



OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

AUG 9 2011

The Honorable Jim Webb
Chairman, Subcommittee on Personnel
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

This letter responds to House Report 111-491, page 317, to accompany H.R. 5136, the National Defense Authorization Act for Fiscal Year 2011, which requested the Secretary of Defense take into account the medical benefits of micro-stimulators controlled by low-powered radio frequencies for Active Duty Service members. The Report asked for a report on any spectrum sharing issues for parts of the spectrum under the control of the Department of Defense (DoD) related to micro-stimulators.

DoD conducted a literature review and queried the Walter Reed Army Institute of Research and the Telemedicine and Advanced Technology Research Center of the U.S. Army Medical Research and Materiel Command to discern the current uses of this technology for Wounded Warriors. There are no published studies for the use of this technology for Wounded Warriors, and there is a lack of reliable evidence that shows the use of this technology is a safe and effective treatment option for patients. The identification of spectrum sharing issues is premature at this time until additional research has been done on the use of micro-stimulator technology. The Department is always interested in well designed research proposals that help explore the value of emerging technologies to assist in the recovery of Wounded Warriors. Investigators are encouraged to contact the U.S. Army Military Research and Materiel Command Armed Forces Institute of Regenerative Medicine for details of submission requirements to be considered for DoD funding. A brief report is enclosed. A similar letter is being sent to the other congressional defense committees.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families.

Sincerely,

A handwritten signature in black ink, appearing to read "Jo Ann Rooney".

Jo Ann Rooney
Principal Deputy

Enclosure:
As stated

cc:

The Honorable Lindsey Graham
Ranking Member



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WASHINGTON, D.C. 20301-4000

PERSONNEL AND
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306 6 1

The Honorable Carl Levin
Chairman, Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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The Honorable John McCain
Ranking Member



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PERSONNEL AND
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AUC 10/17

The Honorable Howard P. "Buck" McKeon
Chairman, Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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The Honorable Adam Smith
Ranking Member



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WASHINGTON, D.C. 20301-4000

PERSONNEL AND
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The Honorable Joe Wilson
Chairman, Subcommittee on Military Personnel
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

100 7 10

Dear Mr. Chairman:

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The Honorable Susan A. Davis
Ranking Member



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PERSONNEL AND
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DDG 6

The Honorable Daniel K. Inouye
Chairman, Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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The Honorable Thad Cochran
Vice Chairman



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The Honorable Daniel K. Inouye
Chairman, Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

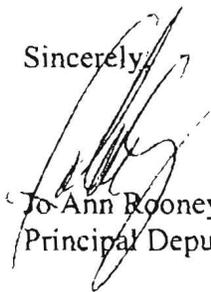
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PERSONNEL AND
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The Honorable Harold Rogers
Chairman, Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

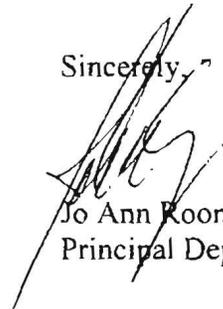
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The Honorable Norman D. Dicks
Ranking Member



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The Honorable C. W. Bill Young
Chairman, Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

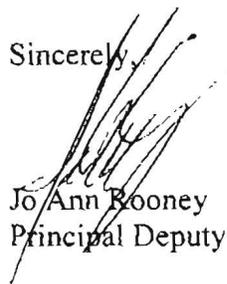
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MEDICAL TECHNOLOGY and SPECTRUM SHARING

Preparation of this study/report cost the Department of Defense a total of approximately \$2,151 for the 2011 Fiscal Year.

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Reference: 1-F71418C

MEDICAL TECHNOLOGY and SPECTRUM SHARING

House Report 111-491, page 317, to accompany H.R. 5136, the National Defense Authorization Act for Fiscal Year 2011, requested the Secretary of Defense take into account the medical benefits of micro-stimulators controlled by low-powered radio frequencies for Active Duty Service members. This type of technology has also been called 'functional-neuromuscular stimulation feedback-control system' (Troyk PR, 1999); 'neuromuscular microstimulators' (Kaplan HM, 2009); and Radio Frequency Micro-stimulator (RFM) (Fitzpatrick on the ClinicalTrials.gov site, 2010). The Report also requested a report on any spectrum sharing issues related to micro-stimulators.

The Department of Defense believes the use of micro-stimulators controlled by low-powered radio frequency has not met the clinical or efficacy standards needed in order to use on Active Duty Service members. A clinical literature review found several ongoing animal studies, and a few promising clinical trials; however, no study indicated a well-controlled clinical trial with this technology. Accordingly, there is much more research to be done to reach the level of evidence required for use with our wounded warriors.

In order to ensure our beneficiaries receive services that meet the standard of care, that is, appropriate medical care, the Code of Federal Regulations (32 CFR 199.4(g)(15)) requires there be reliable evidence, as that term is defined in 32 CFR 199.2(b), showing that any medical treatment or procedure has been the subject of well-controlled studies of clinically meaningful endpoints that demonstrate safety and efficacy compared with the standard means of treatment or diagnoses. The term clinically meaningful endpoints means objectively measurable outcomes of clinical interventions or other medical procedures, expressed in terms of survival, severity of illness or condition, extent of adverse side effects, diagnostic capability, or other effect on bodily functions directly associated with such results.

The definition of reliable evidence provides the hierarchy of reliable evidence used to determine whether a drug, device, medical treatment or procedure has moved from the status of unproven to the position of nationally accepted medical practice as follows:

1. Well-controlled studies of clinically meaningful endpoints, published in refereed medical literature;
2. Published formal technology assessments;
3. Published reports of national professional medical associations;
4. Published national medical policy organizational positions; and,
5. Published reports of national expert opinion organizations.

Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence, or personal professional opinions. Also, not included in the meaning of reliable evidence is the fact that a provider or number of providers have elected to adopt a drug, device or medical treatment or procedures as their personal treatment or procedure of choice or standard of practice.

Beyond the clinical literature review, the Department determined that there is no such device in the research portfolio at either Walter Reed Army Institute of Research or at the Telemedicine & Advanced Technology Research Center (TATRC). TATRC is an office of the

MEDICAL TECHNOLOGY and SPECTRUM SHARING

headquarters of the U.S. Army Medical Research and Materiel Command (USAMRMC)) which performs medical review and special investigations to address critical gaps that are underrepresented in DoD medical research programs. TATRC fosters research on health informatics, telemedicine, medical training systems, and computational biology, and promotes and manages science and engineering in other key portfolios. Through an extensive network of partners, TATRC is focused at both ends of the research spectrum, exploring models of high risk and innovative research, and putting research findings into the hands of warfighters while looking toward wider civilian utility. TATRC augments core medical research programs through special funding and partnership opportunities.

Spectrum sharing issues related to micro-stimulators has not been considered as this issue is secondary to the safety and efficacy of the use of the microstimulator technology for use by patients. When a sufficient number of well-controlled clinical trials, with results defined by the parameters noted above, spectrum sharing may be considered.

The Department is always interested in well designed research proposals which help us explore the value of emerging technologies to assist in the recovery of our wounded warriors. Investigators are encouraged to contact the United States Army Military Research and Materiel Command Armed Forces Institute of Regenerative Medicine for details of submission requirements to be considered for DoD funding at:

Project Director, Armed Forces Institute of Regenerative Medicine (AFIRM)

US Army Medical Research and Materiel Command

ATTN: MCMR-RTR

504 Scott Street

Ft. Detrick, MD 21702-5012

Email: afirm@amedd.army.mil.