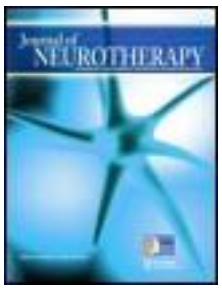

Journal of Neurotherapy: Investigations in Neuromodulation, Neurofeedback and Applied Neuroscience

Editorial

Fred Johnson Acting Managing Editor

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Editorial

Fred Johnson, Acting Managing Editor

The best laid plans of mice and men, my mother always cautioned me, don't always work out the way you expect. In the last issue, I started my editorial by stating it was my last editorial for the Journal. Wrong. Since then, Cindy Olson resigned as Managing Editor and we have been in a bit of chaos.

Cindy did a tremendous job for us getting the Journal of Neurotherapy up and operating. She worked closely with the peer reviewers and the authors to improve the quality of the papers we are publishing. She was an outstanding editor and we will miss her. The staff is working diligently to get caught up and we are looking for a suitable replacement. In the meantime, I will fill in as the managing editor for the next couple of issues.

Photic stimulation is a process of using flashing lights to change brain wave patterns. The flashing lights may be of any color though red and white are most commonly used. The lights are normally flashed onto the closed eyelids of both eyes. The frequency of the flashing lights varies considerably and devices are currently available which flash in the delta, theta, alpha, and beta frequencies.

Some clinicians are starting to incorporate photic stimulators into their neurotherapy practices; if they are properly trained in the use of these devices, I have no problem. However, some of these clinicians are not properly trained in the use of these devices, nor in handling adverse reactions to the devices when and if they occur. Additionally, several mail order catalogues and some retail businesses are now offering these devices to the public, and with this I have a problem.

In the first place, photic stimulators are defined by the Food and Drug Administration as medical devices because they change the function and structure of the human body. Under the law, it is not legal to sell these devices to the public without a physician's prescription. It is legal to sell them to licensed healthcare practitioners if and only if the device is properly registered with the FDA.

This leads to my second problem. In preparing this editorial I spoke with several photic stimulator device manufacturers. The devices manufactured by Cadwell, Grass, Nicolet, Nihon Khoden, and Teca were all approved by the FDA. These companies all reported their photic stimulators are normally used for diagnostic purposes.

The other companies I contacted all made various claims about their devices being effective for remediation of sleep disorders, learning disorders, anxiety, depression, stress, and a variety of other medical problems. None of these companies is registered with the FDA. One manufacturer told me straight out there was no way the FDA would ever approve his equipment so he wasn't even going to try. A couple of other manufacturers suggested as much.

This frightens me. Here we have seemingly legitimate business people who have decided to market their medical devices directly to the public because they believe our government will not approve their equipment for medical use. What am I missing here? If what they say is true, then their behavior is unconscionable.

In discussing the effect of these devices on the human mind with several of our edi-

tors, I believe photic stimulators are dangerous and should not, absolutely should not, be used by the public except when under competent medical supervision. To me this means that the clinician is licensed in a recognized medical field and has been fully trained in the use of these devices. The reason for this lies in the list of side effects attributed to photic stimulators.

The side effects run the gamut from simple things like headache, slight disorientation, queasiness of the stomach, feelings of nausea, and irritability, to more serious conditions. Conditions like insomnia, panic, depression, and seizures head this list. Now if I were to have one of the minor side effects when I used a photic stimulator, I would not be a happy camper but I could live with it if the benefit outweighed my discomfort. But, if I were to suffer a seizure there would be no amount of benefit I can think of that would be worth the tradeoff. Either way, I would prefer to be under the care of a very competent and knowledgeable physician.

This is what the unknowing public is getting into. They are buying medical equipment which is not, and probably does not qualify to be, approved by the FDA for human use. At the same time they are not being educated in the proper use of this potentially very dangerous equipment, nor are they being told about the potential hazards.

I asked two salesmen whether they were informing the public of the potential hazards of their photic stimulators and they told me it wasn't their responsibility to inform the public about insignificant side effects. Great! I believe this is the same argument used by several major tobacco companies until just recently. Just whose responsibility is it to inform the public about photic stimulation?

Until the FDA cleans up that industry as they cleaned up the drug and tobacco industries, who bears the responsibility for properly informing the public about the hazards of using photic stimulation equipment? There will be side effects, and these side effects can be constructively managed by medical practitioners who are properly trained in the use of the equipment.

In the meantime, protect yourself. Should any patient of yours ever report any adverse effects from photic stimulation, file a report with the FDA and keep yourself out of a potentially very damaging lawsuit. Failure to report such an incident could cost you your license. It could also cost you an FDA fine.

Selling non-FDA registered photic stimulators to the public or suggesting their use could not only cost you your license, it could cost you a big FDA fine of up to $10,000 per device. To speak with the FDA regarding these issues or to obtain a complaint form, call the MedWatch Consumer Affairs Hotline at 1-800-332-1088 and select the medical care provider option. Be prepared to wait several minutes until you can speak with a specialist who is well informed about these devices.

A Note from the Editor

Changes in our editorial staff have caused our production schedule to be delayed. We apologize for any inconience caused by the delayed publication of recent issues of the *Journal of Neurotherapy*. We are making every effort to resume our normal production schedule.