surgeon caring for elderly war veterans published that on occasion following a febrile reaction to cellulitis there was resolution of chronic osteomyelitis, non-union fractures, and oral cancer (P Burns 1888). Dr. Coley sampled post-surgical infected wounds at Sloan Kettering and grew mixed-bacterial cultures, boiled, filtered and injected the residue into cancer patients. A high febrile reaction occurred and some advanced cancer disappeared. Stromal sarcomas and Ewing sarcoma in children were the most responsive (W Coley 1892). The investigation of what came to be known as Coley's Toxins continued until Dr. Coley's death in 1936. He treated over 1000 malignancy-laden patients before his death. Mrs. Nauts searched for survivors of Dr. Coley's therapy and published cases of Ewing sarcoma and other cancers with poor survival rates. She found some that lived to an elderly age cancer free and stated that Dr. Coley was ridiculed, ignored, assailed, insulted, his papers were rejected for publication, the diagnosis of responding cases was reversed and his results rejected. Independent re-reviews of long term survivors decades later confirmed the initial malignant diagnosis, according to Helen Coley Nauts.

A team at NYU fractionated Coley's toxins and identified the bioactive moiety to be lipopolysaccharide (LPS) (JF Shears, et al 1943). When LPS was injected into mice, tumors underwent hemorrhagic necrosis, lethal bacteria were counteracted, and there was radiation protection from LD 100 dosing. Use of LPS was challenging due to the cardiotoxicity of the lipid A fraction.

Yeast cell wall LPS was shown to induce gamma interferon production in monocyte cultures using a plaque assay (V Lackovic, et al 1970). By systematically extracting the LPS, it was found that the functional LPS component was complex mannans comprised of over 90% mannose polymers with additional trace monosaccharides by use of paper chromatography.

In France during the 1980's various investigators used an ELISA assay for LPS induction of Interleukin 1 (IL1) in monocyte cultures (JM Cavaillon, et al 1986). Using highly specific enzymatic disassembly of the saccharide portion of LPS, the domain that triggers IL1 production is the monocyte receptor bound with di-keto,dioxy,manno-occulonic acid (KDO). The addition of saccharide side chains of increasing molecular weight increased the synthesis of IL-1 in a logarithmic manner. This provided a rationale for how the innate immune system is induced by the complex polymannose to destroy malignant cells and to boost general host defense.

A review article in 1985 described the intracellular assembly of complex glycoproteins and the fact that nine mannose sugars are polymerized into three coding chains on the ends of peptides in the endoplasmic reticulum (Kornfeld 1985). Thus, mannose from the aloe leaf is utilized in synthesizing general defensive cytokines, including those that are anti-cancer.

In 1980, a multi-specialty team was formed in Texas to determine why human beings have used aloe vera leaf gel since the dawn of recorded history. The bioactive moiety in the aloe leaf gel was found to be beta 1,4-linked polymannose (APM) (BH McAnalley, et al 1988). A component of the bioactive domain of LPS that is free of the toxic lipid is a complex polymannose. In cell cultures, with small and large animals and human volunteers, it was determined that APM as a dietary supplement or glyconutrient supports the biochemistry and innate physiology of host defense that is anti-viral, anti-neoplastic, and radiation protective. APM also supports colony growth factor synthesis and endogenous stem cell proliferation to foster healing and regeneration. The passage of the Dietary Supplement Health and Education Act of 1994 has made widespread public dietary use common and within a short time remarkable responses in advanced cancer cases were reported anecdotally, and a pilot evaluation of 100 cases was published (G Hyland 1999). Long term survival of former hospice cases and extended pancreatic cancer survivor cases with elucidation of the molecular mechanisms of abnormal cell destruction has been described (HR McDaniel 2000). This work continues in the collection and documentation of a "Best Case Series", examples of which are provided below.

MECHANISM OF ANTI-NEOPLASTIC ACTIVITY

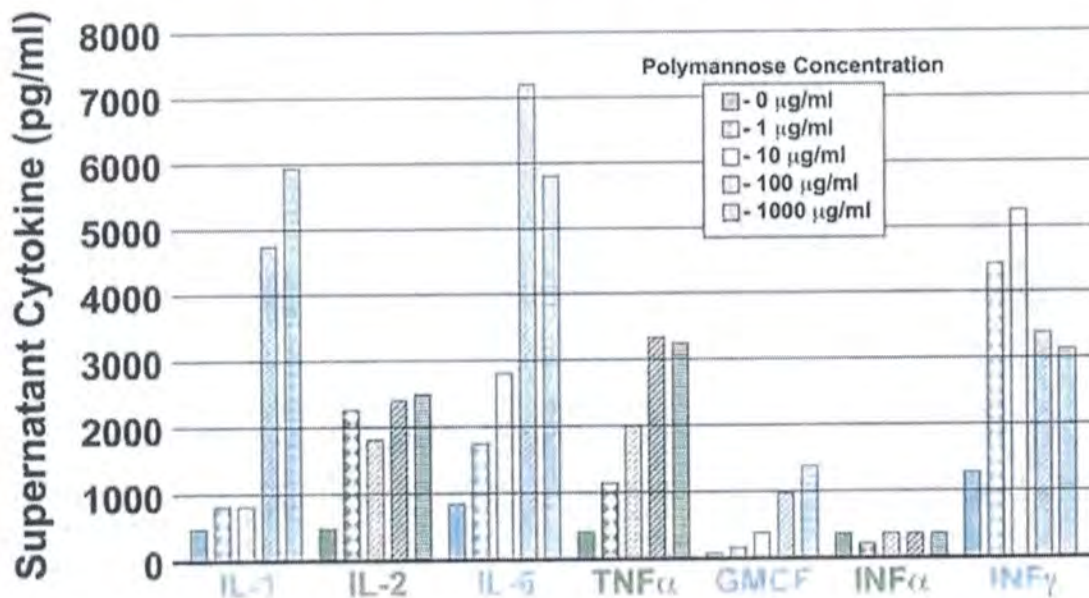
Multiple human cases reporting health restorations in hospice and terminal cases of malignancy were received from patients who consumed an aloe beverage in the 1980s. Adding a putative bioactive extract from aloe leaf gel to a cancer cell line produced cytolytic destruction of HeLa cells (J Measles 1988). This was followed by testing an aloe polysaccharide in a 100% fatal murine Norman sarcoma test cell line. No agent had ever altered the death rate. One IP injection of the aloe polysaccharide resulted in 40% survival of the animals (SY Peng, D Busbee 1991). Twice weekly injections produced a 65% survival and combined with surgery, 90% survived (D Busbee 1996). In parallel with these experiments the bioactive aloe polysaccharide (APM) was found to be >90% beta 1,4-linked mannose chains in polydispersed molecular weights.

Passage of the Dietary Supplement Health and Education Act of 1994 resulted in widespread usage of the aloe source of glyconutrient. Reports of restorations of health in advanced cancer cases greatly increased. Experiments were conducted to elucidate a scientific basis for how a glyconutrient micronutrient could be anti-neoplastic.

Mixed leukocyte cultures having an incremental increase in APM added to the medium were assayed by ELISA for anti-neoplastic cytokines following overnight growth. Anti-neoplastic cytokines, including Tumor Necrosis Factor (TNF), were quantified. (G Marshall 1993). See graph 1.

GRAPH I

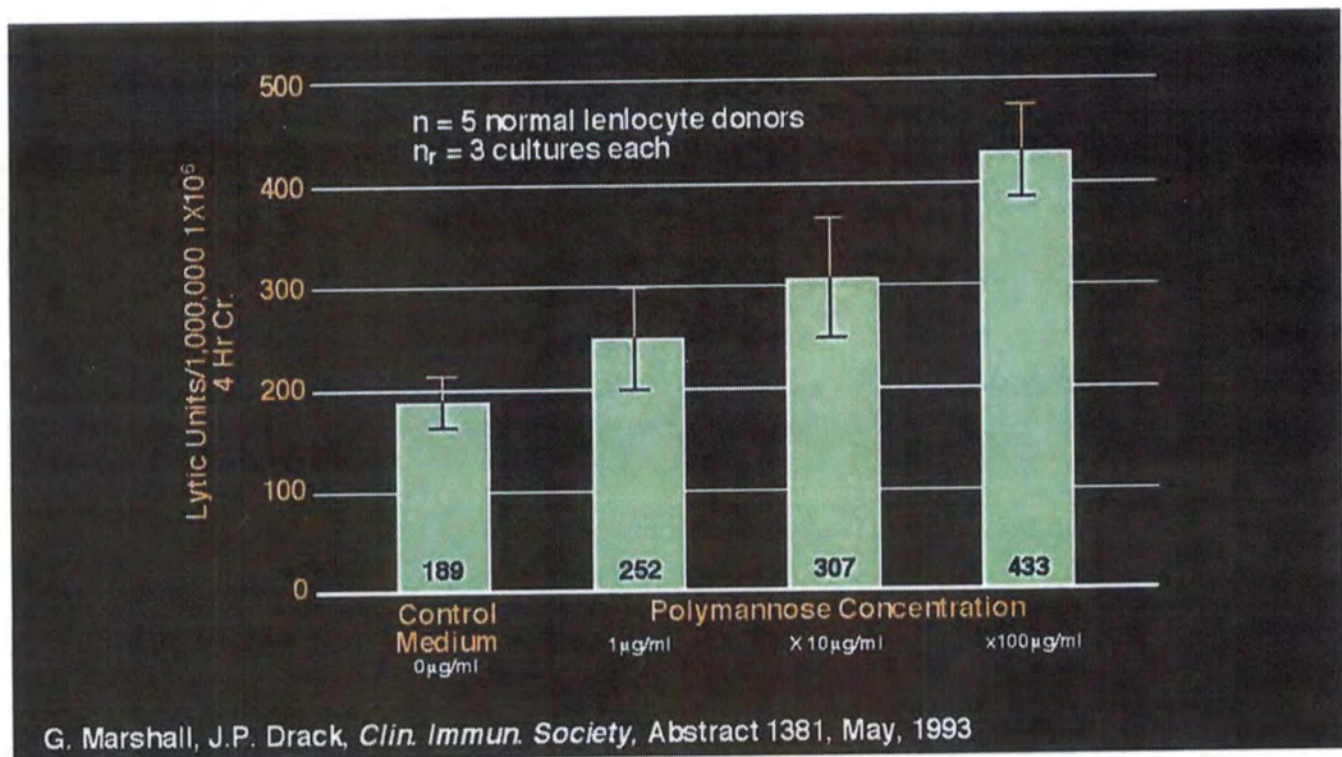
Cytokines Produced by Human PBMC After Culture with Polymannose Glyconutrient



G.Marshall, et al., Amer. Acad. Aller. Immuno., 1992

Interactions of defensive cytokines with leukocytes orchestrate the tumor cell surveillance system. Graph II demonstrates that Natural Killer cells (NK) respond to the increased synthesis of the anti-cancer cytokines (G Marshall 1993). NK cells from the prior cultures were put on Cr-51 loaded cancer cells. NK cells secrete perforin that cuts holes in the membrane of cancer cells and release Cr-51 into the medium that is counted in an isotope well-counter. The increased leakage of Cr-51 from dead cancer cell destruction follows a dose-response gradient as shown on Graph II.

GRAPH II In Vitro Effect of Polymannose on Human PBL in 4 Hour NK Cytolysis Functional Assay



The synthesis of anti-cancer cytokines follows the kinetics of the Michalis-Menten phenomenon. Thus by supplying cells micronutrients freeze-dried to a powder, one supplies components required for cytokine synthesis at a level never attainable in nature due to the volume of water and fiber in food. The importance of supplementing mannose sugar at high levels was made apparent by a paper in Annual Reviews of Biochemistry (R Kornfeld 1985). A medical investigator with squamous cell carcinoma on the base of the tongue with bilateral regional metastasis elected to use oral Glyconutrition instead of radical surgery, radiation, and chemotherapy. Survival without evidence of tumor is now in excess of 5 years. Information in this paragraph is available in the Cancer Syllabus produced for Comprehensive Cancer Care 2000 and is obtained from the Fisher Institute for Medical Research by e-mail: Helen@fisherinstitute.org, or on the web at www.fisherinstitute.org.

Chronic Lymphocytic Leukemia

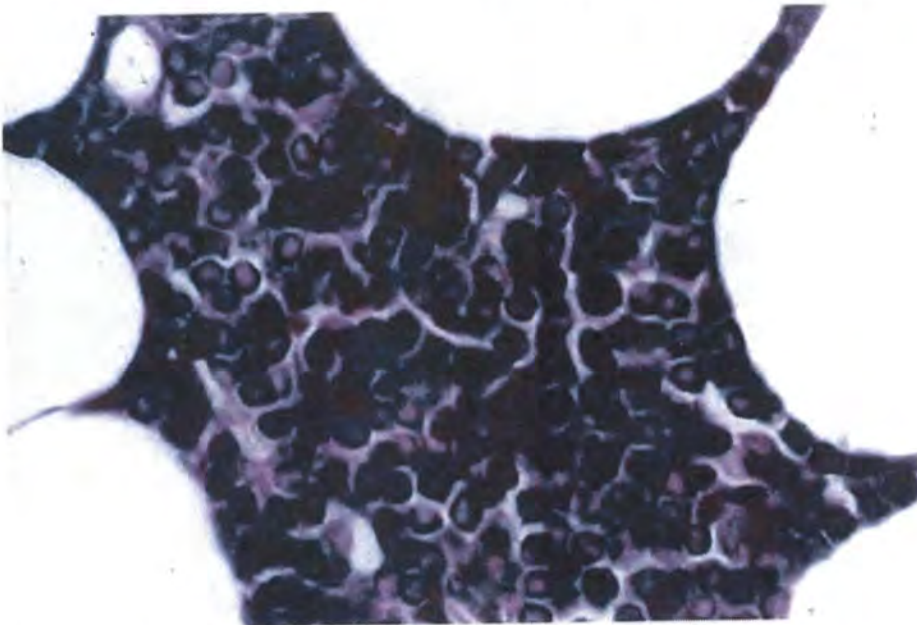
CASE # 3931 G. G. - DOB 9/10/22

In 1989 at the age of 66 there was the chief complaint of increasing fatigue over a 5 year period. History and physical examination was unremarkable. A complete blood count (CBC) disclosed: June 19, 1989

WBC	Hgb	Platelets	Segs	Bands	Lymphs	Monos	Eos	Indices
21,600	8.5	544,000	43	3	49	4	1	WNL

A bone marrow aspirate was conducted. The report was: "Hypercellular marrow with clusters of mature infiltrative lymphocyte sheets free of follicles (See plate 1). Diagnosis: Consistent with chronic lymphocytic leukemia." Peripheral smears contained mature small lymphocytes.

Plate 1 (500 X) A mature lymphocyte sheet with no additional elements



A consultant medical team recommended cytotoxic chemotherapy with aloe polymannose in view of the results being seen in cats with leukemia in a then ongoing study at Texas A&M School of Veterinary Medicine. In June 1990 the patient returned for an annual evaluation and reported a total restoration of energy and endurance with some mild arthritic complaints.

A CBC was performed: June 1990

WBC	Hgb	Platelets	Segs	Bands	Lymphs	Monos	Eos	Indices
9,600	12	411,000	73	0	20	6	0	WNL

At this time it was discovered that the patient, unknown to the physicians, elected to take only aloe polymannose. Her husband, a retired research biologist, and she chose to only do what was working in leukemic cats that had a 75% elimination of the feline leukemic virus antigen and normal CBC within 6 months of aloe polymannose intake (MA Sheets 1991).

June 1993

WBC	Hgb	Platelets	Segs	Bands	Lymphs	Monos	Eos	Indices
12,200	13	246,000	47	0	45	5	2	WNL

This 81 y/o patient continues to age gracefully and in April 2003 is mentally alert, has osteoarthritis, atrial fibrillation with no evidence of blood abnormalities.

Non-Hodgkin's Lymphoma

CASE DFW-23578 M.A. - DOB 12/8/48

In December 1987 this 39 y/o HIV-1 positive architect had rapid onset of abdominal fullness and inability to close his pants or use his belt due to increase in girth. He had anorexia and rapid satiety. Physical exam disclosed an enlarged, painless liver. CBC and liver profile were normal. A CAT scan showed a markedly enlarged liver with over 20 masses. A needle biopsy contained sheets of lymphocytes consistent with non-Hodgkins lymphoma (See Plate 2). A standard CHOP protocol was instituted. The patient also added aloe polymannose to his diet and had virtually no toxic effects for his chemotherapy.

Plate 2 (500 X)

Thin needle aspirate of liver mass demonstrating clusters of lymphocytes typical of non-Hodgkin's lymphoma.

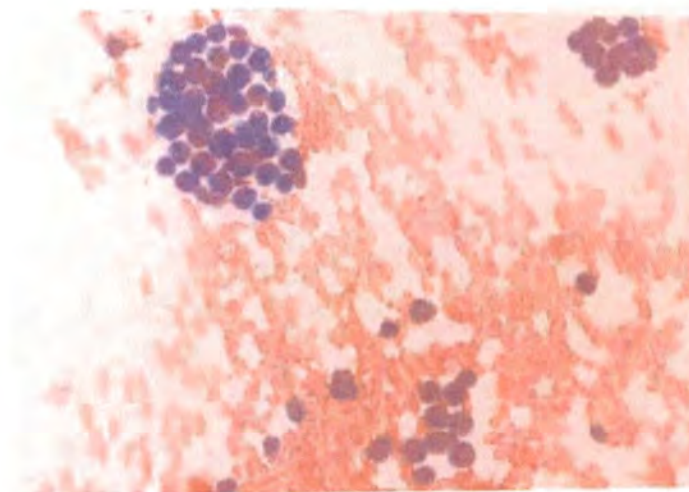


Plate 3 a cross-section of the liver on CAT scan.

April 1988

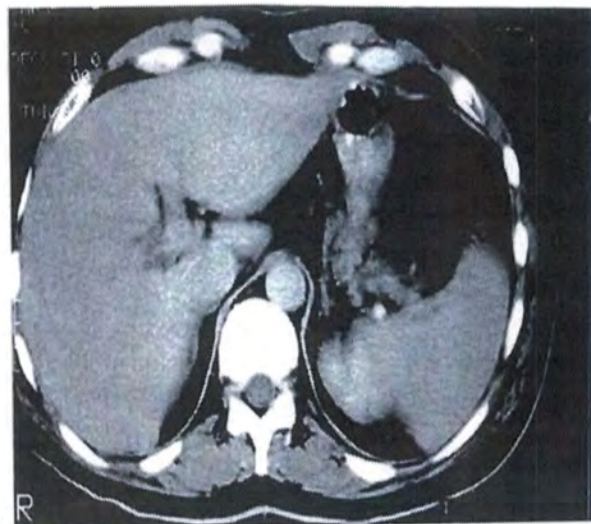


Plate 4 the scan 19 months later when special analytical software showed a normal liver in size and consistency.
November 1989

The patient developed cytomegalovirus retinitis in 1989 and was treated with ganciclovir resulting in life-threatening bone marrow suppression and liver toxicity. He recovered. However, due to progressive retinitis, foscarnet was given that induced severe liver, kidney and bone marrow damage. The patient died with overwhelming pneumonia in 1990. There was no evidence of lymphoma.

Adenocarcinoma of Rectum

CASE 88-83199 C. M. - DOB 10/15/39

In 1988, after two years of complaining of blood in stools she was properly examined and a polypoid, ulcerated lesion 40 X 30 X 15 mm was noted on the anal verge. An abdominal peritoneal resection was performed with a permanent colostomy. Distant lymph nodes were replaced with adenocarcinoma with one 15 mm node 14 cm above the lesion and 1 cm from the mesenteric surgical margin (See Plate 5). Tumor board prognosis was 6 months for recurrence and one to two years survival.

Plate 5 Pathologist's drawing of dissection with block key

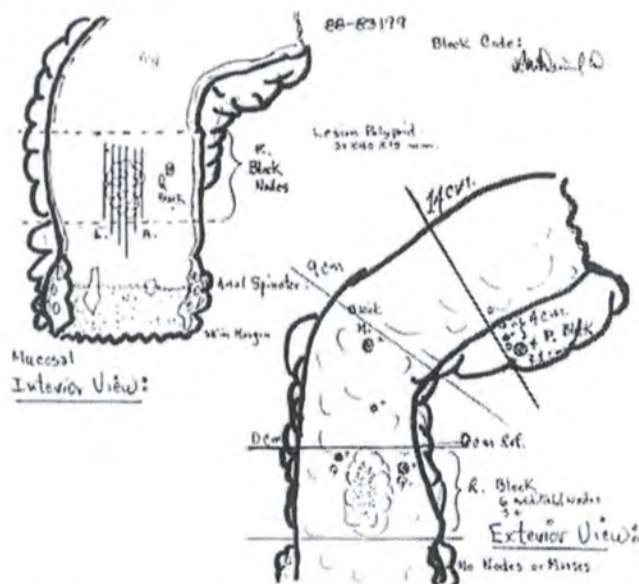
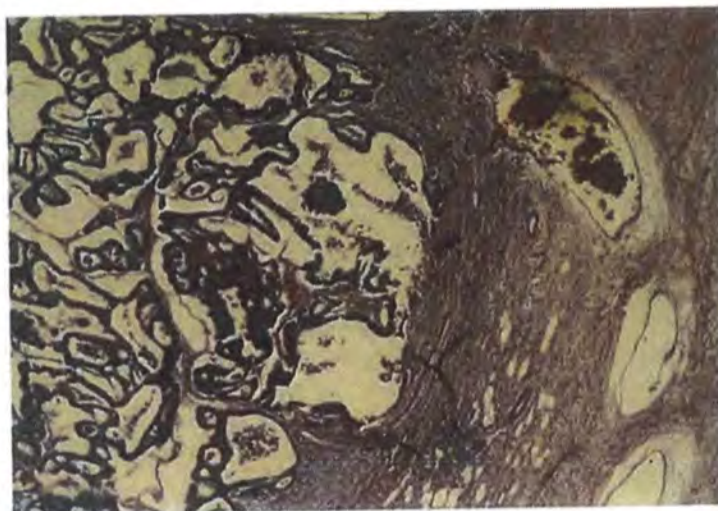


Plate 6 (100 X) Extensive local infiltration into surrounding rectal tissues beyond the bowel wall was present as shown and multiple distant lymph nodes were replaced with tumor.



The patient received weekly 5-FU infusions for 6 months and added 800 to 1000 mg/day aloe polymannose to her diet. She had virtually no side effects associated with chemotherapy.

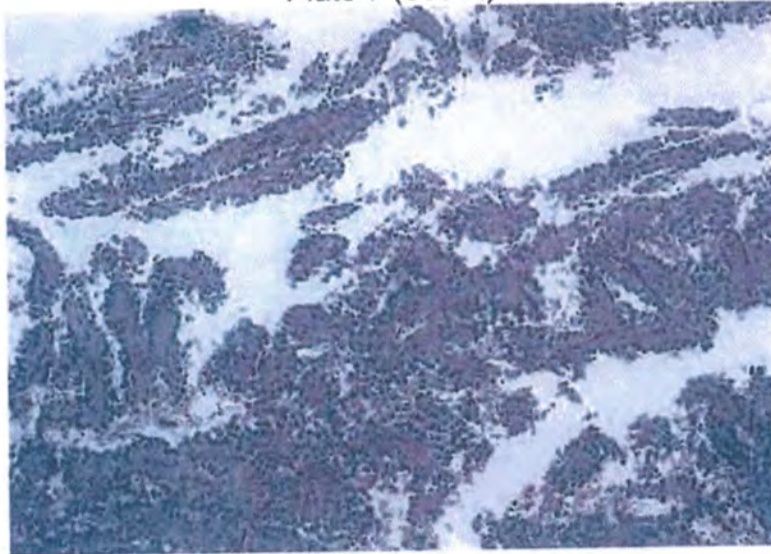
In April 2003 this 64 y/o female works part-time in a beauty shop and has no problems from the adenocarcinoma diagnosis and surgery performed 15 years ago.

Pancreatic Carcinoma (Case 1)

CASE JH #E005233374 - DOB 12/10/53

In July 1994 at the age of 39 this female oncology nurse had a chief complaint of abdominal pain radiating into the upper back. Failing therapy for pancreatitis, she had an MRI, and an 8 cm mass in the tail of the pancreas with multiple liver metastases was reported. A Whipple procedure with wedge liver resection of the discrete distant tumors was performed. The pathologic diagnosis was papillary adenocarcinoma (Plate 7).

Plate 7 (500 X)



In January 1995 a second wedge resection for 8.7 cm and 4.2 cm liver metastases was conducted. In July 1996 recurrent liver masses were noted on periodic scans, and in November 1997 vinyl alcohol embolism was performed. She became progressively debilitated and was put on hospice in pain, jaundiced with marked weight loss for her progressive disease. In the Fall of 1999 progressive amounts of micronutrient dietary supplementation consisting of glyconutrients, phyto-nutrients, and phytosterols was instituted. Plate 8 is the MRI in July 1999. Plate 9 is the MRI of July 2000. The patient was still alive and active in March 2003 with stable, non-progressive liver metastasis. She has been speaking for cancer support groups, churches, and professional groups. This oncology nurse continues taking micronutrients and refuses professional recommendations for combining the nutritional support with cytotoxic chemotherapy.

Plate 8 - July 1999



Plate 9 - July 2000

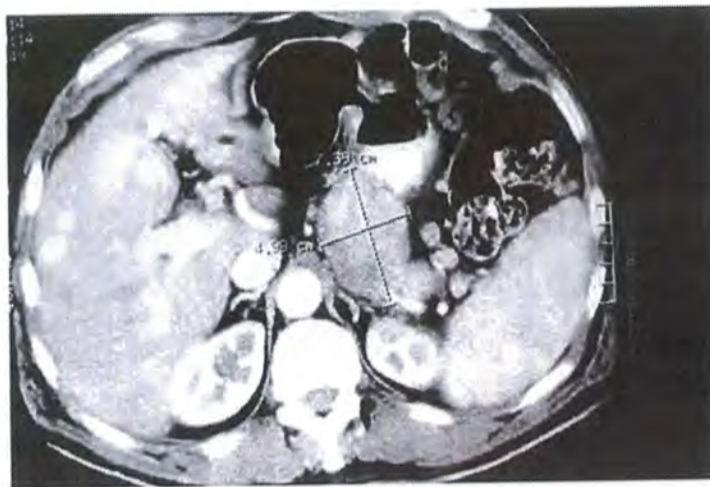


Pancreatic Carcinoma (Case 2)

CASE 10482444 K.S.T. - DOB 6/24/29

In the summer of 1999 this 70 year old male complained of abdominal pain and was conservatively treated for a small duodenal ulcer detected by an upper GI series. The pain progressed and weight loss exceeded 20 pounds by January 2000. He underwent a wide resection of a 1.8 cm mass in the tail of the pancreas detected by MRI that on pathological examination (SU-000608) disclosed a 5 X 7 cm. mass in the body of the organ that extended into peripancreatic tissues (See Plate 10).

Plate 10



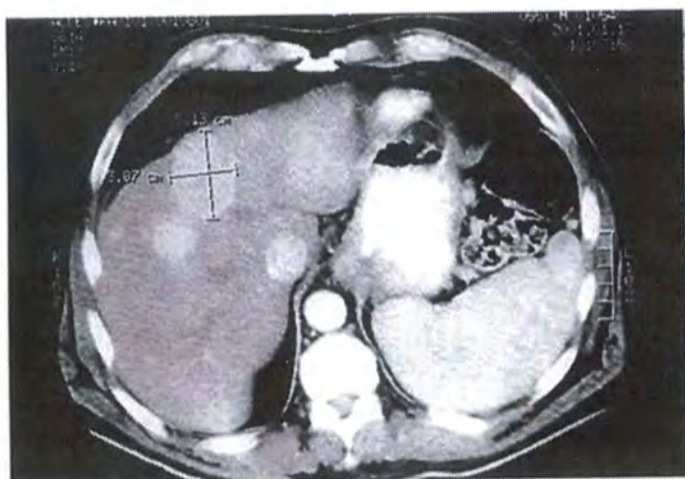
The spleen was clear, but perineural and lymphatic metastasis were demonstrated. The patient started on large amounts of micronutrients in combination with weekly Gemcitabine infusions in March 2000. At that time, severe pain led to scans showing extensive recurrent tumor 3 cm in diameter in the celiac plexus area, and the Ca 19-9 was 778 units. Chemotherapy was continued and in July 2000 no residual tumor was detected and the Ca 19-9 was 17 units while gaining 10 lbs. The patient continues to have Gemcitabine infusion every two weeks, takes micronutrients, is pain free, has a Ca 19-9 of 35, and no tumor is detected as of February 2003 three years after his initial diagnosis and surgery.

Pancreatic Cancer (Case 3)

CASE 8736660 L. D. - DOB 12/7/45

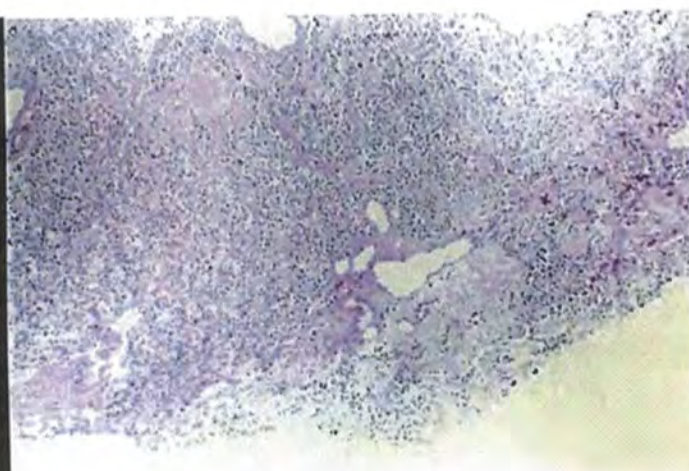
In July 2000 a diagnosis of "consistent with pancreatic cancer" was made by thin-needle biopsy of a liver mass (Plate 11) correlated with findings in MRI scans of the abdomen (Plate 12) demonstrating "a pancreatic mass with liver and lung masses." The patient elected to add micronutrient dietary supplements to his diet. He has regained lost weight, has no pain, and scans taken in February 2003 indicated "no change in size of liver masses." Ca 19-9 of April 2001 was 177 U/ml and in March 2003 80.5U/ml. The patient has refused a repeat needle biopsy due to his favorable health status. Dietary supplement use is being continued.

Plate 11



Original 2000 scan that was repeated in 2003 and read as "Stable, unchanged liver masses."

Plate 12



Magnification 100 X
Diagnosis: "Consistent with pancreatic cancer."

Summary:

For over a century evidence has accumulated indicating that cell wall complex polysaccharides comprised principally of mannose polymers support mechanisms of innate anti-cancer cellular physiology. Technology has only recently been available to demonstrate the molecular and cellular mechanisms of cancer cell destruction, concentrate bioactive oligosaccharides, and assemble pilot patient responses.

Conclusions:

1. Basic science experiments in cell cultures, animals and human subjects indicate that complex glyconutrients supplied for cellular synthesis by supplementation supports up-regulation of innate cancer cell destruction (D Busbee, et. al. 1996).
2. Anecdotal case responses in advanced and non-responding types of malignancy provide evidence of potential efficacy when glyconutrients are added to the diet during standard cancer therapy (H McDaniel 2000).
3. A small clinical pilot study in 100 patients provided micronutrient dietary supplementation (primarily glyconutrients) while undergoing standard protocol radiation and chemotherapy indicated (G Hyland 1999):
 - A. Chemotherapy and radiation therapy were not neutralized.
 - B. Tumor was destroyed more rapidly and completely by radiation and chemotherapy.
 - C. There was protection of normal cells near tumor, bone marrow, liver, kidney & stem cells.
 - D. Sarcomas and resistant tumors responded to standard therapy and micronutrients.
 - E. Quality of life during standard therapy was improved in all patients in that vomiting, nausea, anorexia, fatigue, mucositis, and bone marrow element damage was reduced.
4. Prospective clinical pilot studies conducted on a progressive intake for benefit efficacy are warranted.

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The Influence of Micronutrients on Quality of Life When Combined with Standard Therapy Protocols for Aggressive and Advanced Malignancies

•

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The Influence of Micronutrients on Quality of Life When Combined with Standard Therapy Protocols for Aggressive and Advanced Malignancies

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NOVEMBER 17-19, 2004 NEW YORK, NY

ABSTRACT

In 1985 pilot studies using the bioactive extract from aloe leaf gel, polymannose (APM) was used in AIDS patients. Elevations of CD4 lymphocytes and reductions in HIV-1 viral load was noted (McDaniel 1988) in parallel with remissions of Kaposi's sarcoma and lymphoma tumor mass. This led to adding APM to the diet of advanced and hospice cancer patients that had failed standard treatment protocols. Tumor mass reduction and increase in quality of life was noted in 40 to 50% of patients (McDaniel 1990). The working hypothesis was that innate immune mechanisms that counter viral infections that integrate nucleic acid sequences into the genome have similar activity to detect and destroy cells with oncogenous mutations. It was recognized that 9 molecules of mannose-6PO₄ were required in the endoplasmic reticulum (Kornfeld 1985) to start synthesis of antiviral and anti-malignant cell cytokines. Michaelis-Menten substrate supply dynamics predict that synthesis of cytokines will be increased if the APM supply is increased (Murray 1990). In mixed-leukocyte cultures a dose-response gradient by ELISA assay for increased synthesis of γ -interferon, IL-1, IL-2, IL-6, and TNF was noted (Marshall 1993). A 4-hour incubation of cells from the previous experiment (NK assay) demonstrated a rising lysis gradient released by Cr 59 laden target malignant cells and herpes II-seeded cells that was proportional to the supply of APM provided leukocytes (Marshall 1993). Murine sarcoma 100% resistant to therapeutic modalities responded to a single APM injection by a 40% eradication of tumor cells. Bi-weekly administration raised survival to 65% and combined with surgical removal survival rose to 85-90% (Busbee 1996). A report of 100 miscellaneous anecdotal cases of various types of malignancy in which micronutrients were provided with standard protocols claimed an increase in quality of life during treatment, enhanced tumor mass reduction, protection of bone marrow and stem cells and responses in cell types resistant to standard therapy (Hyland 1999) have been noted.

The current report is a case series survey of human malignancies associated with short survivals that combined micronutrient dietary supplementation with standard therapy for malignancies. It is prepared for a "Best Case Series" Center for Complementary and Alternative Medicine cooperative NCI grant. For review, there will be 6 cases of pancreatic cancer with metastases that have an average survival of 82 months survival with a range of (48 - 140) months with 3 living; 4 astrocytoma Grade III-IV average survival of 73 months, ranging (20-117) with two living; 5 sarcomas averaging 94 months survival ranging (87-131) with 5 living; and 6 miscellaneous advanced recurrent malignancies with initial hospice status with an average survival of 178 months, ranging (94-263) months survival. While undergoing standard radiation or chemotherapy, there was a significant improvement in quality of life as indicated by less fatigue, pain, nausea, vomiting, bone marrow toxicity, mucositis, loss of appetite, weight loss, and hair loss. It is concluded that formal prospective studies with and without micronutrient dietary supplementation combined with standard treatment protocols for a comparison of quality of life, tumor mass impact, and survival is warranted.

BACKGROUND

IN 1985 EIGHT PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) REPORTED HEALTH IMPROVEMENTS THAT WERE ASSOCIATED WITH DRINKING A BEVERAGE PRODUCED FROM ALOE VERA LEAF GEL. PILOT STUDIES WERE CONDUCTED IN A TOTAL OF 55 PATIENTS UNDER A FDA EXEMPTION FOR HUMAN EXPERIMENTATION WITH IRB REVIEW (McDANIEL 1987,'88,'93) IN RESPONDING PATIENTS, CD4 LYMPHOCYTES ROSE AND VIRAL LOADS WERE REDUCED AS CLINICAL SIGNS AND SYMPTOMS IMPROVED AS WAS DETERMINED BY THE WALTER REED STAGING OF AIDS (REDFIELD 1984). AN ADDITIONAL CLINICAL PHENOMENON WAS NOTED. COMPLICATIONS OF THIS CHRONIC RETROVIRAL INFECTION IMPROVED OR WERE ELIMINATED. THIS INCLUDED THE DISAPPEARANCE OF KAPOSI'S SARCOMA AND LYMPH NODES ENLARGED BY LYMPHOMA. AN ANALYTICAL TEAM ISOLATED A FRACTION OF THE ALOE LEAF GEL THAT WAS DETERMINED TO BE β -1,4 ALOE POLYMANNOSE (EBERENDU 1988). MULTIPLE STRAINS OF VIRUS CHALLENGES CONDUCTED IN TISSUE CULTURE WITH THIS SUBSTANCE (McDANIEL 1988) AND ANIMALS (CARPENTER 1988, '89) WERE FOUND TO HAVE BROAD ANTIVIRAL AND GENERAL ANTI-INFECTIONOUS ACTIVITY WHILE ENHANCING THE DESTRUCTION OF MALIGNANT CELLS IN CULTURE AND IN ANIMALS (KING 1991, PENG 1991). ALSO, FELINE LEUKEMIA ANTIGENS CLEARED WITH CLINICAL AMELIORATION IN 75% OF ANIMALS WHEN THE POLYMANNOSE WAS ADDED TO THE DIET (SHEETS 1991). A RATIONAL MECHANISM OF ACTION WAS DEMONSTRATED IN THAT MIXED-LEUKOCYTE CULTURES INCREASED PRODUCTION OF CYTOKINES, γ INTERFERON, AND ESPECIALLY TUMOR NECROSIS FACTOR ON A CONCENTRATION GRADIENT BASIS (MARSHALL 1993). THIS WAS FOLLOWED BY COLLECTING 50 ELDERLY HOSPICE QUALIFIED TERMINAL CANCER PATIENTS WITH SIGNIFICANT TUMOR MASS AND ADDING AN EXTRACT OF THE ALOE LEAF GEL TO THEIR DIETS. APPROXIMATELY 50% SHOWED NO RESPONSE. 25% HAD REDUCTION OF TUMOR MASS OR GROWTH WAS ARRESTED. 25% CLEARED ALL EVIDENCE OF DETECTABLE TUMOR. FOUR SUCH ADVANCED PATIENTS ARE ALIVE AND TUMOR FREE OVER 15 YEARS LATER (McDANIEL 1993, 2004).

IN 1985, EFFORTS TO MAKE A PHARMACEUTICAL FROM β 1,4 ALOE POLYMANNOSE (APM) WERE INSTITUTED. PHASE I TOXICITY STUDIES, BOTH ACUTE AND CHRONIC IN ANIMALS AND HUMANS, DISCLOSED NO TOXICITY OR UNTOWARD SIDE EFFECTS. IN 1994 THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT (DSHEA) WAS PASSED BY THE U.S. CONGRESS. AFTER THE DSHEA LAW WAS PASSED, ATTEMPTS TO MAKE APM A PHARMACEUTICAL WERE ABANDONED. THE APM WAS MARKETED AS A DIETARY SUPPLEMENT DUE TO THE PASSAGE OF DSHEA. MILLIONS OF HUMAN/YEAR INTAKE OF THE PRODUCT HAS BEEN CONSUMED WITHOUT SIGNIFICANT TOXICITY OR UNTOWARD SIDE EFFECTS. SOON AN UNPARALLELED PROGRESSION OF BENEFITS WAS REPORTED BY THOSE THAT ADDED THE SUPPLEMENT TO THEIR DIETS. AMONG SUCH ANECDOTAL REPORTS FROM MANY REGIONS WERE PATIENTS AND ONCOLOGISTS THAT OBSERVED IMPROVEMENTS IN RESPONSE TO STANDARD RADIATION AND CYTOTOXIC THERAPY FOR MALIGNANCY. ALSO, QUALITY OF LIFE WAS ELEVATED WHILE UNDERGOING STANDARD CANCER TREATMENT PROTOCOLS AND RESPONSES TO STANDARD THERAPY WERE ENHANCED IN 100 SUBJECTS (HYLAND 1999).

BASIC SCIENCE AND CLINICAL PROGRESSION

ANECDOTAL RESPONSES OF AIDS PATIENTS IN 1984-85 LED TO CLAIMS THAT THEIR CONSUMPTION OF AN ALOE BEVERAGE RESULTED IN CLINICAL IMPROVEMENTS. AN ALCOHOL PRECIPITABLE FRACTION WAS EXTRACTED FROM THE ALOE LEAF GEL AND WAS TESTED OVER A WIDE RANGE OF POTENTIAL CLINICAL APPLICATIONS. PHASE I FDA TOXICITY STUDIES

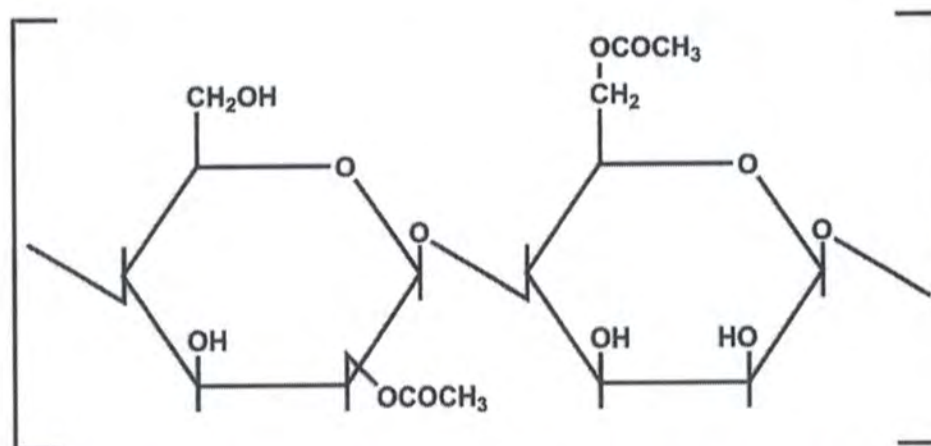
DEMONSTRATED VIRTUALLY NO TOXICITY (FOGELMAN [1, 2] 1992). FIFTY-FIVE AIDS PATIENTS WERE ORGANIZED INTO THREE PILOT STUDIES. THE WALTER REED STAGING OF AIDS IMPROVED 70% AT 90 DAYS (McDANIEL 1988). HIV-1 VIRAL LOADS WERE REDUCED AND CD4 LYMPHOCYTE LEVELS WERE PROGRESSIVELY ELEVATED AND SUSTAINED FOR UP TO 8 YEARS (McDANIEL 1993). TWO AIDS PATIENTS TAKING ORAL ALOE CONCENTRATE EXPERIENCED REDUCTIONS IN TUMOR MASSES FOR LYMPHOMA, AND MULTIPLE KAPOSI'S SARCOMA LESIONS WERE ELIMINATED (McDANIEL 1993).

PLATE A RESOLUTION OF A BIOPSY PROVEN KAPOSI'S SARCOMA IN A SYMPTOMATIC AIDS PATIENT PROVIDED POLYMANNOSE



THE PATIENT HAD MULTIPLE CUTANEOUS MALIGNANT VASCULAR TUMORS OVER THE BODY. OTHER KS LESIONS ALSO FADED AWAY WHEN A POLYMANNOSE BASED DIETARY SUPPLEMENT WAS TAKEN ORALLY AND A HYDROGEL CONTAINING THE BIOACTIVE POLYSACCHARIDE WAS APPLIED TOPICALLY.

PLATE B WHAT IS THE MOLECULAR STRUCTURE FOR THE IMMUNE SUPPORT PRINCIPLE SYNTHESIZED IN ALOE VERA LEAF GEL?



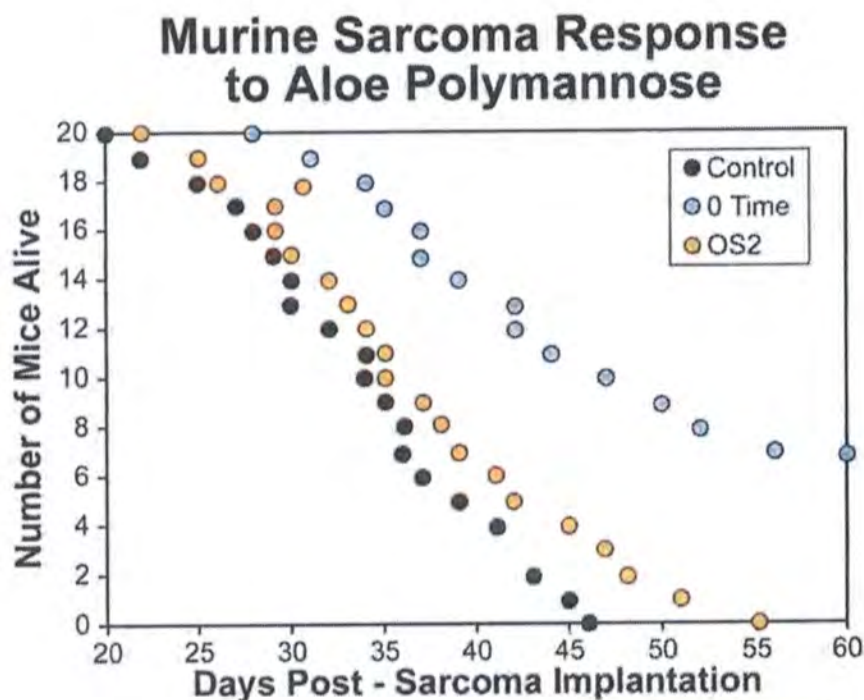
HPLC, MOLECULAR RESONANCE, INFRA-RED AND MASS, ULTRA-VIOLET SPECTROSCOPIC ANALYSIS COMBINED WITH ANALYTICAL DESTRUCTIVE THERMOGRAPHY WERE USED TO CHARACTERIZE β -(1,4) ACETYLATED POLYMANNOSE EXTRACTED FROM ALOE VERA LEAF GEL (SEE PLATE B) (EBERENDU 1988). POLY DISPERSED MOLECULAR WEIGHT CHAINS OF ACETYLATED MANNOSE SUGARS WERE IDENTIFIED THAT DEMONSTRATED A WIDE RANGE OF BENEFICIAL BIOACTIVITY IN CELL CULTURES (McDANIEL 1988), ANIMAL MODELS (CARPENTER 1988) AND HUMAN SUBJECTS WITH DISEASE (McDANIEL 1988, 1992,), (CLUMECK 1988), (PULSE

1990), (McMULLEN 1990), (RUEDY 1992), (THOMPSON 1993). IT IS BELIEVED THAT THE COMPLEX MANNOSE HAS THE STRUCTURE AND CONFIGURATION FOR THE ANTI-NEOPLASTIC ACTIVITY OF COLEY'S TOXINS FIRST IDENTIFIED AT SLOAN KETTERING (COLEY 1892). THE ACTIVE FRACTION WAS FOUND TO BE LIPOPOLYSACCHARIDE (LPS) (SHEARS 1943). IT IS PROPOSED THAT MANNOSE IS A CRITICAL PORTION OF THE IMMUNE SYSTEM, THE TRIGGERING PORTION OF LPS THAT BINDS IN THE MONOCYTE MEMBRANE DOMAIN TO TRIGGER SYNTHESIS OF ANTITUMOR AND ANTIVIRAL CYTOKINES, INCLUDING γ INTERFERON (LACKOVIC 1970), IL-1 (CAVAILLON 1985), AND IL-1, IL-2, IL-6, γ INF, TNF (MARSHALL 1993).

DOES ALOE POLYMANNANOSE SHOW ANTI-SARCOMA ACTIVITY IN A MURINE NEW DRUG SEARCH MODEL?

THIS COMPLEX SACCHARIDE FRACTION WAS USED TO CHALLENGE MURINE NORMAN SARCOMA INJECTED MICE. INJECTIONS OF THE PRESUMED ACTIVE INGREDIENT FROM THE ALOE GEL WERE DETERMINED TO BE COMPLEX HIGH MOLECULAR WEIGHT MANNOSE CHAINS. THE POLYMANNANOSE HAD PREVIOUSLY SHOWN ANTIVIRAL ACTIVITY IN VITRO FOR MULTIPLE ANIMAL AND HUMAN VIRUS STRAINS (McDANIEL 1988, CARPENTER 1989). THERE WAS A 100% DEATH RATE FOR CONTROLS IN NORMAN SARCOMA INJECTED MICE, AND A SINGLE IP INJECTION OF 30 MG/KG RESULTED IN A 40% SURVIVAL RATE (SEE GRAPH I). A BI-WEEKLY POLYMANNANOSE INJECTION PRODUCED A 65% SURVIVAL RATE WITH NO DETECTED TUMOR IN SURVIVING MICE (BUSBEE 1996).

GRAPH I



Advances in Anti-Aging Medicine, p. 197

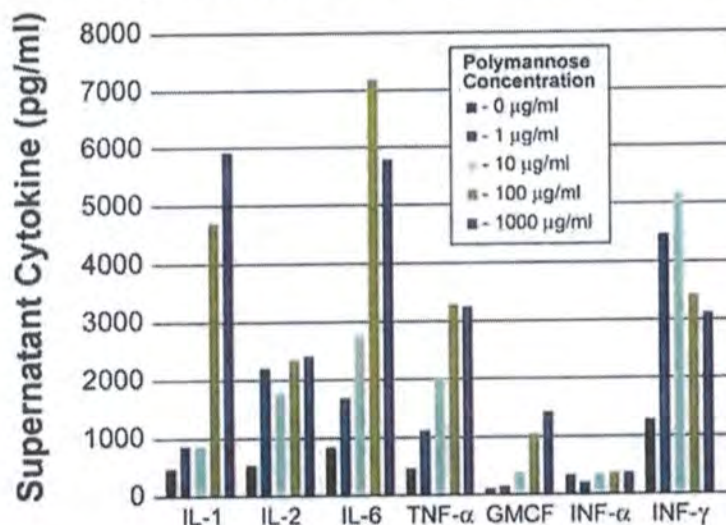
DOES THE SUPPLY OF POLYMANNOSE EMPACT CYTOKINE SYNTHESIS?

AN EFFORT WAS MADE TO DETERMINE THE NATURE OF THE OBSERVED ACTIVITY POLYMANNOSE HAD ON MALIGNANT CELLS. HUMAN MIXED-LEUKOCYTES WERE INCUBATED OVERNIGHT IN TRIPPLICATE CULTURES WITH A PROGRESSIVE GRADIENT OF POLYMANNOSE ADDED TO COMPLETE CULTURE MEDIUM FORTIFIED WITH FETAL BOVINE ALBUMIN. ELISA QUANTITATIVE ASSAYS FOR ANTI-VIRAL AND ANTI-MALIGNANT CYTOKINES WERE PERFORMED (MARSHALL 1992). THERE WAS A CONCENTRATION GRADIENT DEPENDENT INCREASE IN CYTOKINE PRODUCTION. (SEE GRAPH II) THE INCREASE IN BIOACTIVE CYTOKINE SYNTHESIS WOULD BE PREDICTED TO ENHANCE THE PHYSIOLOGY OF MALIGNANT CELL DETECTION AND DESTRUCTION.

GRAPH II

ENZYME-LINKED IMMUNOASSAY (ELISA) FOR LEUKOCYTE SYNTHESIZED CYTOKINES CULTURED IN A POLYMANNOSE GRADIENT

Cytokines Produced by Human PBMC After Culture with Polymannose Glyconutrient



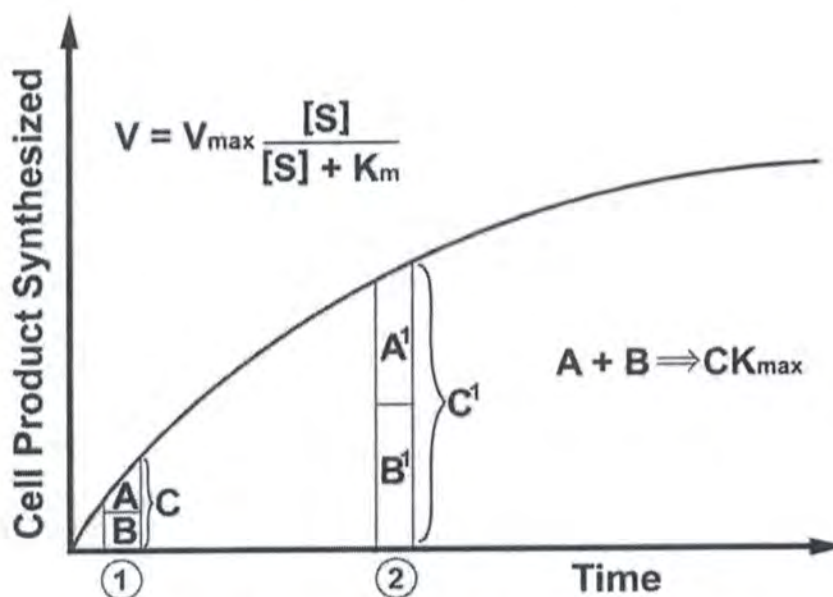
G. Marshall, et al., *Am J. Acad. Allergy Immunol.*, 1992

AN INCREASED SUPPLY OF MICRONUTRIENTS PREDICTS ENHANCED CELLULAR SYNTHESIS OF BIOACTIVE COMPOUNDS

THE PRODUCTION OF GENERAL DEFENSE AND HEALING CYTOKINES THAT CONTROL PHYSIOLOGY AND BIO-ACTIVITY FOLLOWS THE PRINCIPLES OF SUBSTRATE SUPPLY THAT INFLUENCES THE RATE OF CELLULAR SYNTHESIS. THIS IS KNOWN AS THE MICHAELIS-MENTEN PHENOMENON (SEE GRAPH III). THE DYNAMICS OF AN INCREASED SUPPLY OF CRITICAL MICRONUTRIENTS IS VITAL FOR GRASPING THE POWER OF HOW ENHANCED SYNTHESIS OF BIOACTIVE COMPOUNDS CAN SUPPORT IMPROVED PHYSIOLOGY. THIS IS FUNDAMENTAL FOR UNDERSTANDING WHY DIETARY SUPPLEMENTATION CAN IMPROVE HEALTH. AT THE HEART OF THIS ISSUE IS AN INCREASED SUPPLY OF THE CRITICAL MICRONUTRIENT, MANNOSE-6PO4, AS

EVIDENCED IN THE QUANTITATIVE ELISA ASSAYS OF CYTOKINES (GRAPH II). IT IS A RATIONAL BASIS FOR WHY VIRUS INFECTED CELLS AND MALIGNANT CELLS ARE DESTROYED (SEE GRAPH IV). THE ACTIVITY OF THE INNATE GENE-CONTROLLED MALIGNANT CELL RECOGNITION AND DESTRUCTION SURVAILLANCE SYSTEM IS ENHANCED AS INDICATED BY THE STEP-WISE INCREASE IN SYNTHESIS OF CYTOKINES REQUIRED TO INSTRUCT LEUKOCYTES TO ATTACK AND DESTROY ABNORMAL CELLS THAT MAY BE VIRUS BEARING OR MALIGNANT.

GRAPH III AN INCREASED SUPPLY OF NUTRIENTS INCREASES SYNTHESIS OF BIOACTIVE COMPOUNDS ACTIVE IN TUMOR CELL DESTRUCTION



- 1 - Availability in nature due to water and fiber content
- 2 - Substrate supply in freeze-dried and extracted supplements

IT SHOULD BE RECOGNIZED THAT ALOE GEL, AS IT IS PRODUCED IN THE PLANT LEAF, IS 98.5 % WATER, AND THIS IS NOT UNLIKE MANY SOURCES OF NUTRIENTS, AS THEY OCCUR VERY DILUTE IN NATURE SUSPENDED IN A MIXTURE OF WATER AND INSOLUBLE FIBER (SEE CONDITIONS A GRAPH III). THIS PLOT IS VITAL TO UNDERSTAND, FOR IT DEMONSTRATES THE SIGNIFICANCE AND POWER OF DIETARY SUPPLEMENTATION IN ITS ROLE TO SUPPORT OPTIMAL HEALTH. BY DEHYDRATION, NUTRIENTS ARE CONCENTRATED. THIS GREATLY REDUCES THE FOOD VOLUME, AND THE ORAL INTAKE CAN BE GREATLY INCREASED. THE AVAILABLE SUPPLY OF THE CRITICAL MICRONUTRIENT MANNOSE TO THE CELLS CAN BE GREATLY INCREASED. THEREFORE, THE RATE OF BIOACTIVE MOLECULE SYTHESIS CAN BE INCREASED, AS SHOWN BY THE RED LINE, AND THERE BECOMES THE POTENTIAL FOR AN ENHANCEMENT OF THE PHYSIOLOGY OF TUMOR CELL AND VIRUS INFECTED CELL DESTRUCTION. PLATE C DISPLAYS WHY MANNOSE IS A CRITICAL MICRONUTRIENT IN CELLULAR SYNTHESIS.

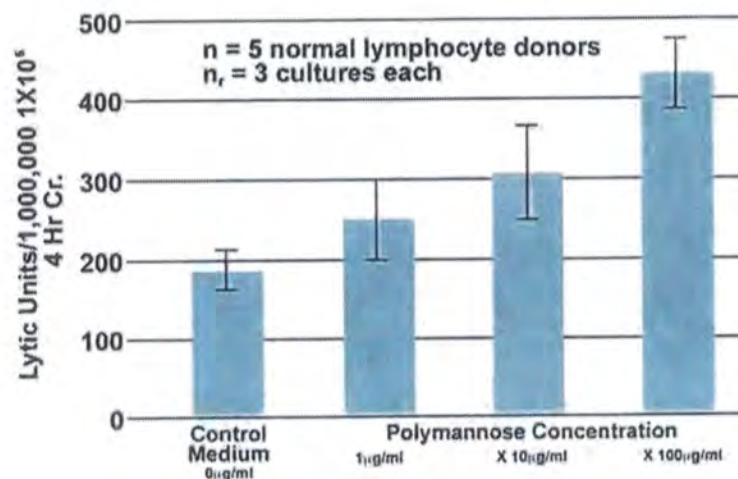
IS MALIGNANT CELL DESTRUCTION INCREASED BY INCREASING THE SUPPLY OF POLYMANNOSE?

THE NATURAL KILLER CELL (NK) CYTOSIS ASSAY IS A FUNCTIONAL TEST FOR MEASURING DESTRUCTION OF VIRUS LADEN CELLS OR MALIGNANT CELLS. THIS IS A PHYSIOLOGICAL MEANS THAT INNATE DEFENSE MECHANISMS DESTROY SUCH PATHOLOGICAL CELLS. MIXED PERIPHERAL LEUKOCYTES WERE INCUBATED WITH TARGET MALIGNANT CELLS OR VIRUS

INNOCULATED CELLS LOADED WITH AN INTRACELLULAR RADIO ISOTOPE MARKER CHROMIUM-51. THE TARGET CELLS CONTAINING THE ISOTOPE ARE WASHED FREE OF ANY EXTRACELLULAR CR-51. THE ISOTOPE LOADED CELLS ARE SEEDING WITH THE MIXED-LEUKOCYTES FROM THE PREVIOUS EXPERIMENT (GRAPH II) THAT WERE CULTURED WITH AN INCREASING CONCENTRATION OF POLYMANNOSE. THIS IS TO DETERMINE IF RECOGNITION AND DESTRUCTION OF THE MALIGNANT AND VIRUS LOADED CELLS IS CARRIED OUT AS THE INCREMENTAL INCREASED CYTOKINE PRODUCTION WOULD PREDICT. THE STEP-WISE INCREASED RELEASE OF CR-51 IS PLOTTED BY THE BAR GRAPHS (GRAPH IV). A PROGRESSIVE INCREASE IN NK CELL ACTIVITY IS SHOWN AS ATTACK, DESTRUCTION, RECOGNITION, AND RELEASE OF THE PROTEOLYTIC ENZYME PERFORIN. LYSIS HOLES IN THE ABNORMAL CELLS TO DESTROY THEM IS DEMONSTRATED BY THE PROGRESSIVE LEAKAGE OF CR51 FROM THE TARGET CELLS. THIS PROVIDES A RATIONAL BASIS FOR THE ANECDOTAL REPORTS OF PATIENT BENEFITS THAT INCLUDE LYMPHOMA AND SARCOMA REGRESSION OBSERVED IN AIDS PATIENTS, ASSOCIATED BY A REDUCTION IN HIV-1 VIRAL LOADS, AND DESTRUCTION OF MURINE NORMAN SARCOMA IN A SIGNIFICANT NUMBER OF MICE INJECTED WITH POLYMANNOSE. THE AMELIORATIVE ANTIVIRAL AND ANTI-MALIGNANT CELL IMPACT OF VIRTUALLY NONTOXIC POLYMANNOSE IN TISSUE CULTURE WAS REPORTED (CARPENTER 1989, KAHN 1991, MERRIAM 1996). CLINICAL EVIDENCE COMPATIBLE WITH THIS PHENOMENON HAS BEEN REPORTED IN ANIMALS (SHEETS 1991, PENG 1991, HARRIS 1991, KING 1991, YATES 1992) AND ADVANCED HUMAN MALIGNANCY (HYLAND 1999, McDANIEL 2000, 2003).

GRAPH IV

***In Vitro* Effect of Polymannose on PBMC After Culture with Polymannose Glyconutrient**



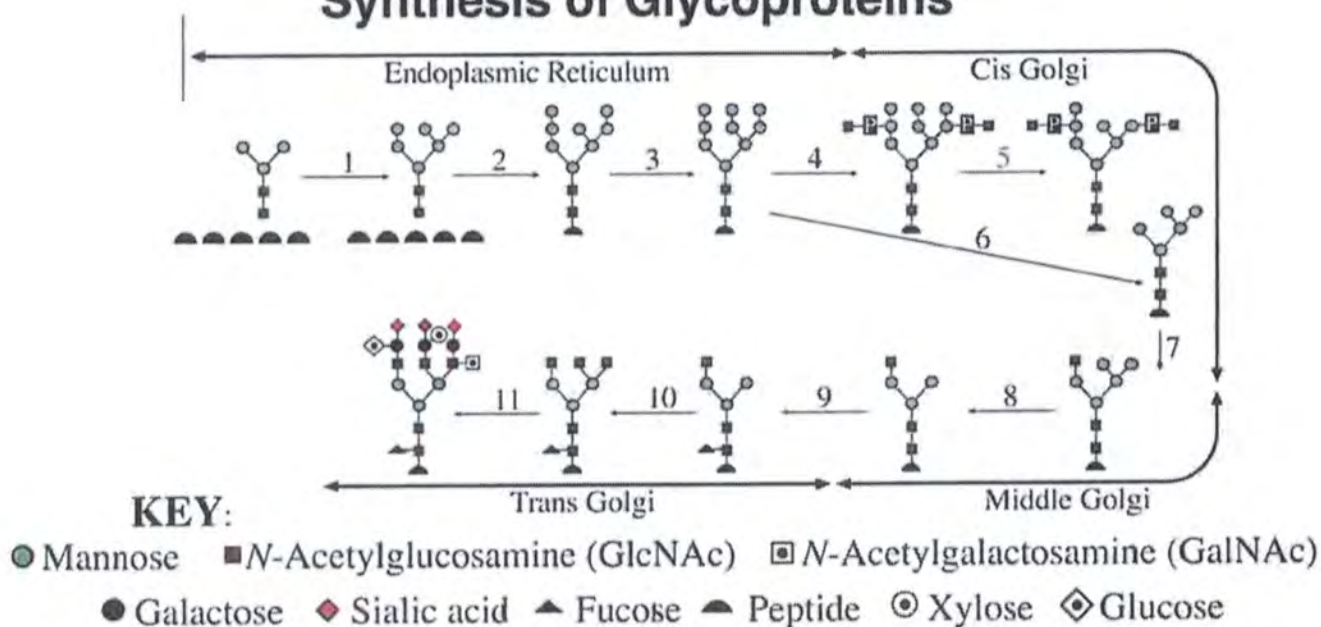
G. Marshall, J.P. Drack, *Clin. Immun. Society*, Abstract 1381, May 1993.

INTRACELLULAR ASSEMBLY SYNTHESIZES ALL STRUCTURE/ FUNCTION BIOACTIVE MOLECULES

THE DETAILED BIOCHEMICAL SYNTHESIS THAT PRODUCES GLYCOPROTEINS IS DISPLAYED IN PLATE C (KORNFIELD 1985). IT SHOULD BE STRESSED THAT IN THE ER 9 MOLECULES OF MANNOSE-6-PO₄ ARE REQUIRED TO FORM THE THREE-CHAIN DOMAIN FOR CELL TO CELL RELATIONSHIPS AND INSTRUCTIONAL CODING FOR GENERAL DEFENSE (INCLUDING TUMOR CELL DETECTION AND DESTRUCTION), REPAIR, HEALING AND HOMEOSTASIS. MANNOSE IS LOW IN SUPPLY ALONG WITH OTHER SACCHARIDES IN THE MODERN DIET.

PLATE C GLYCONUTRIENTS ARE UTILIZED IN ANTI-CANCER CYTOKINE SYNTHESIS BY CELLULAR ORGANELLES

Synthesis of Glycoproteins



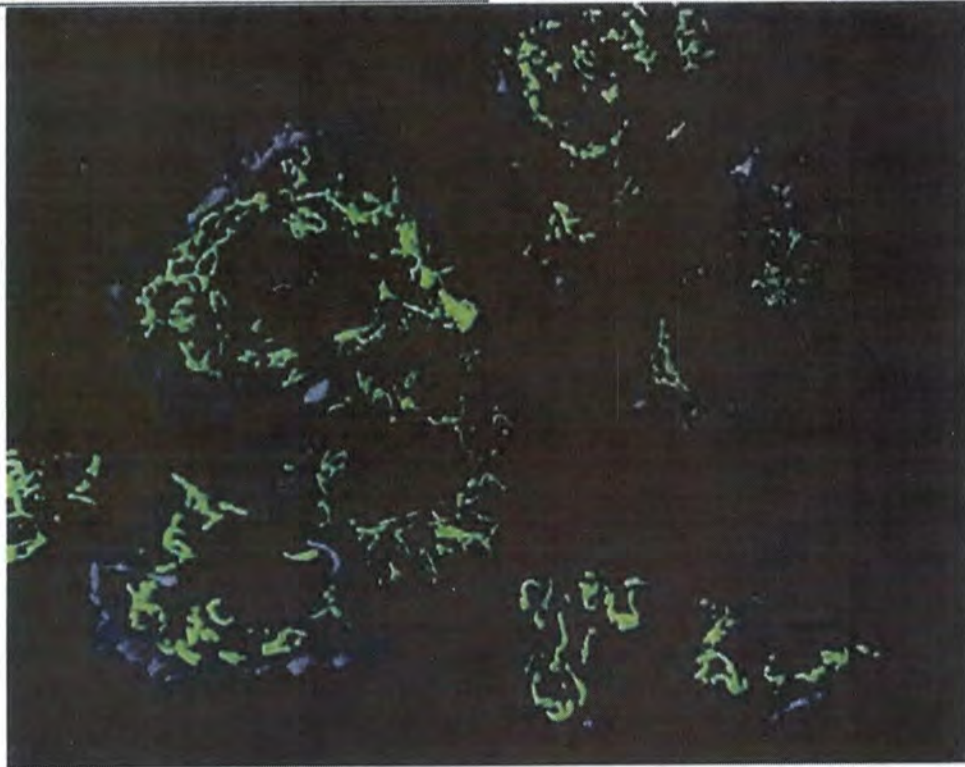
AS NOTED IN GRAPH II, INCREASING THE SUPPLY OF POLYMANNOSE TO CELLS ENHANCES THE PRODUCTION OF DEFENSE AND REPAIR BIOACTIVE INSTRUCTIONAL MOLECULES ON THE ASSEMBLY SCHEMA SHOWN IN PLATE C. THE HIGH MANNOSE OLIGOSACCHARIDE IS TRANSFERRED FROM THE ER TO THE GOLGI FOR FINAL SYNTHESIS WHERE OTHER GLYCONUTRIENT MONOSACCHARIDES ARE ADDED OR SUBSTITUTED TO THE THREE MANNOSE CHAINS TO COMPLETE THE INSTRUCTIONAL CODING FOR FUNCTIONAL ACTIVITY.

HOW CAN POLYMANNOSE PROTECT NORMAL CELLS AND IMPROVE QUALITY OF LIFE DURING STANDARD CANCER THERAPY?

PASSAGE OF THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994 (DSHEA) LED TO MILLIONS OF CITIZENS IN THE USA CHOOSING TO ADD GLYCONUTRIENTS TO THEIR DIETS AS A CONCENTRATED SUPPLEMENT. IN A SHORT TIME, ONCOLOGISTS AND PATIENTS REPORTED A WIDE VARIETY OF MALIGNANT CONDITIONS WITH ENHANCED RESPONSES TO STANDARD MEDICAL TREATMENT. SIGNIFICANTLY ENHANCED QUALITY OF LIFE WHILE UNDERGOING RADIATION AND CYTOTOXIC CHEMO THERAPY WAS REPORTED. ALSO TREATMENT RESISTANT TUMORS (STROMAL SARCOMAS) RESPONDED TO INEFFECTIVE THERAPY WHEN GLYCONUTRIENTS WERE ADDED (HYLAND 1999). SUCH REPORTS LED TO EXPERIMENTS DESIGNED TO TRY AND DETERMINE HOW APPARENT PROTECTION OF NORMAL CELLS WAS BEING ACHIEVED THROUGH ENHANCED NUTRITION.

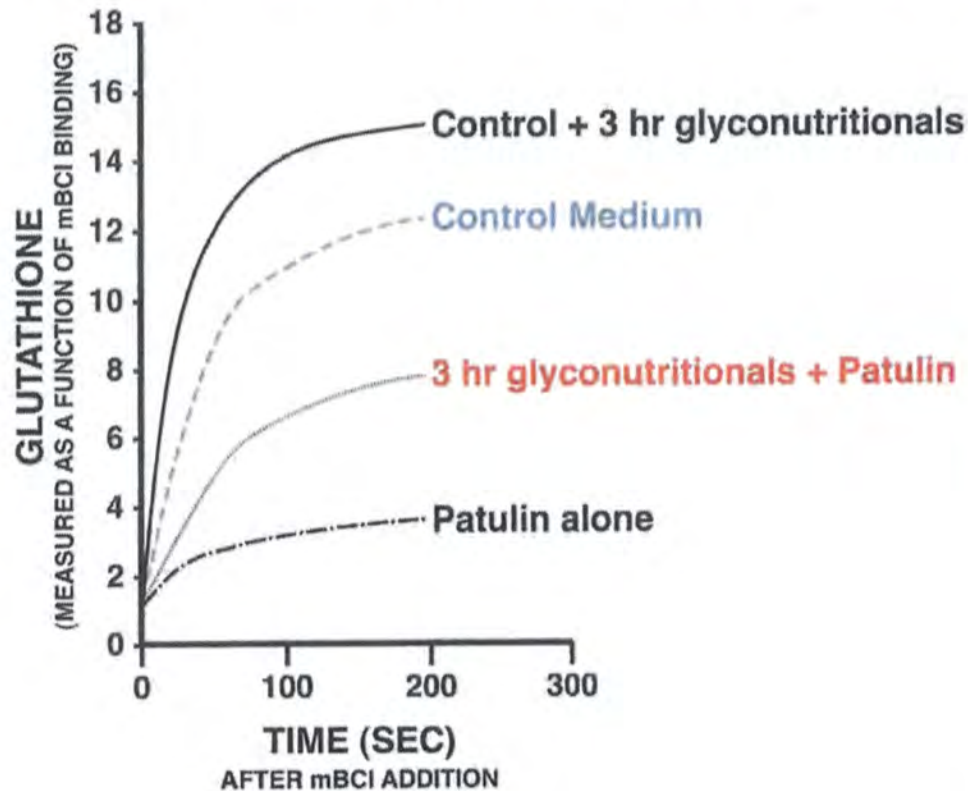
LIVER CELLS IN CULTURE WERE SCANNED BY CON-FOCAL SCANNING SPECTROMETRIC MICROSCOPY. THE SUPRA VITAL MARKER MONOCHLOROBAMINE WAS ADDED TO THE CELLS. REDUCED-GLUTATHIONE (R-G) BINDS WITH THIS MARKER AND GLOWS BLUE WHEN THE INTRACELLULAR ENVIRONMENT IS IN THE REDUCED OR PROTECTIVE STATE (SEE PLATE D). WHEN FREE RADICALS ARE BOUND, THE GLUTATHIONE MOLECULE IS OXIDIZED AND NO LONGER GLOWS UNDER THE LASER SCANNING MICROSCOPE.

Plate D LIVER CELLS SCANNED BY CON-FOCAL SPECTROMETRIC MICROSCOPY



THE BLUE MATERIAL (R-G) IS IN THE AQUEOUS CYTOPLASM OF THE CELLS. THE YELLOW AND GREEN PIGMENT IS SUPEROXIDE DESMUTASE (SOD) IN AND SURROUNDING THE MITOCHONDRIA. SOD IS PROTECTIVE AGAINST FREE RADICALS GENERATED IN THESE ORGANELLES. R-G IS AN INTRACELLULAR RESERVIROR FOR PROTECTION OF FUNCTIONAL CELLULAR MOLECULES FROM OXIDATIVE DAMAGE FROM FREE RADICALS. NORMAL CELLS PRODUCE R-G MORE EFFECTIVELY IN THE S-1 CELL CYCLE THAN MALIGNANT CELLS. THE CYTOPLASMIC POSITION OF R-G IS ADVANTAGEOUS FOR REACTING WITH FREE RADICALS QUENCHED BY VITAMIN E IN THE CELL MEMBRANE PHOSPHOLIPID LAYER COVERING THE CELL. IN THE CELL WATER OF THE CYTOPLASM WITH ITS BUFFER SALTS IS VITAMIN C, WHERE R-G IS INTERMIXED. WHEN VITAMIN C BINDS WITH A FREE RADICAL AND IS NO LONGER PROTECTIVE, THE R-G REACTS WITH THE OXIDIZED VITAMIN C AND RESTORES IT TO THE PROTECTIVE OR REDUCED STATE. WHEN R-G MOLECULES REACT TO BE OXIDIZED-GLUTATHIONE (O-G), THEY CAN NO LONGER SERVE TO PROTECT DNA OR CELL MEMBRANES, FOR THEY HAVE QUENCHED A REACTIVE FREE RADICAL. THE ADDITION OF POLYMANNOSE TO LIVER CULTURES INITIATES A SIGNIFICANTLY PROTECTIVE RESPONSE (SEE GRAPH V) IN THAT THE R-G LEVEL INCREASES 50%.

GRAPH V EFFECT OF GLYCONUTRIENT ON INTRACELLULAR REDUCED GLUTATHIONE IN LIVER CELLS AND AN OXIDATIVE CHALLENGE



NOTE THAT IN 5 MINUTES FOLLOWING THE ADDITION OF POLYMANNOSE TO THE CULTURE MEDIUM, THE COMPUTER GENERATED ASSAY FOR 1,000 SCANNED LIVER CELLS SHOWS THAT THE LEVEL OF FREE RADICAL PROTECTING R-G INCREASES 50% (BARHOUMI 1997).

SUMMARY FOR "BEST CASE SERIES" CLINICAL SURVEY OF PATIENTS WITH MALIGNANCY

ANECDOTAL REPORTS HAVE BEEN ACCUMULATED WITH REMARKABLE RESPONSES BY PATIENTS WITH MALIGNANCY THAT ADDED GLYCONUTRIENTS TO THEIR DIET. PARTICULARLY NOTABLE WERE ADVANCED PANCREATIC CANCER, PERSISTENT HIGH GRADE ASTROCYTOMAS (GLIOBLASTOMA MULTIFORMI), AND OTHER ADVANCED CANCER CASES CLASSIFIED AS HOSPICE ASSIGNED OR QUALIFIED. PRESENTATION OF A SMALL SERIES OF SUCH CASES WAS MADE AT THE COMPREHENSIVE CANCER 2000 CONFERENCE. THIS LED TO A CHALLENGE TO GATHER A "BEST CASE SERIES" OF RESPONDING CASES WITH MALIGNANCY AS REQUIRED BY THE CENTER FOR ALTERNATIVE AND COMPLEMENTARY MEDICINE IN ITS JOINT PROJECT WITH THE NATIONAL CANCER INSTITUTE.

FORMAL DOCUMENTATION OF DIAGNOSIS BY TISSUE BIOPSY, TREATMENT AND CURRENT CLINICAL STATUS SUPPORTED WITH DETAILED OBJECTIVE STUDIES IN ADVANCED CANCER PATIENTS THAT HAVE RESPONDED TO DIETARY SUPPLEMENTS HAS BEEN ASSEMBLED.

EACH BAND IS COMPOSED OF A SERIES OF CASE SUMMARIES AND SOURCE DOCUMENT LOG. ALL GROUPS HAVE HAD REMARKABLE RESPONSES ASSOCIATED WITH DIETARY SUPPLEMENTATION ADDED TO STANDARD CANCER THERAPY.

SECTION A – PANCREATIC CANCER SERIES
SECTION B – HIGH GRADE ASTROCYTOMAS SERIES
SECTION C – STROMAL SARCOMA SERIES
SECTION D – MISCELLANEOUS CANCER SERIES

PLATE E

CASE SERIES DOCUMENTATION SUMMARIES

Pancreatic Cancer Series

Total Cases:	5
Mean Survival Months	68
Maximum Survival Months	120
Minimum Survival Months	30

High Grade Astrocytoma Series

Total Cases:	4
Mean Survival Months	70
Maximum Survival Months	110
Minimum Survival Months	22

Stromal Sarcoma Series

Total Cases:	6
Mean Survival Months	95
Maximum Survival Months	140
Minimum Survival Months	63

Miscellaneous Malignancy Series

Total Cases:	5
Mean Survival Months	164
Maximum Survival Months	255
Minimum Survival Months	35

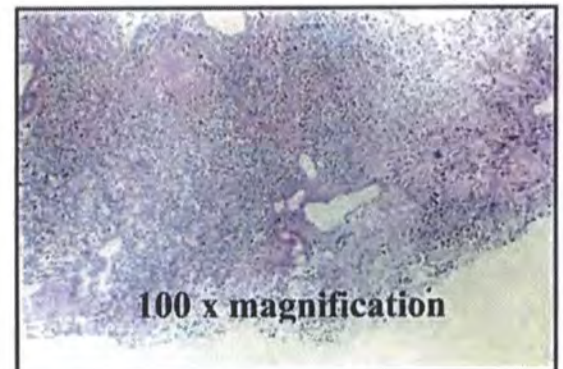
Best Case Series Clinical Abstract

Patient: L.D.

Pancreatic Cancer

DOB 7/12/1945 White Male - At the age of 54 following a thirty pound weight loss (200>170lbs.) with episodes of left abdominal pain radiating into the back in July of 2000, this man was given three months to live on finding a 7.2 X 5.9 cm pancreatic cancer mass with multiple metastases to the liver and 2 nodules in the lung that eventually cleared without medical treatment. A needle biopsy of the liver confirmed the diagnosis of an undifferentiated adenocarcinoma. No therapy was medically offered and the patient elected to go on a "healthy diet" and take dietary supplements containing large amounts of glyconutrients with phytochemicals, phytogenins, and vitamins and minerals. This action was taken on the advice of a friend with breast cancer that claimed remarkable results associated with this approach. CA-19-9 was **108** on 10/5/00; **234** IU on 3/9/ 01; **177**; **115** on 3/1/02; **147** on 5/2/02; **80.5** on 3/10/03; CT scan of March 04 revealed the largest liver mets had increased to 10.5 and 8.3 cm in diameter. Despite initial and continued urging of the patient to combine micronutrient dietary supplements with gemcytobine, and the primary pancreatic and liver mets slowly enlarging, he has refused to follow through. However, he is free of pain and his health and activity level are very high, and he has enjoyed both a better quality and quantity of life, having lived over 4 years beyond the initial prognosis.

Diagnosis July/2000: 53 months survival as of Nov. 2004

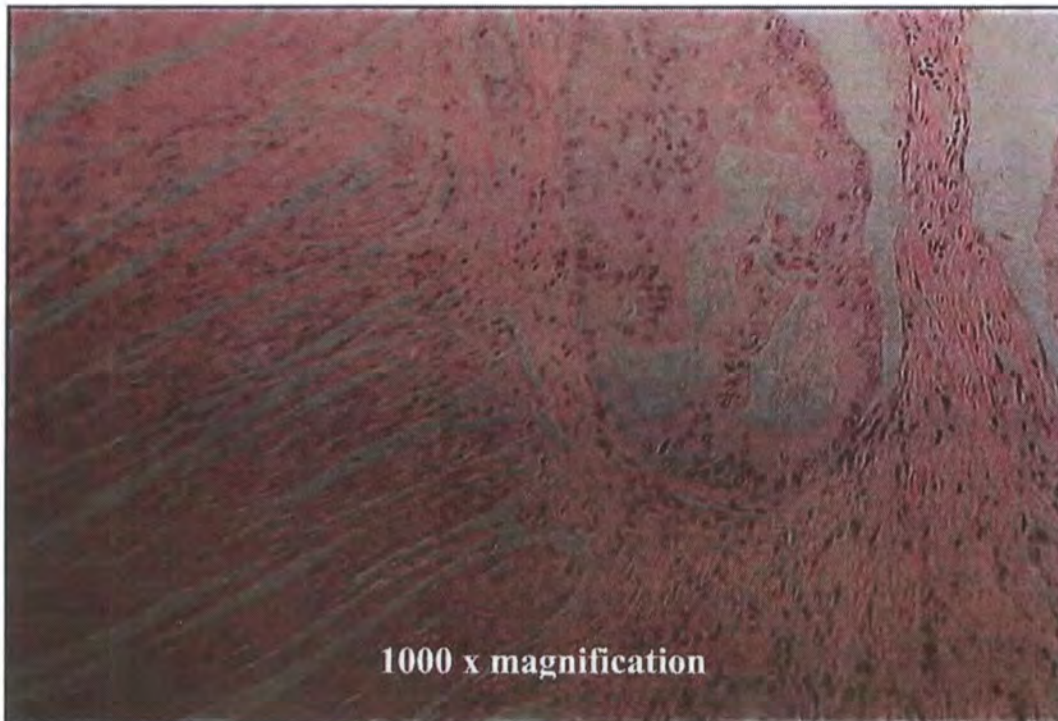


Best Case Series Clinical Abstract

Patient: S.F. Pancreatic Cancer

DOB 2/15/1939 White Female - At 58 years old, this woman had the onset of jaundice, itching and dark urine, bilirubin 14.7 mg/DL, Alk Phos 291 IU, GGT 122 IU. Brushing of the ampulla of Vater on 3/31/97 contained poorly differentiated adenocarcinoma (S97-03596). En block resection (4/17/97) of the head of the pancreas, duodenal duct region, common duct, gall bladder, partial gastrectomy and mesentery were surgically extrapolated (S97-04288). Sections reveal wide sub mucosal tumor extension along the duodenum, multiple microscopic tumor nodules in endothelial lined spaces extending into the muscle layers and beyond into mesenteric lymphatics at a distance from the primary. A 3 to 6 month prognosis was given and no radiation or chemo was recommended. In May 1997, dietary supplementation with abundant glyconutrients, in addition to phytochemicals, phytogenins and vitamins and minerals were instituted. The surgeon estimated in 4 to 8 weeks the post-surgery activity and status was beyond typical after 6 to 8 months. CT scans were negative 12/1997, 11/1998, 6/1999. The patient continues in good health on no further medical management than micronutrients.

Diagnosis March 1997: 92 months survival as of Nov. 2004



1000 x magnification

Best Case Series Clinical Abstract

Patient: JH

Pancreatic Cancer

As presented in the Cancer Care Conference of 2003, Washington, DC.

In July 1994 at the age of 39 this female oncology nurse had a chief complaint of abdominal pain radiating into the upper back. Failing therapy for pancreatitis, she had an MRI, and an 8 cm mass in the tail of the pancreas with multiple liver metastases was reported. A Whipple procedure with wedge liver resection of the discrete distant tumors was performed. The pathologic diagnosis was papillary adenocarcinoma. In January 1995, a second wedge resection for 8.7 cm and 4.2 cm liver metastases was conducted. In July 1996, recurrent liver masses were noted on periodic scans, and in November 1997, vinyl alcohol embolism was performed. She became progressively debilitated and was put on hospice in pain, jaundiced with marked weight loss for her progressive disease. In the Fall of 1999, progressive amounts of micronutrient dietary supplementation consisting of glyconutrients, phytonutrients, and phytosterols was instituted. Below are the MRI's in July 1999 and July 2000. The patient was still alive and active in November 2004 with stable, non-progressive liver metastasis. She has been speaking for cancer support groups, churches, and professional groups. This oncology nurse continues taking micronutrients and refuses professional recommendations for combining the nutritional support with cytotoxic chemotherapy.

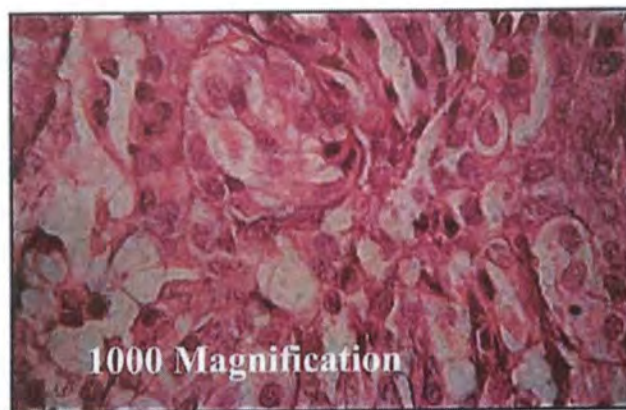
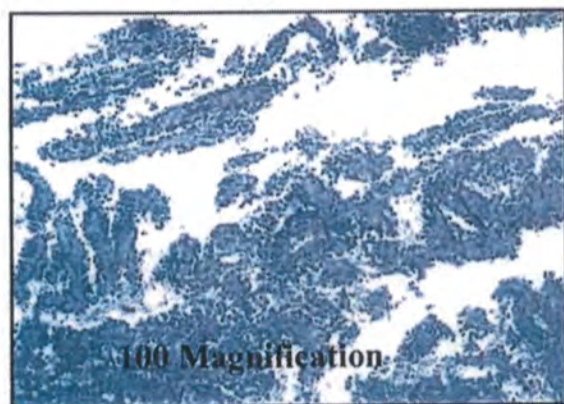
Diagnosis July 1994 with inoperable pancreatic cancer with liver mets. Patient started on glyconutrients when on hospice in 1999 and is alive and active with a total of 10 years or 120 months survival or 5 years i.e. 60 month survival since on hospice.



July 1999



July 2000



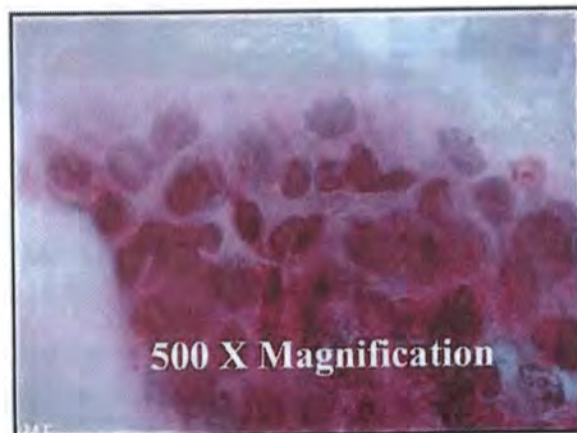
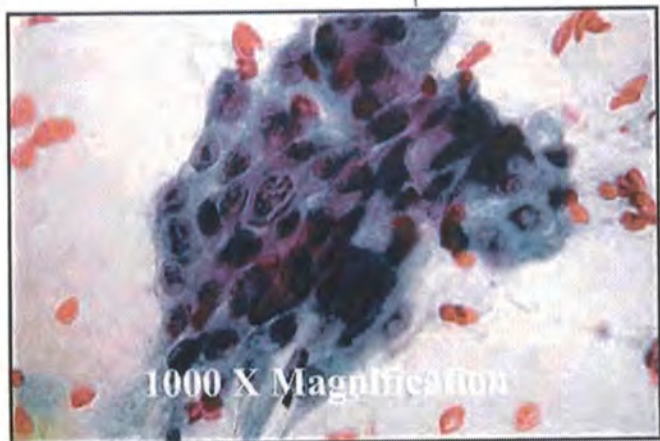
Best Case Series Clinical Abstract

Patient: TM

Pancreatic Cancer

In 1997, this 80 year old male developed jaundice, penetrating upper back pain, and overwhelming fatigue with rapid weight loss of 165 down to 125 pounds in 6 months. He presented to a large satellite regional hospital where abdominal scans, with and without contrast media, and ultra sound were conducted. The common bile duct and hepatic ducts were well distended. Multiple intra-hepatic masses were shown in the hilus of the liver and the pancreas head was enlarged in a manner typical of a pancreatic tumor. A fiber-optic pancreatic cannulation was performed and cellular material was obtained for pathological examination. The patient was informed that due to the cell clusters collected, clinical picture of weight loss, pain, jaundice, masses detected by scan, distention of the biliary tree and pancreatic duct system, masses of tumor in the central and right lobes of the liver, that he had inoperable pancreatic carcinoma. The patient was sent home with a 6 month expected term of survival. He started large amounts of Nutraceutical dietary supplementation. His jaundice cleared, his energy returned, laboratory values consistent with bile duct distention normalized and his lost weight was regained. At 6 months, his scans were repeated and no masses or ductal dilation were detected. He returned to his passion of fancy ballroom dancing. In April 2001, he expired from a series of strokes and cardiac arrhythmia, a condition he had the last few years of his life.

Diagnosis July 1997 with his demise in January 2000 after a series of strokes, he had 30 months survival having been given 6 to 12 months and given no therapy with all evidence of tumor disappearing while taking glyconutrients.



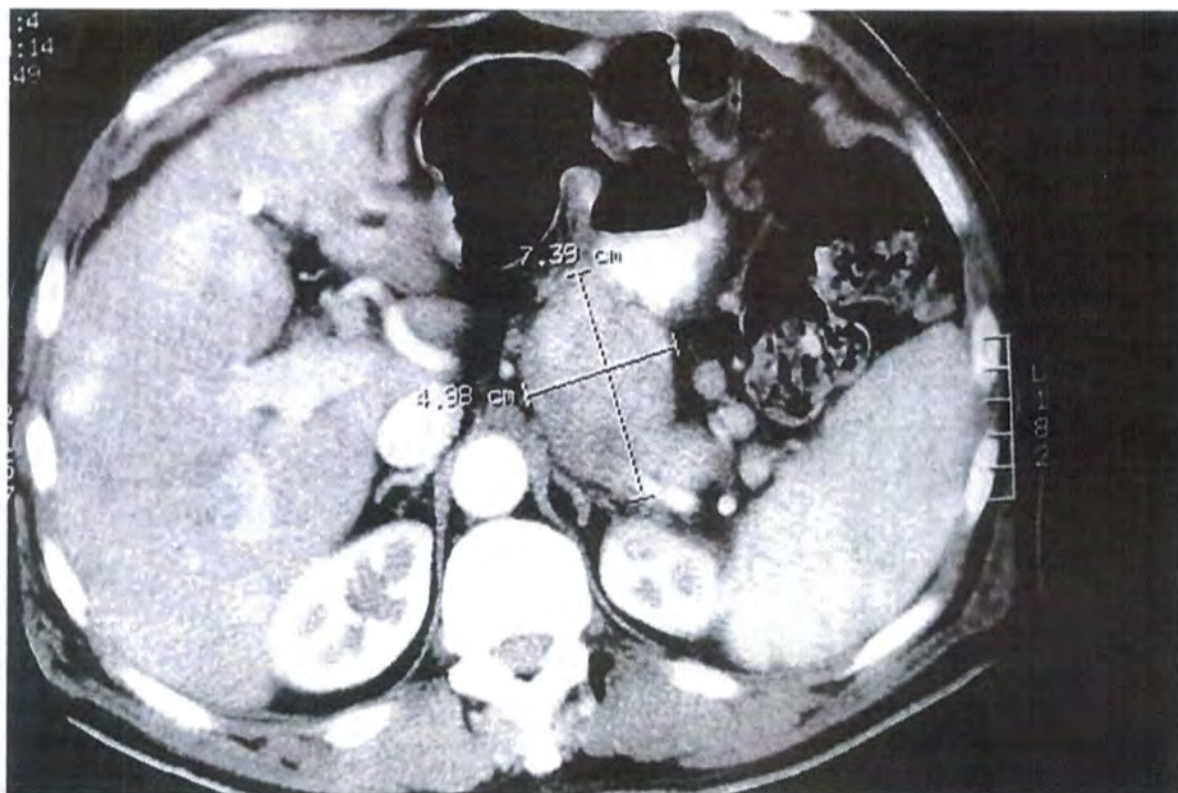
Best Case Series Clinical Abstract

Patient: K.T.

Pancreatic Cancer

In the summer of 1999, this 70 year old male complained of abdominal pain and was conservatively treated for a small duodenal ulcer detected by an upper GI series. The pain progressed and weight loss exceeded 20 pounds by January 2000. He underwent a wide resection of a 1.8 cm mass in the tail of the pancreas detected by MRI that on pathological examination (SU-000608) disclosed a 5 x 7 cm mass in the body of the organ that extended into peripancreatic tissues. The spleen was clear, but perineural and lymphatic metastasis were demonstrated. The patient started on large amounts of micronutrients in combination with weekly Gemcitabine infusions in March 2000. At that time, severe pain led to scans showing extensive recurrent tumor 3 cm in diameter in the celiac plexus area, and the Ca 19-9 was 778 units. Chemotherapy was continued and in July 2000, no residual tumor was detected and the Ca 19-9 was 17 units while gaining 10 pounds. The patient continues to have Gemcitabine infusion every two weeks, takes micronutrients, is pain free, has a Ca 19-9 of 35, and no tumor is detected as of February 2003, three years after his initial diagnosis and surgery.

Diagnosis January 2000. On his demise April 2004 he had 51 months survival.



Best Case Series Clinical Abstract

Patient: GEM

Astrocytoma Grade IV

DOB 11/22/63 White Male - This 28 year old had a grand mal seizure at work in August 1991. CT scans revealed a right frontal mass that on surgical exploration was diagnosed as a anaplastic astrocytoma. The patient was transferred to a major cancer treatment center and received a combination of cisplatin and radiation. He went AMA due to the quality of life he experienced with numerous seizures. In September 1991 he started on the 1st generation glyconutrient and his last seizure was in November 1991. Tumor growth was stopped. When in an auto accident in February 1993 scans were repeated and the original surgeon and neurologist were called to give care. CT scans were repeated and the cavitation and calcification of the stable mass were noted on the scan of that date. The patient continued to function until he stopped taking the glyconutrients and he died in May 1997 from brain damage assumed to be due to the tumor and brain trauma of the auto accident.

Diagnosis August 1991 with 63 months of survival by the time he expired in May 1997.

Post Treatment Scan with Contrast
August 1991



Post-Auto Accident Scan Without
Contrast

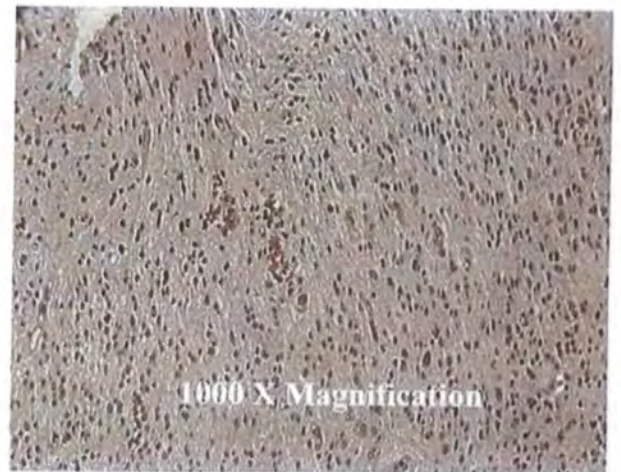
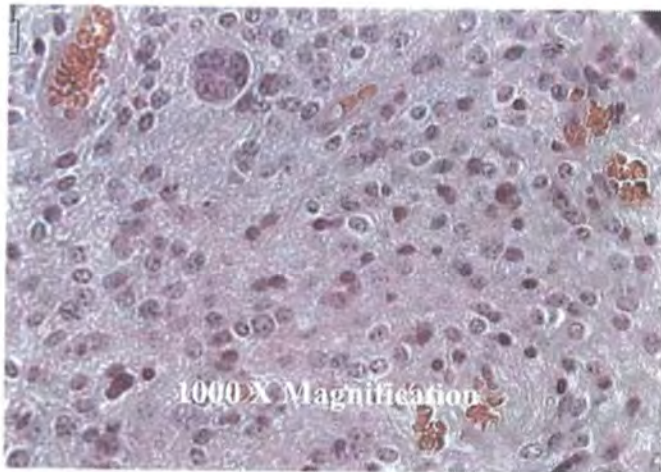


Best Case Series Clinical Abstract

Patient: TV Astrocytoma Grade III-IV

DOB 12/20/1995 - At 7 years old with Type 1 neurofibromatosis in the fall of 2002, this young man had progressive, persistent nausea, vomiting and loss of appetite. A MRI demonstrated an exophytic brain stem mass on 11/26/02 and surgery was performed on 1/15/03. A report on the excision (S02-42941) was diagnosed as Anaplastic astrocytoma with giant cells. Treatment with temozolomide and radiation was given. The patient requires physical therapy, has suffered significant neurological damage and has other CNS tumors due to his genetic disease.

Diagnosis Nov. 2002 with 24 months survival as of Nov. 2004



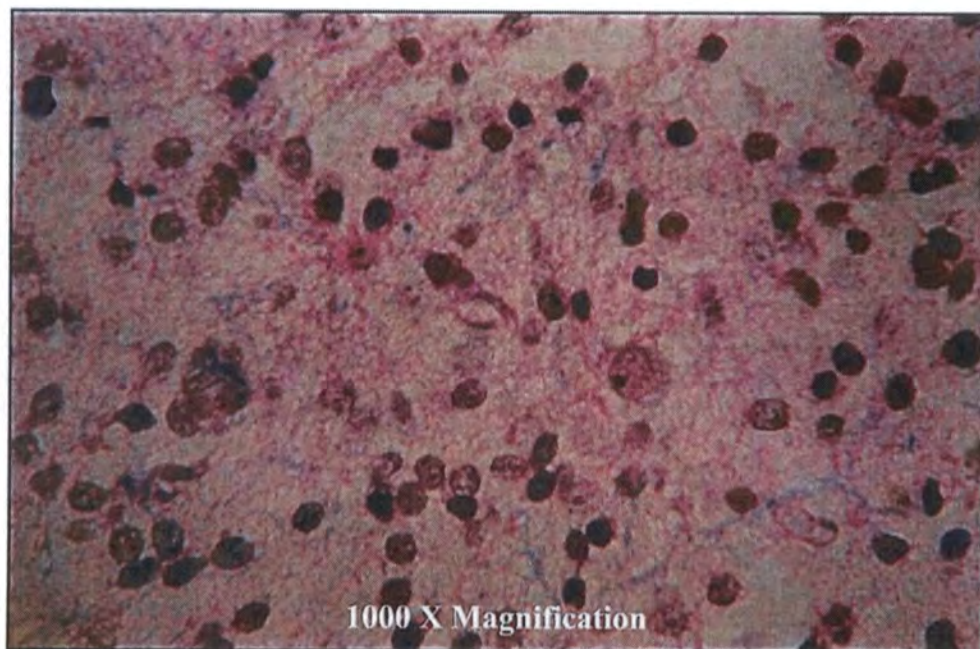
Best Case Series Clinical Abstract

Patient: CT

Astrocytoma Grade 2 -4

DOB 1/14/1973 - At the age of 24 years old, this Oriental male had the onset in August of 1997 of partial seizures starting with involuntary vocalizations. A left frontal mass was found by CT scan. Surgery was performed on 8/28/97 (S97-30199), and a diagnosis was made; malignant astrocytoma grade 2 to 4 with deep and anterior margins positive for tumor. He received 11 months of chemotherapy combined with radiation. The patient elected to take Pycnogenols, selenium, shark cartilage vitamin A and extended intake of glyconutrient supplements with phytochemicals of fruit and vegetable origin during his standard treatment. The patient reports a capacity much better than he had been prepared to enjoy and is still employed.

Diagnosis in August 1997 with 87 months survival as of November 2004

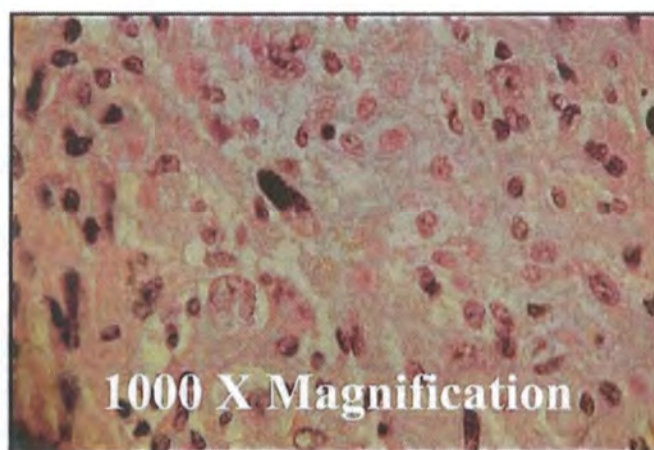
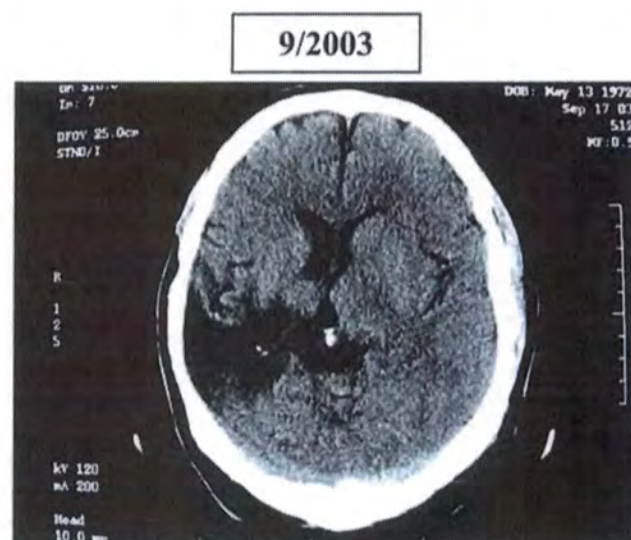
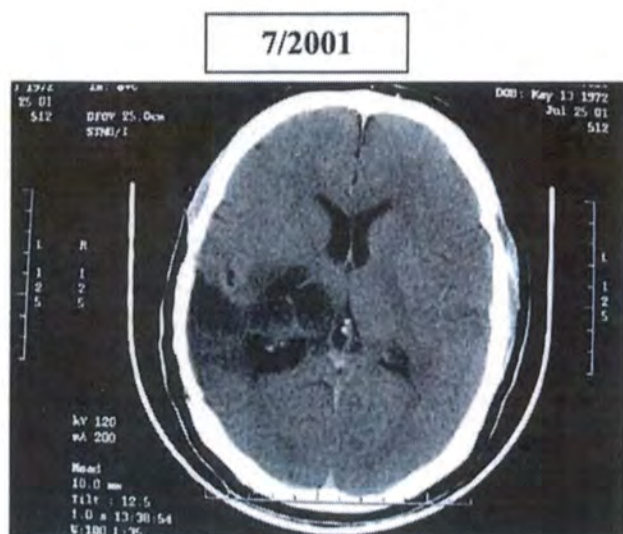


Best Case Series Clinical Abstract

Patient: CH (M) Glioblastoma multiforme

DOB 5/13/72 White Male - In September 1995 while at Mass, this 23 year old had a grand mal seizure and later that night had a second. In the work-up a mass was found in the right hemisphere of the brain. Surgery was first performed on 10/5/95 and a diagnosis of astrocytoma grade 2-3 was initially made. The patient had radiation with hemorrhage and recurrent tumor (Dx-astrocytoma grade 3-4) and excisions, strokes, and seizures with several years of complications. The patient attributes starting glyconutrient and other dietary supplements being added to his diet in August 2001 for more recent improvements in his quality of life. He is attempting to start a new business and is having a progressive improvement in his ability to function after the tumor surgery, radiation, regrowth, repeated surgeries, hemorrhage, and stroke damage.

Diagnosis September 1995: 110 months survival as of Nov. 2004



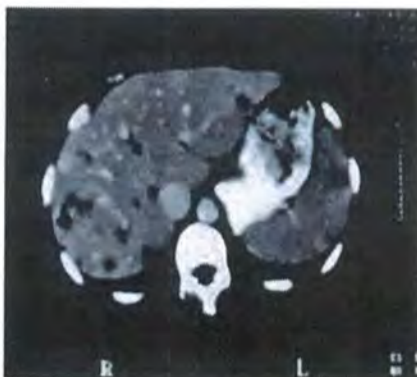
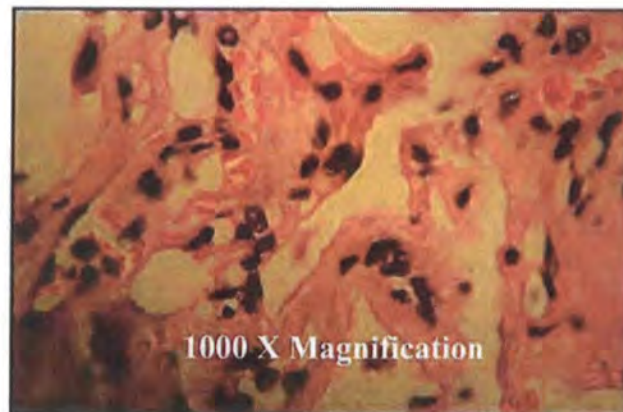
Best Case Series Clinical Abstract

Patient: AK

Malignant Epithelioid Hemangioendothelioma, “Angiosarcoma”

DOB 10/21/1961 - At the age of 36, there was onset of abdominal pain, diarrhea, bloating, indigestion, and poor appetite in August of 1998. CT scans showed “extensive liver masses and multiple lung nodules 2-3 mm in diameter”. Extensive pathology evaluations of the nodules gave a diagnosis of malignant epithelioid hemangioendothelioma, “angiosarcoma” (CA S98-25614). AFP, CEA and CA 125 were normal. On 10/27/98 lung wedge resection was performed. Hyalinized and calcified masses were reported. Micronutrients high in glyconutrients were started in September 1998. Multiple medical specialists made evaluations for a liver transplant. In 2000, she had high dose IV vitamin C for 3 weeks with Haelen and shark cartilage enemas. Sept. 2001 four hour NK cytolytic assay was 2 (N 20-250). CT scans were performed 7/1999, 12/1999, 8/2000, 1/2002, 6/2002, with “stable liver and lung masses” reported. 5/04 a repeat scan was performed, and all scans reviewed “reductions in less dense masses since 1998”. The patient has remarried and reports having full and normal life with stable nodules in the liver and lung fields.

Diagnosis October 1998 72 months survival as of Nov. 2004



Sept. 1998



May 2004

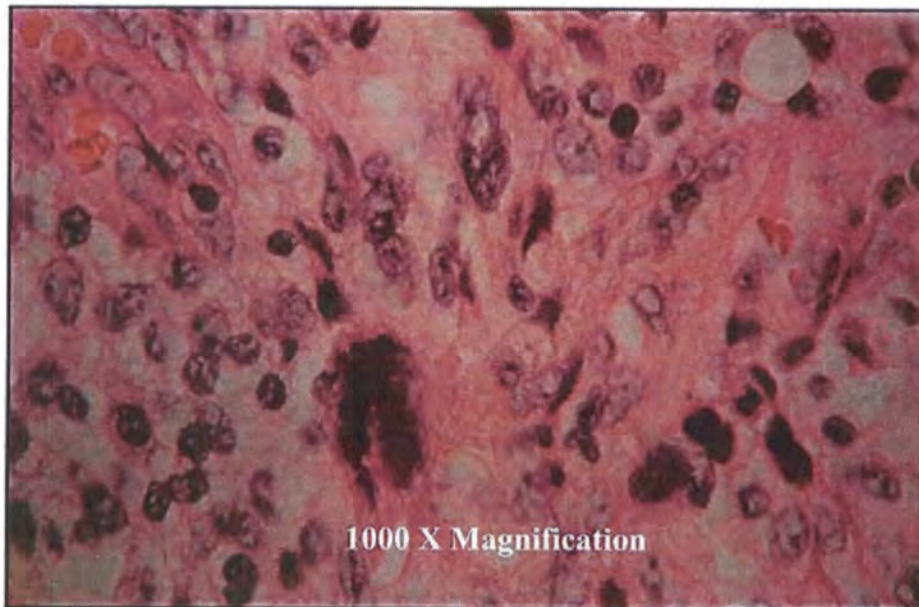
Best Case Series Clinical Abstract

Patient: IO

Uterine Carcinosarcoma

DOB 8/6/38 White Female - At 60 years old in 1999, this patient had post menopausal bleeding of uterine origin, and a D&C on 3/14/1999 produced a "uterine sarcoma" (FX99-005096) diagnosis. Elective hysterectomy on 4/13/1999 with wide resection provided tissue showing extensive deep myometrial extension of tumor with "multiple areas of lymphatic spread and involvement of the lower uterine segment." Pelvic fluid cytology was negative. The patient was sent home with a grave prognosis and told there was no treatment for such a sarcoma and she would be helped with her pain until the end. Glyconutrient dietary supplementation was instituted in April 1999 and the patient was followed by the NK cytolytic assay. Cancer cell NK lysis (N 20 -50 units) was reported as: 6/28/1999 - 29 LU, 10/29/1999 >100 LU, 4/24/2000 was 256 LU. The patient continues her dietary supplementation and has a full quality of life with no evidence of residual tumor.

Diagnosis March 1999 68 months survival as of Nov. 2004



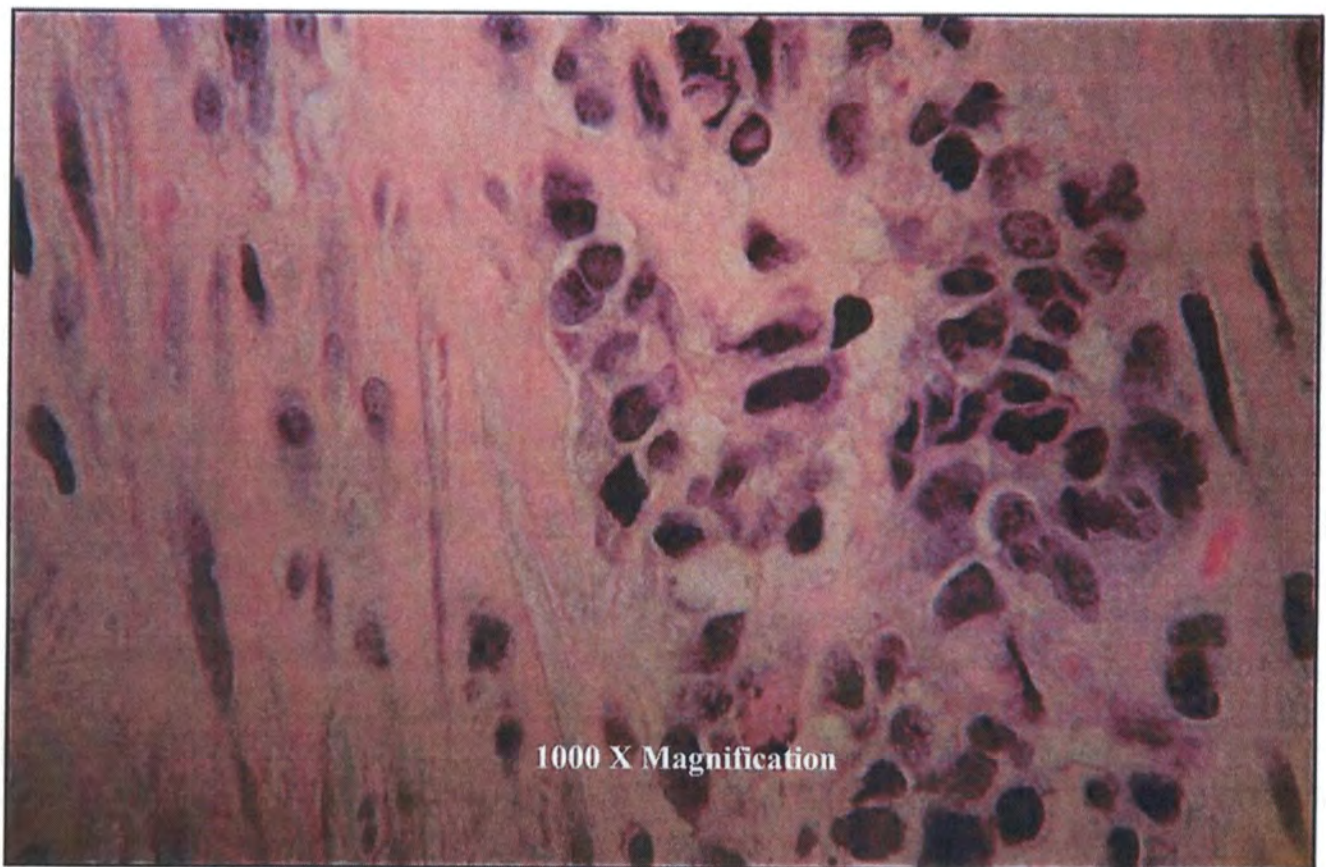
Best Case Series Clinical Abstract

Patient: M.S.

Rhabdomyosarcoma

DOB 2/16/1995 White Male - This 2 year old in March 1997 had a painless swelling in the left neck without other symptoms. CT scans showed a 8 X 10 cm. neck mass that was surgically resected, and a diagnosis was made of a highly malignant sarcoma, (rhabdomyosarcoma). A CT scan also revealed a 0.6 cm lung mass. He was given a 30% 3 year prognosis. Glyconutrients with phytochemicals and Essiac tea were started in June 1997 and were continued. Radiation and chemotherapy were given, and despite multiple selective and pancytopenic episodes with antibiotic treatment of infections and cellular blood product infusions, the chart notation is frequent that "his bone marrow bounds back" over the 41 weeks of chemotherapy completed in March 1998. No neck mass was detected by physical and CT scans. The young 9 year old continues to live and develop in good health.

Diagnosis February 1997 and 92 months survival as of November 2004

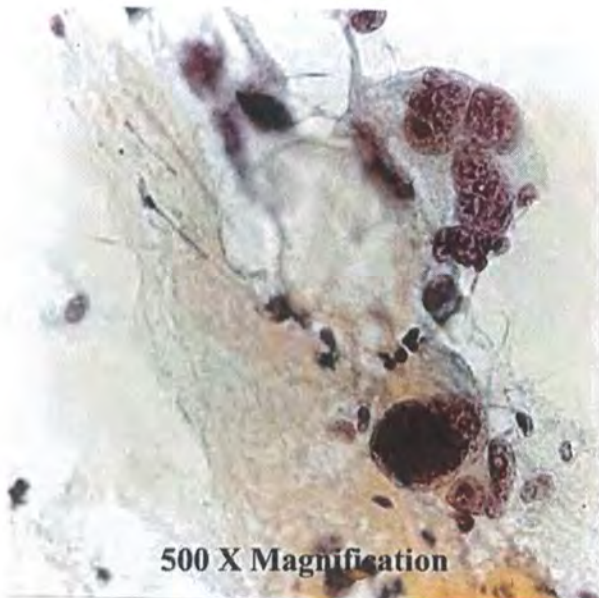


Best Case Series Clinical Abstract

Patient: W.A. High grade spindle-cell sarcoma right humerus

DOB 4/19/1937 White Female - This 54 year old had the onset in March 1993 of right upper arm pain and a pathological fracture. A needle biopsy revealed a high grade spindle-cell sarcoma. On 3/11/1993, she started aloe polymannose glyconutrient 20mg. This was in addition to 5-FU 500 mg, Cytosin, dicarbazine 20 mg. Mitomycin C 2.5 mg IV weekly started on 7/22/1993. Referred for a segmental humerus resection with methacrylate implant formed 12/93 at M.D. Anderson Cancer Center. Cisplatin and adriamycin chemo was given with a good response, 99% necrosis at surgery. Right pulmonary nodules were resected and no viable tumor was found. In 1972 bilateral breast cancer was treated by a right mastectomy and right lumpectomy. The patient has severe lymph edema of the right arm and is otherwise in good health.

Diagnosis March 1993 140 months survival as of Nov. 2004



500 X Magnification



1000 X Magnification

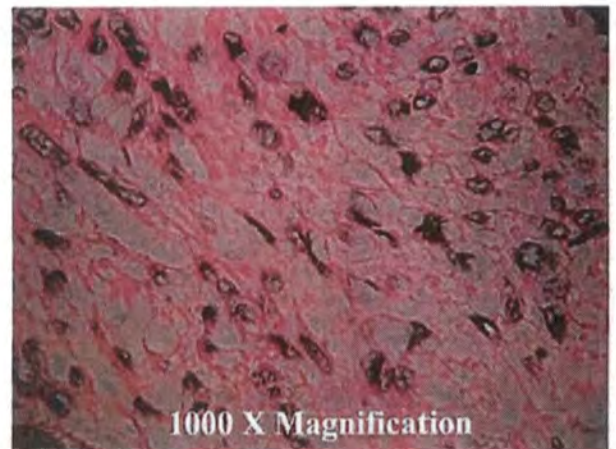
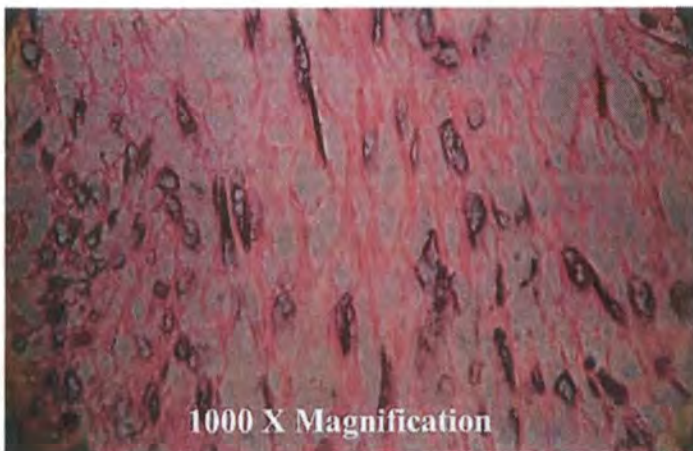
Best Case Series Clinical Abstract

Patient: RM

High grade leiomyosarcoma

DOB 12/29/61 - At the age of 35 in 1997 this African male had expanding abdominal girth, polyuria, and nocturia. The patient noted an abdominal mass. Sigmoidoscopy was normal. Physical exam disclosed a large, non-pulsatile, slightly mobile retroperitoneal mass. CT scan showed a 15 X 15 focal necrotic, solid mass. Surgical removal on 4/18/1997 found the mass at the aortic bifurcation, (S97-3037) diagnosed as a high-grade leiomyosarcoma with left hydronephrosis, incorporation of the tumor with the iliac vein. Thus en bloc removal and sparing of the artery was executed. No metastatic masses were noted, but residual transected tumor was reported in the deep margins. The patient had a difficult case with thrombosis and marked swelling of the left quadrant that necessitated an embolectomy and vascular graft to restore circulation and to save the left leg. No additional therapy beyond surgery has been instituted besides micronutrient dietary supplements. The patient has remained free of detectable tumor over 7 years, is employed, and enjoys a full active life, continuing to add the micronutrients to his diet.

Diagnosis April 1997 with 91 months survival as of Nov. 2004



Best Case Series Clinical Abstract

Patient: CH (F) Undifferentiated Sarcoma

DOB 2/21/1990 - At the age of 5 years old, following the development of a mass of the left buttock with a metastatic mass to the lungs, a surgical resection was done on 11/16/1995 (SP95-03919) and a diagnosis of undifferentiated sarcoma of muscle origin was made. Over the next 12 months Vincristine, Doxorubicin, Cyclophosphamide, MESNA, Etoposide and G-CSF were administered and the lung was radiated with 1200 cGy and residual tumor in the hip with 4500 cGy. In parallel with the standard therapy, the parents added micronutrient dietary supplements to the child's diet and this has been continued. The child is alive with an active life, but is plagued by problems due to growth plate damage and skin problems in the areas of radiation.

Diagnosis Nov. 1995 with 108 months survival as of Nov. 2004

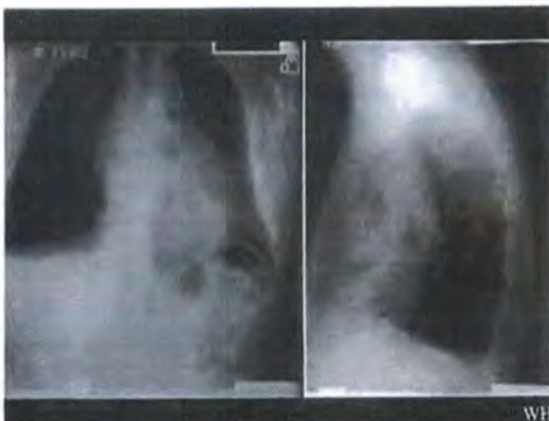
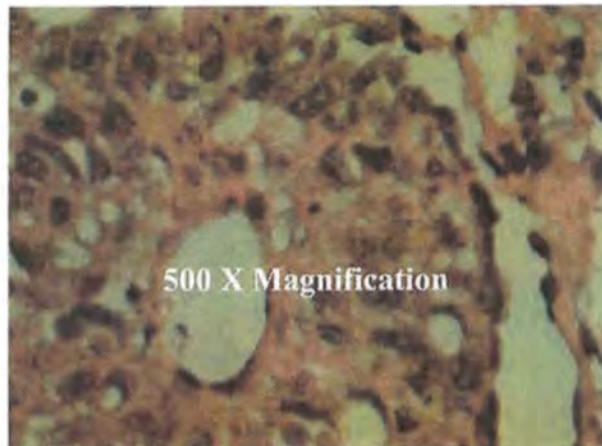
Tissue sections and scans being obtained but not currently available

Best Case Series Clinical Abstract

Patient: WH Malignant Embryonal Sinus Tract Tumor

WH - In 1983, this 43 year old male presented to a suburban hospital with acute chest pain. Emergency chest X-rays suggested an aortic aneurysm due to a widened mediastinum. He was transferred on an emergency basis to a major hospital where vascular studies with contrast media showed that a solid mass of an unknown, but not vascular, nature extended from the lower neck to the diaphragm, between the lungs and around the heart. The tumor obliterated the heart shadow with widening of the mediastinum in the standard Post or Anterior and lateral presentation. Note that on the lateral, no air filled blackness is present above and anterior where the heart outline is obscured. This should be contrasted with an approaching post treatment, Post or Anterior and lateral. A surgical biopsy was performed and the diagnosis was a malignant embryonal sinus tract tumor. You may note that there are sheets of undifferentiated cells characteristic of the embryo in the disk stage of development with slits in the masses not unlike an amniotic sac. This is a very malignant, rare tumor (a literature search providing no survivors beyond one year). Therapy administered was cytotoxic chemotherapy with multiple agents on a sarcoma protocol. The patient is alive and well in 2004, having been interviewed in person in March 2004, over 21 years after the initial clinical detection of his malignancy. Significant past history indicated that the patient had ulcerative colitis. He found that an aloe beverage, the first generation glyconutrient vital for synthesis in the endoplasmic reticulum, controlled his symptoms.

Diagnosis August 1983 with 21 years or 255 months survival as of November 2004.



Best Case Series Clinical Abstract

Patient: BS Prostate cancer with extensive lung metastasis

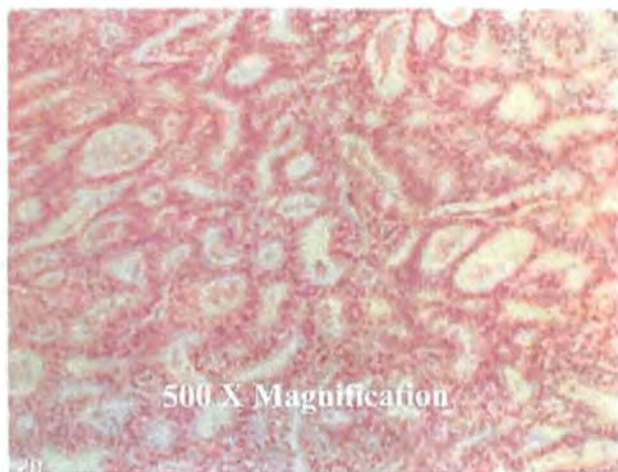
DOB 3/22/20 White Male – This patient developed prostate symptoms in 1987. An initial needle biopsy was negative, but a repeat effort disclosed adenocarcinoma Gleason's grade 5-7 4/20/1988 (S88-3637). The patient had surgical removal of the gland. Regional lymph node and pelvic bone metastasis were irradiated, and Lupron monthly injections were given with a temporary response. Surgical castration was conducted with a temporary response. In February of 1991, over 100 metastatic nodes were noted in the lungs, and a thoracic biopsy with immuno-peroxidase staining revealed that the tumors were prostate cancer. He was medically dismissed to plan his funeral. July 1991 – February 1993 at the Fisher Institute for Medical Research, aloe polymannose glyconutrient in combination with 5 FU, dicarbazine, and Mitomycin C weekly injections accompanied with oral aloe beverage approximately 350 mg/day were administered IV. From March 1993 to November 1996, 20 mg IV polymannose only was given by IV push. In February 1992 the chest scans were repeated and found free of tumor. Chest scans and periodic chest X-rays have confirmed the continued absence of tumor. The patient has continued oral aloe polymannose dietary supplementation. In October 2004 the patient was last seen and is quite slow due to his 84 years of age. He enjoys the fact that he won the Texas Table Tennis Championship for his age bracket 5 years ago, went to the national competition in Las Vegas, and he continues daily oral aloe polymannose intake with meals.

Diagnosis terminal metastasis Feb. 1992 with 153 months survival Nov. 2004

February 2001



February 2002



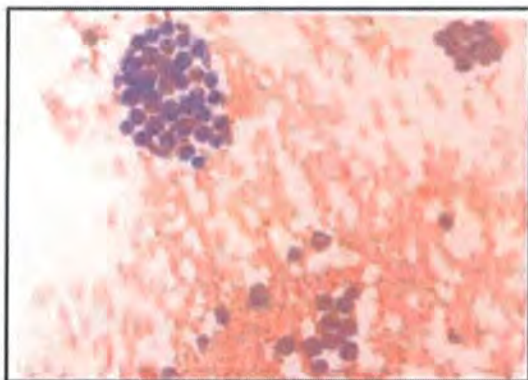
Best Case Series Clinical Abstract

Patient: M.A.

Non-Hodgkins Lymphoma

In December 1987, this 39 year old HIV-1 positive architect had rapid onset of abdominal fullness and inability to close his pants or use his belt due to increase in girth. He had anorexia and rapid satiety. Physical exam disclosed an enlarged, painless liver. CBC and liver profile were normal. A CAT Scan showed a markedly enlarged liver with over 20 masses. A needle biopsy contained sheets of lymphocytes consistent with non-Hodgkin's lymphoma. A standard CHOP protocol was instituted. The patient also added aloe polymannose to his diet and had virtually no toxic effects for his chemotherapy. The patient developed cytomegalovirus retinitis in 1989 and was treated with ganciclovir resulting in life-threatening bone marrow suppression and liver toxicity. He recovered. However, due to progressive retinitis, foscarnet was given that induced severe liver, kidney, and bone marrow damage. The patient died with overwhelming pneumonia in 1990. There was no evidence of lymphoma.

Diagnosis in December 1987 with a demise during therapy for cytomegalic retinitis secondary to drug toxicity to bone marrow, liver and kidneys in November 1990. 35 months survival



The needle aspirate of liver mass demonstrating clusters of lymphocytes typical of non-Hodgkin's lymphoma.



A cross-section of the liver on CT scan.



The scan 19 months later when special analytical software showed a normal liver in size and consistency.

Best Case Series Clinical Abstract

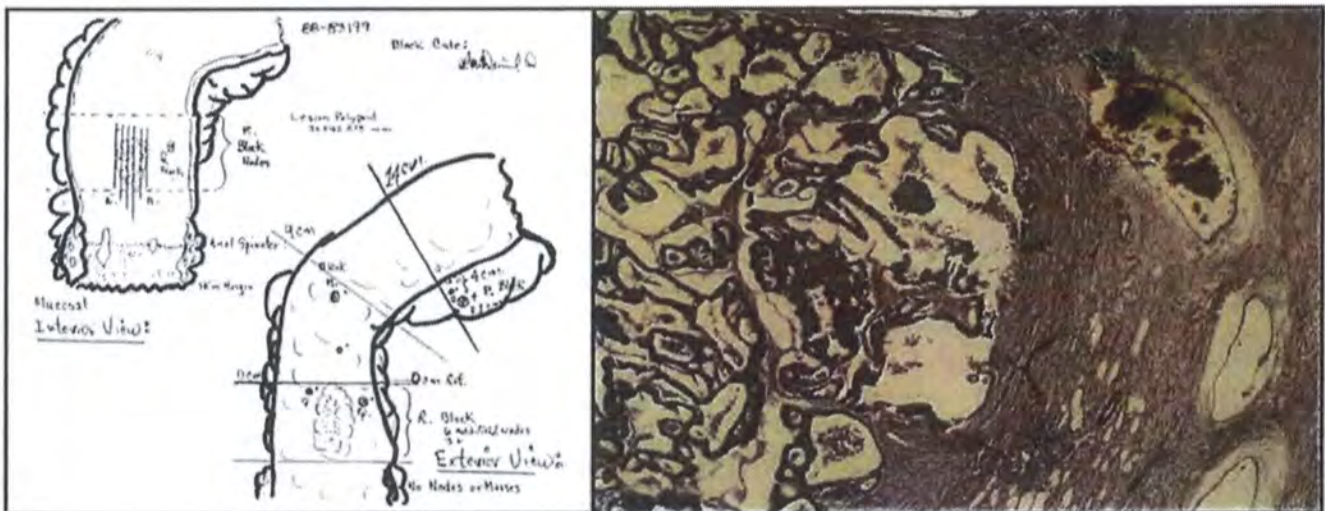
Patient: C.M.

Adenocarcinoma

In 1988, after two years of complaining of blood in stools, this female was properly examined and a polypoid, ulcerated lesion 40 x 30 x 15 mm was noted on the anal verge. An abdominal peritoneal resection was performed with a permanent colostomy. Distant lymph nodes were replaced with adenocarcinoma with one 15 mm node 14 cm above the lesion and 1 cm from the mesenteric surgical margin. Tumor board prognosis was 6 months for recurrence and one to two years survival. The patient received weekly 5-FU infusions for 6 months and added 800 to 1000 mg/day aloe polymannose to her diet. She had virtually no side effects associated with chemotherapy. As of April 2003 this 64 y/o female works part-time in a beauty shop and has no problems from the adenocarcinoma diagnosis and surgery performed 15 years ago.

Pathologist's drawing of dissection with block key.

Extensive local infiltration into surrounding rectal tissues beyond the bowel wall was present as shown and multiple distant lymph nodes were replaced with tumor.



Best Case Series Clinical Abstract

Patient: VG Chronic lymphocytic leukemia

DOB 9/10/22 White Female - This 66 year old in 1989 had increasing fatigue over 5 years. Physical exam was negative. A complete blood count (CBC) on June 19, 1989 showed:

WBC	HGB	Platelets	Segs	Bands	Lymphs	Monos	Eos	Indices
21,800	8.5	544,000	43	3	40	4	1	WNL

A bone marrow aspirate was performed and reported as a hypercellular marrow with sheets and clusters of mature lymphocytes consistent with a diagnosis of chronic lymphocytic leukemia. Peripheral smears showed small mature lymphocytes. Cytotoxic chemotherapy was recommended; however, the patient did nothing but add glyconutrient dietary supplementation to her diet. June 1990 the CBC values were:

WBC	HGB	Platelets	Segs	Bands	Lymphs	Monos	Eos	Indices
9,500	12.0	411,000	73	0	20	6	0	WNL

The patient's husband is a research biologist and he knew of studies in feline leukemia done with the glyconutrients and that morphologically human lymphocytic and feline leukemia are indistinguishable. The most recent CBC result follow:

WBC	HGB	Platelets	Segs	Bands	Lymphs	Monos	Eos	Indices
12,200	13.0	245,000	47	0	45	5	2	WNL

This 82 Y/O patient continues to age gracefully and is mentally alert, complains of rheumatism, has atrial fibrillation with no other health complaints.

Diagnosis June 1989 and survival of 185 months as of Nov. 2004



500 X Magnification

CONCLUSIONS:

1. GLYCONUTRIENT DIETARY SUPPLEMENTATION IN COMBINATION WITH STANDARD CANCER THERAPY HAS A RATIONAL BASIS, SUPPORTED BY BASIC SCIENCE THEORY AND EXPERIMENTATION, FOR PROVIDING THE CLINICAL BENEFITS REPORTED ANECDOTALLY BY ONCOLOGISTS AND PATIENTS.
2. IMPROVED CLINICAL RESPONSES ARE RELATED TO INNATE MECHANISMS OF HOST DETECTION AND DESTRUCTION OF MALIGNANT CELLS. FINDINGS THAT SPAN IN VITRO CULTURES, QUANTITATIVE ASSAYS OF BIOACTIVE ANTI-NEOPLASTIC COMPOUNDS SYNTHESIZED BY HOST CELLS, INVESTIGATION OF MULTIPLE ANIMAL SPECIES, AND HUMAN PILOT STUDIES/SURVEYS INDICATE THAT THERE IS A SCIENTIFIC BASIS FOR BENEFITS REPORTED IN CANCER PATIENTS THAT ADD GLYCONUTRIENTS TO THEIR DIETS DURING THERAPY.
3. REPORTS OF MARKEDLY INCREASED QUALITY OF LIFE WHILE UNDERGOING CANCER THERAPY AND PROTECTION OF NORMAL CELLS IS SUPPORTED BY GLYCONUTRIENT SUPPLEMENT FOSTERED INTRACELLULAR ANTI-OXIDANT PRODUCTION.
4. MULTIPLE RESPONSES IN DOCUMENTED ADVANCED HUMAN MALIGNANCY CASES THAT HAVE ESTABLISHED POOR RESPONSES TO STANDARD THERAPY SUPPORT THE POSITION THAT A PROSPECTIVE CLINICAL PILOT STUDY IN AGGRESSIVE MALIGNANCIES COMBINING STANDARD RADIATION AND CHEMOTHERAPY WITH ENHANCED MICRONUTRITION CONTAINING GLYCONUTRIENTS AND OTHER MICRONUTRIENTS IS WARRANTED.