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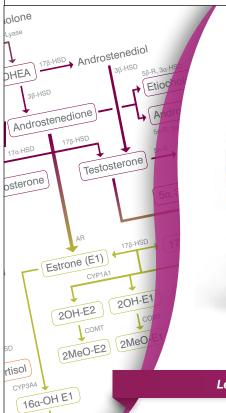
# From the Publisher

## Sometimes a Jump Into the Lake Can Be Deadly

When the weather turns warm, we can't wait to spend time outdoors. What would summer be without a trip to the woods and camping around the lake? A sunny afternoon with the tranquil waters beckoning — who could resist taking a plunge? But when a family visited Anderson Lake near Port Townsend, Washington, last May their dog did not fare well after jumping into the water. Within minutes the canine began convulsing, and hours later it died despite valiant resuscitation efforts by

the veterinarian. Fortunately, the family's child did not immerse herself although she was moderately sickened just cradling the dog. The lake had an explosive algae bloom caused by a cyanobacteria capable of forming a neurotoxin, anatoxin-a. The state had measured the lake's biotoxin level as 9.5 microgram/liter with a standard accepted level required to be less than 1.0 microgram/liter. Anatoxin-a is an amino alkaloid and cyanotoxin that is classified as a very fast death factor (VFDF). The responsible organism was a cyanobacteria, Dolichospermum species (formerly classified as Anabaena).

In the weeks after the incident resulting in the dog's death, the anatoxin-a level dropped to just above the 1.0 microgram/liter level, still not safe. There were signs posted around the lake warning the public about the toxicity threat that the lake poses with orders to not swim, fish, or boat on the lake. Still, a ranger observed a family park their vehicle near the lake in June, and their four-year-old ran from the car toward the lake heedless of the danger until the ranger yelled to stop. Despite the clearcut peril to humans and animals, the state



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#### **Letter from the Publisher**

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and local authorities have not established fencing or other means prohibiting entry to the lake; indeed, the surrounding park offers trails for hikers that is freely accessible. Algae blooms in freshwater lakes are not an uncommon event and have been observed on all continents. Taking a plunge on a warm sunny day is yet another risk that we must assess while engaging in the outdoors.

The poisonous aspect of Lake Anderson did not start this year; two dogs died after drinking water from the lake in 2008. This led to an investigation and discovery that the water was laden with cyanobacteria, evident from the green coloration of the blooms. As the lake is located in the Pacific Northwest, the blooms are sparse during the winter months; but as the weather warms and sunlight increases, the algae grow rapidly. It is conjectured that agricultural run-off and other nutrients alter the lake ecology favoring cyanobacterial growth. Not all algae lake blooms are harmful; only certain harmful algae blooms (HAB) produce serious biotoxins. Visual assessment of the algae is unhelpful in distinguishing HAB from non-toxic blooms.

As noted earlier both ingestion and contact with the neurotoxin will endanger human and animals. After inducing seizures, the neurotoxin will shut down important neurologic functioning leading to loss of coordination, respiratory failure, and death. While shellfish are generally unaffected by the algae, biotoxin accumulation will produce illness if affected shellfish are eaten. Even the non-toxic algae blooms can be harmful in the lake by clogging fish gills and overconsuming oxygen leading to hypoxic lake water.

Anatoxin-a was discovered in 1960 after cattle herds were found dead after consuming water containing cyanobacteria initially identified as *Anabaena flosaquae*. When anatoxin-a was isolated and injected into a variety of animals, all showed very quick neurologic poisoning with seizures, neurologic shutdown, and death. It was established that the nicotinic acetylcholine receptor was irreversibly bound by anatoxin-a, blocking all neurologic transmission requiring acetylcholine. From a public health standpoint, anatoxin-a always poses a threat of entering our reservoirs; monitoring for the biotoxin is critical for all water supply systems. At Lake Anderson, the state has posted several more signs warning of the danger of exposure and swimming. But sometimes when we camp, we just don't pay attention to warnings.

### The 2019 LDN Conference in Portland, Oregon Was an Eye-Opener

For the past few years I have made naltrexone an important part of my medical practice. It is a remarkable tool for alcoholism and alcohol dependency. Following the protocol of the Sinclair Method, 50 mg of naltrexone is taken one hour prior to commencing drinking. Generally, after just several days of naltrexone use, there is a notable decrease in alcohol craving. For those who want to seriously cut back on their alcohol consumption but are not seeking to become sober, this approach is easy without the need to depend on will power to quit. Of course, anyone who is habituated to alcohol drinking will need to decondition their behavior, which will take time. The effort is worthwhile, and the medication is not expensive nor does

continued on page 7 ➤

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it require institutionalized rehab or "cold turkey" withdrawal approaches. It is remarkable that there is such a lack of interest in the medical community. Who wouldn't want to take one little pill instead of endless hours of participating in meetings and counseling?

At the other end of the spectrum is another protocol for naltrexone use known as low dose naltrexone (LDN). As a general rule, LDN administration starts at 0.5 mg and works up to 4.5 mg. Unlike the Sinclair Method, LDN has a wide range of applications in medicine and psychiatry. Naltrexone is recognized as an opiate antagonist binding to the mu receptor. Not so well recognized is its antagonist activity on the TLR (Toll-like receptor). The blockade of the TLR suppresses the overactivity of the immune system as manifested in autoimmune disease. Just like with the Sinclair Method, low dose naltrexone takes some time to modify the immune response within the central nervous system and peripherally. Dosing at nighttime is recommended; but some patients experience excess dreaming or sleep disturbance, so the naltrexone is administered earlier in the day. The application of LDN is breathtaking in its diversity: from Crohn's disease to lupus, from fibromyalgia to depression, from neurologic disease to cancer, from autism to Alzheimer's, from pain control to benzodiazepine withdrawal, from Hashimoto's thyroiditis to peripheral neuropathy.

As this issue of the *Townsend Letter* is focused on cancer, LDN is increasingly being reported to support cancer care. Some workers have found that CBD touted to have anti-cancer activity works very well in combination with LDN and with anti-inflammatory

#### **Letter from the Publisher**

herbals, Boswellia, and turmeric. Effective anti-cancer activity has been seen in melanoma, liver, renal, and pancreatic cancer. Given the abysmal ineffectiveness of chemotherapy and radiation treatment in most solid-tissue cancers and the limited benefit of biologic modifiers and checkpoint inhibitors in extending life, why shouldn't most patients be given LDN in combination with their other cancer treatments? LDN not only does not inhibit chemotherapy, it enhances it!

The LDN Research Trust is a charitable organization set up to educate doctors and patients about LDN. The entire series of lectures from the Portland conference is available at a \$100 discount from the LDN Research Trust (use the code RT100 for the discount). For those who prefer a book, consider *The LDN Book* by Linda Elsegood available from Chelsea Green Publishers. These are great ways to educate oneself about LDN without needing to wait for the next conference.

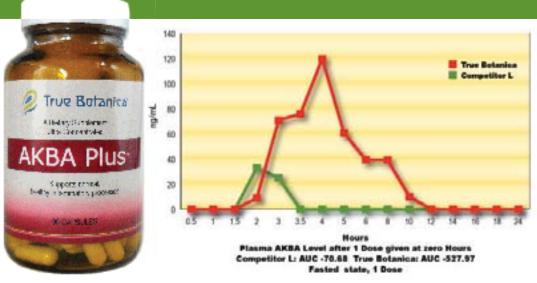
#### Prof. Serge Jurasunas on NK Cell-Based Immunotherapy

Dr. Jurasunas, a clinician practicing near Lisbon, Portugal, has been a frequent contributor to the *Townsend Letter* with his first article appearing in 1999. His work has focused on employing naturopathic and nutritional approaches to enhance cancer survival. He has lectured extensively in Europe and received numerous accolades including a Lifetime Achievement Award. Much of his recent writing has focused on examining the role of the p53 tumor suppressor gene in metastasis and employing

continued on page 11 ➤

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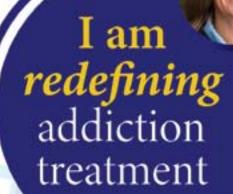
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#### > continued from page 7

nutritional and alternative cancer therapies to optimize and modify its expression. In this issue Jurasunas considers the role of the natural killer (NK) cell in controlling tumor cell growth and facilitating apoptosis. His paper reports on the activity of rice bran arabinoxylan compound in enhancing natural killer cell activity.

Prof. Jurasunas explains that conventional cancer care frequently fails because natural killer cell activity is dramatically reduced. Important immunological functioning, including secretion of pro-inflammatory cytokines as well as interferon, are impaired. Rice bran arabinoxylan (RBAC) is a nutritional supplement developed by the Daiwa company in Japan. Curiously, the product is made from modified rice bran that has been enzymatically treated by an extract derived from a combination of mushrooms. Studies of RBAC have demonstrated increased immunological activity, reduction of cancer treatment adverse effects, decrease in anti-gene tumor markers, and significant improvement in treatment outcomes. Jurasunas discusses the efficacy of RBAC as demonstrated in the literature as well as his own observations of employing the compound with cancer patients.

### Helicidum (Salicinium<sup>R</sup>) Demonstrates Improved Five-Year Cancer Survival

Despite pronouncements by the American Cancer Society and ASCO that progress has been made on the "War on Cancer," statistics generally disclaim that assertion. Chemotherapy remains a mainstay for oncology even though there is little

#### **Letter from the Publisher**

evidence that quality of life is extended. A number of very expensive immune-based drug treatments, antibody and vaccine agents, and genetically based T-cell therapies have been very promising but have had limited benefit with advanced solid-tissue malignancies. Alternative cancer treatments based on dietary change, herbal and nutraceutical supplementation, intravenous nutrient administration, and other unapproved compounds have been employed for several decades but lack survival data. Even much touted intravenous ascorbic acid does not have observational studies of long-term outcomes.

Jeffrey King, MS, JD, a consultant for Cognate 3, manufacturer of Salicinium, has compiled survival and disease progression data for 675 patients with stage IV cancers treated with helicidum, a glycol-benzaldehyde. The compound's mechanism is based on its ability to impair glycolytic metabolism both in cancer and virus-infected cells. Patients were monitored for at least sixty months. Salicinium is administered initially intravenously daily for two weeks or every other day for one month. The treatment protocol requires oral consumption when intravenous Salicinium is not administered. Oral use was required for one year or until remission was verified. Remarkably, there was substantially improved survival in a variety of malignancies over the five-year period. Stage IV breast cancer patients demonstrated a 69% survival rate; in contrast, conventional care of advanced breast cancer patients has a 16% survival rate. Other cancer types revealed similar improvements in sixty-month survival. One of



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the arguments employed by skeptics has been that there is no data substantiating benefit from the use of alternative cancer treatments. King's observational report not only disputes that criticism but argues against the use of conventional care unless the chemotherapy or other modality clearly establishes documented quality long-term survival. For naturopathic and integrative oncology practitioners, Salicinium certainly deserves consideration in prescribed treatment protocols. Furthermore, other alternative cancer treatments should undergo observational monitoring for sixty months to determine survival outcomes.

#### Ralph Moss, PhD's Cancer Journey: Our Cover Story

It is one of those not entirely coincidental ironies that health workers frequently succumb to the disease that they research or treat. Such is the case with Ralph Moss, PhD, who has spent much of his life working with cancer patients, advising them of their best chances for survival employing conventional and alternative cancer care. Moss has been a long-time columnist for the *Townsend Letter* writing critically about pharmaceutical oncology care as well as alternative cancer treatments. Ralph and I had a chance to collaborate in the late 1980s when the US Congress funded the Office of Scientific and Technology Assessment to

write a report about Unconventional Cancer Treatment. We would meet as a panel every six months in Washington, D.C. together with Andrew Weil, PhD, and a few other well-known individuals in the world of unproven cancer treatment. While the report was no glowing imprimatur for funding alternative medicine, it did lead to the establishment at the NIH of the Office of Alternative Medicine, which later evolved into the Center for Complementary and Alternative Medicine. The CCAM continues to fund research in integrative and naturopathic medicine and provides some degree of acceptance for alternative cancer care.

Moss tells us of his past four years of cancer diagnosis and treatment; the outcome has been very successful, and he is very pleased with how he has been doing. Some of the takeaways of his story are (1) The specialist is not always right with the diagnosis; (2) The alternative cancer laboratory test does provide useful additional information; (3) When the lab test suggests but does not prove cancer, it is worthwhile seeking additional diagnostics; (4) Some imaging procedures that provide better information may be only available in distant medical centers; (5) Friday afternoon consultations when the doctor is tired may not be the best time to consult; (6) Cancer centers offer a myriad of treatment options, and it is worthwhile seeing which one may be best even if it is a distant facility; and (7) Follow-up diagnostics reassure one that cancer stability and remission have been achieved.

Jonathan Collin, MD





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# **Shorts**briefed by Jule Klotter jule@townsendletter.com

#### **GcMAF Manufacturer Closed**

Immuno Biotech, Ltd, the research and manufacturing center for GcMAF, a promising cancer therapy, has been closed and its CEO, David Noakes, was sentenced to jail last Fall. GcMAF (GC protein-derived macrophage-activating factor) is a protein made in the body from vitamin D3 binding protein. "About 3% of blood plasma is Gc protein," says health writer Bill Sardi. "Just a tiny fraction of that Gc protein, a billionth of a gram, is converted to GcMAF." Immuno Biotech, based on the island of Guernsey off the coast of Normandy, developed a 22-step process to extract GcMAF for therapeutic use. In addition, each batch was tested nine times for sterility and potency.

First described in 1993 by Nobuto Yamamoto, GcMAF incites macrophage activity, increasing the immune system's ability to destroy and remove microorganisms, abnormal cells, and cellular debris. Inhibition of macrophage activity, via an enzyme called nagalase (α-N-acetylgalactosaminidase), is a key defense mechanism of cancer cells and viral particles. GcMAF reduces nagalase levels and inhibits angiogenesis, slowing cancer growth. Independent researchers from Japan, US, Israel, and other countries have found laboratory evidence that supports the use of GcMAF to treat cancer and other serious illnesses. Published studies also report that GcMAF increases mitochondrial energy production, improves neuronal metabolic activity, promotes neural growth, and reduces neuropathic pain, according to journalist lain Davis.

Company scientists and doctors conducted laboratory research to assess safety and efficacy and published over 30 studies (many are laboratory rather than clinical) in peerreview journals. In addition to treating several hundred patients in their clinics, the company provided GcMAF to researchers, practitioners, and patients (at the suggestion of their doctors) in other parts of the world and collected data on its use in over 11,000 people with diverse illnesses, such as cancer, autism, myalgic encephalomyelitis, chronic fatigue syndrome, multiple sclerosis, Parkinson's, Alzheimer's, and Lyme.

Clinical studies involving patients with terminal cancers demonstrated that GcMAF produces measurable physiological

effects as well as clinical improvement. A 2013 study, written up in the August/September 2016 "Shorts," documented GcMAF's ability to significantly lower nagalase levels in 20 patients with incurable cancers (Thyer L, et al. Oncoimmunology. August 2018). A 2014 study, published in Anticancer Research, investigated the synergistic effect of an oleic acid-GcMAF (OA-GcMAF) complex on people with advanced cancer. The patients were also instructed to consume a very low carbohydrate and high-protein diet, fermented milk products containing naturally produced GcMAF (Bravo Probiotic, Les Alpes, Wellington, NZ), and take vitamin D3, low-dose acetylsalicylic acid, and omega-3 fatty acid supplements. The researchers monitored blood pressure and blood flow to the macrophagerich spleen before and after OA-GcMAF administration to assess its effects. Activated macrophages release nitric oxide (NO), a compound that causes vasodilation, lowering blood pressure.

Blood pressure dropped significantly within a minute after administration with a nebulizer, and ultrasound showed increased blood flow in the spleen. Moreover, tumor size measurably reduced (about 25% reduction in some Stage IV cancer patients) within five days. No serious adverse effects from Immuno Biotech's GcMAF have been reported although the company website says that some people experience general side effects from the activated immune response: tiredness, fever/hot flushes.

In February 2015, the UK's Medicine and Healthcare Products Regulatory Agency (MHRA) raided Immuno Biotech and removed 10,000 vials of GcMAF that it claimed were contaminated. The MHRA, the UK's equivalent of the FDA, raided the company multiple times. Eventually, it closed the company's laboratory, clinics, and offices, and arrested Noakes and four of his staff, charging them with sale and supply of an unlicensed medicine and money laundering. Noakes pled guilty to all charges. Iain Davis explains, "Technically, Noakes broke the law because he sold some GcMAF to those who could afford it. He also gave away 25% of Immuno Biotech's GcMAF, to those who couldn't afford it, free of charge." The

#### **Shorts**

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£7.6 million (\$9.5 million US) that Immuno Biotech made over six years by selling GcMAF financed the company's laboratories and supplies, travel expenses, and salaries for 27 staff members, including four research scientists, seven doctors, two ultrasound personnel, four nurses, and administrative staff. Any surplus was put back into research and development.

The judge sentenced Noakes to 15 months instead of the 14 years sought by MHRA. He was released in Spring 2019, after serving about five months. The judge, according to Davis, "made it clear that GcMAF was not on trial. He accepted that Noakes had acted out of a genuine desire to treat people; he noted that GcMAF had been instrumental in successfully treating people who had been written off by the medical profession and added that he was looking forward to GcMAF being made available to the public." Following the MHRA's lead, the MHRA/FDA-equivalent in France (the OCLAESP) has sought extradition of Immuno Biotech biomedical research scientist, Lyn Thyer — even though she was cleared of all charges in the UK.

When I contacted Immuno Biotech via the email provided on its website, I received an automated reply that said the office was closed and directed me to www.mhracorrupt.st/gcmaf, a site that chronicles MHRA's alleged corruption. It is no longer possible to get the GcMAF used in many of the peer-reviewed studies.

Just because a product is labeled "GcMAF" does not mean it will have the same results. The Immuno Biotech website says, "You can tell if a GcMAF is genuine by the number of tests it has. The fewer the number of tests, the more certain it is not genuine, or has no activity. We do nine tests...We are concerned that the Israeli company Efranat was given \$4.5 million to carry out GcMAF trials, but don't [sic] seem to have a product that works....We are also concerned the trials have been going for two years without excellent results. We had our first result, a full chronic sinusitis recovery, in 2 weeks. We had cancer recoveries in six months. Has this trial been designed by the big pharmaceutical companies to fail?"

It wouldn't be the first time, as Pauling and Cameron could attest regarding the Mayo Clinic's vitamin C trial and Nick Gonzalez recounted in his book *What Went Wrong* about the Columbia University-National Institutes of Health study on the nutritional method used for inoperable pancreatic cancer.

Being a natural substance made in the body, GcMAF cannot be patented. A course of Immuno Biotech's GcMAF cost £380 (\$475 US), according to Davis, compared to £5000 to £40000 for chemotherapy; and evidence indicates it is/was far more effective and without adverse effects. It's hard not to view GcMAF as another example of the pharmaceutical industry's campaign to eliminate a promising therapy that patients claim has cured their cancer.

Davis I. GcMAF – The Persecution of David Noakes and Lyn Thyer. May 24, 2019.

Klotter J. GcMAF and Cancer. *Townsend Letter*. August/September 2016; #397/398: 24.

Ruggiero M, et al. Oleic Acid, Deglycosylated Vitamin D-Binding Protein, Nitric Oxide: A Molecular Triad Made Lethal to Cancer. *Anticancer Research*. 2014; 34: 3569-3578.

Sardi B. This IS the Cure for Cancer. May 17, 2017.

#### **5G Wireless**

Wireless companies around the world are pushing 5G (fifth generation) telecommunications that use higher frequencies to transmit data at faster speeds, but these higher frequencies cannot travel as far as the frequencies emitted by cell phone towers now in use so more antennas will need to be put in place. The 5G technology requires a huge network of microcell wireless facilities to be attached to streetlights and utility poles and will emit microwaves (non-ionizing radiofrequency radiation) from 10 feet up to several hundred feet. Environmental Health Trust reports that hundreds of scientists and doctors from around the world have pleaded with the Secretary General of the United Nations to advocate for more protective policies regarding wireless technology. Fiber optic cable provides a safer, faster, and more reliable alternative to wireless; it also has a greater capacity and is more cyber-secure, according to Environmental Health Trust. "All wireless communication devices put out polarized EMFs that carry information via pulsations. Both the pulsations and the polarization make these EMFs much more biologically active," explains Martin L. Pall, PhD.

Peer-reviewed studies show that wireless radiation increases cancer risk, alters brain development, and produces infertility. Children and pregnant women are most vulnerable to the adverse effects of cumulative radiation exposure. Pall wrote a scientific review about the risks of 5G, focusing on eight pathophysiological effects caused by this type of electromagnetic field (EMF) exposure. Non-ionizing radiation produces oxidative stress and free radical damage. It disrupts the endocrine system (including melatonin production) and damages the nervous system. It produces single strand and double strand breaks in cellular DNA. It increases programmed cell death (a factor in neurodegenerative disease and infertility). And it causes cancers. All of these effects are based upon the fact that microwave EMFs activate voltage-gated calcium channels (VGCC) in cell membranes and, thereby, produce downstream effects. In a chapter for Mobile Communications and Public Health, edited by Marko Markov, Pall explains the mechanisms whereby increases in intracellular calcium and increased peroxynitrite/free radicals/oxidative stress, which occur during VGCC activation, can cause cancer.

"The extraordinary sensitivity of the VGCC voltage sensor to the forces of the EMFs," Pall says in his review article, "tells us that the current safety guidelines allow us to be exposed to EMF levels that are something like 7.2 million times too high. That sensitivity is predicted by the physics. Therefore, the physics and the biology are each pointing to the same mechanism of action of non-thermal EMFs."

If wireless technology is so harmful, why hasn't the European Commission or the US FDA taken measures to curtail its expansion? Mark Hertsgaard and Mark Dowie wrote an article for *The Nation* that explains how the cellular communications and internet industry use the same tactics that the tobacco industry used to hide the dangers of smoking cigarettes. According to these journalists, wireless executives have known since the 1990s that cell phone technology causes cancer and genetic damage. The industry feeds an ongoing

debate about safety by funding studies designed to obscure hazards, attacking studies that show harm, and smearing the reputations of researchers, such as Henry Lai, who question its safety. Industry-friendly appointees to government regulatory agencies and the World Health Organization lend further support. "The [public-relations] playbook's key insight," say Hertsgaard and Dowie, "is that an industry doesn't have to win the scientific argument about safety; it only has to keep the argument going."

Although US agencies, especially the Federal Communications Commission (FCC), support the expansion of wireless technology, some states and local communities are more cautious. Environmental Health Trust explains how local governments can restrict microcell wireless installations, prohibiting small cell installations in residential areas and requiring them to be a certain distance away from schools, hospitals, and other areas.

Environmental Health Trust. USA City Ordinances to Limit and Control Wireless Facilities Small Cells in Rights of Ways. www.ehtrust.org

Environmental Health Trust. What You Need to Know About 5G Wireless and Microcells ("Small" Cells). www.ehtrust.org

Hertsgaard M, Dowie M. How Big Wireless Made Us Think That Cell Phones Are Safe: A Special Investigation. *The Nation*. March 29, 2018.

Pall M. 5G: Great risk for EU, US, and International Health! Compelling Evidence for Eight Distinct Types of Great Harm Caused by Electromagnetic Field (EMF) Exposures and the Mechanism that Causes Them. May 17, 2018

#### **EMF Treatments for Cancer**

In a 2018 paper, a team of North Carolina researchers discuss non-invasive devices, such as TheraBionic™ and Novocure™, that use non-ionizing electromagnetic radiation (EMR) to treat cancer. TheraBionic™ is the result of work by B. Pasche and colleagues, who began investigating low, safe levels of specific radiofrequency EMR to improve sleep in the 1990s. In the early 2000s, Pasche and A. Barbault began looking for tumorspecific modulation frequencies to treat cancer - not unlike Royal Rife who used frequencies to treat cancer and other illnesses nearly 100 years ago. Pasche and Barbault discovered that patients responded to a tumor-specific set of frequencies with changes in skin electrical resistance, pulse amplitude, and blood pressure. Healthy people showed not such response. Breast cancer, heptocellular carcinoma, prostate cancer, and pancreatic cancer each had their own set of frequencies. The only frequencies that appear in sets for each type of cancer were 1873.5 Hz, 2221.3 Hz, 6350.3 Hz and 10456.4 Hz.

Sixteen patients involved in this study agreed to receive treatment with the identified frequencies, using the TheraBionic™ device. All had "limited therapeutic options." The frequencies are delivered by a spoon-shaped antenna placed in the patient's mouth for three hours a day. Six of the sixteen reportedly responded. A woman with hormone-refractory breast cancer that had spread to the adrenal glands and bones had "a complete response lasting 11 months." Another woman with breast cancer and metastasis to liver and bones had a partial response lasting

#### **Shorts**

13.5 months. A patient with thyroid cancer with metastasis to the lungs was stable for over seven years. One with non-small cell lung cancer was stable for 5.1 months, another with pancreatic cancer (metastatic to the liver) was stable for 4.1 months, and a person with leiomyosarcoma (metastatic to the liver) was stable for 4.0 months. The North Carolina researchers say, "These results indicate that treatment not only has an impact on the primary tumor but can also treat metastatic tumors implying that this treatment is systemic." Controlled laboratory experiments have confirmed that the frequencies used clinically inhibit the proliferation of the specific, corresponding type of cancer and do not affect normal cells.

NovoTTG-100A (brand name Optune®) uses transducer arrays applied to the scalp to deliver low-magnitude (1-3 V/ cm), intermediate frequencies (100-300 kHz). The frequencies cause cytoplasmic stress in multiple cancer cell lines and inhibit proliferation. Surprisingly, Optune has US FDA approval for use in treating adults with confirmed glioblastoma. A Phase III clinical trial was stopped early when newly diagnosed glioblastoma patients who were receiving Optune treatment showed statistically significant improvement in progressionfree survival and in overall survival. All 315 patients in the study had undergone chemoradiation treatment and were receiving maintenance temozolomdie chemotherapy. Median overall survival in the 196 who used Optune was 20.5 months (95% CI, 16.7-25.0 months), compared to 15.6 months (95% Ci, 13.3-19.1 months) in the 84 people receiving chemotherapy alone. (I can't help wonder what effect the EMR treatment would have had if given before chemoradiation.) Like TheraBionic™, Optune uses frequencies that target tumor cells but do not affect healthy cells that divide normally. Recommended treatment time is 18 continuous hours per day.

Jimenez H, et al. Use of non-ionizing electromagnetic fields for the treatment of cancer. *Rontiers in Bioscience, Landmark.* January 1, 2018;23:284-297.

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# Literature Review & Commentary

by Alan R. Gaby, MD drgaby@earthlink.net

#### Vitamin D for Lung Cancer

One hundred fifty-five Japanese patients (mean age, 68 years) with non-small cell lung cancer were randomly assigned to receive, in double-blind fashion, 1,200 IU per day of vitamin D or placebo, beginning after surgery and continuing for one year. During a median follow-up period of 3.3 years, the relapse rate was 28% and the death rate was 17%. There was no significant difference between groups in relapse-free survival or overall survival time. However, in the pre-specified subgroup analysis of patients with early-stage adenocarcinoma and a serum 25-hydroxyvitamin D level less than 20 ng/ml, the vitamin D group had significantly better five-year relapse-free survival (86% vs. 50%; p = 0.04) and overall survival (91% vs. 48%; p = 0.02), compared with the placebo group.

Comment: This study showed that vitamin D supplementation may increase survival times and increase the time until a relapse occurs in patients with early-stage adenocarcinoma of the lung and a low serum 25-hydroxyvitamin D level. However, vitamin D was not beneficial in patients with higher 25-hydroxyvitamin D levels, later-stage lung cancer, or lung cancer other than adenocarcinoma. If correcting vitamin D deficiency is beneficial for a subset of patients with lung cancer, the mechanism may involve an improvement in immune function.

Akiba T, et al. Vitamin D supplementation and survival of patients with non-small cell lung cancer: a randomized, double-blind, placebo-controlled trial. *Clin Cancer Res.* 2018;24:4089-4097.

#### More on Vitamin D and Cancer

One hundred thirty-nine patients (mean age, 56 years) with advanced or metastatic colorectal cancer were randomly assigned to receive, in double-blind fashion, high-dose or low-dose vitamin D in addition to chemotherapy. High-dose vitamin D was 8,000 IU per day for the first chemotherapy cycle, followed by 4,000 IU per day. Low-dose vitamin D was 400 IU per day. At baseline, the median 25-hydroxyvitamin D level was 16.1 ng/ml in the high-dose group and 18.7 ng/ml in the low-dose group. During a median follow-up period of 23 months, the median progression-free survival time was 13 months in the high-dose group and 11 months in the low-dose group (p = 0.07). When expressed as a hazard ratio, the multivariable-adjusted hazard ratio for progression-free survival was 0.64 (p = 0.02), which suggested a beneficial effect of vitamin D.

In a second study published in the same issue of the same journal, 417 Japanese patients with digestive tract cancers (48% colorectal, 42% gastric, 10% esophageal) were randomly assigned to receive, in double-blind fashion, 2,000 IU per day of vitamin D or placebo, beginning at the first postoperative outpatient visit. At baseline, 42% of the patients had a 25-hydroxyvitamin D level below 20 ng/ml. During a median follow-up period of 3.5 years, the death rate was 15% in each group. Five-year relapse-free survival was nonsignificantly higher with vitamin D than with placebo (77% vs. 69%). There was no evidence that vitamin D was more effective in patients with baseline 25-hydroxyvitamin D levels below 20 ng/ml than in other patients.

Comment: The results of these studies, when combined with the study cited above, are consistent with a modest benefit of vitamin D supplementation in certain subsets of patients with cancer. Further research is needed to determine which types of cancer patients are most likely to benefit from vitamin D and what the optimal dosage range is.

Ng K, et al. Effect of high-dose vs standard-dose vitamin D3 supplementation on progression-free survival among patients with advanced or metastatic colorectal cancer: the SUNSHINE randomized clinical trial. *JAMA*. 2019;321:1370-1379. Urashima M, et al. Effect of vitamin D supplementation on relapse-free survival among patients with digestive tract cancers: the AMATERASU randomized clinical trial. *JAMA*. 2019;321:1361-1369.

#### **Unmetabolized Folic Acid and Cancer Risk**

In a previous randomized controlled trial of folic acid supplementation in patients with a history of colorectal adenomas, there were indications that folic acid increased the risk of adenoma recurrences during later years. In a post hoc analysis of the original study, researchers measured serum levels of methylated folates (the sum of 5-methyltetrahydrofolate 4-alpha-hydroxy-5-methyltetrahydrofolate) unmetabolized folic acid in 924 participants at baseline and after three years of supplementation. No association was found between plasma methylated folates or unmetabolized folic acid (measured at 3 years) and risk of adenoma recurrences. However, during later follow-up (up to 8 years of supplementation), the pre-specified endpoint of high-risk findings (multiple or advanced adenomas) was positively associated with plasma methylated folates (p for trend < 0.01), with a 58% increased risk for participants in the highest vs. the lowest quartile. There was an inverse association between plasma unmetabolized folic acid and high-risk findings (p for trend < 0.05) and between plasma unmetabolized folic acid and advanced adenomas (p for trend = 0.07). A significant inverse association was also seen between methylated folates and risk of serrated adenomas, with a 39% lower risk in the upper versus the lower quartile (p for trend = 0.03).

Comment: There is conflicting evidence regarding whether folic acid supplementation affects cancer risk. Various studies have suggested increased risk, decreased risk, and no effect. Some researchers and practitioners have suggested that, if folic acid does increase cancer risk, the effect might be due to unmetabolized folic acid. If that is the case, then 5-methyltetrahydrofolate (also called 5-MTHF or methylfolate) might be preferable to folic acid for use as a nutritional supplement. I have previously challenged the argument that 5-MTHF is generally a more effective supplement than folic acid, and I have cited evidence that in some cases 5-MTHF may be less effective than folic acid (including in patients with the 677C  $\rightarrow$ T polymorphism of methylenetetrahydrofolate reductase).<sup>2</sup>

In the present study, higher serum concentrations of unmetabolized folic acid were associated with a lower incidence of high-risk precancerous adenomas. That finding does not support the idea that unmetabolized folic acid increases cancer risk. The findings with regard to 5-MTHF were

less clear, with both adverse and protective effects observed, depending on the outcome being measured. The results of the present study do not suggest that unmetabolized folic acid is preferable to 5-MTHF with respect to cancer risk.

Rees JR, et al. Unmetabolized folic acid, tetrahydrofolate, and colorectal adenoma risk. Cancer Prev Res. 2017:10:451-458.

#### **Organic Foods and Cancer Risk**

Some 68,946 French adult volunteers (mean age, 44 years) completed a questionnaire regarding the frequency with which they consumed the organic version of 16 food items (never, occasionally, or most of the time). From these data, an organic food score was calculated. During a mean follow-up period of 4.6 years, 1,340 first cases of cancer were documented, the most prevalent being 459 breast cancers, 180 prostate cancers, 135 skin cancers, 99 colorectal cancers, 47 non-Hodgkin lymphomas, and 15 other lymphomas. After adjustment for potential confounding variables (including age, sex, occupation, education level, marital status, income, physical activity, smoking status, alcohol intake, family history of cancer, body mass index, energy intake, fiber intake, and processed meat intake), high organic food scores were inversely associated with the overall risk of cancer (hazard ratio for the highest vs. the lowest quartile = 0.75; p for trend = 0.001). The absolute risk reduction for the highest vs. the lowest quartile was 0.6%, indicating six fewer cases of cancer per 1,000 individuals during the study period.

Comment: In this study, more frequent consumption of organic foods was associated with a lower risk of developing cancer. Numerous other observational studies have reported similar findings, and animal studies indicate that some pesticides are carcinogenic. Although randomized controlled trials would be needed to prove that eating organic foods prevents cancer, avoiding pesticides as much as possible seems like a prudent thing to do.

Baudry J, et al. Association of frequency of organic food consumption with cancer risk: findings from the NutriNet-Sante Prospective Cohort Study. *JAMA Intern Med*. 2018;178:1597-1606.

#### Cow's Milk, Estrogen, and Cancer

One hundred nine postmenopausal women consumed 1 liter per day of semi-skimmed milk (1.5% fat) for four days and 1 liter per day of whole milk (3.5% fat) for four days, with a four-day washout period between the interventions. Sex steroid hormone concentrations were measured in 24-hour urine samples at baseline and at the end of each intervention. Compared with baseline, mean urinary excretion of estrone increased significantly with both types of milk; the increase was somewhat greater with semi-skimmed than with whole milk. Urinary excretion of estradiol and estriol increased after consumption of semi-skimmed milk but not after consumption of whole milk.

Comment: In order to maximize milk production, milk cows are kept pregnant most of the time, with only short intervals between pregnancies. However, the milk of pregnant cows

#### **Gaby's Literature Review**

contains higher levels of pregnancy hormones, compared with the milk of non-pregnant cows. The increase in estrone concentrations after consumption of cow's milk might explain the reported association between cow's milk consumption and several hormone-sensitive cancers (including breast, uterine, and prostate cancer).

Michels KB, et al. Urinary excretion of sex steroid hormone metabolites after consumption of cow milk: a randomized crossover intervention trial. Am J Clin Nutr. 2019:109:402-410.

#### Choline Decreases Some of the Adverse Effects of Alcohol **Consumption During Pregnancy**

Sixty-nine pregnant women in Cape Town, South Africa, who had been heavy alcohol consumers during at least part of their pregnancy were randomly assigned to receive, in double-blind fashion, 1 g of choline twice a day or placebo, beginning at a mean of 20 weeks of gestation and continuing until delivery. After exclusion of four children whose mothers took less than 20% of the study medication, the proportion of children who passed the eye blink conditioning test (an indicator of neurological development) at age 6.5 months was significantly higher in the choline group than in the placebo

group (66.7% vs. 34.6%; p < 0.04). While both groups were small at birth, the choline group (but not the placebo group) showed considerable catch-up growth in weight and head circumference at 6.5 and 12 months of age. At 12 months of age, the choline group had better visual recognition memory than the placebo group.

Comment: Choline plays a key role in the development of the fetal brain, whereas prenatal alcohol exposure impairs fetal brain development. The results of the present study indicate that choline supplementation during pregnancy can decrease some of the adverse effects of maternal alcohol consumption on the child's neurological development, postnatal growth, and cognition. Pregnant women should be strongly discouraged from drinking alcohol, but in women who do not comply with that recommendation, choline supplementation may provide some benefit.

Jacobson SW, et al. Efficacy of maternal choline supplementation during pregnancy in mitigating adverse effects of prenatal alcohol exposure on growth and cognitive function: a randomized, double-blind, placebo-controlled clinical trial. Alcohol Clin Exp Res. 2018;42:1327-1341.

#### **Does Eating Sugar Impair Fertility?**

The association between sugar-sweetened beverage consumption and fertility was examined in a prospective cohort study of 3,828 North American women (aged 21-45 years) who had been attempting to become pregnant for six

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months or less and 1,045 of their male partners. Participants completed a baseline questionnaire that assessed sugar-sweetened beverage consumption during the previous four weeks, and they were followed until pregnancy or for up to 12 menstrual cycles. As compared with no intake of sugar-sweetened beverages, consumption of seven or more servings per week was associated with a significant 20% decrease in both males and females in the fecundability ratio (defined as the probability of conception in any given cycle).

Comment: In a previous study, consumption of a diet high in sucrose (2.6 g per kg of body weight 2 days a week) inhibited oocyte maturation in monkeys.<sup>3</sup> In addition, feeding sugar-sweetened drinks (25% of total calories) resulted in impaired fertility in male mice.<sup>4</sup> In a cross-sectional study of college men, higher intake of sugar-sweetened beverages was significantly associated with lower sperm motility.<sup>4</sup> The results of the present study suggest that excessive sugar consumption may decrease fertility in humans as well.

Hatch EE, et al. Intake of sugar-sweetened beverages and fecundability in a North American preconception cohort. *Epidemiology*. 2018;29:369-378.

#### **Probiotic for Chronic Periodontitis**

Forty-one Brazilian patients with chronic periodontitis were randomly assigned to receive, in double-blind fashion, lozenges containing *Bifidobacterium animalis* subsp. *lactis* HN019 (10<sup>9</sup> colony-forming units per lozenge) or placebo lozenges twice a

#### **Gaby's Literature Review**

day for 30 days. All patients received scaling and root planing at the beginning of the study. At 90 days, the mean decrease in probing pocket depth and the mean clinical attachment gain were significantly greater in the probiotic group than in the placebo group.

Comment: In this study, treatment with lozenges containing *Bifidobacterium animalis* subsp. *lactis* HN019, when used as an adjunct to scaling and root planing, were beneficial in the treatment of chronic periodontitis. While the mechanism of action is not known, this probiotic might work by decreasing the number of pathogenic organisms in the mouth.

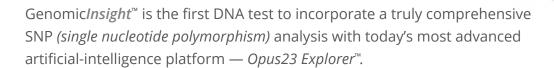
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# **Environmental Medicine Update**

by Marianne Marchese, ND www.drmarchese.com

# **Endocrine-Disrupting Chemicals and Breast Cancer**

#### Introduction

Endocrine-disrupting chemicals (EDCs) are compounds found in the air, water, food, personal care products, cleaning products, carpet, furniture, and more. Women are exposed daily to low doses of these chemicals, which can interfere with the body's hormone system. Some can mimic hormones, and others block natural hormones from functioning normally. Numerous health effects in women have been linked to EDCs such as phthalates, bisphenols, parabens, and heavy metals. This article will focus on the link between these compounds and breast cancer. It's important to understand the sources of exposure and methods for avoidance as a way to decrease risk of developing breast cancer.

Phthalates are a class of chemicals present in many consumer products. They are a plasticizer used to make plastic more flexible. They are in products such as toys, vinyl flooring, mattress covers, vinyl shower curtains, detergents, and plastic food packaging such as storage containers and plastic wrap on food. Phthalates are in personal care products such as nail polish, hairsprays, aftershave lotions, soaps, shampoos, perfumes, and more. Phthalates are also found in soft and flexible plastic beverage bottles such as water bottles or plastic bottles containing soda. Phthalates are known to leach from the product into food, beverages, and personal care products, creating a common source of low-dose exposure. There are different forms of phthalates and metabolites, called monoesters, that can be tested for in blood and urine. Several studies suggest that certain phthalates may be associated to breast cancer since they can bind and activate the estrogen receptors. Studies even show that phthalates are linked to breast density on mammography, which can make breast cancer detection more difficult.1-3

Parabens are a class of compounds used as preservatives in most personal care and grooming products and cosmetics. They are found in deodorants, toothpastes, shampoos, conditioners, body lotions, and makeups. The parabens used most commonly in cosmetics are methylparaben, propylparaben, butylparaben, and ethylparaben. Typically, parabens are used in combination,

meaning more than one, to increase the anti-microbial effect. Parabens are known endocrine-disrupting compounds with estrogenic effects and links to breast cancer. The non-profit Campaign for Safe Cosmetics (CSC) has for years urged the FDA to remove these compounds from consumer products, but the FDA states more research needs to be done to prove they are harmful. Yet, in 2012, the European Union banned parabens from personal care products due to endocrine-disrupting effects. Numerous studies link parabens to breast cancer. Parabens stimulate oncogene expression and breast cancer cell proliferation in vitro via estradiol receptor-alpha. Studies show, in vitro, parabens can influence not only proliferation but also migratory and invasive properties of human breast cancer cells.<sup>4,5</sup> Parabens are best tested for in tissue samples, but that option isn't readily available to clinicians; so urine testing is the next best method of detection.

Bisphenols are a class of chemicals found in numerous household products, including water bottles, plastics dishes, cutlery, food packaging, canned food, paper sales receipts, and more. There are different classes of bisphenols with the most common one being bisphenol-A (BPA). As research has emerged linking BPA to endocrine conditions, many products have removed BPA only to replace it with other bisphenols such as bisphenol-B (BPB), bisphenol-F (BPF), and bisphenol-S (BPS). These are just as harmful as BPA. Bisphenols are best tested for in the blood. Based on the definitions of "carcinogen" put forth by the International Agency for Research on Cancer and the National Toxicology Program, BPA may be reasonably anticipated to be a human carcinogen in the breast. Studies have shown that low-dose BPA can cause adverse health effects and hormone disruption. One study looked at 167 blood samples from breast cancer patients and hospital controls between 1994 and 1997 and found associations between BPA levels and breast cancer. Another study showed serum BPA correlated with elevated mammographic breast density in postmenopausal women from Wisconsin.3,6

Heavy metals such as cadmium, lead, mercury, and arsenic are also considered endocrine-disrupting compounds with links to breast cancer.7-10 Women are exposed daily to these metals through air pollution, water, food, and personal care products. Cadmium can be present in the soil thus contaminating nonorganic vegetables. Leafy vegetables such as lettuce and spinach, potatoes and grains, peanuts, soybeans, and sunflower seeds contain high levels of cadmium. Tobacco leaves accumulate high levels of cadmium, and people who smoke or are exposed to cigarette smoke are exposed to cadmium. Most women are exposed to various forms of mercury from the diet and air pollution. Methylmercury from fish is the main source of dietary exposure. Lead can be a contaminant in drinking water, the soil (accumulating up the food chain), air pollution as well as in cosmetics. Lipstick is a source of lead exposure, and many women are not aware of this fact. Arsenic is present in the air, water, and soil. Contaminated water used for drinking, food preparation, and irrigation of food crops poses the greatest threat to public health from arsenic. Arsenic is in pesticides and sprayed on crops and accumulates up the food chain. It is in tobacco due to soil contamination, making cigarette smoke a source of exposure as well. These metals can be tested for in both the blood and urine.

Genetics plays a role in whether or not a woman exposed to endocrine-disrupting compounds will be affected. Every day, women are exposed to low doses of these compounds, but not all women develop breast cancer or breast density. Individual traits in liver metabolism called single nucleotide polymorphisms (SNPs) play a role in breaking down these compounds and

determining their detrimental effects. SNPs of liver detoxification and metabolism can be tested for through various labs. These compounds also affect genes and the functioning of genes, offering a mechanism of action for disruption. EDCs alter estrogen receptor signaling pathway genes and inflammation-associated genes in women with breast cancer. For example, phthalates and BPA altered five common genes — CYP19A1, EGFR (epidermal growth factor receptor), ESR2 (estrogen receptor 2), FOS (FBJ murine osteosarcoma viral oncogene homolog), and IGF1 (insulin like growth factor 1) — associated with breast tumors. All of these genes are estrogen responsive. <sup>11</sup>

#### **Case Example**

A 42-year-old woman comes in for an initial visit for menstrual cramps. She has a past medical history of endometriosis diagnosed via laparoscopy five years ago. She has had menstrual cramps her entire life, and seven to eight years ago had difficulty getting pregnant. After the laparoscopic procedure, she was able to conceive. Only recently have the menstrual cramps returned, and she rates them as a 3/10 but is concerned the endometriosis is coming back. She is also concerned about breast cancer because her older sister was just diagnosed with triple negative BRCA. She is on no prescription medication, and supplements with a multivitamin/mineral, fish oil, B complex, and vitamin D (1,000 iu a day). Her initial labs of CBC, CMP, TSH, FT4, lipids, ESR, iron, B12, vitamin D, Day 3 estradiol, testosterone, FSH, and Day 21 progesterone were all normal. A screening mammogram



#### **Environmental Medicine**

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with ultrasound, which was just ordered by her MD, showed breast density. Breast density on mammography is a risk factor for BRCA as it makes cancer detection more difficult. So where to begin?

There is a link between endometriosis and BRCA. Both are driven by estrogen and share similar inflammatory markers and genetic traits as well as a link to endocrine-disrupting compounds. EDCs are also linked to breast density on mammography. An indepth environmental exposure history is a critical part of the initial work-up. Start with in-utero exposures, exposure during lactation, and exposure during critical windows of development such as childhood and menarche. The environmental evaluation includes a history not only on the patient but her parents as well. Consider air pollution (both indoor and outdoor air), source of drinking water, hobbies, parents' health status, and medications the parents took before and during the pregnancy as well as during lactation. Did the parents or patient live near a farm, orchard, golf course, or industrial plant? Consider dietary factors such as mercury from fish and pesticide residue on food. Consider chemicals leaching from plastics in food. Look for home and work exposures in the patient as well as her parents such as water leaks and mold in the home or office, age of the house/office and possible exposure to lead paint, and HVAC system integrity. Ask about chemicals from cleaning products, flooring, furniture, paints, glues, and cabinetry. This is especially important if the home or office was recently remodeled. Ask about the type of personal grooming products and cosmetics she uses and what type of air and water filters are in the home and used at work. These are only an example of where to begin.

The environmental exposure intake will help guide the physician on what the patient may have been exposed to that could be contributing to her health condition or help guide the doctor on how best to prevent future health issues such as breast cancer. The exposure intake also helps determine if any testing needs to be done for EDCs. Numerous labs offer both blood and urine tests for heavy metals, phthalates, bisphenols, pesticides, parabens, and more. Most women are exposed to low doses of EDCs on a daily basis, but not all develop health conditions linked to chemicals. This is probably due to the genetic make-up of the patient and single nucleotide polymorphisms, SNPs, of liver metabolism. Several labs offer testing for SNPs that may help explain why some patients suffer the effects of exposure to EDCs more than others. If lab testing reveals the presence of heavy metals or other EDCs, then the patient may need a treatment plan consisting of chelation and/or detoxification. Detoxification is explained in detail in my book, 8 Weeks to Women's Wellness.

Dr. Marianne Marchese is the author of the bestselling book *8 Weeks to Women's Wellness* about the environmental links to women's health and how to detoxify from toxicants. She maintains private practice in Phoenix, Arizona, and is adjunct faculty at Southwest College of Naturopathic Medicine, teaching gynecology. She served on the State of Arizona Naturopathic Physicians Medical Board, National Association of Environmental Medicine, Arizona Naturopathic Medical Association, and Council on Naturopathic Medical Education. She lectures throughout the US and Canada on women's health, environmental, and integrative medicine topics. www.drmarchese.com

Next comes educating the patient on avoidance. Some examples on how to avoid toxins in your daily life include the following:

- 1. Eat only organic and non-GMO fruits and vegetables that are free of pesticide residues.
- 2. Eat organic and non-GMO meats and dairy products.
- 3. Buy fresh or frozen foods and avoid canned foods lined with BPA.
- 4. Eat wild-caught fish low in mercury.
- 5. Do not store or heat food in plastic containers; use glass.
- 6. Buy in bulk to decrease plastic packaging.
- Avoid gluten as most wheat is sprayed with chemicals prior to harvest.
- 8. Drink water out of glass or metal containers rather than plastic.
- 9. Filter your own water.
- 10. Use a home HEPA air filter.
- 11. Use non-toxic detergent, cleaners, and soaps.
- 12. Use natural pest control instead of insecticides in and around the home.
- Replace vinyl mini blinds, shower curtains, and placemats with fabric.
- 14. If you're building a home or remodeling, use non-toxic materials.
- 15. Use natural, organic, non-bleached tampons without a plastic applicator.
- 16. Avoid the use of fragrances, and remember that unscented is not fragrance free.
- Use cosmetics and grooming products free of parabens, phthalates, lead, and solvents.
- 18. Consider a small air filter at work, and drink only filtered water at work,
- Avoid hobbies with exposures to chemicals such as solvents, metals, and pesticides.
- 20. Remove your shoes when you enter the home.

#### Summary

Endocrine-disrupting compounds are present in small amounts in the air, water, food, cleaning, and personal care products. These compounds are shown to alter hormones in the body and are linked to breast cancer and breast density. It is important for physicians to consider the link between EDCs and BRCA for both prevention and treatment. An in-depth environmental exposure questionnaire, testing for toxicants, detoxification, and education on avoidance are part of a comprehensive approach to care.

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#### Clinical Study #1 (1999)

In a study of 319 women visiting three medical clinics, most women's normal vaginal bacterial residents included L. crispatus (32%), followed by L. jensenii (23%), L. 1086V (15%), L. gasseri (5%), L. fermentum (0.3%), L. oris (0.3%), L. reuteri (0.3%), L. ruminis (0.3%), and L. vaginalis (0.3%).\*

Antonio MAD, et al. Journal of Infectious Diseases 1999;180:1950-6.

#### Clinical Study #2 (2007)

In another study involving 126 healthy pregnant women, L. crispatus and L. gasseri were the most dominant species found, followed by L. jensenii and L. rhamnosus.\*

Kiss H, et al. BJOG: An International Journal of Obstetrics & Gynaecology 2007;114: 1402-1407.

#### Clinical Study #3 (2014)

In a double-blind, randomized placebo-controlled trial, 1-week of oral supplementation with the four Astarte strains significantly enriched Lactobacilli in the vaginal tract and reduced Nugent score in the neo-vagina of post-operative transsexual women, an environment typically resistant to colonization by Lactobacilli.

Kaufmann U, et al. Eur J Obstet Gynecol Reprod Biol. 2014 Jan;172:102-5.

#### Clinical Study #4 (2016)

In immunosuppressed pregnant women with herpes infection, oral supplementation with the four Astarte strains significantly reduced undesirable microbes in the intestines and vagina, and simultaneously increased vaginal Lactobacilli 3-fold compared to placebo.\* This was accompanied by reduced incidence of placental insufficiency, pre-eclampsia and fetal distress in the probiotic supplemented women.

Anoshina TM, et al. Perinatologiya I Pediatriya 2016;4(68):22-25.



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# FCT® and Cancer

#### by Savely Yurkovsky, MD<sup>©</sup>

FCT's (Field Control Therapy) approach to cancer is as unorthodox and specialty-free as its approach to all diseases – from pediatrics to geriatrics. It focuses far less on the label, but far more on the main causes of disease. Obviously in cancer, the causes are carcinogens as well as factors that lead to another important component, a weak immune system that has failed to nip cancer in the bud. Not to be overlooked are weak organs with cancer or any chronic pathology.

Departing from the FCT perspective, here is a brief review concerning the corresponding deficiencies, benefits, and potential for improvement for conventional and alternative-integrative approaches to this vicious disease. Progress in its treatment and prevention is vital since this epidemic is expanding and is expected to soon bypass heart disease as a leading cause of death.

#### **Conventional Oncology**

There are three deficiencies in conventional oncology. First, diagnosis and treatment of carcinogens is, at this time, nonexistent.

Second, correctly addressing immune deficiency is another blind spot. Instead of identifying and properly treating its causes, this approach simply resorts to more drugs, immunotherapy in this case. As expected, whenever the main causes of any complex problem (such as disease) are ignored or improperly addressed, even oncologists, themselves, have had to admit that immunotherapy has become a failed hype. The main treatment,

chemotherapy, is well-known for its side effects, including fatalities.

science Third. corrupt another Conventional deficiency. medical academicians and journals have repeatedly exposed pharmaceutical industry has turned medicine into a virtual flea market. Books such as On the Take, Overdosed America, and published this year, Can Medicine Be Cured? The Corruption of A Profession, make this blatantly transparent. Many studies showing increased survival rates for different cancer types, which were sponsored by pharmaceutical companies, were intentionally forged. As a result, in an unknown number of cases, any benefits of chemotherapy are actually non-existent. As a typical example, recently the New York Times and other major media outlets have exposed a chief cancer scientist in a premiere cancer center being paid millions of dollars, as a 'consultant', by the pharmaceutical industry. He published numerous articles in medical journals that dictate treatment standards for oncologists; yet, he concealed being paid by the very drug companies that make the drugs he recommended to 'improve' chemotherapy regimens. The so-called "new experimental cancer treatments," which are presented to desperate patients as the latest secret breakthrough, are usually nothing but a necessity for the pharmaceutical companies to enroll human "rabbits" in order to fulfill FDA requirements for human trials before a drug can be considered ready for the market. It is

not impossible that a drug might be of benefit; yet, it is just as possible that a drug may have devastating side effects and kill, even before cancer would. All in all, these new 'hopes' are a shot in the dark.

As a benefit, however, physical eradication of certain tumors and leukemia through surgery, chemo, and radiation therapy, as appropriate, have improved survival rates.

Overall, according to conventional academicians, the notorious war on cancer, initiated by President Nixon in the 1970s, has failed despite its staggering spending over decades. Prevention is virtually nonexistent; and what is portrayed as such, screening tests and doctor visits, are only earlier diagnosis of already formed cancerous and precancerous lesions. Even with the children, pediatricians` 'wellness visits', which use the same general preventative approach, is little more than a joke. When I saw eight-year-old Avery, who was operated on shortly before for a potentially fatal kidney cancer, her mom told me that only two weeks before the diagnosis, Avery was pronounced healthy by her pediatrician at a 'wellness' visit. In many cases, even an early detection of cancers such as lung, liver, pancreas, brain, and others – renders low benefit in reducing mortality.

Since the effective prevention cannot possibly exist without properly identifying the primary causative agents of cancer – immune suppression and weak organs – the epidemic keeps growing and afflicting a progressively

younger population. According to the American Cancer Society, cancer is on the rise among children. But, instead of focusing on these deficiencies in the war on cancer that would drastically undermine the enemy, conventional oncology keeps adding only more impressive-looking bullets, smoke, and astronomical costs to the war.

Fairly recently, I watched on 60 Minutes another impressive looking bullet/smoke combo joining the war, which the program, for lack of understanding medicine, was hyping into big progress. This concerned a new super database on cancer that contained mega-million pieces of information the immune concerning system, genetics, oncological treatments, you name it. But as the program went on pumping up this new hope, while its "leading scientists" remained mum on the issues of causes of cancer and immunosuppression, the more hopeless I felt about it. Unfortunately, the end of the program proved my concern as patients who were treated based on all

the "best" in oncological science had the same tragic end.

## Alternative-Integrative Approach to

The benefit of the alternativeintegrative approach is that it's far more eclectic than conventional oncology and contains many treatments that do not produce the degree of morbidity and mortality of conventional oncology.

The deficiency is that it excessively relies on laboratory tests, bio-medical treatments, and procedures that fall short in properly determining and treating the main causes of cancer, immune deficiencies and afflicted organs. As a result, many approaches still resort to chemotherapy in varying doses.

Overall results of this approach, as in vaccine cases, are difficult to reliably evaluate for the true incidence of failures because of underreporting, similar to pediatricians concerning vaccination damage. The outcomes, in my observations, vary depending on the

severity and the type of cancer as well as the nature of the approach.

Another confounding factor is that many of these patients have already undergone surgeries and/ or chemotherapy that, depending on the type and stage of cancer, may have contributed, or not, to a positive outcome of alternative-integrative treatments.

Since the issue of causes of cancer and poor immunity are fundamental to the outcome, quality of diagnostic and therapeutic methods to address these are vitally important, as can be judged from the following tragic case.

A fairly new patient of mine, a middle-aged woman, was diagnosed with breast cancer. Following this she traveled to the mecca of alternative cancer treatments, a cancer clinic in Mexico. She underwent many treatments and tests at a high cost for over a year and emailed periodically encouraging reports to her husband and me. Yet, the issue of carcinogens

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#### FCT® and Cancer

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and causes of her faulty immunity was of concern, and I advised her to either stop by my office, during her short visits home, in order to address these through bioresonance testing and FCT remedies, or do these elsewhere. She ignored this advice and kept reporting that cancer tests continued to improve to the point of no cancer remaining. However, soon after her return home, she suddenly experienced a turn for the worse and died weeks later.

#### FCT Experience with Cancer and High-Risk Patients (No Claims Made)

In her late 50s, Mrs. S was advised to have prophylactic removal of her ovaries due to testing positive for one of the mutated BRCA genes, placing her at high risk for developing ovarian and breast cancer. Yet, having been a longterm patient who enjoyed good results with her health issues on FCT and having faith in its bioresonance testing, she chose to avoid the surgery and conduct prevention through this test and remedies. Over the years, whenever any weakness was detected with her ovaries and breasts and immune organs, through bioresonance testing, the remedies stimulated release of their causes through the specific energetic signals. She also has been provided with guidance concerning a healthy diet and environment, which she adhered to loosely.

Today, 13 years later, being in her 70s, she has had no evidence of malignancies, by periodic conventional tests for breasts and ovaries. In addition, she enjoys overall good health and leads more of an active lifestyle than most people in their 30s. Like the great majority of long-term FCT patients who are in their 60s, 70s, and 80s, she does not take any medications and is free of any chronic disease.

#### A Case of Breast Cancer

A woman in her early 70s presented with invasive breast cancer and a mediastinal mass that doubled in size on the prior imaging scans. The mass was of unknown identity with one of the possibilities being a thymic cyst. The cancer came as a shock for her, as for many people who assume that a healthy diet and taking supplements to prevent serious diseases is sufficient. Following her diagnosis, she had a partial breast surgery, refused chemotherapy, and undertook massive alternative treatments for cancer. which also included detoxification and immune support. Nevertheless, the cancer marker CA 27.29 showed a steady rise that continued into an initial phase of FCT. Her bioresonance testing indicated a cancerous field in her breast and massive intoxication with heavy and other toxic metals and pesticides. Many of these were carcinogens that were affecting her immune, endocrine, digestive, liver and other organs.

Multiple infections, which usually drain immune and endocrine systems, were also present.

Based on these readings, the homeopathic corresponding getics were administered to stimulate release of toxicological and infectious agents as well as recovery of the malfunctioning organs. homeopathic cancer vaccine was periodically administered. Her massive supplementation was discontinued since, based on bioresonance testing, these were rejected by her body. Instead the test suggested only a few glandulars for immune and endocrine support. Following the stoppage of the supplements, her chronic nausea ceased. She was also recommended to drastically reduce exposure to electronics and reduce environmental electromagnetic stress through protective Memon technology.

subsequent course was remarkable for a decrease in cancer marker CA 27.29 and the mediastinal mass. The latter indicated a steady growth on six consecutive scans prior to FCT and consecutive reduction in the size in three consecutive scans under FCT. The mass changed in consistency from a suggested cystic form to a solid one. Concerning the change, it was possible that the original mediastinal cyst had contained malignant fluid and the solid mass was more of a benign calcification. However, without the prior and follow up biopsy, it was difficult to



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determine if a benign cyst has possibly become a malignant mass, even though bioresonance testing did not indicate this. Another documented change while on FCT, was that an ultrasound of her multinodular goiter demonstrated reduced size of the nodules. Her total FCT course was four years, and she had to discontinue it five years ago due to undertaking a very expensive eve treatment elsewhere. She was told and knew that, instead, the best treatment for her eyes was to discontinue heavy computer use; however, according to her, she couldn't because of her work. To the best of my knowledge, she, at this time, is alive and in her early eighties. This, in retrospect, makes the aforementioned mediastinal mass being malignant as extremely unlikely, other than, hypothetically, being encapsulated.

#### A Case of Metastatic Colon Cancer

A woman in her seventies was diagnosed with colon cancer and metastases to the liver in the latter part of 2017. This was an extremely unusual case for a long-term FCT patient; however, her indulgence in sweets and alcohol, being 100 pounds overweight, and never keeping her maintenance care on time helped little. She underwent colon surgery but refused chemotherapy due to its side effects and it having little benefit for this stage of the disease.

Following the surgery, she returned with a great loss of weight, lowered energy and appetite, and, overall, very sick looking. Prior to her return, she could not regain any weight for weeks. Besides addressing her carcinogens and malfunctioning immune system and other organs, FCT also focused on her gastrointestinal parasitic and fungal infections. She was told of the necessity of a 100% sugar- and alcoholfree diet since in her condition there was no margin left for error as both cancer cells and infections use sugar for growth. Also, infections, in their turn, lead to chronic inflammation, which is considered to be carcinogenic by and of itself. Alcohol does the same and is very toxic to the liver particularly when it has metastases. Periodically, a homeopathic

cancer tissue remedy was administered in order to induce a specific immune response, similar to vaccines against cancer. The next visit she looked well and reported good increase in energy, appetite, and weight, and had returned to full time work: "I feel stronger, as each day goes by, my coworkers said you look remarkable and the oncologist and surgeon were surprised how I looked, too." The visit after: "My chiropractor who saw me before I resumed FCT, said, 'You look healthy, not like a person with cancer.""

Over more than a year since, she continues doing clinically well, having good energy and gaining weight to the point of being overweight again. As expected, with her easygoing personality, once the initial scare was over and she felt well again, she resumed her cookie and wine rounds, slacking on

#### FCT® and Cancer

her follow up appointments in spite of my warning. The sugar and wine rounds have led to different infections, which she preferred, for convenience reasons, to treat with more poisons, antibiotics prescribed by local doctors, without bothering with FCT. Perhaps this latest email of hers summarizes well where she is today (see below).

#### **Deadly Glioblastoma**

I presented in 2017, in this journal, a case of the most aggressive deadly tumor of the brain, glioblastoma ("FCT, Cancer, and Sloan Kettering Cancer Center Oncologist: 'You Better Continue This Alternative Treatment.'"). This is the very tumor that killed Senators

 From:
 \_\_\_\_\_\_@aol.com

 Sent:
 Wednesday, July 03, 2019 7:51AM

**To:** info@yurkovsky.com

Subject: Update Flag Status: Flagged

I had my scan of my liver yesterday at Sloan. The two specks that appeared at the beginning of last year have now grown to the size of oranges. The doctor was furious that I did not return to have them removed right after my colon surgery last year on April 2, 2018. The fact that I had a series of medical problems starting in August of last year and canceled my follow-up appointment with him in August, Didn't matter to him. He said I could have had the liver surgery at the same time that I had my toe infection/foot surgery or my abscess infection. Surgeries can be done at the same time as dealing with infections, I was told.

So, he said that I have liver cancer and it must have surgery ASAP. I mentioned to him that this surgery was to be done at the same time as my colon surgery last year, but that, after telling my colon surgeon that he would be attending my colon surgery, he decided to leave the hospital early. This made him even more angry with me.

However, he was in disbelief that, in spite of my liver cancer, that I managed to look so healthy, that I managed to gain 25 lbs., that I am not running a constant fever, that I have regular bowel movements and that I have energy. And, that I have all these positive things without have taken chemotherapy.

Susan

#### FCT® and Cancer

Edward Kennedy and John McCain and other celebrities, in spite of the best of conventional oncological care. This case concerned a young veteran who engaged in FCT following a few years of unsuccessful oncological treatment and while on a new experimental immunotherapy protocol.

The patient entered FCT in a poor state of health, suffering from poor energy, nutritional state, and control of seizures and headaches. The protocol kept producing severe side effects, which were successfully palliated by FCT. My report at the time ended with the young veteran making overall good progress in his health and also demonstrating for the first-time improvement in the size of his brain lesion. One brain scan had registered a cessation of the lesion growth and one after, its reduction. Certainly, whenever the case scenario is not "clean," (since the patient was receiving two different treatments, conventional and alternative), neither side is entitled to claim the benefits to itself. However, and tragically so, the case became clean in the months following that report. As the veteran's health kept progressing to the point of regaining good energy and muscles, he abandoned both FCT and its main ban for him, computer avoidance.

From a few hours a week of exposure, he went to doubling it and as "nothing bad happened," he kept increasing this up to 40 hours per week. In addition, being loyal to his spartan army training, he engaged in an extremely intense athletic program with running in the mountains and other very draining activities.

Following all of this for months, he finally collapsed; and his brain scan, accordingly, registered lesion growth. Not willing to go back to FCT's computer ban, he took a better liking to an opinion of an "expert" oncologist in alternative medicine cancer treatments. The suggested treatments I knew were virtual bandaids for that aggressive of a tumor. Both his wife and I have exchanged this concern and the fact that he abandoned FCT. In clear terms, I stated that the end will be tragic and speedy. Unfortunately, this became the case and he died shortly after.

#### Against All Odds?

A woman in her mid-sixties presented in the early part of 2016 with metastatic cancerous breast mass to the lymph nodes and lungs. She also had another primary tumor, colon cancer with metastases to bone. She was losing weight, felt fatigued, anxious, and depressed over her prognosis. After undergoing colon surgery, she refused chemo and radiation therapy for both cancers and metastases. Her projected life expectancy was less than a year, with or without oncological treatment. She was tested through bioresonance testing and managed through the cause-based FCT approach, as generally above, that included mentioned periodic administration of homeopathic cancerous tissues in ascending potencies, based on bioresonance testing and the state of her immune system. As usual, no substances to kill the tumor were administered.

She complied with a generally healthy diet, by no means of an austere kind, and kept her visits on time, only initially. She promptly regained her energy, weight, and general wellbeing and her old sins, sweets and wine. She was last seen at the end of June

continued on page 32 ➤





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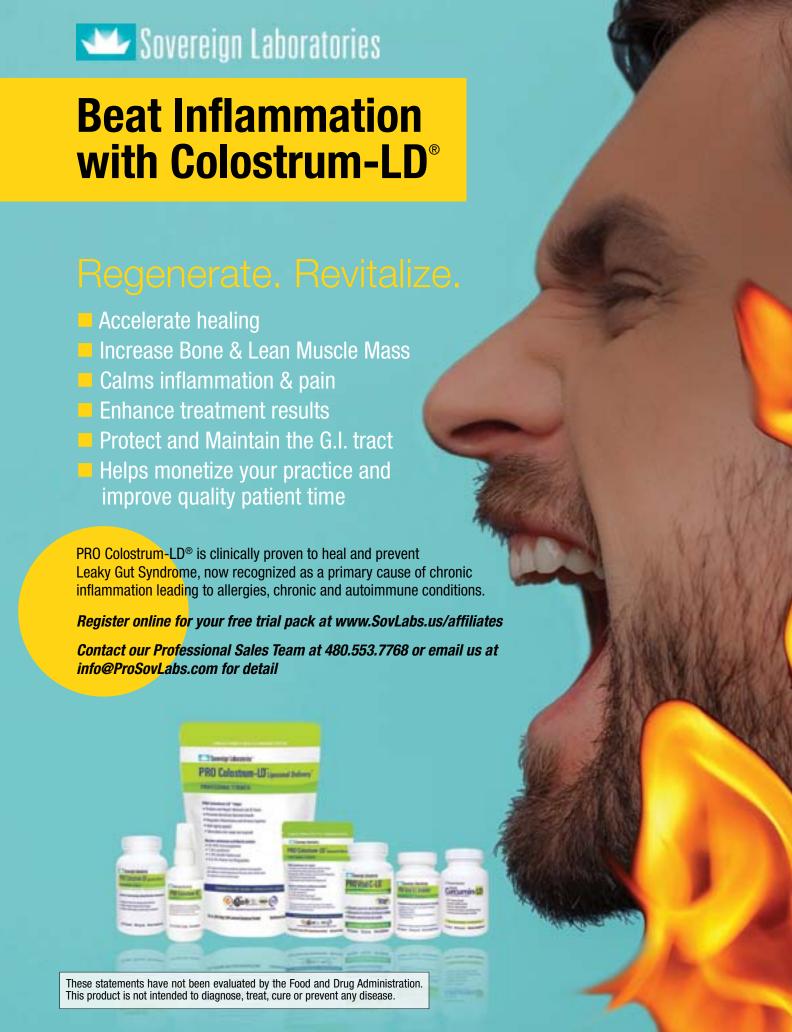
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#### FCT® and Cancer

#### > continued from page 30

this year, that is over three years since her original diagnosis. Throughout this time, short of occasional respiratory infections, she has been leading a normal lifestyle and working. She stopped seeing her oncologist two years ago, who was surprised to see her still alive and told her, "Keep doing what you are doing."

#### **Against More Odds?**

A man in his late seventies presented with malignant pleural effusion in his lungs caused by a deadly cancer, mesothelioma. There is no effective oncological treatment available for this stage of disease, and his life expectancy was, considering his age, far below twelve months. By good fortune, his friendly relationship with a pulmonologist was helpful by the latter providing a sample of the malignant fluid, upon my request. bioresonance testing, Based on consecutive courses of homeopathic vaccine prepared from this fluid were administered. This was accompanied by a homeopathic stimulation of a

release of asbestos from his lungs and strengthening of the pleura and the immune organs.

Close to a year into this course he made good progress and our doctor-patient relationship had to be discontinued for non-medical reasons. He did not engage in oncological treatments afterwards but in Chinese medicine, which can be of a great support when the primary causes are properly addressed. He lived for nine years (!) after being diagnosed with end stage mesothelioma and died at the age of 86 from its recurrence.

#### Conclusion

It is obvious that, as in all chronic diseases and particularly cancer, the optimal approach must properly address the primary causes or bullets that are lodged in the sick organs. This alone renders many tests and treatments unnecessary or used only very selectively, if necessary, to further enhance benefits to patients. Considering the well-established facts that there are so many factors that cause cancer and other chronic diseases, one must use the appropriate diagnostic methods to properly determine these. These factors are thousands of

environmental pollutants in our air, drinking water, and food, with only a handful of these having been screened for carcinogenicity. Other factors consist of chronic infections, junk food diet, EMF, chronic inflammation, depression, low melatonin level and poor sleep, certain medications, excessive weight, and genetic predispositions.

Environmental pollutants never act as singular entities but in complexes whose formation inside individual patients' bodies cannot be predicted. Likewise, any of the aforementioned factors act together, which makes it equally impossible for lab tests to determine. The only viable prevention and basis for on-target treatment is provided by bioresonance testing that can derive pertinent information directly from the internal organs. Thorough information concerning a patient's lifestyle must also be gathered and properly addressed. The bottom line is if a "bullet" is not removed from a leg, brain, or any organ in cancer or any disease, both prevention and treatment outcomes will suffer.

We invite capable health practitioners to engage in FCT training with its entire focus on bullet removal.



Savely Yurkovsky, MD is board certified in internal medicine and board eligible in cardiovascular medicine. He undertook a particular interest in mercury toxicity as both its victim and as a clinician managing a busy private practice. Shortly after moving to the US from the former Soviet Union, he received several silver amalgam fillings, which he recognized later as the cause of his mounting health problems. These problems persisted, despite removal of fillings, which prompted him to explore various mercury detoxifying approaches: oral, intravenous, homeopathic. After observing their corresponding partial benefits, limitations, and aggravations on himself and his patients, he resorted to bioresonance testing and causative homeopathy, based on relevant knowledge from physics and toxicology to optimize benefits and safety of the detoxification. The guidance of his physics consultant, the Stanford University materials science Professor William A. Tiller, PhD, was instrumental in enhancing the diagnostic ability of bioresonance testing to address the known limitations of lab tests to detect

the presence of toxicants in the internal organs. This testing also was used to draw a better comparative capacity between various mercury detoxifying treatments as well as to evolve a safer therapeutic strategy, leading to minimize the reintoxication or dumping effect that are common to these treatments. It also guides the unlimited therapeutic potential of homeopathy that has a unique capacity to therapeutically connect with any organ and tissue, via specific signals, as no other treatment can.

His book, *Biological, Chemical, and Nuclear Warfare – Protecting Yourself and Your Loved Ones: The Power of Digital Medicine*, has been endorsed by Professor Emeritus William A. Tiller, PhD, of Stanford University and IT Physics Professor George Pugh, PhD. He presented this system at the Combating Bioterrorism Conference in 2005, sponsored by the Office of Homeland Security.

Dr. Yurkovsky founded a teaching organization, *SYY Integrated Health Systems, Ltd.*, in 1999, which is dedicated to training health practitioners in this biophysical system under the concept of FCT – Field Control Therapy®. He has lectured extensively in the US and Europe.

# NK Cell-Based Immunotherapy in the Treatment of Cancer Using a New Arabinoxylan Rice Bran Compound

#### by Professor Serge Jurasunas

#### Introduction

Despite advances in cancer treatment achieved over the last decades, it still remains a failure where the outcome of standard and especially palliative treatment is often poor due to cancer cell resistance. However, in these past few decades, we have assisted in a series of articles in international publications from many countries, proclaiming that our own immune system is now a new weapon against cancer. This has become the fourth pillar of oncology after surgery, chemotherapy, and radiation.

One particular immune cell has gained more interest over the past two decades from researchers: the natural killer (NK) cell, which seems to play a crucial role in cancer.

A number of publications and published scientific papers demonstrate the association between the NK cell and cancer, particularly breast cancer. Boosting the NK cells increases the killing of cancer and presents a significant advantage both in the prevention and treatment of cancer.

Among many available compounds investigated, one has commonly been the subject of publication for its efficacy to activate NK cell activity and for the killing of cancer cells in vitro and in vivo. This compound is known as rice bran arabinoxylan compound (RBAC). It has been widely investigated especially over the past 25 years by scientific researcher M. Ghoneum, PhD, from Drew University in Los Angeles, California. This researcher has spent most of his professional life studying NK cell activity and substances that are able to modify immune function.

According to Dr. Ghoneum, RBAC is the most powerful compound we have to activate immune cells, particularly NK cells. But we are going to see that RBAC not only increases NK cell activity but has other qualities as an anticancer agent. In some studies, patients that were treated with RBAC in addition to conventional therapy (CT) compared with those treated with CT alone showed less recurrence of cancer, higher survival rates, and improved quality of life (QQL).

Various animal studies and human clinical trials, including different types of malignancies, have demonstrated that RBAC is a potent biological response modifier (BRM), being a safe compound with no toxicity that does not exhibit hyporesponsiveness.

It was only around 1990 when I discovered the newly developed rice bran arabinoxylan compound from my Japanese contact in Tokyo and learned about natural killer cells that I started studying NK cells and began to include this compound in my cancer protocol. The more you read about NK cells, the more you understand about the necessity to activate these unique immune cells to increase the death of cancer cells. Twenty-eight years is a long time, and it has permitted me to experiment with various protocols and compounds with cancer patients. You can imagine what I have accomplished during this period and how many cancer patients I have treated in my clinic. Of course, we always expect that what we use offers some efficacy, but this article will show what RBAC is able to do. You can read reports explaining how RBAC increases NK cell activity, and how a tumor can decrease in size, or that tumor markers decrease; but if you directly witness the results with your patient, it may better convince you.

#### What Are NK Cells and Their Role in Cancer?

Natural killer cells were first discovered in humans and mice in 1975 and were initially identified as unique lymphocytes

Figure 1. Landscape of the Immune Tumor Microenvironment

TAM

TGF-F

NK cell

ARG

TGF-F

L-10

TGF-F

TGF

## **Arabinoxylan Rice Bran**

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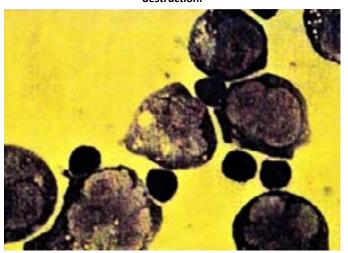
distinct from B and T cells, being critical to the innate immune system but also bridging the innate and adaptive immune systems. NK cells are known to differentiate and mature in the bone marrow, lymph nodes, spleen, tonsils, and thymus, where they then enter into the circulation. They are a large granular population of leukocytes that can directly kill virus-infected cells or tumor cells.3 Today NK cells are viewed as our first line of defense against intruders and cancer. As we age, NK cells lose their functionality thus leaving us with more vulnerability to viral diseases and especially cancer, which could be one cause of increased cancer rates in aged individuals. In the aging, NK cells may be fewer, secrete perforin with more difficulty, and die faster compared to NK cells in younger people. Many new animal and human studies show that NK cells play a central role in the immune surveillance of transformed cells,5 while evidence suggests that our low NK cell activity may be a risk factor for malignancy or metastases, as well as a negative prognostic indicator.<sup>6</sup> In fact, our lifestyles, as well as our environment and food habits, influence human natural killer cells, increasing or decreasing their activity to protect against infection or cancer<sup>7</sup>; today, we probably have decreasing NK cell activity, which increases the risk of cancer. Cancer patients have very low NK cell activity, about 50-70% decreased activity compared to healthy individuals.

#### **Function of NK Cells**

NK cells constantly patrol in our blood and lymph in their resting phase; but if infected or cancer cells are detected through the ligand place on the surface of target cells, they become active with cytotoxic properties.

Unlike other immune cells, NK cells require no special instruction to recognize a specific antigen. They have the ability to directly recognize cellular targets without prior sensitization, mediated by a network of inhibitory or activating receptors expressed on the cell surface that control NK cell

Figure 2. RBAC activating NK cells and attacking cancer cells. We observe a single NK cell attaching itself to 3 cancer cells for destruction.



activation. It is the integration of the activating and inhibitory signals that determine if the NK cell becomes cytotoxic. The use of immunotherapeutic agents to increase activation and decrease inhibitory signaling has the potential to generate NK cells with enhanced tumor-lytic capacity.

NK cells become active in response to immuno-regulatory proteins called cytokines that interact with NK cell receptors. NK cells are regulated by various cytokines such as IL-1, IL-12, IL-15, IL-18, and IL-21 that interact with inhibitory or activating receptors on NK cells and communicate with other cells. For instance, the combination of IL-12 and IL-18 is especially potent to trigger interferon (IFN)-y. The NK cells are converted into lymphokine-activated killer (LAK) cells. These LAK cells propagate, produce cytokines and adhesion molecules to target cells, and increase tumor lysis activity.

NK cells also generate an adaptive immune response by secreting pro-inflammatory cytokines and interferon such as TNFa and IFN-y that activate other immune cells such as macrophage, B-cells, and dendritic cells.<sup>8</sup>

#### **NK Cell Cytotoxicity**

The natural killer cell cytotoxicity can be demonstrated in several related ways. The primary and most important known mechanism when attacking cancer cells is based on the release of cytotoxic granules from their cytoplasm after becoming active in response to cytokines.

First, NK cells attach themselves to receptors on the membrane of cancer cells and inject granules called perforin, which is a membrane-disrupting protein that perforates the target cell membrane and forms pores, creating an aqueous channel that permits the entry of another cytotoxic protease.<sup>9</sup> (See Figure 2)

When the pores are formed, NK cells release and inject, via this channel, granzymes serine proteases, <sup>10-11</sup> which cleave caspases 3-7-9 and subsequently induce apoptosis in target cells by degrading protein involved with DNA integrity. This is the main channel utilized by NK cells to destroy cancer cells. One NK cell can kill a cancer cell in five minutes time and repeat this 27 times before dying. It shows the great capacity of this unique cell to kill cancer. As we have already indicated, cancer patients have a low NK cell activity compared to healthy individuals. Both in vitro and in vivo tests confirmed that the number of cytotoxic granules increase with NK cells stimulated by RBAC.

It seems that our lifestyle and diet can also increase the activity of NK cells with a balanced diet that included a variety of vegetables, fruits, meat, and fish being associated with higher levels of perforin and granzymes, efficiently serving as protection against cancer cells.<sup>12</sup>

#### **Natural Killer Cells and Cytokines**

Not only can NK cells target and kill cancer cells through cytotoxic granules, but when activated they have one other interesting indirect targeting mechanism. When activated NK cells release pro-inflammatory cytokines and interferons such as IFN-y and TNFa<sup>8</sup> that can cause direct tumor necrosis by inflicting tumor-associated capillary injury but also (and

this is important) generate an adaptive immune response by activating other immune cells such as macrophages, T-cells, and dendritic cells.<sup>13</sup> The secretion of IFN-y by NK cells plays a key role in the stimulation and maturation of dendritic cells and thus increasing, even more, the killing of cancer cells.<sup>14</sup> Also, one other advantageous factor is the fact that IFN-y secreted by the NK cells contributes to inhibiting angiogenesis and blood vessels, a major step required for tumor growth and expansion. Therefore, NK cells seem to have a wide targeting effect besides killing cancer cells directly.

#### **Perforin-Independent Apoptotic Channel**

NK cells use another apoptotic weapon channel to kill cancer cells. This is a perforin-independent mechanism using the death receptor ligand. This cytotoxic pathway relies on tumor necrosis factor (TNF) receptor superfamily members.<sup>15</sup> The two main TNF receptors used in apoptotic induction are FAS (CD95) and Trail (TNF-related apoptosis-inducing ligand).<sup>16</sup> Trail is an apoptotic molecule that interacts with the death receptors Dr4 and Dr5 and activates intracellular apoptosis through cleavage of caspase 8, which in turn can directly activate caspases 3-9. Literature has shown that Trail can kill any cancer or leukemia cell regardless of their degree of malignancy.

Trail is also considered a natural anti-tumoral cytokine expressed on a wide variety of tissue<sup>17,18</sup> and on the surface of NK cells, T-cells, macrophages, and dendritic cells. IFN-y released by NK cells induces Trail expression that in turn induces apoptosis or lysis of cancer cells. It was proven that many types of tumor cells express high levels of ligands for NK cells receptors, which leads to their recognition and killing by NK cells.

#### **Factors That Depress NK Cell Activity**

NK cell populations can be affected by several factors that decrease their capacity to secrete perforin and granzyme in cancerous patients. For instance, surgery and chemotherapy may contribute to decreased immune system activity, which is already reduced in cancer patients. 19,20 In breast cancer patients, there is a strong association between depression and the disease, especially associated with breast cancer recurrence. Depressive disorder was associated with a higher risk of breast cancer recurrence among patients after breast surgery.21 Professor Ron Herbeman (NCI), now in charge of the Institute of Oncology at the University of Pittsburgh, demonstrated with a group of 116 surgically treated breast cancer patients that the more the NK cells are active in the week that follows the surgery, the better are the chances of long term survival.<sup>22</sup> Evidence also demonstrates that radiotherapy significantly decreases the number and function of cells from both innate and adaptive immune systems, including natural killer lymphocytes, TNFa, and interferon-y cytokine activity.<sup>23</sup> Therefore, we may understand why repeated chemo/radiation can in many cases contribute to stimulating tumor growth.

A decline in NK cell count and function appears to be a biomarker of overall risk for disease and cancer.

## **Arabinoxylan Rice Bran**

#### Rice Bran Arabinoxylan Compound

Rice bran arabinoxylan compound (RBAC) is a nutritional supplement developed by Daiwa Pharmaceuticals Co. Ltd. of Japan and sold as a functional food in Japan. RBAC is produced by enzymatic hydrolysis of hemicellulose B, a dietary fiber found in rice bran. The principal ingredient, arabinoxylan, which is a highly branched and complicated sugar composition of mainly arabinose and xylose, is obtained from modified bran rice with a hot water extraction consisting of *Lentinula edode, Coriolus versicolor*, and shitake mushroom mycelia culture. The process breaks long polysaccharide molecules into small ones. Hemicellulose B contains a relatively small amount of a molecule with a polymerization degree of approximately 200, which can be absorbed through the intestinal wall after oral intake.

Before the process, arabinoxylan itself has no immunostimulating activity. When the long polysaccharide molecules are broken up into smaller components, they can be rapidly absorbed by the small intestine in undigested form and enter the blood circulation with strong immuno-stimulating action, especially on natural killer cells (NK cells),<sup>24</sup> and additional oncogenic effects.

During the past 24 years, a large number of rigorous preclinical and clinical research studies have shown that RBAC's anticancer effects are founded on the ability of this natural compound to act as a potent biological response modifier. (See Figure 3) RBAC has been shown to possess immunomodulating anticancer effects and can work synergistically with chemotherapeutic agents in vitro.

Eleven studies, including non-randomized pre-postintervention studies and six randomized controlled trials (RCTs), reported the following effects of RBAC:

- Enhanced immunoprofile,
- Reduced side effects,
- Decreased antigen tumor markers,
- Improved treatment outcomes, and
- Significantly increased lifespan.

This is what I am going to discuss in this article based on many reports, but also this is what basically I have observed with patients that we have treated using RBAC, as well as in long-term administration.

#### **RBAC Boosts NK Cell Activity**

When taken orally as a food supplement, RBAC has the ability to activate different arms of the immune system to attack cancer such as by the proliferation of T and B cells and macrophages,<sup>25</sup> and activation of dendritic cells<sup>26</sup> and especially NK cells function, while also enhancing the production of several cytokines.<sup>27</sup> Both in vitro and in vivo tests confirmed that RBAC increases the amount of cytotoxic granular content (perforin and granzyme B) of NK cells. This has been demonstrated morphologically and biochemically since NK cells of cancer patients are usually degranulated with no cytotoxic effect.<sup>28</sup> NK cells kill virally infected cells or cancer

### **Arabinoxylan Rice Bran**

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cells through the secretion of cytotoxic granules to target cells, causing their rapid death.<sup>29</sup>

The increase in the binding ability of NK cells was also investigated. The NK cells of a human who took 45 mg/kg/day of RBAC for 30 days were incubated

with K-562, which were the target cells, and then the increase of the binding ability was measured. In a subject who took RBAC, this significantly increased to 38.5% compared with 9.4% before intake.<sup>24</sup>

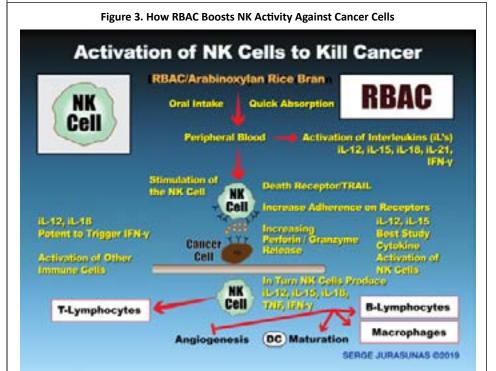
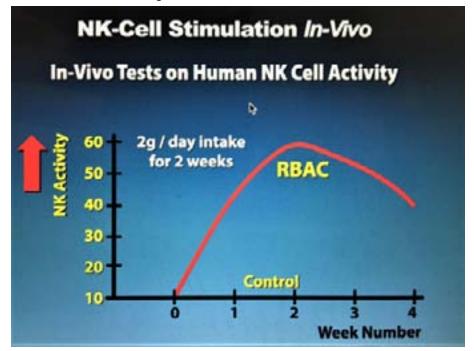


Figure 4. NK-Cell Stimulation In-Vivo



In NK cell stimulation in vivo with volunteers (without disease or cancer), we observed a remarkable increase of NK cell activity after two weeks with a 2 g/daily intake of RBAC, which was sufficient for this test. It then started to decrease, but remaining at the same dose enhanced NK activity, which continued to rise at three to six months after treatment. (See Figure 4)

In another study, 27 cancer patients with different types of advanced malignancies (7 patients with breast cancer, 7 with prostate cancer, 8 multiple myelomas (MM), 3 leukemia, and 2 cervical cancers) were examined. All patients were under treatment with conventional therapy and were given 3 g of RBAC daily; 3 g is an optimal dose for cancer patients since they have lower NK cell activity.

NK activity was then examined at two weeks, three months, and six months. NK cell activity was examined by a 51Cr-release assay using K-562 tumor cells as a target. Target ratios ranged from 12.1-100.1. The result showed that patients had a low level of basal NK activity. Treatment with RBAC caused a remarkable increase in NK activity after two weeks and the percentage of induction were as follows:

Breast cancer: 154-332%.Prostate cancer: 174-385%.

Leukemia: 100-240%.

• Multiple myeloma: 100-537%.

• Cervical cancer: 100-275%.

Enhancement of NK cell activity continued to rise both after three months and six months after treatment.<sup>30</sup> What is interesting is the fact that this increase in NK cell activity continued and was maintained for five years with continued supplementation, indicating that RBAC was still active with no hypo-responsiveness, which is the case with some other compounds.

An additional study to check on the immunomodulatory effects of RBAC included thirty-two cancer patients with different types of malignancies with depressed NK cell activity after post-conventional cancer treatment who were treated with RBAC for two weeks.<sup>28</sup> A significant increase in NK cell activity up to 10-fold was observed;

and an increase in NK cell granularity and binding capacity were detected in all types of cancer, and tumor markers decreased.

As explained above, most cancer patients have low NK cell activity, which can decrease even more after repeated cycles of chemotherapy and radiotherapy that may promote resistant tumors as well as local and systemic toxicity. I was not surprised that RBAC dramatically increased NK cell activity so high in prostate cancer but also MM. In the past, some of my cases of MM lived up to eight years taking a daily dose of RBAC. Professor Ron Herbeman stressed that there is considerable evidence that patients with cancer express an abnormal immune response, which has been observed with many types of cancers including breast cancer.

For example, a 44-year-old female was diagnosed with breast cancer in December 1994. She received surgery and chemotherapy, after which her NK cell activity baseline was 39.9% in May 1995. One month after starting RBAC/MGN3 supplementation, it was 48.9%. By October 1995 it was 83.5%. Since then this level has been maintained, and all follow-up mammograms have shown no sign of relapse.

As another example, five patients with breast cancer were given RBAC at 3 g/day and their NK cell activities were measured by 4-hr 51 Cr-release assay using K-562 tumor cells as a target. The results showed the following:

- 1. Patients had a low level of basal NK activity 12.7%-58.3%. Participants had their NK activity significantly enhanced by RBAC (41.8%-99.5%) on a ratio basis of 10%-100%.
- The augmentation in NK activity was detected as early as one to two weeks post-treatment and was further increased with the continuation of RBAC at 3 g/day.
- 3. Two patients who participate early in the study (6-8 months) went into complete remission.<sup>31</sup>

In one other study in human patients with malignancies, RBAC showed remarkable results in 48 patients with multiple myeloma, whose median age

### **Arabinoxylan Rice Bran**

was 65 years.<sup>32</sup> A dose of 2 grams per day for three months produced nearly an 84% increase in NK cell activity by the end of the second month of supplementation. This correlates with my own clinical experience and the

example that I spoke about, not to mention an overall better quality of life.

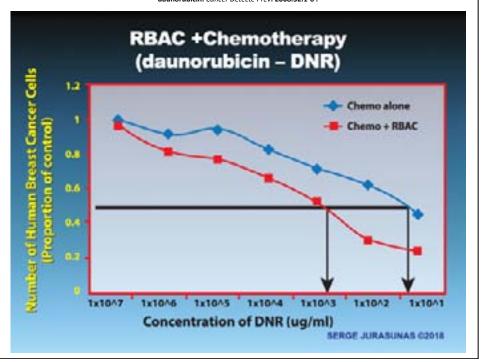
A very interesting study has been conducted at the Sano Surgical Clinic by Kamataso Sano.<sup>33</sup> After surgery, 205 patients who had a recurrence and

Figure 5.
Rice Bran Arabinoxylan Improves Survival Rate in Cancer Patients



Figure 6. RBAC Improves Chemotherapy Effectiveness

Gollapudi, S, Ghoneum M. Modified arabinoxylan from rice bran, sensitizes human breast cancer cells to chemotherapeutic agent, daunorubicin. Cancer Detecte Prev. 2008.32.1-6.



## **Arabinoxylan Rice Bran**

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metastatic disease (late stages III-IV) were hospitalized and treated with complementary alternative medicines

and anticancer drugs with lesser side effects. The 205 patients, hospitalized for six months, were divided into two

#### Figure 7.

Comparative Treatment Groups – RBAC Sensitizes Metastatic Breast Cancer Cells to Paclitaxel In-Vitro. Co-culture of RBAC sensitized 4T1 cells to Paclitaxel causing an even greater decrease in cell survival. 4T1 cells were co-cultured with varying concentrations of RBAC 500 and 600 µg/ml and Paclitaxel for (24 hours and 48 hours). M. Ghoneum. *Anticancer Research*. January 2014.vol 34. N.1. 81.87

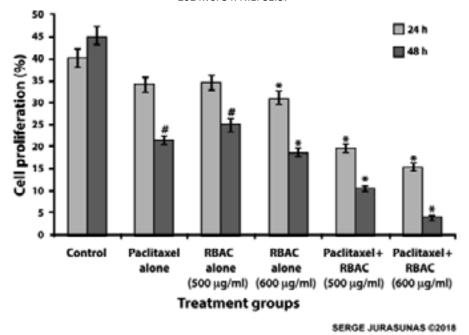
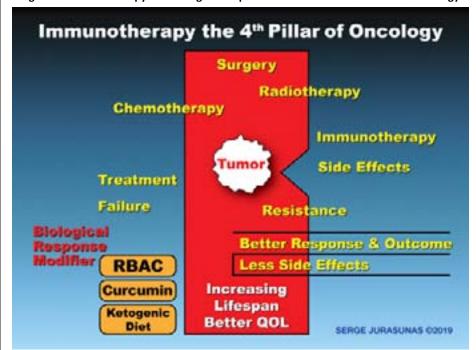


Figure 8. Immunotherapy and Biological Response Modifiers – The 4th Pillar of Oncology



groups: 109 patients were treated with the prescribed therapies (control group), and 96 patients were additionally treated with RBAC along with their prescribed therapies (the RBAC group) for 18 months. RBAC was given orally at 1 gram, three times per day after meals.

All patients were monitored for NK cell activity as an indication for the variation of immunoparameters. Patient QOL was also checked by observation and inquiry during the study. It had already been shown that patient NK cell activity after surgery was low. However, after administration of RBAC, NK cell activity increased as did the survival rate. As a result the 18-month survival rate after treatment was 54.2 % in the RBAC group and only 33.9 % in the control group after taking alternative medicine (mushroom, Gerson therapy, etc.). Increased NK cell activity was higher in the RBAC group than in the control group, resulting in a 1.5 times higher survival rate in the former group.

Figure 5 shows that the more NK cells that are activated, the higher is the survival percentage. Even with only a 20% NK cell increase, the survival rate is higher compared to the control group. Some patients with NK cell activity higher than 40% prior to entering the study had a very high survival rate compared to the control group. Also, QOL was greatly improved in the RBAC group in terms of less pain, fatigue, nausea, and diarrhea, along with having a better appetite.

#### RBAC and Chemotherapy

When working with chemotherapy, increasing its effectiveness to obtain better results and fewer side effects should be a main concern in integrative oncology. Many reports, studies, and also cases from my own clinical practice have proven that daily intake of RBAC may improve the efficacy of chemotherapy by reducing tumor size and decreasing tumor markers more quickly with better QOL. Citing more recent examples, a pancreatic tumor of 4 cm. was reduced to 1 cm. in about 30 days before surgery and chemotherapy by taking only RBAC at a daily dose of 3 grams. A female of 38

continued on page 40 ➤



Defend: v.t.[ME. defenden, L. defendere] To ward off, repel. 1a. BRM4 1b. To guard from attack; keep from harm; protect.

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### **Arabinoxylan Rice Bran**

#### > continued from page 38

years with a stage II breast cancer could not undergo chemotherapy because of heart dysfunction. Her CA 15.3 blood test at 67.7 decreased to 21.2 after four months of taking RBAC together with curcumin. A 5 cm-wide tumor in the case of an aggressive cancer was reduced to 13 mm. after three months with chemotherapy and daily intake of

RBAC sensitizes chemotherapy for a better result.

#### **RBAC in Advanced Cancers**

RBAC intake has been shown to extend lifespan with the improvement of quality of life for progressive cancer.<sup>33,36</sup> Cancer patients can take RBAC for several years without toxicity

... RBAC works in synergy with curcumin to stop the cellular cycle at GO/G1, to induce apoptosis. Each one works in synergy with chemotherapy, and both substantially increase chemotherapy effectiveness.

RBAC. We have other examples with CA 125 decreasing from 218 to 50, and then 11.5 and 5 when RBAC was taken together with the agent paclitaxel in a case of stomach cancer.

In fact, several studies have shown how RBAC sensitizes metastatic paclitaxel34 breast cancer cells to Daunorubicin<sup>35</sup> in vitro, to via activation of caspase 3 and 8, increasing apoptosis of cancer cells. (See Figures 6 and 7) Paclitaxel is a powerful chemotherapeutic drug for the treatment of a number of cancers, including breast, ovary, and prostate, that is supposed to kill cancer cells by inducing cell cycle arrest and apoptosis. Its action, in fact, can be improved with a variety of natural compounds that also arrest cell cycles at G1 or G2 like curcumin, for instance. However, a high concentration is required to induce an apoptosis effect on cancer cells. Such a high dose, however, is associated with severe side effects, including cardiomyopathy and neutropenia. The study showed that RBAC potentially contributed to a reduction in chemo side effects while also reducing the dose yet offering the same efficiency in killing cancer cells.

One other interesting ability of RBAC is to help increase the accumulation of the chemotherapeutic agent Daunorubicin in the tumor. As we may know, some agents may not fully penetrate or accumulate into a tumor and therefore show less efficiency. Therefore, these studies show how

(LD50=36.0 g/kg) as demonstrated by extensive toxicity study that shows complete safety. RBAC is still efficient and without hypo-responsiveness, which is the characteristic of several other compounds, even when taken for few years.37 I have observed in many advanced cancers with metastasis that taking RBAC has up to a five-year life extension period, improving patient QOL and physical condition and, for some, no further progression of the disease, meaning that RBAC is still active.

#### Conclusion

This article reviewed the ability of NK cells to target cancer cells from several options and examines key studies that were published examining the effect of RBAC on NK cells, dendritic cells, T and B cells, and on malignancy.<sup>28</sup> This is only a small review about scientific studies<sup>38,39</sup> citing the enormous capacity of RBAC as a biological response modifier and as an anticancer agent. It is also important to mention that RBAC is superior to various other compounds that claim to have anticancer properties but have little or no scientific evaluation – which is not the case with RBAC.

Chemotherapy and radiation treatment have not brought significant improvement to the longevity of cancer patients for the past 30 years or more. According to some official reports, most of the drugs don't even work with most patients and are apparently effective for about a quarter of patients.<sup>40</sup> Our

aim is to support conventional therapy in a way that has better results with chemotherapy, such as by reducing tumor size, decreasing the number of metastatic lesions, decreasing antigen tumor markers, minimizing side effects, and having long-term remission – if not speaking of cure. This is what we can accomplish when associating RBAC with chemotherapy.

Now I would like to mention the fact that RBAC works in synergy with curcumin to stop the cellular cycle at GO/G1, to induce apoptosis.<sup>41</sup> Each one works in synergy with chemotherapy, and both substantially increase chemotherapy effectiveness. I have seen cases with breast cancer recurrence and multiple metastases getting much worse after new chemotherapy but rapidly improving by taking only RBAC and curcumin.

Therapeutic daily dose: RBAC - one sachet of 1 g three times per day, and liquid liposomal curcumin - from 3000 to 4500 mg per day.

Surely more studies about RBAC will be done in the coming years since immunology will take a most important place as a new weapon in the panoply of conventional therapy but also of alternative medicine.

RBAC is available as MGN-3 in Europe and was sold as MGN-3 in the past in the US and is now available as BRM4.

The research studies on RBAC can be found online at www.ipraxic.org.

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Professor Serge Jurasunas has devoted over five decades treating cancer of all types and grades, developing innovative therapies, being a pioneer in several approaches to cancer including cellular respiration and mitochondria immunotherapy, stem cell therapy, and live blood analysis and the oxidative dried blood test, since 1979.

He spent the past 12 years investigating, researching and putting into clinical application P53 tumor suppressor gene and other apoptotic players, telomerase etc. He delivered lectures in over 45 countries, including Russia, Australia, Poland, Hungary, Croatia, Germany, and Lithuania. He has been honored and decorated for his work, including the Silver Medal for Research and Invention by the French Academy and the Grand Academic Gold Collar of the Accademia Internazional Di Pontzen in the field of medical research, In 2017 he received the Lifetime Achievement Award (USA) for his 50 years of work and a pioneer in the field of education and natural health care.

He is the author of over 150 papers, lectures, articles, and eight books in three different languages and has been a frequent *Townsend Letter* contributor since 1999. Professor Serge Jurasunas maintains a private part-time practice only for cancer patients but also has outside patients from several countries via E-mail and Skype.

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# Salicinium<sup>®</sup> Treats and Prevents Cancer and Viral Infections

by Jeffrey J. King, BS, MS, JD<sup>1</sup>

#### **Abstract**

This article describes a long-term, multi-site study demonstrating potent anti-cancer and antiviral effects of glyco-benzaldehydes and related compounds developed under the tradename Salicinium®.2 Results from 675 cancer patients show that Salicinium effectively treats many different types of cancer, significantly extending survival for all groups studied (including a majority of patients with treatment-resistant Stage IV cancer). In related studies, Salicinium effectively treated chronic viral infections, including Epstein-Barr virus (EBV), hepatitis C virus (HCV), cytomegalovirus (CMV) and herpes viruses (HVs). Additional data presented here demonstrate that Salicinium safely and effectively treats cancer and viral infections by disrupting glycolytic metabolism in cancer and virus-infected cells, causing cell death (apoptosis). Additionally, Salicinium restores and potentiates healthy immune function in patients with cancer and chronic viral infections by disrupting synthesis and reducing blood levels of the immunesuppressive enzyme "nagalase" (alpha-N-acetylgalactosaminidase).

- Jeffrey J. King is a technical consultant to Cognate 3, Inc., and has no financial or official conflicts relating to this report. Mr. King's authorship here is editorial, compiling reports of numerous medical, naturopathic and scientific contributors.
- Salicinium is a Registered US Trademark of Cognate 3, Inc. of Bellevue, Washington.
- Dr. Virginia Osborne, a study participant, previously reported a segment of this study in *Townsend Letter*, August 2017.

#### Introduction

Cancer is the second leading cause of death in the US and other developed nations. The National Cancer Institute (NCI) reported 8.2 million cancerrelated deaths and 14.1 million new cases diagnosed worldwide in 2012. In the US alone, the NCI projected over 600,000 cancer deaths and 1.73 million new cases for 2018. New cancer diagnoses worldwide are expected to rise to approximately 24 million by 2030. Current standard of care treatment for cancer typically involves a combination of surgery, chemotherapy, radiation, and hormonal therapy. Each of these treatment modalities imposes significant morbidity and health risks, including high risks of infection, impaired healing and regeneration, and immunosuppression.

Despite decades of advances in cancer diagnosis and treatment, the need for new modalities and tools for cancer prevention, treatment, and management grows ever more urgent. A related need exists for new methods and agents to treat chronic viral infections, which often beset cancer patients opportunistically and contribute to cancer incidence and morbidity. The instant study, funded and coordinated by Cognate 3 Inc. in conjunction with a large consortium of medical and naturopathic experts and study facilities in the US and abroad, makes a substantial contribution toward fulfilling these needs.

#### Clinical Cancer Study of Salicinium

Salicinium® is a tradename for glycobenzaldehydes and related compounds

that impair glycolytic metabolism in cancer and virus-infected cells. For this report, the glyco-benzaldehyde, helicidum (alt. helicin), was selected for its proven activity, safety, and tolerance.

Clinical Study Protocol: 675 Stage IV cancer patients were treated and monitored through four participating medical and naturopathic following standard therapeutic monitoring and reporting protocols for each patient tracked over a minimum study period of 60 months.<sup>3</sup> All patients entered the study with Stage IV cancer, diagnosed according to standard methods (e.g., using tumor visualization, cytology, biopsy, blood markers and other diagnostic tools). For the purpose of this study "Stage IV" means that the subject cancer had spread from a primary site to other, distant sites in the patient's body, such as the lungs, bones, skin, liver, gastrointestinal (GI) tract, brain, or distant lymph nodes. In the case of head and neck cancer patients, this "metastatic" staging requirement corresponded to a Stage IVC disease diagnosis. In the case of lymphoma subjects, the Stage IV entry criteria were met by 1) cancer present in two or more groups of lymph nodes above or below the diaphragm and in one or more organs outside the lymph system not near the affected lymph node(s); or (2) cancer found in groups of lymph nodes both above and below the diaphragm and in any organ outside the lymph system. For all study subjects, cancer types were grouped by confirmed primary cytology/histochemistry, patient history, and other standard criteria. The following therapeutic and diagnostic/monitoring protocols were employed.

Each patient was provided an initial aggressive treatment of intravenous (iv) Salicinium<sup>®</sup> therapy, comprising 15 iv treatments administered over a treatment period of between 15-30 days. These treatments were typically scheduled over three blocks of fiveday treatment periods with two-day intermissions, with oral dosing of Salicinium® as described below on non-iv days. During each of the 15 iv treatments, patients were administered 500 ml iv Salicinium comprising a 0.06% helicidum solution (3.0 g of helicidum in 500 ml saline) over a two-hour administration period. In certain cases, all 15 iv treatments were administered over a consecutive 15-day period, while in others the 15 iv treatments were scheduled over an extended period, up to one month, to accommodate patient scheduling factors.

After the initial aggressive iv treatment period, all patients were switched to oral Salicinium® treatment. A 3 g/day helicidum dosing protocol was carried out for one year or until a subject was evaluated to be in disease remission. Subjects self-administered three 500 mg Salicinium doses (either solid-form gelatin capsules, or in liquid dosage form) twice daily between meals. Subjects who progressed rapidly to partial or complete remission remained on oral Salicinium for one month after positive diagnosis of remission, while other subjects remained on oral treatment for a full treatment period of one vear.

All subjects were regularly examined diagnostic cancer indicators throughout the study, according to standard methods. Study subjects were evaluated monthly, quarterly, or biannually based on their prior status other oncologist-determined criteria. Patient status was assessed using CT scans, PET scans, blood work, cytology, biopsy, and other standard diagnostic methods. Disease status was monitored throughout the 60-month study period for each subject, and all substantial changes in status were noted for each subject. This monitoring was scheduled and conducted at the discretion of the responsible physician, depending on each patient's unique circumstances. Further, as expected, patients in different cancer groups, and within groups, showed considerable variation in their timing and/or rates of disease recovery or progression. For these reasons, compiled mid-term data from this study are not analyzed or presented here to show rates of disease recovery or progression over

progression (for example, stable tumor number and size, no new metastases, and no substantial increase in tumor blood marker levels). Other subjects exhibited disease progression and mortality as noted. Cancer-related symptoms (e.g., pain, fatigue, mood disorders, functional limitations, etc.) were also monitored; and the severity of these symptoms generally paralleled the patients' disease status.

The clinical study results summarized in Table 1 demonstrate that Salicinium® potently stabilizes and frequently eradicates cancer of all types evaluated, including Stage IV, treatment-resistant cases in all groups.

time for subjects throughout the study period. Rather, the data presented here focus exclusively on disease status at the beginning and endpoints of the study (i.e., from confirmed Stage IV diagnosis at the beginning of Salicinium treatment, to final status determined 60 months later).

Disease status was scored according to NIH standard criteria,4 as follows. Subjects were determined to be in "complete remission" when there was no detectable cancer using conventional diagnostic measures (e.g., negative PET scan, CT scan, MRI, biopsy, blood marker tests, blood count tests, histopathology [e.g., PAP], colonoscopy, ultrasound, radiography, or combinations thereof). A subject was scored as being in "partial remission" when quantitative evidence was determined showing "a decrease in the size of a tumor, or in the extent of cancer in the body" (NCI Dictionary of Cancer Terms). For the purposes of this report, each subject's original status was compared to the status at 60 months, and "partial remission" was scored in most cases when there was a substantial reduction in detectable tumor number, tumor distribution, and/or tumor volume. For certain cancer types (e.g., leukemias), partial remission was determined based on changes in diagnostic quantitative biopsy, histopathology, blood count, and/or tumor marker levels, among other conventional methods. Subjects were classified as presenting with "stable disease" when the monitoring physician observed persistent disease with no detectable disease reduction or

All patients who did not reach a state of complete remission within the first year completed a full, one-year oral Salicinium dosing regimen. Certain patients presenting with high risk diagnostic indicators (e.g., new tumors or actively growing tumors by CT and/or PET scans, high levels of cancer blood markers, etc.) continued oral Salicinium® as long as these risk indicators remained high, though for most patients oral treatment was determined to be completed/successful by 12-18 months.

Of the 675 enrolled patients, 128 patients entered the study with diagnosed Stage IV breast cancer, 91 with Stage IV colon/rectal cancer, 34 with Stage IV head/neck cancer, 86 with Stage IV lung cancer, 32 with Stage IV non-Hodgkin's lymphoma (NHL), 28 with Stage IV melanoma, 36 with Stage IV ovarian cancer, 37 with Stage IV pancreatic cancer, 76 with Stage IV prostate cancer, 18 with Stage IV renal cancer, 23 with Stage IV sarcoma, and 34 with Stage IV uterine cancer. A majority of study subjects enrolled after one or more failed rounds of standard oncotherapy (typically surgery, chemotherapy, radiation and/ or hormone therapy) and presented at enrollment with disease progression to Stage IV, or Stage IV relapsed cancer. These subjects were classified as "treatment resistant" or "refractory" Stage IV cancer patients. Less than 10% of participants had not received prior,

See National Cancer Institute (NCI) Dictionary of Cancer Terms. www.cancer.gov/publications/dictionaries/cancerterms

### Salicinium<sup>®</sup>

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conventional oncotherapy; therefore, the data here represent treatmentresistant classes for all studied cancer types.

As noted, all patients remained throughout the study period in contact with medical providers who maintained regular monitoring of the subject's disease condition (with regular exams, including blood work testing for cancer markers, cytology, CT scans, PET scans, biopsy where indicated, and other diagnostic monitoring). Fifty-two percent of study subjects maintained or initiated some form of standard oncotherapy (commonly low dose chemotherapy, and in some cases additional surgery, radiotherapy, and/ or chemotherapy) during the course of this study. Many patients with breast cancer, ovarian cancer, uterine cancer, and prostate cancer remained on oncologist-prescribed hormonal therapy throughout the study.

Cumulative data for 675 study subjects reveal potent anti-cancer efficacy of Salicinium®. As summarized in Table 1, Salicinium therapy is highly effective to transition patients from intractable Stage IV cancer to stable disease, partial remission, or complete remission, with few or no adverse side effects.<sup>5</sup>

The clinical study results summarized in Table 1 demonstrate that Salicinium®

potently stabilizes and frequently eradicates cancer of all types evaluated, including Stage IV, treatment-resistant cases in all groups. Stage IV breast cancer patients showed a 69% survival rate 60 months after initiation of Salicinium treatment. This contrasts starkly with a 16% median five-year survival reported for all Stage IV breast cancer subjects by the National Institutes of Health (NIH). Of the 128 Stage IV breast cancer patients enrolled in this study, more than 16% were diagnosed as essentially cured (i.e., in "complete remission,"), and 53% were diagnosed with "stable disease" or in "partial remission" at the end of the study term. Comparable results were observed for all cancer

As detailed in Figures 1 and 2, for all of the most common, costly, and fatal types of cancer, Salicinium treatment yielded extraordinary clinical benefits. Among 91 colon/rectal cancer patients who completed the study, 5% achieved total remission, and 56% survived with stable disease or partial remission, compared to a median survival of only 8-15% published by the NIH (Figure 1). For lung cancer, Salicinium treatment resulted in a 62% survival at the study endpoint, marking a 12% increase in survival expectancy over the NIH published median of 50% (Figure 1). For prostate cancer patients, Salicinium treatment yielded a 78% survival rate, more than double the NIH published median survival of 33%.

In the prostate cancer study group, Salicinium mediated total remission in 20% of subjects, with an additional 58% completing the study in stable or partial remission status (Figure 1). For the Stage IV melanoma study group, Salicinium treatment yielded an unexpectedly high 52% survival outcome (compared to the NIH published median fiveyear survival for all types of Stage IV skin cancer of 15-20%) (Figure 2). The Stage IV pancreatic cancer study group showed the most marked increase in survival (46%) compared to the grim 4% median five-year survival expectancy published by the NIH (Figure 2). Stage IV ovarian cancer patients exhibited an overall survival rate of 55% at the end of the study term, with more than 10% in complete remission, compared to a median survival of 17% for Stage IV ovarian cancer published by the NIH.

Salicinium® mediated prolonged survival for all Stage IV cancer groups studied. Non-Hodgkin's lymphoma subjects treated with Salicinium exhibited five-year survival of 53%. with 19% of subjects in total remission and 34% stable or in partial remission at study's end (Table 1). For uterine cancer subjects, survival was 47%, with 41% stable or in partial remission and 5% in full remission. For patients with Stage IV head/neck cancer, survival was 53%, with 41% in stable disease or partial remission and 12% in complete remission, at the end of the study. For renal cancer subjects, 56% survived the full study term, with 17% in total remission and 39% with stable disease or in partial remission. Sarcoma subjects exhibited 48% survival, with 9% in total remission and 39% stable or in partial remission.

In addition to the 624 patients reported in Table 1 for the above groups, 51 additional patients were treated and evaluated in smaller groups, presenting with acute lymphocytic leukemia, acute myeloid leukemia, astrocytoma, bladder cancer, chronic lymphocytic leukemia, esophageal cancer, gall bladder cancer, stomach cancer, glioblastoma, Hodgkin's disease, liver cancer, mesothelioma,

Table 1. Cumulative Salicinium® Clinical Study Results, by Patient Status Through End of 60 Month Study Period

Cancer Type	Number of Patients Studied	Stable Disease	Partial Remission	Complete Remission	Not Surviving
Breast	128	38	30	21	39
Colon/Rectal	91	36	15	5	35
Lung	86	38	10	5	33
Prostate	76	22	23	15	16
Melanoma	29	7	8	0	14
Non-Hodgkins	32	6	5	6	15
Lymphoma					
Ovarian	36	11	5	4	16
Uterine	34	10	4	2	18
Head/Neck	34	14	0	4	16
Renal	18	7	0	3	8
Sarcoma	23	7	2	2	12
Pancreatic	37	17	0	0	20

Serious side effects reported by study participants all appeared attributable to standard oncotherapy and were limited to patients who combined Salicinium® and standard oncotherapy

myeloma, testicular cancer, and thyroid cancer. In these smaller groups Salicinium treatment yielded significant therapeutic benefits over the treatment and monitoring period, including significantly increased rates of survival consistent with the larger study groups reported here.

# Salicinium Potently Induces Apoptosis in Cancer Cells

Further investigations here show that Salicinium potently induces apoptosis in cancer cells. Circulating tumor cells (CTCs) were isolated and characterized from patients with a wide variety of primary cancer types, with and without metastasis, using conventional flow cytometry modified to a multiparameter flow cytometric panel. In one exemplary study, CTCs from breast cancer patients were isolated with a flow cytometry panel using CD45-PE/Cy7, CD31-RPE, pancytokeratin-PE/Cy5, c-met-PE and MUC-1(CD227)-FITC. CTCs were identified as CD45-/CD31-/PanCK+/ MUC1+ and metastatic cells as CD45-/c-met+. CTC isolation and cultivation used peripheral blood mononuclear cells (PBMCs) from patients isolated using Ficoll centrifugation methods and incubated with EpCAM magnetic beads to isolate the CTCs. Other procedures were adapted using comparable flow cytometric panels adapted for different cancer types according to known methods (see for example, Pantel et al., (1994); Radbruch et al., (1995); and Ma et al. (2017)).

Isolated CTCs were cultured in serum free RPMI medium. Test samples were exposed to Salicinium® (represented here by helicidum, added to 0.5 mg/ ml in test samples) and incubated 24 hours before microscopic observations were made in replicate series to observe and quantify apoptosis in the CTC samples. Apoptosis quantification was based on observed cytoplasmic, nuclear and membrane changes diagnostic for apoptosis. Data were analyzed using SPSS software, and T test methodology was used to compare data sets. A significance level of p<0.05 was considered statistically significant.

From these studies, CTCs were isolated with high fidelity and shown

to be powerful tools to monitor cancer disease progression in individual patients, and more particularly for determining efficacy of anti-cancer drugs and methods against patient-specific samples. A total of 967 patient CTC samples were tested within this study, and of these samples 82% showed statistically significant sensitivity to Salicinium for inducing apoptosis in the cultured CTC cells (82% of samples

#### Salicinium<sup>®</sup>

showed significant apoptotic activity above control samples). As illustrated in Figure 3, Salicinium potently induced CTC apoptosis in virtually all cancer types. For more sensitive cancer types, including lung, colorectal, sarcoma, and renal cancer, a single dose

Figure 1. Survival of Salicinium-Treated Stage IV Breast, Colon, Lung, and Prostate Cancer Patients Compared to NIH Published Median Survival

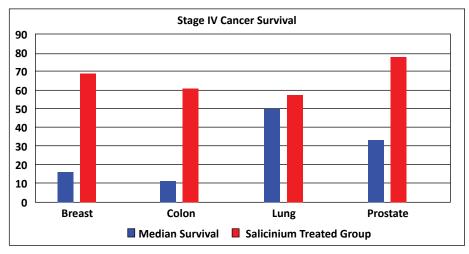


Figure 1 graphically depicts disease progression and survival data for groups of breast, colon, lung and prostate cancer patients receiving anti-cancer treatment with Salicinium® compiled at the end of a 60 month study term (as compared to median survival statistics over the same term for all stage IV subjects in the same groups published by the NIH). Patients diagnosed with stage IV breast, colon, lung and prostate cancer were administered Salicinium as described above. Left axis = surviving percentage of original patient population in each group. Surviving subjects were evaluated at the end of the study and grouped as either in stable disease, partial remission, or complete remission, as presented in Table 1.

Figure 2. Survival of Salicinium-Treated Stage IV Ovarian, Pancreatic, and Melanoma Cancer Patients Compared to NIH Published Median Survival

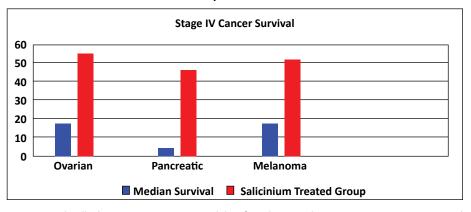


Figure 2 graphically depicts comparative survival data for subjects with Stage IV ovarian, pancreatic, and melanoma cancer receiving Salicinium (comparison to NIH published median survival data over the same term for all patients diagnosed with the indicated Stage IV cancer). Patients diagnosed with Stage IV ovarian, pancreatic and melanoma cancer were administered Salicinium as described above. Left axis = surviving percentage of original patient population in each group. Surviving subjects were evaluated at the end of the study and determined to be either in stable disease, partial remission, or complete remission, as presented in Table 1.

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>

(comparable to a clinical therapeutic dose) of Salicinium induced apoptosis in approximately 30-35% of all CTC cells present in positive samples. For the majority of other cancer types tested, Salicinium effectively induced apoptosis in about 20-25% of CTC cells in samples after a single exposure and 24-hour test period. Less sensitive cancers, for example squamous cell carcinoma (SCC) and head/neck cancers, nonetheless also showed potent induction of apoptosis (greater than 70%), predictive of profound therapeutic benefits.

Additional studies evaluated caspase levels in CTC samples treated or untreated with Salicinium. Caspases are major executants of apoptosis. They are cysteine proteases generally inactive in healthy cells. During apoptosis these pro-enzymes are converted into active enzymes and potentiate apoptosis by degrading intracellular proteins, for

example cytoskeletal proteins, causing profound morphological changes of cells. Caspase-3 is activated by upstream caspases (caspase-8, caspase-9 or caspase-10), and in turn Caspase-3 activates endonuclease CAD (caspase activated DNase). In proliferating cells, CAD normally combines with ICAD (an inhibitor of CAD) to form an inactive complex. In apoptosis, ICAD is cut by caspase-3 and releases CAD, followed by rapid fragmentation of DNA.

Caspase-9 levels were compared in control CTC samples and Salicinium-treated CTC samples according to conventional assay methods. Commensurate with the observed induction of apoptosis by Salicinium, potent induction of elevated caspase-9 levels was observed in Salicinium-treated versus control samples in CTCs from diverse cancer types.

#### Salicinium and Nagalase

Additional studies here reveal that Salicinium® also fights cancer and

viral infections by disrupting alpha-Nacetylgalactosaminidase (nagalase) synthesis and reduces nagalase blood levels in patients with high viral loads, mediating potent anti-cancer and antiviral responses. Pre- and post-treatment nagalase levels were assayed in blood samples from 158 patients diagnosed with a heavy load, chronic viral infection and/or Stage IV cancer. Some subjects presented with only viral infection, and some with only Stage IV cancer, whereas a sizeable group of 64 subjects had comorbid Stage IV cancer attended by heavy load chronic viral infection. The principal viral subjects in these studies were Epstein-Barr virus (EBV), hepatitis C virus, cytomegalovirus (CMV), and herpes virus. Nagalase levels and viral load were quantified using conventional assays for each patient, before and after successive iv Salicinium® treatments, and after extended oral Salicinium follow-on therapy (using the iv and oral helicidum protocol described above).

continued on page 48 ➤

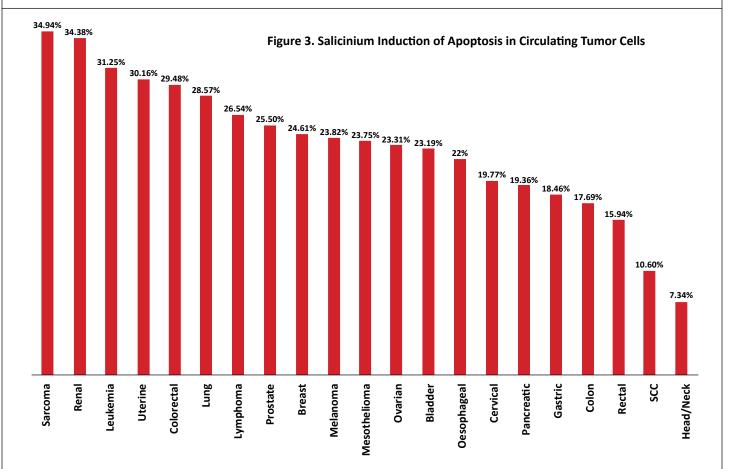


Figure 3 illustrates Salicinium® induction of apoptosis in circulating tumor cells (CTCs). Each bar depicts the percentage of cultured CTC cells from patient samples grouped by primary cancer types exhibiting apoptosis within 24 hours following a single exposure to Salicinium as described.



# Salicinium has recently been added to the R.G.C.C. Circulating Tumor Cell test as well as the BioFocus Labs Cellular NK test:



to order test: Research Genetic Cancer Center info@rgccusa.com or www.atmctx.com/cancer-test

to order test: Bio Focus Labs <a href="www.prix@biofocus.de">www.prix@biofocus.de</a>

# The Science of Glycobiology

Salicinium changes the way the macrophage of the immune system recognizes diseased cells through immune modulation. The Nagalase enzyme produced by anaerobic cells shuts down the natural function of the immune system providing safety for these diseased cells.

The composite Salicinium molecule will only affect anaerobic cells destroying the enzymatic "cloak" which allows them to hide from the immune system's NK cells. Salicinium stops the production of Nagalase and lactate removing their protection while simultaneously stimulating the the innate immune macrophage to eliminate these diseased cells.

Circulating tumor cells are at the forefront of an ongoing or escalating malignant process. CTC testing has shown Salicinium affects these cells first therefore halting the spread of malignancy. Continued use of Salicinium will allow the immune system to steadily attack remaining malignant cells. The same testing also induces the death of cancer stem cells and Salicinium therapy, whether I.V. or oral, should be continued without interruption until testing shows no further indicators of malignancy.

- In a study by R.G.C.C. of 967 patients
  Salicinium showed a 26.28% average apoptosis rate from a single dose with 82% sensitivity. A much higher cumulative apoptosis rate is recognized with ongoing treatment as the level of Salicinium builds within the tissues.
- Salicinium can be used alone or as an adjunct to other complementary therapies or as an integrative therapy to allopathic treatments.
- Salicinium is completely targeted it will only enter anaerobic cells.
- Salicinium allows Gc-Maf to resume operation, greatly increasing Immunoglobulins
- ➤ Salicinium does not kill the malignant cells the immune system does. Only the immune system can destroy anaerobic cells, Salicinium increases immune natural killer (NK) cells/Gc-Maf

for more information about Salicinium:

#### Salicinium<sup>®</sup>

#### > continued from page 46

Data obtained within this study show that nagalase levels are typically very elevated in Stage IV cancer patients. In particular, whereas a conditional "normal" nagalase level corresponds to about 0.65 Units (nmol/min/mg), Stage IV cancer subjects in this study exhibited elevated nagalase levels routinely above 0.95 units, often between about 1.2-2.5 Units. Extreme outlier patients, with the most severe and pervasive cancers, exhibited extraordinarily high nagalase levels, up to 4.0 Units and even higher. On average, Stage IV cancer subjects evaluated here to assess Salicinium impacts on nagalase blood levels tested with a median nagalase blood level of 1.43 Units at the time of enrollment, prior to the initial Salicinium treatment. This study group of 158 patients was followed up for nagalase assays every month for the first three months after treatment, again at six months, and again at one-year post treatment.

The cumulative data from these studies show that iv Salicinium treatment effectuates pronounced reduction in nagalase levels in a large majority (83%) of patients over the first three monthly post-treatment checkpoints, so that by one month after treatment median nagalase levels in these subjects was decreased from a starting value of 1.43 Units to about 1.15 Units. By the third month, median nagalase levels in these subjects was decreased to about 1.12 Units. By six months, 72% of the study patients exhibited nagalase levels below 1.0 units, and by one year 86% of study patients exhibited nagalase levels in a conventionally accepted "normal" range of below .95 Units. The median nagalase level determined at one-year post-treatment was 0.78 Units.

For the cancer group, all data showed a strong relationship between nagalase levels and severity of an individual

patient's initial cancer status. Patients initiating the study with large involved cancerous tissue volumes expressed the highest nagalase levels, and showed a more gradual percentage reduction in nagalase levels over time. In contrast, patients with smaller tumors and less pervasive forms of cancer (e.g., prostate and breast cancer, versus high load skin cancer) showed lower initial nagalase levels and a more rapid recovery to normal levels.

Conventional viral load assays showed anti-viral efficacy of Salicinium closely tracking the nagalase attenuation data presented above. For EBV, HCV, CMV, and herpes II virus in particular, median viral loads among study subjects for all these viruses dropped by about 20-25% in the first month, and by an additional 20% within three months after treatment. The most compelling data was related to total viral eradication numbers (i.e., yielding no detectable virus in subjects). For EBV

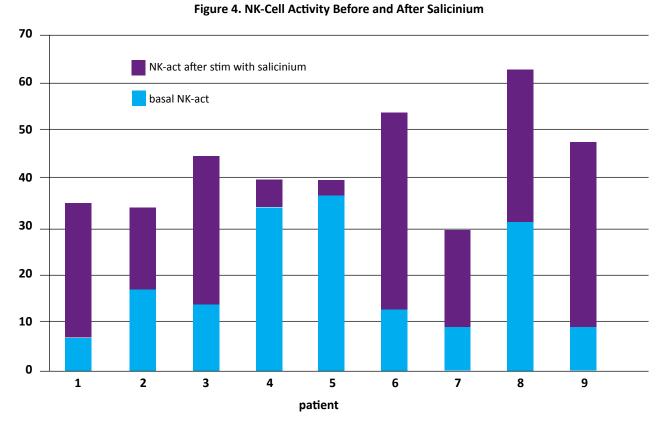


Figure 4 depicts assay results measuring Salicinium®-mediated increases in NK cell cancer-killing activity using immune cells harvested from cancer patients (originally demonstrably immunosuppressed by nagalase) activated against cancer cells in culture.

and herpes II subjects, initial high load viral infections became undetectable in 50% of treated subjects within six months following initial Salicinium iv treatment (supported by oral Salicinium maintenance treatment as described). After one year, 87% of all viral subjects (presenting with EBV, hepatitis C, herpes virus, and CMV) were entirely clear of detectable virus.

#### **Salicinium and Immune Response**

Anti-cancer and anti-viral activities of salicinium are further mediated by anticancer and anti-viral immune responses potentiated by downregulation of nagalase. Additional studies here demonstrate that Salicinium® activates potent anti-cancer and anti-viral responses, including immune by potentiating natural killer (NK) cells isolated from cancer patients. Immune cells were obtained from blood samples of 73 cancer patients. The capability of these immune cells to kill tumor cells in vitro was determined using a conventional cellular NK activity assay (Neri et al. Clin Diagn Lab Immunol. 2001 November; 8(6): 1131–1135). Basal killing activity of NK cells was compared to killing activity after exposure of test samples to therapeutic concentrations of Salicinium. Isolated immune cells were cultured in serum free RPMI medium. Test samples were exposed to Salicinium (helicidum, at 0.5 mg/ml in samples) and incubated 24 hours before microscopic observations were made in replicate series to observe and quantify NK cell destruction of tumor cells. Results were determined as percent NK cell-mediated lysis in control samples (tumor cells killed in the absence of Salicinium) and treatment samples (tumor cells killed with Salicinium present). Control samples for these assays employed immune cells from well patients with no detectable cancer.

One exemplary assay (Figure 4) compared nine patient samples side by side (samples 4 and 5 are controls, from patients with no cancer). Comparable data were observed from additional assays using a total of 73 patient samples. These data show that Salicinium mediates a major increase in cancer killing activity by NK cells. In the

cumulative samples tested, the average Salicinium-mediated increase in NK cancer-killing activity was approximately two- or three-fold (average 2.6 times greater) compared to basal NK cancer-killing activity. Controls routinely showed little or no increase in NK cell activity in the presence of Salicinium. These data correlate with the evidence above showing potent down-regulation of nagalase by Salicinium.

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uptake and utilization of glucose (widely known as the "Warburg effect"). Both cancer cells and cells chronically infected with virus overexpress glucose receptors. Thus, these cells are targets for preferential uptake of Salicinium compounds, which selectively targets cancer and virus-infected cells and disrupt their glycolytic metabolism.

The cumulative data from these studies show that iv Salicinium treatment effectuates pronounced reduction in nagalase levels in a large majority (83%) of patients ... For the cancer group, all data showed a strong relationship between nagalase levels and severity of an individual patient's initial cancer status.

Nagalase suppresses GcMAF and impairs macrophage activation and macrophage-mediated stimulation of downstream immune functions (including NK cell activation). These activities of nagalase suppress immune cells circulating in patients with cancer; but when these cells are harvested, cultured, and treated with Salicinium. as in the current studies, nagalaseimmunosuppression mediated reversed. This occurs over a period of time, wherein Salicinium disrupts nagalase synthesis by the cultured cancer cells and titer of nagalase in the test cultures drops dramatically, relieving inhibition of GcMAF and NK function of immune cells in those cultures. No such inhibition is present in control cultures initially, due to normal nagalase levels, so the dramatic increase in NK cell activity is not observed and baseline NK cell activity is much higher.

#### Discussion

This report details the surprising potency of Salicinium® compounds (exemplified here by helicidum) for treating cancer and viral infections. Salicinium induces apoptosis by disrupting glycolytic metabolism in cancer and virus-infected cells. The metabolism of cancer cells is oxidatively stressed and biased toward glycolytic energy utilization (see, e.g., Jang et al., 2013). Attending this metabolic shift, cancer metabolism features enhanced

Jang et al. (2013) describe various aspects of cancer metabolic dysfunction, many of which relate to Salicinium's mechanisms of action. Briefly, one mechanism of Salicinium action manifests through the glucose transporter (GLUT) pathway. GLUTs are present in all cell types, but cancer cells dramatically overexpress GLUTs. In the GLUT transportation pathway, Salicinium is met by the enzyme hexokinase II (HK2) and through enzymatic reaction with ATP is changed to glucose 6-phosphate-benzaldehyde (G 6-p-b). G 6-p-b, again through a further enzymatic reaction and another investment of ATP, becomes fructose 1 6-bisphosphate-benzaldehyde (FBP-b). Glucose and fructose that provide energy to anaerobic cells are converted into FBP. Salicinium disrupts this pathway, by virtue that it irreversibly modifies the activities of HK2, G 6-P, F 6-p, and FBP, in part by altering their chemical structure, electrical potential and/or substrate recognition, binding and electrochemical interaction potentials.

In more detailed mechanistic aspects, Salicinium® alters the physiology of a key metabolic enzyme, pyruvate kinase (PK). Most tissues express either PK1 or PK2. PK1 is found in normal differentiated tissues, whereas PK2 is expressed in most proliferating cells, including all cancer cell lines and



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tumors tested to date. Although PK1 and PK2 are highly similar in amino acid sequence, they have different catalytic and regulatory properties. PK1 has high constitutive enzymatic activity. In contrast, PK2 is much less active but is allosterically activated by the upstream glycolytic metabolite fructose 1, 6-bisphosphate (FBP). PK enzymes are

generally inhibited by ATP; and in the case of the downstream PK2 enzyme, its activity is held in check by ATP until FBP activates it. Relevant here, Salicinium (exemplified by a glycome bound with a benzaldehyde or other glycolysis-disruptive moiety) is converted into an unnatural FBP-b analog. In this state Salicinium disrupts the HK2 pathway. With no upstream glycolytic metabolite having interactive potential with the low energy PK2 enzyme, normal FBP

metabolism is irreversibly changed; and when HK2 enzymes interact with Salicinium upon its entry through the GLUT pore, PK2 activity is likewise halted.

Salicinium® also interacts adversely with nicotinamide adenine dinucleotide phosphate (NADP). NADP plays an important role in the oxidation-reduction involved in protecting against toxicity of reactive oxygen species (ROS). Salicinium's interaction with HK-II upon entry into anaerobic cells irreversibly disrupts NADP metabolism, whereby the glycolytic energy function of the anaerobic cell becomes completely dysfunctional, with the result being induction of apoptosis.

other detailed mechanistic aspects, Salicinium interacts in the glycolytic pathway when oxidative stress triggers conversion of pyruvate to lactic acid by fermentation. During lactic acid fermentation, pyruvate and NADH are converted to lactic acid and NAD+. NAD+ is also used in glycolysis to generate ATP in which C6Hi2O6 + 2ATP + 2NAD+ =>2pyruvate + 4ATP + 2NADH. Cancer cells create a slightly acidic intracellular environment (cancer cell pH is about 7.00, whereas normal cellular pH is about 7.36) contributing to metabolic conversion of normal, aerobic cells into fermenting cells. In the process of fermentation, Salicinium functions as a deactivator of NAD+. Upon entry into the cytosol, benzaldehyde (and other comparable effectors linked to a carrier glycome) reduces NAD+ to NADH+H, blocking the normal function of NAD+, interfering with the normal acid detoxification process, and resulting in a decrease in pH (due to the inability to convert pyruvic acid to lactic acid) - powerfully disrupting glycolysis, curtailing cancer proliferation, and ultimately inducing cellular apoptosis.

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#### OPTIMAL NUTRITIONAL SUPPORT

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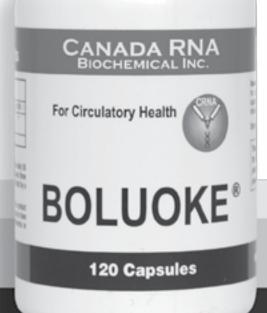
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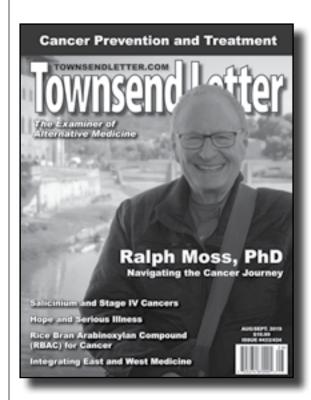
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# On the cover

# My Cancer Journey by Ralph W. Moss, PhD<sup>©2019</sup>

I had been writing about cancer for 40 years (and almost 20 years for *Townsend Letter*) when I myself was diagnosed with an aggressive form of the disease in the summer of 2015. That summer, my wife and I had taken an unconventional blood test called ONCOblot, which purported to tell not only *if* one had cancer, but the specific type. (This test is no longer available.) My wife's results were all clear, but I scored positive for prostate cancer.

But when I took these results to my urologist, she was skeptical. In fact, she assured me, "I am 100 percent certain you do not have prostate cancer!"

In August 2015, my Prostate Specific Antigen (PSA) blood test score at that time had edged up to 6.57 ng/mL. Traditionally, a normal score is 4.0 or lower. But the PSA score is not definitive. As the National Cancer Institute has pointed out:

There is no specific normal or abnormal level of PSA in the blood, and levels may vary over time in the same man. In the past, most doctors considered PSA levels of 4.0 ng/mL and lower as normal. Therefore, if a man had a PSA level above 4.0 ng/mL, doctors would often recommend a prostate biopsy to determine whether prostate cancer was present.

Because I have a history of benign hyperplasia of the prostate as well as prostatitis, my PSA score had always been somewhat high. Looking back, in 2011, my PSA had already been over 6.08. So the fact that the PSA had continued to edge up was concerning, but not alarming. My urologist had no familiarity with the ONCOblot test and was uninterested in learning about it. I was concerned, however.

#### Free PSA

Another indication of looming trouble in 2015 was my "free PSA" score. Free PSA measures the level of unbound prostate-specific antigen in the blood. When the ratio of free to total PSA is between 0 and 10 percent, the risk of having cancer is relatively high. But when the ratio remains greater than 25%, the risk is lower. In 2011, although my total PSA was over 6.0, my free PSA was still marginally normal. But in 2015, as my total PSA score rose, my free PSA score sank. It sank to 17%, instead of the desirable 25% or above.

Given my history, my urologist confidently ascribed these scores to enlargement and inflammation of the gland, not cancer. She offered to do a biopsy, although she didn't think it was necessary. I was happy to hear this. I dreaded having a prostate biopsy, because I feared the invasiveness of the procedure. It wasn't just a fear of pain, fever, bleeding, or transient urinary problems. I also knew that there was a risk of bacterial infection from the biopsy. A 2013 article from the well-respected *Consumer Reports* had warned:

An alarming number of the men who undergo [prostate biopsy] are also getting infections that are resistant to antibiotics. The problem is so serious that *Consumer Reports'* medical consultants say men should be cautious about prostate cancer screening.

#### **MRI First**

I was also familiar with the work of some urologists who were advocating Magnetic Resonance Imaging (MRI) of the prostate gland before doing biopsies. I reasoned that doctors should first look at my prostate using a less invasive scan (MRIs, of course, use magnetic fields, not ionizing radiation

to see inside us) before poking 20 or more holes in such a sensitive location.

But although this seemed logical, I discovered that it is not conventional thinking. American urologists perform over a million prostate biopsies per year, and the great majority of these are done on the basis of abnormal PSA scores, and not MRI findings.

Through my work as a medical writer, I had come to know James Morré, PhD, the inventor of the ONCOblot test. I had had many discussions with him and trusted in the accuracy of the procedure. However, the main problem with ONCOblot was that it was *too* accurate. In other words, it would detect tiny tumors that might never pose a clinical problem.

So, I was optimistic that, although I probably did have something that was technically cancer, this might be what urologists call "prostatic intraepithelial neoplasia" (PIN).

After an argument, my urologist reluctantly agreed to write a prescription for me to have an MRI exam in advance of a biopsy. I insisted on having the latest "3 Tesla" magnetic scan. But this was not available in the town where I then lived. I felt strongly enough about the superiority of the "3T" scan, that my wife and I drove over 200 miles to the nearest such facility. This was a comprehensive cancer center on the East Coast, whose urology department was highly rated.

But things did not go well there. This facility had both 1.5T and 3T machines in operation. Without telling me, and against my explicit request, the staff had arbitrarily switched me to a 1.5T machine. As I was going in, I verbally checked to make sure that I was getting the test I had come for. I then discovered the change. I explained, rather heatedly, that I had just driven 200 miles specifically to get the 3T test. They sent me back to the waiting room for an hour and then gave me the 3T test. It pays to be outspoken and sometimes to ask the "stupid question."

But the 3T MRI showed the opposite of what I was expecting. This was not some stray cancer cells. There were in fact two large tumors dominating the gland. It was too soon to say exactly how dangerous or aggressive these were likely to be.

#### **Nearly Disastrous**

The next step in my journey was nearly disastrous. Of course, I needed to see a urologic oncologist immediately. Because we were so far from home, the urology department agreed to squeeze us in as the last scheduled appointment on Friday afternoon. I have since learned that this is not a good idea. Studies show that doctors "wear down" in the course of the week, and, as a result, may make inappropriate recommendations. There is even a name for this problem: "Decision Fatigue." One doctor has even said: "The potential for complete decision exhaustion is astronomical."

That Friday afternoon is indelibly etched in my memory. The urologist I was assigned to slunk into the room, mumbled his last name by way of introduction, and, without making eye contact, sat down at the computer terminal and began pecking away at the keys. I had a sinking feeling that this weary middle-aged man could not wait to be done with

his work week –and with me, the final patient of a long and difficult week.

He pulled up some records on the screen and glanced over the radiologist's written summary of the MRI. I had the impression that he had not considered my case until that very moment. After a minute or so, he blurted out words to this effect: "You've got a prostate full of cancer. And it's broken through the capsule."

These carelessly uttered words came as indescribable shock to my wife and me. The prostate gland is encased in a kind of shell. So cancer has to be pretty aggressive to fight its way outside that shell. That is why "escaping the capsule" are among the most undesirable words you can hear about your prostate cancer.

But nothing we had heard so far had prepared us for this idea. The MRI report that we had seen had said nothing about the *spread* of the cancer. Knowing this, but still shaken, I asked the urologist to put the MRI *scans themselves* up on the computer screen and to *show* my wife and me where, and how, the tumors had broken through the prostatic capsule.

This seemed like a reasonable request. After all, my life hung in the balance. But his reaction was totally unexpected. He actually yelled in anger and frustration, "I'm a *urologist*, not a *radiologist!* I don't look at MRIs. I rely on the radiologists' reports." Meanwhile, his interpretation of the radiologist's report was so different from what we had read, that it seemed that he was looking at somebody else's report!

He then suggested a prostate biopsy, which he said could be arranged for early in the following week. The doctor who would do my biopsy, he told us, was the chairman of the department. I already knew this because there was a poster in the waiting room announcing that man's retirement dinner! Apparently, I was to be among his last patients before his retirement due to advancing old age. This made me even more apprehensive.

#### **Fusion Biopsy**

I asked whether or not they would do a *fusion* biopsy, a relatively new procedure in which the MRI images are fused with live-time ultrasound to yield a more accurate sampling of the gland. He agreed that this was a superior technology but then said, "No, we don't have that here." When I asked why, he said, "We can't afford it."

I thought this was strange, since in the waiting room I had read an article about the hospital's new Proton Therapy Center, which had been installed at a cost of \$140 million. A fusion biopsy set-up costs on average \$165,000, or about 1% of the cost of a proton generator.<sup>2</sup> He then rattled off the names of various East Coast medical centers that did have this advanced technique, as if inviting me to go anywhere other than his clinic.

The only treatment he could suggest for my condition was radiation therapy since, as he claimed, my cancer was too far advanced for surgery. When I asked my chances of being left impotent and/or incontinent after treatment he exclaimed, exuberantly, "One hundred percent!"

## **My Cancer Journey**

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That night, sitting in my hotel room, I felt lost and confused. As I said, I have been writing about cancer steadily for over 40 years. In that time, I had also counseled thousands of patients. But this swirling mixture of fear, anger, hope, and despair bore little relation to my calm deliberation of other peoples' cases.

#### Enter Dr. Geo

At that point, I thought of my friend, Geo Espinosa, ND.<sup>3</sup> Geo is a naturopathic doctor working in the urology department of a major hospital, in his case, Langone New York University (NYU) Medical Center. Geo listened to my story and then strongly urged me to cancel the biopsy appointment that I had made and get a second opinion. So that is how, a few weeks later, I wound up in the New York City office of Samir Taneja, MD, of NYU.<sup>4</sup>

Unlike the previous doctor, Dr. Taneja had no problem in walking my wife and me through the relevant online MRI images of my disease. Later, he performed a fusion biopsy. The good news was that there was no indication that the cancer had pushed its way outside the capsule. That had been a complete misreading of my situation. I was in fact still a candidate for curative treatment.

But the bad news was that my cancer, upon biopsy, was classified as a **Gleason 8 (4+4).** Other names for this are high grade, poorly differentiated, and aggressive. At this point the textbook recommendations is for surgery or intensive radiation therapy. But Dr. Taneja offered me another alternative: to *ablate* my tumors. Ablation means the destruction of cancer through non-surgical and non-radiological means. There are various ways of doing this. But what Dr. Taneja suggested was focal **cryoablation.**<sup>5</sup>

This is the destruction of tumors through the insertion of very thin, very cold probes. This would destroy just the tumors and a surrounding margin of normal cells but would spare most of the non-cancerous tissue. The normal portion of my prostate would be left intact, and some of the crucial nerves would be spared. I thus had a better chance of avoiding the two main dreaded consequences of more traditional procedures, sexual impotence and urinary incontinence. I also avoided ionizing radiation, which by its nature is carcinogenic.

The procedure was performed a few weeks later, on an outpatient basis. It was fully paid for by Medicare and my supplemental health insurance. My out-of-pocket expenses involved staying in New York City for a few days before and after the procedure. I experienced no pain from the procedure itself.

Following the procedure, you are encouraged to stay active. And so on the day after the ablation, I felt well enough to walk 20 blocks from our hotel to a bookstore in Greenwich Village. Most importantly, I had few lingering side effects from the treatment. And, surprisingly, some of my previous symptoms of benign prostatic hyperplasia also improved.

All this happened four years ago, but I am still involved in NYU's follow-up program. At the one-year mark, I had a repeat biopsy, which was normal. I go to New York City yearly for a follow-up MRI. I also have a complete PSA blood test twice per year. All of my subsequent tests have been normal.

Some people familiar with the usual treatment of prostate cancer might be surprised to learn that I have a measurable PSA level at all. After prostatectomy, one expects to see either an undetectable or a negligible amount of PSA. But since I still have most of my prostate, it continues to produce some PSA. This is normal and not a sign of cancer. But the score remains steadily under 4. My free PSA is a normal 30% and this also hasn't changed in several years. As a result, Dr. Taneja is optimistic about my prospects; and of course I am very grateful for the excellent care I received at my alma mater, New York University. Pretty soon I hope to reach the point where I will no longer need follow-up MRIs at all.

Naturally, I have also employed food supplements and stepped up my dietary and activity regimen to enhance the effect of this unusual innovative treatment. Such things are important, but I was not willing to risk my life to find out if they would be sufficient to eliminate two large tumors. There are a lot of theories that this is so, but with an insufficient amount of hard evidence.

#### **Personal Encounter**

A personal encounter like this with cancer is, to put it mildly, quite a different animal than reading and writing about it, even for half a century. It has certainly made me more aware of what many of my readers and clients have been going through on their own journeys. After many years in the field, I knew a great deal about cancer *intellectually*. But the crucial component was missing. And it was not exactly what I expected. I saw gross incompetence at that first institution, and amazing skill at the second. I feel like I dodged a bullet by having a "male lumpectomy" through cryoablation instead of opting for the total destruction of my prostate gland. For me, this was the right choice. And while one never would choose to have cancer, it can pay dividends in terms of greater understanding and empathy for others.

After my diagnosis, I necessarily scaled back some of my activities, including my regular "War on Cancer" column for *Townsend Letter*. But as I approach the five-year disease-free mark, the psychological burden of this cancer diagnosis is lifting. I therefore am looking forward to resuming more regular contributions to the "examiner of medical alternatives."

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# The Role of Genetics in Prostate Cancer and Its Clinical Application: Beyond Family History

by Dr. Geo Espinosa, ND, LAc, IFMCP, CNS

One in seven men will be diagnosed with prostate cancer (PC) during their lifetime, with an estimated 307,000 deaths representing 6.6% of total male cancer mortality. An estimated 1.1 million men worldwide were diagnosed with prostate cancer in 2012, with almost 70% of them (759,000) occurring in more developed regions.<sup>1</sup>

Epidemiological studies have identified age, positive family history, and ancestry as the most prominent risk factors for prostate cancer. Incidence is highest among men of African ancestry, followed by men of European and Asian ancestries.<sup>2</sup> Prevalence in metastatic and potentially deadly prostate cancer, however, does not seem to correlate with age at diagnosis or with family history of prostate cancer.

Within the last decade or so, there has been an emphasis on genetic mutations associated with aggressive disease; and that data has shown that approximately 12% of men with metastatic prostate cancer have germline mutations in DNA compared to men with localized and less aggressive disease.<sup>3</sup>

Therefore, it is up to the astute practitioner to identify the risk factors for potentially advanced disease so that proper patient screening takes place along with aggressive lifestyle interventions.

# Genetic Mutations Associated with Advanced Prostate Cancer

Men who carry germline mutations in DNA repair genes (including BRCA1,

BRCA2, CHEK2 and ATM, which are involved in DNA double-strand break repair) are at increased risk of developing aggressive prostate cancer, defined by Gleason scores >7 in primary tumors, and of death from the disease.

Pritchard et al have found that the incidence of germline DNA-repair gene mutations among men with metastatic

cell division and can also direct cells to enter a natural cell death pathway when sufficient growth has taken place by inducing G1-phase cell cycle arrest through the retinoblastoma protein.

As a regulator of PI3K signaling, loss of *PTEN* leads to over-activation of Akt, which, in turn, is associated with uncontrolled cell proliferation,

Getting a handle on genetic predisposition for potentially dying from prostate cancer can help patients choose the best treatment options, along with staying the course with prescribed natural and lifestyle methods.

prostate cancer (mPC) is higher (11.8%) than in men with localized PC (4.6%) or men without cancer. In mPC, most mutations are located in the following genes: BRCA2 (5.3%), ATM (1.6%), CHEK2 (1.9%), BRCA1 (0.9%), RAD51D (0.4%), and PALB2 (0.4%).<sup>3</sup>

Another gene of interest for prostate cancer that I have seen in several European studies is HOXB13, which is a gene involved in embryonic development of the prostate gland and which appears to maintain homeostasis in adult gland. A study carried out by ICPCG (The International Consortium for Prostate Cancer Genetics) showed the presence of the HOXB13 G84E mutation in around 5% of prostate cancer European families and a higher G84E mutation incidence described in men with prostate cancer.<sup>4</sup>

#### **PTEN**

Phosphatase and tensin homolog gene (*PTEN*) is a tumor suppressor and primary negative regulator of the PI3K pathway. PTEN signaling regulates

decreased apoptosis, and enhanced tumor angiogenesis.<sup>5</sup>

In prostate cancer, early reports on the *PTEN* gene focused on small changes of DNA sequence or point mutations that led to inactivation of PTEN protein function. In addition, the *PTEN* gene may also be inactivated by epigenetic events such as promoter methylation.<sup>6</sup>

#### BRCA 2

Men with localized prostate cancer (enclosed within the gland) and with germline *BRCA2* mutation have an elevated risk of prostate cancer diagnosis and a worse prognosis than non-carriers even if they present with low-volume, low-grade disease.<sup>7</sup>

But wait, there's more. The combination of BRCA 2 mutation and localized disease is common in men who fail to respond to local radical therapy (radiotherapy or radical prostatectomy). This translates to the likelihood of a PSA recurrence in men after local radical therapy.<sup>8</sup>

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#### The Role of Genetics in Prostate Cancer

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In my practice, prostate patients come to me not just for a naturopathic protocol, but also to help objectively guide them on what conventional treatment to undergo. Part of the evaluation considers looking for BRCA2 mutations. Why? *BRCA2* mutation carriers have worse survival outcomes when managed with radiotherapy rather than surgery, so, those with *BRCA2*-mutant prostate cancer might be best treated with surgery.<sup>9</sup>

# Clinical Application of Genetic Mutations

That all sounds good above, but what do I do with all this information? Great question.

Remember, we are only interested in identifying prostate cancer that can be potentially deadly; low grade disease, roughly Gleason 6 or less, will unlikely kill anyone. With that in mind, there are three parts to identifying whether the patient has potentially deadly cancer or not: the pre-diagnostic phase, post-biopsy phase, and the post-prostatectomy phase.

#### **Pre-Diagnostic Phase**

The person with concerns about developing prostate cancer or with a family history should know their genetic risk for the advanced type of disease. While I'm aware that popular genetic kits like 23andme are used for overall genetic risk of disease, to my knowledge, for about \$250 there are only two genetic tests that mainly focus

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on cancer: Color (www.color.com) and Invitae (www.invitae.com). Combined, they test for BRCA1, BRCA2, CHEK2, PTEN, ATM, and HOXB13.

Note: there are other *non-genetic* tests that help determine the likelihood of a man having aggressive prostate cancer; 4K Score and Prostate Health Index (Phi) are more specific and sensitive than PSA alone. 4k Score (www.4Kscore.com) measures total PSA, free PSA, intact PSA, and hK2. Phi (www.mycancerisk.info/phi) is an office blood test that includes total PSA, free PSA, and 2proPSA using the following formula: ([-2]proPSA/fPSA) × VPSA.

#### **Post-Biopsy Phase**

After a man undergoes a prostate biopsy, it's good to know, first, if a negative biopsy result truly means there is no cancer in the prostate; biopsy needles miss cancers often. Second, if the biopsy result shows Gleason 6 or Gleason 7 prostate cancer, it is good to know if that result is indeed representative of the whole gland, or is there a tumor somewhere in the gland higher than a Gleason 7 that the biopsy needle missed?

If a prostate biopsy shows no cancer, a *Confirm MDx* examination of the tissue biopsied helps in determining if the result is a true negative. What do I mean by a "true negative"? Sometimes patients present with a high PSA, but when a biopsy is performed the result is no cancer. The problem is there can be hidden prostate cancer that the biopsy needle did not catch. The Confirm MDx (www.mdxhealth.com) can help determine the likelihood of missed cancer in the prostate from a biopsy.

How to get the test done? The physician completes the requisition form, sends in to MDxHealth for the pathology report, and the prostate sample is sent in by the pathology lab where biopsy prostate tissue is stored.

If the prostate biopsy shows lowgrade cancer, then test if the biopsy result is truly "low-grade" with an Oncotype Dx genomic test. The Oncotype® Genomic Prostate Score (GPS; Genomic Health Inc., Redwood City, CA, USA) is a quantitative realtime PCR assay performed on small fixed paraffin-embedded tissue samples obtained by needle biopsy. This assay includes 12 cancer-related genes involved in four different biological pathways (androgen pathway, cellular organization, proliferation, and stromal response) and five reference house-keeping genes algorithmically combined to calculate the GPS.

Oncotype DX® (www.genomichealth. com) yields a Genomic Prostate Score (GPS), on a scale of 1-100, where higher scores are more suggestive of adverse pathology. It is important to remember that a GPS score is a measurement of gene expression within prostate tumors and must be interpreted within the context of other relevant clinical factors.

In a cohort of 395 prostate cancer patients with low and intermediate risk who underwent prostate removal, Oncotype proved to be an independent and better predictor of high-grade (primary Gleason score of 4 or any pattern of 5) and/or high-stage disease (pT3 or higher) at the time of prostatectomy.<sup>10</sup>

Who qualifies for the Oncotype Dx? Patients who have had a prostate biopsy within the last three years and had a positive result for prostate cancer with a low to intermediate grade disease – meaning, in general, a Gleason 6 or Gleason 7 (3+4).

What does the Oncotype Dx tell you? The probability of more aggressive disease in the prostate, say Gleason 7 (4 + 3) or higher, that was not picked up by needle biopsy. The report provides a GPS score from 0 to 100. The lower the score, the less likelihood there is advanced prostate cancer somewhere in the prostate.

Prolaris by Myriad Genetics (www. prolaris.com) shows expression of 31 genes involved in cell-cycle progression (CCP), an important regulatory step in the development of cancer. A study examining the Prolaris panel in prostate

#### The Role of Genetics in Prostate Cancer

biopsy specimens from 582 men with prostate cancer demonstrated that the test was a very strong predictor of later clinical outcomes, including disease recurrence and progression to metastasis following surgery.

Who qualifies for the Prolaris test? Patients who have had a prostate biopsy within the last three years and had a positive result for prostate cancer with a low to intermediate grade disease – meaning, in general, a Gleason 6 or Gleason 7 (3+4).

What does the Prolaris test tell you? It gives the probability of more aggressive disease in the prostate, say Gleason 7 (4 + 3) or higher, that was not picked up by needle biopsy. Also, the Prolaris test helps determine if patients are candidates for active surveillance and the 10-year risk of developing metastasis following definitive treatment (prostatectomy or radiation). The report provides a Prolaris score, which will fall between 0 and 10 with a higher score indicating more aggressive cancer. For every single unit increase in the Prolaris score, the patient's mortality risk doubles.

How to get the test done: The physician completes the requisition form, sends in for the pathology report to Myriad, and the prostate sample is sent in by the pathology lab where biopsy prostate tissue is stored.

#### **Post-Prostatectomy Phase**

Lastly, after the prostate is removed due to cancer, it is good to know the probability of the patient's risk of the cancer returning or risk of metastasis. *Decipher®* is a genetic test by GenomeDx Biosciences (Vancouver, BC, Canada) and Mayo Clinic (Rochester, Minnesota, USA). Decipher (www.deciphertest. com) can only be used after the prostate is removed, not when any other treatment (i.e. radiation alone) is performed. Decipher® generates a score between 0-1 in increments of 0.1.

The Decipher® test was examined in a study of 545 prostate specimens of men treated with surgery at the Mayo Clinic. In this study, the results of the

Decipher® GC were able to predict onset of metastasis better than other currently available tools using pathology findings, stage, grade, or PSA.

A meta-analysis of five different studies examined the performance of Decipher to prognosticate the risk of metastases in 855 men with adverse pathology at the time of radical prostatectomy (RP).<sup>11</sup> Decipher emerged as an independent predictor of metastasis.

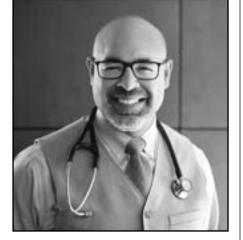
How to order the Decipher test? The physician completes the requisition form, sends in for the pathology report to the lab, and the prostate sample is sent in from where the prostate was removed.

Finally, men after prostate cancer diagnosis are typically more motivated to follow comprehensive naturopathic protocols when faced with a potentially deadly disease, in my opinion. While this article is primarily a discussion about the genetic landscape of prostate cancer and not a detail prescription on aggressive lifestyle and natural interventions, the four pillars of thriving after prostate cancer include food, exercise, sleep, and targeted dietary supplements. Being perfect in all four can be a challenge for most. Getting a handle on genetic predisposition for potentially dying from prostate cancer can help patients choose the best treatment options, along with staying the course with prescribed natural and lifestyle methods.

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# Pancreatic Glandular Therapies: From Absorption to Cellular Interactions in Cancer

# by Carrie Decker, ND

We can all surmise to some extent the mechanisms by which oral intake of pancreatic glandular substances may impact digestion. As an organ that produces many digestive enzymes their proenzyme (zymogen) precursors, it stands to reason that a minimally processed preparation of pancreatic tissue would also contain these substances and thereby positively impact digestion. Beyond this, however, there are many valid questions about how these substances can have activity in other remote regions of the body. The potential degradation by harsh gastric juices, absorption in the digestive tract, stability in the bloodstream, and mechanisms via which they interact with the cells in different tissues each are important issues to consider. In this piece, we look at these questions in full and present substantial research that supports the positive clinical outcomes many physicians have had in their work with pancreatic glandular substances.

#### **Survival in the Gastric Environment**

The potential for modification of a substance in the gastric environment is great and is a question not only for supplements but also food, drugs, and even toxic substances. A broad range of acidity exists in the upper portion of the digestive tract, as the pH can fluctuate from 1.5 to nearly 7 (in the case of achlorhydria) in the stomach and 2 to 6 in the duodenum. Further modification of substances can occur

not only via the digestive secretions of the pancreas and gallbladder, but also by the diverse array of microbes that make up the microbiome.<sup>2</sup> Additionally, the detoxifying ability of the gut lining is significant, with many of the cytochrome p450 enzymes and other detoxification-related proteins being found at very high levels in the intestinal epithelium.<sup>3</sup>

Numerous scientists have investigated the impact environment has on pancreatic enzyme activity in attempts to better understand how these substances can be employed for both medicinal and industrial purposes. A series of experiments by Legg and Spencer in 1975<sup>4</sup> looked at the influence of pH and temperature on the stability of human-sourced pancreatic amylase, trypsin, and lipase in duodenal fluid. In the set of variable temperature experiments, it was shown that amylase activity at room temperature was 65% of its initial values after four weeks and trypsin activity was 20% at four weeks; however, very little activity of lipase remained at both room temperature and 4°C after just four days. In the series of variable pH experiments (with a citrate buffer as the pH altering agent), it was shown that trypsin retained a high level of activity at a pH of 5 to 8 (roughly equal to the initial values or higher), lipase had a similarly high level of activity from a pH of 6 to 8, and amylase had this high activity at a pH of 7 or 8. At the lower pH of 4, both trypsin

and lipase had approximately 50% of their initial activity while amylase was no longer active. It was noted that in the pH experiments, time was not a factor, with the majority of the change occurring immediately and the activity being stable after that.

Although not all of these results suggest that a high level of enzyme activity will remain after being subject to the acidic environment of the stomach, further research in this realm does. Experiments have demonstrated both trypsin and  $\alpha$ -chymotrypsin experience *reversible* denaturation at an acidic pH ranging from 1.0 to 3.0 and 2.0 to 2.5 respectively.<sup>5,6</sup> Reversible conformational changes of porcine pancreatic elastase over a pH range from 2.6 to 4.15 have also been shown, suggesting similar patterns of this enzyme activity when the pH is altered.<sup>7</sup>

The work of Moskvichyov BV et al<sup>8</sup> suggests that the reversible denaturation of trypsin has a complex temperature dependency. Although activity is lost with an increasing equilibrium temperature to a certain point, it is regained when temperature is further increased. Other studies specifically using porcine-sourced amylase suggest residual activity of 25% or greater remains at a pH of 4 with optimal function at a pH of 6.9 and temperature of 53° C. It has been reported that proteins like albumin and mucin, as well as calcium, increase amylase activity, protecting it from environments that otherwise would inactivate it. 9,10

# Absorption Through the Intestinal Mucosa

The intestinal epithelium has been shown to absorb various proteins, including digestive enzymes and their zymogens. 11,12 Experimentally, chymotrypsinogen, trypsin, and amylase have each been shown to be transported through the intestinal epithelium. 13,14,15 Much like the enterohepatic circulation of biliary acids in the digestive tract, it has been proposed that to some extent, enteropancreatic recycling of digestive enzymes also may exist. 16,17

Just as free amino acids at the apical surface of enterocytes are absorbed by specific transporters, di- and tripeptides also have a specific apical transporter.18 In addition to this, passive diffusion, paracellular transport, and endocytosis of peptides, the later which also allows for the transport of large proteins, are other processes via which peptides may be absorbed into the enterocyte. Although many of these apically absorbed proteins are degraded by cytosolic peptidases in the cell, a low level of efflux of peptides across the basolateral membrane into the hepatic portal vein has been shown.19

In addition to absorption by these processes in a normal, healthy organism, increased intestinal permeability may be an avenue via which absorption of large proteins like enzymes occurs. Hyperenzymemia without symptoms of pancreatitis has been shown to be more common in inflammatory bowel disease,20 а condition associated with increased intestinal permeability. Elevated serum levels of enzymes without symptomatology, a condition known as benign pancreatic hyperenzymemia or Gullo's syndrome,<sup>21</sup> also exists and has an unknown etiology. Positive findings from clinical studies using oral proteolytic enzymes therapies for the purpose of managing inflammation-associated pathology also support that these enzymes pass through the digestive tract and exert their effects in circulation.<sup>22,23</sup>

#### Fate in Circulation

Pancreatic proteins (proenzymes and active enzymes) in circulation have a variety of fates: some are taken up in the tissues (such as the kidney, liver, spleen, pancreas, and lung), 15,24,25,26 some are excreted intact into the urine (which increases in the setting of albuminuria),27 and a small amount are excreted intact in the bile or pancreatic juice. Complexing of the enzymes or proenzymes with other proteins that act as enzyme inhibitors may be one means by which they remain in circulation, while complexing with albumin or calcium also may have a stabilizing effect.<sup>9,10,28,29</sup> In the bloodstream, trypsin interacts with serine protease inhibitors (serpins) and other trypsin inhibitors such as alpha-1-antitrypsin. Research suggests that catalytic activity remains when trypsin is complexed with alpha-1-antitrypsin as well as when the complex dissociates.30 Clearance of these enzymes from circulation ranges from fast (with amylase having a halflife of roughly 90 minutes outside of pancreatitis) to relatively slow, with some having a half-life of roughly seven to 18 hours. 26,31

# Cellular Interactions of Proenzymes and Proteolytic Enzymes

Investigations into the effect of pancreatic glandular substances on malignancies goes back to the late 1800s and the work of John Beard, PhD, an embryologist, who had observed that developmentally, the trophoblast is much like a cancer. Its cells, sheltered from immune attack, invade and implant

into the uterine lining, producing their own blood supply much like a malignancy does in tissues surrounding it. He discovered that at the same point the poorly differentiated tissue invading the uterus became the mature placenta, production of pancreatic enzymes begins to occur (confirmed by modern research).32,33 He wondered what caused these cells to essentially "behave"; and upon discovering the embryo production of the enzyme trypsin, he tested his theory by injecting trypsin (diluted in distilled water) into tumor-burdened mice and found their tumors regressed – results which were published in the British Medical Journal in 1906.34 Numerous physicians aware of his research began treating their human cancer patients under his direction, finding success that they also detailed in case study publications.<sup>35,36</sup>

Interest in this use of pancreatic enzymes has waxed and waned with time, with many doctors, such as the late Nicholas Gonzalez, MD, electing instead to use high oral doses of freezedried (lyophilized) pancreatic glandular substances prepared in a manner so the fatty content remained.<sup>37,38</sup> Fat, it was suspected, contributed to a more stable product while in a water-containing environment the enzymes were prone to autodigestion. By using these whole freeze-dried glandular materials, in addition to the active enzyme fraction, the proenzymes and cofactors normally present in the tissue also remained.

In recent years, researchers have looked at the interactions that the



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compounds found in pancreatic glandular substances may have with receptors on the surface of cancer cells and trophoblasts. Protease activated receptors (PARs) have been shown to play a role in both tumor cell invasion and placenta growth and development.<sup>39,40</sup> In cancer cells expressing certain PARs, trypsin actually may be prooncogenic,41,42 although other studies have shown it to have anti-metastasis, anti-motility, PAR-desensitizing, and pro-cellular differentiation effects. 43,44

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It also may be that the proenzymes protease inhibitors found in pancreas glandular products are the substances having anti-oncogenic effects.45,46 Proenzymes have been shown to have angiostatic properties and selectively activate on cancer cells, enabling them to directly deliver their proteolytic action to the tumor cells.47 A combination of proenzymes with their active enzyme form (as found in a crude pancreatic extract) was shown to have a far more dramatic effect on survival than trypsinogen or amylase alone in a murine model of melanoma metastasis. In findings published as recently as 2017, proenzyme preparations have been shown to inhibit angiogenesis, tumor growth, and cancer cell migration and invasiveness as well as promote cell adhesion and differentiation in vitro. and to be well tolerated and effective clinically.48,49

Clearly, many questions remain unanswered as to the biological potential of pancreatic glandular preparations. That said, due to their high level of tolerability and the low incidence of adverse reactions, they continue to be used in difficult-to-treat conditions such as cancer.

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Dr. Carrie Decker graduated with honors from the National College of Natural Medicine (now the National University of Natural Medicine) in Portland, Oregon. Prior to becoming a naturopathic physician, Dr. Decker was an engineer and obtained graduate degrees in biomedical and mechanical engineering from the University of Wisconsin-Madison and University of Illinois at Urbana-Champaign respectively. Dr. Decker continues to enjoy academic research and writing and uses these skills to support integrative medicine education as a writer and contributor to various resources. Dr. Decker supports Allergy Research Group as a member of their education and product development team.

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# Magic, Hope, and Cancer: Why Was This Morning So Magical?

# by Gabrielle Duebendorfer, ND

It started with a crispy cold but brilliantly sunny morning. Something stirred deep within me. Somehow, I saw beauty everywhere as I was sitting in my meditation corner: the sparkles shining on the dripping icicle; the warm sunlight illuminating the wooden walls; the silence in the house; all the familiar objects stirring old memories of connections. Somehow all these objects filled with tender memories created a safe holding container within, which I simply relished.

So, what made this day different from any other? The objects in the house, the trees surrounding my house have stood watch for a long time; my skiing excursion routine had not changed. And yet the whole forest was lit with magic as I worked myself up the mountain, towards frost-tinged treetops higher up. I stood there for a while just listening to the wind gently rustling the treetops, soaking up the warmth of the sun, relishing the song of some chickadees and the lazy hum of an airplane. The sun painted the bark of the big pines in such warm browns that I literally smelled the vanilla/cinnamon flavor they exude when you stick your nose right into the bark.

It was Spring that was stirring deep within me as it was in nature around me a sense of joy and hope for summer to come, of hikes to take, and warm lakes to swim in. This did not distract me from being present in the still wintery landscape. To the contrary, it made me even more open and receptive to all the beauty surrounding me. It filled me with the plain joy of being alive to witness the change of seasons; the trust that regardless of the circumstance I can tap into the even deeper sense of wonder and mystery that is always present - in fact, that it will call to me from the beyond as long as I listen and am available.

And herein lies the key for hope. Sometimes that calling from the beyond is stronger than others and to be treasured. Other times it is subtler and requires a present centeredness to be heard. Consider for a moment the times when you have felt intense joy, or maybe more gentle contentment, or just basic okay-ness. What is the common denominator to these situations? In all likelihood it is a sense of fully being present, open and connected to the environment inside and around you – a sense of intimacy.

Gabrielle Duebendorfer has practiced for 25 years as a naturopathic physician with a focus on weaving meditation-based inquiry into managing chronic disease naturopathically. While supporting the body with herbs, nutritional supplements, hormonal balancing and bio-therapeutic drainage, she assists patients to recognize and untangle obstacles that tend to surface while facing chronic illness, develop inner resources, and discover meaning and purpose. As a certified iRest instructor, she teaches patients mindfulness tools to better meet and manage these challenges. Her other passion is to advocate for climate change action so that her grandkids and patients will have a future in a healthy environment. She lives with her husband in northern Idaho, where she enjoys the outdoors.

This might just be another definition of hope. Not the kind of hope that anticipates a future good; not the kind of hope that, like my teacher Frank Ostaseski describes, consists of wishful thinking, a childlike belief for some external delivery of some desired result. This latter false hope is the flip side of fear disguised as an expectation fixed on an outcome. It rejects the here and now and causes great pain and suffering when the outcome is not achieved: hope destroyed.

I see this kind of hope a lot in my patients with chronic disease, especially those with advanced cancer that is in remission. There is currently a movement that fosters great hope that you will stay or go into permanent remission as long as you do the right things. While this can lead to very valuable lifestyle changes in diet, exercise, stress management, attitude, mental/emotional inquiry etc, it tends to be quite crushing when the cancer does return. This kind of hope can give a false hope of being in control of our life and keeps people from preparing for death when it comes.

One of my patients, a pharmacist, was so convinced of being in control that she researched seemingly every single supplement and herb on the planet that could be helpful. I actually learned a lot of new facts from her. However, it was extremely difficult to convey that doing everything right doesn't guarantee survival. We rarely found even a little moment to just be present as there always was a new item to discuss and consider. When the cancer returned,

she did not choose to continue care. Often, shame for having failed prevents patients from continuing relationships that were focused on healing, regardless of outcome.

On the other hand, one young woman was very empowered by this kind of hopeful hope. The first cancer recurrence was crushing, but she went right back on track, focusing on living and resolutely refusing to look at the potential of death. Her quality of life was excellent, having cleaned up her diet as well as long-time stressors and having reoriented to nourishing inputs. She was a great inspiration to many people to the very end. However, when the final stage arrived, she and her family were utterly unprepared for death. Perhaps we shouldn't call this "false" hope, even if the orientation was to a particular outcome, i.e. remission! It allowed her to focus on life amidst a lot of suffering and upheaval until just a few weeks before her death.

Let's consider the other kind of hope, however. Frank Ostaseski says, it is a quality, a capacity of Being rather than a strategy towards a particular outcome, where we have a deep trust that we can meet every moment, to surrender to every challenge as it comes. This capacity arises out of being in continuous contact with what is — right now. This definition of hope relies more on an intimate, open quality of Being that refuses to quit. A kind of hope that is more a dynamic living process, interdependent with all of life, that leads to great resourcefulness and joy.

I think it was this that called to me this morning: the intimacy that arises out of being really present. This is much easier when we are in a situation that provokes it, such as the stirring of Spring in the air, an accident, a loss of a loved one, falling in love. But really it doesn't have to be the extraordinary; it can be simply the mundane of daily life. In one of my iRest meditation classes, a student surprised me - and I think herself. She explained that the practice of body-sensing and simply Being with things as they are, allowed her to surrender to and actually feel strong rage and resulting sadness instead of constantly strategizing to get rid of it. She was delighted to discover that these emotions went and came like a wave if she stayed with them, eventually resolving into a state of ease. Rage and sadness didn't disappear, but she didn't identify with it anymore; and therefore, it began to control her less. The hope here is the realization that one can meet whatever arises in the moment. And with that comes a sense of intimacy, joy,

buoyancy, of real hope. I close with the ending of Rumi's poem "Buoyancy":

Why should we grieve that we have been sleeping?

 It does not matter how long we have been unconscious.

We are groggy, but let the guilt go.

– Feel the motions of tenderness around you.

The buoyancy.



# Moldy Buildings, CIRS, Sick People, and Damaged Brains: 25 Years of Research Brought Us to the Cure Word, Part 2

# by Ritchie C. Shoemaker, MD

Medical Director, Center for Research on Biotoxin Associated Illnesses

#### **David Lark**

Mycologist, MouldLabs, Australia

# James C. Ryan, PhD

Chief Science Officer, ProgeneDx

Editor's Note: Exposure to mold in water-damaged buildings causes a frustrating number of puzzling symptoms and eventually leads to chronic inflammatory response syndrome (CIRS), as explained in the first article of this five-part series, published in the July 2019 issue. In Part 2, the authors explain the importance of maintaining the building envelope in order to prevent health-damaging mold from infesting buildings. This is the first step in prevention...and in healing.

#### **How Does Water Get Inside?**

ROOFS: Have you ever put on a new roof or watched someone else do the work? How many thousand nails are required to shingle a 3000 square foot roof (4 nails/shingle in low wind areas; 320 nails per 100 square feet)? If one in a hundred nail heads are exposed, that means 10 exposed/300 square feet. Not much room for error! Remember, it takes fewer than 10 exposed nail heads to create a significant risk for a leak.

How long does it take to get out the binoculars and look for exposed nail heads peeking out from under your shingles reflecting light on a sunny day?

How about flat roofs with special membranes? How long is the shelf life of a man-made material used to prevent gravity from finding a way for water to seep in through a pinhole defect in that membrane? Oops, not 30 years.

And look at the "boots" woven under shingles around the ventilation pipes

that take moisture out of bathrooms to exhaust to the outside world? They range in price from \$25 to \$75. The cheap ones might last 10 years until they leak. Newer boots are rated at 50 years (is that with 20 nights of 40 mph winds per year or just 15?) but cost \$75 each. How many builders use the \$25 boots? Take a trip to your attic. Look at the attic side of your boots. Are there any moisture stains? Make sure all vent pipes go through the roof deck too.

Look at your ventilating soffits, inside the attic and out (binoculars time again). Is air flowing as expected through the soffit and out the ridge vent? If you have a chimney, can you see daylight between the edge of the roof and the chimney stack? If you see light, there will be water coming down the outside of the chimney inside your home. Time to flash and counter-flash. Or how about the chimney that is off center in a gable end of a house? Water coming down from the higher pitched areas will be directed against the flashing around the chimney. Time for a mini-roof ("cricket") used to deflect water away from the pocket created by siding touching flashing.

And for cold weather folks, what are those little iron things sticking up and out of the roof near the fascia board? Those snow dogs will help prevent ice dams, but all snow dogs eventually leak. Inspect the dogs and the attic below where ice dams might form.

How about your attic insulation? See anything discolored?

WINDOWS: Windows turn out to be tricky to install. It is not surprising to find moisture from leaking windows in wall cavities below windowsills, especially in new construction. As an aside, new construction ends up being far riskier for hidden construction defects than older construction. The reason might not be obvious. It can take a year or two to recognize construction problems and microbial growth, but water-damaged buildings (WDB) are usually shown to have moisture intrusion over time as one defect or another comes to light.

**DOORS:** Doors leak from above and below when they aren't installed right. Inset fan lights over doors must be caulked yearly. What makes your steel door warp and wood door swell?

GUTTERS: Don't forget to look (or hire someone else to look) at your gutters. Gutters that are high off the ground (second floor and above) require a long ladder to reach; they often are neglected. What a mistake! It doesn't take too many pine needles or decaying leaves to create a mat that will block flow of rainwater or melting snow from entering the downspout. If an overhanging tree is present, the obstruction problem is essentially guaranteed. As the gutter continues to fill, the water goes somewhere. It will usually overflow the front or the back. If there is a slight backward pitch of the gutter, water will impact against the fascia board. If this wide flat board is not tight, there is free entry for water behind the fascia into the attic or inside of the cladding. Once inside the attic, water can then run downhill, sometimes going a very long way along a rafter. When water meets a drop off point, maybe just a bow of the wood or a protruding nail head, gravity will direct the water downwards. I have seen homes with blocked gutters showing their leaks 40 feet away on the other side of the attic from a blocked gutter. It happens.

SIDING (CLADDING): Any siding materials can leak. Brick, stone, wood, vinyl, concrete, block, and stucco are just barriers. Wind-driven water can track uphill under edges of siding, through nail holes and cracks too. Where one expanse of fake stucco meets another, the seals often are open invitations for water intrusion. If porous oriented strand board (OSB, I call it oriented sponge board) has been used to protect the stud walls underneath the cladding on the inside of the house, the water coming from the leaks of the seals is an invitation to microbial growth that no one will suspect, as OSB is the nurturing sponge of life for microbes. Mold and bacteria, especially, will grow through the fourfoot-by-eight-foot wood particle-chipglue sheet rapidly, leading to microbial growth on both sides of the OSB. As the OSB continues to stay wet and fungi digest cellulose in the OSB, it doesn't take too long before additional water is dumped into a wall cavity creating the potential for massive problems. As particulates from microbial growth become airborne, even in wall cavities, they can find their way into the inner sanctum, traveling on air flowing around switch plates, receptacles, defective drywall joints, or even nails used to hang pictures. Actinomycetes get through to interior walls more often than fungi, but bacteria are the swiftest to penetrate.

The same problem of moisture penetration applies when people have masonry exterior walls as there is a space (void) behind bricks or stone in which air circulates. Bricks and stone are both porous, which means that moisture that hits the outside of the brick can migrate through to the inner side. At the inner surface it will then drain downward under the influence of gravity. At the bottom on the exterior wall, there should

be an opening, called a "weep hole" that will let water leave the inner space and not create microbial disasters between the brick and plywood or OSB.

Vinyl siding goes up quickly, is inexpensive, and comes in many colors. It is no surprise that we have so many vinyl-sided homes in the US. While the vinyl itself is impervious to inflow of outside water, the junctions between pieces of vinyl or areas where the vinyl has been nailed create potential portals for water intrusion. Wind makes gaps in vinyl walls!

The nice green material growing on the outside of exterior walls is not mold but instead is **algae**. The algal growth can be so profuse such that a mat of algae can form in corners. Under the mat there can be an air space between overlapping pieces of siding that lets water wick underneath.

A word of caution regarding vinyl siding. Attempts to clean siding can create their own sets of problems. Power washing will remove algae (not so quickly!) but use of bleach solutions to clean siding can damage plant life below making it a high price to pay to clean up algae. In siding as in all things, sometimes when we use chemicals that kill living things, we sacrifice the overall good for temporary improvement!

Leaving the outside of the house, the building envelope, we then head downstairs into the basement or the crawlspace. Here is the source of microbial growth that is found in 95% of homes that have these subterranean structures. Having a walkout basement is no guarantee of safety in that the inground side of a walkout basement is subject to additional water pressure that can create a wet wall. Water pressure will overcome any temporary barrier created by tar solutions or fancy paints designed to be waterproof. Don't believe the manufacturers' claims!

Many people with a walkout basement will dig trenches on the inground side approximately 3-4 feet deep, installing perforated pipe covered by pebbles to create a "French drain." At each end of the building, pipes are connected to side pipes, making a right angle at the corners of the home that direct ground water away from the in-

ground wall to the side of the home. The pipes extend beyond the downhill side of the house. When patients have done this kind of preventive maintenance work, they are surprised about how much water comes out of the drainpipes. It is an ideal source for making a year-round freshwater pond as part of the garden (and not an aquarium 30' by 40' in the basement).

To take care of moisture problems created by subterranean structures, some people will install sump pumps using a chiseled notch or trench cut into the concrete slab of the floor that leads to the sump pump and then the pump will move the water somewhere, hopefully outside of the basement. This approach sounds pretty good except when we recognize that the water that has just come in and is in a trench creates a microclimate of elevated A (w) that is perfect for bacterial growth. Sump pumps themselves are almost guaranteed to be sources of bacterial colonization and endotoxin. A better solution is not to have a basement!

In our coastal area of Maryland, basements are uncommon, but crawl spaces are common. Usually threeto-four cinder blocks high, crawls are the standard approach to lower cost on new home construction. A finished crawl space will often have several vents installed every 8-12 feet, as if making a portal of entry for hot humified air in summertime into the cool climate of a crawl space was a good idea. When the hot moist air hits the cool air over the exposed soil in the crawl (usually about 54 degrees), it doesn't quite rain under the house but close to it. The excessive moisture that comes from Mother Earth herself provides a continuous source of moisture to nourish micro-organisms growing in soil. Don't be confused by the dry appearance of the soil in a crawl space: it just means that soil water has evaporated over time. More is on the way from deeper soils for sure.

A simple approach to crawl spaces is to condition or seal off the crawl space such that the air in the crawl is never exposed to moisture from soil or moisture from the side walls. By putting 20-28-gauge plastic (pond

### **Moldy Buildings**

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liners are better than swimming pool liners; swimming pool liners are better than thick plastic) and then folding the edges of the liner upwards so that the liner can be attached to the board (sill plate) sitting on top of the foundation, we can create a water intrusion barrier that works. Meanwhile, any water coming from Mother Earth runs into the underside of the piece of plastic and stays with Mother Earth. There is no excessive moisture on the floor side of the liner available to nourish microbes that might be living opportunistically in the crawl space. The vents are sealed shut.

This conditioning idea sounds radical, understanding that many people feel that all crawl spaces should have vents (compare that to the newer approaches where no crawl spaces have vents); their moisture problem continues. Conditioning is defeated when someone hooks up a HVAC vent or a duct that will pump warm or cool air into the crawlspace. Now we are creating the opportunity to share indoor moisture with a sealed crawl space system,

thereby defeating the purpose of making a moisture-tight sealed air chamber.

As always, if there is a basement or a crawl space, it makes sense to seal (using expandable foam) any holes that are made in the subfloor to permit passage of pipes, electrical wires, central vacs and the like. It is amazing how much air can come through 3/8" circle around each pipe penetration through the subfloor! Such spray foams will release VOCs, so seal well before occupying the building.

INTERNAL SOURCES of moisture are often overlooked. Outside humidity, transferred to the inside when an outside door is opened is a definite problem in tropical areas. Two choices exist to prevent exposure. The first involves matching tonnage of HVAC (heating, ventilation, air conditioning) equipment to size of a building that will permit drying out of indoor air. The second approach is to increase ventilation (windows wide open, for starters). In the US, buildings often use HVAC to safeguard homes from tropical fungi (especially *A. penicillioides*).

**COOKING** creates the biggest source of moisture in the first floor of most homes, with bathrooms creating the

source of moisture most commonly in the second floor. This is assuming of course that there are no sliding glass doors that leak, no sky lights that leak, no elaborate roof structures with valleys and pitches that are impossible to close off and no flat roofs that will leak regardless of what is done.

**HUMAN SOURCES** of moisture (think of breathing!) also contribute to the availability of water inside the home. Leaking shower pipes are notorious for having small pin hole leaks just above the sweat joint where a copper supply tube meets a plastic or PVC junction. These pin hole leaks rarely are visible in the bathroom side of a wall cavity but if there is a closet that abuts the back of the wall cavity, that is where you will see moisture and mold growth. If the closet is closed most of the time, expect to find A. penicillioides, an organism that does its damage by the company it keeps as opposed to being a horrible toxin former. A. penicillioides does not like to be ventilated. You will find it in vanities, behind refrigerators, at the end of hallways that are not ventilated or in closets. When you see shoes in a closet growing mold, be thinking about reduced ventilation. A. penicillioides is also found on carpets, soft furnishings, and drapes.

**DECKS**: Adding decks makes for enjoyable living, but if the deck ribbon board is screwed into the foundation board of the home, make sure that there is adequate flashing to protect the home from water coming from the deck itself through the deck understructure.

**STILTS**: A special circumstance applies to coastal living. There is a financial benefit to building homes on elevated pilings, usually 8-10 feet off the sand, in order to avoid flood damage. For some people, this 10-foot high space the size of the footprint of the building, is too tempting. Just look at this ground floor bonus room! Up go the walls and up go the fungal counts coming from the damp coastal soil. What we now have is an outdoor fungal growth chamber sitting outside of the entry door so that every time you go in or out there becomes a vortex of sick air entering the living space. Not a good idea; don't make extra storage space or living space and sacrifice your health. Ventilate it!

**TOWNSEND LETTER - AUGUST/SEPTEMBER 2019** 



Ritchie C. Shoemaker, MD, remains active in the field of biotoxin-associated illnesses, the focus of his practice since 1997. At that time, an outbreak of unexplained human illness, associated with exposure to blooms of a dinoflagellate. Pfiesteria piscicida, attracted his attention and interest. Pfiesteria was the first example of an acute and then chronic biotoxin-associated illness recognized and published in peer-reviewed literature. Shoemaker's two papers on diagnosis and then treatment were the first in the world's literature on acquisition of illness from Pfiesteria in the wild. Since that time, other sources of biotoxin-associated illnesses have come forward including other dinoflagellates, cyanobacteria and, most importantly, organisms resident in water-damaged buildings.

Shoemaker has spent the last 22 years treating patients and conducting research that unveils the

extraordinary complexity of these illnesses, now called chronic inflammatory response syndromes (CIRS). Starting with no biomarkers and now progressing to over 25, CIRS has been shown to have abnormalities in proteomics and transcriptomics with differential gene activation, the final ultimate pathway of disease production in the world of chronic fatigue.

His collaboration with Dr. James C Ryan, transcriptomist, has led to multiple publications that have application, not just to chronic fatiguing illnesses but to the inflammatory illnesses of the 21st century including atherosclerosis, diabetes, obesity, and autoimmune illness.

As Shoemaker's work has progressed on the complex problems of grey matter nuclear atrophy, a small but growing cohort of patients with multinuclear atrophy and cognitive impairment have led to improvements that may have application to illnesses such as Alzheimer's disease.



# In Memoriam: Hans Kugler, BS, PhD

**December 11, 1935 – May 5, 2019** 

by Scott C. Tips

Originally Published in Health Freedom News
(The National Health Federation)

The artillery thundered ever closer as the Red Army advanced into eastern Germany. Young Hans, not even a teenager then, learned to shelter himself in a doorway as Russian fighter planes strafed the nearby ground. It was the kind of childhood that caused a young boy to grow up quickly into manhood.

#### Two Dogs and a Principled Stand

But it had not always been like that — at least not until 1943, when Hans' father, a wealthy, conservative German landowner, had commanded his two very-protective German shepard dogs to attack and chase off his property a feckless Nazi Party leader who had come to the family home demanding land. Unfortunately for the Nazi, the two canines were faster runners and managed to take some chunks of flesh out of his fat limbs before he could escape. Two weeks later Hans' father received his draft notice, with orders to report to the Russian Front.

Although the family was left fatherless during this critical time, Hans' father returned home safely after having served as a medical assistant. But, in the meantime, the Red Army had overrun eastern Germany and occupied the region where Hans and his family lived. And after the fall of Berlin, the Soviets quickly set up the local German communists as the new totalitarian proxy rulers.

To instill obedience to the new order, the Soviets created a political-indoctrination process of weekly communist-party meetings; and Hans' father was ordered to attend. Having more important things to do, he did not go. Finally, under much pressure, Hans' father went to one of these meetings where he then proceeded to verbally lambast the local party leader for being a no-good, lying opportunist. Being somewhat thin-skinned, the communists took offense and threw the father in jail for six weeks. From then on, he plotted his and his family's escape to the West.

#### **Escape to the West**

In 1945, with Germany a shambles and confusion still rampant everywhere, it was not yet terribly difficult to escape from the East to the West. At the wall-less border, the new East German border guards made a pretense of firing over the family's heads as they pointed them in the right direction with a friendly wave. It was in this way that Hans and his family crossed the border into West Germany, pausing briefly in Bavaria before continuing on to Stuttgart where they settled. At ten years of age, then, Hans began his new life in Stuttgart.

After finishing school there, Hans joined the West German Air Force. From 1958 to 1960, he advanced up the ranks to jet training. But instead of ordering him into a fighter-jet squadron, the air force recognized his abilities as a teacher and made him a platoon leader

and instructor for three crews in the West German Air Force Academy. Then, it was back to school in Munich with Hans alternating between military reserve training and more education. During those days Hans operated an air force flight simulator outside of Munich.

Fellow NHF Board member Dr. Murray (Buz) Susser, himself a former fighter pilot but with the US Air Force remarked, "It's strange to think that my good friend Hans and I, had we been born just a short time sooner might have been mortal enemies chasing each other across the skies in dog fights and shooting at each other. Instead, we have been close friends."

#### **And Then Even Farther West**

By 1964, Hans had been awarded his bachelor of science degree by the University of Munich School of Medicine, where he had majored in physiology under the noted Nobel Laureate Doctor A. Butenandt. Deciding, though, that the United States might be the best place for him to continue his post-graduate studies, Hans applied for admission into the chemistry program of the State University of New York at Stony Brook. Parenthetically, Stony Brook is now recognized as one of the top universities in the world for medicine and sciences.

Not letting its reputation overawe him, however, Hans zipped through the program there, obtaining his PhD (in organo-phosphorus chemistry) in the shortest time of anyone in New York. The end of the 1960s and the start of the 1970s saw Hans at Stony Brook doing post-doctoral work and teaching chemistry as an assistant professor.

This and other research were the basis for Hans' first book on antiaging — *Slowing Down the Aging Process* — published in 1971, which was a groundbreaker in the field of anti-aging. I myself bought the book at the time and still have the copy today.

Leaving New York for Indiana in 1971, Hans worked for two years in the research department of the Standard Oil Company of Indiana in the field of environmental chemistry. Of particular interest to Hans were the effects of pesticides on chemistry, food, and human metabolism. He also researched the sound-stimulated rate of growth of agricultural plants.

#### **Academia Calls**

As interesting as the research was, though, Hans was drawn back to academia. Hans began teaching chemistry again, this time to premed students as well as teaching quantum chemistry to graduate students at Roosevelt University in Chicago in 1972; and he continued doing that for two years. While teaching at the university, Hans did his first studies on anti-aging and cancer. His research there led him to postulate and present at medical meetings his "Combination"

## Hans Kugler, BS, PhD

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Theory of Aging." At the same time, Hans developed the groundwork for a "multi-factorial approach" to human and animal longevity, cancer, heart disease, brain functions, and chronic mental diseases, emphasizing immune and free-radical pathology.

Hans also associated himself with the famous Professor Dr. Robert Mendelsohn of the Illinois University School of Medicine. Together, they researched the combined effects of environmental and nutritional factors on overall health (such as immunity and base metabolism).

Later, when Hans moved to California, he continued teaching chemistry, this time at El Camino College. Academia and teaching seemed to be in his blood, as did writing.

In fact, Hans also authored Seven Keys to a Longer Life (Stein & Day, 1978), Tripping the Clock, A Practical Guide to Anti-Aging and Rejuvenation (Health Quest, 1983), and some 200 articles in such various publications as Let's Live, Prevention, and Health Freedom News. As if that were not enough to keep him occupied, until the time of his death, he was also the editor of Preventive Medicine Update and the senior science adviser to the Journal of Longevity.

#### The Apple Doesn't Fall Far from the Tree

Like his father, Hans was never shy about taking a stand and speaking his mind. All who knew him will definitely agree with this point. A frequent speaker at general health and medical meetings, Hans was known for stating his views clearly and firmly, whether those views were on science, medicine, or politics. And he didn't care who became angry because of those sincerely held views.

Hans also made appearances on radio and television programs, with easily more than 500 such appearances under his belt. The programs included AM New York, AM Canada, KPIX San Francisco, and many others. Reflecting his Renaissance-man personality, the topics covered by Hans on these programs had a wide ambit — primarily nutrition, anti-aging, drug prevention, politics, and climate change.

Translating his views and knowledge into action, Hans even ran for political office. Although unsuccessful, he made a strong showing that attracted attention.

This urge to act also meant being actively involved on the board of directors and in other leadership roles of organizations such as the National Health Federation and the International Academy of Anti-Aging Medicine. In fact, Hans was a past president of NHF and, at the time of his death, on our Board of Governors for 28 straight years, having joined the board in January 1991. As a result of his efforts, he received some eleven awards from various medical and health organizations.

Still, while engaged in all of these various activities, Hans always made time for his special personal loves – flying aircraft and riding horses. Observing that the two activities often go together, Hans remarked several times that "it is interesting that the highest percentage of jet jockeys also own and ride horses." The Empty Saddle Club in Palos Verdes, California, which was originally founded as an old cowboy club and of which Hans was a long-time member, saw Hans participating in its cowboy events where he quickly became known as the "German Cowboy." As for his flying, I flew with Hans in his twin-engine plane not too long ago out of Torrance, California airport, and he was a natural-born flyer. A pilot myself, I also flew Hans' plane but was not a match at all for his skill level.

#### Most Recent Studies and Work

Stem cells were Hans' most recent fascination. For the last many years, he had been focusing his research activities on applying stem cells to improve health and extend life. According to Hans, stem cells could give the body a boost similar to what Dr. Paul Niehans' injected-cell therapy achieves. In fact, Niehans' therapy has helped Down's syndrome individuals tremendously and many other previously untreatable conditions.

Hans was very quick to point out, though, that he was not working on stem cells derived in any way from fetuses and that it is a bunch of nonsense that they must come from this source. Rather, the research that Hans pursued was based upon modifying our own skin cells (because at present, to be useable, stem cells must come from our own DNA), inserting the cells into a donated female egg cell that has had its own DNA removed, and then growing the culture in a Petri dish.

An avid bodybuilder, Hans had survived a serious automobile accident that would have killed a less-fit person. For a while, he was told by doctors and others that because of the accident and his reduced heart function, he would just have to adjust to a slower pace and a lower quality of life. But they hadn't known the young Hans who had grown up dodging bullets. Here was just another bullet to dodge, and he did, at least for many years. As Hans himself put it after engineering his own recovery with stem cells and sheer grit, "With a car accident and reduced heart function, everyone told me that I could not do anything about it – but, now, here I am completely back to normal, thanks to stem cells!" But the accident still had left Hans with a weakened heart, and this eventually caught up with him.

Still, others such as NHF Executive Director Katherine Carroll, were impressed with his physical appearance and strength. As she put it, "It always impressed me that in his 80s, Hans was committed to retaining his vigor and musculature. I met him once in a tank-tee shirt and he looked amazing for his age — or any age for that matter. It impressed me that when he encountered robbers in his garage, he kick-boxed them into submission and literally beat them up."

Whenever I would meet Hans for lunch at his favorite watering hole – The Good Stuff Restaurant – in Redondo Beach, California, he always impressed me the same way, someone having great strength undiminished really by age. But, as we all knew, Hans was not just brawn, he was brains as well; and you could see it in the many, diverse topics he expounded on, from chemtrails and climate change to politics to the latest advances in medical science. He was current on all and not ever shy about letting you know his opinion on them.

#### His Death

Unfortunately, though, on a Sunday morning, May 5, 2019, while driving with his beloved and always present companion dog, Miss Boogle, down a city street, Hans' weakened heart finally gave way; and without it working properly, he lost consciousness. His truck smashed into a power pole, and he was taken from the wrecked vehicle to a local hospital where he died. His dog was saved, but Hans was lost to all of us.

Hans Kugler was more than just a great, kind, and smart man, he was my friend for almost 30 years. At the time of his death, Hans was chairman of the board of the world's oldest health-freedom organization — the National Health Federation — and we should all remember that Hans was personally responsible on at least three separate occasions of having played a key role in saving the NHF from takeover by dissident board members and outsiders. NHF owes Hans a huge debt. Having served on the NHF Board for almost three decades, Hans was virtually a one-man "NHF institution."

I miss Hans and his wisdom terribly. He instilled so much of that wisdom in those who had the privilege to be part of his inner circle. I was lucky to have had him as a close friend. We all were.

# **Intermittent Fasting and Cancer**

# by Mauris Emeka

In the early part of the last century, before the use of pharmaceutical drugs, fasting played a vital role in healing. Within the last five years something called intermittent fasting has been increasingly observed as a way to prevent and help overcome cancer. Studies show that fasting is good for cleansing and recharging the body, reducing harmful free radicals, and strengthening the all-important immune system. In effect, the body's own healing power gets a boost. How, then, does intermittent fasting play a role, and why is it helpful against cancer?

First, it needs to be understood that cancer cells generate energy by consuming one and only one nutrient — and that nutrient is called glucose. Without glucose, cancer cells begin starving. In addition, cancer cells consume glucose every minute of each 24-hour day. On the other hand, healthy cells are not limited to glucose for generating energy; and healthy cells do not need to generate energy every minute of a 24-hour day.

Intermittent fasting involves establishing a routine of eating two meals spread over about a six-hour period during the day. A common practice for carrying out this routine is to eat lunch at 12:30 to 1 pm and eat dinner later that day at 5:30 to 6 pm; and then to avoid eating any solid food until the next afternoon at 1 pm. That completes an 18 to 19 hour fast. When this routine is done for several days, and assuming one eats the right foods, then this can greatly challenge the cancer cells because it puts them on the road to starvation.

What are the foods we need to be concerned about? As mentioned earlier, cancer cells generate their energy by consuming glucose, and large amounts of it. The body makes glucose from sugar and simple carbohydrates from refined grains such as white flour and whole wheat flour. Glucose is also made from various refined foods and simple carbohydrates such as white potatoes, white rice, macaroni,

spaghetti, and pasta. Any food that produces glucose and produces it fast is dearly loved by cancer cells. Regrettably, that describes a high percentage of the food eaten in the USA.

As already mentioned, cancer cells need to consume glucose every minute of the day and night. That is not the case for healthy cells because they are not limited to glucose for producing energy. Healthy cells can also produce energy from something called ketones, which comes from eating a ketogenic diet. To follow the ketogenic diet, one must avoid sugar and simple carbohydrates that were just noted. The ketogenic diet includes eating fresh fruits and vegetables (mostly vegetables), moderate amounts of animal proteins, and high amounts of good fats (such as unrefined coconut oil, butter, avocados, nuts). One can include small amounts of legumes such as lentils, black beans, and lima beans. Since these are complex carbohydrates, they are high in fiber; and unlike simple carbohydrates, they are slow to convert to glucose. The ketogenic diet does not include highly processed hydrogenated fats. And the good news is that this diet produces ketones instead of glucose for generating energy. Ketones are known to be much cleaner than glucose, and the human body uses them more efficiently than glucose. In short, ketones can make cancer cells go by the wayside.

Following a ketogenic diet fasting routine for several days a week and drinking lots of good water (i.e., high pH ionized water) helps cleanse and detoxify the body and makes for a stronger immune system. The number of days to fast intermittently to get free of cancer depends on how far a particular cancer condition has advanced. Admittedly, fasting is not an easy thing to do for most of us. But if there are serious concerns about either preventing or overcoming cancer, it can motivate one to consider fasting.

This fasting procedure is completely safe; and, assuming that one has commitment and discipline, it can be easy to implement. Professor Valter Longo of the University of Southern California is quoted as saying "...by undergoing a fasting-mimicking diet, you are able to let the body use sophisticated mechanisms to identify and destroy the bad but not the good cells in a natural way."

Dr. David Jockers, DC, is an accomplished chiropractor who notes that one of the benefits of intermittent fasting is to normalize insulin within the body. He also points out that fasting reduces inflammation and reduces oxidative stress – and that can be a great benefit for anyone challenged with cancer.

Research shows that fasting increases tumor killing T-cells, and it also strips away the covering from cancer cells, which enables the immune system to recognize cancer cells and target them for destruction. Dr. Thomas Seyfried, professor of biology at Boston College, has completed extensive study of cancer cells. He presents proof that cancer cells can be destroyed with five- to 10-day intermittent fasting when consuming the ketogenic diet. And since this diet produces ketones instead of glucose, we can all be eternally grateful! The bottom line: intermittent fasting on its own can be a big help against cancer; and when it's accomplished along with a ketone-rich diet, this proven approach makes the body a place where cancer is NOT welcomed.

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## East-West Medicine: Towards a More Complete Integrative Paradigm

by Richard Kitaeff, MA, NMD, DipAc, LAc

When Rudyard Kipling wrote, "East is East and West is West and ne'er the twain shall meet," he could not have predicted the era of global communications that is simultaneously bringing together disparate cultures and diminishing their distinctive identities. While medicine advances on many fronts, including genomic research and immunological treatment of cancer, one of the frontiers must surely also be cross-cultural. After a century during which traditional Chinese medicine had been on the defensive in its homeland, the People's Republic of China after 1949 determined to preserve serviceable elements of the tradition that were not inconsistent with Western scientific medicine,1 according to Chairman Mao's dictum to "let the past serve the present." In the modern era, acupuncture was introduced to the West through an article on the front page of the New York Times in 1971 by the reporter James Reston, who accompanied Richard Nixon on his historic trip to China, describing the elimination of his post-operative pain after an emergency appendectomy at a Beijing hospital through the anesthesia produced by three acupuncture needles.

Currently, China could be considered to have the world's most completely integrative medical system, Western-style allopathic practitioners routinely working alongside traditionalstyle practitioners in hospitals and clinics, each type of practitioner required to train in the other's style of medicine as well as their own. In the West, naturopathic physicians required to study basic medical sciences and clinical medicine, as well as "nature cure" modalities, have also completed training in traditional Chinese medicine in many cases, and are therefore uniquely positioned to accomplish a three-way, most complete integration of not only allopathic and naturopathic traditions, but also Eastern and Western medicine.

According to an article published in a Korean-language medical journal, the integration of traditional Chinese medicine (TCM) and Western medicine began 400 years ago. In the modern era, the concept of what is now routinely "integration of traditional Chinese and Western medicine" (ITCWM) took root following the establishment of the People's Republic of China, particularly through research leading to the eradication of epidemic diseases such as schistosomiasis. Following a lapse in progress during the period of Cultural Revolution, China established an Institute of ITCWM and departments of ITCWM in hospitals and medical schools, to foster research in clinical practice and book publications.2 Chinese researchers have established diagnostic classifications of PCOS, differentiating anovulation from hyperandrogenism, based on the differentiation of TCM syndromes of kidney yin deficiency with phlegm blockage and blood stasis from kidney deficiency with liver qi stagnation.3 An article in the Journal of Integrative Medicine has brought attention to the parallels between the modern Western approach of "precision medicine" and the personalized style of treatment provided by the TCM model.4 An integrated Western and Chinese medical approach to glucolipid metabolic disease encompasses the Chinese medical concept of liver dysfunction in metabolic and emotional regulation leading to endogenous production of dampness and phlegm.5

Numerous research studies, primarily randomized controlled trials, have compared the effectiveness of the integrated East-West medical model with the effect of Western medicine by itself. When traditional acupuncture combined with conventional rehabilitation therapy and compared with rehabilitation therapy alone for treatment of shoulder hand syndrome after stroke in 20 studies involving 1918 participants, the combined therapy significantly reduced pain on a visual analogue scale, improved limb movement and the performance of activities of daily living with a 95 percent confidence interval for the mean difference.<sup>6</sup> For 60 hospital patients diagnosed with thoracolumbar burst fracture, randomly assigned to "three-step reduction (TSR) therapy of integrated Chinese and Western medicine" or posterior open (PO) surgery, results showed reduction of the fracture, rebuilding the height of the centrum, recovering the biomechanical function of the spine, and reducing bleeding better in the TSR group than the PO group (P< 0.05).7 In treatment of 89 patients with delayed encephalopathy after acute carbon monoxide poisoning, randomly divided groups received either hyperbaric oxygen (HBO) therapy alone or HBO in combination with granules of the Chinese traditional herbal formula, XingZhi-YiNao. The groups were compared on activities of daily living (ADL), cognitive function, and the impairment degree of cerebral white matter. On all measures, efficacy of the combined treatment group was superior to that of the HBO group (P< 0.05).8 A total of 60 patients with diabetic xeropthalmia were randomly assigned to a control group of Western medical treatment alone or an experimental

group of treatment with traditional Chinese and Western medicine. With 95 percent confidence, the combined treatment was effective in reducing inflammatory biomarkers and reducing corneal injuries.<sup>9</sup>

Other research studies have been mainly on ITCWM treatment in cases of cancer and severe acute respiratory (SARS). A retrospective syndrome study was conducted on 67 patients with Stage II-IIIA non-small-cell lung cancer after radical surgery from two Chinese hospitals treated either with conventional chemotherapy alone or traditional Chinese medicine integrated with chemotherapy. With a 95 percent confidence level, the study concluded that addition of TCM therapy reduced the rate of tumor recurrence and metastasis and prolonged median disease-free survival.10

In a study of 54 castration-resistant prostate cancer patients, a randomly selected control group was treated by endocrine therapy (bicalutamide and goserelin), chemotherapy (docetaxel), and prednisone, while oral experimental group received the same treatment with the addition of the Fuyang Huayu traditional Chinese medical herbal prescription for tonifying yang and dispersing blood stasis. Comparing the two groups of patients, Karnofsky, FACT-P and TCM symptoms scores were all significantly improved in the trial group but not in the control group. 11

In animal and histological research on cell lines in vitro and in vivo of pancreatic cancer, an aggressive disease with a particularly poor prognosis, treatment with gemcitabine, a chemotherapy agent, was combined with baicalein, a type of bioflavonoid originally isolated from the roots of the Chinese herbs Scutellaria baicalensis and Scutellaria lateriflora. The results demonstrated that the inhibitory effect of gemcitabine on pancreatic cancer cells and promotion of apoptosis were enhanced by the combined use with baicalein.12 Also, a meta-analysis of 27 articles with randomized trials involving 4,368 patients was conducted on mammary gland hyperplasia, a common breast condition that confers an increased risk of carcinoma. The results showed with a high level of statistical significance that the combined treatment of tamoxifen with the Chinese herbal

formula Ru-Pi-Xiao achieved better therapeutic effects than tamoxifen alone, and furthermore suggested that this combination could improve the level of progesterone and decrease the size of breast lumps to a greater extent, providing a possible pharmacodynamic mechanism for the combination.<sup>13</sup>

Western countries. According to Paul Unschuld, a prominent historian of Chinese medicine, this Western variant of Chinese medicine is "conditioned more by the expectations and demands of a Western population than by the marshalling of scientific evidence." Or, as Nigel Wiseman writes in the Translator's

Findings from the history and physical examination could reveal, from the Eastern perspective, for example, indications of internal heat (yin deficiency or pitta dominance), usually reflecting inflammation or infection. For the same patient, the Western exam might show elevated temperature or blood pressure or pain (localized or general).

In a controlled study of 49 patients with SARS, one group was treated with antibiotic, antiviral and other drugs, while the other was treated with an ITCWM combined protocol. Treatment of the latter group was superior in symptom improvement, terms of shortened therapeutic course, recovery of immune function and absorption of lung inflammation, and decreased dosage of medication required.14 In another study, 48 hospital patients diagnosed with SARS were randomly divided into a corticosteroid treatment group and a combined ITCWM treatment group. The hospitalization time, body temperature stabilization time, and time of corticosteroid use were shorter in the trial group than in the control group (P<0.05).15 These findings were confirmed by another controlled study involving glucocorticoid treatment of SARS in 461 patients compared with the integrated approach. In the ITCWM group, the average time in hospital and duration of pneumonia were shortened, mortality fell, and average dosage of glucocorticoid was decreased, with a statistically significant difference in favor of the integrated therapy group.<sup>16</sup>

The classical theoretical underpinning of acupuncture and Chinese herbal medicine has featured philosophical concepts of energetic phases and correspondences in nature (Yin and Yang, Five Elements), but this system that has not developed significantly in 1000 years has been minimized in modern official Chinese government pronouncements, paradoxically the complete traditional theoretical system is the version taught at over 100 professional colleges of acupuncture and Chinese medicine in

Forward to Unschuld's book, "a medical system develops its theories and gains and maintains the acceptance of the community it serves not by its clinical effectiveness but by the acceptability of its underlying ideas."

The need for such a conceptual alternative to modern biomedicine has arisen partly from the reaction to wellpublicized negative aspects of chemical agents and technology and alienating aspects of a medical system based on a nineteenth century industrial/mechanical rather than a holistic model and a medical culture of an expert elite whose training and practice have not emphasized the doctor-patient interaction. The result, according to Unschuld, is "a conceptual adaptation to Western fears." Medical choices in popular consciousness are thus placed in the realm of belief, similar to religious preferences, dependent more on family or cultural environment than on scientific data.

At the same time, there has been limited scientific acceptance of acupuncture, in spite of its longprofessed effectiveness, since it does not fit the double-blind controlled experimental model that is best suited to provide a scientific stamp of approval to marketable drugs. This raises the question of what constitutes evidence in the era of "evidence-based medicine." Is evidence-based medicine necessarily the most effective medicine? Do most allopathic physicians even practice evidence-based medicine or is it more honored in the word than the deed? According to a report from the Office of Technology Assessment of the United States Congress, 10-15 percent of medical practice is based on controlled

#### **East-West Medicine**

clinical studies.<sup>17</sup> Furthermore, the most downloaded study from the Public Library of Science states the following:

Published research findings are sometimes refuted by subsequent evidence, with ensuing confusion and disappointment. Refutation and controversy are seen across the range of research designs, from clinical trials ... to the most modern molecular research. There is increasing concern that in modern research, false findings may be the majority ... of published research claims ... It can be proven that most claimed research findings are false. <sup>18</sup>

At the same time, Marcia Angell, former editor of the *New England Journal* of *Medicine*, agrees that such journals constitute "primarily a marketing machine." Ample documentation can be provided for publication bias, i.e. publication of only the positive studies supporting a particular drug, while ignoring the negative studies, and stating "evidence-based" decisions based on a biased sample.<sup>20,21</sup>

Currently, "10 to 30 percent of the world's health care is delivered by conventional Western methods: the remaining 70 to 90 percent is rendered by alternative modes of treatment."22 Herbalists and acupuncturists Michael and Lesley Tierra proclaim, on the basis of a vast empirical accumulation, an "integrated system of Planetary Herbology," incorporating Western naturopathy, early the American Thompsonian system, Chinese herbal medicine, Ayurvedic medicine of East Native American herbology, Middle Eastern Unani medicine, Tibetan medicine, as well as the folk medical traditions of many cultures worldwide.23 Considering the exclusiveness of Western medical orthodoxy in its training and practice, perhaps it is appropriate to quote Shakespeare: "There is more in heaven and earth than is dreamt of in your philosophy."

Is there, in fact, an alternative science or a non-Western body of scientific knowledge? Joseph Needham, the Cambridge biochemistry scholar whose biography describes him as

"The Man Who Loved China,"24 is often credited with the single greatest work of scholarship, Science and Civilization in Ancient China, now posthumously extending to more than 22 volumes.25 Each volume deals with a different branch of ancient Chinese scientific knowledge, such as nautical science, astronomy and astrology, botany and other biological science, etc. One could learn, for example, that in the eleventh century, there was a Chinese practice of using powder derived from aging smallpox scabs for inoculation, although the credit for smallpox vaccination usually goes to Edward Jenner (1796).25

How is such a body of knowledge acquired and verified as a basis for practical application, if not by the experimental method? Evidence may also be empirical, i.e. based on trial and error over an extended period. "The empiricist precedes the man of science, and the work of empiricism finally gives us data that enables man to formulate laws, until at last science is born," says J. Lloyd.23 Apparently, as the survey of the Office of Technology Assessment indicates, modern Western physicians, along with the rest of the world, past and present, depend primarily on applying what has worked through their experience. An extension of the empirical method in the modern era is statistical evaluation, and in fact most of the published evidence for the effectiveness of traditional Chinese acupuncture and herbal medicine is based on the statistical weight of evidence of therapeutic effects on several hundreds or thousands of subjects.

It is well known that many of the drugs utilized in the pharmacopeia of Western allopathic medicine are derived by extracting the chemical part of a plant and later synthesizing it. Examples are aspirin from willow trees, digitalis from foxglove, and reserpine from rauwolfia.<sup>23</sup> In fact, the farther one extends back into antiquity, even beyond Hippocrates to the Sumerians, Babylonians and to prehistoric Neolithic times, the more Eastern and Western empirical medical traditions coincide, particularly on the points enunciated by naturopathic physicians: 1) vis medicatrix naturae (the healing power of nature); 2) use of natural therapeutic agents, such as air, water, sunlight, diet and herbs; 3) emphasis on prevention; 4) using the least invasive or harmful agents; 5) the doctor as health educator; and 6) treating the whole person, recognizing emotional causes of physical disorders.

When the choice between a traditional empirical system and a modern allopathic system is available, how is a decision made? Arthur Kleinman, psychiatrist and medical anthropologist, conducted an inter-cultural study of medical systems available to modern Taiwanese residents, finding that Western medical practitioners are chosen when people believe that they need a drug medication, whereas traditional Chinese medical practitioners or temple fortune-tellers are consulted when the need is felt for a personal emotional interaction.<sup>26</sup>

What would an integrative East-West naturopathic-allopathic encounter between physician and patient look like? There would be considerable overlap of the two approaches in history-taking and examination. Traditionally in China, assessment of internal states was based on examination of external inspection of the face and tongue and palpation of the pulse and acupuncture meridian points. This Eastern-style physical inspection would accompany Western examination of vital signs, along with review of systems. A naturopathic practitioner might include palpation of Chapman reflexes on the trunk area, reflecting the condition of internal organs, as well as evaluation of spinal alignment. Both traditions could utilize symptom survey questionnaires, including a questionnaire to evaluate the Ayurvedic dosha (body type or constitution, i. e. vata, pitta or kapha, corresponding to dominance of nervous system, digestive-circulatory systems, or body tissues and structure). Findings from the history and physical examination could reveal, from the Eastern perspective, for example, indications of internal heat (yin deficiency or pitta dominance), usually reflecting inflammation or infection. For the same patient, the Western exam might show elevated temperature or blood pressure or pain (localized or general). The East-West physician could seek corroboration of these findings through electrodermal testing of meridian extremity points, bioresonance testing, and through laboratory tests - in addition to basic

CBC and metabolic panel, additionally ordering CRP, ESR, viral antibodies (HSV, EBV), or in some cases expanded thyroid and adrenal panels. Considering a different scenario, for the East-West physician, a pale tongue and weak pulse (blood deficiency in Chinese medicine) could correspond to anemia or infertility or several other conditions.

For the most complete individual health profile, the integrative practitioner could order additional panels for mineral and heavy metal analysis, comprehensive amino acids and organic acids, food and environmental allergies, digestive stool analysis, and chemical toxins. Some would now add a genomic profile as well. Of course, each test leads to individual prescription of specific nutrients or therapeutic protocols, while the accumulation of test data, taken in combination with data on blood type, Ayurvedic dosha, body measurements, medical history and symptoms, could generate a complete individual prescription food plan. This process would require a software program such as Food Pharmacy, which permits inputs for all medical conditions, laboratory data, nutrient imbalances and allergens and produces a comprehensive colorcoded list of dietary items that benefit or aggravate one's individual conditions. Such a plan would fulfill Hippocrates' injunction to "let one's food be medicine and one's medicine be food." Maintaining a diet that truly fits one's body would address current health issues, prevent more serious conditions in the future, and maintain stable weight and metabolism.

When a pharmaceutical medication is inadequate to control symptoms, it would be common in clinical practice for the integrative East-West physician to add a phlegm-reducing Chinese herbal formula such as Pe Min Kan Wan to a prescription of drug medication for allergy or to add a digestive formula such as Liu Jun Zi Tang to a prescription of omeprazole for a resistant digestive disorder, of course taking into consideration possible herbdrug interactions. Or when a medication such as lisinopril or hydrochlorothiazide is not sufficiently controlling blood pressure, the combined therapy with acupuncture can usually enhance the results.

While the integrative nutritional prescription could be considered the ultimate lifestyle goal, the integrative East-West physician would in every interaction with patients attempt to maintain an open understanding and application of the fullest possible scope of medical-cultural practices from Eastern and Western sources.

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Richard Kitaeff, MA, ND, DipAc, LAc, was the first Westerner to graduate from Meiji University of Oriental Medicine in Osaka, Japan. Kitaeff was also licensed as an acupuncturist by the government of Japan in 1975, and was a member of the first graduating class of naturopathic physicians from Bastyr University in 1982. He interned at the Osaka Medical College Pain Clinic and the Kyoto Pain Control Institute. Richard Kitaeff's research on acupuncture and endorphins, carried out at the University of Washington School of Medicine and published in the journal *Pain*, was the first to verify the analgesic effect of acupuncture through objective (EEG) measurement.

As a pioneering North American acupuncturist, he founded and directed acupuncture training programs of the Northwest Institute of Acupuncture and Oriental Medicine and Bastyr University in Seattle and was founding president of the Acupuncture Association of Washington. He has additionally taught acupuncture and pain management courses and seminars at Meiji, Friends World College, University of Washington, City University (Seattle), Pacific Acupuncture College and Southwest Acupuncture College. He has been an invited speaker at conferences of the American Association of Holistic Medicine, the American Association of Naturopathic Physicians, the Washington Association of Physician Assistants, the Northwest Naturopathic Conference, and Northwest Hospital. Kitaeff has also published articles on acupuncture and pain management in Pain, the Townsend Letter, the North American Journal of Oriental Medicine, and book chapters in Optimal Wellness, the Textbook of Natural Medicine, and the Encyclopedia of Natural Medicine.

Since 1984, Richard Kitaeff has owned and directed New Health Medical Center in Edmonds, Washington, a multidisciplinary center integrating North American, European, and Asian techniques of pain control, systemic detoxification, allergy elimination and stress management. Since 1999, he has been the only acupuncturist or naturopathic physician to become a staff member of a major hospital in the Northwest, and additionally has been granted privileges at rehabilitation hospitals to treat stroke patients with acupuncture.



# AICR Partners with iThrive to Provide a Valuable Cancer Patient Resource for Free

#### by Jacob Schor, ND, FABNO

I am looking for the right adjectives to describe my emotions. Pleased as punch isn't a bad start. You know how you feel when you discover that your two favorite friends have started dating, actually you find out that they have been going out together for a bit but been keeping it secret? Favorite friends. Friends that are perfect for each other, so perfect that as soon as you hear the news you start thinking about the perfect wedding gift to buy them. This is how I feel now that the iThrive partnership with AICR is out in the open.

These are two of my favorite cancer patient support organizations, and they announced in January that they have joined forces to better help cancer patients. The American Institute for Cancer Research (AICR) joined forces with the iThrive Cancer Survivorship Plan to help AICR supporters who have cancer heal from treatment, reduce risk of recurrence, and achieve optimal wellness.

AICR was founded in 1982 and has focused its efforts on establishing the links between nutrition, physical activity, and cancer risk. Its website is a compendium of research-based information on these topics. For decades I have directed our cancer patients to AICR's "Foods that Fight Cancer" section of their website. It is the best source of solid and reliable evidence-backed information that every cancer patient can benefit from. AICR also funds research, some of the most important studies that are currently

underway on lifestyle and cancer in particular on diet and cancer. They publish landmark reports on diet and cancer and provide free downloads and sell printed copies for nominal fees. Currently, the report "Diet, Nutrition, Physical Activity and Cancer: A Global Perspective" is available for free download (https://www.aicr.org/ cancer-research/dietandcancerreport/). The first and second versions of this report were released in 1997 and 2007. AICR's expert panels review the research and provide the most reliable cancer prevention research available anywhere.

The full version of the new report is over 12,000 pages long. AICR also has a shorter summary report, one that is only 112 pages long: http://www.aicr.org/report-request/.

This is clearly the most authoritative textbook on this subject; nothing else comes even close to competing. Few of our patients will be geeky enough to read the full book, or even the summary. Yet as their doctor you should have a copy on your book shelf. AICR offers a surplus of simpler patient friendly information; short booklets that will help patients plan meals that incorporate the food concepts AICR has researched. One can even sign up for weekly recipes of cancer fighting food recipes. Spend some time poking around on their website. I can't begin to describe how much useful information is there for patients.

iThrive is the brainchild of Lise Alschuler, ND, FABNO and Karolyn Gazella. The iThrive platform creates personalized lifestyle-based wellness plans for cancer survivors. Dr. Alschuler is a past president of the American Association of Naturopathic Physicians and also of the Oncology Association of Naturopathic Physicians. She is currently a professor at the University of Arizona Medical School and still maintains her private practice. Karolyn Gazella is the publisher of the Natural Medicine Journal. Together these two coauthored the well-respected books, The Definitive Guide to Cancer (now in its 3<sup>rd</sup> edition) and *The Definitive Guide* to Thriving After Cancer. Both authors are cancer survivors and when called for can speak from personal experience.

The iThrive Plan is an online tool that creates personalized wellness plans for cancer survivors that helps them heal from treatment, reduce risk of recurrence, and achieve optimal wellness. Cancer centers and clinics can license the iThrive Plan for their patients, and the iThrive Plan can also be customized for large corporations or non-profit organizations. That AICR is offering their supporters this tool for free isn't that much of a surprise. They have always been incredibly generous with their information and services.

For more information: AICR.org or http://www.aicr.org/patients-survivors/ithrive/

### **NEWS | NEWS | NEWS**

# Dr. Kenneth Stoller Files Lawsuit Against the San Francisco City Attorney's Subpoena for His Patients' Medical Records and Genetic Information

Today, Dr. Kenneth Stoller has filed a lawsuit to stop the San Francisco City Attorney's attempt to obtain the medical records and genetic information of his vaccine exemption patients. The basis of the City Attorney's subpoena, which was served and widely reported in the media on May 8, 2019, is a purported public nuisance investigation about Dr. Stoller's practice of writing medical exemptions for children who do not meet the strict CDC (Centers for Disease Control) vaccine contraindications.

We believe that there is no real investigation. Rather, the City Attorney's press conference announcing the subpoena was intended to create public support for SB 276, which would remove medical vaccine exemption decision making from physicians and place it in the hands of state or local public health officials. Under this bill, an important medical decision will be made by state

or local government employees who have never met or spoken to the patient or family.

SB 276 was introduced and is being promoted by Senator Richard Pan who has created the false public relations narrative that SB 276 is necessary to stop a few physicians from writing what he considers to be fake or fraudulent medical exemptions. In reality, some physicians like Dr. Stoller are issuing medical exemptions based on the clear and explicit statements made by Senator Pan and others, that medical exemptions could be written based on considerations much broader than the narrow CDC contraindication guidelines that he now seeks to impose on all Californians via SB 276.

Many of the medical exemptions written by Dr. Stoller (and other likeminded physicians) are for siblings of vaccine-injured children. The

exemptions are to protect the families' other children from potential vaccine adverse reactions.

In addition to seeking to quash the City Attorney's subpoena, this lawsuit seeks to prove that if there is a public nuisance, the vector or cause is not the medically vaccine-exempt children, as well as to establish the legal rights of the families of vaccine-injured children to obtain an exemption based on considerations beyond CDC guidelines as a right to receive medical care and advice different from the conventional medical majority view.

For Further Information: Rick Jaffe, Esq. rickjaffeesquire@gmail.com 916-492-6038 (California office number)

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### **NEWS | NEWS | NEWS**

## MedWatch Safety Alert Added to the FDA Compounding Alert Web Page

FDA warned compounders on February 1, 2019, not to use glutathione L-reduced powder (L-glutathione) distributed by Letco Medical located in Decatur, Alabama, to compound sterile injectable drugs.

FDA received a report concerning seven patients who received an injectable drug compounded with L-glutathione and experienced adverse events due to potentially high levels of endotoxins, a substance that may cause unintended health consequences ranging from fever to death. These adverse events were consistent with reactions patients experience with excessive levels of endotoxin, and FDA's testing confirmed higher levels of endotoxin than is appropriate based on the dose of L-glutathione received intravenously. The L-glutathione powder the pharmacies received was labeled with "Caution: Dietary Supplement" and should not have been used to compound sterile injectable drugs.

Ingredients not intended for use in compounding sterile injectable drugs can be harmful when administered to patients

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because they may contain impurities and contaminants, including endotoxins. Therefore, compounders should ensure that all ingredients they use to produce sterile injectable drugs are manufactured under conditions and specifications appropriate for the intended route of administration.

### Citizen's Petition Challenges FDA on Compounding Ingredients

The Drug Quality and Security Act (DQSA), an amendment to the Federal Food, Drug and Cosmetic Act, was signed into law in 2013. This act gives the federal government expanded authority over the practice of compounding by pharmacists or physicians.

Prior to this, the professional activities in health care were subject to only state regulation rather than federal. This amendment was created in response to contaminated sterile preparations originating in Massachusetts. Consequently, Congress gave the FDA the authority of the DQSA to create regulations in accordance with the provisions of the law to address safety concerns

Concerned about some of the processes that are both being created and being enforced, legislative relief is being sought by the International Association of Compounding Pharmacists and other pharmacy organizations. The Integrative Medicine Consortium (IMC), comprised of practitioners, have recognized problems in the processes instituted by the FDA to allow or disallow particular active ingredients. These approval processes are creating difficulties for addressing the needs of individual patients and patient-centered clinical practice. Valuable active ingredients are in danger of becoming illegal to use. In response, the IMC has taken the first step to challenge the FDA by filing a Citizen's Petition.

Compounding addresses the needs for active ingredients to be dose adjusted, dosage forms changed, combined for convenience, and additives removed. This includes ingredients such as nutrients, bioidentical hormones, peptides, and botanicals.

The Citizen's Petition can be viewed at: www.naturopathic. org/compoundedmeds

Background information has been prepared and posted by the American Association of Naturopathic Physicians (AANP) to make it easy to understand and follow up with your invaluable comments. Support is also requested to help fund this legal challenge.

#### **An Inspiring Look at Cancer Recovery**

review by Dwight L. McKee, MD

I Used to Have Cancer: How I Found My Own Way Back to Health by James Templeton Published by Square One Publishers

Paperback; ISBN 978-0-7570-0478-0; 192 pages; \$16.95 USD

Starting in 1973, I have treated a number of people with cancer challenges: first as a medical student exploring nutritional therapies, then as a young holistic medical doctor exploring alternative cancer therapies, and ultimately as a medical oncologist (having done six years of hospital-based residency and fellowship training after twelve years in practice of holistic/ integrative medicine). Early in this process, I had the insight that viewing cancer as a teacher, who tells us about how we've been living our lives, can be far more productive than battling it as an enemy.

In I Used to Have Cancer, author James Templeton—after telling the engaging story of his enlightening journey being diagnosed with an advanced stage of melanoma at the age of 32 – has reached the conclusion that having cancer actually helped teach him how to live more fully and healthfully. As a general rule over the years, my advice to people facing significant cancer challenges has "Those with cancer will find in Templeton's story a strong and sturdy foundation upon which they might now base their own potential reach towards recovery."

been to find therapies and practitioners that inspire confidence. By reading this inspired new book, those with cancer will find in Templeton's story a strong and sturdy foundation upon which they might now base their own potential reach towards recovery.

Another important lesson to glean from this book is the importance of trusting one's intuition—something that has served James Templeton well over the years. He knew instinctively, for instance, that macrobiotics was to play a major role in his recovery, even before he had learned anything about it.

James Templeton's cancer survival story is an important one, through which doctors and patients alike are poised to benefit. From chapter to chapter, he inspires a confidence in the reader that no oncologist or scientist can. James Templeton has succeeded in staying well despite the odds, which were strongly stacked against him. You can, too.

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### **Beating Chronic Lymphocytic Leukemia Without Conventional Therapies**

review by Jonathan Collin, MD

n of 1: One man's Harvard-documented remission of incurable cancer using only natural methods

by Glenn Sabin with Dawn Lemanne, MD, MPH

FON Press; Softback; 2016; 188 pp; \$16.99

The title, "n of 1," refers to the number of subjects in a study, which in this case is one, the author, Glenn Sabin. When Sabin was diagnosed with chronic lymphocytic leukemia (CLL) in 1991, he had an elevated white blood cell count and a massively enlarged spleen. He was advised to undergo a splenectomy, which he did-his one and only surgery. Of course, he was also recommended to initiate chemotherapy and related drug treatment, but he refused. He had been informed that none of the suggested therapies would be curative. Instead he elected to overhaul his diet foregoing the fatty, sugary foods he was prone to eat as a business entrepreneur and abiding by a plant-based diet. Sabin has always been in good shape physically, and he was determined to work out physically. He also put together, with pharmacists he consulted, a supplement regimen that had some in-vitro evidence of countering blood cancers. Sabin was determined to beat CLL, and he wanted to document the progress he was making.

He worked with local physicians in the Maryland area as well as at distant university centers. He did undergo bone marrow biopsies (multiple), CT and PET scans, blood counts, and flow cytometries not just at initial diagnosis but throughout the course of his illness. Within a year his numbers were improving, and he was determined to eradicate leukemia entirely. Refinement of his supplementation subsequently enabled him to normalize his numbers. He continued to consult with integrative physicians and nutritionists optimizing his overall program.

However, twelve years out he became quite ill suffering with infection, and the numbers were bad. Despite a short round of antibiotics ordered by infectious disease specialists, his condition deteriorated. Ultimately, he was diagnosed with autoimmune hemolytic anemia secondary to CLL. Once again, he was advised a protocol of chemotherapy, even a suggestion of bone marrow transplant, but Glenn refused. His consultation with his oncologist at Harvard offered much of the same advice with the admission that none of these treatments were curative. Sabin dramatically revised his nutraceutical With further consultation Sabin's nutraceutical program intensified, especially with the addition of the green tea extract, EGCG (epigallocatechin-3-gallate).

program; and, in the weeks and months that followed, his illness not only calmed down but the blood count, particularly the anemia, improved markedly. A local oncologist examined his blood with flow cytometry, and there were no leukemia cells. Elated at his progress and feeling vigorous, he requested a repeat bone marrow biopsy three years later; unfortunately, there were still leukemia cells in the bone marrow.

With further consultation Sabin's nutraceutical program intensified, especially with the addition of the green tea extract, EGCG (epigallocatechin-3-gallate). However, in 2010, his white blood cell count began to rise. It had never been higher than 20,000; but in the months that followed, his WBC's increased to 47,000. Yet, physically he felt normal. He had been using some EGCG earlier, but he was now taking a much higher dose of it together with all his other supplements. The WBC count began to drop and drop and within months it normalized. One year later he underwent a bone marrow biopsy: the test revealed no leukemia cells and no evidence of lymphoproliferative disorder whatsoever.

Sabin has continued on his regimen of plant-based diet, exercise, meditation, and nutraceutical supplementation. As of 2016 there was no evidence of relapse. Given the incredible recovery he has experienced, Sabin formed an organization, FON Consulting, to advocate for integrative oncology care. Glenn invites physicians and patients to contact him at fonconsulting.com and glennsabin.com.

For those who would prefer to read about his case in a peerreview journal, search for "Lemanne, D., Block, K., Kressel, B. et al. A case of complete and durable molecular remission of chronic lymphocytic leukemia following treatment with Epigallocatechin-3-gallate, an extract of green tea. Cureus: 7 (12): e441.doi:10.7759/cureus.441."

#### **Treating Root Causes of Perplexing Medical Problems**

review by John Parks Trowbridge, MD, FACAM

AcciDental Blow Up in Medicine: Battle Plan for Your Life by Simon Yu, MD Prevention and Healing, www.preventionandhealing.com ISBN 978-0-578-524177; paperback; 388 pp; c. 2018; \$24.95

I've been treating patients for decades. All too often, success in treating patients leads to a casual conclusion that what you're doing is enough; it's working. For patients who fail to respond, we try other treatments or simply refer them to another physician.

But wait! Those whose illnesses are difficult to treat... those are the ones from whom we can learn more about the hidden causes of disease. Those are the ones who should capture our full measure of attention — not a casual send-off. Simon Yu, MD, has devoted his life's work and studies to discovering and addressing the deeper roots of so-called "undiagnosed" and "untreatable" human misery.

Hundreds of new patients each year find effective solutions to their health challenges through his guiding hand. Many more can be reached if more physicians, like us, broaden our horizons beyond our medical school training and routine conferences and learn how to develop new battle plans to detect and combat asymmetric threats to restore normal energy flows and healthy metabolic functioning in the body.

As physicians, we are trained to look, listen, feel. But all too often, we are looking mostly at lab tests or x-ray reports. You might be one of the many physicians who have said, "Your tests all look fine. We're not sure why you're complaining." Scans and x-rays are supposed to look deep inside... but what if they fail to show "something"? Looking at a patient's teeth might only show a filling or crown here or there... but what if body-threatening infection is festering quietly, deep within? Gums and jaws are even more puzzling, since we ignore most problems "unless it hurts."

You may be skeptical. You may be asking, "If there is something to this, why haven't I heard of it before? Where is the medical literature? Where are the clinical trials studies? Where are the guidelines?" In our medical training, we physicians learn a rigorous approach, a style of thinking.

Like you and me, Dr. Simon Yu learned the rigors of medicine. Then, during his military assignments as a US Army Reserve Medical Corps officer, he began to have uniquely different experiences than his work as the medical director of a Midwest regional health maintenance organization (HMO). He wrote many patients prescriptions to alleviate symptoms, but

Simon Yu, MD, has devoted his life's work and studies to discovering and addressing the deeper roots of so-called "undiagnosed" and "untreatable" human misery.

they did not improve from chronic illnesses. Through careful observations – and moving onward to study other systems of medicine, such as acupuncture at Stanford and German Biological Medicine at Medicine Week in Baden-Baden – he found he could help patients in ways he had never dreamed before. Rather than settling for these first realizations, he began to build upon them, gradually enlarging the number of mystery conditions that he could improve through systematic detection and treatment.

Many patients come to see Dr. Yu with serious, progressive illnesses, cancers, persistent Lyme, suspicions of parasites, and unexplained mystery symptoms. Others come with vague complaints of fatigue, generalized pain, poor sleep, loss of memory, and so on. Where should a doctor look to find a cause, a treatable problem to improve these conditions "when all the tests are normal"? Could their symptoms result from unseen, asymmetric threats, such as invisible fungal or parasite infections, hidden dental infections or dental materials reactivity, nutritional deficiencies, toxic chemicals or heavy metals, unresolved stress, bacterial or viral attacks, or lurking disturbances such as cancer?

Any one or several of these could be involved – so which is it and how to treat? We're familiar with printed lab results of cultures and blood tests and x-rays, allowing us to give marching orders to go forth to do battle. But what about the modern stealth guerilla warfare threats to health? Those unseen, unsuspected and untested assaults which are responsible for most of our patients' suffering? This book will open you to another operating theater in which to detect the root causes of perplexing medical problems and treat them with greater success.



## Optimizing Metabolism

by Ingrid Kohlstadt, MD, MPH www.INGRIDients.com

## Strengthen Your Ability to Predict If an Integrative Therapy Will Help Your Patient, Part 1: Bottom Line Up Front

Modern medicine is practiced in the tradition of the ancient Greeks. But the modern healthcare system appears to be designed in the tradition of the ancient Romans. You've heard the expression, "All roads lead to Rome." In health care today all roads lead to the primary care practitioner. TV ads instruct, "Ask your doctor." The supplement company redirects concerns about side effects: "Tell your doctor." New treatments enter the marketplace by instructing patients to "talk to your doctor about which treatment is right for you." What do the direct-to-consumer lab tests companies instruct? "Talk this finding over with your doctor." So here we are as health care professionals, at the end of the road — Rome!

What should we do about our rapidly-expanded job description? I advise my colleagues to BLUF. It sounds like "bluff" but is definitely not. In medical editing BLUF is an acronym for Bottom Line Up Front. It's a way to remind authors, speakers, teachers, and doctors to give objectives. "Tell 'em what you're gonna tell 'em." Here I apply BLUF to the burgeoning therapies about which our patients ask us.

So how might we help our patients feel heard, understood, and validated about the therapies they think will work? How do we do this efficiently so as not to detract from our patient time? How do we do this wisely so as to be sufficiently open to new ideas but not overrun by them? This column and the next provide health care professionals with strategies to BLUF.

#### What's the Patient's Bottom Line?

Ask the patient to tell you their finish line. What do they hope to achieve with this new therapy they want your opinion on? Some patients "deselect" their question so as not to detract from the primary reason for the visit. Maybe they simply wanted to know if their doctor was open to hearing their ideas.

The finish line that the patient draws gives the practitioner the opportunity to agree and modify: "I agree that the health outcome you are seeking is important and that it is achievable. Have you heard of the Pareto Principle? Approximately 80% of the healing comes from 20% of the treatments. While I think this product can be therapeutic in theory, the time and expense it requires to achieve the results you want does not place it in the 20% category."

#### How Long Until the Bottom Line?

Surprisingly few products, including prescription medications, specify the length of treatment. How do you know when you will reach the finish line for a course of statin medication, for example? It's usually unclear. Consequently, one patient may get many different answers depending on the prescriber. For example: "Take until side effects outweigh benefits...until lab tests improve...lifelong...until lifestyle therapies take hold...until age 70."

There's a bigger problem with a lack of finish line: the lack of research to inform the decision. The health claims the products make, if studied at all, are often unstudied beyond a few months. Duration is important because dose and length of treatment can change a medicine into a poison. Biologic systems are about balance. The treatment that brought the patient into balance would be expected to swing the balance in the opposite direction. It's therefore not uncommon to observe that a product proven effective if taken for three weeks results in net harm if taken for three months.

Many of my colleagues have been surprised to learn that prescription medications, let alone dietary supplements and biologics that have less regulatory requirements, are studied for side effects upon discontinuation. Medications used for neurologic and psychiatric conditions are particularly

problematic in this way. They exert their effects on poorly understood regions of the brain, including appetite centers, mood, and food selection.

Finish-line-first brings needed attention to the study design – the assumptions that went into the research. It also gives us a treatment protocol: "Take the product for only as long as the studied benefit. If symptoms recur consider resuming the product."

#### Does the Product Lead to This Patient's Bottom Line?

Showing patients the logic gap in product claims and advertisements empowers them. The more we look for contradictions, the more facile we become in finding and exposing them. BLUF sheds light on inherent contradictions in logic and defines the healing path:

- A new patient takes a generic prescription medication to treat bowel symptoms, yet her bowel symptoms are getting worse. We focus on her single goal: to improve her bowels. I therefore invest time in researching her generic prescription on Daily Med (https://dailymed.nlm.nih.gov/). The drug label details the excipients, which include lactose. Since the patient avoids uncultured dairy foods, the excipient is likely to actively worsen her symptoms. "Inactive" ingredients known to worsen irritable bowels are common and include lactose, polyethylene glycol, carboxymethylcellulose, wheat starch, artificial dyes, and artificial sweeteners.
- A health-conscious pediatric dentist tells me ADHD makes it difficult for patients to sit
  still. I walked into the clinic's restroom, which included a mouthwash stand. The name
  brand's ingredients included sodium benzoate and blue food dye. Although GRAS,
  both chemicals have been proven to exacerbate hyperactivity and ADHD in children.
  Why encourage kids to use this mouthwash before sitting in a dental chair? Why use
  the mouthwash at all?
- A patient's goal is to get free of allergic rhinitis long-term. The patient shows me his
  nasal decongestant, which works by drying out the nasal passages. I explain that the
  product clears sinuses for a few hours and makes the problem worse long-term. Dry
  linings prevent the cilia from clearing allergens. The patient would reach his desired
  goal more quickly by humming simply humming and letting the vibratory energy
  do its proven sinus-clearing work. He might also consider buying a HealthMate air
  filter and taking herbal supplements such as olive leaf extract to stabilize the immune
  system's mast cells.
- The next patient wants to become pain-free but depends on a medication that doesn't seem to help. Her pain medicine relaxed her muscles, including those of her airways, thereby causing sleep apnea. Disrupted sleep was in turn worsening her pain. Strategies presented in *Metabolic Therapies in Orthopedics*, a medical book I edit, helped her get out of the pain cycle.
- I was invited to attend a session at a nearby hospital's teaching kitchen, a facility aimed at helping patients towards more healthful food selection. Some contradictions surfaced: The "healthful" nut butter's second ingredient was sugar, and third ingredient was hydrogenated plant oils, also known as Crisco. The baking pans were to be sprayed with canola oil, which suddenly caused me to cough. The aerosolized spray included an anti-foaming agent that has a GRAS designation only for ingestion, not inhalation. Why not apply oil with a towel or fill a spray bottle with olive oil?
- "Yes, this product helps people lose weight. But is that your goal, or is your goal to lose fat? This product promotes loss of weight, much of which will be muscle, not fat."
- "Yes, this corticosteroid injection will help with knee pain. Is that your goal or is it to restore your knee? The reason I ask is because you are at a decision point. Corticosteroids work by promoting fat accumulation and breaking down lean tissues like joints. These injections are a way to reduce pain until surgery can be scheduled. You may be able to delay or prevent surgery with regenerative therapies. You may be eligible to be part of a clinical trial."

In sum, too many unofficial road signs point to doctors. However, just because doctors have become Rome doesn't mean we need to roam around for answers on unfamiliar products. By helping patients articulate their health goal up front, we can advise them, even concerning products which lack merit or are unfamiliar to us.

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## Healing with Homeopathy

by Judyth Reichenberg-Ullman, ND, MSW www.healthyhomeopathy.com

#### What Would Dr. Bastyr Say About Naturopathic Medicine Today?

#### Vis Medicatrix Naturae

Dr. Jonathan Collin's From the Publisher editorial in April resonated with me. He started off by mentioning the Spanish naturopathic doctor who failed to renew his long-time subscription to Townsend Letter because it had become too allopathic for his taste. This led Dr. Collin to comment about the change in standard of naturopathic care to rely heavily on evidence-based medicine. I graduated with my ND degree in 1983, the second class at Bastyr. That means 35 years in practice. Dr. Bastyr is long gone, at least physically. I will always be grateful about having chosen to become an ND, and about knowing and being treated by "Dr. B." He was unforgettable...a wellspring of experience and conviction in naturopathic medicine. He was the true embodiment of a healer: his voice, his hands, his presence, his calm demeanor, and his wealth of knowledge. But I keep going back to his profound belief in the healing power of nature.

Back then pretty much no one had even heard of "naturopathic doctor." None of us were covered by insurance (a few of us were part of a Blue Cross pilot program in 1993). We all used handwritten, paper charts. No one used computers, much less telemedicine! We actually relied on books in print form! It was hands-on natural medicine. Homeopathic medicine won my heart and became the lifeblood of my career since that first year at Bastyr when I read about homeopathic philosophy by James Tyler Kent. It just made perfect sense to me and integrated my natural lifestyle, experience as a psychiatric social worker, and my deeply held spiritual beliefs. In fact, many of our naturopathic generation at that time fell upon our careers by way of yoga, meditation, and the like. I knew from that first meeting with the founders of Bastyr that it was my next career. I didn't know then that it would be my dharma, or life's work, for many decades. It has been a labor

of love and lots of hard work. When I embarked on that avant-garde, four-year program, a DO friend of mine warned me: "Why go for two second-rate degrees: an MSW and an ND?" Fortunately, his advice turned out to be extremely narrow-minded and shortsighted. My graduation as an ND was one of the pivotal moments of my life, and I took the Hippocratic oath, of doing no harm and using the gentlest possible methods of healing, to heart.

Vis Medicatrix Naturae, which means "the healing power of nature," was not just an in-vogue slogan; it permeated our naturopathic philosophy classes. It is still at the root of my homeopathic and naturopathic practice. I trust that, at the core, the vital force, of which the defense mechanism is a part, has an innate wisdom and healing ability if nudged in the direction of cure – whether the therapy be hydrotherapy to break a fever (the trusted cold, wet sock therapy), homeopathy, herbs, diet, or other natural therapies. A fever is certainly not a mistake that needs to be immediately countered with acetaminophen (Tylenol) or NSAIDs like ibuprofen or aspirin. That fever is a manifestation of the fundamental inner knowing of the defense mechanism and, even deeper, of the vital force. This means that the vital force exhibits an innate intelligence when it mounts a fever, increasing white blood cells and lymphatic activity in order to stimulate healing.

Dr. B. was not the only shining example of this unquestioning conviction dating back to Hippocrates in 400 BC. Dr. Bill Mitchell was another mentor and role model, for all of us students, who brought to life the healing power of nature. From the memorable student backpacking trip in the Cascades, where we identified our *materia medica* hands on, to precepting with Bill in his office as he imparted wisdom and mixed herbs, he was the real deal. Tragically, he left us way too early.

What we learned about the fundamental healing wisdom of the body remains with me with each and every patient that I see. When I am confronted by acute or chronic illness in my patients, or myself, I reflect on that same unquestionable knowing that the body, mind, and spirit are acting/responding intentionally. Not by accident.

#### Has "Modern" Naturopathic Medicine Lost Its Way?

So, what does all of this have to do with that Spanish ND who bailed on his *Townsend Letter* subscription? Maybe not much, perhaps a great deal. It was when we NDs, 20 years or so ago, were offered the opportunity to do a weekend of pharmaceutical training in order to expand our scope of practice that I really began to ask myself "What is an ND?" Bob and I were two of the handful of licensed NDs who had no interest whatsoever in prescribing drugs. That is why I had become a homeopath – to use the least toxic, most natural and, I believe, most powerful natural medicines. Why, I asked myself, were NDs so eager to prescribe Nystatin and antibiotics when we had so many effective natural alternatives? I feared that naturopathic medicine was selling out. Why would any ND opt first for potentially suppressive drugs when we have so many other effective natural therapies to use first?

I acknowledge that there is a time and place for conventional interventions. But I was taught and still believe that, in many or most cases and if begun early enough, wisely prescribed natural therapies may make allopathic medicine unnecessary. As a two-time breast cancer survivor, I am not one to diss surgery, believe me. But, for the past 21 years I have continued to use natural supplements (I like that term far better than nutraceuticals) to remain healthy. And the only drugs I have taken in my 71 years, were Zometa and Tamoxifen, the latter for four years. I am grateful that Bob had immediate access to antibiotics and surgery when he suffered from appendicitis/peritonitis and then, when he turned 50, a bilateral bacterial pneumonia. But, for me, these are exceptions.

#### **Evidence-Based Medicine or Suppression?**

I spoke earlier this week at a homeopathic conference offered by WAHA, the Washington Association of Homeopathic Practitioners, at Bastyr. I had the opportunity to speak with Nancy Mercer, ND, who supervises students at the homeopathic clinic there. She assured me that their courses in naturopathic philosophy and the healing power of nature were still alive and well. But, she acknowledged, there were a number of students who had a more allopathic approach.

Getting back to that Spanish fellow who canceled his *TL* subscription after years of loyalty...I would ask whether NDs here in the US still recognize and honor the healing power of nature. What do they do when a patient comes with a fever? When a child or adult comes to me with a fever, of course I

need to recognize whether it is a due to a serious infection such as appendicitis or pneumonia; but usually that is not the case, and my first recommendation is the cold, wet sock treatment along with the indicated homeopathic remedy. Have the patient drink hot sage or yarrow tea (or a tastier alternative if a young child), take a hot bath, put cold, wet socks on the feet wrapped in plastic bags, and bundle up in bed with blankets. The great majority of the time, (s)he will wake four to eight hours later having sweated out the fever.

Do US NDs use non-allopathic interventions *first*? Do they recognize and believe in that deep and all-knowing healing process that occurs except when the process is so far advanced that it is not effective? Or, will they resort immediately to pharmaceutical medications? Do they believe that homeopathy can be effective in the hands of those who have mastered it? I asked this of Dr. Mercer and she replied that, in the case of a hypertensive crisis, clinicians would use conventional medication immediately. I asked myself, "What would Drs. Bastyr and Mitchell have done?" What about *Crataegus* (hawthorne) that we learned was a mainstay for hypertension. Or, of course, the homeopathic *simillimum*? And spinal manipulation and the many other hands-on physical therapies that we learned at Bastyr?

Call me a dinosaur, if you wish, but I must question, as did that Spanish doctor, what has become of naturopathic medicine? And what would Dr. B. say? I do hope that this article, if read by NDs or ND students, stimulates discussion and proves me wrong. That the underlying healing principles of nature and the philosophy of using natural therapies first continue to be at the core of contemporary naturopathic medical practice in the US. That the trend towards co-medicine with allopathic practitioners, the use of conventional as well as or along with natural therapies, combines the best of both worlds. That naturopathic medicine has not at all sold out but has expanded its scope only as an adjunct to the natural therapies that we know and love.

Judyth Reichenberg -Ullman and Robert Ullman are licensed naturopathic physicians, board certified in homeopathy. We have written eight books on homeopathy as well as *Mystics, Masters, Saints and Sages – Stories of Enlightenment*. We also have an app: Natural Travel Doctor. Apple version: https://tinyurl.com/I7song8 and Android: https://tinyurl.com/m7cnexh. We are more passionate than ever about homeopathy.

We practice in Edmonds, Washington, and by Skype. Our practice is international and I, Judyth, am fluent in Spanish and French as well. The Edmonds office address has changed, as you will see on our website. We live on Whidbey Island, Washington, and in Pucón, Chile. Visit our website www.healthyhomeopathy.com. Please friend us on Facebook at Healthy Homeopathy. Call us at 425-774-5599 or email us at drreichenberg@gmail.com or drbobullman@gmail.com.



## Ask Dr. J

by Jim Cross, ND, LAc thias1020@yahoo.com

### **Everybody Wants to Be Like Mike**

Even though Michael Jordan took his last jump shot in the NBA in 1993, sales of his sneakers have increased tremendously since he retired. It seems that young athletes still feel his Air Jordan's can make them jump like his Airness previously could. After watching Michael play basketball in the NBA for his entire career, I wish I could be him for just one game. In cancer therapy though, who do you want to be like?

Let's digress slightly into a viral disease called Ebola. It appears mainly in central and western African countries and commands a very high death rate, anywhere from 25-90% of people in the villages infected.<sup>2</sup> This is a very serious disease with unfortunately tragic consequences for many people affected. My question is why doesn't the World Health Organization/WHO compare the blood of the survivors and the deceased? Why did persons A - M succumb to the disease, but

persons N - R survive? I want to move in a similar direction with cancer patients: why aren't we studying the people who have survived more closely? What factor, probably factors, allowed them to survive the disease?

Over the years, I have seen many people with various cancers at different stages. I, of course, have never treated cancer itself. I am only attempting to harmonize the internal milieu of my cancer patients to optimize their response to whatever treatment regimen they are following, to decrease their treatment-induced nausea, and/or to deal with any pain they are experiencing. Let me give you an example as to what I have observed.

I saw two sixtyish males with Stage II stomach cancer, which was located in both gentlemen around their gastroesophageal junction. Both initially had no detectable metastases. Both underwent surgery to remove a portion of their stomachs, and both followed the same chemotherapy regimen. The combination chemotherapy ECF (Epirubicin, Cisplatin, and Fluorouracil/5-FU) was used in both men. One is still alive, and one died.

## Dr. J≪

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Why? Unfortunately, I hadn't come across the superlative integrative cancer treatment of the late, great Nicholas Gonzalez, MD. He differentiated patients into three categories: sympathetic dominant, parasympathetic dominant, neutral, and subcategories of the above three. Quite possibly the man who died was, according to Gonzalez, sympathetic dominant, which means the membranes (membranes that surround all of our cells) didn't resemble the fluid-mosaic model I teach about in physiology class but were much stiffer and more solid. This would limit the ability of chemotherapeutic drugs to enter the stomach cancer cells and destroy them.

Unfortunately, the answer to how accurate and clinically relevant Gonzalez's diagnostic analysis and treatment regimen really is will never be known because no rigorous studies have been performed to establish if it really works or not.

Hopefully some restorative, functional oncological practitioners are reading this column. We need you to start banding together and testing paradigm-changing cancer treatments like Dr. Gonzalez's. The money does not exist for you to perform studies on your own. If several of you with a similar treatment interest were to conduct a study together, you could then corral enough people to make the study's conclusions clinically relevant.

Perhaps our own monthly Townsend Curmudgeon writer could interest some of his colleagues in the OncANP/ Oncology Association of Naturopathic Physicians to begin collaborating and figuring out treatment regimens they have in common. They could then collectively begin a study that could yield viable treatment results for the larger integrative community.

To summarize, I think we need to follow the axioms contained in these relevant quotes if we are truly going to push the frontiers of cancer treatment beyond the algorithmic triad of surgery/chemotherapy/radiation and convince people that utilizing these regenerative/restorative therapies will make them be more like Mike.

- Please stop saying we're thinking outside the box and expand the box.
   David Perlmutter, MD
- If everybody is thinking alike, somebody isn't thinking.
   General George Patton

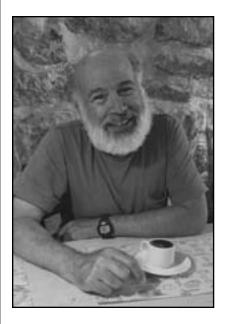
 The most interesting phenomena are of course in new places, the places where the rules do not work – not the places where they do work! That is the way in which we discover new rules.

Richard Feynman, Physicist, Nobel Laureate

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## Curmudgeon's Corner

by Jacob Schor, ND, FABNO drjacobschor1@msn.com

#### **Ultra-Processed Foods and Cancer**

Starting in 2009, a new food classification system emerged in public health research that is so strikingly novel that it has been named the NOVA food classification system. In the past, attention has focused on nutritional content of foods and how the vitamins and their combination with macronutrients such as fats, carbohydrates, proteins, fiber, etc. affect individual health status. Currently, much of our food advertising seems to focus on not what is in foods but what is not as in fat, gluten, cholesterol, GMOs, etc. The NOVA system ignores all those details and focuses only on the degree a food has been processed.

Findings published so far looking at public health as it relates to this NOVA system are troubling, even if not unexpected. We have vastly underestimated the significance of harm that industrial food processing is having on global health.

A significant percentage of the world's population has shifted away from traditional diets to branded, ready-to-eat fast and convenient food and drink products. The food supplies in the US, Canada, the UK, Australia, and a long list of other developed countries are now dominated by packaged, ready-to-eat products.

The NOVA classification divides foods into four groups based on the extent and purpose of processing that the foods have undergone between when separated from nature and when they are eaten.

Group 1 foods are the least processed foods. Group 1 foods are edible parts of plants or animals and also fungi, algae, and water after separation from nature. These include seeds, fruits, leaves, stems, roots, animal muscle and other parts, eggs and milk. They may have inedible or unwanted parts removed, they may be crushed, ground, fractionated, filtered, roasted, boiled, pasteurized, refrigerated, frozen or vacuum

packed. They contain no added substances such as salt, sugar, oil or fats. The purpose of processing of group 1 foods is to extend shelf life, allowing longer storage. Fermentation of milk to make yogurt, roasting coffee beans, etc. are considered group 1 processes. Antioxidants may sometimes be added to preserve freshness.

Group 2 foods are the processed culinary ingredients. These are foods that come directly from group 1 foods or directly from nature by processes such as pressing, refining, grinding, milling or drying. The purpose of this processing is to make things used in the home or in restaurant kitchens. These group 2 foods almost always accompany group 1 foods. Examples are salt derived from seawater, sugar and molasses derived from sugar cane or beets, honey extracted from honeycomb, butter and lard, or combinations of several of these ingredients for example vinegar. Some additives may be added; for example, oils may contain antioxidants, or salt may be added to prevent microorganism growth.

Group 3 foods are the relatively simple food products that are made by adding sugar, oil salt and other group 2 substances to group 1 foods. Most processed foods in this group have two or three ingredients. Processing includes preservation or cooking and in the case of bread and cheese, fermentation. The purpose of this processing is to increase durability of group 1 foods and to modify or enhance sensory qualities. Examples are canned or bottled vegetables, fruits and beans, salted or sugared nuts, seeds, cured meats, fruit in syrup, cheeses, and breads.

Group 4 foods are what the researchers are calling ultra-processed foods and drinks. These are the industrial formulations that typically contain five or more ingredients. These ingredients may include sugar, oils, fats, salt,

antioxidants, stabilizers, and preservatives. Some ingredients are only found in this category and include additives to imitate sensory qualities of group 1 foods or to disguise undesirable sensory qualities. Group 1 foods make up a small proportion of these foods or may be totally absent. Substances that are extracted from real foods, such as casein, lactose, whey, gluten, or modified food extracts such as hydrogenated oil, hydrolyzed protein, soy isolates, etc may be included along with dyes, colors, flavors, non-sugar sweeteners, carbonation, firming, bulking agents, etc. The main purpose of ultra-processing is to create ready-to-eat products that replace less processed foods.

Group 4 foods are often hyper-palatable; they come in sophisticated packaging and have aggressive marketing. They may rely on health claims to help market them; and perhaps most strikingly, they are highly profitable. Transnational corporations usually own the manufacturers of such food.<sup>1</sup>

This seemingly simple NOVA classification system is rapidly proving to be a better predictor of health impact than any other system of food classification to date. A recently published study is a good example.

In a February 2018 issue of the *British Medical Journal*, Fiolet et al reported a positive association between consumption of ultra-processed foods and cancer risk.<sup>2</sup>

They had performed a population-based cohort study that included 104,980 French adults whose median age was just under 43 years old during the period between 2009 and 2017. Food consumption data were collected using repeated 24-hour dietary records, designed to reveal the usual consumption for 3300 different food items. These foods were categorized according to their degree of processing by using the NOVA classification system.

Associations were calculated between group 4 ultraprocessed food intake and the overall risk of cancer and then specifically for risk of breast, prostate, and colorectal cancer using multivariable Cox proportional hazard models adjusted for known risk factors.

Ultra-processed food intake was associated with higher overall cancer risk (n=2228 cases). For every 10% increase in the proportion of calories obtained from ultra-processed foods in the diet, cancer risk increased 12% [HR 1.12 (95% confidence interval 1.06 to 1.18) P <0.001]. For the women in the study risk for breast cancer increased by 11% [n=739 cases; HR 1.11 (1.02 to 1.22); P =0.02]. These results remained statistically significant after adjustment for several markers of the nutritional quality of the diet (lipid, sodium, and carbohydrate intakes and/or a Western pattern derived by principal component analysis). In other words, it appears that food processing may have a more substantial impact than the specific initial ingredients themselves. This should be getting our attention.

The American Institute for Cancer Research claims that about a third of the most common cancers in the world

could be avoided by changing lifestyle and dietary habits in developed countries.<sup>3</sup> Within our naturopathic profession, we have seen some claim that as much as 95% of cancers are preventable by diet and lifestyle—while this writer assumes that the lower estimates may be too conservative and the later are uninformed exaggerations.<sup>4</sup> As there is such a wide range of disparate beliefs being proclaimed, this reader has become particularly attentive to any evidence that might better inform this question. It certainly does not help our professional reputation to make unsupported claims as if they were proven facts.

Those of us of a certain age have borne witness to how much the diets of many countries have shifted dramatically toward higher amounts of ultra-processed foods.<sup>5</sup> Surveys conducted in Europe, the US, Canada, New Zealand, and Brazil have all suggested that ultra-processed foods now contribute between 25 to 50% of total daily energy intake in these countries.<sup>6-9</sup> While it may be hard for us to imagine this level of consumption, we have to remind ourselves that we, and our patients, are not representative of the average global consumer.

There are a number of reasons why ultra-processed foods might increase risk of cancer. We might think it obvious, but in reality, we do not know exactly. These foods certainly have a higher total fat and saturated fat content. Fat consumption may, or may not, be associated with risk for some types of cancer (prostate yes, and breast no). The low vitamin density and high sugar and salt content of these foods may also play a role. Yet it is still unclear whether vitamin deprivation in itself is responsible for cancer. The low fiber content affects gut biome and thus may change cancer risk. 10 Processing may lead to formation of carcinogenic chemicals such as acrylamides, heterocyclic amines, and polycyclic hydrocarbons. Food packaging may contain carcinogens that leach into the food during storage or during preparation such as bisphenol A. Some food additives, such as sodium nitrite, though legal to add to processed meat, may still be carcinogenic. While all of these possible causes may be to blame, we just don't know exactly.

The very concept of studying the effects of food processing on disease risk is still in its infancy. It wasn't until this NOVA classification system was created in the last few years that these effects could be even quantified. <sup>11</sup>

While these data only seem to confirm a message we have been trying to teach our patients for decades, the degree of impact surprises this reader. If every 10% increase in calories derived from ultra-processed foods is associated with an 11% increase in overall cancer, we certainly have a serious problem brewing. Many segments of the population consume far more than 10% of their energy from ultra-processed foods. In some countries, the increases may be five-fold.

Note: The definition according to the NOVA Classification system of ultra-processed foods includes the following:

#### **Curmudgeon's Corner**

.... mass produced packaged breads and buns; sweet or savory packaged snacks; industrialized confectionery and desserts; sodas and sweetened drinks; meat balls, poultry and fish nuggets, and other reconstituted meat products transformed with addition of preservatives other than salt (for example, nitrites); instant noodles and soups; frozen or shelf stable ready meals; and other food products made mostly or entirely from

sugar, oils and fats, and other substances not commonly used in culinary preparations such as hydrogenated oils, modified starches, and protein isolates. Industrial processes notably include hydrogenation, hydrolysis, extruding, moulding, reshaping, and pre-processing by frying. Flavoring agents, colors, emulsifiers, humectants, non-sugar sweeteners, and other cosmetic additives are often added to these products to imitate sensorial properties of unprocessed or minimally processed foods and their culinary preparations or to disguise undesirable qualities of the final product.<sup>1</sup>

Many of us along with our patients believe that foods labeled as natural, organic, GMO free, low fat, cholesterol, or gluten free are healthy choices. None of these labeled categories measure degree of processing, and little data associates these categories with significant inverse cancer risk. In other words, these claims may not be relevant predictors of long-term health. Processing takes its toll whether the food is sold in a chain grocery store or in

For patients who want to lower cancer risk, reducing, or better eliminating, consumption of ultra-processed foods now appears to be a decent evidence-based choice in food selection.

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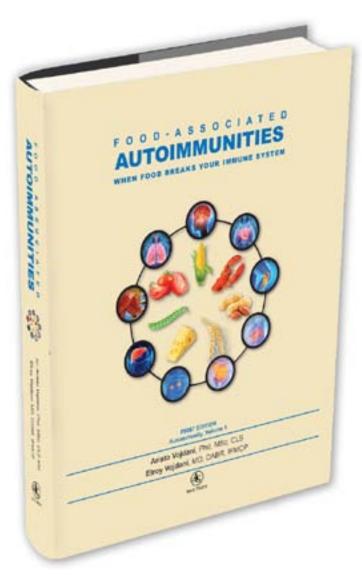
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## Dr. Aristo Vojdani's Latest Book!

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There are a few books that a health professional reads in their lifetimes that are considered "seminal". It is my belief that Drs. Aristo and Elroy Vojdani's book "Food-Associated Autoimmunities: When Food Breaks Your Immune System" is one of them. - Jeffrey Bland, PhD, FACN, FACB, CNS



This book will open the eyes of many readers. While some of the recommendations are clearly on the 'cutting edge,' I encourage you to use these approaches in clinical practice. Your patients will thank you! - Patrick Hanaway, MD



There is a wealth of information in this book that explains so much about autoimmunity, and many a puzzled practitioner will find the answers to their questions here. - Mark Hyman, MD



This book now serves as the "Gold Standard" for the relationship between food and autoimmunity and further supports his undisputed position as the "Father of Functional Immunology." - Datis Kharrazian, PhD, DHSc, DC, MS, MMSc, FACN



This book is the most extensive piece of work that I have read on this subject. As an author of many books on autoimmunity, I read this book avidly and ended it with an admiration for the authors and their encyclopedic knowledge. - Yehuda Shoenfeld, MD, FRCP, MaACR



This book is a masterpiece, a work of art. It's a massive, comprehensive labor of love that tries to explain all the different ways in which the very stuff we depend on for life can go horribly wrong and threaten our health and even that very life. This is a must-read for practitioners and patients alike. - Michael Maes, MD, PhD



Drs. Aristo and Elroy Vojdani not only powerfully relate these diseases to inappropriate responses to various food challenges, but in addition, they provide a long awaited game plan for understanding how laboratory analysis can help create a plan that can allow individuals to finally overcome these maladies. -David Perlmutter, MD, FACN



For anyone interested in the critical role of the immune system in disease, this book is a must-read. - Dale E. Bredesen, MD



When you finish reading this book, there are at least 3 things you will want to do. First, you will make a mental note to read it again very soon; second, you will want to integrate the information you learned into your own life and that of your family's; and third, you will start using this information right away in the diagnosis and treatment of your patients. Dr. Vojdani has written a masterpiece. - Andrew W. Campbell, MD

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## Calendar

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Event publication must be limited to 25 words or less. Multiple event listings require paid advertising.

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AUGUST 15-17: AMERICAN ASSOCIATION OF NATUROPATHIC PHYSICIANS 2019
ANNUAL CONVENTION in Portland, Oregon. CONTACT: https://www.naturopathic.org/

AUGUST 15-18: 10th ANNUAL INTEGRATIVE MEDICINE FOR MENTAL HEALTH (IMMH) CONFERENCE in San Diego, California. CMEs available. CONTACT: https://www.immh2019.com/

AUGUST 22-25: ACUPUNCTURE MERIDIAN ASSESSMENT (AMA) TRAINING For Doctors, Dentists & Health Professionals: Detecting Parasites, Dental & Fungal with Simon, Yu, MD, in St. Louis, Missouri. CONTACT: 314-432-7802; http://www.preventionandhealing.com/pah-training.php

AUGUST 31 - SEPTEMBER 2: 47th ANNUAL CANCER CONTROL SOCIETY CONVENTION in Glendale, California. CONTACT: https://cancercontrolsociety.org/convention2019.

SEPTEMBER 4-7: 20th ANNUAL FALL CONFERENCE ON INTEGRATIVE MEDICINE IN WOMEN'S HEALTH in Napa, California. CONTACT: http://www.symposiamedicus.org/

SEPTEMBER 6-8: EMFC 2019 – DIAGNOSIS AND TREATMENT: EFFECTS OF ELECTROMAGNETIC FIELDS EXPOSURE in Santa Cruz, California. CONTACT: https://emfconference.com/

SEPTEMBER 12-15: 17th ANNUAL RESTORATIVE MEDICINE CONFERENCE in San Diego, California with Tieraona Low Dog, MD. CONTACT: https://restorativemedicine.org/conferences/2019-annual-conference/

**SEPTEMBER 13-15: KOREN SPECIFIC TECHNIQUE (KST)** in Detroit, Michigan. Locate and release physical and emotional stresses. Also, **OCTOBER 11-13** in Philadelphia, Pennsylvania; **NOVEMBER 22-24** in Seattle, Washington. CONTACT: www. korenspecifictechnique.com; phone 267-498-0071.

**SEPTEMBER 20-22: NEURAL THERAPY HANDS ON** in New York, New York with David Vinves Catalonia, MD (Spain). Fascia, ANS, palpation, autonomic ganglia. Organizer Dr. Gurevich. CONTACT: www.HolisticMD.org; 516-674-9489.

SEPTEMBER 20-29: KLINGHARDT IMMERSION WEEK – Injection Techniques, Neural Therapy, and Autonomic Response Testing Workshops in Kenmore, Washington. CONTACT: 908-414-0769; info@klinghardtacademy.com; www.klinghardtacademy.com

SEPTEMBER 27: PERINEURAL INJECTION THERAPY (Neural Prolotherapy) COURSE with Bryan Rade, ND, in Halifax, Nova Scotia. Learn a minimally invasive therapy for pain. Space limited. CONTACT: https://www.eastcoastnaturopathic.com/

SEPTEMBER 27-29: GREAT PLAINS LABORATORY presents ENVIRONMENTAL TOXIN SUMMIT in Seattle, Washington. Also, NOVEMBER 8-10 in Nashville, Tennessee. CMEs available. CONTACT: 913-341-8949; https://www.gplworkshops.com/

SEPTEMBER 28-29: OZONE THERAPY CERTIFICTION COURSE with Bryan Rade, ND, in Halifax, Nova Scotia. Learn intravenous and intraarticular ozone therapy. Space limited. CONTACT: https://www.eastcoastnaturopathic.com/

OCTOBER 3-5: IVC ACADEMY @ Riordin Clinic in Wichita, Kansas. Learn the fundamentals of using intravenous vitamin C for cancer and chronic illnesses. CMEs available. CONTACT: https://riordanclinic.org/events-archive/ivc-chronic-illness-symposium/

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OCTOBER 4-6: DESBIO COMPLEX CLINICAL SCENARIOS SYMPOSIUM in Providence, Rhode Island. CONTACT: 800-827-9529; https://desbio.com/events-calendar/3-day-event-providence-ri/

OCTOBER 10-13: AMERICAN ACADEMY OF ENVIRONMENTAL MEDICINE FALL CONFERENCE – Fatigue: A Complex Diagnosis and Treatment Dilemma in Louisville, Kentucky. CMEs available. CONTACT: http://www.aaemconference.com/fall/

OCTOBER 11-13: AMERICAN INSTITUTE OF HOMEOPATHY CONFERENCE – Mapping the Cancer Journey with Dr. Farokh Master in Charlottesville, Virginia. https://homeopathyusa.org/education/2019-conference.html

OCTOBER 12-14: FIELD CONTROL THERAPY® (FCT) INTENSIVE TRAINING with Savely Yurkovsky, MD, in White Plains, New York. CONTACT: 914-861-9161; http://www.yurkovsky.com

OCTOBER 18-19: GREAT PLAINS LABORATORY, INC. presents GPL ACADEMY PRACTITIONER WORKSHOPS in Costa Mesa, California. A special engagement with The Autism Community in Action (TACA) annual conference. Organic acids testing, toxic chemical testing, mycotoxin testing, and more. CONTACT: http://www.gplworkshops.com/

OCTOBER 23-27: INTERNATIONAL COLLEGE OF INTEGRATIVE MEDICINE (ICIM) – Healthy Parents, Healthy Children in Toronto, Ontario. CONTACT: https://icimed.com/

**OCTOBER 25-26: ANNUAL MICROCURRENT CONFERENCE** in Scottsdale, Arizona. CONTACT: http://microcurrentconference.org/

OCTOBER 25-27: ADVANCED APPLICATIONS IN MEDICAL PRACTICE (AAMP) FALL EVENT – Integrated Oncology at the Next Level in Seattle, Washington. CONTACT: 954-540-1896; https://aampconferences.com/

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# Pain Reduction and Improved Vascular Health Associated with Daily Consumption of an Anti-Inflammatory Dietary Supplement Blend

by Debby Hamilton, MD, MPH

A recent open-label clinical trial showed reduction in chronic pain and an improvement in markers for cardiovascular disease from the nutritional supplement CytoQuel® (Researched Nutritionals).¹ The nutraceutical combines curcumin, resveratrol, EGCG, tocotrienols, and N-acetylcysteine. Twenty-one participants with chronic pain in at least one location were enrolled. The clinical trial lasted eight weeks with evaluations done at baseline, two weeks, and eight weeks for pain and quality of living questionnaires, blood pressure measurements, and blood markers associated with inflammation and cardiovascular health.

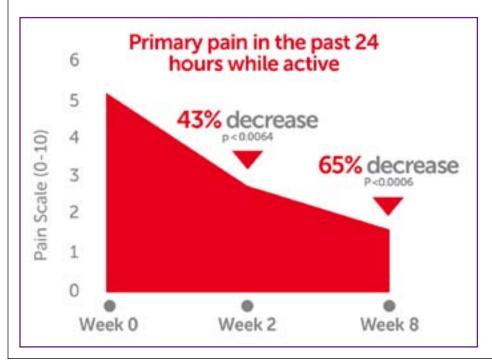
Highly significant reduction of chronic pain was seen after eight weeks (p<0.01), both when at rest and with physical activity. This reduction in pain correlated with a decreased need for support from others (p<0.05), improved sleep quality (p<0.1), and improved social functioning (p<0.01). The

lessening of pain correlated with a decrease in MMP-9, which was highly significant after eight weeks (p<0.01). Significant improvement of the ankle-brachial blood pressure index also illustrated a clinically relevant decrease in inflammation related to an improvement in cardiovascular function. Ankle brachial index values decreased to normal values of almost 1.0 (p<0.01).

Inflammation is one of the pathological mechanisms underlying pain. Therefore, targeting inflammation can lead to a reduction in pain. Cytokines are biomarkers for inflammation. Research has found increased levels of coagulation factors such as fibrinogen and vWF contribute to the development of increased levels of cytokines and inflammation. In the clinical trial, reductions in both fibrinogen and vWF were seen by two weeks and continued on a downward trend over eight weeks. Elevated levels of fibrinogen and vWF have been implicated

in endothelial dysfunction, leading to atherosclerosis and thrombus formation and increasing the risk for cardiovascular disease. Fibrinogen elevation is one of the significant risk factors involved in poor arterial health.

Currently both chronic pain and cardiovascular disease are significant contributors to disability in our country. With our current opioid crisis, it is important to find safe options for treating pain and inflammation. The current researched nutraceutical blend targets inflammation with the end result of reduction in pain, inflammatory and coagulation markers, and ankle brachial index blood pressure.



 Hamilton DE. Jensen GS. Pain reduction and improved vascular health associated with daily consumption of an antiinflammatory dietary supplement blend. Jr. of Pain Research. 2019.May 15;12:1497-1508. PMID: 31190960

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Book by Bill Akpinar, M.D. OMD, Chi Gong faster, Hollstic Dentist



On the internet a Hypothermia Enthusiast posts: "The Relax Sauna is probably the best and only realistic option to do hyperthermia heat stress training at home that can replicate (or actually exceed based on my results) the benefits found in studies due to it cheaper competitors being underpowered."

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> continued from page 96

Second, most of the patients were given chemotherapy after vitamin C or placebo was discontinued. Abruptly discontinuing high-dose vitamin C can cause a "rebound" effect in which plasma levels of the vitamin fall below normal for a period of time. Patients with "rebound vitamin C deficiency" may be at increased risk of being harmed or killed by chemotherapeutic Consequently, administering drugs. chemotherapy after abruptly discontinuing high-dose vitamin C may have biased the results against vitamin C therapy.

Perhaps the most serious flaw in the Mayo Clinic study was that the participants could easily determine which treatment group they were in, because the placebo was lactose, which has a sweet taste, whereas vitamin C has a sour taste. One might assume that many patients in the placebo group opened one of their capsules and

knew they were not receiving vitamin C. Considering the publicity at the time regarding vitamin C as a treatment for cancer, many patients in the placebo group may have started taking vitamin C on their own. That possibility is supported by the results of urine tests in six randomly selected patients in the placebo group. One of these six patients was clearly taking large doses of vitamin C, and another patient was possibly taking large doses. What about the other four? Were any of them taking high-dose vitamin C but discontinuing it a day or two before their appointments, so they wouldn't get caught? We'll never know, but deception by participants in clinical trials is a well-documented phenomenon.6

The question of whether vitamin C can prolong the lives of cancer patients remains unresolved. The only way to answer that question is to conduct another trial like the Mayo Clinic study

but to do it properly this time. The importance of conducting a definitive trial is underscored by reports that continue to appear in the medical literature of dramatic regressions of cancer<sup>7</sup> and improvements in fatigue, pain, and overall quality of life<sup>8</sup> in patients treated with vitamin C.

Alan R. Gaby, MD

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## Is Vitamin C an Effective Treatment for Cancer?

In a 1976 study conducted by Scottish physician Ewan Cameron and Nobel Laureate Linus Pauling, 100 patients with terminal cancer of various types were treated with vitamin C (usually 10 g per day intravenously for 10 days followed by 10 g per day orally). Vitamin C treatment was begun at a time when it was agreed that additional conventional treatment would be of no benefit. For each treated patient, 10 historical controls were found who had the same type of cancer. Mean survival time in the vitamin C group was 4.2 times longer than in the control group (210 vs. 50 days). Sixteen percent of the vitamin C-treated patients, but only 0.3% of controls, survived more than one year.1

In a follow-up study to the Cameron and Pauling study cited above, mean survival time of vitamin C-treated patients had increased to 5.6-fold longer than that of the control group, because of the continuing survival of some of the original patients. Eight of 100 vitamin C-treated patients were still alive, with a mean survival time of 3.5 years. The patients in this study were in part, but not entirely, the same patients as those previously studied.<sup>2</sup>

In addition to the increase in survival times, many patients treated by Cameron and Pauling experienced an improvement in their quality of life. Of five patients who had been in considerable pain from skeletal metastases and had been taking regular large doses of morphine or heroin, four became completely pain-free within five to seven days of starting vitamin C, and the other patient was able to manage his pain with only mild analgesics. None of the five patients experienced withdrawal symptoms upon discontinuing the narcotics.<sup>3</sup>

### Possible Mechanisms of an Anti-Cancer Effect

There are several ways in which vitamin C might be beneficial in the treatment of cancer. First, it enhances immune function, which plays a role in destroying tumor cells. Second, vitamin C appears to promote the synthesis of a physiological hyaluronidase inhibitor, which might reduce the invasiveness of the hyaluronidase released by cancer cells. Third, vitamin C stimulates collagen synthesis, which potentially enhance the body's capacity to encapsulate a tumor. And fourth, vitamin C at high concentrations is toxic to cancer cells in vitro.4

### Mayo Clinic Fails to Confirm Positive Results

Although the results reported by Cameron and Pauling were highly

encouraging, the possibility of a placebo effect could not be ruled out, since cancer patients are known to have better outcomes when they're given new hope. Therefore, investigators at the Mavo Clinic conducted a doubleblind trial, in which 100 patients with advanced adenocarcinoma of the colon or rectum received 10 g per day of vitamin C or placebo. Oneyear survival was 49% in the vitamin C group and 47% in the placebo group (difference not significant). Because of the negative results from that trial, experts in oncology concluded that vitamin C is ineffective, and interest in it as a potential treatment for cancer disappeared.5

Unfortunately, the Mayo Clinic study had serious flaws. First, the vitamin C treatment regimen was not the same as in the Cameron and Pauling study. Patients in the Cameron and Pauling study took vitamin C for the rest of their lives, whereas those in the Mayo Clinic study continued vitamin C only until there was evidence of tumor progression or clinical deterioration. The median treatment period was only 2.5 months in the Mayo Clinic study, and none of the patients in that study died while taking vitamin C.

continued on page 95➤

### Dr. lichiroh Ohhira: A Pioneering Genius in Probiotic Science



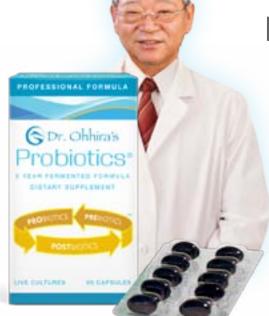
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