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United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

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October 18, 2011

The Honorable Leon Panetta
Secretary of Defense
U.S. Department of Defense
1000 Defense Pentagon
Washington, D.C. 20301-1000

Dear Mr. Secretary:

I am writing to ask for information regarding the Defense Department's plan to implement the recommendations made by the Institute of Medicine (IOM), the health arm of the National Academy of Sciences, in their recent report regarding the effectiveness of cognitive rehabilitation therapy for treating deficits caused by traumatic brain injury.

On January 19, 2011, I wrote to Secretary Gates to request information and documents regarding the Defense Department's contracts to study the effectiveness of cognitive rehabilitation therapy (CRT) for the treatment of traumatic brain injury (TBI). In particular, I asked for information regarding the Defense Department's decision to withhold coverage for CRT as a separate service under the TRICARE health insurance program based on a 2009 study produced by ECRI Institute which found insufficient evidence that CRT is effective. At the time, I raised concerns regarding the Defense Department's contract with ECRI Institute, whose methodology for the study, including the decision to exclude important research, was called "deeply flawed" by other experts.¹

In a report released on October 11, 2011, the IOM found that CRT was "moderately" effective in providing "immediate benefits" for treating language, social communication, and memory deficits caused by moderate to severe TBI. For all other deficits caused by both mild and moderate to severe TBI, the IOM report concluded that there was either "not informative" or "limited" evidence as to the effectiveness of CRT. The IOM based its review and analysis on published scientific reports and approximately 88 studies that it deemed sufficiently reliable to include. The IOM also supported the ongoing clinical application of CRT for treating TBI.²

However, the IOM emphasized the "limitations" with the evidence available to evaluate the effectiveness of CRT. The IOM also found that the variability of definitions for CRT

¹ Letter from Chairman Claire McCaskill to Defense Secretary Robert Gates (Jan. 19, 2011).

² Institute of Medicine, *Cognitive Rehabilitation Therapy for Traumatic Brain Injury: Evaluating the Evidence* (Oct. 11, 2011).

contributes to the lack of clear conclusive evidence as to its effectiveness.³ The IOM committee made several recommendations to improve the standardization, design, and conduct of research studies examining its effectiveness, including the following:

- (1) The Defense Department should work with other rehabilitation research and funding organizations to standardize definitions with regard to cognitive impairments caused by TBI, identify uniform TBI outcome measures, and create a plan of action with regard to the methods of the delivery for CRT interventions.
- (2) The Defense Department should convene a conference to achieve consensus among a multiagency, multidisciplinary team of clinicians and researchers with the purpose of finalizing the standardized definitions and the action plan discussed in the first recommendation.
- (3) The Defense Department should incorporate the selected measures of patient characteristics, outcomes, and defined CRT interventions into ongoing studies and develop a comprehensive registry that encompasses existing cohorts and de-identified MHS medical records to allow ongoing evaluation of CRT interventions.
- (4) The Defense Department should use the data sources established under the third recommendation to evaluate the impact that policy changes related to CRT delivery and payment may have within the MHS, with particular regard to outcomes and cost-effectiveness.
- (5) The Defense Department should collaborate with other research and funding organizations to foster all phases of research and development of CRT treatments for TBI, ranging from pilot studies, to large-scale randomized clinical trials, to comparative effectiveness studies.⁴

To assist the Subcommittee with its ongoing investigation of the Defense Department's contracts to study CRT, I request that you provide information to the Subcommittee regarding the Defense Department's plan to implement the IOM committee's recommendations by **October 31, 2011**.

The jurisdiction of the Subcommittee on Contracting Oversight is set forth in Senate Rule XXV clause 1(k); Senate Resolution 445 section 101 (108th Congress); and Senate Resolution 73 (111th Congress). An attachment to this letter provides additional information about how to respond to the Subcommittee's request.

³ Institute of Medicine, *Cognitive Rehabilitation Therapy for Traumatic Brain Injury: Evaluating the Evidence* (Oct. 11, 2011).

⁴ Institute of Medicine, *Cognitive Rehabilitation Therapy for Traumatic Brain Injury: Evaluating the Evidence* (Oct. 11, 2011).

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I appreciate your assistance. Please contact Margaret Daum with the Subcommittee staff at (202) 224-4462 with any questions. Please send any official correspondence relating to this request to kelsey_stroud@hsgac.senate.gov.

Sincerely,



Claire McCaskill
Chairman
Subcommittee on Contracting Oversight

cc: Rob Portman
Ranking Member
Subcommittee on Contracting Oversight

Enclosure

**Responding to Document Requests from
the Subcommittee on Contracting Oversight**

In responding to the document request from the Subcommittee on Contracting Oversight, please apply the instructions and definitions set forth below.

Instructions

1. In complying with the request, you should produce all responsive documents in your possession, custody, or control.
2. Documents responsive to the request should not be destroyed, modified, removed, transferred, or otherwise made inaccessible to the Subcommittee.
3. In the event that any entity, organization, or individual denoted in the request has been, or is currently, known by any other name than that herein denoted, the request should be read also to include them under that alternative identification.
4. Each document produced should be produced in a form that renders the document capable of being copied.
5. When you produce documents, you should identify the paragraph or clause in the Subcommittee's request to which the documents respond.
6. Documents produced in response to this request should be produced together with copies of file labels, dividers, or identifying markers with which they were associated when this request was issued. To the extent that documents were not stored with file labels, dividers, or identifying markers, they should be organized into separate folders by subject matter prior to production.
7. Each folder and box should be numbered, and a description of the contents of each folder and box, including the paragraph or clause of the request to which the documents are responsive, should be provided in an accompanying index.
8. It is not a proper basis to refuse to produce a document that any other person or entity also possesses a non-identical or identical copy of the same document.
9. If any of the requested information is available in machine-readable or electronic form (such as on a computer server, hard drive, CD, DVD, memory stick, or computer backup tape), you should consult with Subcommittee staff to determine the appropriate format in which to produce the information. Documents produced in electronic format should be organized, identified, and indexed electronically in a manner comparable to the organizational structure called for in (6) and (7) above. Documents produced in an electronic format should also be produced in a searchable format.

10. In the event that a responsive document is withheld on any basis, you should provide the following information concerning the document: (a) the reason the document is not being produced; (b) the type of document; (c) the general subject matter; (d) the date, author, and addressee; and (e) the relationship of the author and addressee to each other.
11. If any document responsive to this request was, but no longer is, in your possession, custody, or control, you should identify the document (stating its date, author, subject and recipients) and explain the circumstances by which the document ceased to be in your possession, custody, or control.
12. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you should produce all documents which would be responsive as if the date or other descriptive detail were correct.
13. This request is continuing in nature and applies to any newly discovered document. Any document not produced because it has not been located or discovered by the return date should be produced immediately upon location or discovery subsequent thereto.
14. All documents should be bates-stamped sequentially and produced sequentially.
15. Two sets of documents should be delivered, one set to the majority staff and one set to the minority staff. The majority set should be delivered to the majority staff in Room 613B of the Hart Senate Office Building, and the minority set should be delivered to the minority staff in Room 442 of the Hart Senate Office Building. You should consult with Committee staff regarding the method of delivery prior to sending any materials.
16. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Subcommittee or identified in a privilege log provided to the Subcommittee.

Definitions

1. The term “document” means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra-office communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone calls, meetings or other communications, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto). The term also means any graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, voice mails, microfiche, microfilm, videotape, recordings and motion pictures), electronic and mechanical records or representations of any kind (including, without limitation, tapes, cassettes, disks, computer server files, computer hard drive files, CDs, DVDs, memory sticks, and recordings), and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
2. The term “documents in your possession, custody, or control” means (a) documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, or representatives acting on your behalf; (b) documents that you have a legal right to obtain, that you have a right to copy, or to which you have access; and (c) documents that you have placed in the temporary possession, custody, or control of any third party.
3. The term “communication” means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise.
4. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of the request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.

5. The terms “person” or “persons” means natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, and other units thereof.
6. The terms “referring” or “relating,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is in any manner whatsoever pertinent to that subject.

CERTIFICATION

I, (*insert name*), am the (*insert title*) of (*Agency name*) (“the Agency”), and have served in this position for (*number of years*) years. I am authorized by the Agency to provide this certification to the U.S. Senate, Committee on Homeland Security and Governmental Affairs, Subcommittee on Contracting Oversight regarding the Agency’s production of documents responsive to the Subcommittee’s document request letter of (*insert date*).

I hereby certify that the Agency has conducted a diligent search of all files and places under its custody and control, including computer servers and other electronic storage media, which reasonably could contain documents responsive to one or more of the enumerated requests in the Committee’s document request letter. I certify that as of the date listed below, the Agency has produced to the Subcommittee, in accordance with the instructions and definitions provided by the Subcommittee with the document request letter, all documents located during the search that are responsive to one or more of the enumerated requests.

Under the pains and penalties of perjury, I attest that the foregoing is true and accurate to the best of my knowledge.

Name

Date