

Medical Maverick Tsuneo Kobayashi

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Melding East and West: a forerunner of cancer treatment and prevention. *by John Dodd*

Your doctor examines the test results, gives you a serious look, and says, "You may have cancer." Perhaps no other words strike greater fear in a patient. Suddenly all your daily worries and professional and personal goals pale with the realization you may be dead within a year. Of course, not all cancer is fatal, but with cancer accounting for 23 percent of deaths in the United States (Source: CDC 2002) and for over 30 percent in Japan (Source: Facts and Figures of Japan 2005), any diagnosis of cancer makes the patient reassess their values.



In the days after diagnosis, we are conditioned to turn

to conventional medical treatment for help. Japan is no different. With an array of technology and compounds being tested around the world, we trust our doctors to give it their best shot to kill the tumor and have us resume a normal life in a few months. In particular, we are conditioned to accept that we do in fact only have "one shot" and if we dally with other forms of treatment, not only will we not get better, but the delay will seal our death warrant.

So the one-chance indoctrination, and the urge to comply, ever so strong in Japanese society, creates a situation where the overwhelming majority of cancer research focuses on improving treatments that have been around for almost a hundred years: radiation, chemotherapies, and surgery -- all of which can be considered "decisive" means of rooting out the cancer. As forms of recurrence treatment, almost all of these therapies have failed. 99 percent of treatments focus on early cancer, and 70 percent of treatments for advanced cancers prolong patients' lives for only a short time.

The establishment gives little credence to "alternative" therapies -- virtually all of which are viewed as irresponsible and without efficacy. At the bottom of the pile of such alternatives are holistic therapies that bring diet and lifestyle into the mix.

Vested Interests -- the Players

Then, of course, there is the matter of big business, and cancer treatment in Japan is certainly big business. Cancer is the number one killer of Japanese, claiming more than 300,000 lives annually (Source: Facts and Figures of Japan 2005). This number is projected to rise to 450,000 by 2020. Correspondingly, the government, the medical establishment, and corporations are focused on a huge, growing, and desperate (to get better) customer base. While the motives no doubt vary, it is clear that this is one industry where the participants have a strong vested interest in the status quo. So if you have just developed cancer and are possibly looking for a better way to deal with it, well, too bad.

According to the Nikkei Shimbun, a major economic daily, 111 hospitals in Japan focus on cancer treatment. The government has announced plans to expand this number to more than 350. This will be achieved by increasing care stations to at least one facility per "secondary care zone" in a grid of such zones laid out in a 10-year cancer-control plan, released back in 2003. The plan is, in part, politically motivated. As the nation grays, an aggressive cancer eradication program can only meet with the approbation of the electorate.

The Japanese market for cancer drugs is huge: about JPY526bn (US\$4.58bn) per year. For many pharmaceutical companies, cancer treatments are a major source of income. Take, for example, Chugai Pharmaceutical, the second largest producer of cancer drugs and the fourth largest of prescription pharmaceuticals in the domestic market. Chugai earned JPY68.5bn, more than 20 percent of its overall profits, from such drugs.

While the level of Japanese pharmaceutical companies' total R&D expenditures is modest compared with that of market leaders in Europe and the USA, Japanese companies are world leaders in terms of R&D spending per employee. For example, Takeda Seiyaku, domestic market leader for prescription pharmaceuticals, spent US\$80,870 per employee on R&D in 2003, compared with Pfizer of the USA, US\$58,451, and GlaxoSmithKline of the UK, US\$47,590 (Source: Economist, Feb 2005). It's no wonder then that Japan has become a hot bed for cancer remedy start-ups, offering everything from nanotech and broccoli sprout powder to new immunotherapy methods.

Then there is the medical establishment itself. As many foreign pharmaceutical companies have come to understand, the Japanese medical establishment, particularly as embodied by the Japan Medical Association (JMA), is no less formidable than its US and European counterparts. As a doctor or pharma supplier, you're either in the loop (more than half of all Japanese doctors belong to the JMA) or you're out. The JMA has a notoriously strong hold over the government, not least because it has been the second largest donor to the ruling Liberal Democratic Party for decades. Thus, if you want to keep your medical license, independent thought and rocking the boat is ill advised.

Rebel with a Cause

That is unless you are Tsuneo Kobayashi (61). Over the last 30 plus years, he has become a thorn in the side of conventional cancer physicians, not least for his idiosyncratic behavior and treatment methods, which are based on a lifetime of experimentation and observation, and a belief in the holistic nature of the human body. He uses Chinese herbal medicines in addition to drugs for biochemical-modulation and apoptosis-inducing and cancer-vessel treatment, as well as sophisticated methods of applying tumor marker combination assay, heat therapy and immunology.

He has had over 2,000 grateful patients in the last 25 years, with an average life span after treatment of seven years, as proof his methods work. In comparison, the average life span of breast cancer patients in remission is 4.5 years (Source: US National Cancer Institute) and for prostate cancer patients it is around 2 years.

Kobayashi completed his medical degree at Tottori University in 1968, finishing near the top of his class. That same year he joined the National Cancer Center, where he did research in the insertion of chromosomes into other cells. He tried his hand at teaching, but the laboratory beckoned. In 1971 he entered the graduate school of medicine at Kyoto University, doing research in biochemistry with a focus on cyclic AMP. In 1973 he went east to Tokyo University, where he continued his research, only now with a focus on the DNA regulation of sea urchin. He earned a doctorate in medicine in 1978.

That same year he began an internship at Isshin Hospital in Tokyo. With a PhD from Japan's top university, he was on track to a position of eminence in the medical establishment. Yet he was never one to think inside the box. He sensed that other medical traditions had something to offer. So while doing his internship, he began research into Chinese herbal medicine treatments for cancer patients and

a new technique of biochemical biopsy for tumor markers.

Tumor Markers

By the early 1980s Kobayashi's personal research took him into the field of oncology, the study and treatment of tumors. As he started to delve more deeply into the etiology of the disease, he realized that within Japan's extensive cancer-screening program, which almost the entire working population submits to twice a year at company expense, the imaging method of detection was too coarse to detect tumors until they were well established. According to Kobayashi, a tumor must measure in the 200-1000mg range to be detected by a barium meal and x-ray program.

He exploited a cutting-edge technique in the field of tumor markers, detecting certain combinations of chemicals released into the bloodstream as a tumor starts to form, as a means of indicating the predisposition or actual presence of cancer. But as US experts had long pointed out, the accuracy levels were less than 50 percent -- the reason why tumor markers never gained much popularity among American doctors.

Kobayashi led a staff of 12 researchers and together they painstakingly gathered blood samples from 20,000 early-cancer subjects across Japan. They analyzed the assay data and developed a much more granular system of mapping markers to blood samples. They came up with 10 markers distributed across three categories (tumor-specific, tumor-associated, and tumor-growth) and eventually fine-tuned the system for a sensitivity level, including the ability to detect early stage cancer, of 80-91 percent, with a higher accuracy of around 84-85 percent. Kobayashi's tumor marker combination assay (TMCA) is twice as sensitive as the PET (positron emission tomography) examination. Although a sophisticated technique, the TMCA is not expensive. Its universal adoption by physicians would usher in an age of cancer primary prevention and recurrence prevention -- an age of few cancer victims and of a world nearly cancer free.

Kobayashi achieved a major breakthrough in developing the new marker system with the discovery that tumors appear to grow in a way similar to human fetuses and possess a similar structure. The fetus develops in the placenta, which develops from the chorion's vascular fingers. In a cancer you have the abnormally multiplying cell, cancer vessels and the "placenta-like" stroma acting as a framework for its growth. With this similarity in mind, Kobayashi and his staff set out to identify markers that would indicate not only the presence of the cancerous cell, but also its two supporting components.

Release of their findings in 1986 caused a stir in the medical fraternity. Kobayashi, in the spotlight as an independent thinker, was now someone to be watched. In response to the skepticism of the medical establishment, Kobayashi submitted to a double-blind test of his marker system by the National Cancer Institute in the USA. In 1988, the Institute arranged to send him 360 samples of blood serum from the Mayo Clinic's Blood Repository.

The samples consisted of 40 early-stage colon cancer patients, 30 benign colon cancer patients, and 50 healthy control subjects. Kobayashi was able to correctly identify the presence of cancer in 87.5% of the samples. The conventional method, Kobayashi explains, is commonly accepted among most doctors as only being able to detect early-stage cancer 20% of the time, the most common of these methods being CEA.

Hyperthermia and Holism

A voracious reader, Kobayashi studies medical journals from around the world, and he has found that there are many cases of spontaneous cancer regression. He came up with a mimic technique of systemic hyperthermia using pyrogen release to induce fever episodes. Purchased from Chugai Pharmaceutical, he used picibanil, a strain of streptococcal, infused intravenously to raise the patient's temperature and bring about systemic hyperthermia.

But perhaps Kobayashi's biggest epiphany came in 1984-86, when he analyzed serum samples from the Mayo Clinic, in Minneapolis, USA, and discovered a new complex tumor marker and multivariate analysis formula. Next he developed a technique to enhance the body's natural healing power using a combination of heat treatment and autonomic nervous system adjustment.

Kobayashi's advocacy of an integral treatment, combining conventional Western medical treatments, thermal treatment, negative ion treatment, and tumor markers, as well as Eastern traditions, some with a 5,000-year history that include diet, herbs, massage, acupuncture, and moxibustion, has met with criticism by some members of the JMA. Kobayashi has made the controversial claim that his holistic medical treatment can cure some 70 percent of all his cancer patients, even if they are in the last stage of the disease.

By the mid-90s, after a lot of publicity and establishment affirmation of his work, Kobayashi was doing well. He had treated more than 20,000 early-stage patients, and more than 2,000 mid-to-latter stage patients who subsequently went into long-term remission. The latter were truly living proof of his work. Indeed, in 1999, a famous medical journalist, Koichi Niwa, reported in the July 18, 1999, edition of the magazine "Weekly Yomiuri" that Kobayashi's cancer treatment was number one in Japan.

But two months after Niwa's piece in the "Weekly Yomiuri" that all changed, owing to one particularly damaging event. Whether from professional jealousy or some deeper reason, a trusted colleague removed a PC, chock-a-block with patient data, from Kobayashi's clinic. The individual then asserted that Kobayashi had not treated the volume of patients claimed. Since most records were in data format, Kobayashi only has a partial record of that period.

Kobayashi's credibility was damaged, which fanned criticism by the JMA. His patient referrals plummeted, but Kobayashi was determined to continue his treatment of cancer patients, and began receiving referrals from overseas clinics. Such referrals now account for about 40-50 percent of his patients, and even wealthy elites are turning to Kobayashi for treatment, such as the wife of a wealthy Southeast Asian high-tech entrepreneur, who started his program in November 2005.

Attracting Attention in the States

Basically, Kobayashi is tired of fighting off JMA criticism -- energy he feels could be better spent treating patients -- and is seriously considering packing up his lab, his clinic, and his notes, and going elsewhere. Such a location could well be Arizona, USA, the site of a number of nationally famous alternative cancer clinics and a nest of supporters for Kobayashi's therapies. One of these supporters is the founder of the Arizona-based Gordon Research Institute, Dr. Garry Gordon, who is no stranger to controversy and legal dueling with medical organizations such as the AMA -- many of which he has won.

At 71, Gordon is somewhat of a guru in the alternative medicine cancer-treatment field. "Dr. Kobayashi is a giant in the overall picture of cancer detection and treatment," he commented. "Based on his research...in the future, we will be able to run a test on a single spot of saliva, and using genetics and Kobayashi-style markers, be able to tell what the risks of cancer are...we all have cancer in our bodies, and it's really just an issue of whether or not that cancer is aggressive or nonaggressive...Koba-yashi has given us the ability to be able to measure and monitor cancer from its earliest stages."

I asked Gordon what he thought of Kobayashi's program of linking marker monitoring with diet and lifestyle treatments. He replied that if patients adopted sound suggestions for behavioral modification, the results would let them "see for themselves how diet and lifestyle and cancer are closely connected. We need Dr. Kobayashi's system here in the USA. There are many patients who would be willing to use it."

In fact, according to Dr Frank George, of the Integrative Medical Healing Center, in Scottsdale,

Arizona, and Rudy Dragone, a Scottsdale businessman, a 300,000-strong association of American firefighters would like to adopt Kobayashi's tumor marker combination assay (TMCA) and cancer prevention program.

So is Kobayashi an eccentric or a man ahead of his time with regard to treating cancer? His standpoint is that he sends it into remission, after which he puts the patient on a calendar of tumor marker checks, to make sure that it isn't becoming active again. Also, his various treatments, while unconventional when first introduced, are starting to make their way into the mainstream. Since 2002, thermal heating has been used experimentally as an improved way to get chemotherapy drugs into the body in the USA. Kobayashi, of course, prefers the use of healing herbal medicines to toxics, but at least the mechanism is the same as his.

Recently the Nikkei reported that a new form of gene testing has been found to be effective as an indicator of the early stage of colon cancer. The research is being done by Tokyo University, which has identified 40 genes out of a sample of 38,500. The genes, extracted from colon tissue samples, appear to indicate a very early stage cancer. The university group is saying that the new test is 90.9 percent accurate in detecting ulcerative colitis, which will develop into colon cancer. The news made me think that the combination of gene testing and Kobayashi's tumor markers would be effective in providing both accuracy and sensitivity.

Generally speaking, one out of three Japanese suffers from cancer by their 74th year, paying an average of \$140,000, and for the 70 percent of those for whom cancer becomes fatal, they have just waited out their time left while suffering with the disease. Compared with Kobayashi's TMCA methods for primary cancer prevention, it's possible that those same patients would pay just \$20,000 and live free from cancer and other diseases for another 20 years.

Kobayashi's methods are attracting attention not only in the USA but also Singapore, Australia, Korea, China and Thailand. Dr. Garry Gordon's discription of Kobayashi as a 'giant' of integrative medicine was validated in November 2005 when Kobayashi received an invitation to speak at the Anti-Aging Medicine World Congress, a gathering of more than 3,000 physicians from around the world, in Paris in March 2006. Kobayashi's lectures will include "The Complete Method of an International Expert in Curing/Increasing the Survival of Cancer with Alternative Therapies", "New Successful Methods of Prevention and Treatment of Cancer: Efficient Improvement of Survival of Cancer Patients by Alternative Treatments; Concrete Examples of Long-Term Surviving Cancer Patients", and "How to Survive Cancer Much Longer: The Keys to Medical Success". JI

If you want to live free of cancer, to suppress cancer recurrence or know someone who does, and would like to try one of the world's top alternative treatments, please contact Dr. Kobayashi at the address below:

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The Ironic Immortality of Cancer

By Bonnie Lee La Madeleine

It is odd, almost cruel, that cancer cells are deadly precisely because they are physical examples of the unattainable -- immortality. Death is the final stage of all life. Humans who, despite centuries of effort focused on its prevention, have not yet discovered how not to die. Yet, a cancer cell has. The "death mechanism" in a cancer cell is switched off, allowing the cell to grow and influence other cells to push the same switch. These cells can rapidly crowd out "altruistic" normal cells, which die to sustain the health of their host, a large fragile, organism.

What is odder is that a cancer cell is the product of the cell's own aging. The closer we are to death, the more likely a cell will stumble upon the key to everlasting life; our own aging enables the discovery. Odder yet, after seeking ways to prevent or delay death for centuries, scientists and medical doctors are now looking for a way to repair the aging process, prevent immortality and kill cancer cells. How? According to Dr. Tsuneo Kobayashi, with whom I discussed possible approaches to defeating cancer, the first line of defense is to prevent aging in cells.

Kobayashi's method for treating, diagnosing and preventing a variety of cancers fuses various holistic approaches, from Chinese herbal medicines and nutrition to aggressive therapies and modern advances in imaging and diagnosis. He has evolved a strategic approach that pits an "at risk" cell's mechanisms for growth against its mechanisms calling for its death. This early detection and treatment system for tumors, according to Kobayashi, has yielded promising results.

How a cell becomes cancerous

Cancer cells are those in which growth and survival processes are notched up to dangerous, aggressive levels. As these cells grow and attack neighbors, they expand their territory. A malignant tumor, hungry for space and nutrients, will spread out from a region over-populated by cancerous cells. Exactly why these cells suddenly turn hostile is not well understood, nor can doctors or scientists explain why the cell and tissue systems, which typically destroy those bad seeds, fail.

Translation errors inside the cell during the duplication of proteins, including the coding of DNA, RNA, and genes, are commonly blamed for turning a cell into cancer. But this is not precise.

"Malfunction in the cell," says Kobayashi, "genetic or otherwise, that cannot be corrected is not only the most likely candidate, but the most likely clue for diagnosis and treatment."

Every cell has maintenance, repair and disposal crews. These crews seek out abnormal proteins and either repairs them or removes them by degrading the proteins into smaller molecules that can be reabsorbed. If the damage is too extensive, the crews will trigger cell death, apoptosis, to remove the entire cell from the body.

The proteins involved in protein degradation or apoptosis can be damaged or prevented from doing their jobs by mutations, or by factors that accelerate the accumulation of garbage in and damage to the cell. Oxidative stress, caused by the accumulation of toxic forms of oxygen in the cell, and problems with cell organelles, like the mitochondria, place stress on cellular clean-up crews. This build-up in the cell occurs over time, and is commonly associated with aging. This is one reason why anti-oxidants have become popular as anti-aging treatments -- they might actually remove these toxins from our cells. If the crews are overwhelmed, the accumulated garbage may also hinder the cell suicide mechanism. Tumors emerge.

Early identification of tumors

Regardless of the process by which normal cells become cancerous, as these toxic cells fatten and grow, they require more nutrients to survive. Over time, a network of blood cells and friendly neighbours start to emerge and the tumor grows into a detectable lump that until recently was one of the few clues for a cancer diagnosis. By then, more often than not, treatment is too late. Early detection significantly increases the likelihood of survival, and much research is geared toward detecting cancer-

prone and individual cancer cells long before a tumor forms. Tumor markers, such as those developed by Dr. Kobayashi, are one method of early detection.

There are currently three types of markers used to identify tumors: tumor specific, tumor associated, and growth related. Basically a tumor marker is a cloned protein, antibody or antigen that is coded to target and bind with proteins, enzymes or proteins having a specific gene, mutation, or property within a cell.

Medical doctors and researchers will use markers to search for molecules or proteins with pathological connections to cancer or tumor formation. Once the marker finds its target, it expresses itself, or makes itself visible. Expression can occur through exposure to ultraviolet light or radiation, or after a certain period of time. These expressions can be observed under a microscope (if the sample was removed in a biopsy) or by using various non-invasive imaging devices, including x-ray, optical imaging, computerized axial tomographic (CAT) scanning, positron emission tomography (PET), or magnet resonance imaging (MRI). Each of these technologies measures different chemo-electrical activity in the body, and can detect potential problems when used with special markers that label specific cells, proteins or other molecules.

"In order to identify pre-clinical cancer risks and proto tumors," explains Kobayashi, "I developed and refined several markers for tumors." His claims that a battery of ten markers, listed below, have a high degree of specificity and sensitivity toward various indicators of tumor development. These are used in combination with a weighted calculation based on the level of importance and the interrelationship of various processes associated with tumor development. The markers attempt to identify and isolate a variety of cell growth factors, like IGF, and the lack of proteins associated with cell death or protein degradation, like caspases that trigger death or heat-shock proteins (HSPs) that start the processes for protein breakdown.

Kobayashi combined individual marker results with a computerized algorithm in order to identify patterns between various marker activities that he uses to identify the patient's tumor stage: tumor free, pre-cancer stage A, pre-cancer stage B, pre-clinical cancer, and tumor over 1 gram, indicating possible cancer. He reports between 85 percent to 93 percent effectiveness in diagnosing the earliest stages of cancer and pre-tumor formation.

Two Duke University reports confirm the efficacy of the sensitivity and specific accuracy of Kobayashi's tumor marker findings, although there has been controversy over questions raised as to the correctness of assessment, interpretation, and acceptance of these tumor marker findings in US medical circles. Kobayashi attributes this controversy to the difficulty of interpreting and assessing marker findings without the benefit of his sophisticated technology.

Non-invasive treatment of early tumors and signs of cancer

For those cases where signs of pre-cancer or cancer probable tumors are indicated, Dr. Kobayashi prefers to use natural approaches: herbal medicines, nutrition, and hyperthermia (or heat therapy). Growing up in an isolated community where doctors were called only when truly ill, Kobayashi was able to observe his mother's use of herbs and traditional healing treatments that most medical practitioners ignored.

"I learned to value what others rejected and observed benefits in many Chinese medicines and foods that I believed would boost a body's efforts to heal itself." Accumulating evidence about how the body's immune system responds to stress, heat and anti-oxidant treatments suggest that these three methods work to boost immunity and strengthen a cell's defense against aggressive assaults.

Chinese traditional medicine, Kampo

The use of extracts from various plants has been practiced almost continuously in Japan since the

Japanese first encountered the Chinese. Observations of cancer patients using these medicines suggested that some of the compounds increased the effects of chemotherapy and, therefore, a patient's chances of recovery. Shosaiko-to, in particular, can stimulate cytokine and up-regulate apoptosis in tumors; in other words, it can push the tumor cell's self-destruct button. Other Kampo treatments have been used to treat fatigue and other symptoms associated with chronic disease or to demonstrate an immunoprotective benefit for cancer patients. These compounds probably do not work directly on the cancer cell, but through the body's immune system, by stimulating white blood cell activity and retarding growth enzymes in or around the tumor. Dr Kobayashi believes that using these medicines prior to the appearance of more intractable tumors and metastasis should be equally, if not more, beneficial in preventing proto tumors and young tumors from maturing.

Hyperthermia

Radio waves or ultrasound waves are bombarded to skin or near surface tumors, subjecting them to sustained high temperatures, between 36° C and 42° f C for at least an hour. Tiny probes are used for deeper tumors, but the necessity to maintain constant temperatures makes the probes less effective than surface applications. High temperatures restrict oxygen to the tumor and stimulate cellular garbage systems that kill or shrink tumors. Using heat to kill or reduce tumors in combination with radiation or chemotherapy is gaining acceptance, and a clinical study in the United States to ascertain the merits of heat in treating tumors is underway. But, here too, the signs are promising.

Dr. Kobayashi claims to have kept over 15,000 patients free of cancer using this early detection system in combination with non-invasion methods of treatment during the pre-clinical cancer and 1-gram-tumor stages.

Dr. Kobayashi's approach to cancer prevention and treatment is more holistic than targeted, and therefore, may not actually be a cure-all for cancer. Yet, we know that proper nutrition and regular medical examinations are essential to early diagnosis and better prognoses of a host of illnesses. The doctor has designed a system that can identify immortal-leaning cells that could wreak havoc in the body and that might also retard aging. There is a clear link between good nutrition and effective immunological activity, which declines with age. By strengthening the immune system, it will be able to mount a stronger attack against cancer cells and induce apoptosis. Cure or prevention? If you have to gamble, prevention offers a better payoff.