LAWYERS AGAINST FRAUD

TO WHOM IT MAY CONCERN:

A medical device is misbranded if its advertising claims are "false, unverified or misleading" in any way Devices that are not authorized for marketing that are marketed for uses not on their approved or cleared labels ("off-label uses") unauthorized intended use of the device would also render the device "misbranded." Knowingly selling such a device constitutes a crime. (21 U.S.C. § 352(q)).

Substantial evidence that Mandelay, Echo North America and SST are marketing an unproven 'off use' of an unverified reactivity matrix has come to us. Our investigation has found this deceptive ploy to be a key factor in all their marketing and sales demonstrations. Many whistleblowers have already turned state's evidence against Mandelay, Echo NA and SST. These whistleblowers will be protected, while later receiving a percentage of penalties recovered Mandelay, Echo NA and SST in a Government lawsuit.

***Qui tam* lawsuits** are a type of whistleblower **lawsuit** that is brought under the False Claims Act. This is a law that rewards whistleblowers in successful cases where the government recovers funds lost to fraud.

Pure biofeedback is legal but using biofeedback to get reactions to substances and even diseases needs extensive science and research that Mandelay, Echo NA and SST have not demonstrated in any fashion. All such unscientific unsupported claims or deceptive demonstrations by any presenter or promoter will result in *qui tam* cases and most likely prosecution of criminal charges.

The FDA enforces the advertising and promotion of medical devices in a variety of ways. The first and obvious way is by reviewing labeling and other publicly disseminated materials. The FDA will find false advertising and promotional materials from any source or by any means, such as reading product web pages and surfing the Internet to learn how a device is really being used by consumers. In addition, FDA compliance reviewers attend trade shows and scientific/medical conferences, read periodicals and inspect company and sales facilities. An FDA agent need not reveal himself even under request. Evidence attained of false claims can be valid in court under the FCA.

Liability under the federal False Claims Act can occur where a defendant knowingly presents (or causes to be presented) a false or fraudulent claim for a medical device. The matrix reactivity of Mandelay, Echo NA + SST is clearly unsubstantiated and a false claim.

FCA (False Claims Act) violations cases are brought by whistleblowers, who typically have previously attempted to call attention to the problem within their company. *Qui tam*, which is a feature of the False Claims Act, is a unique mechanism that allows persons and entities with evidence of fraud against federal programs to sue the wrongdoer on behalf of the government. Currently, *qui tam* provisions include strong financial incentives for a whistleblower to file a lawsuit on behalf of the federal government.

The Federal Trade Commission combats this type of deceptive advertising in coordination with the Food and Drug Administration. The FTC also seeks the expertise of other government authorities, including the National Institutes of Health. All too often, the 'off-use' health claims made for these products are false, unproven and unscientific. Over the last decade, the FTC has filed over one hundred cases challenging health claims made for medical devices.

Medical equipment fraud typically starts with the manufacturer, from off-label marketing. If the manufacturer intends to market a previously cleared device for a new or different indication for use other than the intended use cleared by the FDA, a new marketing authorization is required. While physicians may prescribe medical devices for unapproved uses, a manufacturer may not distribute medical devices in interstate commerce with the intent that those devices be used for unapproved purposes. Such willful intent is a crime which will result in prosecution to any sales person or commissioned presenter.

A representative from LAF called Mandelay and SST for a description of the matrix reactivity and received only unscientific gibberish. It became clear that this was a fraudulent claim used for sales. These companies also reported using TENS, CES, and other therapies not cleared for use on their device in America.

Whistleblowers and or covert agents will attend all conferences and on-line training to witness the invalid claims of the matrix reactivity. Civil and even criminal prosecution will result to all demonstrating unverified unscientific matrix claims. In court, the people making unscientific claims will be asked to fully describe the science, research and studies behind such claims. Unverified claims of results in treating Lyme disease, degeneration, infection, and more were found in the literature and web sites of theses sales agents.

By filing successful *qui tam* actions against manufacturers that engage in FDA fraud, Lawyers Against Fraud is stepping into the forefront in helping the government recoup hundreds of millions of healthcare dollars wasted on devious business practices in medical device industry, in which manufacturers market their devices without FDA approval or for uses not approved or cleared by the FDA. LAF and the federal government have a special interest in exposing these manufacturers.

Medical malpractice is a legal cause of action that occurs when a medical or health care professional deviates from standards in his or her profession, thereby causing injury to a

patient. **Medical Negligence** (Lat. *negligentia*) is a failure to exercise appropriate and or ethical ruled care expected to be exercised amongst specified circumstances.

Knowingly using misbranded devices with unsupported claims is a form of malpractice and negligence. Therapists knowingly participating in such Mandalay + SST fraud will be involved in this Qui Tam lawsuit of the government. Malpractice and Medical Negligence charges will result.

All practitioners using the fraudulent Mandelay SST units can be prosecuted for Medical Malpractice and False Claims to patients. Civil and maybe criminal cases can result.

Summary:

This correspondence is a warning to any who cannot scientifically validate their subtle claims and marketing demonstrations. Continued unverified assertions will constitute knowingly and willful breach of the FCA law. Any who wish to avoid future trouble should consider turning states evidence and write back to us for instructions or should use caution and not risk prosecution by removing contact from any unsubstantiated sales organization.

As we build our case of FCA violations and misbranding, we need to see who the whistleblowers will be and who will be prosecuted.

Important Facts:

1. There will definitely be a FCA government Qui Tam, Whistle-blower lawsuit against Mandalay, Echo NA + SST. The evidence of wilful fraud of unsupported "off use" of matrix reactivity is excessive and increasing.
2. There is undeniable evidence that Mandalay + SST have NO science, NO polography, NO research on their software, NO validation of their main claim whatsoever. Review of this evidence clearly reveals a web of deceit, theft, and fraud.
3. Dubious and unlicensed promoters present unsubstantiated misbranded adulterated "Off Use" claims of a matrix reaction. These charlatan promoters know there is no science and validity behind their Matrix reactions, so they wilfully and knowingly breach the False Claims Act. Sales agents are illegally used as lecturers to promote their fraud. On American soil, American and even foreign sales agents can be detained, questioned and even prosecuted under the FCA.
4. Lawyers Against Fraud will sweep through this entire industry and stop all unsubstantiated "off use" claims. The buyers and the public must be protected from fraudulent claims and deceitful promotion schemes.

http://www.whistleblowerfirm.com/qui-tamfalse-claims-act/what-is-a-false-claim/

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From Lawyers Against Fraud

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