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Medical Alert

Aggravated Symptom Relapses Reported after Use of Widely Available EMR Protection Products

Contact: Dr. George Carlo (drcarlo@safewireless.org); (202) 756-7744

Reasons for this Advisory:

- An alarmingly high number of patients with electro-hypersensitivity and other related conditions are reporting serious symptom relapses after periods of time when symptoms were apparently mitigated by use of products that claim to be protective against electro-magnetic radiation (EMR) related disease.
- The symptom relapses are reportedly more severe than the symptoms that defined the original illnesses – suggesting that the patients are sicker after the use of the purported protective products than before the use.
- We fear that consumers are being lured into a false sense of security by their use of widely available products purporting to prevent disease – causing consumers to unknowingly compound the effects dangerous exposures by increasing their use of wireless devices.
- In the United States as well as globally, no steps have been taken by either the Food and Drug Administration or any other regulatory authority to protect patients and consumers from this apparent danger.
- Thus, our intent is to empower consumers to protect themselves in this regard.

Scientific Underpinning:

- Several patients with electro-hypersensitivity and other conditions associated in the scientific literature with EMR exposure are reporting symptom relapses that is believed to be more severe than the symptoms that led to their original diagnosis.
- These patients, being treated by clinicians in our contact network, also report having used products widely available on the open market that claim to mitigate, neutralize, counteract,

eliminate, or otherwise protect against harmful effects of EMR, without the benefit of careful clinical supervision.

- The average time of using these products before the symptom relapses occurred is reported in the range of 9 to 18 months.
- There is biological plausibility supporting these reports of adverse reactions.
 - The mechanisms of harm now believed to be associated with EMR disease underscore the need to comprehensively and simultaneously address mitigation of exposure, amelioration of symptoms and repair of biological damage done by prolonged exposure to EMR
 - When symptoms are not addressed comprehensively – for example, using symptom amelioration without simultaneous elimination of exposure to all EMR-effect windows – cell membrane adverse reaction and damage continue to occur while the patient is assuming the cause of the problem has been eliminated. This lulls patients into a false sense of security, causing them to aggravate their exposures through increased use of their wireless devices. When the damage reaches a critically harmful level, even the symptom amelioration can no longer be sustained by the damaged cells.
 - Pregnant women are a special concern in view of recent data showing damage to the fetus in the form of both altered secondary sex ratio and latent appearance of adolescent behavioral problems. Low levels of EMR exposure have been reported in these studies – suggesting impacts of even subtle amounts of extraneous energy on fetal development. This suggests that products that produce subtle energy as intervention would be biologically active as well, and especially dangerous to the developing fetus.

What Can Patients and Consumers Do to Protect Themselves?

1. Be Empowered by the Knowledge That Product Testing Standards Exist For Your Benefit and Demand That Protection from Those Selling You Products.

- Whether or not a product is regulated by a government agency, any company selling a product has a legal responsibility to warn consumers of potential dangers. Obtaining the necessary knowledge requires specifically focused scientific study addressing both the safety parameters of the product and the usefulness (efficacy) of its action in preventing or treating disease. This is a product liability requirement for all companies engaged in the sale of products that have biological, chemical or physical activity.
- Note that if a product does not have biological, chemical or physical activity, it by definition can not have a beneficial effect in mitigating disease – because mitigation requires biological, chemical or physical action. Thus, any product that claims to mitigate disease or symptoms is required by law to have supportive science.

- There are international standards of care that define acceptable parameters for safety and efficacy studies. These guidelines can be obtained from the United States Food and Drug Administration (FDA) and other similar agencies around the world.
- The most relevant requirements of the FDA and similar agencies around the world with regard to product testing standards intended to protect consumers and standards to which consumers are legally entitled, include the following:
 - The FDA and similar agencies make decisions about approving products through review of scientific data, submitted by product companies, that attest to company claims of both the **safety** of the product (whether or not it produces adverse reactions such as those reported here), and the **efficacy** (usefulness) in preventing or treating symptoms and disease.
 - Safety Studies: Whenever a company makes a claim of *efficacy*, there is a presumption the product has biological, chemical or physical activity. As such, there is a presumption of potential harm or danger coming from the product if it is misused. The company must therefore address, through science, problems that could occur: if the product is administered in doses that are too high; if administered in an inappropriate manner; or if administered along with other interventions or drugs that may cause an adverse reaction because of combination effects.
 - Efficacy Studies: Specific applications of the product need to be addressed in the pre-market research. Only those uses supported by science can be legally promoted by the company. Other uses – called off label uses – carry stiff monetary and criminal penalties.
 - To ensure the integrity and honesty of the company-submitted science, the FDA requires that all studies follow internationally accepted standards of Good Laboratory Practices (GLP) and Good Clinical Practices (GCP). Studies that do not meet these requirements are not considered by the FDA in decision making because those studies are presumed to be suspect or flawed.
 - Even with these pre-market testing requirements in place, problems can be missed and mistakes can be made. Thus, the FDA also requires post-market surveillance where adverse reactions to products that have been previously approved are catalogued and reported – first to the FDA and then to the public.

2. Demand to See Proof of Safety and Efficacy Before Buying or Using Any Product that Claims Protection.

- Consumers have a right to the highest standard of care from those who claim to have either preventive or therapeutic interventions for EMR hazards, irrespective of whether or not the FDA or another agency requires that specific studies be done prior to marketing and sale. An honest company acting with integrity will do the work required to protect those who use their products – and then be proud to let consumers

know the results of their work. Product inserts and package labeling should contain enough information to insure that consumer rights are not being violated.

- Before buying or using any EMR intervention product, consumers should:
 - Require proof in product inserts or on packaging that studies of safety have been completed according to acceptable scientific protocols, including independent peer review as evidenced by either publication in peer reviewed journals or by disclosure of the names of the independent peer reviewers.
 - Require proof in product inserts or on packaging that those studies of safety address: dosing specific to the manner in which the intervention is used; contraindications – especially with regard to young children and pregnant women; specific administration protocols for both symptomatic and non-symptomatic potential users; and proof that the studies have been corroborated by different laboratories or investigators.
 - Require proof in product inserts or on packaging that studies of efficacy have been completed according to acceptable scientific clinical protocols – also including evidence of independent peer review and corroboration of findings. The studies should include clear written documentation of the mechanisms through which the products are supposed to work in preventing or treating conditions.
 - Require proof in product inserts or on packaging that a program of post-market monitoring of adverse reactions exists as well as procedures to notify and warn consumers of problems when necessary.

3. If You are Symptomatic, Do Not Self Medicate or Take Advice on Your Condition from People Selling Products Who Are Not Clinically Qualified or Otherwise Professionally Knowledgeable of EMR Health Effects and Mitigation.

- Any person with symptoms of electro-hypersensitivity, including multiple chemical sensitivities, Autism, ADHD, anxiety syndrome, Parkinson's, alcoholism, drug addiction and Alzheimer's should only use EMR intervention products with appropriate guidance from a qualified clinician.
- The underlying pathologies in these conditions are similar and thus require careful monitoring whenever EMR targeted interventions are added. If this is not done, severe adverse reactions can occur – sometimes as part of the normal healing process, and sometimes not. Only qualified professionals can identify which is which.