

Presentation 11 – Janet Harris

Department of Defense Congressionally Directed Medical Research Programs



US Army Medical Research and Materiel Command (USAMRMC)

Overview of the Congressionally Directed Medical Research Programs (CDMRP)

Presented to
Research Advisory Committee on Gulf War Veterans' Illnesses

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Director

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Introduction

- ◆ **Overview of the CDMRP**
 - ❖ **Origins and Funding History**
 - ❖ **Structural Features**
- ◆ **Peer Reviewed Medical Research Program (PRMRP) Funded Gulf War Focused Research**
- ◆ **Gulf War Veterans' Illnesses Research Program (GWVIRP)**
 - ❖ **Overview and Funding Priorities**

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CDMRP Philosophy

THE CENTRAL THEME IS INNOVATION

- ◆ **Vision:** Find and fund the best research to eradicate diseases and support the warfighter 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

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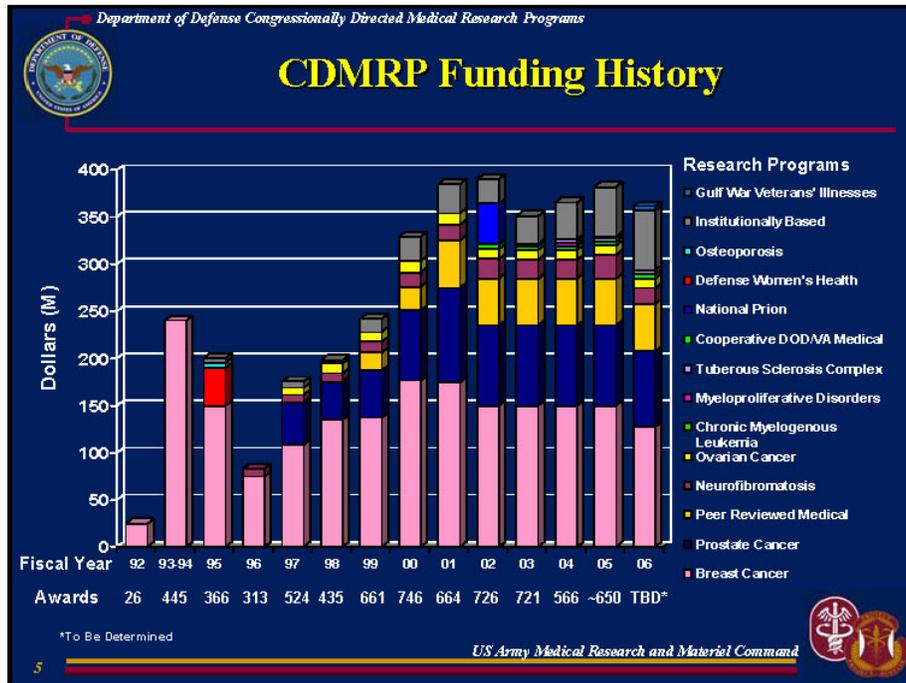
CDMRP History

- ◆ In 1993, grassroots advocacy heightened political awareness of breast cancer.
- ◆ Federal budgetary opportunities spurred Congress to appropriate \$210 million (M) to the Department of Defense (DOD) budget for breast cancer research.
- ◆ Program assigned to the USAMRMC; subsequent consultation with the Institute of Medicine for programmatic advice.
- ◆ Additional research programs added, including neurofibromatosis in FY96, ovarian cancer and prostate cancer in FY97, defense health (now called PRMRP) in FY99, prion, tuberous sclerosis complex, and chronic myelogenous leukemia in FY02, and myeloproliferative disorders in FY04.
- ◆ These and other programs are managed by the CDMRP.

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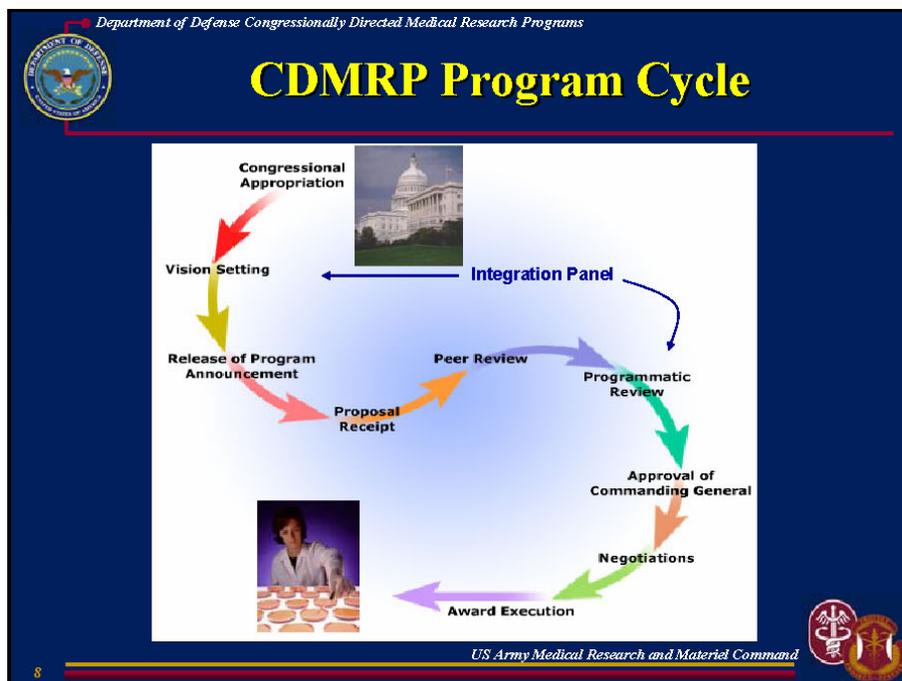
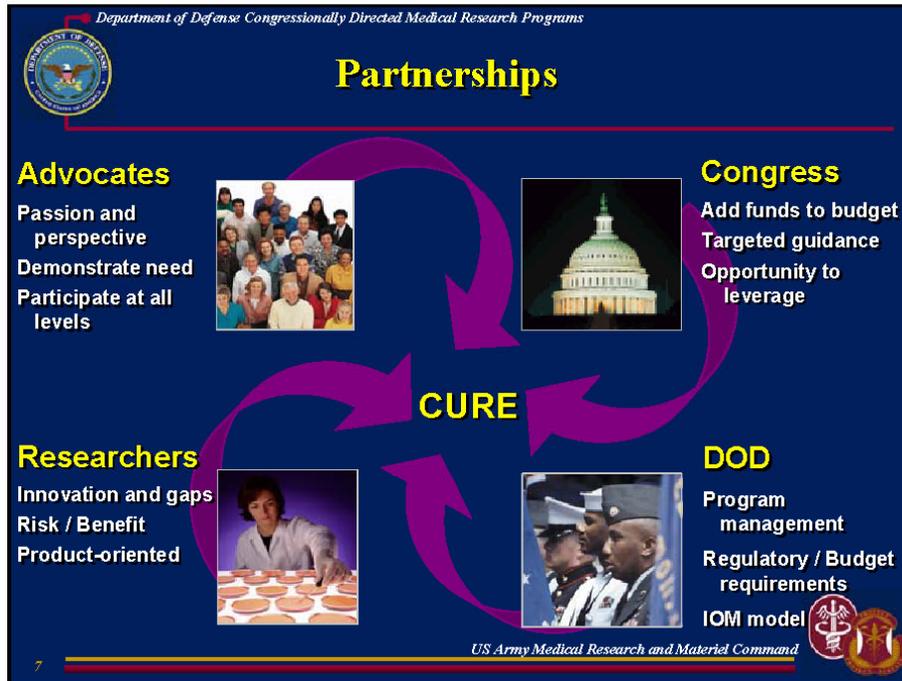
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CDMRP Structural Features

- ◆ Funds added to the DOD budget by Congress
- ◆ Respond to targeted guidance from Congress
- ◆ Two-tier formal review of proposals – Institute of Medicine Model
- ◆ Vision is adapted yearly to accommodate rapid change
- ◆ Highly flexible model to address research gaps
- ◆ Consumer advocate representation



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Two-Tier Review Process

<h3><u>Peer Review</u></h3> <ul style="list-style-type: none">◆ Evaluation of scientific merit◆ Criteria-based evaluation◆ Proposals evaluated within related disciplines <p>Products:</p> <ul style="list-style-type: none">◆ Proposal scoring◆ Summary statements	<h3><u>Programmatic Review</u></h3> <ul style="list-style-type: none">◆ Evaluation of programmatic relevance◆ Comparison-based evaluation◆ Proposals evaluated across multiple disciplines <p>Product:</p> <ul style="list-style-type: none">◆ List of funding recommendations for the Commanding General
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Consumers and the CDMRP

Consumers have been active participants in our program since its inception in the early 1990s

- ◆ Human Use Review Boards
- ◆ Stakeholders Meetings
- ◆ Integration Panels
- ◆ Peer Review Panels



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Value of Consumer Advocacy Involvement

- ◆ **Contributes unique professional and personal experiences**
- ◆ **Adds perspective, passion, and a sense of urgency**
- ◆ **Ensures that human dimensions of disease are incorporated into scientific considerations, program policy, investment strategy, and research focus**



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Filling Research Gaps and Taking Risks

- ◆ **Fund meritorious research that other agencies will not risk funding, supporting more creativity and innovation**
- ◆ **Look for innovative research that can leapfrog advances rather than fund next incremental step**
- ◆ **Fund early concepts, pursue new research (to produce preliminary data needed for traditional research funding)**

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Relevance to DOD Mission

- ◆ Multidisciplinary research that can impact the military mission
 - ❖ Cell death and battlefield deaths
 - ❖ Angiogenesis
 - ❖ Biosensors
 - ❖ Vaccines
 - ❖ Telemedicine
- ◆ Impact of research on DOD beneficiaries
- ◆ PRMRP – “. . . direct relevance to military health”
 - ❖ Sleep Management
 - ❖ Laser Eye Injury
 - ❖ Alcohol Abuse Prevention Research
 - ❖ Smoking Cessation
 - ❖ **Gulf War Illness**

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PRMRP Studies on Gulf War Veterans' Illnesses

- ◆ “Longitudinal Health Study of Gulf War Veterans”
 - ❖ Han Kang, 2001, VA Medical Center, Washington, DC
 - ❖ Assess the health status of Gulf War veterans and non-Gulf War veterans by comparing chronic medical conditions, post-traumatic stress disorder and other psychological conditions
- ◆ “Neuropsychological Functioning in Gulf War Veterans Exposed to Pesticides and Pyridostigmine Bromide”
 - ❖ Maxine Krengel, 2003, Boston University
 - ❖ Evaluate the role of pesticides in the development of central nervous system symptoms reported by Gulf War veterans and assess the additive and/or synergistic effects of combinations of chemical exposures and stress

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PRMRP-Funded Awards Studying Gulf War-Related Issues

- ◆ **“Prospective Study of ALS Mortality among World War II, Korea, and Vietnam Veterans”**
 - ◆ Alberto Ascherio, 2004, Harvard University School of Public Health
 - ◆ Examine whether men who served in the military during World War II, Korea, Vietnam, or the Gulf War have a higher risk of ALS (amyotrophic lateral sclerosis) mortality as compared with men who did not serve
- ◆ **“Neurotoxicity from Chronic Exposure to Depleted Uranium”**
 - ◆ Stephen Lasley, 2001, University of Illinois at Chicago
 - ◆ Gulf War veterans who retained fragments of depleted uranium (DU) have exhibited lowered performance on neurocognitive tests
 - ◆ Determine whether chronic exposure to DU impairs neuronal processes underlying cognitive function via alterations induced at hippocampal glutamatergic synapses that directly modulate Ca²⁺-mediated cellular processes
- ◆ **“Development of Strategies to Treat and Prevent Norovirus Infections”**
 - ◆ Xi Jiang, 2003, Cincinnati Children's Hospital Medical Center
 - ◆ Outbreak of Norovirus during the first Persian Gulf War
 - ◆ Develop new strategies for prevention and treatment of Norovirus

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Overview of the FY06 Gulf War Veterans' Illnesses Research Program (GWVIRP)

- ◆ The Defense Appropriations Act of 2006 (Public Law 109-359) provides \$5M to fund peer-reviewed medical research
- ◆ The intent of this appropriation is to support research on the chronic illnesses affecting veterans of the 1991 Gulf War
- ◆ **Priority Topic Areas**
 - ◆ Identification of mechanisms underlying Gulf War illnesses
 - ◆ Chronic effects of neurotoxic substances to which veterans were exposed during deployment
 - ◆ Studies that expand on earlier research identifying neurological and immunological abnormalities in ill Gulf War veterans
 - ◆ Identification of promising treatments

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Overview of the FY06 GWVIRP Continued

- ◆ **Primary Objectives**
 - ❖ Elucidation of pathophysiological mechanisms underlying Gulf War Veterans' Illnesses which may subsequently be targeted to develop treatments for these conditions
 - ❖ Identification and evaluation of treatments which currently exist and which hold promise for treating these illnesses

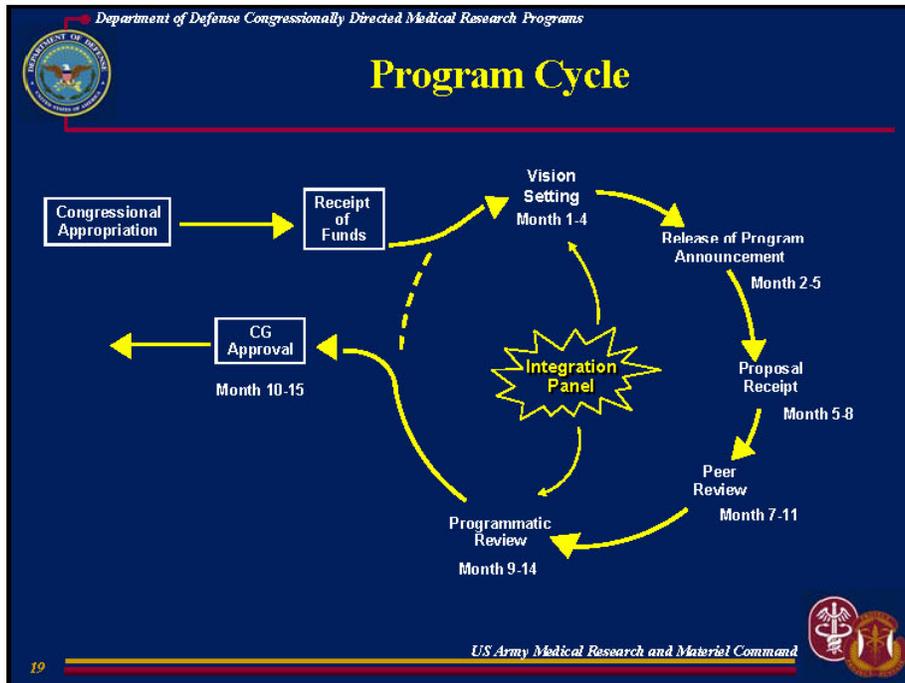
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GWVIRP Anticipated Award Mechanisms

- ◆ **Exploration - Hypothesis Development Award**
 - ❖ Expected to lead to high-risk, potentially high-gain research endeavors that will garner future funding through CDMRP or other funding agencies
- ◆ **Investigator-Initiated Research Award**
 - ❖ Mechanism encourages basic or clinical research dealing with Gulf War Veterans' Illnesses

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GWVIRP Joint Programmatic Review Panel

<p>Research Advisory Committee on Gulf War Veterans' Illnesses</p> <ul style="list-style-type: none"> ◆ Dr. Carolee Barlow ◆ Dr. James P. O'Callaghan ◆ Dr. Lea Steele ◆ Mr. Anthony Hardie 	<p>PRMRP Joint Programmatic Review Panel</p> <ul style="list-style-type: none"> ◆ Maj David Watson, <i>US Air Force</i> ◆ CAPT David Neri, <i>US Navy</i> ◆ COL Bruno Petruccelli, <i>US Army</i>
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CDMRP Enabling the Nation to Cure

- ◆ Mission-oriented and solution-driven
- ◆ Research programs managed to encourage innovation
- ◆ Responsive to changing needs and opportunities
- ◆ Proven stewardship

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Web Site – <http://cdmrp.army.mil>

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