

## **Congressionally Directed Medical Research Programs**

ANNUAL REPORT

September 30, 2010









The Congressionally Directed Medical Research Programs (CDMRP) supports disease-specific research as directed by Congress. Our vision is to find and fund the best research to eradicate diseases and support the warfighter for the benefit of the American public. Individual programs develop an annual vision to fill unique gaps and support groundbreaking research. Our two-tier application review system capitalizes on the strength of traditional scientific review processes while addressing the individual goals of each program. These and other business practices are highlighted in this 2010 Annual Report. Please take a moment to read how we are making a difference in the lives of people with disease, conditions, and injuries. I remain grateful to the dedicated individuals who are committed to our programs—consumer advocates, scientists, clinicians, the military, and support staff whose constant enthusiasm and diligence sustain the research programs.

> E. Melissa Kaime, M.D. Captain, Medical Corps, U.S. Navy Director, CDMRP



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**Department of Defense** 

U.S. Army Medical Research and Materiel Command Congressionally Directed Medical Research Programs

> Annual Report September 30, 2010

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## Table of Contents

Vision and Mission	1
Who We Are and What We Do	1
Our Management Cycle	3
Vital Partnerships1	4
Information Dissemination	0
Consortia Advances and Accomplishments 2	5
Highlighted Advances and Accomplishments	
Funded by the CDMRP20	6
Appendix A: FY92–FY09A-	1
Appendix B: FY09–FY10B-	1
Appendix C: Breast Cancer Research Semipostal AwardsC-	1



## Who We Are and What We Do

A grassroots advocacy movement in the early 1990s campaigned for an increase in breast cancer research funding, and the U.S. Congress responded with an initial congressional appropriation in 1992 of \$25 million (M) to be managed by the Department of Defense (DOD) U.S. Army Medical Research and Materiel Command (USAMRMC).<sup>1</sup> The following year Congress appropriated \$210M to the DOD for extramural, peer-reviewed breast cancer research. These appropriations marked the beginning of the Congressionally Directed Medical Research Programs (CDMRP).

The success in managing the initial congressional appropriations in breast cancer research combined with additional advocacy movements and the need for focused biomedical research catapulted the CDMRP into a global funding organization for cancer research, military medical research, and other disease-specific research. Through fiscal year 2010 (FY10) the CDMRP has been responsible for managing more than \$6 billion (B) in appropriations (see Figure 1, CDMRP Funding History).

The CDMRP is a unique partnership among the U.S. Congress, the public, and the military to support untapped research opportunities to push science and medicine to the leading edge of innovation and ingenuity. Hallmarks of the CDMRP include investing in groundbreaking research; supporting the next generation of researchers as well as established scientists; funding clinical research to prevent, detect, diagnose, and treat diseases, conditions, and injuries; and supporting the warfighter for the benefit of the nation. From small concept award investments to large consortia, the CDMRP strives to find and fund the best research.

This Annual Report highlights the CDMRP's business practices and the financial accounting for FY09–FY10. Additional information about specific research programs can be found in individual program books that are available on the CDMRP website or can be requested by phone (301-619-7071) or by e-mail (CDMRP.PublicAffairs@amedd.army.mil).

Vision

Find and fund the best research to eradicate diseases and support the warfighter for the benefit of the American public.

#### Mission

Provide hope by promoting innovative research, recognizing untapped opportunities, creating partnerships, and guarding the public trust.

#### The CDMRP Key Features

- Represents a federal agency for supporting disease, injury, or condition specific research as directed by Congress
- Adapts individual program visions annually
- Utilizes a two-tier competitive review of applications as recommended by the Institute of Medicine
- Includes consumer advocates throughout processes
- Funds highly innovative research
- Maintains a unique partnership among Congress, scientists, clinicians, consumer advocates, and the military

<sup>&</sup>lt;sup>1</sup> Known as the U.S. Army Medical Research and Development Command prior to 1995.



Figure 1. CDMRP Funding History\*\*

\*Funding is approximate; FY10 will be complete as of September 30, 2011. \*\*Data as of September 30, 2010.



## Our Management Cycle

The CDMRP employs a flexible management cycle to maintain the individuality of each program while also meeting the needs of Congress, the DOD, the research and advocacy communities, and the public at large. This management cycle begins with a congressional appropriation and ends with the completion of the funded research. Each step in the execution and management cycle is depicted in Figure 2 followed by descriptions of each milestone and approximate time course on pages 4–9.



Management Cycle



### **Congressional Appropriation and Receipt of Funds**

Programs assigned for complete life-cycle management to the CDMRP exist because of yearly, individual congressional appropriations. These funds are not in the President's budget; Congress adds them annually to the DOD appropriation to fund new programs or continue existing programs.

## **Stakeholders Meeting**

For new programs, a stakeholders meeting is held within the first months after receipt of funds. The goal of each stakeholders meeting is to determine the current state of the research in a particular field and to identify research gaps so that the CDMRP can design a program to fill these gaps. Stakeholders for each program are world-renowned scientists, clinicians, and consumer advocates<sup>2</sup> (additional information about consumer advocates can be found on page 15). Recommendations from the stakeholders meeting are then used to facilitate vision setting.

### **Vision Setting**

A vision setting meeting is held after the inaugural stakeholders meeting or annually after a congressional appropriation to define an annual investment strategy. The development of an annual investment strategy was recommended by the National Academy of Sciences Institute of Medicine.<sup>3</sup> The CDMRP adopted this recommendation and has since recruited the most visionary scientists, clinicians, and consumer advocates for each program to function as an Integration Panel (IP). Individual members of the IP recommend the annual investment strategy to identify

<sup>&</sup>lt;sup>2</sup> Consumers are patients, survivors, family members, or caregivers of people living with a disease, injury, or condition and are representatives of consumer advocacy, support, or military organizations.

<sup>&</sup>lt;sup>3</sup> Institute of Medicine, *Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command*, The National Academies Press, 1993.

underfunded and underrepresented areas of research and encourage research in those areas that are considered the most critical to patients, scientists, clinicians, and consumer advocates. The annual investment strategy provides a high degree of flexibility and the necessary structure to most effectively obligate each congressional appropriation while avoiding unnecessary duplication with other funding agencies. For the FY10 programs, the CDMRP held 16 vision setting meetings.

#### **Program Announcements**

The product of vision setting is an annual investment strategy that develops the framework for specific award mechanisms to achieve the program's vision. Award mechanisms represent the pressing needs of the research, advocacy, and military communities for each program and are released after vision setting in the form of program announcements. Individual program announcements, i.e., solicitations for applications, provide details about a particular award mechanism, criteria scores, the application process, and requirements for submitting applications, including pre-applications, if required for that award mechanism.



The CDMRP released 63 program announcements in FY10.



#### Receipt

Submission requires a two-step process consisting of a pre-application submission (which includes a letter of intent, pre-proposal, and/or nomination) followed by a full application submission. Pre-applications that require a pre-proposal and/or nomination are screened by the program's IP or by external peer review panels, and invitations for full applications are sent to those selected for submission. By employing the pre-proposal process, investigators are not initially required to produce full application packages but are only required to submit short pre-application packages. This process decreases the overall burden on investigators by only inviting full applications that meet the intent of the award mechanism.

Investigators are typically provided 2–4 months to prepare and submit a full application package in response to a program announcement. The number of applications submitted to the CDMRP has risen drastically since its inception. As summarized in the Table 1 below in FY10, the CDMRP received 9,235 pre-proposals and nominations which, after screening and invitation, resulted in 3,082 full applications received as of the date of this report. In addition, the CDMRP received 6,233 full applications from mechanisms that did not require pre-proposals or nominations for a total of 9,315 full applications received to date.

Table 1: Number of Applications Received from October 1, 2009 to September 30, 2010 across FY09–10 Programs

Total	9,315
From mechanisms that did not require pre-proposals/nominations	6,233
From pre-proposal/nomination screening process	3,082
Full applications received	
Pre-proposals/nominations received	9,235



### Review

The CDMRP adopted the recommendations set forth in 1993 by the National Academy of Sciences Institute of Medicine committee, which concluded that the CDMRP would be best served by a twotier review process to reflect the traditional strengths of scientific review but also is tailored to accommodate individual program goals. Although the two tiers of review are fundamentally different, they are complementary.

All reviewers for the CDMRP must uphold the highest standards of conduct to ensure the credibility of the programs and the processes. Additional details about the two tiers of review can also be accessed on the CDMRP website at http://cdmrp.army.mil/fundingprocess.htm.

#### **Peer Review**

Peer review is conducted after application receipt. It is a criteria-based process where applications are evaluated based on their scientific and technical merit. Peer review is performed by external scientific panels. Applications are categorized by scientific discipline, specialty area, and/ or award mechanism and evaluated by both scientific and consumer peer reviewers. The CDMRP strives to give every application a fair and balanced review, taking steps to ensure conflict of interest does not influence the process. Applications are assigned an overall score as well as individual evaluation criteria scores, as delinated in the programmatic announcements. In FY10, a total of 279 peer review panels were held.

#### **Programmatic Review**

After applications have been scientifically peer reviewed, they undergo programmatic review resulting in a recommended-for-funding list. Programmatic review is conducted by the members of the program's IP. A typical set of criteria used by members of the IP to make funding recommendations includes: ratings and evaluations by the scientific and consumer peer reviewers, programmatic relevance, relative innovation, program portfolio composition, and adherence to the intent of the award mechanism. With these tools, members of the IP recommend the best applications to fulfill the review criteria and answer the vision and mission of the program. In FY10, a total of 25 programmatic review meetings were held.



### **Approval of the Awards List**

The final product of programmatic review is the recommended-for-funding list that is reviewed and approved by the Commanding General, USAMRMC. For certain programs, approval is also attained from the Director of the Defense Medical Research and Development Program Office within the Office of the Assistant Secretary of Defense for Health Affairs. Upon approval, electronic notification letters are sent to program applicants to inform them of their funding status.

In rare instances (less than 1%), applicants voice objections regarding the scientific peer review or programmatic review of their applications. The CDMRP established an Inquiry Review Panel to address applicant queries. These appeals must be based on the occurrence of factual or procedural errors at receipt, peer review, or programmatic review. If a factual or procedural error is identified the application will be sent for re-review at the appropriate level (peer and/or programmatic review).



#### **Award Management**

The negotiation and management of awards are a major focus of the CDMRP. Approximately 600 to 700 new awards are made each fiscal year, with 9,933 total awards throughout the CDMRP funding history (as of September 30, 2010). Award management is an active process that occurs throughout the life of the award beginning with the recommendation for funding through closeout of the award. To ensure success, award management encompasses a partnership among many offices within USAMRMC including the CDMRP, the U.S. Army Medical Research Acquisition Activity (USAMRAA), the Office of Research Protections (ORP), the Office of Surety, Safety and Environment, and Staff Judge Advocate. Following award notification, USAMRAA initiates negotiations with the performing institute. Formalized analysis of the budget with respect to the scope of work to be done is performed through detailed discussions among the CDMRP, USAMRAA, the institute, and the researchers to ensure cost sharing when possible and avoidance of overlap in research funding with other funding agencies. In addition, the CDMRP facilitates regulatory review of each research project. The ORP manages and provides oversight on human subject protection review and animal welfare review for all the CDMRP-funded research. Once all aspects of negotiation are completed, an award is signed by USAMRAA. Awards are made in the form of grants, contracts, or cooperative agreements no later than 24 months after congressional appropriation.

The life-cycle management of awards continues throughout the period of performance with monitoring of the technical progress, financial reporting, and regulatory review. Awards are assigned a Science Officer (SO) ensuring a broad knowledge of each grant, communication among all parties involved, and the most comprehensive assistance possible to the Principal Investigator (PI). At a minimum, all PIs are required to submit annual progress reports and quarterly financial reports. Investigators with awards that include clinical trials or clinical research are required to submit a quarterly report to the SO and USAMRAA. These awards are monitored for approval of the clinical protocols, accrual of patients, and any adverse events. When the SO identifies issues such as slow recruitment to clinical trials, the entire management team (including the CDMRP, ORP, and USAMRAA) works with the PI to resolve the

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Vision Find and fund the best research to eradicate diseases and support the war fighter for the benefit of the American Public.

#### Mission

We provide hope by promoting innovative research, recognizing untapped opportunities, creating partnerships and guarding the public trust.

(including the CDMRP, ORP, and USAMRAA) works with the PI to resolve the issue. The progress of large grants and consortia is also monitored through external advisory boards, site visits, teleconferences, and other meetings throughout the entire period of performance.

To assist with award management, in FY02, the CDMRP developed a state-of-the-art database called the Electronic Grants System (EGS) to enable real-time electronic management of applications from receipt to award closeout. The EGS is an internal, customized, and integrated business system that securely allows the input of application data and the download of reports for programmatic processes and award management. The EGS is utilized throughout the life cycle of the awards to accurately track regulatory requirements and scientific reporting and to assist in the general administrative tasks associated with awards. The implementation of the EGS has allowed the CDMRP to virtually eliminate the paper processing of applications and awards, which not only saves time, money, and the environment but also increases the accuracy of the life-cycle award management process.



Figure 3. FY92–09 CDMRP Research Outcomes by Category



Figure 4. FY92–09 CDMRP Research Category by Phase(s) of Development

### Excellence in Our Programs and Processes

The CDMRP strives to find and fund the best research to advance prevention, treatment interventions, quality of life, and the eradication of disease. As such, a variety of stakeholders have a vested interest in these programs and their outcomes, including Congress, scientists, clinicians, consumer advocates, and the military. To provide information to these stakeholders, the CDMRP maintains a program evaluation committee to collect and analyze data and to use this information to answer questions and make recommendations about different aspects of its programs and processes.

With a vast portfolio of funded research, assessing productivity and outcomes remains a top priority of the program evaluation committee. Portfolio composition is evaluated, and research outcomes are compiled using an innovative classification scheme. By continued monitoring of each program's portfolio, scientific gaps may be easily identified, and the vision and mission of the program may be modified to address the most current scientific and medical needs. A current glimpse at the CDMRP's portfolio of research outcomes by category and phase is illustrated in Figures 3 and 4. These data can be used to inform our constituents of the CDMRP-funded outcomes, highlight gaps in its portfolio that would benefit from additional support, and assist in crafting new award mechanisms to meet the needs of individual programs.

### **Evaluation of Award Management Workload**

An important program evaluation initiative undertaken by the CDMRP was assessing the award management workload. Beginning in 2008, a working group composed of SOs reviewed and identified the critical variables that define the characteristics of each award mechanism. The evaluation demonstrated that grants are not simply defined by the dollar amount but by multiple variables that may influence the proactive management needed to facilitate successful compliance of regulatory requirements, financial reporting, as well as outcomes of the proposed research. Defined variables that drive the complexity of award mechanisms include features such as animal use, proposed clinical trial, and scientific reporting requirements. Following the identification of the variables, the qualitative information was converted into quantitative data using a binomial system. Certain variables, such as clinical research permitted, were weighted to capture the more complex nature of individual award mechanisms. The final calculation was termed the sum of the variables and was the basis for a standardized coding system to describe each award mechanism. The graph (Figure 5) illustrates the complexity of award mechanisms utilized by the CDMRP. This assessment allowed an analytical approach to grant load assignment to individual SOs and the continuation of excellence in award management. With the use of this model system, the CDMRP maintains a proactive management style by optimizing SO workload to increase interaction with our business partners and the PIs for the funded research.



Figure 5. Increasing Complexity of Award Mechanisms



#### Programs

Through FY10, the CDMRP has managed 105 separate research programs that focus on cancer research, military medical research, and other disease, injury, or condition specific research. Congressional appropriations directed toward these research programs total more than \$6B. From FY92 through

appropriations directed toward these research programs total more than \$6B. From F Y92 through FY09 appropriations, the CDMRP has managed 9,933 research grants, contracts, and cooperative agreements. The CDMRP awardees represent 26 countries (Figure 6).

The CDMRP completed execution of the FY09 appropriations that resulted in an astounding number of new awards. While typically 600–700 new awards are made each year, in FY09, 937 new awards were processed. The CDMRP also initiated execution of appropriations for FY10, which totals more than \$580M in funding across 40 programs. An overview of the appropriations and applications received and funded during FY92–FY09 can be found in Appendix A. Table 2 depicts the FY09 and FY10 funding summary information while complete financial data for these fiscal years can be found in Appendix B.

The CDMRP was selected in FY09 by USAMRMC as a major execution agent to provide program support to the Office of the Assistant Secretary of Defense for Health Affairs (ASD(HA)). The primary function of this effort is collaboration with selected ASD(HA) Joint Program Committees (JPCs). JPCs are composed of representatives from the branches of the military, including the Army, Air Force, Navy, Marine Corps, Department of Defense (Health Affairs), Department of Health and Human Services, and Department of Veterans Affairs. They provide oversight and guidance for research portfolios across all services within the DOD. The JPCs manage military medical research portfolios in military infectious diseases, combat casualty care, military operational medicine, and clinical and rehabilitative medicine. The CDMRP collaborates with the



Figure 6. Awardees of the CDMRP Span the Globe

JPCs to provide some or all of the life-cycle management functions of research programs to fill critical military-relevant research gaps. The largest portion of this support has been in the Defense Medical Research and Development Program and the Psychological Health and Traumatic Brain Injury (PH/ TBI) program. An example of

	FY09		FY10			
Program	Appropriations Received (in millions)	Applications Received	Applications Funded	Appropriations Received (in millions)	Applications Received to Date	Applications Funded to Date
Amyotrophic Lateral Sclerosis	\$5.0	43	3	\$7.5	66	
Autism	\$8.0	155	19	\$8.0	203	
Bone Marrow Failure	\$5.0	130	14	\$3.8	81	
Breast Cancer/Breast Cancer Research Semipostal	\$151.5	3,819	328	\$151.0	2,809	221
Defense Medical R&D <sup>a</sup>				\$55.3	417	43 <sup>b</sup>
Defense Medical R&D (Chiropractic) <sup>a</sup>				\$8.2	5	
Genetic Studies of Food Allergies	\$2.5	12	4	\$1.9	48	
Gulf War Illness	\$8.0	44	9	\$8.0	34	
Institutionally Based <sup>c</sup>	\$37.4	21	21	\$42.3	26	26
Lung Cancer	\$20.0	521	29	\$15.0	-	
Multiple Sclerosis	\$5.0	126	21	\$4.5	210	
Neurofibromatosis	\$10.0	75	22	\$13.8	97	
Ovarian Cancer	\$20.0	183	26	\$18.8	133	
Peer Reviewed Cancer	\$16.0	401	38	\$15.0	179	
Peer Reviewed Medical	\$50.0	818	41	\$50.0	606	
Peer Reviewed Orthopaedic	\$112.0	357	95	\$22.5	3	
Prostate Cancer	\$80.0	849	159	\$80.0	1,268	27
Psychological Health/Traumatic Brain Injury <sup>a</sup>	\$50.3	530	39	\$9.7	41	
Psychological Health/Traumatic Brain Injury <sup>d</sup>	\$7.2	n/a	4 <sup>e</sup>	\$50.7	n/a	27
Spinal Cord Injury	\$35.0	298	53	\$11.3	-	
Tuberous Sclerosis Complex	\$6.0	65	12	\$6.0	51	
Total	\$628.9	8,447	937	\$583.1	6,277	344

Table 2. CDMRP Programs, Appropriations, and Applications Received and Awarded in FY09–FY10

<sup>a</sup> The CDMRP assisted with full life-cycle management of a larger appropriation(s).

<sup>b</sup> The CDMRP was assigned as the execution agent for a portion of the applications recommended for funding.

<sup>c</sup> Institutionally Based represents 21 active programs in FY09 and 26 in FY10.

<sup>d</sup> The CDMRP provided only research award negotiation and management for this portion of a larger FY09–FY10 appropriation.

<sup>e</sup> This funding provided for 4 new awards and 4 supplements to existing awards.

The CDMRP individual program books can be accessed at http://cdmrp.army.mil/pubs/pips/default.shtml on the CDMRP website.

this collaboration is the CDMRP's role in providing full life-cycle management of the FY10 PH/ TBI Cognitive Rehabilitation Clinical Trial Award funding opportunity, assisting through program announcement release, peer and programmatic review, and management of resulting awards. The ultimate goal of the JPC and the CDMRP collaborative effort is to support the ASD(HA)'s mission of expediting delivery of products and solutions to address challenges related to the troops and their family members.



## Vital Partnerships

The CDMRP attributes its success through connections or partnerships with individuals and organizations, including the military, scientists, clinicians, consumer advocates, minority and underserved populations, professional organizations, and policy makers. Highlights of some of the central partnerships within the CDMRP are described on the following pages.

#### **USAMRMC**

There are several offices within USAMRMC that the CDMRP works with to execute its research programs as shown in Figure 7. Each partner works collaboratively to ensure that congressional appropriations are used for the benefit of the American public.



Figure 7. The USAMRMC Team

### **Consumer Advocates**

The CDMRP developed a unique model of consumer involvement by including consumers in every aspect of program execution. Consumer advocates for the CDMRP are patients, survivors, family members, or caregivers of people living with a disease, injury, or condition and are representatives of consumer advocacy, support, or military organizations. The unique voices and experiences of consumers continue to play an essential role in the establishment and growth of programs within the CDMRP. The value of consumer involvement is derived from each individual's firsthand experience with the disease, injury, or condition. This adds perspective, passion, and a sense of urgency that ensures the human dimension is incorporated in the program policy, investment strategy, and research focus. Since 1992, more than 1,600 consumers have represented their communities in the peer and programmatic review of applications. For more information on consumer involvement, see the consumer involvement pages on the CDMRP website (http://cdmrp.army.mil).

Table 3.	Consumer	Involvement in	the CDMRP	Since	1992

	Consumers	Consumer Organizations
Peer Reviewers	>1,500	>500
Programmatic Reviewers	>100	>85
Total	>1,600	>585



#### **The Scientific Community**

The growth and magnitude of the CDMRP can be attributed in part to the scientific community. The fulfillment of program goals requires cooperation, communication, and integration across multiple scientific and clinical disciplines. To date, more than 8,500 scientists and clinicians have provided the necessary subject matter expertise on peer review panels. Approximately 375 world-renowned scientists, clinicians, and policy makers have participated in vision setting and programmatic review as IP members, and more than 325 scientists have served as ad hoc programmatic reviewers. At the CDMRP, more than 140 scientists, clinicians, and professionals currently are involved in the day-to-day program execution and science management. Finally, approximately 7,700 researchers have been funded by the CDMRP in an effort to tackle the complex causes of diseases, conditions, and injuries and translate this knowledge to improved prevention, treatment interventions, patient survival, and quality of life.

#### Breast Cancer Research Semipostal Program

As a result of the Stamp Out Breast Cancer Act (Public Law 105-41 [H.R. 1585]), the National Institutes of Health and the DOD Breast Cancer Research Program (BCRP) are the designated recipients of revenues from sales of the U.S. Postal Service's Breast Cancer Research Semipostal (BCRS). The Stamp Out Breast Cancer Act resulted from the work of advocates for breast cancer research. This legislation led to the U.S. Postal Service's issuance of a new first-class breast cancer stamp, which costs 55¢, and can be purchased by the public. Net revenues from the stamp are used to support breast cancer research administered by the National Institutes of Health and the DOD BCRP. Since the stamp was first offered for sale in 1998, the monies received by the CDMRP from the BCRS through FY09 have been used to fully fund 39 BCRP Idea Awards and partially fund 4 additional Idea Awards. Idea Awards have been an essential part of the BCRP portfolio and support highly innovative, high-risk, highreward research that could lead to critical discoveries in breast cancer. In FY07, stamp funds began supporting Synergistic Idea Awards, which also foster

innovative research through collaborative efforts. In 2007, BCRS revenues were able to fully fund 1 Synergistic Idea Award and partially fund 2 others. A list of all awards supported by the BCRS can be found in Appendix C.

First-Class

### **Military Partnerships**

Fundamental to the success of the CDMRP is the coordination of efforts to advance research for the health of our service members and their families. USAMRMC executes and manages the Research Area Directorates (RADs). The RADs within the USAMRMC execute and manage research with a focus specifically on military infectious diseases, combat casualty care, military operational medicine, and clinical and rehabilitative medicine. By partnering with the USAMRMC RADs, the CDMRP facilitates the alignment of award portfolios and RAD mission relevance. Through our award management processes, the CDMRP routinely works with the RADs' program sponsor's representatives to ensure excellence in science that has applicability to the welfare of service members and their families. Awards within the CDMRP portfolio with results critical to the military are highlighted for briefing to the Commanding General and the DOD Health Affairs office. Additionally, the CDMRP has initiated the Technology Development Working Group (TDWG) to develop promising results and products for use by the military and/or civilian sectors. The TDWG partners with the RADs and others to explore ways to continue successful research projects beyond the limits of funding from the CDMRP. By working continually with our partners at USAMRMC, the CDMRP strives to enhance the overall mission of the Command.

#### DOD Small Business Innovation Research and Small Business Technology Transfer Programs

The CDMRP participates in the DOD Small Business Innovation Research and Small Business Technology Transfer (SBIR and STTR) programs. The SBIR and STTR programs are congressionally mandated, government-wide programs that are designed to harness the innovative talents of U.S. small businesses for our country's military and economic strength. These are technology- and productdriven programs intended to develop goods and services that the government can potentially use and the small business can continue to commercialize outside the SBIR and STTR programs.





## Working with Minority and Underserved Populations

In 1998, the CDMRP established the Minority and Underserved Populations Program to provide focus to initiatives aimed at addressing health disparity. The primary function of the program is to promote execution strategies aimed at eliminating the unequal burden of disease among minority and medically underserved populations, as appropriate across the research programs managed by the CDMRP. Program execution includes:

- Surveillance of disease impact on populations
- Solicitation of health disparity-focused research (based upon target disease incidence and mortality among populations)
- Outreach with information about specific funding mechanisms for minority serving institutions<sup>4</sup>
- Collaboration with other funding agencies on assessment of portfolio overlap and complementation
- Exchange of information with public and private advocacy and research organizations, including data on trends and standard of care relevant to disease disparity among minority and medically underserved populations

#### International Cancer Research Partners: One Voice, One Vision

In 2000, the CDMRP joined the National Cancer Institute and the National Cancer Research Institute of the United Kingdom to form the International Cancer Research (ICR) Partners in an effort to maximize the global investment in cancer research. The mission of the ICR Partners is to enhance the impact of research to benefit all individuals affected by cancer through global collaboration and strategic coordination of research.

Today, the ICR Partners include 52 cancer funding organizations from the United States, Canada, United Kingdom, and the Netherlands that have come together to classify their respective research portfolios using a common coding scheme (called the Common Scientific Outline). The most recent member to join was the Dutch Cancer Society. The ICR Partners are currently involved in discussions with other interested cancer research funding organizations in the United States, Europe, and elsewhere to join the partnership, expanding the efforts toward a global strategic mission to eradicate cancer. Additional information about the ICR Partners and research supported by its members can be found at http://www.cancerportfolio.org/.

<sup>&</sup>lt;sup>4</sup> For the purposes of minority institutions, the CDMRP uses the list compiled by the United States Department of Education, which can be accessed at http://www2.ed.gov/about/offices/list/ocr/edlite-minorityinst-list.html.

### **Team Science**

The CDMRP promotes collaboration among the scientific community by offering award mechanisms that promote interdisciplinary team collaboration. These highly collaborative team studies integrate different specialties to achieve groundbreaking advancements that could not be accomplished by an individual or single disciplinary team. The CDMRP began offering award mechanisms that foster team science in 1997. Characteristics of team science include focus on complex issues; integration of large, interdisciplinary teams that are often spread out geographically; highly integrated, comprehensive approaches; and large dollar investments. Examples of team science award mechanisms are included in the graphic.





## Information Dissemination

A core philosophy of the CDMRP is transparency with respect to public awareness of how congressional funds are used and managed. The CDMRP employs many different modes to share information about research supported by the CDMRP, which are highlighted as follows.

## **The CDMRP Website**

The CDMRP website is an important means to disseminate information to the public and scientific community. In 2009, the CDMRP evaluated the utility and effectiveness of the existing website and began an extensive effort to redesign the site. A diverse team was assembled that began to take inventory of the existing content and brainstorm about new and fresh ideas. Keeping in mind the different needs of the audience, the team assessed the strengths and weaknesses of the site including content, navigation, graphics, and animation. Other sites were examined to get ideas about the latest in web design, and new concepts

began to emerge. A redesign was developed and tested, and in May 2010 the newly designed CDMRP website was launched. The redesign more effectively captures our audience's needs, has new and easy-todigest information, and engages the visitor.

#### http://cdmrp.army.mil



## **Research Highlights**

Research highlights are written by staff to inform the public about innovative research being conducted by investigators supported by funds from the CDMRP. Research highlights are typically developed by each program to focus on important research advances, implications in quality of life, and future research directions. Research highlights are posted and archived on the CDMRP website as well as published in individual program books (additional information about program books is referenced on page 24). A total of 40 new research highlights were posted this fiscal year.

### **Multidisciplinary Meetings**

The CDMRP sponsors several multidisciplinary meetings to bring together researchers, clinicians, consumers, the military, and policy makers to share their knowledge and experiences related to a specific disease, injury, or condition. In February 2010, the BCRP supported a multidisciplinary meeting called Leading Innovative Networking and Knowledge Sharing (LINKS) to showcase progress and foster synergy among recipients of select award mechanisms. The meeting enabled participants to develop meaningful collaborations, ask deeper questions about breast cancer research, and cross-fertilize research ideas and knowledge for breast cancer risk, prevention, treatment, and cures.

Last year, the third Military Health Research Forum was hosted by the Peer Reviewed Medical, Gulf War Illness, and PH/TBI Research Programs. Additional multidisciplinary meetings highlighting progress from BCRP and Prostate Cancer Research Program (PCRP) awardees are planned for 2011. PCRP awardees will attend the IMPaCT conference March 9–12, 2011 while the BCRP awardees will attend the Era of Hope conference August 2–5, 2011.



1997, 2000, 2002, 2005, 2008, 2011



2004, 2006, 2009



#### Comments from Attendees

"The CDMRP has brought a lot of innovations to the grant writing and review process. The program should be commended for these...."

"For me it became clear that the CDMRP works more closely with the investigators than some other funding agencies/ programs, which signals that [the organization] is very interested in the outcome of its funded projects."

"I thought it a great service on the part of the CDMRP to set [the session] up, as it was well run, the room was packed and undoubtedly [the information] was useful to those early in their careers or without much experience with funding opportunities and writing applications."

"This was really useful, particularly the presentation from the cancer survivor who is a member of the review panel. It was good to understand things from her point of view."

#### The CDMRP Presents Funding Opportunities in Cancer Research

At the premier cancer research conference, the 101st Annual Meeting of the American Association for Cancer Research (AACR), the CDMRP presented a session on its cancer research funding. The AACR conference was held in April 2010 in Washington, DC and attracted more than 17,000 attendees.

A standing-room only audience learned about the CDMRP, its vision, mission, and the intricacies of the programmatic funding cycle. A panel of experts representing the CDMRP spoke about current funding opportunities and the importance of addressing the goals of each research program when applying for funds. Additional information about the two-tier process of review, participation in the review of applications, and perspectives of a consumer reviewer and funded scientist was provided.

Following the presentations and a general question-and-answer session, attendees were given the opportunity to personally discuss any further questions about the cancer programs with the CDMRP Program Managers and SOs.

In a survey of those who attended the presentations, 94% of respondents indicated that the information provided was valuable to them, and 76% stated that they were more likely to apply for funding than before they had attended the session. Some of the statements made by attendees can be read in the sidebar.

350

300

250

200

100

American Association for Cancer Research

### **Program Announcement Outreach**

The CDMRP makes every effort to alert the scientific research community when new program announcements are released. Program announcements describe the funding opportunities and application process for specific mechanisms within each program. Dissemination strategies are wide and include the following:

- Alerting more than 800 research administrators of upcoming award opportunities
- Posting program announcements to the CDMRP website and Grants.gov
- Notifying websites that specialize in biomedical grant notification
- Notifying more than 60 professional associations, 300 Veterans Affairs facilities and military and medical research laboratories, and 6 federal agencies
- Advertising in professional journals and on federal business websites
- Using targeted e-mails and advertising for specific award mechanisms and outreach
- Maintaining an e-mail distribution list of more than 26,000
- Distributing electronic news items to more than 200 consumer advocacy groups
- Exhibiting the CDMRP display and presenting funding opportunities at national scientific meetings
- Providing research institutions with award details for news releases



### **Program Books**

Program books are developed to highlight each program's vision and mission, partnerships, and detailed highlights of notable research funded by that research program. Program books are distributed at program-specific and national meetings and also can be downloaded from the CDMRP website at http://cdmrp.army.mil.



# **Consortia Advances and Accomplishments**

The CDMRP has funded several multidisciplinary consortia that have successfully linked researchers from across the country and around the world to research all stages of diseases, injuries, and conditions. An example of consortium funded by the CDMRP includes the 2007 multidisciplinary consortia to research TBI and post-traumatic stress. The consortia bring together scientists and clinicians to collaborate on the diagnosis and treatment of TBI and post-traumatic stress.

The TBI Multidisciplinary Research Consortium led by Drs. John Holcomb and Claudia Robertson unites 20 scientists and clinicians working at several institutions in an effort to improve the diagnosis and treatment of mild TBI for service members. Drs. James Tour and Thomas Kent of the TBI Multidisciplinary Research Consortium synthesize potent antioxidant nanomaterials that use small carbon nanotubes to carry antioxidants for the treatment of oxidative stress following TBI, representing an entirely new class of treatment for TBI.

Under the direction of Dr. Alan Peterson, the Post-traumatic stress Multidisciplinary Research Consortium known as STRONG STAR (The South Texas Research Organizational Network Guiding Studies on Trauma and Resilience) is working to develop and evaluate effective interventions for the treatment of combat-related post-traumatic stress. STRONG STAR is a collaborative network of more than 100 investigators at 20 institutions.

Under the leadership of Dr. Murray Stein, the Injury and Traumatic Stress (INTRuST) Consortium conducts clinical trials of novel treatments and interventions for combatrelated post-traumatic stress and/or TBI at 10 clinical sites across the United States.

Lt Col Jeffrey Cigrang, a STRONG STAR investigator, discovers preliminary evidence through a pilot clinical trial that cognitive behavioral therapy may be successfully provided to service members in a primary care setting.

## Highlighted Advances and Accomplishments Funded by the CDMRP

On the following pages are remarkable accomplishments made by investigators supported by funding from the CDMRP across programs since the CDMRP's inception through FY09. These advances are grouped by area of research and demonstrate that much progress has been made. The CDMRP continues to make a global effort to drive its research endeavors to new heights.

Dr. Constantin Ioannides conducts studies on the characterization of immunodominant epitopes in breast cancer that led to the development of E75, a peptide-based vaccine to prevent recurrences; now in Phase III clinical trials.

Dr. Eldon Jupe examines the risk association between BRCA1, BRCA2, prohibitin T allele, and breast cancer, which led to the development of OncoVue, a risk assessment test approved by the U.S. Food and Drug Administration (FDA) that is commercially available. Dr. Allan Belzberg develops the tibial neuroma transposition animal model of neuroma pain to evaluate preventive strategies.

Dr. Jeffrey Pyne develops a virtual reality stress inoculation biofeedback training as a pre-deployment intervention to reduce post-traumatic stress development and related mental health problems.



## **PREVENTION** Studies on the inhibition of disease initiation, condition, or avoidance of injury.

Dr. He Li shows that administration of corticosterone prior to or following intense, repeated stress prevents traumatic memory retrieval in an animal model of post-traumatic stress.

Dr. David Bowtell discovers that the Asn372His genotype of BRCA2 significantly increases the risk of ovarian cancer. Additionally Dr. Bowtell identifies differences in epidemiological risk factors between ovarian, fallopian, and primary peritoneal cancer.



Dr. Liying Zhang develops an idealized three-dimensional human head model to examine the blast phenomena and determines that the maximum peak pressure transmitted to the scalp, skull, and brain was higher than the blast pressure received by the head. Dr. Michael Wigler conducts research that contributes to the discovery of the tumor suppressor gene, PTEN, which is mutated in breast cancer, prostate cancer, and glioblastomas.

Dr. David Goldgar discovers the founder BRCA2 617delT mutation in Ashkenazi Jews.



Dr. Joseph Kissil shows that Pak1 is hyperactive in primary schwannomas isolated from neurofibromatosis type 2 (NF2) patients and suppression of Paks 1-3 via shRNAs reduces the ability of NF2 mutant cells to grow in vitro and form tumors in a xenograft model of NF2. Long-term Pak1 inhibition via shRNA is restored through a methylation-dependent mechanism.

Dr. David Gutmann demonstrates that NF1+/- mice lacking NF1 in astrocytes develop optic gliomas that result from axonal disorganization and damage and culminates in retinal ganglion cell death.

Dr. Kevin Shannon develops mouse models of malignant peripheral nerve sheath tumors (MPNSTs), plexiform neurofibromas, astrocytomas, and ependyomas for assessing the mutagenic potential of NF1 tumor therapies. Dr. Mark Nellist identifies three regions essential for tuberous sclerosis complex 1 (TSC1) or TSC2 function as well as a region of TSC1 required for maintaining TSC1 at sufficient levels in the cell to form a stable TSC1–TSC2 complex and inhibit mTOR.

Dr. Vuk Stambolic implements realtime NMR to characterize the molecular mechanism of GTP catalysis by Rheb and the impact of the TSC2 GAP activity on this process. He also characterizes a series of TSC2 GAP domain mutants found in TS patients and determines the molecular mechanism of action of the TSC2 GAP activity on Rheb. These studies may lead to the development of TSC2-mutation-specific therapeutic strategies.

## **STAGES** Studies on the initiation, promotion, and/or progression of a disease state, injury, or condition.

Dr. Alcino Silva discovers that the deletion of NF1 in inhibitory neurons causes learning disabilities due to increases in GABA release, an effect reversed with GABA antagonists. He also demonstrates that NF1 modulates ERK/synapsin I-dependent GABA release, which modulates hippocampal longterm potentiation and learning.

Dr. Karen Cichowski demonstrates that NF1 is inactivated in sporadic gliomas via two mechanisms: excessive proteasomal degradation by PKC hyperactivation and homozygous NF1 loss when p53 is inactivated.

Dr. Paul Kizakevich develops an easy-touse Personal Health Monitor for longitudinal data collection to study signs, symptoms, triggers, and behaviors in post-traumatic stress and mild traumatic brain injury patients. The device allows for the collection of comprehensive physical and physiological data while minimizing subject burden. Dr. Karen Cichowski discovers a mechanism for the development of prostate cancer metastasis whereby nuclear factor kB, a protein known to play a critical role in prostate cancer progression, is constitutively activated via loss of disabled homolog 2 interacting protein (DAB2IP). DAB2IP expression and subsequent activity, which control cell signaling to NF-kB, are blocked by the EZH2 protein, which has long been implicated in prostate cancer metastasis.

Dr. Bernardo Sabatini conducts studies that show that the TSC pathway regulates neuron soma size, the density and size of dendritic spines, and the properties of excitatory synapses in hippocampal pyramidal neurons both in cell culture and animal models. Dr. Vera Krymskay identifies that complex formation between TSC1 and TSC2 regulates cell adhesion and motility and that dysregulation of the complex formation may contribute to the pathogenesis of TSC.

Dr. Elizabeth Henske demonstrates that hamartin and tuberin play critical roles in amino acid sensing, uptake, and metabolism and tuberous sclerosis symptoms may be linked to defects in those key cellular functions.



#### **The CDMRP-Funded Advances and Accomplishments**

Dr. Robert Vogt shows that higher levels of nerve tissue antigen-specific IgG antibodies in archived dried blood spots of newborns were associated with a reduced risk of autism spectrum disorder compared to matched controls.

Dr. Kathryn Verbanac conducts clinical studies testing the validity and accuracy of sentinel lymph node biopsy, the current standard of care for disease staging in breast cancer. Dr. Susan Love develops a minimally invasive diagnostic procedure for detecting precancerous and cancerous breast cells in fluid from the breast ducts.

Dr. David Getty conducts a Phase III clinical trial demonstrating that stereo mammography is more accurate than standard mammography in detecting true lesions in breast cancer screening.



Dr. Mia MacCollin defines pediatric NF2 phenotype.

Dr. Jan Friedman identifies phenotypic groups and relationships between features of NF1 and of familial phenotypes as candidates for allele-phenotype correlations.

Dr. Bruce Korf establishes volumetric magnetic resonance imaging (MRI) as the standard approach for measurement of plexiform neurofibroma growth in clinical trials.

Dr. Martin McIntosh discovers that MMP7 is elevated in serum up to 3 years prior to diagnosis of ovarian cancer.

## **DETECTION/DIAGNOSIS** Studies on investigations into the presence and/or identification of a disease, condition, or injury.

Dr. Zhen Zhang in collaboration with Vermillion, Inc., develops OVA1TM, the first IVDMIA (in vitro diagnostic multivariate index assay) of proteomic biomarkers cleared by the FDA to help physicians identify ovarian cancer patients whose surgeries should be referred to a gynecologic oncologist.

Dr. Patricia Kruk demonstrates elevated urinary Bcl-2 as a biomarker in women at risk for ovarian cancer, and through a licensing agreement, Geopharma is developing a urinary detection device.

Dr. Jeffrey Mason develops a liposome polymerase chain reaction assay to detect cholera toxin beta subunit in human urine.

Dr. Kai Thomenius develops components for an ultrasound imager suited to remote emergency medicine such as imaging associated with combat casualty care. Dr. Nicole Urban, develops assays to measure HE4 and MSLN in serum; HE4 assay was licensed to Fujirebio Diagnostics Inc., which partnered with Abbott and was approved by the FDA as a new diagnostic test to monitor recurrence or progression of ovarian cancer.

Dr. Xiaoyuan Chen develops multimeric arginine-glycine-aspartic acid (RGD) peptides with high alpha-vbeta-3 integrin affinity for PET imaging of ovarian cancer, receives an exploratory Investigational New Drug (IND), and initiates Phase 0 studies for the peptide tracer having the greatest tumor targeting efficacy in vivo. Dr. Gregory Belenky develops an unobtrusive, wrist-worn actigraph with an embedded mathematical performance prediction algorithm for tracking activity and sleep periods.

Dr. Martin Pomper develops a series of PET radiotracers that target PMSA (prostate membrane-specific antigen), a protein that is made on the surface of prostate cells. The radiotracers were further developed commercially and have now moved to Phase I clinical trials to significantly improve imaging for patients with either newly diagnosed or recurrent prostate cancer. Dr. Cynthia Menard develops an MRI table to allow needle placement for prostate cancer patients lying on their backs (rather than side or stomach) to improve prostate gland stability during prostate biopsies, visualization of local prostate cancer recurrence after radiation treatment, and treatment to areas of recurrent tumor growth after radiotherapy.

Dr. Mikulas Chavko determines that pressure detected in the rat brain following exposure to blast overpressure is contingent on the orientation to the blast direction suggesting that pressure waves enter the protective tube and body by diffraction, moving in an opposite direction to the blast wave. Drs. Victor-Felix Mautner and Samuel Rabkin demonstrate that imatinib mesylate (Gleevec) inhibits Schwann cell viability and reduces the size of human plexiform neurofibroma (PNF) in a xenograft model and reduces tumor volume of PNF fragments obtained from NF1 patients.

Dr. Janet Sawicki develops a targeted treatment using nanoparticles to deliver diphtheria toxin-encoding DNA to ovarian cancer cells, leaving healthy cells unaffected.

Dr. Robert Martuza develops an HSV vector therapy for NF2 that reduces schwannoma tumor volume in an NF2 mouse model. Dr. Fazlul Sarkar identifies a compound from cruciferous vegetables (e.g., broccoli, cauliflower, brussel sprouts, and cabbage) that inhibits prostate cancer cell growth. Dr. K.M. Rahman later shows that this compound, 3,3'-diinolylmethane (DIM), in combination with taxotere, inhibits tumor growth by 80% in animal models. DIM has now moved into Phase I clinical trials.

Dr. Tin Tin Su develops a quantitative Drosophila-based assay to screen compounds and tests their ability to rescue the larval lethality of TSC1 homozygous mutants.

#### **DETECTION/DIAGNOSIS (cont.)**

Dr. Bernardo Sabatini uses the CellProfiler, the first free, open-source system designed for flexible, high-throughput cell image analysis, as part of a highthroughput screen to identify new drug targets for treating TSC.

Dr. David Ingram shows that hyperactivation of p21ras and PI3K cooperate to alter NF1 osteoclast functions in the pathogenesis of NF1 bone disease.

Dr. Nancy Ratner identifies a 159 gene molecular signature distinguishing MPNST cell lines from normal Schwann cells.



## TREATMENT

#### studies on agents for the remediation of a disease, condition, or injury

Dr. Jeffrey Peterson identifies Pak1 inhibitors as a treatment for NF2.

Dr. Gordon Mills identifies lysophosphatidic acids in serum and develops humanized monoclonal antibodies that have been shown to reduce tumor volume and metastasis in preclinical studies; now in Phase I clinical trials for the treatment of solid tumors.

Dr. Yoel Kloog generates a new class of Ras inhibitors for NF1.

Dr. Michael Vitek measures the safety and toxicity of COG1410 in rats and in dogs to form the basis of an IND application to the FDA for the treatment of TBI. COG1410 is a mimetic of the wild-type apoE protein but it is very small and therefore crosses the blood-brain barrier and exerts anti-inflammatory and neuroprotective activities similar to wildtype apoE. Dr. Marianne Sadar discovers an extract from marine sponges that blocks activation of androgen receptor. A synthetic analog of the extract, EPI-001, shrunk prostate tumors to 20% of their normal size with no toxicity in animal models.

Dr. Raymond Mattingly demonstrates that inhibition of both EGFR and ErbB2 by the pan-ErbB inhibitor CI-1033 (canertinib) suppresses NF1 MPNST cell proliferation.



## The CDMRP-Funded Advances and Accomplishments

Dr. Dennis Slamon develops Herceptin<sup>®</sup> (trastuzumab), a monoclonal antibody against the HER-2/neu receptor in breast cancer.

Dr. Serge Przedborski targets ALS drug development by examining differential gene expression in subpopulations of motor neurons that are prone to relatively different vulnerability to neurodegeneration with similar pathology and pattern in both forms of ALS, whether sporadic or familial.



Dr. Richard Peto conducts Adjuvant Tamoxifen Longer Against Shorter (ATLAS) clinical trial, the largest breast cancer treatment trial ever undertaken, examining the optimal duration of adjuvant tamoxifen in earlystage breast cancer.

Dr. Julia Golier conducts a randomized cross-over trial of mifepristone (a glucocorticoid receptor antagonist) to determine its efficacy in improving general health and cognitive functioning in ill Gulf War veterans.

Dr. Ai Lin optimizes imidazolidinedione derivatives that are orally active with potential curative and prophylactic activity against the parasite that causes malaria. Dr. Raymond Mattingly demonstrates that a novel farnesyltransferase inhibitor combined with lovastatin reduces proliferation and induces apoptosis of MPNST cells and is a potential treatment for NF1 MPNSTs.

Drs. Santo Nicosia and Jin Cheng discover API-2/tricirbine (now in Phase I clinical trials as VQD-002), as a putative inhibitor of Aktactivated cancers, which includes over 40% of ovarian tumors.

#### **TREATMENT** (cont.)

Dr. Glenn Prestwich develops novel hyaluronic acid (HA)targeted drugs, now in Phase III clinical trials, which bind HA receptors on breast cancer cells for enhanced delivery of anticancer agents.

Dr. Roger Packer conducts Phase I studies of pirfenidone in children with NF1 and progressive plexiform neurofibromas and determines the optimal dose of pirfenidone for treatment. Recruitment initiatives for a Phase II clinical trial assessing the efficacy of pirefenidone in treating NF1 and plexiform neurofibromas have been completed. Dr. Brigitte Widemann conducts a Phase II trial of the farnesyltransferase inhibitor R115777 in pediatric patients with NF1 and demonstrates that the compound is well tolerated with only mild toxicities.

Dr. Lisa Conboy investigates the effectiveness of acupuncture to address the multiple symptoms of Gulf War illness, in which treatments can be tailored to individual needs.

The 13 Cancer Centers in the Prostate Cancer Clinical Trials Consortium (www.pcctc. org) accrue more than 2,000 prostate cancer patients to 68 Phase I and Phase II clinical trials since 2006. The PCCTC advances 5 therapeutic candidates, including abiraterone acetate, docetaxel plus dasatinib, ipilumumab, MDV3100, and OGX-011, to Phase III study. The Phase I/II study of OGX-011 was funded by a PCRP award to Dr. Kim Chi. Dr. Sundaram Ramakrishnan, develops anginex, a potent anti-angiogenic and anti-cancer peptide (produced by ActiPep Biotechnology) and shows efficacy in combating ovarian cancer.

Dr. Richard Pietras develops and patents treatment of ovarian cancer with squalamine in combination with other anticancer agents/modalities (in Phase II clinical trials through Genaera Pharmaceuticals).



Drs. Gregory Hannon and Stephen Elledge develop gene silencing and genetic screening strategies to identify new potential therapeutic targets.

Dr. Mary Daly establishes a high-risk breast cancer registry, which evolved into a program that now serves a large urban area with a range of risk assessment, screening, and preventive services.

Dr. Kimlin Ashing-Giwa develops a predictive model for the identification of sociocultural mediators and their role in breast cancer survivorship among different ethnic populations to improve health-related quality of life.

Dr. Peter Bergold determines that minocycline and N-acetylcysteine synergistically improve behavioral performance following moderate controlled brain injury in rats.



## **PROTECTION** Physical or pharmaceutical barriers to disease, condition, or injury.

Dr. Karen Cichowski identifies a negative feedback signaling pathway that underlies oncogene-induced sensescence, a mechanism that protects benign lesions from becoming malignant in patients with NF.

Dr. Nicholas Webster identifies the lead drug, 5E5, and 38 other promising compounds for the treatment of brain injury based on their ability to activate the TrkB receptor.

Dr. Donald Stein develops a set of analogs specifically to maintain the neuroprotective properties of progesterone while increasing solubility following TBI.



#### INTERVENTION Improve the health or alter the course of a disease, injury, or condition.



#### **The CDMRP-Funded Advances and Accomplishments**

Dr. Charles Levy leverages combat veterans' comfort and familiarity with communications technology and immersive environments to build a prototype virtual world environment in which to conduct therapy in returning combat veterans with mild TBI/Post-traumatic stress.



Dr. Kathyrn North observes that cognitive ability does not improve as children with NF1 age, despite decreases in the number, size, and intensity of T2 hyperintensities. She also identifies high comorbidiy of ADHD and specific learning disabilities in children with NF1.

Dr. Mary Daly publishes first resource book for high-risk women considering prophylactic oophorectomy: "Ovarian Cancer Risk-Reducing Surgery: A Decision-Making Resource."

#### **REHABILITATION** Recovering, regaining strength, and/or relearning skills

Day-to-day lives of patients

Dr. Steven Sparagana develops a comprehensive clinical database of TSC cases that documents the natural history and variability of TSC over the lifespan of individuals with the disease.

Dr. Joseph Rizzo develops a retinal prosthesis that may be used to treat several forms of retinal blindness that are currently untreatable, including blindness caused by battlefield laser injury to the retina and military-related, blast-induced blindness.





## Appendix A: FY92-FY09

Program	Fiscal Year	Appropriations Received (in millions)	Applications Received	Applications Funded
Amyotrophic Lateral Sclerosis	2007–2009	\$10.0	64	6
Autism	2007–2009	\$21.9	546	54
Bone Marrow Failure	2008–2009	\$6.0	151	15
Breast Cancer	1992–2009	\$2,381.3	41,975	5,839
Chronic Myelogenous Leukemia	2002–2006	\$22.1	252	61
Defense Women's Health	1995	\$40.0	559	69
Deployment Related Medical	2008	\$101.9	1,094	50
DOD/VA	1999–2000	\$6.8	88	9
Genetic Studies of Food Allergies	2009	\$2.5	12	4
Gulf War Illness	2006, 2008–2009	\$23.0	107	30
Institutionally Based Programs	1995–2009	\$444.0	281	242
Lung Cancer	2009	\$20.0	521	29
Multiple Sclerosis	2009	\$5.0	126	21
Myeloproliferative Disorders	2004	\$4.3	18	9
National Prion	2002	\$42.5	136	38
Neurofibromatosis	1996–2009	\$200.3	946	245
Osteoporosis	1995	\$5.0	105	5
Ovarian Cancer	1997–2009	\$141.7	2,206	213
Peer-Reviewed Cancer	2009	\$16.0	401	38
Peer-Reviewed Medical	1999–2006, 2008–2009	\$444.5	3,997	323
Peer-Reviewed Orthopaedic	2009	\$112.0	357	95
Prostate Cancer	1997–2009	\$970.0	10,592	2,172
Psychological Health/Traumatic Brain Injury	2007–2009	\$358.5	2,640	244
Spinal Cord Injury	2009	\$35.0	298	53
Tuberous Sclerosis Complex	2002–2006, 2008–2009	\$23.5	293	69
Total		\$5,437.7	67,765	9,933

Table A-1. Overview of Appropriations, Applications Received, and Awards Made for FY92-FY09



## Appendix B: FY09-FY10\*

 
 Table B-1. FY09–FY10 Amyotrophic Lateral Sclerosis Research Program Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
2009	<b>\$5M</b> for Amyotrophic Lateral Sclerosis	Withholds <sup>a</sup> USAMRMC: \$125,000	Research Therapeutic Development: \$4,485,905
		Management Costs <sup>b</sup>	
		\$389,095 (7.98%)	
	Total: \$5M	Total: \$514,095	Total: \$4,485,905
2010	<b>\$7.5M</b> for Amyotrophic Lateral Sclerosis	Withholds <sup>a</sup> USAMRMC: \$188,000	Research Budgeted Peer-Reviewed Research: \$6,730,000
		Budgeted Management Costs <sup>b</sup>	
		\$582,000 (7.96%)	
	Total: \$7.5M	Total: \$770,000	Total: \$6,730,000

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command. <sup>b</sup> Percentage of management costs=management costs/(appropriation=withholds).

Table B-2.	FY09–FY10 Autism Research Program Congressional Language and Appropriations,
	Withholds and Management Cost, and Execution of Investment Strategy

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
2009	<b>\$8M</b> for Autism Research	Withholds <sup>a</sup> USAMRMC: \$200,000 Management Costs <sup>b</sup>	ResearchClinical Partnership:\$801,970Concept:\$837,072Idea Development:\$5,545,968
		\$614,990 (7.88%)	
	Total: \$8M	Total: \$814,990	Total: \$7,185,010
2010	<b>\$8M</b> for Autism Research	Withholds <sup>a</sup> USAMRMC: \$200,000 Budgeted Management Costs <sup>b</sup>	ResearchBudgeted Peer-ReviewedResearch:\$7,180,000
		\$620,000 (7.95%)	
	Total: \$8M	Total: \$820,000	Total: \$7,180,000

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
2009	<b>\$5M</b> for Bone Marrow Failure Research	Withholds <sup>a</sup> USAMRMC: \$125,000	Research Exploration-Hypothesis Development Award: \$1,441,905
		Management Costs <sup>b</sup>	Idea: \$575,625
		\$426,222 (8.74%)	Synergistic Idea: \$2,431,248
	Total: \$5M	Total: \$551,222	Total: \$4,448,778
2010	<b>\$3.75M</b> for Bone Marrow Failure Research	Withholds <sup>a</sup> USAMRMC: \$94,000	Research Budgeted Peer-Reviewed Research: \$3,365,000
		Budgeted Management Costs <sup>b</sup> \$291,000 (7.96%)	
	Total: \$3.75M	Total: \$385.000	Total: \$3 365 000

Table B-3. FY09–FY10 Bone Marrow Failure Disorder Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

	Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
	2009	<ul> <li>\$150M for the Peer- Reviewed Breast Cancer Research Program</li> <li>\$1,458,516 in proceeds from the Stamp Out Breast Cancer Act</li> </ul>	Withholds <sup>a</sup> USAMRMC: \$3,750,000 Management Costs <sup>b</sup> \$14,684,678 (9.94%)	Research           Concept:         \$6,998,315           Era of Hope Scholar:         \$18,902,807           HBCU/MI Partnership         Training:           Training:         \$3,992,584           Idea:         \$26,186,903           Idea:         \$26,186,903           Idea Collaborative         0ption:           Option:         \$13,242,581           Idea Expansion:         \$5,300,611           Idea Expansion:         \$5,300,611           Idea Expansion:         \$8,096,169           Innovator:         \$8,845,803           Institutional Training:         \$49,947           Multi-Team:         \$7,622,890           Postdoctoral Fellowship:         \$22,554,653           Predoctoral Traineeships:         \$9,099,123           Communication         \$2,131,452
ļ		Total: \$151,458,516	Total: \$18,434,678	Total: \$133,023,838
	2010	<ul> <li>\$150M for the Peer- Reviewed Breast Cancer Research Program</li> <li>\$1,004,833 in proceeds from the Stamp Out Breast Cancer Act</li> </ul>	Withholds <sup>a</sup> USAMRMC: \$3,750,000 Budgeted Management Costs <sup>b</sup> \$12,254,833 (8.32%)	Research Budgeted Peer-Reviewed Research: \$135,000,000
		Total: \$151,004,833	Total: \$16,004,833	Total: \$135,000,000

 
 Table B-4.
 FY09–FY10 Breast Cancer Research Program Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

Table B-5.	FY10 Chiropractic Research Program Congressional Language and Appropriations,
	Withholds and Management Cost, and Execution of Investment Strategy

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
2010	\$372M for Guidance for the Development of the Force Less Funds Managed by Others \$363,850,000	Budgeted Management Costs <sup>ь</sup> \$650,000 (7.9%)	Research Budgeted Peer-Reviewed Research: \$7,500,000
	Total: \$8,150,000	Total: \$650,000	Total: \$7,500,000

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

<sup>b</sup> Percentage of management costs=management costs/(appropriation-withholds).

#### FY10 National Defense Authorization Act

SEC. 725. CHIROPRACTIC CLINICAL TRIALS.

(a) CLINICAL TRIALS REQUIRED.-The Secretary of Defense shall provide for the clinical trials described under subsection (b) to be conducted by the National Institutes of Health or an independent academic institution as the Secretary shall select for the purposes of conducting each trial.

(b) CLINICAL TRIALS DESCRIBED.-

(1) CONTROLLED TRIALS.-The clinical trials required by subsection (a) shall include controlled trials that, at a minimum, compare the outcomes of chiropractic treatment, used either exclusively or as an adjunct to other treatments, with conventional treatment on the following topics:

(A) Pain management.

(B) Orthopedic injuries or disorders that do not require surgery.

(C) Smoking cessation.

(2) INTERVENTIONAL TRIALS.-The clinical trials required by subsection (a) shall include interventional trials that, at a minimum, cover the following topics:

(A) The effect of chiropractic treatment on the reflexes and reaction times of special operation forces.

(B) The effect of chiropractic treatment on strength, balance, and injury prevention for members of the Armed Forces with combat specialties operating in a combat theater.

(C) SCHEDULE.-

(1) FIRST TRIAL.-The first clinical trial required by subsection (a) shall begin not later than one year after the date of the enactment of this Act.

(2) FINAL TRIAL.-The final clinical trial required by subsection

(a) shall begin not later than two years after the date of the enactment of this Act.

(d) TRIAL PARTICIPANTS.-A participant of a clinical trial required by subsection (a) shall be a member of the Armed Forces on active duty

(e) CHIROPRACTIC PROVIDERS.-Chiropractic treatment provided during a clinical trial required by subsection (a) shall be provided by a doctor of chiropractic who is licensed as a doctor of chiropractic, chiropractic physician, or chiropractor by a State, the District of Columbia, or a territory or possession of the United States, subject to credentialing requirements prescribed by the Secretary. (f) REPORTS.

(1) TRIAL PROTOCOL REPORTS.-Not later than 30 days before each clinical trial required by subsection (a) is scheduled to begin, the Secretary shall submit to the congressional defense committees a report on the protocol of such clinical trial.

(2) FINAL REPORTS. Not later than one year after the completion of each clinical trial required by subsection (a), the Secretary shall submit to the congressional defense committees a report on such clinical trial, including any recommendations regarding chiropractic treatment for covered beneficiaries (as such term is defined in section 1072(5) of title 10, United States Code).

Table B-6. FY10 Defense Medical Research and Development Program Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
2010	\$372M for Guidance for the Development of the Force Less Funds Managed by Others: \$316,685,936	Budgeted Management Costs <sup>b</sup> \$2,454,946 (4.4%)	Research Budgeted Peer- Reviewed Research: \$52,859,118
	Total: \$55,314,064	Total: \$2,454,946	Total: \$52,859,118

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

<sup>b</sup> Percentage of management costs=management costs/(appropriation-withholds).

#### FY10 Senate Report:

Military Medical Research-The Committee was pleased that the President's budget request included a substantial increase for military medical research. The additional \$372,000,000 will address the numerous unique military medical areas of concern. The Committee understands that the Department of Defense is finalizing the capability gaps these resources will target and urges the Department to ensure the appropriate level of resources are devoted to address the following areas of research identified by the three Services: traumatic brain injury; psychological health (including suicide prevention, substance abuse, and family health and wellbeing); musculoskeletal injury; regenerative medicine for extremity injuries, burns, and craniofacial injuries; blast-related injury; infectious diseases; pain management; sensory dysfunction; respiratory disease; enroute care research (including studies on compartment syndrome, timing of transport, patient safety during transport, pain management); early recognition, diagnosis, and treatment of emerging threats (e.g., pandemic response, weaponized nanoparticles, etc.); operational medicine (including clinical patient safety studies and clinical medicine enhancements); human performance; wound management throughout the continuum of care; and undersea medicine, diving, and submarine medical research. The Committee recognizes that the while the Assistant Secretary of Defense for Health Affairs is the lead organization tasked with establishing the capability gaps, the Services all play a crucial role in developing the needs and executing the programs. In addition, there are various groups, institutions, and organizations that would like an opportunity to compete for these resources. Therefore, the Committee directs the Assistant Secretary of Defense for Health Affairs to report to the congressional defense committees by November 6, 2009 with a complete list of these capability gaps; a timeline and process for distributing and/or competing the resources; and a detailed description of how Health Affairs has integrated the Services into the development and execution process.

#### FY10 House Report:

#### GUIDANCE FOR THE DEVELOPMENT OF THE FORCE (2010-2015)

The fiscal year 2010 budget submission included \$372,200,000 for traumatic brain injury, psychological health, eye injury, prosthetics, and other battlefield injuries research. The Committee has supported these types of research since 2007 and is encouraged that the Department has for the first time included funding for this type of research. The Committee urges the Department to utilize the established congressional directed medical research program and to work with the U.S. Army Medical Research and Materiel Command in finding the most efficient way of utilizing the unique and military relevant research available.  
 Table B-7.
 FY09–FY10 Genetic Studies of Food Allergies Research Program Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
2009	\$2.5M for	Withholds <sup>a</sup>	Research
	of Food Allergies	USAMRMC: \$63,000	Peer-Reviewed Research:
	Ŭ	Management Costs <sup>b</sup>	Investigator-Initiated Research:
		\$167,356 (6.87%)	\$2,269,644
	Total: \$2.5M	Total: \$230,356	Total: \$2,269,644
2010	\$1.875M for	Withholds <sup>a</sup>	Research
	Genetics Studies	USAMRMC: \$47,000	Budgeted Peer-Reviewed
	of Food Allergies		Research: \$1,685,000
		Budgeted Management Costs <sup>b</sup>	
		\$143,000 (7.82%)	
	Total: \$1.875M	Total: \$190,000	Total: \$1,685,000

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

<sup>b</sup> Percentage of management costs=management costs/(appropriation-withholds).

Table B-8.	FY09	9–FY10	Gulf Wa	r Illness	Research	Program	Congress	sional L	anguage	and
Appropria	tions,	Withhol	lds and N	/lanager	nent Cost,	and Exec	cution of I	Investm	nent Strate	эgy

Fiscal Year	Congressional Appropriation	Withholds and Ma	inagement Costs	Investment Stra	itegy
2009	\$8M for Gulf War	Withholds <sup>a</sup>		Research	
	Illness Peer-	Section 8101:	\$22,000	Innovative Treatment	
	Reviewed Research	Section 8026:	\$6,000	Evaluation:	\$776,077
	Program	USAMRMC:	\$199,000	Investigator-Initiated	
				Research:	\$6,135,486
		Management Cost	S <sup>b</sup>		
			\$861,437 (11.08%)		
	Total: \$10M		Total: \$1,088,437	Tota	l: \$6,911,563
2010	\$8M for Gulf War	Withholds <sup>a</sup>		Research	
	Illness Peer-	USAMRMC:	\$200,000	Budgeted Peer-Reviewed	ł
	Reviewed Research			Research:	\$7,430,000
	Program	Budgeted Manage	ment Costs <sup>b</sup>		
		•	\$370,000 (4.745%)		
	Total: \$8M		Total: \$570,000	Tota	I: \$7,430,000

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
2009	<b>\$20M</b> for the Peer-Reviewed Lung Cancer Research Program	Withholds <sup>a</sup> USAMRMC: \$501,000 Management Costs <sup>b</sup> \$1,540,822 (7.9%)	ResearchConcept:\$1,549,640Clinical Fellow Research:\$575,648Collaborative TranslationalResearch:Research:\$9,849,689Lung Cancer BiospecimenResource Network:Resource Network:\$3,687,787Lung Cancer PromisingClinician Research:\$2,295,414
	Total: \$20M	Total: \$2,041,822	Total: \$17,958,178
2010	<b>\$15M</b> for the Peer-Reviewed Lung Cancer Research Program	Withholds <sup>a</sup> USAMRMC: \$375,000 Budgeted Management Costs <sup>b</sup> \$980,000 (6.7%)	Research Budgeted Peer-Reviewed Research: \$13,645,000
	Total: \$15M	Total: \$1,355,000	Total: \$13,645,000

Table B-9. FY09–FY10 Lung Cancer Research Program Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

<sup>b</sup> Percentage of management costs=management costs/(appropriation-withholds).

FY09 Peer Reviewed Lung Cancer Research Program: The bill includes \$20,000,000 for lung cancer research. Lung cancer is the most lethal of all cancers taking more lives each year than all the other major cancers combined. Furthermore, the five-year survival rate for lung cancer remains 15 percent and a major challenge is that 70 percent of the diagnoses are late stage. Military personnel have heightened exposure to lung cancer carcinogens. These funds shall be for competitive research and the establishment of a tissue bank. Priority shall be given to the development of the integrated components to identify, treat and manage early curable lung cancer. The Army is expected to provide a plan for these funds and to include Walter Reed Army Medical Center in the formulation of this plan. The plan shall be submitted to the congressional defense committees 120 days after enactment of this Act.

#### FY10 House Report:

PEER-REVIEWED LUNG CANCER RESEARCH

The Committee has included \$15,000,000 for peer-reviewed lung cancer research. Lung cancer, continues to be the most lethal of all cancers, taking more lives annually than all other major cancers combined. The five year survival rate is only 15 percent and a major contributor is that 70 percent of the diagnoses are late stage. Furthermore, military personnel have increased exposure to lung cancer carcinogens and are thus more susceptible to lung cancer than the general population. These funds, in conjunction with the funds provided in fiscal year 2009, are primarily for an early detection program for military beneficiaries. It is expected that this early detection regimen will be initially implemented in Military Medical Treatment facilities in the National Capital Region.

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
2009	<b>\$5M</b> for Multiple Sclerosis	Withholds <sup>a</sup> USAMRMC: \$125,000	Research Metric Development and Validation: \$1,355,165
		Management Costs <sup>b</sup> \$482,324 (9.89%)	Synergistic Idea: \$3,037,511
	Total: \$5M	Total: \$607,324	Total: \$4,392,676
2010	<b>\$4.5M</b> for Multiple Sclerosis	Withholds <sup>a</sup> USAMRMC: \$113,000	Research Budgeted Peer-Reviewed Research: \$4,040,000
		Budgeted Management Costs <sup>b</sup> \$347,000 (7.9%)	
	Total: \$4.5M	Total: \$460,000	Total: \$4,040,000

 
 Table B-10.
 FY09–FY10 Multiple Sclerosis Research Program Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

<sup>b</sup> Percentage of management costs=management costs/(appropriation-withholds).

Table B-11.	FY09–FY10 Neurofibromatosis Research Program Congressional Language and
Appropria	ations, Withholds and Management Cost, and Execution of Investment Strategy

Fiscal Year	Congressional Appropriation	Withholds and Ma	anagement Costs	Investment Stra	tegy
2009	\$10M for	Withholds <sup>a</sup>		Research	
	Neurofibromatosis	Section 8101:	\$27,000	Clinical Trial:	\$587,770
	Research	Section 8026:	\$6,000	Exploration - Hypothesis	
	Program	USAMRMC:	\$249,000	Development:	\$1,173,960
				Investigator-Initiated	
		Management Cost	ts <sup>b</sup>	Research:	\$5,191,341
			\$677,003(6.97%)	New Investigator:	\$1,292,216
				Postdoctoral Traineeship:	\$795,710
	Total: \$10M		Total: \$959,003	Total	: \$9,040,997
2010	\$13.75M for	Withholds <sup>a</sup>		Research	
	Neurofibromatosis	USAMRMC:	\$344,000	Budgeted Peer-Reviewed	
	Research			Research:	\$12,410,000
		Budgeted Manage	ement Costs <sup>b</sup>		
			\$996,000 (7.43%)		
	Total: \$13.75M		Total: \$1,340,000	Total:	\$12,410,000

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
2009	\$20M for the	Withholds <sup>a</sup>	Research
	Peer-Reviewed	USAMRMC: \$500,000	Consortium Development: \$577,615
	Ovarian Cancer		Idea Development: \$8,567,547
	Research Program	Management Costs <sup>b</sup>	Ovarian Cancer Academy:
		\$1,361,095 (6.98%)	Academy Dean: \$1,135,112
			Ovarian Cancer Academy:
			Early-Career Investigator/
			Designated Mentor: \$7,773,110
			Translational Research
			Partnership: \$85,521
	Total: \$20M	Total: \$1,861,095	Total: \$18,138,905
2010	\$18.75M for the	Withholds <sup>a</sup>	Research
	Peer-Reviewed	USAMRMC: \$469,000	Budgeted Peer-Reviewed
	Ovarian Cancer		Research: \$16,820,000
	Research Program	Budgeted Management Costs <sup>b</sup>	
		\$1,461,000 (8.0%)	
	Total: \$18.75M	Total: \$1,930,000	Total: \$16,820,000

 Table B-12. FY09–FY10 Ovarian Cancer Research Program Congressional Language and

 Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
2009	\$16M for the	Withholds <sup>a</sup>	Research
	Peer-Reviewed	USAMRMC: \$400,000	Collaborative Translational
	Cancer Research	Management Costs <sup>b</sup>	Science-Melanoma: \$3,572,366
	riogram	\$1.276.817 (8.18%)	Concept - Non-Invasive
		¢ 1,210,011 (01010)	Cancer Ablation: \$484,404
			Idea - Genetic Cancer: \$3,721,034
			Mentor-Predoctoral Fellow -
			Non-Invasive Cacner
			New Investigator -
			Genetic Cancer: \$2,494,479
			Synergistic Idea -
			Pediatric Brain Tumor: \$1,786,299
	Total: \$16M	Total: \$1,676,817	Total: \$14,323,183
2010	\$15M for the	Withholds <sup>a</sup>	Research
	Peer-Reviewed	USAMRMC: \$375,000	Budgeted Peer-Reviewed
	Cancer Research	Dudgeted Menagement Casteb	Research: \$13,455,000
	Program	\$1,170,000 (8%)	
	Total: \$15M	Total: \$1,545,000	Total: \$13,455,000

Table B-13. FY09–FY10 Peer-Reviewed Cancer Research Program Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

<sup>b</sup> Percentage of management costs=management costs/(appropriation-withholds).

FY09 Peer Reviewed Cancer Research Program: The bill provides \$16,000,000 for a peer-reviewed cancer research program that would research cancers not addressed in the breast, prostate, and ovarian cancer research programs currently executed by the Department of Defense, and specifically the U.S. Army Medical Research and Materiel Command (USAMRMC). The funds provided are directed to be used to conduct research in the following areas: \$4,000,000 for research of melanoma and other skin cancers as related to deployments of servicemembers to areas of high exposure; \$2,000,000 for research of pediatric brain tumors within the field of childhood cancer research; \$8,000,000 for genetic cancer research and its relation to exposure to the various environments that are unique to a military lifestyle; and \$2,000,000 for non-invasive cancer ablation research into non-invasive cancer treatment including selective targeting with nano-particles. The funds provided under the Peer-Reviewed Cancer Research Program shall be used only for the purposes listed above. The Department of Defense is directed to provide a report by March 16, 2009, to the congressional defense committees on the status of this new Peer-Reviewed Cancer Research Program as to the relevance of this type of research for servicemembers and their families.

#### FY10 House Report: Peer-Reviewed Cancer Research Program

The Committee provides \$20,000,000 for a peer-reviewed cancer research program that would research cancers not addressed in the breast, prostate, lung and ovarian cancer research programs currently executed by the Department of Defense, and specifically the U.S. Army Medical Research and Materiel Command (USAMRMC). The funds provided are directed to be used to conduct research in the following areas: melanoma and other skin cancers, pediatric brain tumors within the field of childhood cancer research, genetic cancer research and genomic medicine, kidney cancer, blood cancer, colorectal cancer, Listeria Vaccine for infectious disease and cancer, and radiation protection utilizing nanotechnology. The funds provided under the Peer-Reviewed Cancer Research Program shall be used only for the purposes listed above. The Department of Defense is directed to provide a report by February 8, 2010, to the congressional defense committees on the status of the peer-reviewed cancer research program as to the relevance of this type of research for servicemembers and their families.

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
2009	\$50M for the Peer- Reviewed Medical Research Program	Withholds <sup>a</sup> USAMRMC: \$1,250,000 Management Costs <sup>b</sup> \$3,455,764 (7.09%)	ResearchAlcoholism Research:\$1,089,345Autoimmune Diseases:\$6,952,589Blood Cancer:\$3,711,984Childhood Asthma:\$1,132,500Drug Abuse:\$1,142,707Epilepsy Research:\$2,314,809Kidney Cancer:\$1,106,364Listeria Vaccine forinfectious diseaseand cancer:\$955,376Lupus:\$2,387,619Mesothelioma:\$2,750,549Molecular Signatures in Tumors:\$3,014,606Neuroblastoma:\$3,936,594Osteoporosis and related bone disease:\$2,687,526Pediatric Cancer:\$6,155,441Polycystic Kidney Disease:\$1,241,250Tinnitus:\$919,781West Nile Virus Vaccine:\$3,686,016Communication\$3,686,016
	Total: \$50M	Total: \$4 705 764	\$109,180 Total: \$45 294 236
2010	CCOM for the	Withholdo	Total: \$43,274,230
2010	Peer-Reviewed Medical Research Program	Withholds <sup>a</sup> USAMRMC:         \$1,250,000           Budgeted Management Costs <sup>b</sup> \$3,900,000 (8.0%)	Research Budgeted Peer-Reviewed Research: \$44,850,000
	Total: \$50M	Total: \$5,150,000	Total: \$44,850,000

Table B-14. FY09–FY10 Peer-Reviewed Medical Research Program Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

<sup>b</sup> Percentage of management costs=management costs/(appropriation-withholds).

FY2009 Peer- Reviewed Medical Research Program: The bill provides \$50,000,000 for a Peer-Reviewed Medical Research Program. The Secretary of Defense is directed, in conjunction with the Service Surgeons General, to select medical research projects of clear scientific merit and direct relevance to military health. Research areas considered under this funding are restricted to: Alcoholism, Autoimmune Diseases, Blood Cancer, Childhood Asthma, Drug Abuse, Epilepsy, Kidney Cancer, Listeria Vaccine for infectious disease and cancer, Lupus, Mesothelioma, Molecular Signatures in Tumors, Neuroblastoma, Osteoporosis and related bone disease, Paget's Disease, Pediatric Cancer, Polycystic Kidney Disease, Social Work Research, Tinnitus, and West Nile Virus Vaccine. Additional funding provided under the Peer-Reviewed Medical Research Program shall be devoted only to the purposes listed above.

FY2010 Peer-Reviewed Medical Research Program: The recommendation provides \$50,000,000 for a Peer-Reviewed Medical Research Program. The Secretary of Defense, in conjunction with the Service Surgeons General, is directed to select medical research projects of clear scientific merit and direct relevance to military health. Research area considered under this funding are restricted to: Blood Cancer, Chronic Migraine and Post-traumatic headache, Dystonia, Drug Abuse, Epilepsy, Fragile X Syndrome, Inflammatory Bowel Disease, Interstitial Cystitis, Kidney Cancer, Lupus, Melanoma, Meosthelioma, Neuroblastoma, Osteoporosis and related bone disease, Padget's Disease, Pheochromocytoma, Polycystic Kidney Disease, Post Traumatic Osteoarthritis, Scleroderma, Social Work Research, and Tinnitus. The recommendation emphasizes that the additional funding provided under the Peer-Reviewed Medical Research Program shall be devoted only to the purposes listed above.

 
 Table B-15.
 FY09–FY10 Peer-Reviewed Orthopaedic Research Program Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

Fiscal Year	Congressional Appropriation	Withholds and Ma	nagement Costs	Investment Stra	itegy
2009	\$61M for	Withholds <sup>a</sup>		Research	
	Peer-Reviewed	SBIR:	\$1,275,000	Career Development:	\$259,848
	Orthopedic Research	USAMRMC:	\$2,768,000	Clinical Consortium :	\$38,657,995
				Clinical Trial:	\$13,788,277
	\$51M for Orthopedic	Management Cost	S <sup>b</sup>	Hypothesis Development	: \$5,473,928
	Research	9	57,937,706 (7.35%)	Idea Development:	\$12,650,537
				Technology Developmen	t:
					\$21,623,103
				Translational Research	
				Partnership:	\$7,565,606
	Total: \$112M	Т	otal: \$11,980,706	Total:	\$100,019,294
2010	\$22.5M for	Withholds <sup>a</sup>		Research	
	Peer-Reviewed	USAMRMC:	\$563,000	Budgeted Peer-Reviewed	ł
	Orthopedic Research			Research:	\$20,185,000
		Budgeted Manage	ment Costs <sup>b</sup>		
		\$	1,752,000 (7.99%)		
	Total: \$22.5M		Total: \$2,315,000	Total	\$20,185,000

<sup>a</sup> The following abbreviations are used for withholds: SBIR, Small Business Innovation Research; USAMRMC, U.S. Army Medical Research and Materiel Command.

<sup>b</sup> Percentage of management costs=management costs/(appropriation-withholds).

FY09 Peer-Reviewed Orthopedic Research Program: The conference agreement provides \$51,000,000 for orthopedic and other trauma research, treatment and rehabilitation including regenerative medicine. This funding will continue and expand the existing orthopedic trauma research program, amputee rehabilitation and reset research, and restoration of function. Serious limb trauma, vascular injuries, major limb tissue damage, and blood flow disruption contribute heavily to United States military casualties in Iraq and Afghanistan. The Department of Defense estimates indicate that nearly two thirds of injuries sustained in combat in Iraq and Afghanistan are musculoskeletal. Extremity injuries are the most prevalent injury, and amputations following battlefield injury now occur at twice the rate as in past wars. Understanding how to treat and facilitate rapid recovery from orthopedic injuries should be one of the top priorities in the Military Health System.

Fiscai Year	Appropriation	Withholds and Management Costs	Investment Strategy
2009	\$80M for the		Research
	Prostate Cancer Research Program	USAMRMC: \$2,000,000	Collaborative Undergraduate HBCU Student Summer
	5	Management Costs <sup>b</sup>	Training: \$687,649
		\$6,126,290 (7.85%)	Health Disparity Research -
			Early Career Invesigator: \$342,000
			Health Disparity Research - Established Investigator: \$3 501 938
			Health Disparity Training: \$128,676
			Idea Development: \$28,140,007
			New Investigator: \$9,710,180
			Physician Research
			Iraining: \$3,691,952
			Synergistic Idea: \$7,110,580
			Pathology Resource Network-
			Coordinating Center: \$1,136,768
			Pathology Resource
			Network-Pathology
			Resource Network Site: \$1,989,652 Prior Year Clinical
			Consortium Award -
			Clinical Research Site: \$3,299,692
			Prior Year Clinical Consortium
			Award with Option for
			Clinical Research Sile: \$4,418,158
			Communication
			\$1,800,000
	Total: \$80M	Total: \$8,126,290	Total: \$71,873,710
2010	\$80M for the	Withholds <sup>a</sup>	Research
	Peer-Reviewed	USAMRMC: \$2,000,000	Budgeted Peer-Reviewed
	Prostate Cancer	Budgeted Management Costs	Research: \$71,760,000
	Nesealuli Flografii	\$6,240,000 (8.00%)	
	Total: \$80M	Total: \$8,240,000	Total: \$71,760,000

 
 Table B-16.
 FY09–FY10 Prostate Cancer Research Program Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
2009	<ul> <li>\$90M for Traumatic Brain Injury/ Psychological Health Research</li> <li>\$75M for Traumatic Brain Injury/ Psychological Health Research</li> <li>Less Funds Managed by Others \$107,442,200</li> </ul>	Management Costs <sup>b</sup> \$3,449,314 (5.99%)	ResearchAdvanced Technology/TherapeuticDevelopment:\$12,661,152Applied Research and AdvancedTechnology Development:Technology Development:\$4,119,566Clinical Trial:\$11,126,386Concept:\$3,714,516Hypothesis Development:\$105,504Investigator-Initiated\$8,872,338Investigator-Initiated\$8,872,338Investigator-Initiated\$10,617,197Intramural PTSD Investigator-Initiated\$705,200PH/TBI Investigator-Initiated\$2,151,542Research:\$2,151,542TBI Multidisciplinary\$35,085
	Total (CDMRP): \$57,557,800	Total: \$3,449,314	Total: \$54,108,486
2010	\$120M for Traumatic Brain Injury/ Psychological Health Research Less Funds Managed by Others \$59,083,285	Budgeted Management Costs <sup>b</sup> \$3,530,000 (5%)	Research Budgeted Peer-Reviewed Research: \$57,386,715
	Total (CDMRP): \$60,916,715	Total: \$3,530,000	Total: \$57,386,715

Table B-17. FY09–FY10 Psychological Health/Traumatic Brain Injury Research Program Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

<sup>b</sup> Percentage of management costs=management costs/(management costs + research).

FY10 Joint Explanatory Statement: Traumatic Brain Injury and Psychological Health: The recommendation provides \$120,000,000 for Traumatic Brain Injury (TBI) and Psychological Health research and treatment efforts. The fiscal year 2010 budget submission included \$372,000,000 to address numerous unique military medical areas of concern including TBI and Psychological Health. The Department is encouraged to refer to the language in the House and Senate reports regarding gaps in research that need to be addressed within this funding to close those disparities.

FY10 House Report:

TRAUMATIC BRAIN INJURY AND PSYCHOLOGICAL HEALTH

Traumatic Brain Injury (TBI) and psychological health issues have emerged as a significant cause of death to the warfighters in Iraq and Afghanistan. Whether mild, moderate or severe brain injury, the level of assessment and standard of care provided to the warfighter is in need of enhancement. Diagnosis, treatment, and rehabilitation must be at a level to ensure the best possible outcome. To this end, the bill includes \$500,000,000, which is \$127,800,000 above the budget request, to address all levels of brain injury and psychological health issues that servicemembers and their families experience.

The Department provides specialized treatment and rehabilitation for brain injured troops, but much more is needed. The Department is expected to continue to provide the necessary care and treatment to servicemembers and their families. The vast majority of disabled troops will ultimately return to their home communities, which may be far removed from specialized centers. Therefore, the identification of local services is crucial to an appropriate rehabilitation plan. The Department of Defense Military Centers and the Department of Veterans Affairs should coordinate with civilian centers to guarantee that optimal treatments and assistance are available throughout the country.

The Committee is aware of gaps within TBI and psychological treatment methods that need to be addressed. The Department is expected to continue working with the Department of Veterans Affairs, Department of Health and Human Services, academia and industry to focus on the research and treatment necessary to address the gaps that have been identified.

An area of particular interest is the provision of appropriate and accessible counseling to servicemembers and their families who live in locations that are not close to military treatment facilities, other Military Health System health facilities or TRICARE providers. Funding provided in this bill is also to be used for the development and operation of the Defense Center of Excellance (DCoE) and the various centers, programs and initiatives that fall within its purview and resources to support the service medical departments as they continue to build and expand their TBI and psychological health capacity through initiatives and supportive programs. Other initiatives, such as telehealth, clinical standards supporting TBI and psychological health, and training and education outreach should also be included.

Funding has also been provided to continue medical research and development on TBI and psychological health. The following research topics are recommended for consideration under this program: therapeutic drug discovery; optical imaging of blood flow; headache disorders; research into neural prothesis; studies of mental health disorders and Post Traumatic Stress Disorder (PTSD) to include neuropsychiatric studies, biochemical mechanisms that underlie human emotional reactions to combat stress and resulting clinical disorders, metrics for mental health assessment and methods to evaluate and improve PTSD rehabilitation efforts; studies of Traumatic Brain Injury (TBI) including basic research on neural injury treatments, cell replacement and regrowth strategies, specific therapies to prevent and reverse spinal cord and other neurotraumatic damage, pharmaceutical interventions to stimulate neural circuits, "activitybased" physical therapy, and extended rehabilitation focused on impairments in vision and cognitive functioning; clinical research of blast-related cell damage and the resulting effects on neurological response; 3D models of IED blast waves to develop equipment to mitigate injury to servicemembers; a fully automated, self-contained, disposable chip to diagnose TBI at the point of onset; DA-EEG assessment and MRI quantization to allow an accurate assessment of TBI; computational approaches to integrate global transcriptomics and proteomics information to identify the biological networks altered following TBI; studies of PTSD and/or TBI including basic research in neurorehabilitation, the integration of informatics, and advanced computational research to analyze brain tissue and activities, the use of advanced neuroimaging, behavioral and genetic information to develop biomarkers, diagnostics, and treatments for semi-acute and chronic injury stages. Funding provided for research and development shall incorporate all aspects of research in the areas of TBI and psychological health by conducting basic science and translational research for the purposes of understanding the etiology, developing preventive interventions and new treatments, and evaluating the outcomes to arrive at best-practice solutions. This requirement includes incorporating training, combat theater operations, post deployment evidence-based preventive and early intervention measures, practices, or procedures to reduce the likelihood that personnel in combat will develop PTSD or other stress-related conditions or sustain traumatic brain injuries.

Fiscal Year	Congressional Appropriation	Withholds and Manage	ement Costs	Investment Str	ategy
2009	\$35M for the	Withholds <sup>a</sup>		Research	
	Peer-Reviewed	USAMRMC:	\$875,000	Advanced Technology/T	herapeutic
	Spinal Cord			Development:	\$5,854,233
	Research Program	Management Costs <sup>b</sup>		Clinical Trial-	
		\$2,42	2,449 (7.10%)	Rehabilitation:	\$7,575,131
				Exploration/Hypothesis-	
				Development:	\$1,417,616
				Investigator-Initiated	
				Research:	\$10,749,566
				Translational Research	
				Partnership:	\$6,106,005
	Total: \$35M	Total	: \$3,297,449	Tota	I: \$31,702,551
2010	\$11.25M for the	Withholds <sup>a</sup>		Research	
	Peer-Reviewed	USAMRMC:	\$281,000	Budgeted Peer-Reviewe	ed
	Spinal Cord			Research:	\$10,255,000
	Research Program	Budgeted Management	Costs⁵		
		\$714	4,000 (6.51%)		
	Total: \$11.25M	Tot	al: \$995.000	Tota	I: \$10.255.000

Table B-18. FY09–FY10 Peer-Reviewed Spinal Cord Research Program Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

<sup>b</sup> Percentage of management costs=management costs/(appropriation-withholds).

FY10 House Report:

Spinal cord injuries are one of the many serious wounds resulting from conflicts in Iraq and Afghanistan that require many levels of research and treatment. Significant funding has been provided for research and treatment for neuro-traumatic wounds. However, given the complexity of these types of injuries and the steep learning curve associated with establishing effective treatment regimes, there is much more to be done. For the coming years, research into regenerating damaged spinal cords, arthritis research, and improving rehabilitation therapies offers real promise for enhancing the long-term care of wounded soldiers. Therefore, the Committee provides \$15,000,000 to continue a competitive, peer-reviewed spinal cord injury research and treatment program. The Secretary of Defense is directed to submit a report to the congressional defense committees not later than 120 days after enactment of this Act on how these funds are to be allocated.

Table B-19.	FY09–FY10 Tuberous Sclerosis Research Program Congressional Language	and
Appropri	ations, Withholds and Management Cost, and Execution of Investment Strategy	y

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
2009	\$6M for Tuberous	Withholds <sup>a</sup>	Research
	Scierosis	USAMRMC: \$150,000	Career Transition: \$494,392
	Complex		Clinical Research: \$1,103,808
		Management Costs <sup>b</sup>	Concept: \$925,215
		\$385,231 (6.59%)	Idea Development: \$2,941,357
	Total: \$6M	Total: \$535,231	Total: \$5,464,769
2010	\$6M for Tuberous	Withholds <sup>a</sup>	Research
	Sclerosis	USAMRMC: \$150,000	Budgeted Peer-Reviewed
	Complex		Research: \$5,385,000
		Budgeted Management Costs <sup>b</sup>	
		\$465,000 (7.95%)	
	Total: \$6M	Total: \$615,000	Total: \$5,385,000

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
ALS Therap	y Development for Gulf V	Var Illness Research	
2010	<b>\$1.6M</b> for ALS Therapy Development for Gulf War Illness Resarch	Withholds <sup>a</sup> Army:         \$8,000           USAMRMC:         \$40,000           Budgeted Management Costs <sup>b</sup> \$122,000 (8%)	Research Budgeted Peer-Reviewed Research: \$1,430,000
	Total: \$1.6M	Total: \$170,000	Total: \$1,430,000
Biological a	and Immunological Infect	ious Agent and Cancer Vaccine Resea	lirch
2009	<b>\$0.8M</b> for Biological and Immunological Infectious Agent and Cancer Vaccine Research	Withholds <sup>a</sup> Section 8101:         \$2,000           Section 8026:         \$1,000           USAMRMC:         \$20,000           Management Costs <sup>b</sup> \$37,000 (4.76%)	Research Dana-Farber Cancer Institute: \$740,000
	Total: \$0.8M	Total: \$60,000	Total: \$740,000
Cancer Pre	vention Through Remote	Biological Sensing Research	
2009	<b>\$1.6M</b> for Cancer Prevention Through Remote Biological Sensing	Withholds <sup>a</sup> Section 8101:         \$4,000           Section 8026:         \$1,000           USAMRMC:         \$40,000           Management Costs <sup>b</sup> \$	Research SUNY - Stonybrook: \$1,480,000
		\$75,000 (4.82%)	
	Total: \$1.6M	Total: \$120,000	Total: \$1,480,000
2010	<b>\$1.6M</b> for Cancer Prevention Through Remote Biological Sensing	Withholds <sup>a</sup> Army:         \$8,000           USAMRMC:         \$40,000           Budgeted Management Costs <sup>b</sup> \$122,000 (8%)	Research Budgeted Peer-Reviewed Research: \$1,430,000
	Total: \$1.6M	Total: \$170,000	Total: \$1,430,000
Center for (	Cancer Immunology Rese	arch	
2010	<b>\$1.6M</b> for Center for Cancer Immunology Research	Withholds <sup>a</sup> Army:         \$8,000           USAMRMC:         \$40,000           Budgeted Management Costs <sup>b</sup> \$100,000 (000)	Research Budgeted Peer-Reviewed Research: \$1,430,000
	Total: \$1.6M	Total: \$170,000	Total: \$1,430,000

#### Table B-20. FY09–FY10 Institutionally Based Research Programs Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
Childhood	Cancer		
2009	<b>\$1.6M</b> for Oncology Group Pediatric Cancer Research	Withholds <sup>a</sup> Section 8101:         \$4,000           Section 8026:         \$1,000           USAMRMC:         \$40,000	Research National Childhood Cancer Foundation: \$1,480,000
		Management Costs <sup>b</sup> \$75,000 (4.82%)	
	Total: \$1.6M	Total: \$120,000	Total: \$1,480,000
2010	<b>\$1.6M</b> for Pediatric Cancer Research and Clinical Trials	Withholds <sup>a</sup> Army:         \$8,000           USAMRMC:         \$40,000           Budgeted Management Costs <sup>b</sup> \$122,000,(8%)	Research Budgeted Peer-Reviewed Research: \$1,430,000
	Total: \$1.6M	Total: \$170.000	Total: \$1,430,000
Cold Spring	s Harbor Laboratory Wo	men's Cancer Genomics Center	τοται: ψ1,430,000
2009	\$2.8M for Cold Spring Harbor Laboratory- Women's Cancer Genomics Center	Withholds <sup>a</sup> Section 8101:         \$8,000           Section 8026:         \$2,000           USAMRMC:         \$69,000           Management Costs <sup>b</sup> \$136,000,(5%)	Research Cold Springs Harbor Laboratory: \$2,585,000
	Total: \$2.8M	Total: \$215.000	Total: \$2 585 000
2010	\$2.4M for Women's Cancer Genomics Center Research	Withholds <sup>a</sup> Army:         \$13,000           USAMRMC:         \$60,000           Budgeted Management Costs <sup>b</sup> \$187,000 (8%)	Research Budgeted Peer-Reviewed Research: \$2,140,000
	Total: \$2.4M	Total: \$260,000	Total: \$2,140,000
Cooperativ	e International Neuromus	cular Research Group	
2010	\$3.28M for Cooperative International Neuromuscular Research Group	Withholds <sup>a</sup> Army:         \$17,000           USAMRMC:         \$82,000           Budgeted Management Costs <sup>b</sup> \$251,000 (8%)	Research Budgeted Peer-Reviewed Research: \$2,930,000
	Total: \$3.28M	Total: \$350,000	Total: \$2,930,000

Table B-20. FY09–FY10 Institutionally Based Research Programs Congressional Language andAppropriations, Withholds and Management Cost, and Execution of Investment Strategy (cont.)

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
Duchenne I	Muscular Dystrophy Rese	arch	
2009	<b>\$4.0M</b> for Duchenne Muscular Dystrophy Research	Withholds <sup>a</sup> USAMRMC: \$100,000 Management Costs <sup>b</sup> \$200,000 (5.13%)	ResearchChildren's Hospital ofPittsburgh:\$1,849,999Children's National MedicalCenter:\$164,432Children's ResearchInstitute:\$1,685,569
	Total: \$4.0M	Total: \$300,000	Total: \$3,700,000
2010	<b>\$3.75M</b> for Duchenne Muscular Dystrophy Research	Withholds <sup>a</sup> USAMRMC: \$94,000 Budgeted Management Costs <sup>b</sup> \$291,000 (7.96%)	Research Budgeted Peer-Reviewed Research: \$3,365,000
	Total: \$3.75M	Total: \$385,000	Total: \$3,365,000
Enhancing	Wound Healing, Tissue R	egeneration and Biomarker Discovery	I
2010	<b>\$2.0M</b> for Enhancing Wound Healing, Tissue Regeneration and Biomarker Discovery	Withholds <sup>a</sup> Army:         \$10,000           USAMRMC:         \$50,000           Budgeted Management Costs <sup>b</sup> \$155,000 (8%)	Research Budgeted Peer-Reviewed Research: \$1,785,000
	Total: \$2.0M	Total: \$215,000	Total: \$1,785,000
Fighting Co	, ombat-Related Fatigue Re	search	
2010	<b>\$0.8M</b> for Fighting Combat-Related Fatigue Research	Withholds <sup>a</sup> Army:         \$4,000           USAMRMC:         \$20,000           Budgeted Management Costs <sup>b</sup> \$61,000 (7.86%)	Research Budgeted Peer-Reviewed Research: \$715,000
	Total: \$0.8M	Total: \$85,000	Total: \$715,000
Gallo Prost	ate Cancer Research Prog	gram	
2009	<b>\$2.4M</b> for UMDNJ Cancer Initiative	Withholds <sup>a</sup> Section 8101:         \$7,000           Section 8026:         \$2,000           USAMRMC:         \$60,000	Research UMDNJ: \$2,190,005
		Management Costs <sup>b</sup> \$140,995 (6,05%)	
	Total: \$2.4M	Total: \$209,995	Total: \$2,190,005

#### Table B-20. FY09–FY10 Institutionally Based Research Programs Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy (cont.)

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy			
Infectious a	nfectious and Inflammatory Disease Center at the Burnham Institute for Medical Research					
2009	\$2.4M for Infectious and Inflammatory Disease Center at the Burnham Institute for Medical Research	Withholds <sup>a</sup> Section 8101:         \$7,000           Section 8026:         \$2,000           USAMRMC:         \$59,000           Management Costs <sup>b</sup> \$117,000 (5%)	Research Burnham Institute: \$2,215,000			
	Total: \$2.4M	Total: \$185,000	Total: \$2,215,000			
Mary Bird F	Perkins Cancer Center					
2009	<b>\$2.4M</b> for Mary Bird Perkins Cancer Center	Withholds <sup>a</sup> Section 8101:         \$7,000           Section 8026:         \$2,000           USAMRMC:         \$59,000           Management Costs <sup>b</sup> \$117,000 (5%)	Research Mary Bird Perkins Cancer Center: \$2,215,000			
	Total: \$2.4M	Total: \$185,000	Total: \$2,215,000			
Marty Dries	ler Lung Cancer					
2010	<b>\$1.6M</b> for Marty Driesler Lung Cancer Research	Withholds <sup>a</sup> Army:         \$8,000           USAMRMC:         \$40,000           Budgeted Management Costs <sup>b</sup> \$122,000 (5%)	Research Budgeted Peer-Reviewed Research: \$1,430,000			
	Total: \$1.6M	Total: \$170,000	Total: \$1,430,000			
Military Peo	liatric Training and Suppo	ort				
2010	<b>\$4.0M</b> for Military Pediatric Training and Support	Withholds <sup>a</sup> Army:         \$21,000           USAMRMC:         \$99,000           Budgeted Management Costs <sup>b</sup> \$310,000 (8%)	Research Budgeted Peer-Reviewed Research: \$3,570,000			
	Total: \$4.0M	Total: \$430,000	Total: \$3,570,000			
Musculosk	eletal Interdisciplinary Re	search Initiative				
2010	<b>\$1.6M</b> for Musculoskeletal Interdisciplinary Research Initiative	Withholds <sup>a</sup> Army:         \$8,000           USAMRMC:         \$40,000           Budgeted Management Costs <sup>b</sup> \$122,000 (8%)	Research Budgeted Peer-Reviewed Research: \$1,430,000			
	Total: \$1.6M	Total: \$170,000	Total: \$1,430,000			

 Table B-20.
 FY09–FY10 Institutionally Based Research Programs Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy (cont.)

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
Neutron/Ha	dron Particle Therapy an	d Proton Therapy Research	
2009	\$1.2M for Neutron/ Hadron Particle Therapy \$4.8M for Proton Therapy	Withholds <sup>a</sup> Section 8101:         \$3,000           Section 8026:         \$1,000           USAMRMC:         \$150,000	Research Northern Illinois University: \$5,550,000
		Management Costs <sup>b</sup> \$296,000 (5.06%)	
	Total: \$6.0M	Total: \$450,000	Total: \$5,550,000
2010	\$1.6M for Hadron Particle Therapy \$2.8M for Northern Illinois Proton Treatment and Research Center	Withholds <sup>a</sup> Army:         \$24,000           USAMRMC:         \$110,000           Budgeted Management Costs <sup>b</sup> \$296,000 (7%)	Research Budgeted Peer-Reviewed Research: \$3,970,000
	Total: \$4.4M	Total: \$430,000	Total: \$3,970,000
Novel Appr	oaches to Reduce Severit	y of Battlefield Combined Tissue Inju	ry
2009	\$1.6M for Novel Approaches to Reduce Severity of Battlefield Combined Tissue Injury	Withholds <sup>a</sup> Section 8101:         \$5,000           Section 8026:         \$1,000           USAMRMC:         \$39,000	Research Nevada Cancer Institute: \$1,480,000
		Management Costs <sup>b</sup> \$75,000 (4.82%)	
	Total: \$1.6M	Total: \$120,000	Total: \$1,480,000
Prader-Will	i Syndrome		
2009	<b>\$1.6M</b> for Prader-Willi Syndrome (PWS) Research	Withholds <sup>a</sup> Section 8101:       \$5,000         Section 8026:       \$1,000         USAMRMC:       \$39,000	Research California State University, Fullerton: \$1,479,950
		\$75,050 (4.83%)	
	Total: \$1.6M	Total: \$120,050	Total: \$1,479,950
2010	<b>\$1.6M</b> for Prader-Willi Syndrome (PWS) Research	Withholds <sup>a</sup> Army:         \$8,000           USAMRMC:         \$40,000           Budgeted Management Costs <sup>b</sup> \$122,050 (8%)	Research Budgeted Peer-Reviewed Research: \$1,430,000
	Total: \$1.6M	Total: \$170,000	Total: \$1,430,000

## Table B-20. FY09–FY10 Institutionally Based Research Programs Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy (cont.)

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy
Preventive	Medicine Research Institu	ute	
2009	<b>\$1.75M</b> for Expanding Access to Proven Lifestyle Modification Treatments Focused on Preventing and Reversing Chronic Diseases	Withholds <sup>a</sup> \$           Section 8101:         \$5,000           Section 8026:         \$1,000           USAMRMC:         \$44,000           Management Costs <sup>b</sup> \$85,000 (5%)	Research Preventive Medicine Research Institute: \$1,615,000
	Total: \$1.75M	Total: \$135,000	Total: \$1,615,000
2010	<b>\$1.5M</b> for Lifestyle Modifications to Reduce Chronic Disease in Military Personnel	Withholds <sup>a</sup> Army:         \$8,000           USAMRMC:         \$37,000           Budgeted Management Costs <sup>b</sup> \$105,000 (7%)	Research Budgeted Peer-Reviewed Research: \$1,350,000
	Total: \$1.5M	Total: \$150,000	Total: \$1,350,000
Prostate an	d Ovarian Cancer Biomar	kers Research	
2009	<b>\$1.2M</b> for Prostate and Ovarian Cancer Biomarkers Research	Withholds <sup>a</sup> Section 8101:         \$3,000           Section 8026:         \$2,000           USAMRMC:         \$29,000	Research Immunotope Inc.: \$1,110,000
		\$56,000 (4.8%)	
	Total: \$1.2M	Total: \$90,000	Total: \$1,110,000
Respiratory	/ Biodefense Initiative Re	search	
2009	<b>\$1.6M</b> for Respiratory Biodefense Initiative Research	Withholdsa           Section 8101:         \$4,000           Section 8026:         \$1,000           USAMRMC:         \$40,000           Management Costsb         \$115,000 (7.4%)	Research National Jewish Medical and Research Center: \$1,440,000
	Total: \$1.6M	Total: \$160,000	Total: \$1,440,000
2010	<b>\$2.4M</b> for Center for Respiratory Biodefense	Withholds <sup>a</sup> Army:       \$13,000         USAMRMC:       \$60,000         Budgeted Management Costs <sup>b</sup>	Research Budgeted Peer-Reviewed Research: \$2,140,000
	T-1-1 60 414	\$187,000 (8%)	T-1-1 60 140 000
	Iotal: \$2.4M	Iotal: \$260,000	lotal: \$2,140,000

 
 Table B-20.
 FY09–FY10 Institutionally Based Research Programs Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy (cont.)

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.

Fiscal Year	Congressional Appropriation	Withholds and Management Costs	Investment Strategy		
Spinal Muscular Atrophy Research Program					
2009	<b>\$3.2M</b> for Spinal Muscular Atrophy (SMA) Research Program	Withholds <sup>a</sup> Section 8101:         \$9,000           Section 8026:         \$3,000           USAMRMC:         \$79,000	Research Columbia University: \$2,949,996		
		Management Costs <sup>b</sup> \$159,004 (5.11%)			
	Total: \$3.2M	Total: \$250,004	Total: \$2,949,996		
2010	<b>\$3.0M</b> for Spinal Muscular Atrophy (SMA) Research Program	Withholds <sup>a</sup> Army:         \$16,000           USAMRMC:         \$75,000           Budgeted Management Costs <sup>b</sup> \$199,000 (7%)	Research Budgeted Peer-Reviewed Research: \$2,710,000		
	Total: \$3.0M	Total: \$290,000	Total: \$2,710,000		
Technology	Solutions for Brain Can	cer Detection and Treatment			
2010	<b>\$1.2M</b> for Technology Solutions for Brain Cancer Detection and Treatment	Withholds <sup>a</sup> Army:         \$6,000           USAMRMC:         \$30,000           Budgeted Management Costs <sup>b</sup> \$89,000 (8%)	Research Budgeted Peer-Reviewed Research: \$1,075,000		
	Total: \$1.2M	Total: \$125,000	Total: \$1,075,000		
Translational Research for Muscular Dystrophy					
2010	<b>\$1.6M</b> for Translational Research for Muscular Dystrophy	Withholds <sup>a</sup> Army:         \$8,000           USAMRMC:         \$40,000           Budgeted Management Costs <sup>b</sup> \$122,000 (8%)	Research Budgeted Peer-Reviewed Research: \$1,430,000		
	Total: \$1.6M	Total: \$170,000	Total: \$1,430,000		
Warfighter Cancer Care Engineering					
2009	\$2.4M for Warfighter Cancer Care Engineering	Withholds <sup>a</sup> Section 8101:         \$7,000           Section 8026:         \$2,000           USAMRMC:         \$59,000	Research Indiana University \$2,150,000		
		Management Costs <sup>b</sup> \$182,000 (7.8%)			
	Total: \$2.4M	Total: \$250,000	Total: \$2,150,000		

#### Table B-20. FY09–FY10 Institutionally Based Research Programs Congressional Language and Appropriations, Withholds and Management Cost, and Execution of Investment Strategy (cont.)

<sup>a</sup> The following abbreviations are used for withholds: USAMRMC, U.S. Army Medical Research and Materiel Command.



## Appendix C: Breast Cancer Research Semipostal Awards

Fiscal Year	Principal Investigator	Amount	Institution	Application Title
FY99	Daly	\$283,649	Garvan Institute	Identification of Novel Prognostic Indicators for Breast Cancer Through Analysis of the EMS1/Cortactin Signaling Pathway
	Deuel	\$5,000 <sup>1</sup>	Scripps Institute	Novel Angiogenic Domains: Use in Identifying Unique Transforming and Tumor-Promoting Pathways in Human Breast Cancer
	Heyer	\$111,444	University of California, Davis	In Vitro Recombination Activities of the Breast Cancer Predisposition Protein BRCA2
	Musgrove	\$222,652	Garvan Institute	Role of Cyclin D1 and p27 in Steroidal Control of Cell Cycle Progression in the Mammary Gland in Vivo
	Shah	\$279,000	University of Arkansas	Role of a Novel Matrix-Degrading Metalloproteinase in Breast Cancer Invasion
	Wang	\$317,510	Texas A&M University	Scanning Microwave-Induced Acoustic Tomography
	White	\$334,094	University of Texas Southwest Medical Center	Isolation of Factors That Disrupt Critical Protein/Protein Interactions Within the Telomerase Holoenzyme for Use in Breast Cancer Therapeutics
	Wreschner	\$225,000	Tel Aviv University	Analysis of the Secreted Novel Breast Cancer-Associated MUC1/Zs Cytokine
FY00	Adamson	\$578,183	Burnham Institute	Cripto: A Target for Breast Cancer Treatment
	Akporiaye	\$454,500	University of Arizona	Tumor-Mediated Suppression of Dendritic Cell Vaccines
	Penn	\$296,142	University of Toronto	Exploiting the Novel Repressed Transactivator Assay to Identify Protein Interactors and Peptide Inhibitors of the Myc Oncoprotein

<sup>1</sup> Award was only partially funded by breast cancer stamp funds; total funding amount for award was \$404,176. The DOD BCRP supplied the majority of the funds for the award.

Fiscal Year	Principal Investigator	Amount	Institution	Application Title
FY01	Cai	\$560,144	Vanderbilt University	Genetic Polymorphisms, Mitochondrial DNA Damage, and Breast Cancer Risk
	Carraway	\$427,225	University of California, Davis	Identification of a Functional Human Homolog of Drosophila Kek1, an Inhibitor of Breast Tumor Cell Growth
	Chaudhary	\$312,434	University of Texas Southwest Medical Center	The Role of Ectodysplasin A (EDA) and Its Receptors in the Pathogenesis of Breast Cancer
	Geahlen	\$425,425	Purdue University	Characterization of Syk in Breast Carcinoma Cells
	Rosner	\$454,181	St. Luke's- Roosevelt Hospital Center	Autocrine and Paracrine Control of Breast Cancer Growth by Sex Hormone-Binding Globulin
FY02	Dou	\$491,999	University of South Florida	Synthetic Beta-Lactam Antibiotics as a Selective Breast Cancer Cell Apoptosis Inducer: Significance in Breast Cancer Prevention and Treatment
	Godwin	\$504,000	Fox Chase Cancer Center	The Nuclear Death Domain Protein p84N5, a Candidate Breast Cancer Susceptibility Gene
	Perkins	\$490,500	Yale University	Rapid Genomic Approach to Cancer Gene Discovery in Breast Cancer
FY03	Chung	\$490,447	Yale University	Quantitative in Situ Assessment of the Somatostatin Receptor in Breast Cancer to Assess Response to Targeted Therapy with 111-in- Pentetreotide
	Kaaks	\$367,639	International Agency for Cancer Research	Fatty Acid Synthesis Gene Variants and Breast Cancer Risk: A Study Within the European Prospective Investigation into Cancer and Nutrition (EPIC)
	Yaswen	\$508,790	Lawrence Berkeley National Laboratory	Functional Analysis of BORIS, a Novel DNA-Binding Protein
	Ziv	\$767,171	University of California, San Francisco	Admixture and Breast Cancer Risk Among Latinas
FY04	Bissell	\$386,569	Lawrence Berkeley National Laboratory	Use of HA-Metal Nanoparticles to Identify and Characterize Tumorigenic Progenitor Cell Subsets in Breast Tumors
	Clarke	\$588,738	Northern California Cancer Center	The Hygiene Hypothesis and Breast Cancer: A Novel Application of an Etiologic Theory for Allergies, Asthma, and Other Immune Disorders
	Giorgio	\$453,000	Vanderbilt University	Surface Functionalized Nanoparticles and Nanocrystals for Proximity- Modulated, Early Neoplasia Detection, Imaging, and Treatment of Breast Cancer
	Lemmon	\$475,500	University of Pennsylvania	Harnessing Novel Secreted Inhibitors of EGF Receptor Signaling for Breast Cancer Treatment

Fiscal Year	Principal Investigator	Amount	Institution	Application Title
FY05	Zinn <sup>2</sup>	\$436,500	University of Alabama at Birmingham	Novel Screening and Precise Localization of Early Stage Breast Cancer in Animal Model
	Huang	\$483,600	Cornell University, Weill Medical College	Migrastatin Analogues as Potent Inhibitors of Breast Cancer Metastasis
	Liu	\$448,500	Ohio State University	Hunting for Novel X-Linked Breast Cancer Suppressor Genes in Mouse and Human
	Rao	\$468,000	Stanford University	Ribozyme-Mediated Imaging of Oncogene Expression in Breast Tumor Cells
FY06	Devi	\$155,085 <sup>3</sup>	Duke University Medical Center	Modulation of Regulatory T Cells as a Novel Adjuvant for Breast Cancer Immunotherapy
	Lee	\$489,000	University of Southern California	A New Mechanism for Estrogen-Starvation Resistance in Breast Cancer
	Li	\$438,455	Baylor College of Medicine	The ER/PR Status of the Originating Cell of ER-Negative Breast Cancer
	Mousa	\$377,620	Albany College of Pharmacy	Enhancing the Efficacy of Chemotherapeutic Breast Cancer Treatment with Non-anticoagulant Heparins
	Rastinejad	\$454,500	University of Virginia	Structural Characterization of the Interdomain Features of the Estrogen Receptor
FY07	Kuperwasser	\$817,500	Tufts University	Mechanisms of Breast Cancer Associated with Obesity
	Kelly	\$244,450 <sup>4</sup>	Massachusetts General Hospital	Genetically Encoded Targeted, Amplifiable, Imaging Agents for Early Detection of Breast Cancer
	Gerbi	\$155,550⁵	Brown University	Hormonal Involvement in Breast Cancer Gene Amplification

<sup>2</sup> The original Principal Investigator Dr. Tandra Chaudhuri is deceased.

<sup>3</sup> Remaining monies for Devi were from the BCRP FY06 funds for a total amount awarded of \$461,933.

<sup>4</sup> Award was partially funded with \$244,450 of the BCRS funds; the remaining monies are from the FY06 BCRP funds. Total award amount is \$687,397.

<sup>5</sup> Award was partially funded with \$155,550 of the BCRS funds; the remaining monies are from FY06 and FY07 BCRP funds. Total award amount is \$787,325.

Fiscal Year	Principal Investigator	Amount	Institution	Application Title
FY08	Park	\$111,663	North Dakota State University	In Utero Exposure to Dietary Methyl Nutrients and Breast Cancer Risk in Offspring
	Radosz	\$528,939	University of Wyoming	Breast Cancer-Targeting Nuclear Drug Delivery Overcoming Drug Resistance for Breast Cancer Therapy
	Hill	\$577,500	Oregon Health and Science University	Vaccine Vector for Sustained High-Level Antitumor CTL Response
	You	\$503,666	South Dakota State University	Targeted Delivery and Remote-Controlled Release of Chemotherapeutic Agents
	Seagroves	\$166,6676	University of Tennessee Health Science Center	The Role of HIF-1 Alpha in Breast Cancer: A Positive Factor in Cancer Stem Cell Expansion via Notch?
FY09	Reynolds	\$730,000 <sup>7</sup>	Cancer Prevention Institute of California	Hazardous Air Pollutants and Breast Cancer: An Unexplored Area of Risk
	Wysolmerski	\$620,626	Yale University	Effects of Nuclear Parathyroid Hormone-Related Protein Signaling in Breast Cancer

<sup>6</sup> Award was partially funded with \$166,667 of the BCRS funds; the remaining monies are from FY08 BCRP funds. Total award amount is \$554,987.

<sup>7</sup> Award was partially funded with \$730,000 of the BCRS funds; the remaining monies are from FY09 BCRP funds. Total award amount is \$860,883.



For more information, visit: http://cdmrp.army.mil or contact us at: CDMRP.PublicAffairs@amedd.army.mil 301-619-7071

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