HEALTH AND STRESS

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The American Institute of Stress

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SOME HIGHLIGHTS FROM OUR TENTH CONGRESS

Key Words: Ross Adey, Symtonic LEET, CES, rTMS, NET, GigaTENS, picotesla and pulsed stimulation, FDAMA, PTSD, workplace health promotion, societal and workplace violence, subtle energy circulatory system

William Ross Adey, M.D. was the Hans Selye Award recipient at The Tenth International Montreux Congress on Stress (February 28 - March 5, 1999). He was honored for his seminal contributions to our understanding of the biologic effects of electromagnetic forces, and for defining the parameters of the "Adey window" of activity. In Congress presentations for more than a decade, he has demonstrated that feeble electromagnetic stimuli can produce powerful psychophysiologic effects, that can not be explained by current "laws" of thermodynamics and Newtonian physics.

Good health depends on good communication, and Ross Adey has been the architect of an emerging paradigm of communication in the body at a physical/atomic level, as opposed to the current chemical/molecular model.

He has also attracted colleagues and other scientists to report on research findings that support this view. As a result, long before these became popular topics, Congress participants became aware of such things as: the effects of electromagnetic fields on melatonin production and its implications for breast cancer and the treatment of Parkinson's, Alzheimer's and other neurodegenerative diseases; the ability of free radicals to accelerate various oxidative stress manifestations of aging; the crucial role of nitric oxide in regulating arteriolar blood flow and mediating the effects of Viagra and other drugs. We also learned that electromagnetic forces are two edged swords that can both heal and harm, and promote or retard malignant growth.

Drs. Ross Adey and Paul J. Rosch with certificate of star named in Dr. Adey's honor, along with The Hans Selye Award plaque.. (Hannah Ruby Newton is supervising the presentation)

ALSO INCLUDED IN THIS ISSUE

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In acknowledgment of Dr. Adey's seminal contributions, six sessions were devoted to basic research and clinical advances in magnetotherapy. In 1992, Dr. Andrew Bassett, one of the pioneers in the field, predicted that in the decade to come, bioelectromagnetic therapies would replace many drugs and surgical procedures. It seems quite apparent that this prophecy has already been fulfilled well ahead of schedule.

There are already major applications for stress related complaints and disorders such as pain, insomnia, anxiety, and depression. The problem is that there are numerous magnetotherapy devices advertising benefits for the above conditions, or making other claims. These are primarily based only on glowing testimonials that are purely anecdotal, and since there is usually no scientific support, the medical community has understandably been turned off. It is often difficult to distinguish these from authentic products that have successfully completed double blind trials.

Therefore, a major purpose of this program was to identify proven products and approaches or others that seem to have great potential. In addition, we wanted to provide participants with criteria that would allow separating the wheat from the chaff in this rapidly expanding and often confusing field.

Magnetotherapy In The Millennium

At our very first Congress in 1988, we presented preliminary information on the Symtonic device, since early clinical trials had been conducted at the Biotonus Clinic under the direction of Dr. Claude Rossel. We also had the opportunity to hear Dr. Björn Nordenström explain his theory of an "electrical circulatory system" and demonstrate how he had been able to cure two patients with multiple pulmonary metastases from cancer of the uterus and ovary. Both patients were well with no sign of recurrence on five and ten year follow-up. Drs. Norman Shealy and Saul Liss presented their results on the use of transcranial electrical stimulation for the treatment of depression. This produced a prompt and progressive increase in serotonin, patients improved much more rapidly than with antidepressants, and there were no adverse side effects.

Since then, we have had periodic updates on all of the above, and these and other advances in electromedicine were again featured at our 1999 Congress. The Symtonic device delivers a form of Low Energy Emission Therapy (LEET) which is in the range of a CB radio. Treatment is administered via a small, battery powered unit attached to an electrode that is in contact with the oral mucosa. The apparatus has been progressively refined, and variations in electrical parameters and modulation frequencies of the signal can be utilized to achieve different effects.

Dr. Boris Pasche, who is now directing Symtonic research, reported on double blind polysomnography studies at two leading sleep laboratories in the U.S. based on FDA approved protocols. The results suggest that using the Symtonic device for just 20 minutes three times a week, is more effective and much safer than hypnotic drugs. There are no adverse or long time side effects, or tendency towards addiction or dependency problems. Studies at Harvard Medical School in patients with anxiety disorders using a different set of modulation frequencies, reveal that anxiety levels improved by more than 50% in the first week in the majority of subjects, and by 90% after three weeks.

(Continued on Page 3)

Dr. Daniel Kirsch presented an overview of other forms of cranioelectrical stimulation that have been successfully used for the treatment of insomnia, anxiety, pain, depression, and other stress related complaints. There was also a paper on repetitive transcranial magnetic stimulation (rTMS) for the treatment of drug resistant depression by Dr. Thomas Schlaepfer. This relatively new technique uses a hand held device to deliver a very rapidly fluctuating magnetic field to a specific area of the frontal cortex where metabolic abnormalities have been demonstrated in depressed patients with sophisticated imaging procedures. Patients who have failed to respond to antidepressant drugs often improve within two weeks as these abnormalities disappear.

Dr. Meg Patterson's NeuroElectric Therapy (NET) approach for treating benzodiazepine dependency was discussed by her son Lorne. The Patterson clan also submitted a paper describing how this relatively low current stimulation could relieve nicotine addiction. Dr. Saul Liss reported on research studies conducted with Dr. Norman Shealy showing how cranioelectrical and Gigahertz stimulation applied to specific acupuncture sites could increase blood levels of growth hormone and neurotensin. In addition, a follow-up was provided on their previous report on GigaTENS stimulation to improve diabetic neuropathy and boost DHEA levels.

Dr. Demetrio Sodi Pallares also provided an update on the amazing results he has obtained in patients with far advanced metastatic malignancy and terminal cardiomyopathy with his combined magnetotherapy-metabolic protocol. Decades ago, he had demonstrated that cardiac damage in acute myocardial infarction could be sharply reduced by the prompt administration of his "polarizing solution" that promoted the production of ATP. This was recently confirmed in a multicenter trial which found it to be the most effective treatment for acute infarct. This new protocol is based on subsequent research studies demonstrating that the buildup of ATP could be dramatically enhanced by concomitant magnetotherapy.

Dr. Jerry Jacobson reviewed the reported successes of picotesla stimulation in patients suffering from Parkinson's and Alzheimer's disease, multiple sclerosis, migraine, epilepsy, cerebral palsy and muscular dystrophy. There was also a report on Dr. Brij Saxena's sciatic nerve studies in mice showing that this type of stimulation could significantly improve nerve growth and regeneration following severe injury. Dr. Bridget Duffy traced the development of the recently FDA approved Medtronic implantable device for the treatment of Parkinson's disease. In clinical trials, it eliminated or significantly reduced tremor and disability in more than four out of five suffering from Parkinson's or essential tremor.

Dr. Martha Lappin summarized the results of pulsed electromagnetic therapy in multiple sclerosis with the Enermed device. A multicenter double blind study showed significant improvement, particularly with respect to fatigue; promising results have also been obtained in migraine. Dr. Alan Bennett reported on the use of "pulsed magnetic therapy" in patients with symptoms of low back and arthritic pain using an improved Medicur device. This new model includes a frequency setting that approximates delta brain waves during sleep and appears to be more effective, although the length of treatment required varies considerably.

One of the most impressive presentations was Dr. Richard Markoll's review of the results of his Pulsed Signal Therapy (PST) for the treatment of osteoarthritis. Double blind and randomized studies conducted on 25,000 patients in the U.S., Canada, France, Italy, and Germany, reveal a success rate for pain relief that approaches 90 percent. There is also improvement in mobility and range of motion, and unlike most other treatments, these benefits persist. In most instances, patients receive treatment for one hour on nine successive days. The procedure is non invasive and painless, and there are no side effects. In addition, very careful long term follow-up studies confirm that benefits persist, with no evidence of adverse consequences.

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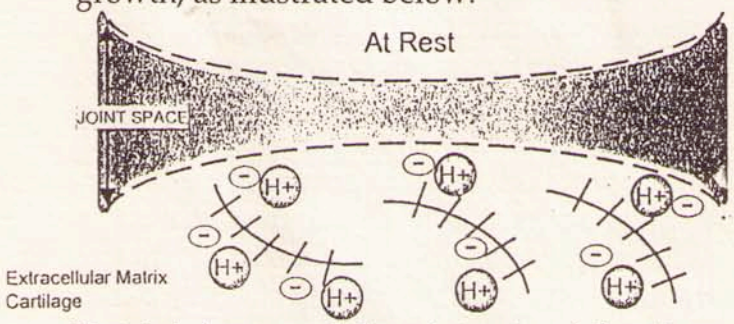
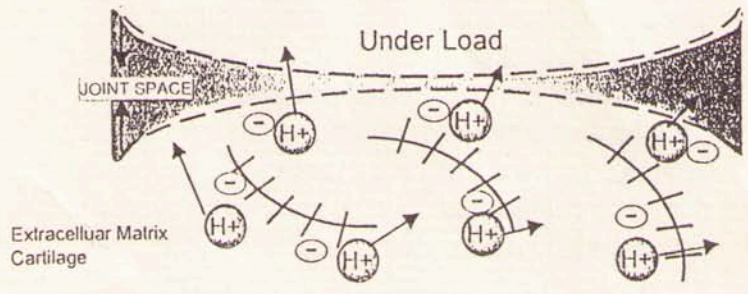
Pulsed Signal Therapy (PTS)

What distinguishes Pulsed Signal Therapy from most other magnetotherapy modalities is its evolution from solid scientific basic research that began thirty years ago. Early biophysical and biochemical studies confirmed that like all other living tissues, bone is constantly being broken down and built up. While endocrine and nutritional influences are important, physical pressure seemed especially crucial to stimulate regeneration. When absent, as for example, during immobilization in a cast, bone begins to atrophy. Conversely, physical exercise which provides this pressure or load helps to build stronger bones.

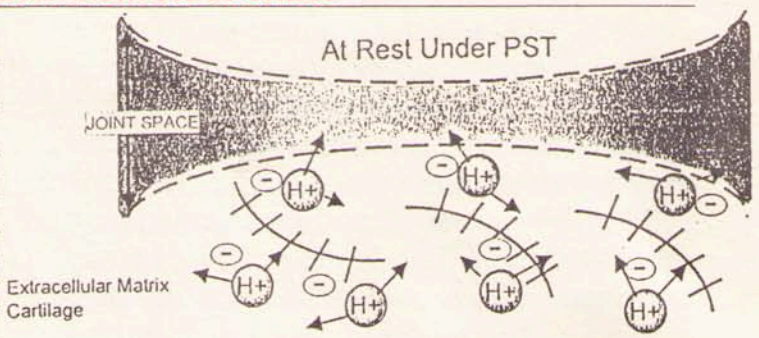
Every joint in the body is surrounded by an electrical field that promotes this ability of pressure to build up bone. Osteoarthritis and traumatic injuries can cause a disruption of this energizing force that significantly impairs its reconstructive capabilities. Pulsed Signal Therapy (PST) utilizes a very specific biological frequency signal directed to the affected joint's adjacent cartilage and connective tissue that recreates the same electrical field and flow of ions needed to promote bone regeneration and growth, as illustrated below.



Electrical charges are balanced at rest, and there is no stimulus for hydrogen protons to enter the joint space.



When the joint space is compressed by some pressure or load, negatively charged fluid is forced out of cartilage tissue. This change in electrical potential forces protons into the joint space to initiate regenerative activities.



At rest, PST energy signals stimulate chondrocytes in the matrix connective tissue, forcing the migration of hydrogen protons into the joint space, reduplicating the regenerative effects produced by physical pressure.

As this healing electrical field is restored, there is a progressive reduction in the pain and swelling that result when cartilage and bone wear away due to disease or trauma. This patented form of pulsed signal therapy was used to treat over 30,000 patients last year in some 250 locations in 13 countries, where it has passed rigorous requirements for proof of efficacy and safety. This number is expected to increase to 60,000 in 1999. Fiscal intermediaries, including Government insurance reimburse for PST, because it avoids the disabling and costly complications associated with long term drug therapy for arthritis, and thus provides huge savings over the long run.

In addition to osteoarthritis, PST is effective in rheumatoid disease and traumatic injuries such as meniscus and rotator cuff tears, and even bursitis due to calcium deposits. Pulsed Signal Therapy can be targeted to the neck, back, elbow, a finger, and almost every joint in the body. It has been particularly successful in alleviating the pain and disability of various ligamentous sports injuries like "tennis elbow", "golfer's arm", and "pitcher's shoulder", with a ninety percent success rate. Pilot studies suggest PST may also be beneficial for patients suffering from otosclerosis, tinnitus, TMJ syndrome and osteoporosis; it is increasingly being used by veterinarians.

While not yet available here, many U.S. patients have received PST in Canada and Mexico, and European facilities such as The American Hospital in Paris. Obtaining FDA approval is an expensive and time consuming process, and this was thoroughly discussed.

The FDA Dilemma

As indicated in a previous Newsletter outlining the problems associated with herbals and other nutritional supplements, the FDA is between a rock and a hard place. On one side, they are criticized by drug and device manufacturers because of the arduous approval process, and by patients who don't understand why they have to travel out of the country to obtain beneficial medications and treatments that are readily available abroad. On the other, consumer activist groups complain that drugs are released prematurely without adequate proof of safety. They point to the numerous recent recalls of pharmaceuticals, some of which have been widely used for years, and the thalidomide tragedy is still fresh in many minds.

The FDA is responsible for guaranteeing the safety and efficacy of $1 trillion in products, that include, in addition to drugs and devices, such things as donated blood, foods, cosmetics, vaccines, and a host of other things that are used daily. The number of new products that must be evaluated every year increases 12 per cent; the FDA is severely understaffed and exceeded last year's budget by $165 million. Insuring the safety of foods is their current leading priority, but they are short 500 inspectors. Only a fraction of the fish, meat and produce that reaches consumers can be checked. This problem has been highlighted by repeated recalls of products from reputable manufacturers that have caused mini-epidemics of food poisoning. The FDA must also safeguard us against dangerous new viruses, and the growing problem of antibiotic resistant bacteria. As one FDA official recently complained, "We cannot do everything that is expected of us."

There is the additional thorny problem of herbals and nutritional supplements. While these are currently exempt from FDA regulation, increasing reports of injuries and deaths have prompted efforts to place certain products under their control, as has been done in other countries. At the same time, powerful political forces and commercial interests oppose this.

With respect to approval of drugs and medical devices, the major stumbling block has been convincing the FDA of safety and efficacy through double blind clinical trials. The protocol for this must be approved by the Institutional Review Board (IRB) of a Medical School or other qualified facility, and be painstakingly adhered to so that the study can be replicated by any other investigator. Simultaneous multicenter trials are encouraged, preferably at different geographical locations to study a larger population of different ethnic backgrounds. Physicians and other health care personnel with the expertise, willingness, and ability to recruit suitable subjects must be rounded up and reimbursed.

Another hurdle that has to be overcome is obtaining "informed consent". All participants must be fully informed of any potential dangers, the availability of alternative treatment options, and reassured that there will be no penalty should they decide to withdraw at any time. They must also understand that they may not be receiving the new therapy, but will be in an inactive placebo group. Both the active and sham groups must be as identical as possible with respect to age, gender, severity of the disorder being treated, past medical history, educational level, socioeconomic status, ethic background and any other characteristic that could conceivably influence results. The assignment to a treatment or control group should be done on a random basis to minimize bias, and all participants must be "blinded", i.e., ignorant of which group they are in. In double blind studies, the physician is also unaware of this. The double blind study is the gold standard, and while not a problem for testing drugs, this procedure is not always possible for devices.

But who would want to participate if there was a 50 per cent chance of being forced to take something worthless for months, during which time no other treatment would be allowed? There are ways to downplay this, and Federal funding was recently suspended from Duke University due to IRB deficiencies. Clinical trials are prohibitively expensive and time consuming, especially if the original study group must be increased. New legislation may alleviate many of these present problems.

The FDA Modernization Act (FDAMA)

The Food and Drug Administration Modernization Act was passed by Congress in 1997 to improve patient access to medical products without compromising standards for efficacy and safety. Several important changes were made in the existing statutes to streamline the approval process for medical devices. These were explained by James Dillard, Deputy Director of the Radiologic Division who has had extensive experience in evaluating device applications.

This new legislation encourages more collaborative efforts by mandating preliminary and ongoing meetings with manufacturers to take maximal advantage of relevant resources and eliminate bureaucratic problems that can cause things to fall through the cracks. There are more clearly defined time limits to insure that all requests will be responded to promptly in order to prevent frustrating delays. The applicant now has the right to meet with the FDA to establish the type of valid scientific evidence needed to satisfy all standards without being prohibitively costly and time consuming. Among other refinements, the law also requires the agency to consider whether data requirements can be reduced based on post market study results. One of the major changes is that a Class II device may now be cleared without proof of a predicate product prior to enactment of the original medical device regulation law over twenty years ago.

There is also a trend towards global harmonization and developing consensus standards. Thus, properly conducted studies done elsewhere that comply with the European Union's Medical Device Directives are likely to carry more weight. Other countries are better informed and have more stringent requirements in some areas. For example, the German Commission E, a multidisciplinary group that includes pharmacologists, botanists, chemists, nutritionists, and physicians, regulates herbal and nutritional supplements. It mandates satisfying the same standards for proof of safety and efficacy that is required for prescription and non prescription drugs.

However, once a legitimate product is approved, there is always the danger that worthless imitations will insinuate having the same status by claiming to provide similar benefits. There are currently many devices that promise pain relief from "Pulsed Therapy", "Pulsed Energy", or other confusing names that imply Pulsed Signal Therapy. Indeed, it might be difficult to prevent using this or PST for any instrument that emits an electromagnetic field. To evaluate any new device, Dr. Markoll suggests asking the following six questions.

Is the Scientific Director of the organization a qualified scientist with appropriate academic credentials, as opposed to a salesman, entrepreneur, or self-styled inventor?

What are the qualifications of the principal investigator, and were clinical studies or double blind trials conducted at an established University affiliated facility?

Have any relevant basic science research studies been completed that were supervised and approved by an academic body?

Were clinical trials and other study results published in peer reviewed journals, or primarily reported in the lay press and media?

Have protective patents been obtained, and if so, are they process patents covering the technology or merely simple design patents?

Are copies of pertinent publications and presentations available, and is there a definitive database of the device's biological effects similar to that provided for Pulsed Signal Therapy?

Few manufacturers of copycat devices claiming to offer the same benefits as PST can provide a satisfactory response to more than one or two of the above questions, which are also useful for screening other products.

This brief summary has been limited to clinical applications, since it would be impossible to adequately cover the basic science and overview presentations by Drs. Adey, Liboff, Jenrow, Balzer, Blank, Coghill, Lednyicsky, Rakovich, Markov, Tiller, and others in these sessions, but tapes of all speakers will be available. Rollin McCraty's presentation on the use of heart rate variability feedback for stress reduction will be featured in a future Newsletter. Because of this embarrassment of riches, not all papers submitted could be presented, but their abstracts were included in the Program.

PTSD And Health Promotion At Work

The scientific program started with a session on Post Traumatic Stress Disorder organized by the Critical Incident Stress Foundation under the aegis of George Everly and Jeffrey Mitchell. It included a state of the art review of crisis intervention outcomes, dealing with stress disorders in practitioners who treat PTSD victims, experiences gained from the 1991-1993 Croatian conflict, and reducing the psychological consequences of violence in hospital personnel with the Assaulted Staff Action Program (ASAP). This would seem to be a particularly appropriate acronym for this stunningly successful prevention and early intervention approach.

In the afternoon session, Health Promotion In The Workplace, Lennart Levi explained that properly designed programs would not only improve workers' health, but also the bottom line for employers, and could eventually result in better health and quality of life for the community. Unfortunately, we are still far away from achieving this goal. In Europe, only half of workers have access to occupational health services. Those that are available are limited to providing symptomatic medical care, rather than the prevention of illness or promotion of health.

Al Weijman had planned a symposium on Stress and Creativity at Work with others from the Netherlands. Last minute cancellations prevented this, but a summary of these presentations was presented. Ken Pelletier reported on the status of his 5 year NIH funded General Electric worksite intervention program to reverse coronary heart disease. Brian Crawford, Executive Director of The Center for Health Futures in Celebration Florida, described the Accelerating Community Transformation study to accelerate the development of healthier lifestyles. One important facet of this intriguing study being conducted in ten communities, is to encourage employers to take a more active role in community affairs. Lennart Levi had emphasized that job stress often spills over into family and societal life. It is equally essential to recognize that the reverse is also true. Corporations can provide help at both ends, and we hope to provide a follow-up on this innovative intervention.

Violence In The Workplace And Society

Jim Quick chaired a session on these very timely and increasingly disturbing problems, and outlined strategies that can effectively reduce violence on the job. Other speakers addressed the importance of anger control, predicting patterns of violence, and the causes and consequences of dysfunctional behavior in organizations.

Violence at work and society is pandemic, and other papers described the escalating epidemic of road rage in Switzerland, Europe, and the U.S., how stress contributes to these and other violent behaviors, as well as various psychosomatic disorders.

The Sisi And Sisyphus Syndromes

The "Sisi Syndrome" is characterized by manifestations of depression accompanied by hyperactive physical and mental behaviors designed to disguise or alleviate signs and symptoms of sadness. The term derives from Empress Elisabeth of Austria (1837-98), whose nickname was Sisi. The syndrome is seen most often in females over the age of 45, and according to Karl Hecht of the Institute of Stress Research in Berlin, is present to some degree in almost one out of three depressed patients. It is very common in those complaining of insomnia, and affects about 2.5 million women in Germany.

Sisyphus was the cunning King of Corinth who allegedly cheated death, and was condemned to spend the rest of his life repeatedly pushing a large boulder up to the top of a hill, only to have it roll back to the base as soon as the summit had been reached. Other Greek mythological portrayals of Hell also viewed it as a place of perpetual but fruitless labor. Stewart Wolf described individuals who were constantly preoccupied with their work, even if it was not productive, as suffering from the Sisyphus syndrome, and showed that they were at increased risk for heart attacks. This was about the same time that Rosenman and Friedman described Type A behavior, which included this trait. Ray Rosenman was unable to attend this Congress, but his Type A update presentation was included in the Program.

Lessons Learned From Our Tenth Congress And A Peek Into Our Eleventh

In Ross Adey's Hans Selye Lecture, "Whispering Among Cells", he explained how the emerging discipline of bioelectromagnetics had led to an appreciation of communicative processes in the brain not associated with any discernible caloric exchange. These are not chemical reactions between molecules, but exquisite regulating mechanisms that operate at much lower energy levels and influence physical activities at an atomic level. The cell wall can no longer be viewed as merely a protective barrier studded with receptor sites for small peptide messengers. It has emerged as a powerful signal amplifier that mandates a revision of our understanding of how communication takes place in the body. Similarly, A. R. Liboff argued that our current appreciation of human physiology is so strongly rooted in biochemistry, that we are unable to explain well documented responses to electromagnetic stimulation. What is required is a revised approach based on electromagnetic field theory, and learning a new language whose vocabulary has still not been delineated. As indicated in my chapter and discussion of Björn Nordenström's new book updating his concept of biologically closed electrical circuits, it is proposed that there is a flow of energy in the body analogous to ancient Chinese concepts of *Qi* that travel through prescribed pathways or meridians, with positive and negative charges much like *yin* and *yang*. In addition, it is likely that we are also sensitive to natural and man made subtle signals in our environment, which may be detected and amplified by numerous acupuncture sites around the body. Conversely, we have the capability of generating such forces to affect not only internal milieu activities, but also animate and inanimate objects without making physical contact. This can be demonstrated by certain *chi gong* masters and healers in other cultures. Further confirmation was provided by Bill Tiller, who showed how intentionality could be utilized to change the pH of an aqueous solution, increase the thermodynamic activity of a specific liver enzyme system, and significantly reduce the development time of fruit fly larvae by increasing ATP / ADP ratios.

Such forces could explain such things as the salubrious benefits of prayer, a firm faith, strong social support, therapeutic touch, and placebo phenomena. This brings us to our next Congress, which will honor Dr. Herbert Benson of Harvard, an old friend and founding member of the Board of Trustees of The American Institute of Stress. While best known for his research on the psychophysiologic effects of meditation and development of The Relaxation Response, he has also written extensively on the placebo effect. In recent years, he has devoted his attention to investigating and documenting the health effects of religiosity, and a strong belief in God, or some higher power. We will present scientific evidence of the nature of these benefits, and explore possible mechanisms that may explain how they are mediated. We hope to have the Dalai Lama, and senior representatives of major faiths to provide their insights and perspectives, in an attempt to learn how we can tap into the vast innate potential for self-healing that resides in all of us.

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