THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP 26 2008

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

Dear Mr. Chairman:

The enclosed report responds to the National Defense Authorization Act for Fiscal Year 2008, House Report 110-146 to accompany H.R. 1585, which requests the Secretary of Defense to establish and report on a Military Mental Health Initiative to coordinate mental health research and development for the Department.

The report describes initiatives that provide the opportunity for researchers to compete for funding on both the basis of scientific merit and the contribution that the studies could make to the identification, diagnosis, and treatment of mental health issues.

Thank you for your continued support of the Military Health System.

Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable John McCain
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP 26 2008

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

Dear Mr. Chairman:

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S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable Lindsey O. Graham
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP 26 2008

The Honorable Ike Skelton
Chairman, Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Thank you for your continued support of the Military Health System.

Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable Duncan Hunter
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP 26 2008

The Honorable Susan Davis
Chairwoman, Subcommittee on Military Personnel
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Madam Chairwoman:

The enclosed report responds to the National Defense Authorization Act for Fiscal Year 2008, House Report 110-146 to accompany H.R. 1585, which requests the Secretary of Defense to establish and report on a Military Mental Health Initiative to coordinate mental health research and development for the Department.

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S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable John M. McHugh
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

The Honorable Robert C. Byrd
Chairman, Committee on Appropriations
United States Senate
Washington, DC 20510

SEP 26 2008

Dear Mr. Chairman:

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Enclosure:
As stated

cc:
The Honorable Thad Cochran
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP 26 2008

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

Dear Mr. Chairman:

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The Honorable Thad Cochran
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP 26 2008

The Honorable David R. Obey
Chairman, Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable Jerry Lewis
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

The Honorable John P. Murtha
Chairman, Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

SEP 26 2008

Dear Mr. Chairman:

The enclosed report responds to the National Defense Authorization Act for Fiscal Year 2008, House Report 110-146 to accompany H.R. 1585, which requests the Secretary of Defense to establish and report on a Military Mental Health Initiative to coordinate mental health research and development for the Department.

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Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable C.W. Bill Young
Ranking Member

Department of Defense

Report to Congress on Military Mental Health Initiative National Defense Authorization Act for Fiscal Year 2008, House Report 110-146

Military Mental Health Initiative

BACKGROUND

In the National Defense Authorization Act for Fiscal Year 2008, House Report 110-146 the Committee anticipated that Department of Defense (DoD) challenges would arise from Mental Health Task Force conclusions. Specifically, they expected a number of findings that would require applied research and technology developments to resolve. Based on that perception, they stated the following:

> The committee is aware of the challenges the Department of Defense faces providing mental health programs to combat veterans and their families. To help the Department deal with these challenges, Section 723 of the National Defense Authorization Act for FY06 (Public Law 109-163) required the Secretary of Defense to create a DoD Task Force on Mental Health. The committee understands that the task force will report its findings in August 2007. The committee notes the wealth of new concepts and technologies of varying levels of maturity that emerge annually from the nation's academic and medical base. The committee directs the Secretary of Defense to establish a Military Mental Health Initiative to coordinate mental health research and development for the Department. The Initiative would provide the opportunity for researchers to compete for funding on both the basis of scientific merit and the contribution that the studies could make to the identification, diagnosis, and treatment of mental health issues. The committee further directs the Secretary to submit a report on the status of the Initiative to the congressional defense committees within 180 days of passage of this Act.

The committee recommended several projects for funding consideration, and these projects were evaluated. The Soldier Wellness Assessment Pilot Program (SWAPP), which originated at Fort Lewis, was funded for expansion to two additional sites, one of which included a reserve component unit. The SWAPP program includes mandatory one-on-one counseling with a mental health provider as an essential component. In addition, that component was incorporated into the evaluation project. Studies of a variety of stages of post-traumatic stress disorder (PTSD) onset and treatment, effects on children and families, and specific focus on women were considered in the overall strategic planning for research in this area.

In a separate action, to facilitate research in the broad area of mental health, DoD received a Fiscal Year (FY) 2007 appropriation of $301 million (M) to conduct research in the area of military and combat related traumatic brain injury (TBI) and PTSD along with other relevant psychological health (PH) issues. These funds were used, in part, to satisfy this Military Mental Health Initiative.

DEPARTMENT OF DEFENSE ACTIONS

DoD is committed to providing excellence in protection, prevention, diagnosis, treatment, recovery, and transition of care to our military members and their families who experience mental health conditions or traumatic brain injuries as a result of the global war on terror.

The PTSD/TBI research program was assigned to the DoD Congressionally Directed Medical Research Program (CDMRP) that is currently under the lead of the United States Army Medical Research and Material Command. FY 2007 Congressional appropriations for this program totaled $301M of which $151M was allocated for peer-reviewed research related to PTSD and other psychological health conditions and concerns, with the remainder allocated to TBI related research.

The goal of the PH/TBI research program is, as directed by the Military Mental Health Initiative, to fund scientifically meritorious research to prevent, mitigate, and treat the effects of traumatic stress and traumatic brain injury on function, wellness, and overall quality of life for Service members as well as their caregivers and families. The program strives to establish, fund, and integrate both individual and multi-agency research efforts that will lead to improved prevention, detection, diagnosis, and treatment of combat-related PH and TBI.

In June 2007, a stakeholders meeting identified and prioritized research gaps related to the prevention, detection, diagnosis, and treatment of PTSD and TBI. A group of expert scientists and clinicians from academia, industry, the military, and other federal government agencies assembled to identify and discuss possible ways to address the highest priority gaps. The information gathered at this stakeholders meeting helped determine the programmatic goals and objectives of the PTSD/TBI research program vision-setting meeting that subsequently occurred on June 13, 2007.

The prioritized PTSD research gaps include: 1) treatment and intervention; 2) prevention; 3) measures of screening, detection, and diagnosis; 4) epidemiological studies; 5) families/caregivers projects; and 6) neurobiology/genetics.

The prioritized TBI gaps include: 1) treatment and clinical management; 2) neuroprotection and repair strategy; 3) rehabilitation/reintegration strategies; 4) field epidemiology; and 5) physics of blast as it relates to brain injury.

The investment strategy for each award mechanism developed during the PTSD/TBI research program vision setting follows: (1) intramural (four award mechanisms), $74M; (2) PTSD/TBI clinical consortium, $60M; (3) advanced technology-therapeutic development, $16M; (4) investigator-initiated research, $10M; (5) concept, $9M; (6) multidisciplinary research consortium, $50M; (7) new investigator,

$6M; and (8) DoD Center of Excellence for PH and TBI (DCoE)was allocated $45M to both conduct clinical research and to provide on-going strategic planning for continued research in this important area.

The PTSD/TBI research program challenged the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators into the fields of PTSD- and TBI-focused research. Program announcements for 12 extramural and 4 intramural (Departments of Defense and Veterans Affairs) award mechanisms were released in July 2007. The deadlines for proposal submission ranged from August 16, 2007, to November 26, 2007.

A total of 640 PTSD- and 1,052 TBI-focused proposals were submitted in response to the FY07 PH/TBI Research Program Intramural and Extramural Program Announcements. Additionally, the DCoE solicited proposals focused on Complementary and Alternative Medicine (CAM) and received several submissions through the USAMRMC Command Broad Agency Announcement (BAA).

Proposal review for all submissions was conducted according to the USAMRMC two-tier review model recommended by the National Academy of Sciences Institute of Medicine. This model has received high praise from the scientific community, advocacy groups, and Congress. The first tier is a scientific peer review of proposals against established criteria for determining scientific merit. The second tier, programmatic review, compares submissions to each other and recommends proposals for funding based on scientific merit and overall program goals. The first tier of review involved both scientist and consumer (individuals suffering from TBI and/or PTSD and family members) reviewers. The Joint Program Integration Panel (JPIP) conducted programmatic review of proposals. Panel members included representatives from the Armed Services Biomedical Research Evaluation and Management Secretariat (Army, Navy, Air Force, the Office of the Secretary of Defense/Office of Health Affairs); Uniformed Services University of the Health Sciences; Director of Defense Research and Engineering; the Department of Veterans Affairs; the National Institutes of Health; and clinical consultants from each of the Military Services.

Following the first three rounds of programmatic review, 121 projects were recommended for funding by the JPIP and approved for funding by the final approval authority, the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness (DASD[FHPR]). Additionally, 62 proposals recommended by the DCoE, including 10 CAM proposals and 1 BAA proposal, were approved for funding by the DASD(FHPR). Finally, due to cost savings, the CDMRP was able to partially fund the first proposal on a prioritized alternate list in July 2008. The FY07 PH/TBI Research Program's investment profile is provided in Tables 4a and 4b by JPIP prioritized research gap areas.

Table 4a: PH/TBI Research Program: PH Investment by Research Gaps (Total)

PH Research Gaps	Funded/ Received	Budget (M)	Percent Invested	Percent Recommended by JPIP
Treatment and Intervention	43/225	$101.4	76.1	50
Prevention	7/37	$4.2	3.1	15
Screening, Detection, and Diagnosis	5/93	$5.7	4.3	10
Epidemiological Studies	9/54	$4.9	3.7	10
Families/Caregivers	5/29	$2.9	2.2	10
Neurobiology/Genetics	20/180	$10.3	7.7	5
CAM	8	$3.9	2.9	NA**
BAA	1	$65K	0	NA

*The $60M budget for the Clinical Consortium Center and Study Sites was distributed between both PH and TBI gaps.

Table 4b: PH/TBI Research Program: TBI Investment by Research Gaps (Total)

TBI Research Gaps	Funded/ Received	Budget (M)	Percent Invested	Percent Recommended by JPIP
Treatment and Clinical Management	29/305	$94.9	68.0	40
Neuroprotection and Repair Strategies	21/432	$20.7	14.8	22.5
Rehabilitation/Reintegration Strategies	12/145	$10.6	7.8	15
Field Epidemiology	9/66	$4.2	3.0	15
Physics of Blast	13/73	$8.0	5.7	7.5
CAM	2	$1.0	0.7	NA**

*The $60M budget for the Clinical Consortium Center and Study Sites was distributed between both PH and TBI gaps.

Eighty-five proposals remain on a prioritized Alternate list. These projects will be funded in priority order, commensurate with cost savings. Detailed information on all PH/TBI Research Program awards is posted at http://cdmrp.army.mil (under Search Awards) for each award at the time of completion of award negotiation. Award

negotiation for all projects approved for funding will be completed by September 30, 2008.

The PTSD/TBI research program is designed to facilitate translational science to quickly bring forth cutting-edge preclinical research to the clinic for evaluation in clinical trials. These efforts make possible a dynamic continuum of scientific knowledge between clinical observation and basic research.

The Multidisciplinary Research Consortium works to optimize research and accelerate the solution of a major overarching problem in PTSD or TBI research within an integrated consortium of the best scientists and clinicians as members of a synergistic, multidisciplinary team.

The overarching goal of the PTSD/TBI Clinical Consortium is to combine the efforts of the nation's leading investigators to bring to market novel treatments or interventions that will ultimately decrease the impact of PTSD and TBI, and improve the function, wellness, and the overall quality of life of Service members, their families, and caregivers, and the American public. The Clinical Consortium will consist of a coordinating center plus multiple clinical research sites. Investigators from the Clinical Consortium will integrate with the DoD Center of Excellence.

CONCLUSIONS

The comprehensive and detailed planning and execution of a systematic program of research for psychological health and TBI were designed to carry forward the recommendations of the DoD Mental Health Task Force and other external review groups. In addition, during this process, academic and industry applicants were highly encouraged to collaborate with military and VA scientists and clinicians. A positive outcome of the execution of the research program will be the establishment of many new collaborations among DoD, VA, academia, and industry that will ultimately make an impact on the care of our active duty Service members and their families affected by PTSD and TBI. Further, the establishment of the DoD Center of Excellence for PH and TBI will further assist the DoD research community in continuing to review, refine, and execute the research strategic plan that was initiated during this effort. This robust research plan and execution clearly exceed the expectations expressed in the Military Mental Health Initiative Requirement.