

## **Submission for the Record** **House Committee on Veterans Affairs, Subcommittee on Health**

**Thomas T. Tierney, George C. Carpenter IV**

In July, we asked that the Committee take note of the growing role of predictive analytics in reducing harm from mental health medications chosen by trial and error. Our news today is very positive, and it is our belief that HR 5059 may accelerate adoption of such innovations.

### **Suicide Prevention — the best place to start is to avoid the wrong medications**

In mental health, the elephant in the room is that standard treatments don't work very well, and evidence for them has deteriorated substantially since the medications were first approved. Since each medication used to treat mental disorders carries an FDA "black-box warning" for suicidality, reducing trial and error treatment is a military imperative.

Predictive analytics — in the form of PEER Interactive — have significantly reduced trial and error in multiple clinical trials. Results of the Walter Reed PEER Trial became clear in the first 10% of trial enrollment, as shared with Congress in April. When physicians used PEER information:

- Suicidality scores were 75% lower
- Depression scores were 144% lower
- Post-Traumatic Stress Disorder (PTSD) scores were 139% lower
- 43% more patients remained in treatment, with over 50% gain in treatment efficiency

As every PEER trial has demonstrated, **doctors with more information achieve better outcomes**. From a budget standpoint, we can no longer afford trial and error prescribing of medications as our dominant treatment, with costs that are 4 times higher than effective first-line treatment. And the human costs of trial and error therapy, for veterans and their families, are intolerable.

### **Preventable medical error — the problem**

In July, the parents of Clay Hunt and Daniel Somers gave us stories that were hard to hear: they spoke of treatment delays, trial and error pharmacotherapy, and inexplicable differences in treatment between facilities. Still, VHA faces challenges in improving access, because:

- VHA cannot hire clinicians fast enough - only 681 residents enter the specialty each year
- Clinicians in private practice cannot fill the gap - only 13% have capacity (per RAND)
- Current treatments are not effective enough to prevent dropouts

### **Comment on HR 5059**

- We ask the Subcommittee to be cognizant of the severe supply limitations in Psychiatry, which impacts hiring and retention of mental health professionals.
- We recommend that VHA prioritize research on physician extending technologies, like PEER, which can multiply the reach of VHA's current pool of Psychiatrists.

### **The Military response to preventable error**

In September 2014, Defense Secretary Hagel committed to "system-wide improvements in quality and safety", with a mandate to reduce preventable error across the board and to achieve results that are not just average, or above average, but the best in class. The review was prompted by internal reports and a New York Times series finding widespread evidence of preventable error.

By the end of the year, each military hospital must have metrics in place to track quality improvement. Army Surgeon General Patricia Horoho articulated some of the principles behind this system-wide commitment to reducing preventable error:

- Take corrective action immediately — at the point of care

- Ensure transparency and accountability
- Use outcome data to improve the quality of treatments

The Army Surgeon General’s leadership is welcome, and we believe the hard lessons of its adoption path can be useful for the VHA in the course of its transformation under Sec. McDonald.

**Comment on HR 5059**

- Performance Metrics and Annual Independent Review are critically important components of 5059 — the only way to drive out fear of reporting and address root causes.
- Standards of evidence - VHA must set clear and transparent standards for evidence of superiority, so new innovations can be rapidly tested and adopted.
- Need to improve on VHA’s ability to rapidly execute public-private partnerships.

**Emerging Technology Improves the Odds**

Physicians in the 1990s made a surprising discovery: if they could match known medication outcomes to a standard test of electrophysiology, they could target medications directly to patients who would be more likely to respond to a particular agent. Even better, they could avoid the wrong medications. Just like most other specialties, where doctors use tests like x-rays, blood tests, or bone scans to guide their choice of treatment. The database, which now exceeds 37,000 clinical endpoints for 10,000 unique patients, is called PEER (Psychiatric EEG Evaluation Registry).

PEER is an outcome registry and recommendation engine based on machine-learning, so outcomes in this trial can make future generations of the PEER Report more predictive and useful to physicians. This same approach was pioneered by pediatric oncologists beginning in the 1970s, when cancer registries allowed physicians to better match treatments to patient phenotypes, driving cure rates for childhood cancers approaching 90% today.

**The Walter Reed PEER Trial**

The Walter Reed PEER Trial is designed to follow up to 1,600 soldiers under a public-private partnership with Walter Reed National Military Medical Center. First interim results focused on 150 evaluable subjects who were treated for up to six months at Walter Reed National Military Medical Center and Fort Belvoir Community Hospital, two of the nation’s largest psychiatric treatment centers for active military members.

The findings have been peer-reviewed for publication in *Neuropsychiatric Disease and Treatment*, the journal of the International Neuropsychiatric Association. Each of the interim trial results above were statistically significant, and were consistent with multiple prior studies of PEER technology. Accordingly, the FY15 Defense Appropriations Bill calls for expansion of this approach:

**Prescription Effectiveness of Psychotropic Medications...**

*The Committee understands that this research is currently taking place at Walter Reed NMMC and Ft Belvoir Community Hospital and encourages its expansion to additional sites as preliminary findings have shown promising early results.*

**Cumulative evidence**

While the evidence base for antidepressants has worsened in recent years, the evidence base for quantitative EEG biomarkers has grown: there are now 98 controlled trials of EEG-medication response prediction, representing 6,025 subjects. Most were independent studies of similar technologies or sub-components of PEER, with 6 controlled studies sponsored by CNS Response.

**Conclusion**

Improving medication performance for our veterans is a problem that neuroscience can answer, that can improve lives today. We support passage of HR 5059, to help the VHA accelerate adoption of the best evidenced-based psychiatric care that our country has to offer.

### **CNS Response Disclosure of Federal Grants**

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| Grantor:   | Dept. of the Army  |
| Subagency:   | USAMRAA<br>United States Army Medical Research<br>Acquisition Activity |
| Grant/contract amount:   | \$1,782,211.00 (pending)   |
| Paid to date:  | \$54,000.00  |
| Performance Period:  | 07/01/2013 to 09/30/2015   |
| Indirect cost limitations or<br>CAP limitations:   |  |
| Grant number:  | 1217707  |
| Grant/contract award notice provided as part of<br>proposal:   | Yes  |
| Cooperative Research and Development<br>Agreement(CRADA) with Walter Reed National<br>Military Medical Center (WRNMMC) | 378604-12  |
| <u>ClinicalTrials.gov</u> identifier:  | NCT01794559  |

## **Thomas T. Tierney**

Thomas T. Tierney is Chairman of CNS Response and a Vietnam Veteran. He holds a BS (Business) and MS (Logistics Management) with distinction and holds graduate credentials in National Security Management from the Industrial College of the Armed Forces and Air War College. After completing a combat tour in Vietnam, he was assigned as a Pentagon Research Associate at the world-famous RAND Corporation in Santa Monica, California. In 1971 he joined Vitatech Nutritional Sciences, Inc. establishing it as a thought-leader in health-empowered nutritional formula innovation and production processes. In addition to operating one of the most respected FDA licensed manufacturing facilities in the industry, he has held positions as chairman of the board of the University of California, Irvine Foundation, and is a legacy trustee covering over 28 years service. Mr. Tierney also participates as a member of the UC Irvine Health Affairs Strategic Advisory Board and leadership initiatives to enhance programs in Veterans Affairs, the brain aging, stem cell applications in human health, longevity and disease prevention strategies, translational science and diabetes. He is a member of Orange County Advisory Boards for Homeland Security and Sheriff's Department.

**BACKGROUND****PRESIDENT & CEO**

CNS Response Inc. (CNSO:OB)

**CHAIRMAN & CEO**

WorkWell Systems Inc.

**CHAIRMAN & CEO**

CORE Inc. (Nasdaq: CORE)

**VICE PRESIDENT, OPERATIONS**

Baxter International Inc.

**AWARDS**Innovation in Healthcare Award,  
ABL, 2004Ernst & Young Entrepreneur of the  
Year Finalist, OC, 1998**PUBLICATIONS***Journal of Managed Care Medicine*,  
Vol 9, No. 1, 2006**The Shape of Things: The Rising  
Impact of Obesity**  
LRP Publications, 2006**BOARDS**Remedy Interactive Inc.,  
Sausalito, CA**WEBSITE**[www.cnsresponse.com](http://www.cnsresponse.com)

## George C. Carpenter IV CEO, CNS Response Inc.

A results-oriented biomedical executive with a passion for leading high growth and turn-around companies, George's focus is bringing new technology and business processes to underserved markets.

As CEO of CNS Response, Inc. (CNSO:OB) George is leading the commercialization of the company's patented PEER INTERACTIVE® technology for psychotropic medication management. CNS Response is the first biomarker solution for providers, in behavioral medicine.

Prior to CNS Response Inc., George ran WorkWell Systems, a national physical medicine firm managing occupational health testing programs for Fortune 500 employers. From 1990 to 2001, George served as Chairman and CEO of CORE, Inc., (Nasdaq: CORE) after leading the management buyout of this division of Baxter Healthcare. CORE was a pioneer in workforce health care management and analytics, establishing a record for clinical



<http://youtu.be/qdlsj2WnEkw>

software innovation and talent development that, in the words of one Wall Street analyst, "created an industry". CORE was acquired in 2001 by Assurant Inc.

Prior to founding CORE, George was a Vice President of Operations with Baxter Healthcare, served as a Director of Business Development and as strategic planner for Baxter's alternate site businesses. His career began at Inland Steel in manufacturing process control and Sales.

George serves on a variety of biomedical advisory and fiduciary boards, and is a frequent speaker and writer on healthcare technology and financing issues.

He earned his MBA in Finance from the University of Chicago and a BA with Distinction in International Policy & Law from Dartmouth College. George and his family live in Laguna Niguel, CA.

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