

Smart Life Forum

SmartLifeForum.org Presents

Gar Hildenbrand

On

**Cancer Immunotherapy:
Coley Fluid, Diet Therapy, & Photopheresis**

Thurs., Sept 17, 2009, 7 PM

LOCATION: Cubberley
Community Center - Room H1
4000 Middlefield Rd
Palo Alto, CA

FUTURE SPEAKERS

Oct. 15 – Bill Andrews, PhD
Nov. 19 -John Dommissie, MD
Dec. 17-Dawson Church, PhD

Short Presentation: Jake Brzakovic, a Los Altos fitness instructor, will speak on "Life Fitness: How to Design an Effective Program for Health, Vitality and Injury Prevention." He will talk about how exercise methods such as Swimming, Yoga, Walking, Pilates, Core Training, etc., complement each other and can play an important role in a comprehensive fitness program. Jake will also discuss and dispel several fitness myths regarding exercise, weight loss promotion and the role of competitive sports in healthy aging.

Main Presentation

Liberating the Human Immune System

The historical medical literature reveals that observers have long been aware of the remarkable immune response elicited by exposure to *Streptococcus pyogenes*. While the microbe central to William Coley's famous vaccine produced an infection with miserable symptoms including chills, shakes, and high-spiking fevers, the immune pathways activated by *S. pyogenes* repeatedly led to remissions of syphilis, resolution of skin diseases and, astonishingly, to the clearing of malignant tumors.

The healing agent in all of these conditions was not the microbe, but the special type of immune response it elicited. A trade war and lobbying campaign led by the American Cancer Society led, in the mid-1950's, to the abandonment by Parke-Davis of its license to produce Coley Fluid. When the FDA gained jurisdiction over biologicals in 1972, it enacted a 33-year moratorium on interstate commerce for any product containing *S. pyogenes*, thereby practically putting the human immune system in exile from its rightful place at the center of cancer research. The time is right to undo this terrible mistake and employ modern technology in the real-time study of induced tumor remissions while they are happening.

Gar will lace this discussion with other examples of issues vital to immune competence, including nutrition, protein and calorie restriction, exposure to exogenous microbes, maintenance of commensal microbes (where one organism benefits but the other is unaffected), toxin exposures, and more.

Coley Fluid (Coley's toxins)

Dr. William B. Coley (1862–1936) was a late-nineteenth century surgeon who systematically mapped out the clinical

Meet Gar Hildenbrand

Gar Hildenbrand is an epidemiologist and methodologist with broad knowledge and experience in the evaluation of alternative methods of cancer management; he is also a federal policy expert. As a whistle-blowing advisor to the U.S. Office of Technology Assessment (OTA), he exposed stealth "quackbusters" on the OTA staff and salvaged the study "Unconventional Cancer Treatments." The advisory panel for this report included Mr. Hildenbrand, as well as C. Norman Shealy, M.D., Ph.D. and Andrew Weil, M.D. (A link to this report is provided in the "References" section at the end of the present article.) Gar was formerly executive director of the Gerson Institute and is currently director of the Gerson Research Organization.

Gar was appointed by Iowa Senator Tom Harkin to monitor the introduction of a coordinating office, the Office of Alternative Medicine, into Office of the Director of the National Institutes of Health, and was promptly labeled a "Harkinite" in the pages of Science. A tireless advocate for fair evaluation of promising alternatives, Gar is currently conducting a Freedom of Information Act investigation into the FDA's long term war against Coley Fluid, the first and by far most effective immunotherapeutic agent for cancer.

course of non-surgical treatment of cancer through stimulation of the immune system with bacteria.

In 1890, Dr. Coley received 19-year-old Elizabeth Dashiell, (girlfriend of John D. Rockefeller, Jr.), for treatment of a nonhealing blunt-trauma wound on her wrist. Despite many attempts to debride it, the wound would not heal. Coley was obliged by his training to amputate this beautiful young woman's arm below the elbow. By January 23, 1891, the underlying malignant sarcoma had spread throughout her torso, and young Bessie died, leaving Coley distraught.

Unable to calm himself, Coley pored over the sarcoma charts of the New York Postgraduate Medical School and Hospital, where he taught surgery. Of nearly 100 sarcoma cases, all but one patient had died of advanced disease. Fred Stein, in October 1884, had been operated for the fourth time by Coley's mentor, William Bull, for a round cell sarcoma of the jaw. Stein's surgery was palliative, because the disease was not resectable; but what seemed worse was that he had contracted an intercurrent infection of erysipelas (*Streptococcus pyogenes*). As Stein remained hospitalized for supportive care and observation, he experienced weeks of life threatening high spiking fevers; but his tumors completely regressed. According to his chart, "After each [attack of erysipelas], the cicatrization [healing] of the ulcer has rapidly proceeded, and during the attacks the flabby and apparently sarcomatous granulations have been absorbed. There is now left a healthy ulcer the size of a silver dollar."

Coley went to the Lower East Side of New York and began pounding on doors of the immigrant ghetto, asking for Stein's whereabouts. To his complete wonder, Coley found Stein, and quickly arranged to have him examined by Dr. Bull, who pronounced Stein healthy with a durable complete remission of round cell (later Ewing's) sarcoma. This case led Coley to the Index Medicus and the umpired journals, where he learned that others before him had observed what Dr. Ralph Moss refers to as "this experiment of nature."

Moss has pointed out that cancer was not the only disease that might be eliminated by the human immune response to erysipelas. Prof. Wilhelm Zuelzer reported that both chronic and acute skin conditions were resolved in patients battling erysipelas. Doctoral candidate J.C. Sabatier wrote in his dissertation for the Faculty of Medicine of Paris that no other treatment could cure syphilis as fast as erysipelas. Dr. Charles Maurice reported observing an epidemic of erysipelas at Paris' Charité Hospital in which patients with syphilis were cured. Drs. Armand Despres and Philippe Ricord reported in 1862 their efforts to use erysipelas to treat syphilis.

Then there was Prof. Wilhelm Busch who, in 1866, watched with astonishment as a woman he had unsuccessfully operated for metastasized head-and-neck sarcoma contracted erysipelas and, during the multiple fevers of the infection, absorbed all of her tumors. Then, Busch wrote in 1867, it happened again with a second cancer patient. It was Busch who made the decision to deliberately infect an advanced head-and-neck cancer patient, a feat he accomplished by placing her in a dangerous bed, a bed in which patients with open wounds developed nosocomial erysipelas. Busch then wounded one of

the tumors and within days she became infected. Busch described the disappearance of a tumor near her spine, and the shrinkage of her neck tumor from the size of a child's head to the size of an apple. Treatment was abandoned due to complications Busch attributed to the body's inability to handle the toxins being absorbed. Moss has speculated that this may have been tumor lysis syndrome, a potentially fatal intoxication resulting from extremely fast tumor necrosis.

It is Prof. Friedrich Fehleisen who is credited not only with proving that *Streptococcus pyogenes* caused erysipelas, but with using the first cultured *S. pyogenes* to treat cancer. With the culture available, many other physicians reported their successful efforts to treat cancer with erysipelas, including Richter, Petruschky, Volkmann, Ricord, Depres, Kleebat, and others. Even the great playwright and physician, Anton Chekhov, weighed in writing, "It was observed long ago that with the development of erysipelas, the growth of malignant tumors is temporarily checked."

Fortified by knowledge of his predecessors, Coley moved rapidly. On referral from Prof. Bull, Coley received a twice operated head-and-neck sarcoma patient, a Mr. Zola, who was in pitiable condition, unable to swallow and starving. Coley infected Zola several times with cultures of *S. pyogenes* from different labs. After a month of slow improvement, a culture arrived from Germany that was so potent that Zola became deathly ill, as did his niece who contracted erysipelas while caring for him. But the massive tumors were destroyed by fevers as high as 105 F°, and the process took only about 2 weeks. Mr. Zola remained well for 8 years.

As Coley treated more patients, he came to realize that even when inoculation failed to infect, tumors would shrink, apparently due to the type of immune response the patient had. Additionally, it became clear to him that the *S. pyogenes* infection itself was a potential killer with an unacceptably high mortality rate. Two of the 12 patients he treated, after Mr. Zola, died of erysipelas (a 17% mortality rate). To eliminate this risk, Coley decided to carefully kill the microbe over low heat before injecting it.

Coley profited from the work of Prof. G.E.H. Roger, who demonstrated that *S. pyogenes* co-cultured with *Serratia marcescens* (*bacillus Prodigiosus*) became much more virulent. He also benefited from Dr. V.C. Vaughn's demonstration of the *S. marcescens*-induced complete remission of sarcomas in dogs. Coley's seminal contribution to tumor immunotherapy was to co-culture *S. pyogenes* with *S. marcescens*, gently heat kill the culture, and to safely induce a simulated mixed infection.

The first case treated with Coley's toxins, also known as Coley Fluid or Mixed Bacterial Vaccine, was cured. The patient was a 16-year-old boy with a metastatic sarcoma that left him bed ridden with no bladder control. The disease had taken his abdomen and pelvis. The toxins worked brilliantly, and the lad achieved complete remission in a matter of about 6 months. He remained well until dying of unrelated myocarditis 26 years later. According to Stephen A. Hopton-Cann, University of British Columbia professor of epidemiology and chief science officer of the Canadian biotech firm MBVax

Bioscience (a manufacturer of Coley Fluid), "He had successes you simply couldn't hope for today, curing even extensive metastatic disease."

Dr. Coley developed the most effective anticancer therapy in the medical literature. It is not in general use today due to a very effective negative propaganda effort within the medical-industrial-regulatory complex of the 1960s, a lack of contemporary initiative to undo the damage, and the advent of X-ray and radium treatment and, subsequently, chemotherapy

Oncology professor William Donald Regelson of the Commonwealth University of Virginia at Richmond wrote, "There is no question...that inappropriate judgments have resulted in injury to good observations: if we look at Coley's toxins, a turn-of-the-century pyrogenic bacterial endotoxin anti-cancer treatment, we see a valid approach to nonspecific host resistance set back by being falsely labeled a 'quack remedy' by the American Cancer Society." (*Journal of the American Medical Association*. 1980;243(4):337-339).

However, when treated with Coley Fluid (Coley's toxins) alone, the five-year survival rates for advanced, inoperable cancers of the breast, ovary, cervix, and uterus, as well as giant cell bone sarcoma and Hodgkin's lymphoma met or exceeded two thirds of all patients. For inoperable melanoma, the five-year survival rate was a remarkable 60%. (Helen Nauts. Cancer Research Institute Monograph No. 18:1984).

These survival rates are all the more remarkable in light of the fact that Coley did not attempt to adjust for many variables, such as nutritional status of the patient, immune competence, negative influences like liquor, tobacco, etc. Further, there were no antibiotics in his time, no heart drugs, no blood pressure drugs, not even insulin (until 1922). Coley simply injected his vaccine (Coley's toxins) repeatedly.

Prof. Hoption-Cann recently wrote, "Despite the 'crude' approach taken by Coley, his vaccine stimulated a complex immune response that could induce the complete regression of both extensive primary and metastatic lesions. Furthermore, his vaccine was effective against many types of malignancies. Tumors that were observed to partially or completely regress following treatment with Coley's vaccine included: lymphomas, melanomas, myelomas, sarcomas and a wide spectrum of carcinomas." (*Medical Hypotheses*. 2002;58(2):115-119).

In the same article, Hoption-Cann lamented the fact that standardized cancer management not only fails to consistently produce lasting cures, it has in all likelihood reduced the number of non-treatment-related remissions of the disease: "Modern approaches to treatment have reduced the occurrence of spontaneous regressions. Aseptic techniques and antibiotics significantly reduce postoperative infections, while chemotherapy and radiation impair immune activation even when an infection does occur."

Here are two excellent overviews by Hoption-Cann of the historic development and use of Coley's vaccine:

<http://www.mbvax.com/pdf/SRegression.pdf>
http://www.mbvax.com/pdf/Hoption_Cann_2003.pdf

Additional literature is available at the following URL:
<http://www.mbvax.com/publications.htm>

Integration of Coley Fluid & Gerson's diet therapy

Diet therapy after the manner of Gerson is not understood by Hildenbrand to be a stand-alone treatment for most advanced cancers; however, it is an indispensable part of integrative immunotherapy for cancer, per se.

The Gerson Research Organization (GRO), has in its registry 7,785 cases (as of 4/30/2007) from all five (5) Mexican hospitals that offered variants of the Gerson diet therapy for cancer and other diseases from 1977 through 1996 (Hospital La Gloria, Hospital Jardines de la Mesa, Hospital del Sol, Centro Hospitalario Internacional Pacifico, SA, and Hospital Oasis). Of 7,785 charts, 4,738 are cancer cases and comprise our tumor registry. GRO has published and presented many retrospective analyses of the outcomes of these patients.

In 1958, Max Gerson published a viable "best case series" in his last monograph, *A Cancer Therapy: Results of Fifty Cases*. In his book, Gerson described the essentials of his treatment, and discussed the rationales known at that time. Unfortunately, the record Gerson left did not yield a "plug-and-play" treatment. Beginning practitioners, indeed even seasoned practitioners, cannot consistently reproduce results like those 50 cases, simply because they were Gerson's best cases.

What emerged as GRO analyzed the data was a clear picture of clinical benefit. The performance status of even bedridden patients frequently improved to the extent that disabilities were overcome, pain medications were reduced or eliminated, appetite was restored, and patients could again get up and engage family, friends, and community. It became clear that this global improvement also led to the successful employment of additional treatments, e.g. one strong trend in the data is the survival advantage seen in patients who could be operated to remove tumors during or just prior to adherence to diet therapy for melanomas, colorectal cancers, and ovarian cancers. It also became clear that the majority of advanced cancer patients would not be cured by diet therapy as sole treatment.

It is also evident in the historical record that Gerson did not feel that his treatment was complete. Indeed, in *A Cancer Therapy*, he recommended fever-inducing vaccines, explaining his rationale: "The idea of helping the cancerous organism [of regenerating the patient] through a strong inflammation is old but was correct from the beginning." Over 30 years of treating and observing the responses of cancer patients, Gerson came to believe that inflammation and fever were manifestations of healing: "The healing apparatus seems to have retained part of its embryonic capacity and healing purpose for a type of regeneration, when it falls back into the embryonic state temporarily and is activated above the degree of its normal function."

Photopheresis & Dendritic Cells

Gerson saw his diet therapy as capable of setting the stage for, and sustaining, a vaccine-triggered inflammatory response: “The completely detoxified body is then able to produce an allergic inflammation if the healing apparatus (liver, visceral nervous system and reticulo-mesenchymal system) can be activated sufficiently. Everything that can help to bring it about and strengthen the necessary allergic inflammation may be used for that purpose after the general detoxification has taken place. Bacterial preparations (Coley and others) or Pyrififer, or any similar preparations are effective, as far as they can stimulate the visceral nervous system in connection with the liver and the mesenchymal defense and healing apparatus.” Max Gerson died only months after this monograph was published, and he was never able to investigate and develop the combination of his diet therapy and fever vaccines.

Thirty-eight years passed before the exploration envisioned by Gerson began in 1996 as a collaborative effort by the Gerson Research Organization and CHIPSA. Much of the credit for this goes to Wayne Martin and his decision to sponsor and supervise the first new production of Coley’s vaccine in decades. Wayne Martin passed away May 13, 2006, but philanthropic entrepreneur Don MacAdam had already stepped up to fill the void with his creation of MBVax Bioscience and the manufacture of a superbly potent formulation of Coley Fluid.

Because fevers place an enormous demand on protein reserves, Gerson’s lengthy period of protein restriction is not employed by us. Early in the treatment, vegetarian protein is added, along with small quantities of cultured dairy. Protein restriction was part of Gerson’s strategy to sensitize the connective tissue immunities in order to trigger a fever, a feat that he could normally accomplish within 6 to 8 weeks. With the introduction of Coley Fluid, it is possible to induce a fever at will, as soon the patient is judged clinically ready.

A Central Mechanism

Uwe Hobohm has recently observed in an article about Coley’s toxins that the following cascade might explain its effectiveness: “fever generates inflammatory factors with co-stimulatory activity, which activate resting dendritic cells (DC), leading to the activation of anergic T cells, maybe accomplished by a second process, where a possible physical damage of cancer cells leads to a sudden supply of cancer antigens to DC.” (Cancer Immunol Immunother. 2001;50:391-396).

In other words, fever is a state in which the body’s own self/not-self recognition mechanism turns on to such a high level of activity that it becomes capable of recognizing cancer and microbial invaders. Specialized cells (DCs) then communicate the identity of the pathogen to lymphocytes to establish active immunity against stealth diseases.

Fever is a good thing according to knowledgeable physicians. Cellular damage occurs only at temperatures above 108° F, but much good is accomplished at lower temperatures. To exceed 108° F requires outside influences, whereas the body’s internal response to infection (and therefore to bacterial vaccines) is limited to temperatures at or below 106° F.

Transfusing activated DCs into the bloodstream and tissue of patients who are in a vaccine-induced fever is a logical strategy to increase the likelihood of successful immunization. DCs are controlled by the signaling environment in which they function. (Cells perceive danger and talk to each other through a process called signaling. This process is fundamental to growth, repair, and immunity. Errors in cell information processing can lead to cancer, autoimmunity and diabetes). If transfused into a patient in whom the signaling environment is controlled (suppression/tolerance) by malignant or infectious disease, DCs may very likely go to work for the disease. DCs introduced into a signaling environment controlled by an acutely responding self/not-self mechanism — characterized by fever and robust inflammation — will work for the body and against the disease.

The daunting challenge of harvesting mononuclear white cells (monocytes) and stimulating them to convert them to DCs has been answered by a wonderful observation. Like Alexander Fleming’s serendipitous discovery of penicillin, Carole Berger and Richard Edelson found a “magic agent” that enabled them to create DCs overnight. Their first cancer experiment, which involved treating a small amount of a patient’s blood with a photosensitizing drug (psoralen) and long-wave ultraviolet light (UVA), yielded an impossible-to-believe 40% long-term complete remission rate in cutaneous T-cell lymphoma. Their patients would be several decades older (still in complete remission), before Berger and Edelson would learn just how they had been cured. Just as Fleming’s discovery resulted from accidental mold contamination, Berger’s and Edelson’s discovery of “overnight dendritic cells” profited from the inadvertent introduction of acrylic plastic to the flow system. Research shows that monocytes are “insulted” by acrylic plastic and perceive it as not-self. They cling to acrylic and begin to emit danger-signaling molecules of the interferon and interleukin families, as well as growth factor. This begins the process of conversion to dendritic cells, a process that can be greatly accelerated by tumbling them through narrow acrylic tubes called cuvettes. This tumbling creates multiple adhesion incidents in which monocytes get stuck to, ripped off of, and stuck again to the wall of the cuvette. These adhesion incidents greatly amplify the reaction against acrylic, and result in extremely rapid conversion of tens of millions of monocytes to angry DCs.

With this principle in mind, it became possible for us to construct a flow system incorporating copious quantities of acrylic cuvette (small tube) in a circuit including a UVA generator and driven by a Baxter cell separator. The harvest of 40% monocytes in 250 ml whole blood is cultured overnight in a semi-permeable plasma bag to produce highly viable dendritic cells (DC), which are administered through a central line and subcutaneously at bilateral axillary and inguinal sites during CF-induced fevers. DC can be injected intratumorally subsequent to peritumoral injections of CF. The capture and culture of monocytes into dendritic cells, and the transfusion of these cells, primes the patient’s immune system to recognize “not self” pathogens and to activate lymphocytes to eradicate them. Ironically, this is the same putative mechanism exploited by William Coley more than a century earlier.

The cancer patient's body does not know it is sick. The two branches of immunity are not talking to each other. The potentially life-saving, cancer-eradicating strike force led by T lymphocytes (the lead cells of the adaptive immune system) is completely out of the loop, almost like a "Strategic Air Command" having high tea during an enemy missile strike. There are plenty of jets, fuel and bombs, but no one is giving orders to scramble. On the early-detection-and-alert side of things (the innate immune system), our radar dishes are down because "NORAD" (the North American Aerospace Defense Command) has been infiltrated by counterespionage agents. Not only are our best agents (dendritic cells) too few in number, but those that do exist in the cancer patient are unwittingly working for the enemy by sending orders to the connective tissue to support malignant growths, all the while telling T lymphocytes "don't worry about Mr. Malignancy, he is one of us." T cells that have been tricked become counterespionage agents, spreading the message of "tolerance" for all cancer outposts. Because of this, macrophages (large white cells of the innate immune system) swarm to the cancer, eventually comprising up to half of the volume and weight of each tumor. Tumor-associated macrophages clearly demonstrate that cancer gains control of the innate immune system. It is important to note here that monocytes are pluripotent and can grow up into either macrophages or dendritic cells, according to their signaling environment. In cancer, monocytes are preferentially converted into tumor-associated macrophages.

The combined vaccine management can be conceived of as working in the following way: With the introduction by injection of Coley's vaccine, the entire connective-tissue system of innate immunity is put on high alert, and all the alarms go off at once. The PUVA-photopheresis process literally shines a bright light on the turncoats, while at the same time whisking away monocytes before the cancer can grab them.

By sensitizing turn-coat cells to UV-spectrum-A light, photopheresis treatment retires sell-out dendritic cells and T cells. At the same time, activated monocytes are recruited and put through boot camp (mechanical stimulation and overnight growth-factor culture) to make them into special-operations soldiers (activated DCs). Psoralen is adsorbed onto the DNA of malignant cells, pathological microbes, and misprogrammed T cells, and is activated by UVA to create DNA adducts (breaks), which exposes their antigens (protein markers needed by DCs to show T cells what the enemy looks like).

When T cells attack the tumor and the underlying tissue disturbance (with its putative microbial colonization), a process called adaptive immunization occurs. This is the goal of immunotherapy, because the disease is neutralized, its concomitant tissue damage is healed and, ultimately, the immune system develops a lymphocytic imprint, a permanent memory, of the disease. This is the mechanism by which we become immune to measles or mumps; it provides the certainty that once we have had the disease, we will not get it again. We are protected by our immune-cellular memory of the disease, which includes an early-response component

(antibodies produced by B and T memory cells) that nips the disease in the bud, before it can re-establish itself.

Current Status of This Therapy

Our intent is to apply all evidence-based appropriate measures within our grasp to counter the complex and, as yet, unexplained set of pathological changes that occur in cancer. We do not represent our therapy as unique or exclusively correct in any way, and we most certainly do not claim that the US FDA in any way knows about, understands, or approves of the above language or the treatments here described.

The historical record reveals that there have been few systematically applied methods of cancer management associated with credible, positive human outcomes data, i.e., long-term, disease-free survival. In fact, relatively few medicines and technologies have been shown to provide benefit of any clinical relevance to malignant diseases, even in an adjuvant role. The identification of the treatments discussed here is based on the available human outcomes evidence. Our group has had long experience with most of these treatments (with the exception of the recently developed PUVA-photopheresis protocols), and we are convinced of their integrative potential.

References

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- 5/ Hobohm, U., "Fever and cancer in perspective." *Cancer Immunol Immunother* 2001; 50(8):391-6.

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