HEALTH AND STRESS

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WHY THE BASIS FOR LIFE AND HEALTH IS ELECTRIC

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"*I sing the body electric*" wrote Walt Whitman in his 1885 *Leaves of Grass*, but what was he referring to? It was obviously not the the electric current that would later be used to provide light and radio communication. Nor was it the electric shock from certain fish that had been known since antiquity. Egyptian papyri from 2750 B.C. had alluded to these as the "Thunderers of the Nile", suggesting that they believed this force was in some way similar to the energy in a bolt of lightning. Greek and Roman physicians later used the shock from torpedo fish (electric rays) to treat headache and other pains.

Also Included In This Issue

But Whitman's poem had nothing to do with these electrical bodies. It was rather a paean of praise for the wonders of the male and female human body. He was in awe of how perfectly they had been constructed and their ability to give new life. He believed that our physical bodies were just as important as our souls and that the two could not be separated.

Whitman, who was called the "father of free verse, is considered by some to be the greatest English poet since Shakespeare. His quixotic use of words was once described as "wild, raging, soaring, lunatic language". *Leaves of Grass*, the title of his book is a good illustration, because it had nothing to do with either leaves or grass. It was more of a pun, since at the time, "grass" was a term given by publishers to works of minor value, and "leaves" was another name for the pages they were printed on. Similarly, since poems were almost always chanted or sung in ancient times, to "sing",

originally meant to praise or celebrate something or someone in verse. And "body electric" probably meant "exciting", "energetic" or "thrilling", e.g. " I praise the thrilling aspects of the human body".

Another interpretation is that "electric" meant "full of potential" like the primitive battery Alessandro Volta had invented, which led to our present concept of electricity. In 1786, Luigi Galvani, an Italian professor of medicine, was slowly skinning a frog at a table where he had been conducting experiments with static electricity by rubbing frog skin. His assistant happened to touch the exposed sciatic nerve of a dissected frog with a metal scalpel that caused a spark and the leg to kick as if it were alive. Galvani thought that the muscles of the frog contained an electrical fluid carried by nerves, which he called "animal electricity. His colleague, Alessandro Volta, disagreed, since after many similar experiments, he concluded that this response was due to the fact that the moist specimen had come into contact with two different metals – the tin plate it was on and the steel knife that touched it. He later showed that this happened when he used other different metals when there were tissue juices between them. With certain combinations of two different metals, the response was even greater, which led to the invention of the first battery in 1800. Volta made this electric storage device by using sheets of copper and zinc separated by cardboard soaked in brine, and stacking 15 or 20 of these little metal sandwiches on top of each other. When the copper top of the stack was connected to the zinc bottom with a wire, an electric current would flow through the wire. This "voltaic pile" as it was referred to, created a new kind of electricity that flowed steadily like a current of water, instead of discharging itself in a single spark or shock. The more metal sandwiches in the pile, the stronger the current, which is why the unit of electrical potential is called the volt. It is important to recognize that electricity was thought to be a fluid that had a positive or negative charge, as a French mathematician had explained in an 1803 book that actually used the phrase "body electric":

> But the friction of certain bodies, glass for example, collects on the surface of them a greater quantity of the fluid; so that if the glass be in contact, or very near to a body electric by communication, such as a mass of iron, the fluid accumulated by the surface of the glass tends to pass into the iron in order to preserve equilibrium. By these means, the mass acquires a greater quantity of electric fluid and is then electrified *positively*. But if the electric body, instead of acquiring by friction a greater quantity of the electric fluid, loses some of what it had, as is the case with sulfur, the body in contact with it will lose part of its natural electricity, and would then be charged *negatively*. The one will have more electric fluid than it has in its natural state, and that of all the bodies which have a communication with the earth; the other will have less. Such is the nature of *positive* and *negative* electricity.

The Latin adjective, *electricus*, meaning "of amber" was created by William Gilbert in his 1600 book *De Magnete*. In it, he clarified the difference between the force that attracts feathers when amber is rubbed, and the seemingly similar power that made iron filings cling to a magnet. The Chinese had used lodestones (magnetic stones) for over a thousand years to determine direction, since they always pointed north. By Gilbert's time, compasses using a magnetized needle of iron or steel were in common use by explorers and seafaring vessels as a navigational aid. Gilbert showed that this was because the earth itself was a giant magnet, with magnetic North and South poles that were fairly close to its geographic poles. The earth's magnetic field permeated the atmosphere, such that if a railing fence made of iron faced north and south, it would eventually become magnetized.

Frankenstein, Michelangelo's "Spark Of Life" And The Reanimation Chair

Whitman also thought that there were powerful parallels between the electrical energy in the body and similar forces in nature that might supplement this, or have healing powers. The latter belief was well entrenched at the time, since the British poet John Keats had written "There is an electric fire in human nature tending to purify" and Mary Shelley's novel, *Frankenstein*, was very popular. It described how a creature constructed from cadaver parts was given life by the electricity from a bolt of lightning. Support for this had already come from Benjamin Franklin's kite experiments showing that lightning was a form of electricity, since a key attached to its string would draw sparks. And when the string was attached to an empty Leyden jar, a device that stored static electrical charges, it became full after a thunderstorm. Some theologians felt that Frankenstein's creation was sacrilegious, since Genesis states "God formed the man of dust from the ground and breathed into his nostrils the breath of life, and the man became a living creature." This is echoed in Ezekiel, where God resurrects dead bones by his life-giving breath. In the New Testament, Jesus breathed in the faces of his disciples, telling them that they were receiving the Holy Spirit, and that "If you forgive the sins of any, they are forgiven them; if you retain the sins of any, they are retained", and this power was passed down to all ordained priests. Although it was different than the "breath of life", Egyptian Coptic priests still breathe on the faces of infants during baptism saying, "Receive the Holy Ghost", and are ordained by the reigning bishop's breathing on the new prelate’s face. In Egyptian mythology, *Kneph*, which meant soul-breath, was a spirit who could convey or instill the breath of life and was usually depicted as a ram. The Egyptian word for ram was *ba*, which was also a major component of their concept of the soul. This is similar to the life force the ancient Greeks called *Pneuma*, which not only referred to air, breath and wind, but also "spirit” and "soul". In the Hindu tradition, God, *Prana*, and Divine Consciousness are one and the same, which is why *Prana* is also called "the Breath of God".

The word *electricus* would not be coined by Gilbert until a century later, but Michelangelo's 1511 depiction of the creation of Adam on the ceiling of the Sistine Chapel seems to have anticipated this. It is also more consistent with *Job* 33:4, in which God first creates man and then breathes into him the breath of life, in order to give him a human soul.

Michelangelo's version showing the three quarter inch separation between the two finger tips is probably the most famous detail in Western art. It suggests a transfer of some invisible energy from God To Adam. Some scholars believe this may have been inspired by *Veni Creator Spiritus* (Come, Creator Spirit) a ninth century hymn that asks the *digitus paternae dexterae* (finger of the paternal right hand) to give the power of speech to the faithful. It is usually sung as a Gregorian chant at dedications, ordinations, and other solemn occasions, such as the entrance of Cardinals to the Sistine Chapel to elect a new Pope.

While this mural is traditionally called the "Creation of Adam", many believe the "Endowment of Adam" would be more appropriate. Adam is obviously already alive as he lies partially sitting up, eyes open, waiting to receive something from God that Michelangelo would later refer to in his sonnets as "intellect". By this he meant not only intelligence and spirit, but also creativity and the ability to remember. He understood that his superb skill in sculpture and painting came not from his hands, but his brain. His magnificent knowledge of anatomy came from meticulous dissections of human corpses, so it is not surprising that the image that surrounds God with his left arm around Eve's forehead surrounded by angels, has the shape of a brain. The bilobed pituitary gland and its stalk are depicted by the foot and leg of the angel that extends below the base of the picture, and the

flowing green robe at the base represents the vertebral artery. Neurophysiologists point out that God's right arm extends to the prefrontal cortex, the most creative region of the brain, and below the right arm is a sad angel in an area that is often activated on PET scans in people who are depressed. God is also superimposed over the limbic system, the emotional center of the brain. Michelangelo was unaware of electricity, but believed there was a divine spark that originally came directly from God, which infused and inspired Adam, and was transferred to his descendants.

It was not until 1801, that the British painter and art critic, Henry Fuseli, suggested that Michelangelo had predicted an electrical "spark of life". He observed how "the Creator, borne on a group of attendant spirits, moves on toward his last, best work... the immortal spark, issuing from his extended arm, electrifies the new-formed being, who tremblingly alive, half raised half reclined, hastens to meet his maker". Electricity was very much in the air since it had become an important field of research and a fashionable form of entertainment. Galvani twitched the legs of dead frogs with a spark from his electrostatic generator and showed that when he suspended them with brass hooks from an iron railing, they all jumped in unison whenever there was lightning, and before any thunder was heard. His assistant, Giovanni Aldini, toured Europe showing how he could make the legs of dead animals move and kick, or their ears wiggle and eyes blink on their amputated heads when electric shocks were administered from a crude voltaic pile. In England, he had access to the corpse of a murderer one hour after execution, and he demonstrated how he could make his dead man's legs move as if he was walking or lifting a fairly heavy weight. The results were so impressive, that many thought some people who had suddenly died could be brought back to life if ample electricity could be applied to the correct body sites shortly thereafter. There were various devices, such as the Reanimation Chair of Dr. De Sanctis, shown below from Richard Reece's 1820 *Medical Guide*.

The chair had three main parts: a bellows to give forced ventilation; a metallic tube to be inserted into the esophagus; and a voltaic pile battery that was hung on the back of the chair, with a wire from one pole to the metal esophageal tube, and from the other pole, to an electrode that which was then successively touched to the "regions of the heart, diaphragm and the stomach" in an effort to stimulate those structures. The bellows was inserted into the mouth, the nose was clamped shut with a forceps, and an assistant pressed on the chest to cause expiration after each ventilation with the bellows.

These items and accessories were packed in a small piece of luggage that could be carried around. Although it is not known if there were any successful resuscitations, this modified CPR therapy could have acted as a temporary pacemaker or defibrillator for patients with certain arrhythmias. Further evidence that electicity gives the gift of life is that cloning is not possible unless a minute electrical impulse is applied to an unfertilized ovum to make it fuse with a donor cell. Successive electrical pulses are then required for it to accept the new nucleus as its own, and again to trigger biochemical activities that jump start the process of cell division and growth. Thus, electricity is literally, as well as figuratively, "the spark of life".

The Rise And Fall Of Electrotherapy To Treat Diseases And Enhance Health

Interest in electrical therapies steadily expanded. An induction coil with sponge tipped electrodes was used to treat arrhythmias and angina in 1853, and as batteries steadily improved, various types of "medical coils" were developed for different purposes. In the 1880s, Edison electrified Manhattan and installed generating stations in cities in New York, Massachusetts and Pennsylvania, and by the turn of the century, electric lighting had now spread to numerous cities. Medical textbooks were devoting chapters to the use of magnetism and electricity to treat neurological and emotional disorders and electrotherapy was viewed as a legitimate medical specialty much like the growing fields of radiology and radium therapy. Various electrical energy emitting instruments were being used by over 10,000 physicians and many others to treat anemia, hysteria, convulsions and neuralgia, to insomnia, migraine, arthritis, fatigue and any type of pain. ranging from amnesia and hysteria to insomnia and epilepsy. There were devices with names like "The Dynamiser", and "Oscilloblast", based on theories that each organ and individual were "tuned" to specific wavelengths that could be applied to rejuvenate them or cure cancer.

Many such devices disappeared following the 1910 Flexner Report on medical education initiated by the AMA, which castigated these and many other widespread abuses in medical practice. It found that only 16 out of 155 medical schools required applicants to have completed two or more years of college education. Many were merely small, profitable trade schools owned by doctors not affiliated with any recognized academic institution. A degree was awarded after only two years of study that often did not require any dissections or laboratory training. Instructors were typically local doctors who taught part-time, and whose own training and teaching qualifications left much to be desired. Flexner urged the AMA to mandate that admission to medical school require a high school diploma and at least two years of college primarily devoted to basic science. There should be four years of medical school that included anatomy, physiology, chemistry and pharmacology courses. These recommendations were swiftly adopted with

dramatic results. When the study began, there were 160 M.D. granting institutions with more than 28,000 students. By 1920, there were only 85 such institutions with 13,800 medical students and by 1935, there were only 66 accredited U.S. medical schools. Flexner felt that "alternative" medical practices such as osteopathy, chiropractic medicine, naturopathy, homeopathy and eclectic medicine that used botanicals should not be taught since they had no scientific validity. Medical schools were told to drop them from their curriculum or lose their accreditation and any Federal or state financial support and all of them eventually complied, closed or established a facility devoted to one or more of these practices.

Regulation of doctors and drugs by state governments was minimal or nonexistent. Shysters sold cure-all "patent medicines" with high alcoholic content fortified by morphium, opium and/or cocaine from the back of their trucks as they traveled from town to town with their Medicine Shows. These usually featured shills claiming remarkable results, and there is little doubt that these high alcoholic narcotic laced products provided temporary relief of pain and other complaints. But they could be disastrous or even lethal when given to treat colic in infants, and sometimes led to addictions. The 1906 Pure Food And Drug Act forbade the manufacture, sale, or transportation of adulterated food products and potentially poisonous patent medicines. It also required that alcohol, cocaine, heroin, morphine, and cannabis be accurately labeled with contents and dosage. However, these drugs continued to be legally available without a prescription as long as they were labeled. The regulations were difficult to enforce, especially for physicians, many of whom now made and sold their own concoctions for different disorders, so it is not surprising that the term "quack" became popular. And since there was no scientific rationale to support the claims made for electrotherapy devices, physicians who used them were also considered to be quacks. Not included were x-ray diagnostic instruments or electrocautery treatments, since these had proven benefits. Unlike food or drugs, there was little if any regulation of medical devices until 1976, when the FDA defined what was included under this heading and classifed them into three categories based on their safety risk and need for regulatory oversight.

The modern era of electrotherapy began in 1958 with pacemakers developed by Earl Bakken and defibrillators by Bernard Lown to correct heart rhythm disturbances. Norman Shealy introduced dorsal column stimulation for the treatment of pain in 1967, and transcutaneous electrical stimulation (TENS) seven years later. Margaret Patterson found that small pulses of electric current administered across the head induced a feeling or relaxation, and in 1972, showed how her "NeuroElectric Therapy" (NET)" reduced the stress of acute and chronic withdrawal from addictive substances. Daniel Kirsch as well as Saul Liss subsequently found that electrical brain stimulation could

augment the analgesic effects of TENS. In addition, it was also effective for relieving insomnia and depression. Around 1981, they each developed what are now called craniotherapy electrical stimulation (CES) devices for the treatment of pain, insomnia and depression that are still in use.

My Cranioelectrical Stimulation Odyssey: From Skeptic To Crusader

My interest in cranioelectrical stimulation and electromagnetic therapies was kindled in 1983 when I was asked to evaluate the use of the Symtonic Low Energy Emission Therapy (LEET) device for the treatment of insomnia that had been developed by Swiss scientists. At the time, I was a consultant to the Biotonus Clinic in Montreux Switzerland, whose Director, Claude Rossell M.D., Ph.D., had been involved in clinical trials that appeared to confirm claims for efficacy and safety. I was somewhat skeptical, since there was no apparent rationale or mechanism of action to support this. By coincidence, I had been invited to participate in a week long conference entitled "Electromagnetic Fields And Neurobehavioral Function" being held in Belgium the following August. It was conducted in a former monastery in Priorji Corsendonck, a remote and secluded area of Belgium, and since there was nothing nearby to visit, everyone spent their meals and evenings together. It was here that I first met and developed a life long close friendship with Dr. Ross Adey, and we spent most of our spare time together. I was aware of his prior studies of the effect of weak electromagnetic fields on behavior in animals, and his conviction that this could have important clinical implications. He had shown that Extremely Low Frequency (ELF) waves could pass easily through the skull to produce predictable EEG changes in monkeys, and since very little heat was generated, there were no observable physical effects. He had also implanted transmitters in the brains of cats and chimpanzees that sent signals to a receiver that displayed varied electrical activity patterns. Based on this information, he could send back specific radiofrequency signals that allowed him to control the animal's behavior to conform to whatever he wanted.

He told me about the research of Dr. Jose Delgado, a Yale neurophysiologist, who implanted tiny wires and electrodes in different parts of the brain and then stimulated them to see what emotional or physical changes occurred. His goal was to change the patient's mood, so that those who were depressed perked up and anxious ones were calmed down. He later developed his "stimoceiver"; a quarter size chip that could be operated by remote control after it was inserted in the head. For several years, he experimented on monkeys and cats, and found he could make them yawn, fight, play, mate, and sleep by remote control. He was particularly interested in managing anger and began to experiment with Spanish bulls by implanting stimoceivers into several, and testing his equipment by making them lift their legs, turn their heads, walk in circles, or moo 100 times in a

row. His most famous experiment that made international headlines in 1963 was stepping into a bullring in Cordova, Spain, with a ferocious charging bull named Lucero, who was notorious for his temper. Delgado had never fought a bull and had no sword for protection, but when Lucero barreled towards him, Delgado tapped his remote control and brought the animal to a screeching halt. He tapped his remote control again, and the bull began wandering around in circles, oblivious to his presence. This groundbreaking advance in cranioelectrical stimulation paved the way for current neural implants that help patients manage conditions ranging from Parkinson's disease, epilepsy, pain, tremors and dystonia, and are being explored for use in depression and other disorders.

Ross Adey's presentation dealt with the role of the cell membrane in the detection and transductive coupling of oscillating electromagnetic fields, and delineating the activation of intracellular systems responsible for amplifying these signals. It seemed far removed from my assignment that was the concluding talk, in which I had been asked to summarize previous speakers' findings with respect to their future implications for clinical medicine. The title that I had been given for this was "Electromagnetic waves and neurobehavioral function: comments from clinical medicine", and although I had made copious notes, thought it would be an ideal opportunity to discuss the Symtonic device before this distinguished audience. Adey urged me to do so, as did others from the U.S. including Carl Blackman, another pioneer in ELF stimulation from the EPA, and Yale's Eleanor Adair, an authority on thermoregulation and microwaves. I felt it would be best for Dr. Rossell to present this in case there were technical questions I could not answer, as well as to demonstrate the device. After discussing this with the sponsors, who agreed, l called him and he immediately arranged to join us for the final day of the conference to report on his latest findings.

His presentation was very stimulating, since he had some new supportive data. Ross Adey was particularly intrigued with Symtonic's novel delivery system and its ease of administration and asked several stimulating and critical questions. Dr. Rossell was impressed with his extensive knowledge and experience with both the basic science and clinical aspects of extremely low frequency field therapies and we both felt he would be a valuable consultant. Dr. Rossell subsequently proposed that we organize an annual International Montreux Congress On Stress under the aegis of the American Institute of Stress that would include sessions dealing with relevant advances in electromedicine. I was given carte blanche to select the speakers and topics, and the Congress would be conducted at the five star Grand Excelsior Hotel adjacent to the Biotonus Clinic, which provided all the funding for speaker accommodations, airfare and honoraria.

At our first 1988 Congress, Dr. Boris Pasche provided an update on the Symtonic device, which emits a carrier frequency of 27.12 MHZ that is modulated at specific frequencies between 0.1 and 90,000 Hz. delivered by an electrode applied to the roof of the mouth, as illustrated below.

Left – The Walkman size battery-powered emitting box (1) connects to a coaxial cable (2) that ends with a spoon like electrode (3) that is applied to the roof of the mouth. In addition to insomnia, Symtonic has also been found to be effective in treating anxiety states (4) using a different frequency program. Center – patient before treatment. Right – during treatment.

Other presentations at our 1988 Congress included one by Saul Liss on CES effects on brain neurotransmitters and Björn Nordenström's very successful electrochemical treatment of pulmonary metastases and his theory of an electrical circulatory system. They have provided updates on all of these at subsequent Congresses, in addition to presentations on Neurostimulation for addictive disorders (Margaret Patterson), Alpha-Stim CES (Daniel Kirsch), CES for electrosleep and stress relief (M.T. Haslam), CES for multiple sclerosis and migraine (Martha Lappin), Gigatens stimulation (Norman Shealy), deep brain stimulation for Parkinson's disease (Bridget Duffy), rTMS for drug resistant depression (Mark George), and others from German, Russian, Eastern European and Asian scientists. Ross Adey has also made valuable contributions to almost all of these events.

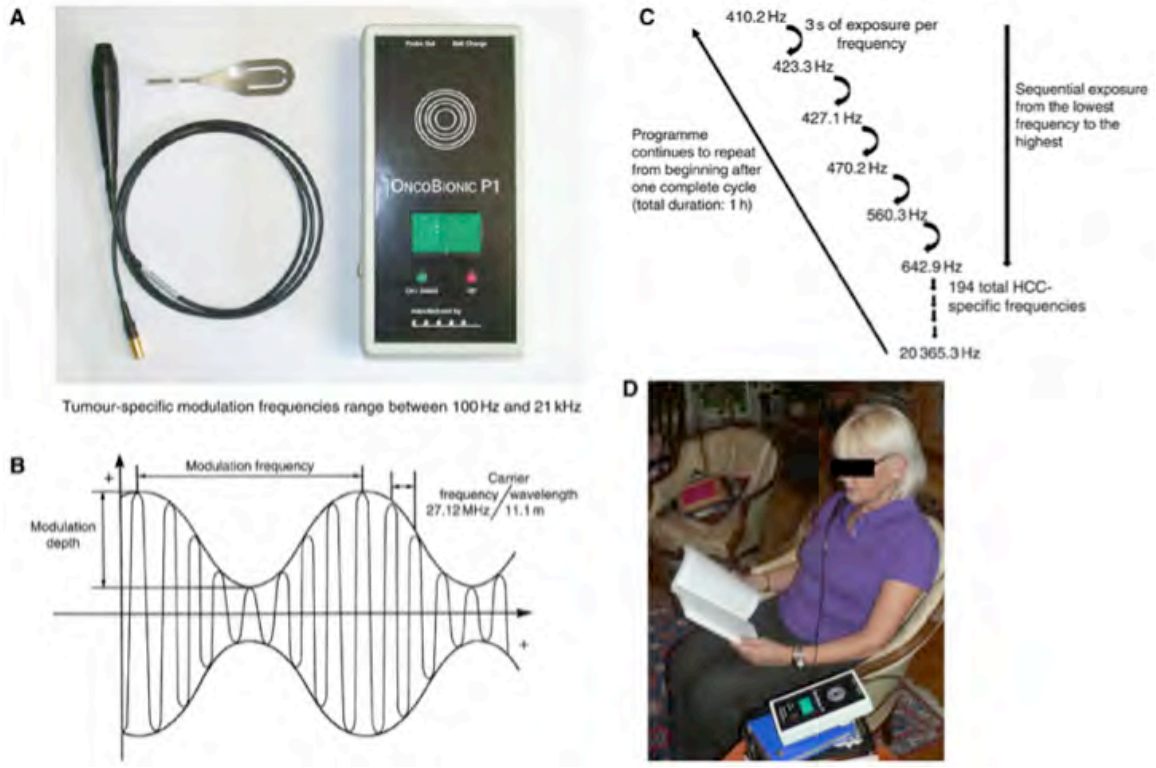
Since our first Congress, the Symtonic device has been shown to be effective for the treatment of insomnia in two polysomnography studies at leading sleep centers, in double blind and crossover trials, and to reduce anxiety, in papers published in peer reviewed journals, including *The New England Journal of Medicine* as well as authoritative texts. Treatment is non-invasive, painless, varies from 15-30 minutes twice a day to three times a week, has few, if any side effects, and is completely safe. Levels of absorbed electromagnetic energy are approximately 100 to 1,000 times lower than those generated by handheld cell phones. The programming of the Symtonic device has been progressively refined to improve its efficacy and to explore other applications. One of these was the discovery of groups of frequencies

that were specific for certain cancers. The number of frequencies varied from 2 for thymoma, to 278 for ovarian cancer. In a small pilot study of 28 patients in Brazil and Switzerland, one patient with breast cancer, that had spread to the pelvis and adrenal, had limited mobility due to excruciating hip pain that was not relieved by large doses of opiates. She had previously been treated with radiation, five different hormonal protocols, as well as chemotherapy, which had to be discontinued because of severe side effects. Within two weeks of treatment with breast cancer-specific frequencies, her pain completely disappeared and her general condition improved. Imaging studies obtained three months later showed a complete disappearance of her metastatic lesions, and she remained symptom free without the need for any pain medication for 11 months. Another patient with treatment resistant breast cancer that had spread to her liver and bones had a partial response lasting 13.5 months. None of the patients suffered any significant side effects and most noted perceptible improvement.

Determining the various frequencies that are specific for each tumor is a tedious process involving feedback of several parameters, and over 1500 different frequencies were identified in this report. While the majority were specific for one type of tumor, some applied to more than one. Therapy is based on a trial and error approach that requires periodic monitoring to evaluate responses, which may necessitate changes in the protocol. Another option would be to administer all the frequencies that may be effective in a manner that insures adequate exposure to those that are optimal. It now appears that this approach may be a major breakthrough for inoperable liver cancer, which is notoriously refractory to radiation and chemotherapy, and has an **average survival time of 3 to 6 months**. Hepatocellular carcinoma (HCC) is the second leading cause of cancer deaths in men worldwide and is the most common malignancy in parts of East Asia, Africa, and certain South American countries. While less frequent in Europe and North America, it has become the fastest rising tumor in the U.S., with a 27% increase since 2004. This may be related to the rising rates of Hepatitis C, which is the most common blood borne illness and reason for liver transplantation in developed countries. Hepatitis C infection, the most frequent cause of liver cancer, now affects 4 to 5 times more people than HIV, and there is no effective vaccine.

In a very recent study of 41 patients with terminal liver cancer treated with CES published in the June issue of the *British Journal of Cancer*, researchers reported that 10% of patients had a 30% or more shrinkage of their tumors. By comparison, only 2% of patients treated with Sorafenib, the current drug of choice, had a similar response. Eight patients receiving CES either saw their tumors shrink, **survived for longer than two years,** or both. Of the 11 patients reporting pain prior to CES therapy, 5 reported a complete disappearance and 2 said it had decreased soon after treatment began.

Therapy is delivered in the same fashion as that previously described for the Symtonic device, but the program is quite different, since 194 frequencies in the 100Hz to 21 kHz range specific for liver cancer had now been identified. (Insomnia frequencies range from 2 Hz to 200 Hz). In this new Therabionic CES treatment program, all 194 frequencies are used in ascending order and this sequence is constantly repeated. The Symtonic device has been replaced by the OncoBionic PI, as explained below.



Delivery of Hepatocellular Carcinoma-Specific Modulation Frequencies

(A) The source of amplitude modulated electromagnetic fields is a battery-driven radio frequency electromagnetic field generator connected to a spoon-shaped mouthpiece. (B) Schematic description of amplitude modulated electromagnetic fields. The carrier frequency (27.12 MHz) is sinusoidally modulated at specific frequencies that have been programmed in a specific order. (C) The liver cancer treatment program consists of sequential emission of 194 modulation frequencies for 60 minutes. (D) Patient receiving Therabionic stimulation therapy.

(Revised legend adapted from *British Journal of Cancer*, (June 2011) 105: 640 – 648.)

Patients are treated for three one-hour sessions a day at home, during which the radiofrequency generator runs through 194 different modulations, beginning with 410 Hz and rising to 21 kHz as illustrated in (C). Each lasts three seconds, and at the end of the cycle, the sequence repeats itself. Patients feel nothing during treatment and (D), can read or watch TV.

"We believe this treatment has great potential and will be explored for other types of cancer," the lead author told reporters. He also described how **one of his breast cancer patients with metastases to the adrenal gland and bone, had a "complete response" after 11 months of treatment.** Although this was with a different set of frequencies, they were in the same range as those used for liver tumors and delivered with the same device. Specific frequencies for brain, breast, ovarian and prostate cancers have now been elucidated, and Therabionic trials for these are planned. There is also anecdotal evidence that Alpha-Stim may have anti-cancer effects (See http://www.thebyway.org/ for a physician's compelling personal account) and the FDA recently approved the NovoTTF-100A (24/7 CES with four electrodes) for the treatment of certain brain tumors.

The last phase of my CES odyssey occurred earlier this year, when I met with the upper echelon of physicians and scientists at the National Intrepid Center of Excellence (NICoE) in Bethesda to discuss the growing problem of accurately diagnosing and treating post traumatic stress disorder (PTSD). This is a major source of disability and expense to the Department of Defense (DOD). It is well established that the current treatment of PTSD with antidepressant and antipsychotic drugs is a disaster that often worsens the quality of life for these patients and likely contributes to rather than prevents their alarmingly high rates of suicides. I had written extensively about this and also knew that the VA and DOD had used Alpha-Stim with great success for the treatment of PTSD and traumatic brain injury (TBI). I was particularly interested in NICoE, since it had recently been reported that PTSD could be diagnosed with over 90% accuracy with new magnetoencephalography imaging, and it had one of the few advanced units in the country. My objective was to develop a study to determine whether magnetoencephalography could objectively validate these Alpha-Stim benefits. I was surprised that everyone there was familiar with Alpha-Stim and several of these high-ranking officers and officials had used it personally. The response was enthusiastic and I learned that in one VA study, 75% of patients preferred Alpha-Stim to other devices and non-drug approaches. The difficulty would be the red tape involved in the lengthy approval process and funding, even though the devices were being donated. I was told privately after the meeting that there would likely be opposition from powerful pharmaceutical interests that did not want to see their lucrative contracts jeopardized. This brings me to the current problem in exploring the potential of CES devices.

Why The Government Is Hindering Rather Than Helping To Develop CES

The approval of CES devices and their marketing is under the jurisdiction of the FDA's Center for Devices and Radiological Health (CDRH), described by a former commissioner David Kessler as dysfunctional," and "in meltdown."

The Agency had been under attack by both Houses of Congress, and in November 2008, The Energy and Commerce Committee's Democratic and Republican leaders sent a letter to FDA Commissioner Andrew von Eschenbach, saying it had "received compelling evidence of serious wrongdoing" and that their findings supported removal of certain managers in the device division. This was based on a letter they had received from a group of nine FDA physicians and scientists who claimed CDRH managers "failed to follow the laws, rules, regulations and Agency Guidance to ensure the safety and effectiveness of medical devices and consequently ... corrupted the scientific review of medical devices. This misconduct reaches the highest levels of CDRH management including the center director and director of the Office of Device Evaluation. Under the banner of regulatory 'precedent,' managers at CDRH have demanded that physicians and scientists review regulatory submissions employing methods, and accepting evidence and conclusions, that are not scientifically proven and clinically validated." They also alleged that scientists who had opposed and objected to these decisions often faced retaliation from their superiors.

A similar letter was sent to President-Elect Obama's transition team in January 2009, which described the FDA as a "fundamentally broken" agency and a place where honest employees committed to integrity can't act without fear of reprisal. "There is an atmosphere at FDA in which the honest employee fears the dishonest employee." They accused managers of ordering, intimidating and coercing scientists to "manipulate data" during product reviews and urged Obama to overhaul the approval process and enact new legislation that would give protection to government employees who speak out against corruption. The FDA had previously commissioned the prestigious Institute of Medicine to look into the matter, and in its July 2011, blistering 280 page report, it berated the agency for foot dragging, noting that "After 35 years, the FDA has not completed the task of calling for PMAs or reclassifying preamendment Class III device types", noting that "Congress in 1990 directed the FDA to complete this task in a timely manner."

A PMA or premarket approval is used to demonstrate efficacy and safety by well-controlled clinical trials. The FDA estimates that **the cost of preparing a PMA is $1 Million for each CES company and that the FDA will spend $8.4 Million to review the initial PMA and then $1 Million per year thereafter to review additional PMAs.** Alpha-Stim submitted a PMA in 1995, a mandated reclassification petition 515(i) of five volumes in 1998, another 515(i) petition (i) in 2007, as well as one two months ago. None of these have been responded to. Now the FDA is demanding still another PMA, despite the fact that Alpha-Stim has been marketed in the U.S. for 30 years with an unblemished safety record in millions of patients. It is so safe that it is sold without a prescription in every other country where it has been

certified as safe and effective by regulatory agencies. With respect to efficacy, it has already submitted 144 clinical trials as well as information on 11 currently in progress. What additional proof is needed? In addition to being a waste of taxpayer money, couldn't these funds be used to better advantage by supporting other promising uses for this technology?

In her first interview as FDA Commissioner in May 2009, Dr. Margaret Hamburg emphasized that one of her main goals was to "streamline the medical device approval process". A month later, in a *Wall Street Journal* interview, she explained, "There obviously have been some problems" at the Center for Devices and Radiological Health, and correcting them would be "a high priority." To her credit, she has made changes in its hierarchy, but the old way of doing business is so entrenched that little has changed. In a recent statement to the Oversight and Investigations Subcommittee in July entitled "FDA Medical Device Regulation: Impact on American Patients, Innovation, and Jobs", Representative Joe Barton said that the present approval process not only inhibits innovation and stifles economic and job growth, but also harms the sick. "The Medical Device Review Process at the FDA has become overly burdensome, unpredictable and inconsistent under its current leadership. . . . we need a regulatory system that is predictable, consistent and open. These words do not describe the current regulatory environment at the FDA, especially at the Center for Devices and Radiological Health." What is needed most in my opinion is complete transparency. The names, qualifications and affiliations of all experts and Advisory Panel numbers should be made public, as well as how they voted on each issue, along with list of any potential conflicts of interest.

The FDA has asked for public comments on its proposed rule requiring new PMAs for all CES devices. So far they have received several dozen letters, most of which have expressed views very similar to mine. But can anything be done to correct these abuses? — stay tuned to see what happens!!!
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