

# Submission for the Record House Committee on Veterans' Affairs

**George C. Carpenter and Henry T. Harbin, MD**

**July 10, 2014**

Chairman Jeff Miller, Ranking Member Michael Michaud, and distinguished members of the House Committee on Veterans' Affairs:

We are honored to present this Statement for the Record to the hearing on July 10, 2014. I'm Henry T. Harbin, a Psychiatrist with over 30 years of experience in the behavioral health field. I've run two national behavioral healthcare companies covering 70 million Americans, headed the public mental health system in Maryland for ten years, and served on the President's New Freedom Commission. I'm George C. Carpenter, and I serve as Chief Executive Officer of CNS Response, a technology company working with the U.S. military to improve medication outcomes in mental health.

Today, you will hear from the veterans and families most affected by the state of mental health care in this country. Their stories should move you to action. Our story may provide insight into what positive actions this Committee can take.

## **Recent IOM Findings**

The Institute of Medicine (IOM) report released in June 2014<sup>1</sup> was a catalyst for a system-wide review of treatment practices across both the Veterans Health Administration and the Department of Defense. The findings are relevant to this Committee's mission because despite a significant increase in spending, this four-year study of PTSD research and treatments came to a striking conclusion – we have no way to judge whether any of these programs work, because there's no collection of outcome data. To some extent, we're flying blind.<sup>2</sup> The Institute of Medicine recommended systematic collection of patient outcomes to support benchmarking, continuous improvement, and provider accountability across both departments.

We have a different story to share with the Committee, about a technology currently being piloted at Walter Reed NMMC which is doing ALL of these. Thanks to military leaders like Dr. Terry Rauch in Defense Health and the Behavioral Health leadership at Walter Reed National Military Medical Center, we may have **simple, powerful tools today that can improve medication outcomes, improve access to care, and reduce suicide risk for veterans.** It's good news. We ask that the Committee take notice of research in this area and encourage the VA and DOD to collaborate on rapid advancement and deployment of this type of research.

## **PEER Background**

PEER is an outcome registry that helps double the effectiveness of medications by providing doctors with objective information. This quality assurance information helps physicians to reduce trial & error prescribing, and thereby reduce patient exposure to ineffective medications.<sup>3</sup>

Physicians developed PEER to address a fundamental gap in mental health: while medications currently represent the dominant treatment for mental disorders, historically there has been no way to personalize therapy to an individual's unique physiology. Unlike most other specialties, where there is, for example, an x-ray or a blood test on which to base treatment, there has been no physiological test in Psychiatry to guide treatment. As a result, the most common treatment modality for mental disorders is trial and error pharmacotherapy. Which is exactly what it sounds like: your doctor will try one or more medications for up to six weeks to learn whether you respond and/or have intolerable side-effects, before proceeding to a different medication.

Even though it is the standard of care for most VA/DOD treatment, patients aren't often informed of the limitations of trial and error:

*For veterans to make such informed treatment decisions, they need to be educated about what treatment options are available and the risks, benefits, and possible outcomes associated with each option, including no treatment (VA/DoD, 2010).<sup>4</sup>*

We see in the IOM Report and from testimony before this Committee that real world clinical results for trial and error are not very good, and the evidence is not as strong as once thought. As a result, multiple studies have confirmed that 50% of patients will never seek treatment, 50% will dropout after a single visit, and 50% will not respond to prescribed medications.<sup>5</sup> Accordingly, SAMHSA has reported that only 12.7% of Americans get “minimally adequate” mental health treatment.<sup>6</sup> The IOM Report found that 33% of PTSD patients received “minimally adequate” treatment, but persistent trends in terms of stigma, dropout rates, and response rates have continued<sup>7</sup>. This is how military physicians have summarized the unmet need:

*“Despite the magnitude of the problem, treatment of mental illness is unsophisticated at best and unsatisfactory at worst. Current psychopharmacotherapy practices are clinician-dependent, inductive and assume that certain behavioral symptoms respond to a specific medication class. This selection process is highly subjective. Further, there has been no objective method to select which of the numbers psychoactive medications will be effective in any particular patient. Additionally, a large pharmaco-economic benefit could be seen if medications for patients could be based on an objective tool to inform the choice of medication by responsiveness or decreased adverse events.”<sup>8</sup>*

## **PEER Technology**

PEER\* is a crowdsourced registry of patient outcomes that is used to compare responsiveness or non-responsiveness to particular medications according to a common test of brain function, the Electroencephalogram (EEG). The process is simple: a patient receives a 20-minute EEG (a painless, non-invasive procedure) which is uploaded to the cloud, and within an hour their physician receives a 2-page report on medication sensitivity to his/her computer or iPad. Physicians enter outcomes at each visit which are then fed back into the database to improve its predictiveness for future releases.

Evidence for this approach is consistently strong. Over 84 prior clinical trials<sup>9</sup> representing over 3,500 subjects using PEER, its predecessor technology rEEG, and other quantitative EEG tools have demonstrated success in predicting medication response. These trials have consistently shown **a doubling in medication effectiveness, and more recent trials have shown substantial reductions in medication risk, improvement in adherence to treatment, and improved physician efficiency.** In a randomized, prospective controlled multisite trial including Harvard, Stanford, and the University of California, Irvine, in 2011, DeBattista et al reported:

\* PEER: Psychiatric Electroencephalography Evaluation Registry

*“...rEEG-guided pharmacotherapy [PEER] would represent an easy, relatively inexpensive, predictive, objective office procedure that builds upon clinical judgment to guide antidepressant medication choice.”<sup>10</sup>*

Similarly, a 2012 retrospective study of 435 patients for a commercial healthcare payer identified significant potential to reduce medication risk, **including a statistically significant 87% reduction in suicidality:**

*This chart review demonstrated significant improvement on the global assessment scales Clinical Global Impression – Improvement and Quality of Life Enjoyment and Satisfaction – Short Form as well as time to maximum medical improvement and decreased suicidality occurrences. The review also showed that 54.5% of previous medications causing a severe adverse event would have been raised as a caution had the PEER Report been available at the time the drug was prescribed.”<sup>11</sup>*

Because PEER captures outcomes, provides physicians with objective data, and has machine-learning algorithms which foster continuous improvement, this technology addresses the major requirements established in the IOM report.

### **Walter Reed PEER Interactive Trial**

The PEER Interactive Trial at Walter Reed National Military Medical center was initiated in January 2013, and has so far enrolled approximately 10% of its planned 1,922 service members. The trial is designed as a “real-world evidence” trial in which subjects are randomized to a treatment group (physician receives PEER Report) or a control group (no PEER Report provided), and physicians are permitted to either follow or not follow PEER recommendations.<sup>12</sup> Interim results have been peer reviewed by a leading neuropsychiatric journal.<sup>13</sup>

### **Potential Impacts for Veterans**

By repurposing existing technologies (like EEG) with the scalability of cloud computing, we believe tools like PEER offer the potential to rapidly meet each of the key IOM requirements:<sup>14</sup>

#### ***IOM Recommendation: physiological markers for treatment***

“Developing markers — biological, physiological, and psychosocial — to identify better approaches for PTSD prevention, diagnosis, and treatment.”<sup>14</sup>

- Over 84 clinical trials have confirmed the efficacy of physiological markers for medication response based on Quantitative EEG

#### ***IOM Recommendation: continuous improvement based on outcome data***

“Given that DOD and VA are responsible for serving millions of service members, families and veterans, the committee found it surprising that no PTSD outcome measures of any type are consistently used or tracked in the short or long term...”<sup>15</sup>

- Automated collection of outcomes on each patient is the core of the PEER approach

- With over 37,000 clinical endpoints for 9,800 unique patients, PEER represents the largest brain-based biomarker registry for effective mental health treatments based on patient physiology.<sup>16</sup>

***IOM Recommendation: provider accountability and transparency***

“In its phase 1 report, the committee recommended that DOD and VA mental health providers follow their own guideline.”<sup>17</sup>

- “Studies indicate that many veterans do not receive evidence-based treatments in the recommended manner.”<sup>18</sup>
- “There are few data, however, to indicate that the five performance measures for mental health in the 2011-2015 plan are being met 4 years into the plan.”<sup>19</sup>

PEER automates tracking of treatment selection and has the potential to improve provider adherence to guidelines, resulting in:

- Up to 40% improvement in physician efficiency, with potential to dramatically reduce patient waiting lists
- 2-3x improvement in medication effectiveness
- Significantly reduced medication risk, reduced suicidality
- Increased patient adherence to treatment

**Conclusion**

Given these findings, we strongly believe that the Committee should take notice of research in this area and encourage the VA and DOD to work toward rapid advancement and deployment of this type of research.

We recognize that advances in medicine often are delayed not by science, but by failures in financing, technology and leadership. We believe the IOM recommendation in this regard is applicable to all mental health treatments:

*“A high-performing PTSD management system should expedite the translation of positive research findings into practice. Optimally, the translation would take advantage of proven methods for the delivery of clinical services in a way that breaks down barriers to care. The best evidence-based treatments will have little value without a model for promoting their effective and widespread delivery.”<sup>20</sup>*

This Committee has found veterans waiting 30 days to three months for health care at the VA. That is unacceptable. It should be no more acceptable for veterans to wait years for doctors to begin using a technology that we know can help them today. 84 studies say PEER can improve outcomes, improve access to care, and reduce suicide risk for veterans. On behalf of everyone who could benefit from better, more evidence-based mental health care, we thank you for your commitment to improving veterans health care.

Henry T. Harbin, MD  
George C. Carpenter IV

## References

1. Institute of Medicine (IOM), Treatment for Post-traumatic Stress Disorder in Military and Veteran Populations — Final Assessment, June 2014 p 74.
2. New York Times, 2/13/11

*Virtually all of the evaluations of both departments have found the lack of data on which to make quantitative assessments of the programs' effectiveness to be a major shortcoming. The most recent evaluation of DOD mental health programs prepared by DCOE is unavailable. The VA collects more programmatic information than does the DOD, but outcome data are still scarce.*

*The response of modern psychiatry to modern warfare has not always been perfect... "These decisions about medication are difficult enough in civilian psychiatry, but unfortunately in this very-high-stress population, there is almost no data to guide you," said Dr. Ranga R. Krishnan, a psychiatrist at Duke University. "The psychiatrist is trying everything and to some extent is flying blind."*

3. Hoffman DA, DeBattista C, Valuck RJ, Iosifescu DV. Measuring severe adverse events and medication selection using a "PEER Report" for nonpsychotic patients: a retrospective chart review. *Neuropsychiatr Dis Treat.* 2012;8:277–284.
4. Institute of Medicine, June 2014 p 163.
5. Thomas R. Insel, MD in CantonRep.com, 5/13/14
6. Milliman Global Actuaries, Client Advisory, 8/08
7. MSMR, Vol 19 No. 11, Nov 12.
8. Statement of Work, A study to evaluate the efficacy of using PEER Interactive to inform the psychopharmacological treatment of patients with a primary diagnosis of Depression with or without comorbid disorders, grant application 4/13.
9. [www.cnsresponse.com/evidence.html](http://www.cnsresponse.com/evidence.html)
10. DeBattista C, Kinrys G, Hoffman D, et al. The use of referenced-EEG (rEEG) in assisting medication selection for the treatment of depression. *J Psychiatr Res.* 2011;45(1):64-75.
11. Hoffman DA, DeBattista C, Valuck RJ, Iosifescu DV. Measuring severe adverse events and medication selection using a "PEER Report" for nonpsychotic patients: a retrospective chart review. *Neuropsychiatr Dis Treat.* 2012;8:277–284.

12. Walter Reed National Military Medical Center, PEER Interactive Clinical Investigation Protocol 378604 v7.3, “A prospective, double blind, randomized, multicenter study to evaluate the utility, safety, and efficacy of using PEER Interactive to inform the prescription of medications to patients with a primary diagnosis of a depressive disorder and comorbidity of non-psychotic behavioral disorders versus treatment as usual.”
13. [dovepress.com](http://dovepress.com)
14. IOM p 228
15. IOM p 220
16. [www.cnsresponse.com/evidence.html](http://www.cnsresponse.com/evidence.html)
17. IOM p 130
18. IOM p 144
19. IOM p 217
20. IOM p 193

## CNS Response Disclosure of Federal Grants

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

July 2, 2013, 6:45 PM ET

## U.S. Military Tests Predictive Analytics to Better Treat Depression in War Veterans

Joel Schectman  
Reporter



The military is testing whether a cloud-based predictive analytics tool can help doctors do a better job treating depression in military personnel.

The effort to find a more objective basis for treatment comes as the U.S. military hospital system faces the dual strains of continued long term care of veterans of the wars in Afghanistan and Iraq, and severe cuts from the sequestration. "People would like us to find more cost effective treatment models," said Col. Brett J. Schneider, a psychiatrist running the study at Walter Reed National Military Medical Center, where sequestration has forced thousands of planned worker furloughs. Dr. Schneider hopes the new self learning software, built on a cloud based Salesforce.com Inc. platform, will allow the military to more precisely treat wounded veterans, who often must spend years trying different medications before they identify an effective treatment for depression symptoms. "Wounded warriors are the population that has the highest risk for multiple medications," Dr. Schneider said. "Multiple medications can have side effects and if we could avoid that by getting it right on the first try, that would be the way to go."

The 2,000-patient study at Walter Reed National Military Medical Center and Fort Belvoir Community Hospital, which began last April, aims to assess whether a self-learning software can make better recommendations for medications to treat depression in military personnel—many of them wounded veterans—compared with doctors prescribing treatments based solely on their own judgment.

The study is using PEER Interactive software, from Aliso Viejo, Calif.-based vendor CNS Response Inc., which crunches mental health data from 9,402 patients, who

have already been treated using its database recommendations, and provides practitioners with recommendations for psychiatric medication and a calculation of the probability the treatment will work.

Rather than basing its recommendation solely on patient responses to questions, the software tool compares a measurement of the patient's brain waves—the squiggly line printout known as an EEG—with those of thousands of past patients, and how those patients responded to drug regimens

Past studies have found a correlation between EEG measurement and various forms of mental illness. The software is designed to sharpen those correlations by continually updating its recommendations based on how well patients with particular, distinct, EEG patterns respond to different medication regimens. The software will not adjust its recommendations during the study based on new patient data, but the military hopes its patients will benefit from the analysis already done on thousands of treated patients, whose data was gathered over the course of more than a decade.

Other areas of medicine have already made strides in using self-learning tools to improve treatment. For example, at Vanderbilt University Medical Center, a database compares patient genetic attributions with treatment results from various blood thinners drugs, and continuously improves treatment recommendations based on results, said Dr. Blackford Middleton, chief informatics officer at the hospital. Dr. Middleton says the method allows the hospital to continue to improve results instead of relying solely on periodic, costly studies. "Otherwise we won't be able to afford progress in the field," said Dr. Middleton. "Learning from the data that exists is a very attractive alternative."

But self-learning software in psychiatry is a greater challenge. Treating mental health conditions has traditionally relied more on observation than concrete, easily comparable indicators like blood tests, making it harder to create the empirical results needed for self-learning.

"Currently we have to go with clinical wisdom rather than more objective tests," said Dr. Schneider who hopes recommendations from the system helps patients "get better sooner with less trial and error and fewer side effects. If we can get the right medication the first time that's just good for the patient."

## **Brief Bio for Henry Harbin MD**

Dr Harbin is a Psychiatrist with over 30 years of experience in the behavioral health field. He has held a number of senior positions in both public and private health care organizations. He worked for 10 years in the public mental health system in Maryland serving as Director of the state mental health authority for 3 of those years.

He has been CEO of two national behavioral healthcare companies – Greenspring Health Services and Magellan Health Services. At the time he was CEO of Magellan it was the largest managed behavioral healthcare company managing the mental health and substance abuse benefits of approximately 70 million Americans including persons who were insured by private employers, Medicaid and Medicare.

In 2002 and 2003 he served on the President's New Freedom Commission on Mental Health. As a part of the Commission he was chair of the subcommittee for the Interface between Mental Health and General Medicine. In 2005 he served as co-chair of the National Business Group on Health's work group that produced the Employer's Guide to Behavioral Health Services in Dec 2005. Since 2004 Dr Harbin has been providing health care consulting services to a number of private and public organizations.

## 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, 2004

Ernst & 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 turnaround 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.

### CBS MarketWatch

