SECTION 15

EVIDENCE BASED ON EMF MEDICAL THERAPEUTICS

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I. Introduction

Electromagnetic fields are widely used in therapeutic medical applications. Proof of effectiveness has been demonstrated in numerous clinical applications of low-intensity ELF-EMF and RF-EMF, each treatment employing specific characteristics of frequency, modulation and intensity to achieve its efficacy. On the other hand, higher levels of EMFs encountered in the environment which are indiscriminately generated by technologies of the 20th and 21st centuries may result in harm. EMF levels which are allowable today under thermally-based public exposure standards do not take into account these clear indications of the sensitivities of the human body to EMFs. If we are to promulgate public exposure standards that are protective of public health, then this body of evidence on healing with EMFs is of primary importance in developing biologically-based public exposure standards.

"Although incompletely understood, tissue free radical interactions may extend to zero field levels. Emergent concepts of tissue thresholds to imposed and intrinsic magnetic fields address ensemble or domain functions of populations of cells, cooperatively whispering together in intercellular communication and organized hierarchically at atomic and molecular levels." 10

II. Therapeutic Uses for Electromagnetic Fields

Since EMFs have been shown to be effective in treating conditions of disease at energy levels far below current public exposure standards, this body of evidence forms a strong warning that indiscriminate EMF exposure is ill advised. Health concerns from indiscriminate exposure to EMF, as opposed to EMF exposures done with clinical oversight, could lead to harm as can the unsupervised use of pharmaceutical drugs. The consequence of multiple sources of EMF exposure in daily life, with no regard to cumulative exposures or to potentially harmful combinations of EMF exposures will pose

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future difficulties in identifying sources of disease (because of multiple and overlapping exposures) and time-varying and geography-varying differences from person to person. Just as ionizing radiation can be used to effectively diagnose disease and treat cancer, it is also a cause of cancer under different exposure conditions. Since EMFs are both a cause of disease, and also used for treatment of disease, it is vitally important that public exposure standards reflect our current understanding of the biological potency of EMF exposures.

"there is an abundance of experimental and clinical data demonstrating that exogenous EMFs of surprisingly low levels can have a profound effect on a large variety of biological systems. Both electrical and electromagnetic devices have been demonstrated to positively affect the healing process in fresh fractures, delayed and nonunions, osteotomies, and spine fusion in orthopedics and for chronic and acute wound repair. These clinical results have been validated by welldesigned and statistically powered double-blind clinical trials and have survived meta-analyses. The FDA has approved labeling for these biophysical devices, limited at present to these indications." "The potential clinical applications of EMF therapeutics extend far beyond those considered here and the clinical rewards are certain to be huge." "Cancer, cardiac muscle regeneration, diabetes, arthritis, and neurological disorders are just some of the pathologies that have already been shown to be responsive to EMF therapy. Successful applications of lowfrequency EMFs have been reported for treatment of bronchial asthma, myocardial infarction, and venous and varicose ulcers. There is emerging research on EMF effects on angiogenesis and the manner in which this may increase stem cell survival in the treatment of Altzeimer's (sic) and Parkinson's diseases. There are also many studies that point to the possibility of the use of EMF for peripheral nerve regeneration" and "the treatment of cancer." "EMF therapy modalities are simple, safe and significantly less costly to the health care system. They offer the ability to treat the underlying pathology rather than simply the symptoms. The time is particularly opportune given the increased incidence of side effects from the use of pharmacological agents. EMF therapeutics will have a profound impact upon health and wellness and their costs worldwide." 1

A. Bone Repair

Clinical use of pulsed EMF has been demonstrated to achieve bone repair, particularly in fractures that do not heal on their own. Bone healing is stimulated by very weak electromagnetic fields that are far lower in strength than would produce tissue heating. The FDA approved pulsed EMF for use in bone healing in 1979. Since that time, many millions of patients have benefited from this therapy. Since PEMF treatments are non-invasive and clinically effective, it has advantages to the patient in terms of reduced pain and suffering, reduction in health care costs, and effectiveness where other methods have failed to produce adequate clinical results.

"It is now commonplace to learn the successful use of weak, nonthermal electromagnetic fields (EMF) in the quest to heal, or relieve the symptoms of a variety of debilitating ailments. This chapter attempts to give the reader an introduction and assessment of EMF modalities that have demonstrated therapeutic benefit for bone and wound repair and chronic and acute pain." ²

Pilla provides extensive discussion of the "clinical evidence that time-varying magnetic fields (EMF) can modulate molecular, cellular and tissue functions in a physiologically significant manner." A description of the various waveforms and EMF modalities which are effective in bone and wound repair are beyond the scope of this paper, but are well documented. In addition to documenting that bone repair in fractures is achieved with pulsed EMF at low intensities, Pilla also reports that pulsed EMF has been successful in promoting bone repair and healing of spine fusions for the treatment of chronic back pain from worn and/or damaged spinal discs. The FDA has approved pulsed EMFs for bone healing and this is a widely recognized treatment, particularly for fractures that are slow to heal, or do not repair with conventional medical treatment. It represents one of the best documented cases in science where the body clearly responds to low-intensity EMF signals for healing purposes; these EMF signals are far below current public exposure standards and are proof of the bioactivity (in a beneficial form as applied).

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Liboff describes signal shapes in electromagnetic therapies that contribute greatly to our understanding of the various forms of EMF signal delivery that are fundamental to eliciting specific bioeffects. He simply and elegantly describes electric and magnetic signal characteristics, their signature shapes and methods of delivery (time-varying, oscillatory, or modulated) which create special interactions with human tissues and organs for healing. ⁴

"It is likely that the future will see combinations of such signals in therapeutic applications, especially as more information filters back from the laboratory elaborating on the nature of electromagnetic interactions with living tissue." ⁴

B. Wound Repair

The clinical application of pulsed EMF has been shown to enhance wound repair and healing. ^{2,5} Devices that use pulsed EMF have been approved for use in the United States by the FDA. Pilla reports "the clear clinical effectiveness of PEMF signals has resulted in significantly increased use" in treating wounds that do not heal. In Pilla's extensive summary presented on beneficial effects of EMF on wound healing, he reports pulsed EMF has been reported to reduce edema, increase blood flow, modulate upregulated growth factor receptors, enhance neutrophil and macrophage attraction and epidermal cell migration, and increase fibroblast and granulation tissue proliferation. Most wound studies were conducted on arterial or venous skin ulcers, diabetic ulcers, pressure ulcers, and surgical and burn wounds. Wound repair under the influence of very low level pulsed EMFs is a second solid documentation in science that very low level EMFs are bioactive (in this case, beneficial) when applied in very specific clinical applications where the exposure variables are carefully selected.

Oschman provides an overview of the evolution of energy medicine and electromagnetic energy treatments related to bone repair, wound healing, pain relief, depression, insomnia, inflammation of tissues and other medical conditions. ⁶ He also underscores the counter-intuitive thesis that low-intensity EMFs can be more effective in eliciting

healing responses than larger intensity exposures; and that understanding of the subtle energies and their specific interactions with human functioning is imperative.

(l)iving tissues are far more sensitive to external fields than previously realized. After a period when physicists were certain that observed sensitivities to nonionizing and nonthermal radiations wer physically impossible, we now know that biological systems defy the simple logic that larger stimuli should produce larger responses. For many living systems, extremely weak fields can be more effective than strong fields."

C. Pain Management

Pulsed magnetic field (PMF) devices are also used with FDA approval for "relief of acute and chronic pain and the reduction of edema (swelling), all symptoms of wounds from post-surgical procedures, musculoskeletal injuries, muscle and joint overuse, as well as for chronic wounds." ⁵

Pulsed EMF has been shown to be effective in relief of chronic pain associated with connective tissue injury (cartilage, tendon, ligaments and bone) and soft-tissue injuries associated with the joints. Both acute and chronic pain may be successfully treated with EMFs as an alternative to non-steroidal anti-inflammatory drugs (NSAIDs). Relief from chronic pain due to osteoarthritis has been reported with treatment by EMFs. ²

Markov reports that EMF is used in treatment of pain associated with tendonitis, multiple sclerosis, carpal tunnel syndrome and some forms of arthritis. He discusses the use of pulsed EMF for headache and migraine pain relief; neck and whiplash injuries, postoperative pain, sprains, chronic pelvic pain, and nerve regeneration. Pain reduction by clinical application of pulsed EMF is achieved with non-thermal levels of exposure, and produces a nonthermal biological effect. ⁸

D. Depression, Anxiety Disorders, Insomnia

"Today (2002) we are at a threshold for the acceptance of electromagnetic therapy as a clinically accepted form of therapy for such diverse diseases as unipolar depression, Parkinson's disease, and sleep disorders and the treatment of debilitating chronic and acute pain."

Shealy et al (2007) detail clinical findings for treatment of depression and mood management, reduction in anxiety, and treatment of insomnia. 10 Electrical energy stimulators that deliver very low-level EMF have been reported to be clinically effective in the alteration of neurobioechemicals including serotonin and cortisol. Depression, mood disorders and insomnia have been related to disregulation of serotonin levels. Use of EMFs to reduce symptoms of depression, anxiety and insomnia are authorized by the FDA, and have been in use since the 1970's. Shealy reports that transcranial stimulation by EMFs led to a significant relief of depression in 85% of patients who had failed pharmacological agents, and was at least twice as effective as any known antidepressant drugs and without complications. ¹⁰

E. Protection from Anoxia (Protection for the Heart)

The work of Albertini, Litovitz and di Carlo, Goodman and Blank, Han, Pipkin, Rasmark and Kwee, ¹¹⁻¹⁷ has shown that very weak ELF-EMF and RF-EMF exposures can actually help to protect cells against tissue damage. They can induce an adaptive stress response in cells, which in turn helps the cell fight damage. The response is production of stress proteins (heat shock proteins or HSP). These stress proteins help to protect the cells against injury and death. A 20-minute exposure to electromagnetic fields at only 80 mG will start stress protein production, which helps to fight cellular damage from lack of oxygen, for example. Protection from anoxia (or lack of oxygen) is important in heart attacks. Pre-treatment with ELF-EMF (and also RF-ELF) before blocking oxygen to cells has been shown to be protective against the lack of oxygen to heart tissues. The exposure level is on the order of 80 mG ELF-EMF or far below any

possible thermal heating.

This means that there are clinical applications for protection against heart attack damage that can be provided by very low-dose EMF exposures. Such protection could be vitally important in reducing damage from oxygen loss during heart attacks. It is another line of proof that low-intensity electromagnetic fields are bioactive, and when applied in specific therapeutic ways, are beneficial. It also underscores that the body can detect and decode these very weak signals, providing further evidence that thermally-based standards are incomplete because they do not take into account the sensitivity of the human body to non-thermal levels of EMF exposure.

IV. Conclusions

Since EMFs have been shown to be effective in treating conditions of disease at energy levels far below current public exposure standards, this body of evidence forms a strong warning that indiscriminate EMF exposure is ill advised.

Based on extensive clinical applications of low-intensity EMFs since at least the 1970s, it has been demonstrated beyond argument that some forms of EMFs can be medically effective in treating a wide variety of human health disorders and injuries. Since all of these treatments are conducted at energy levels that do not involve tissue heating per se, it is convincing proof that the human body both reacts to and can be affected by exposures to EMFs. Exposures can be beneficial when EMFs are applied with conscious knowledge of the exposure factors that are proven to lead to specific biological (healing) consequences. The intensity of such therapeutic exposures nearly always falls below current public exposure standards as discussed in Section 3.

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V. References

- 1. Pilla AA. Mechanisms and Therapeutic Applications of Time-Varying and Static Magnetic Fields. Handbook of Biological Effects of Electromagnetic Fields Third Edition: Biological and Medical Aspects of Electromagnetic Fields, 2007. Barnes FS and Greenebaum B. editors, pages 392-393.
- 2. Pilla AA. Mechanisms and Therapeutic Applications of Time-Varying and Static Magnetic Fields. Handbook of Biological Effects of Electromagnetic Fields Third Edition: Biological and Medical Aspects of Electromagnetic Fields, 2007. Barnes FS and Greenebaum B. editors, page 352.
- 3. Ibid, page 356.
- 4. Liboff AR. Signal Shapes in Electromagnetic Therapies: A Primer. Bioelectromagnetic Medicine. 2004, Rosch PJ and Markov MS, editors, page 32.
- 5. Pilla AA. Mechanisms and Therapeutic Applications of Time-Varying and Static Magnetic Fields. Handbook of Biological Effects of Electromagnetic Fields Third Edition: Biological and Medical Aspects of Electromagnetic Fields, 2007. Barnes FS and Greenebaum B. editors, page 357.
- 6. Oschman JL. Recent Developments in Bioelectromagnetic Medicine. Bioelectromagnetic Medicine. 2004, Rosch PJ and Markov MS, editors, page 79. 77-92 entire chapter?
- 7. Markov MS. Magnetic and Electromagnetic Field Therapy: Basic Principles of Application for Pain Relief. Bioelectromagnetic Medicine. 2004, Rosch PJ and Markov MS, editors, page 258.
- 8. Prato FS. Image-Guided Electromagnetic Therapy. Bioelectromagnetic Medicine. 2004, Rosch PJ and Markov MS, editors, page 51.
- 9. Shealy CN Liss S Liss BS. Evolution of Electrotherapy: From TENS to Cyberpharmacology. Bioelectromagnetic Medicine. 2004, Rosch PJ and Markov MS, editors, page 93-114.
- 10. Adey, WR. Potential Therapeutic Applications of Nonthermal Electromagnetic Fields: Ensemble Organization of Cells in Tissue as a Factor in Biological Field Sensing. Bioelectromagnetic Medicine. 2004, Rosch PJ and Markov MS, editors, page 1.
- 11. Albertini A, Zucchini P, Noera G, Cadossi R, Napoleone CP, Pierangeli A. 1999. Protective effect of low frequency low energy pulsing electromagnetic fields on acute experimental myocardial infarcts in rats. Bioelectromagnetics 20:372-377.

- 12. Di Carlo AL, Farrell JM, Litovitz TA. 1999a. Myocardial protection conferred by electromagnetic fields. Circulation 99:813-816.
- 13. Goodman R, Blank M. 1998. Magnetic field stress induces expression of hsp70. Cell Stress Chaperones 3:79±88.
- 14. Goodman R, Blank M, Lin H, Dai R, Khorkova O, Soo L, Weisbrot D, Henderson A. 1994. Increased levels of HSP70 transcripts induced when cells are exposed to low frequency electromagnetic fields. Bioelectrochem Bioenerg 33:115-120.
- 15. Han L, Lin H, Head M, Jin M, Blank M, Goodman R. 1998. Application of magnetic field-induced heat shock protein 70 for presurgical cytoprotection. J Cell Biochem 71:577-583
- 16. Pipkin JL, Hinson WG, Young JF, Rowland KL, Shaddock JG, Tolleson WH, Duffy PH, Casciano DA. 1999. Induction of stress proteins by electromagnetic fields in cultured HL-60 cells. Bioelectromagnetics 20:347-357.
- 17. Raskmark P, Kwee S. 1998. The minimizing effect of electromagnetic noise on the changes in cell proliferation cause by ELF magnetic fields. Bioelectrochem Bioenerg 40:193-196.