

**Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554**

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| In the Matter of |) | |
| Regulatory Issues Arising from Health |) | FCC Docket No. ET 10-120 |
| Care Devices that Incorporate |) | FDA Docket No. FDA-2010-N-0291 |
| Wireless Communications Networks |) | |
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To: The Federal Communications Commission and the Food and Drug Administration

**Comments from David A. Larson
FCC Licensed Technician Class Operator KI6JJN**

David A. Larson, (hereinafter “Mr. Larson”), respectfully submits the following response to the above-captioned Federal Communications Commission (FCC) and Food and Drug Administration (FDA) rulemakings relating to the Commission's June 15, 2010, public notice, DA 10-1071, and in opposition to experimental license operations conducted by licensee Alfred Mann Foundation (AMF). Mr. Larson prevailed in the November 2009 consolidated election, and serves as an elected Director of a state agency. In addition to serving as an elected Director, Mr. Larson also serves on the Planning, Legislative, Engineering, Grants and Security (PLEGS) Committee, engaging in bi-monthly conference calls with other elected officials and lobbyists in Washington D.C..

Mr. Larson has been involved in research and development efforts of implantable microstimulator devices since March of 1997, and has followed the intellectual property and research endeavors of the Alfred Mann Foundation for many years. In the interest of transparency and accountability, Mr. Larson wishes to introduce into record, the following facts and issues relevant to these proceedings:

While there is indeed humanitarian medical potential for such FES technologies, AMF has conducted the bulk of their research under a “cross-cutting” directive, which indicates a focal on defense and intelligence applications as well as the humanitarian or medical applications. This cross-cutting

directive has been made public by government funding bodies, including the NIH/NIBIB which has funded AMF in the past. Mr. Larson has been directly involved in R&D efforts through an informal relationship with contract personnel, and has a well-founded belief that the defense and intelligence directives of AMF are primary to the medical aspect. The challenges and obstacles in bringing neural prosthesis technology to market are many, including grossly expensive FDA PMA and 510(k) regulatory approval processes, unfair Medicaid/Medicare reimbursement classifications, and volatile product liability. Even if regulatory approval is attained and the product is marketed, the significant costs of multiple electronic devices which require surgical placement is likely to be deemed a luxury rather than a medical necessity by HMO's. The fiscal outlook for such technology is grim, and is explained with remarkable detail in a thesis authored by Samuel Hall. In contrast, defense and intelligence contracting comes with practically no civil liability, and revenue remains at unprecedented levels.

In determining if this technology will ever benefit “millions of Americans” as is repeatedly claimed by AMF supporters, one only needs to look at cochlear implants. According to the Archives of Otolaryngology and as reported in Reuters, the Food and Drug Administration approved cochlear implants for adults in 1985 and since then an estimated 41,500 adults have received one. The implants require surgery and extensive post-implant follow-up for programming the device and monitoring, leading to costs of around \$40,000 per patient. There are tens of thousands of candidates in our nation who are eligible for, and would benefit greatly from, a cochlear implant, but the costs are prohibitive. AMF and it's supporters have in fact grossly exaggerated the humanitarian medical potential.

AMF has been developing the microstimulator technology, originally dubbed “ μ Stims”, and later as the “BION”, under government contractual obligation since January of 1989. For more than 20 years, AMF has claimed to be only a few months away from “upcoming clinical trials”. In 2006, AMF submitted comments in response to the MedRadio NPRM/NOI (ET Docket No. 06-135, RM-11271), which state “*AMF expects to conduct testing and clinical trials of the technology next year*”. That was 4 years ago. In 2004, AMF was issued experimental license WD2XLW for the purpose of conducting research studies and when FCC/OET asked for specifics regarding AMF's arrangements with study participants,

AMF replied “*The Alfred Mann Foundation (AMF) does not have any contractual arrangements with the participants in the studies*”. That was six years ago.

The California Medical Board has received complaints alleging that a AMF employee, a licensed M.D. , had initiated studies which used human subjects without informed consent or IRB approval. The University of Southern California Office of Compliance investigated the AMF faculty personnel during an investigation that lasted many months. AMF has been litigated in U.S. District Court for conducted unlawful research efforts using the WD2XLW experimental license. The FCC/OIG has failed to act or prevent abuse of the WD2XLW license which allows operation anywhere in the United States, by an unlimited number of personnel, and the requirement to identify the call-sign for WD2XLW has been waived. AMF has had the license for 8 years and has not used it to conduct any FDA approved clinical trials. Prior to 2004, the FCC received complaints that AMF personnel were using an Amateur license of it's President (K6BWA) for research endeavors, which is in violation of FCC Amateur regulations.

In closing, there exists underlying motive relevant to these proceedings and I wish to remind the FCC as well as parties involved, the priority here should be protecting the interest of the public. The potential for abuse of this technology is far too great. The FCC must consider the defense and intelligence implications to this technology and take safeguards to prevent harm to U.S. Citizens. This is not policy that affects defense and intelligence operations on a battlefield, but clearly, it is policy that affects us in our homes, schools and workplace.

/s/ David A. Larson

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