Public Health Subcommittee

Improving Defense Health Program Medical Research Processes

Defense Health Board June 2, 2016



Overview

- Membership
- Tasking
- Timeline
- Meeting Highlights
- Preliminary Observations
- Way Ahead



Membership

Public Health Subcommittee

10 members including the Chair





"I request that the Defense Health Board (DHB)... provide recommendations to the Department regarding approaches that would optimally support military medical professionals who oversee and conduct DHP medical research."

- Acting Under Secretary of Defense (Personnel & Readiness) (USD(P&R)) Memo dated September 30, 2015





(2 of 3)

Request that the Defense Health Board address and develop findings and recommendations on the following:

- Determine how DoD may improve visibility on Defense Health Program (DHP) medical research supported through separate funding sources (RDT&E and O&M) to enhance coordination of effort, oversight, and collaboration.
- Determine the major challenges that DoD investigators face in initiating, funding, conducting, and publishing DHP medical research.
- Determine how DoD may facilitate more efficient initiation and conduct of high-quality DHP medical research without compromising safety or data protection standards.

(3 of 3)



Request that the Defense Health Board address and develop findings and recommendations on the following:

- Determine how DoD may improve Institutional Review Board processes to facilitate more efficient approval of multicenter studies and clinical trials.
- Determine cost-effective mechanisms to encourage more professionals to become engaged in medical research.
- Determine mechanisms to improve acknowledgement in public communications by other government agencies and industry of DoD's contributions to products it has funded or partially developed and subsequently handed off.





Meetings Since Previous Board Meeting

- March 4, 2016 Meeting at San Antonio Military Medical Center (SAMMC)
- April 19, 2016 Teleconference
- May 17, 2016 Meeting at Ft Detrick

Upcoming Meetings

- June & July 2016 Teleconferences
- August 2016 Military Health System Research Symposium



Meeting Highlights

(1 of 2)

March 4, 2016

 Roundtable discussions at SAMMC with Army and Air Force clinical research leadership and senior/midcareer/junior investigators.

April 19, 2016

Draft Report Materials Discussion



Meeting Highlights

(2 of 2)

May 17, 2016

- Roundtable discussions with:
 - DHP RDT&E program and Service research and development leadership;
 - Policy representatives from the Defense Health Agency (DHA), Office of the Assistant Secretary of Defense for Health Affairs, and Army, Navy, and Air Force;
 - Junior and senior scientists; and
 - Congressionally Directed Medical Research Programs (CDMRP) leadership.



DoD Medical Research: Historical Contributions

- DoD has a long history of providing significant contributions to health/medicine including:
 - Combat Trauma Care
 - Vaccines
 - Vector control
- However, a crisis in DoD medical research has been developing over a period of time.



Preliminary Observations

(1 of 2)

- Factors leading to deterioration in some aspects of DoD research processes/programs:
 - Level of infrastructure support for medical research, especially human subjects research
 - Laboratory funding paradigm: investigators may not be funded for research and have to compete for funds that may or may not support Service priorities; at the same time, DoD funds may be flowing to outside entities in support of those priorities
 - Lack of clear research career paths; vanishing pool of senior researchers to lead programs/mentor new talent



Preliminary Observations

(2 of 2)

- Commanders of medical treatment facilities with a designated research mission are not evaluated on research conducted in their facility
 - Lack of standardized research performance metrics
 - Research "on your own time"
 - Implicitly devalues research
- Increasingly complex bureaucracy requiring leadership and investigators to manage competing and sometimes duplicative demands



Enacted FY15 DHP Budget

- DHP Appropriation*
 - O&M: ~\$30.3 Billion
 - RDT&E: ~\$1.7 Billion
 - CSI: ~\$1.1 Billion
 - Core DHP RDT&E: ~\$622 Million
 - Procurement: ~\$308 Million

Total = \sim \$32.3 Billion

^{*}Source: Defense Health Program FY 2016 Budget Estimates, Vol I-II (CSI = congressional special interest)



Congressionally Directed Medical Research Programs (CDMRP)

(1 of 2)

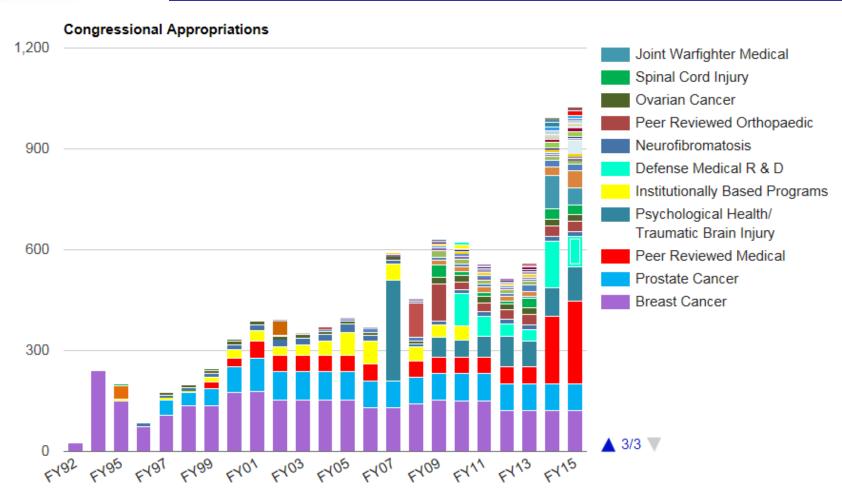
- In response to lobbying, Congress authorized funds in 1993 to support breast cancer research within DoD, creating the "CDMRP to develop, direct, and manage an innovative agenda for breast cancer research."*
- Expanded to 27 programs currently
- Implements the investment of congressionally directed dollars and core (presidential budget appropriation) research dollars.**

*Source: Young-McCaughan S, Rich IM, Lindsay GC, Bertram KA. The Department of Defense Congressionally Directed Medical Research Program: Innovations in the federal funding of biomedical research. Clinical Cancer Research. 2002;8:957-962.

**Source: CDMRP Annual Report, 2015.



CDMRP (2 of 2)



Accessed from: http://cdmrp.army.mil/about/fundinghistory.shtml. Site last updated 01/19/2016



Way Ahead

- Continue monthly teleconferences/meetings
- Information gathering through mid 2016
- Military Health System Research Symposium (August 2016)
- Begin deliberation of findings and recommendations in Fall 2016
- Draft report for February 2017 DHB meeting