THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

APR 0 4 2005

The Honorable John W. Warner
Chairman, Committee on Armed Services
United States Senate
Washington, DC 20510-6050

Dear Mr. Chairman:

The enclosed report responds to the reporting requirement in the Fiscal Year 2004 (FY04) Department of Defense (DoD) Appropriations Act Conference Report 108-283. The U.S. Army Medical Research and Materiel Command (USAMRMC), which is responsible for administering many of the appropriations, prepared this report.

In the FY04 DoD Appropriations Act Conference Report, the conferees requested the Assistant Secretary of Defense for Health Affairs (ASD(HA)), in consultation with the Surgeons General and the Institute of Medicine (IOM), investigate alternative funding sources that could be used to leverage appropriated funds without biasing the peer review selection process. The conferees requested a report of findings and recommendations by March 1, 2004. An interim report was provided to Congress on that date. This report provides background information on the investigation and serves as an introduction to the final IOM report.

The IOM convened an expert committee to provide recommendations to the ASD(HA), through the Commander, USAMRMC, regarding options for leveraging appropriated federal funds for biomedical research using alternate or novel funding strategies from non-federal sources without biasing the peer review selection process. The final published version of the IOM report was provided to the USAMRMC in October 2004 (Enclosure 1). An Executive Summary of the report is provided in the Report to Congress (Enclosure 2).

In brief, the IOM made four recommendations, two are already consistent with on-going Congressionally Directed Medical Research Program (CDMRP) business processes and require no changes. The fourth recommendation was to issue guidelines for collaboration with the private sector. We have tasked Commander, USAMRMC, to make assessments and forward any recommended actions through appropriate channels. The other recommendation was that Congress should provide CDMRP with authority to receive gifts and donations from individuals, companies, foundations, and other organizations for the support of research grants and contracts awarded by CDMRP, and

charter a nonprofit foundation with authority to solicit and transfer nonfederal funds for the support of research grants and contracts awarded by CDMRP.

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

Sincerely,

William Winkenwerder, Jr., MD

Enclosures:
As stated

cc:
Senator Carl Levin

STRATEGIES TO LEVERAGE RESEARCH FUNDING

Guiding DOD's Peer Reviewed Medical Research Programs

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

ENCLOSURE 2

REPORT TO THE US CONGRESS

INVESTIGATION OF ALTERNATIVE FUNDING SOURCES FOR MEDICAL RESEARCH PROGRAMS

March 2005

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PURPOSE OF REPORT

The US Congress adds funds to the Department of Defense budget for targeted biomedical research. The US Army Medical Research and Materiel Command (USAMRMC) is responsible for administering many of these appropriations. In the fiscal year 2004 (FY04) Defense Appropriations Conference Report the conferees requested that the Assistant Secretary of Defense for Health Affairs [ASD(HA)], in consultation with the Surgeons General and the Institute of Medicine (IOM), investigate alternative funding sources that could be used to leverage appropriated funds without biasing the peer review selection process. The conferees requested a report of findings and recommendations be provided by March 1, 2004. An interim report was provided to Congress on that date. This report provides background information on the investigation and serves as an introduction to the final IOM report that is attached.

EXECUTIVE SUMMARY

I. Introduction

The USAMRMC is a major subordinate Command of the United States Army Medical Command. The Commanding General (CG), USAMRMC is assigned authority as the Executive Agent for a number of medical research, development, and acquisition programs. Congressional appropriations of $2.2 billion since FY92 have been made for peer reviewed medical research to include breast, prostate, and ovarian cancer, Defense Health, neurofibromatosis, Defense women's health, osteoporosis, and other programs. The CDMRP is the USAMRMC subordinate organization responsible for planning, coordinating, integrating, programming, budgeting, and executing these programs.

The FY04 Defense Appropriations Conference Report commended the Department of Defense for its management of the peer reviewed medical research and cancer research programs. The conferees noted with concern that there were challenges in achieving funding increases within existing resources for military spending. Consequently, the conferees requested that the ASD(HA), in consultation with the Surgeons General and the Institute of Medicine (IOM), investigate alternative funding sources, including private and non-federal sector contributions, that could be used to leverage appropriated funds without biasing the peer review selection process.

In a letter dated December 19, 2003 the Deputy Assistant Secretary of Defense, Force Health Protection and Readiness, directed the USAMRMC Commander to negotiate with the Institute of Medicine to study the issue and provide recommendations. As directed by the ASD(HA), the CDMRP through the US Army Medical Research Acquisition Activity (USAMRAA) executed this requirement using prorated funds from the peer reviewed medical research and cancer research programs. A contract with the IOM was signed on 2 February 2004 for a 6-month study to be completed by 31 July 2004.

II. Institute of Medicine Management Process to Determine Alternative Funding Strategies for DOD's Biomedical Research Programs

Process

The IOM convened an expert committee to provide recommendations to the DOD ASD(HA), through the Commander, USAMRMC, regarding options for leveraging appropriated federal funds for biomedical research using alternate or novel funding strategies from non-federal sources without biasing the peer review selection process. This panel was to (1) assess current and alternate funding mechanisms and funding sources, which include private sector and non-federal entities, for conducting biomedical research, and (2) advise DOD on how these sources and mechanisms can be leveraged to augment appropriated funds; (3) identify and advise on new, possible future avenues of funding other than described in task one; (4) identify and advise

on (a) issues inherent in the federal procurement system that would impact grants and cooperative agreements, and (b) regulations and policies should alternate funding strategies be used; and (5) identify risks and solutions regarding bioethics and peer review bias with respect to alternate funding.

Work Plan

Over a course of 6 months, the committee met and compiled presentations from representatives within the DOD and the National Institutes of Health, major philanthropic foundation grant officers, as well as not-for-profit service organizations and health coalition groups that support research. Organizations performing collaborative research using multiple funding strategies were also consulted.

III. Recommendations

The final published version of the IOM report was provided to the USAMRMC in October 2004. The report contained four recommendations: (1) CDMRP should facilitate collaborative arrangements for funding research when collaboration would be beneficial and appropriate—for example, when it would achieve greater results through synergy or economies of scale or critical mass—but CDMRP should not expect such arrangements to augment significantly overall program funding; (2) Congress should provide CDMRP with authority to: a. receive gifts and donations from individuals, companies, foundations, and other organizations for the support of research grants and contracts awarded by CDMRP, and b. charter a nonprofit foundation with authority to solicit and transfer nonfederal funds for the support of research grants and contracts awarded by CDMRP; (3) CDMRP should not impose cost-sharing or matching fund requirements beyond those currently required, except when a tangible benefit to the award recipient is anticipated beyond the immediate term or scope of CDMRP-supported activity (for example, funding of instruments and facilities), and (4) DOD should issue guidelines for collaboration with the private sector, paying special attention to the potential impact of research collaborations with nonfederal funders on (a) program costs; (b) the integrity of the peer review process; (c) program priorities; (d) perceived and actual conflicts of interest; (e) openness in scientific communication, and (f) other issues that may arise in federal-private co-funding arrangements. Recommendations 1 and 3 are already consistent with on-going CDMRP business processes and therefore require no changes. Recommendations 2 and 4 would require action at levels higher than CDMRP or USAMRMC.

IV. Product and Dissemination

The IOM report was formally staffed to the CG, USAMRMC and the Deputy Assistant Secretary of Defense, Force Health Protection and Readiness on 1 September 2004 at 4:00 p.m. Bound copies of the final document are provided.