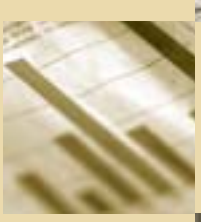







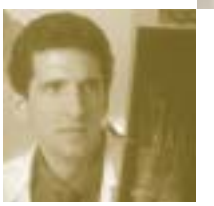


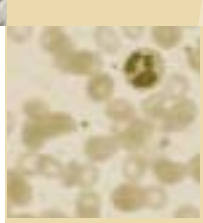
Executive Summary

CDMRP Vision: To find and fund the best research to eradicate diseases and support the warfighter for the benefit of the American public.

CDMRP Mission: To provide hope by promoting innovative research, recognizing untapped opportunities, creating partnerships, and guarding the public trust.

...shaping the future of health care to prevent, control, and cure diseases.





Recent scientific breakthroughs and exciting new opportunities in research have increased anticipation and hope that a cure for cancer and other diseases is within our reach. Due to the work of highly motivated consumer advocacy groups, public awareness of scientific research continues to rise and shape this field. The Office of the Congressionally Directed Medical Research Programs (CDMRP) is one organization that is recognizing and mobilizing untapped opportunities to advance health care solutions identified by Congress and the Department of Defense (DOD).

The CDMRP is a research area directorate within the U.S. Army Medical Research and Materiel Command (USAMRMC). The CDMRP manages congressional research appropriations that will improve the life of all Americans. As a manager for programs in targeted diseases, the CDMRP has interpreted congressional directives for each appropriation with rigor and integrity. As a result, the CDMRP has developed and implemented programs that are intended to bring sound scientific research forward in specific medical areas that is responsive to the needs of the American public.

Since its inception, the CDMRP has managed 29 research programs that total almost $2.6 billion (B) in congressional appropriations. The appropriations set forth by Congress for fiscal year 2002 (FY02) total over $390 million (M), with focus on breast, prostate, and ovarian cancers, military health, neurofibromatosis, tuberous sclerosis, transmissible spongiform encephalopathies, chronic myelogenous leukemia, and other diseases.

The Early Years

The origin of the CDMRP can be traced back to 1992 when a congressional appropriation of $25M was made for "army breast cancer research." At the same time, the breast cancer consumer community, led by the National Breast Cancer Coalition (NBCC), was raising public and legislator awareness of gaps in breast cancer research and lobbied to increase the nation's investment in breast cancer research. In 1992, the NBCC presented President Clinton with a petition with 2.6 million

signatures for a comprehensive plan to put an end to breast cancer. This grassroots movement led to an FY93 congressional appropriation to the DOD for $210M targeted toward breast cancer research. The USAMRMC was assigned responsibility for administering these dollars. Within the USAMRMC, a new research area directorate, the CDMRP, was established to administer the FY93 Breast Cancer Research Program (BCRP), as well as to manage awards that were supported by the FY92 DOD breast cancer research appropriation.

The USAMRMC is the medical research, development, logistics, and acquisition arm of the U.S. Army. The Command operates six medical research laboratories and institutes in the United States that are centers of excellence in specific areas of biomedical research. A large extramural research program and numerous cooperative research and development agreements with leading civilian organizations enhance the in-house capabilities of the USAMRMC. Part of the mission of the USAMRMC is to "invent global medical solutions for tomorrow." Despite this history of research infrastructure and scientific rigor, in 1993, breast cancer was not considered part of the Army's existing research and development expertise. As such, the USAMRMC sought the advice of the National Academy of Sciences Institute of Medicine (IOM) to identify gaps in breast cancer research and make recommendations as to how this new appropriation could best be used. The IOM made two important

Breast Cancer

The mission of the BCRP is to foster new directions, address neglected issues, and bring new investigators into the field of breast cancer research.

One out of every eight women will develop breast cancer in her lifetime. Approximately 39,800 women and 400 men were projected to die from this disease in 2003.[1]

The BCRP is the second largest funder of extramural breast cancer research in the world, having been appropriated $1.52B in FY92–03 to eradicating breast cancer. More than 3,600 grants have been awarded.

[1] *American Cancer Society–Cancer Facts and Figures 2003.*

recommendations: (1) to establish a defined strategy as to how the monies would be spend and (2) to institute a two-tiered review process in which both the scientific merit as well as the programmatic relevance would be addressed. These recommendations were applied to the FY93 BCRP and have been subsequently adapted for other programs managed by the CDMRP.

The CDMRP in Fiscal Year 2002

The CDMRP originated within an environment that necessitated and fostered novel approaches to its operation as a funding agency. The continued successes of the CDMRP and the work of consumer advocates have resulted in yearly appropriations for peer reviewed research. FY02 is the eleventh year that Congress has appropriated monies to be managed by the CDMRP, totaling almost $2.6B. FY02 core programs within the CDMRP include the following:

- BCRP
- Prostate Cancer Research Program (PCRP)
- Neurofibromatosis Research Program (NFRP)
- Ovarian Cancer Research Program (OCRP)
- Peer Reviewed Medical Research Program (PRMRP)
- Chronic Myelogenous Leukemia Research Program (CMLRP)
- Tuberous Sclerosis Complex Research Program (TSCRP)
- National Prion Research Program (NPRP)

Prostate Cancer

The vision of the PCRP is to conquer prostate cancer.

Prostate cancer is the second leading cause of cancer death in men, with almost 29,000 deaths expected to occur in 2003.[2]

Beginning in FY97, Congress appropriated money to fund peer reviewed prostate cancer research. To date, $480M has been appropriated to the USAMRMC PCRP. Almost 800 awards have been made to support innovative ideas and technologies aimed at preventing, detecting, treating, and improving the quality of life of men with prostate cancer.

[2] *American Cancer Society–Cancer Facts and Figures 2003.*

Neurofibromatosis

Neurofibromatosis (NF) includes two distinct genetic disorders of the nervous system, NF1 and NF2. The mission of the NFRP is to promote research directed toward the understanding, diagnosis, and treatment of NF1 and NF2 and to enhance the quality of life for individuals with the disease.

NF1 occurs more commonly, affecting 1 out of 4,000, whereas NF2 occurs in 1 out of every 40,000 persons.[3]

Appropriations to the USAMRMC NFRP for FY96–03 total $110.3M, representing the largest public research funding for NF.[4] A total of 103 awards have been made to develop a multidisciplinary research portfolio that encompasses basic, clinical, and population-based research projects.

The Vision for the Fiscal Year 2003 Programs

The CDMRP continues to fulfill a unique niche in biomedical research. In FY03, Congress appropriated $350M to continue investing in innovative research aimed at understanding and curing life-threatening diseases.

Scientific Outcomes and Advances

Noteworthy CDMRP accomplishments for the past year can be reported in four broad areas: promoting innovative research, recognizing untapped opportunities, creating partnerships, and guarding the public trust.

Promoting Innovative Research

Since its inception, the CDMRP has sought to "create an environment in which creative ideas and first-rate research can flourish and in which investigators are not afraid to gamble on risky but alluring ideas." Although each award mechanism has different award requirements, an underlying goal of all the mechanisms offered by the CDMRP is to encourage investigators to seek out novel, creative ideas and solutions that will lead disease-specific research in new directions.

Examples of such innovative work are displayed by the following awards: Research from Dr. Skobe's laboratory, for a BCRP Concept Award, has shown that lymphangiogenesis does in fact occur, in the tumor microenvironment and may lead to an a new therapeutic target. A PCRP Idea award granted to Drs. Asem and Kinch from Purdue University has

Peer Reviewed Medical Research Program

The mission of the PRMRP is to support biomedical research with direct relevance to military health. To this end, congressional appropriations for the PRMRP from FY99–03 totaled nearly $195M. As of 2002, 98 awards have been made to preserve the health of our military forces.

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[3] *Report on Neurofibromatosis, Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Neurological Disorders and Stroke, 2003.*

[4] *The National Neurofibromatosis Foundation, Inc.*

supported research to develop antibodies that will only target the cancerous prostate cell and not the normal cell. Dr. Andreas Kurtz, who was awarded an NFRP Idea award in 1999, discovered that mutations in mitochondrial DNA exist in normal tissues from NF1 patients (a finding that may aid in the prediction of disease severity and eventually lead to new treatments). One of the projects that encompass an OCRP Program Project awarded to Dr. Daniel Meruleo has obtained preliminary data indicating that using a specific vector (specific DNA sequences that can be used to transport genetic material) in conjunction with a protein capable of producing an immune response to elicit cell death in ovarian cancer cells may be a viable treatment option for women with ovarian cancer.

Recognizing Untapped Opportunities

The CDMRP continues to devote itself to finding unique solutions that address underinvestigated areas of research and improve the management of its research programs. Each individual program decides which area(s) of research is of highest priority annually. Training and recruitment of new investigators, as well as the building of research resources in the form of centers of excellence, consortia, and imaging equipment, continue to be a major investment by the CDMRP. In addition to fostering these groundbreaking award mechanisms, the CDMRP continues to emphasize new and innovative practices to advance program management and execution by implementing electronic technology for proposal submission, review, and management. These processes have allowed the CDMRP to virtually eliminate paper processing, thus saving time and increase quality control of these documents.

Ovarian Cancer

The mission of the OCRP is to support innovative, integrated, multidisciplinary research efforts that will lead to a better understanding, detection, diagnosis, prevention, and control of ovarian cancer.

In 2003, approximately 25,400 women will be diagnosed with ovarian cancer in the United States, and 14,300 will die from the disease.[5]

Nearly $72M was appropriated for the USAMRMC OCRP in FY97–03. As of 2002, 63 awards have been made.

[5] *American Cancer Society–Cancer Facts and Figures 2003.*

Chronic Myelogenous Leukemia

The vision of the CMLRP is to perfect the existing and develop new diagnostic and therapeutic approaches for chronic myelogenous leukemia (CML). CML is an overgrowth of granulocytes, a type of white blood cell; its cause is unknown. In 2003, approximately 1,700 people will die from the disease.[6] The CMLRP was established in 2002, with congressional appropriations over the past 2 years totally over $9M.

Creating Partnerships

Public, private, government, and military partnerships have been the key to the success of the CDMRP. Consumers are voting members on scientific peer-review panels and the Integration Panel, as well as active participants in executing some research projects. Therefore, the relationships developed between the research managers and scientists and those individuals affected by policies and research are critical for the success of the CDMRP. Military partnerships play an important role within the CDMRP; military personnel, civilian, and contractor staff are responsible for executing the congressional directives and work together to implement each program's vision. Additionally, several programs managed by the CDMRP have a direct military focus, particularly to improve the health of our military forces. The CDMRP's relationships with the scientific community, which serves on peer-review panels and the integration panel and assists in vision setting, are essential in fulfilling the program's vision of eradicating diseases. Without these partnerships the CDMRP's war against disease would be a losing one.

Tuberous Sclerosis

Tuberous sclerosis is a genetic disorder that can affect any or all systems of the body. The disorder is characterized by seizures, developmental delays, kidney disease, behavioral problems, and the growth of benign tumors (tubers) on vital organs such as the brain, kidneys, and heart. The mission of the TSCRP is to encourage innovative research aimed at understanding the role and function of proteins produced by the TSC1 and TSC2 tumor suppressor genes.

Nearly 1 million people worldwide have been diagnosed with tuberous sclerosis, with approximately 50,000 of those cases were reported in the United States.[7]

The TSCRP was established in FY02 with a $1M appropriation; the TSCRP was continued in FY03 with an appropriation of $2M.

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[6] *American Cancer Society–Cancer Facts and Figures 2003.*

[7] *Tuberous Sclerosis Alliance, 2003.*

Guarding the Public Trust

As the CDMRP was created in response to the concerns of individuals affected by cancer and disease, guarding the public trust is of upmost importance. Over the past 11 years, the CDMRP has implemented efficient, cost-effective processes to administer its increasing number of programs and awards while compressing the time frame for funding. The Special Populations Program underscores the CDMRP's effort to bridge the gap that exists in the incidence, morbidity, and mortality among different ethnic groups for which the CDMRP provides support. The Common Scientific Outline reflects CDMRP's support for improved communication among funding agencies in the United States and abroad. Over the past year, a great amount of effort was put forth to increase public awareness of the CDMRP through advertising specific award mechanisms in national newspapers, distributing award information to consumer advocacy groups, and sponsoring funded investigators to attend scientific meetings.

Looking Ahead

Solving today's health crises remains a challenge. The CDMRP believes that by continuing to be responsive to the needs of consumers, researchers, and clinicians, the future of health care can be shaped to prevent, control, and cure diseases. In 2003, the CDMRP will move toward advancing health care solutions in areas identified by Congress and DOD by recognizing and mobilizing untapped opportunities, funding excellent research, creating partnerships, and guarding the public trust. Together we can succeed.

Prion Disease—Transmissible Spongiform Encephalopathies

"Transmissible spongiform encephalopathies" refers to several apparently related diseases that are relatively rare in humans but have been documented most extensively in hoofed mammals. The current disease theory attributes transmissible spongiform encephalopathies to "prions," normal cell-membrane proteins with atypical three-dimensional configurations. The main goal of the NPRP is to eliminate the occurrence of this disease and to develop a diagnostic test to detect the presence of prion disease.

The USAMRMC NPRP was established in FY02 with a congressional appropriation of $42.5M for research on prion disease; a total of 38 awards were made from the FY02 appropriation.