

LEGAL ISSUES OF BIOENERGY MEDICINE TECHNOLOGY

I. INTRODUCTION

The purpose of this section is to present the most pressing legal issues which affect all practitioners and engineers involved with bioenergy devices, and give practitioners a useful understanding of the legal system which transcends the popular horror stories or conspiracy theories. The author wishes to emphasize strategies for the development and legitimization of bioenergy technologies, and facilitate the effective legal representation by licensed attorneys through providing this substantive information.

There are three primary areas of the law which are used to prosecute practitioners who use bioenergy devices or psychotronics: (1) Medical device regulations enforced by the FDA, (2) State regulations about the scope of therapeutic practice, and (3) State prohibitions against unlawful practice of medicine. This section will address these areas of law, and make detailed strategic recommendations for professional associations related to energy medicine, and political advocacy organizations in alternative health. Any specific legal advice for individual practitioners, however, is beyond the scope of this writing.

II. MEDICAL DEVICES AND FDA JURISDICTION

The primary legal reason for the FDA's aggressive regulation of psychotronic devices is the claims made by proponents of bioenergy devices. For the past 3 decades, practitioners claimed that psychotronics works to diagnose and heal medical problems. As a result, such devices fall into the category defined by the congressional statutes as "devices that are intended to affect the structure or function of the body," and they are legally classified as "medical devices" under the jurisdiction of the FDA. (Food Drug and Cosmetic Act, Sec. 201(h), 21 U.S.C. 321). Compounding the problem is that the FDA developed decades of case law with expensive accredited expert witnesses testifying that psychotronic devices such as Radionics machines do not work.

The fact is that many bioenergy devices do work, but what they do and how they work has never been properly presented in court. The FDA experts simply testify that the machine does not produce sufficient current or does not touch the patient, and therefore can have no effect, but the psychotronic practitioner (defendant) claims the device can physically heal a medical condition. To the FDA and the court this discrepancy looks like fraud. These court cases are extremely harmful and threatening to the existence of psychotronics, because the legal system cannot understand psychotronics on its own, and the cases set precedents that make all bioenergy devices look fraudulent or illegal.

The clearest illustration of how psychotronic devices are presented (and misrepresented) in the trial courts is the federal case People v. Leonard Chapman. In this case, the defendant Leonard Chapman was a licensed medical doctor who used a DeLaWarr type Radionics machine for diagnosis. Chapman made multiple dire diagnoses for each patient, purportedly based upon readings from the machine, telling every patient that they had

some terminal illness that could only be cured with a special hypodermic shot that he administered. The “life saving” shot was proven to be ordinary bottled water, and the doctor charged at least \$100 for each shot. The Radionics machine was used for supposed adjunctive treatment in combination with the fraudulent shot. After trial and on appeal, the defendant was convicted of criminal theft by fraud and false pretenses.

While the words “Radionics” or “psychotronics” were not used to refer to the device nor to any possibly existing science or practice which could legitimize the doctor’s devices, the judge’s written opinion (legal ruling) described the devices as follows:

“It is generally rectangular in shape, 25 inches long, 10 inches high and 11 inches deep. It has handles on each end and an attached electrical cord with an ordinary electrical plug at the end. On the face of this machine, there are two needle gauges, 10 small adjustable dials, four larger dials, three on-off switches, a removable fuse, several small lights and some sockets or jacks for receiving plugs attached to electrical wires . . . A small flat plastic plate is located on the ledge in front of the face of the machine.” (People of California v. Leonard R. Chapman (4th Cir.1962) 207 Cal.App.2d 557, at 562, 24 Cal.Rptr. 568, at 570).

The testimony of state witnesses who were undercover agents posing as patients described the treatment procedure. The defendant “adjusted dials on the machine during the diagnosis,” while the nurse was “reading numbers from a book.” During the treatments, “a copper plate was put on Mr. Johnson’s body over the area to be treated. The plate was attached to a machine. He could feel nothing during the treatment.” (People of California v. Leonard R. Chapman (4th Cir.1962) 207 Cal.App.2d 557, at 563, 24 Cal.Rptr. 568, at 571). Another witness testified that the nurse “called out a series of numbers and letters. Defendant repeated them and rubbed the fingers of his hand on a plastic disk on the machine. At the same time, he turned dials on the machine with his left hand.” (People of California v. Leonard R. Chapman (4th Cir.1962) 207 Cal.App.2d 557, at 567, 24 Cal.Rptr. 568, at 574).

The state retained as an expert witness Dr. Moses A. Greenfield, a physicist and professor of radiology at the Medical Center of the University of California at Los Angeles. He testified that “no current reached the jacks used to connect the wires attached to various plates to the machine,” and that “it was physically impossible for this machine to transmit or receive impulses of any kind via the jacks used to connect the patients to the machine.” He further testified that “none of these machines could possibly serve any useful purpose in diagnosing or treating illnesses of human beings.” (People of California v. Leonard R. Chapman (4th Cir.1962) 207 Cal.App.2d 557, at 562, 24 Cal.Rptr. 568, at 571).

The defense offered two expert witnesses in rebuttal. The first, James Riggs, a Ph.D. in physics from Texas A & M and professor of physics at La Sierra College, testified that “it produced some electrical energy, but that the current emanating from the machine was in the micro-amp range,” and that “the coils in the machine were a crude form of electrical transformer with an air core,” which “created an extremely small amount of electrical current in the ‘open’ circuit to which the wires touched by the patients were connected.” On cross-examination by the prosecution, however, he admitted that he did not know whether the machine could have any effect on human beings, stating that this was outside his area of expertise. (People of California v. Leonard R. Chapman (4th Cir.1962) 207 Cal.App.2d 557, at 572, 24 Cal.Rptr. 568, at 576)

The second expert witness for the defense was Dr. John Gozzi from the National College of Chiropractic and Drugless Physicians and a member of the board of the Electronic Medical Foundation in San Francisco. Dr. Gozzi testified that using the device is an acquired skill learned by apprenticeship with another practitioner, to develop sensitivity to the “pull” on the fingertips that is transmitted by the diagnostic machine. Most importantly, Dr. Gozzi testified that each human cell contains electricity that establishes direct current to facilitate a treatment, and that there is a second type of electricity in the cell that has a frequency or alternating current subject to a harmonic resonance. He stated that there is a certain critical frequency of energy that can be applied to affect the cell and destroy bacterial cells. He further testified that Radionics analysis is a useful tool in diagnosis, and an effective adjunct treatment of any disease. (People of California v. Leonard R. Chapman (4th Cir.1962) 207 Cal.App.2d 557, at 572, 24 Cal.Rptr. 568, at 577)

On Appeal, the defendant charged that the trial court improperly prejudiced his case by disqualifying as an expert witness a Lieutenant who worked on electronics in the navy for 20 years, who would have testified to the effect of low level energies upon human cells. The Appellate Court ruled that the expert was properly excluded, because he did not possess any accredited degrees in the field, and the conviction was upheld.

Although the courts did not make any actual ruling on the merits of the Radionic devices, the published judicial opinion contains more than 10 pages about the device, and merely one sentence indicating that the hypodermic needle contained ordinary bottled water. It is clear that the defendant was properly convicted for fraud by selling water shots as medicine, and diagnosing even healthy undercover agents with dire terminal diseases which supposedly required the shots. It is also clear that notwithstanding the effectiveness of Radionics, the defendant abused the machines by using them merely for show, as an excuse for his predetermined fraudulent diagnoses. However, while the trial court did not specifically rule that the devices did not work, it also did not rule that they were legitimate, and this case as published in the law reporters also serves as unfair precedent to indicate that such devices may inherently engender fraud.

This is precisely why it is imperative to the survival and legitimization of bioenergy technologies to litigate all cases responsibly, and avoid calling into question the effectiveness of often experimental devices where the case could be litigated on other

grounds. Most importantly, the psychotronics industry must develop more expert witnesses with accredited degrees, who can be called upon to defend the devices. In the above case, even the expert witnesses for the defense failed to mention the existence of the technical sciences of Bioenergy, Energyinformatics or torsion field physics, nor the decades of technical research in the U.S. and Soviet Union that would legitimize psychotronics.

Because of the high risk of setting negative precedent which is prejudicial to psychotronics, professional associations and political advocacy organizations must also discourage practitioners from representing themselves in litigation, and encourage them to seek effective lawyers who have experience in alternative health care. In the absence of specialized lawyers, such associations should retain think tanks and consulting firms that are capable of facilitating effective legal representation by supplementing lawyers with scientific research reports, and helping them locate admissible expert witnesses.

The prevailing theory of psychotronic treatment of illness is that if each illness emits characteristic electromagnetic disturbances, then any illness might be healed by applying a complementary electromagnetic treatment of a complex waveform designed to balance and neutralize the illness. However, it is not yet certain whether the electrofield patterns emitted from the human body are causal or symptomatic. Research in Europe and Russia, at major universities such as Moscow Bauman State Technical University, indicates that these electromagnetic signals are in fact more similar in character to brain waves, and not directly related to actual biomedical conditions.

This means that the result of psychotronic analysis is to show how the brain and subconscious mind of the patient perceives their own health condition, and it is not necessarily indicative of actual health conditions. It is sufficient to say that the patient subconsciously believes that they have a condition, or that they have brain waves and bioenergy traits characteristic of others who in fact have a particular medical condition, without going so far as to claim a diagnosis. Therefore, psychotronic treatment can be used to correct client psychology that psychosomatically causes or otherwise perpetuates their illness. This description clearly separates the intended use of the device from any medical issue, does not in any way diminish the value and effectiveness of psychotronic analysis, and is legally safer in many respects.

Despite this safer, well-supported and useful scientific description, the majority of alternative health practitioners actively represent that such devices can actually diagnose, treat and cure physical illness directly. This expression, and the resulting pseudo-medical practice, has caused the F.D.A. to regulate alternative devices so aggressively that they have effectively prevented further development of any such devices.

Many psychotronics practitioners rely on the popular misconception that calling devices “experimental” somehow gives them a disclaimer or exception to the medical device restrictions. This is legally false. In a leading federal case U.S. v. Toftness Radiation Detector, a chiropractor invented and patented a device which consists of a plastic cylinder containing several lenses, which detected electromagnetic radiation from the human body and focused that radiation so that when a trained user scans close to the patient’s skin

while rubbing the detection plate, the user may detect neurological disturbances by feeling “resistance to the movement of the fingers.” The chiropractor was researching the device’s potential use in the diagnosis of chiropractic disorders, calling it an “experimental” device. The FDA wanted to ban the device as “misbranded” because it was a medical “device” under the Federal Food Drug and Cosmetic Act, and because it did not bear directions adequate for a layman to use it safely and effectively. Under the Federal Act, a medical “device” is defined as any instrument “intended for use in the diagnosis. . . cure, mitigation, treatment or prevention of disease,” or “intended to affect the structure or any function of the body.” (Food Drug and Cosmetic Act, sec. 201(h), 21 U.S.C. 321).

The defendant Toftness argued that the device was only used for research, and should not be regulated. The FDA argued, and the U.S. Court of Appeals ruled, that the definition of “medical device” includes experimental instruments used merely for research, as long as the device is *intended* to eventually be used for diagnosis or treatment. The federal court reasoned that even experimental research could not be carried out without using the device for its intended diagnosis or treatment, so its investigational status did not minimize its risk to public health and safety. The court additionally noted that the fact that a device is only in the research stage does not change its intended use. (U.S. v. Toftness Radiation Detector (7th Cir.1984) 731 F.2d 1253, at 1257). Since the Toftness device was intended for use in the diagnosis and treatment of disease, it was subject to the statutory labeling requirements as a medical “device.”

With respect to the FDA’s claim that the device lacked adequate directions for safe use by lay persons, Toftness presented the counter argument that the device was not for laymen to use, and could only be used by licensed specially trained professionals. While the court acknowledged that there was a special statutory exception for “prescription devices” (see 21 C.F.R. 801.109 (1983)) - which require supervision by a licensed practitioner - it insisted that “a prescription device is misbranded unless it can be used safely and effectively for the purposes for which it is intended.” (U.S. v. Toftness, 731 F.2d 1253, at 1259).

Unfortunately, the burden of proof for effectiveness of the device is placed on the defendant, because they are in the best position to have and understand information to support the effectiveness of their own invention. This creates a great obstacle for new devices still under development, because a device that is not fully developed cannot yet prove its effectiveness, by definition.

In light of U.S. v. Toftness, the only lawful way for alternative devices to avoid regulation is to declare their intended use for non-medical analysis, indirect supplemental treatment dealing only with brain waves and external bioenergy fields, or merely collecting data. Furthermore, the actual use and real context of the device must support its declared non-medical application. In other words, if one gives a perfunctory disclaimer, but proceeds to diagnose and treat, the courts will see through it. It is necessary to be consistent in using a safe technical description of one’s activities which supports the theory of indirect external effects on brain waves and bioenergy fields. Licensed practitioners who really do want to diagnose and treat, however, must make use of the less restrictive labeling requirements that apply to investigational devices. (See 21 U.S.C. 360(j)(g)).

Thus, the psychotronic practitioner can only be safe by learning the detailed legal analysis of the Food Drug and Cosmetic Act and how it is interpreted by courts, and following the many intricate requirements of claims and labeling. While it is true that there is an “investigational device exception” provided for in the Food Drug and Cosmetic Act, this exception requires registering the device with the FDA for approval, and is not really a full exception, but merely offers less restrictive labeling requirements along with the many other legal formalities that must still be complied with.

The solution to the “medical device” restrictions and FDA persecution is threefold: (1) Practitioners must learn to use descriptions which more accurately reflect the present abilities and actual functioning of psychotronic technology, not its desired status for the future; (2) engineers of bioenergy devices must present scientific theories which support (and do not contradict) the legitimate use of psychotronics for purposes that are not physically medical (such as bioenergy or mental energy), to avoid FDA jurisdiction; and (3) there must be available expert witnesses from the energy medicine community to develop case law with positive precedents. Their testimony can prove that bioenergy technologies can have legal, proper and legitimate uses in therapy, and that psychotronic devices are not “intended” as medical devices.

Now, if claims and descriptions are presented properly, and avoid claims of actual “diagnosis” or “treatment,” psychotronic devices cannot be classified as medical, and will be clearly outside of FDA jurisdiction, and the FDA can only ban them if the agency proves that they do “effect the structure or function of the body.” However, the FDA is highly unlikely to show this, because it would contradict decades of its own expert witnesses and case law saying that Radionics machines don’t work.

In this way, practitioners can turn the tables on the FDA, avoid FDA intimidation by mere jurisdiction over certain devices, and stop being automatic losers in court from reuse of flawed case law precedents. If the agency can’t prove that psychotronics works physically, it won’t have jurisdiction, and psychotronics is safe. If it can prove that psychotronics works physically, then it can’t say its fraudulent or illegal, and the FDA will have already done the \$30 million approval testing, so psychotronics is also safe.