

EXECUTIVE SUMMARY



CONTENTS

The Early Years

The CDMRP in FY00

Partnerships

CDMRP Accomplishments

Scientific Achievements

- Research Awards
- Infrastructure Awards
- Training and Recruitment Awards

Looking Ahead

CDMRP





EXECUTIVE SUMMARY

Congressionally Directed Medical Research Programs

Vision: To be the preferred and responsive source for accessible research funding, shaping the future of health care to prevent, control, and cure diseases.

Mission: To advance health care solutions in areas identified by Congress and the Department of Defense by funding excellent research, recognizing and mobilizing untapped opportunities, creating partnerships, and guarding the public trust.

The Office of Congressionally Directed Medical Research Programs (CDMRP), a research area directorate within the U.S. Army Medical Research and Materiel Command (USAMRMC), is proud to have contributed to the advancement of biomedical research that can improve the health and lives of Americans. The CDMRP joined the fight against cancer in 1993 when the United States Congress directed the Department of Defense (DOD) to manage a \$210 million (M) appropriation for breast cancer research. The CDMRP's responsibilities were expanded in 1995 when it administered a research program that addressed militarily relevant health issues; similarly focused initiatives have also been managed in fiscal year 1999 (FY99) and FY00. CDMRP's involvement in managing cancer research grants was extended in 1997 as a result of congressional appropriations for both prostate and ovarian cancer. In addition, the CDMRP manages appropriations targeted to other diseases, including appropriations for neurofibromatosis research since FY96. Overall, the CDMRP is responsible for 15 research programs that represent over \$1.5 billion (B) in congressional appropriations from FY92–00.

The Early Years

Grassroots advocacy organizations provided the impetus that led to a FY93 congressional appropriation to the DOD for \$210M targeted toward breast cancer research. The USAMRMC¹, the medical research, development, logistics, and acquisitions arm of the U.S. Army, was assigned responsibility for administering the FY93 Breast Cancer Research Program (BCRP). Within the USAMRMC, a new research area directorate, the CDMRP, was established to administer the FY93 BCRP and to manage awards that were supported by a FY92 DOD appropriation for \$25M for breast cancer research.

¹ Known as the U.S. Army Medical Research and Development Command prior to 1995.

In 1993, breast cancer was not considered an area that was covered by the Army's existing expertise in research and development. Therefore, the USAMRMC sought the advice of the National Academy of Sciences Institute of Medicine (IOM). The IOM made two important recommendations that were applied to the FY93 BCRP and were subsequently adapted and applied to other programs managed by the CDMRP. The first recommendation defined a strategy for how the FY93 appropriation should be spent. To carry out this recommendation, the CDMRP sought the advice of a council of experts to develop an investment strategy. Today, individual investment strategies are designed annually for each program to maximize the applicability of available money and to address the current and most relevant needs of the research, consumer, and clinical communities. The second recommendation outlined a two-tier review process that consists of a scientific merit review followed by a programmatic review to ensure that the most meritorious science that meets the vision and goals of each program is supported. Since 1993, the two-tier review process has been further developed and applied to other programs managed by the CDMRP. Section I of this report contains additional information on the CDMRP history and management strategies.

The CDMRP in FY00

The continued successes of the CDMRP and the work of consumer advocates have resulted in yearly appropriations to the DOD for peer-reviewed research to be managed by the CDMRP. FY00 is the ninth fiscal year in which Congress has appropriated money, now totaling more than \$1.5B and encompassing 15 separate programs. The five core programs within the CDMRP are the:

- ◆ BCRP
- ◆ Prostate Cancer Research Program (PCRP)
- ◆ Neurofibromatosis Research Program (NFRP)
- ◆ Ovarian Cancer Research Program (OCRP)
- ◆ Peer Reviewed Medical Research Programs (PRMRP)

These five programs are summarized in Sections III–VII of this report. In addition, the CDMRP has been responsible for the management of 10 other programs that received a one-time appropriation and/or were institutionally based. These programs are summarized in Section VIII of this report. Congressional appropriations and awards for FY92–99 are summarized in Appendix A. Additional details on congressional language, withholds, management costs, and investment strategy for the FY99–00 programs are found in Appendix B.



Breast Cancer

One out of eight women will get breast cancer in her lifetime.¹

Due to the ongoing efforts of advocacy groups and increased public awareness on health issues, Congress has continued since FY92 to appropriate money for breast cancer research to be managed by the USAMRMC through the office of the CDMRP. For FY92–00, Congress appropriated more than \$ 1B to the BCRP for a multidisciplinary effort aimed at eradicating breast cancer.

Over 2,250 awards were made in FY92–99, resulting in 2,300 publications and 30 patents or licensures.

The BCRP is a well-recognized leader for its emphasis on consumer involvement and has served as a model for other programs within the CDMRP and other funding agencies.

The BCRP is making an impact on the lives of breast cancer patients and their families by bringing them closer to effectively treating and preventing breast cancer. ♦

¹National Cancer Institute (NCI) – Cancer Rates and Risks, 4th ed., 1996.



Partnerships

Partnerships among the public, private, government, and military sectors occur throughout all aspects of the CDMRP. In the past year, the CDMRP has continued to enhance existing partnerships and form new relationships. As the executive agent for these targeted appropriations, the U.S. Army is a key participant in these partnerships. A dedicated team of individuals, who are committed to improving health through research funded by these programs, is responsible for the daily coordination and administration. (The CDMRP Program Staff is highlighted in Appendix C.) The public, through consumer participation, has played an integral role in providing advice to the CDMRP. As a leader in consumer involvement, particularly in peer review, the CDMRP has focused its efforts in the year 2000 on sharing information about consumer participation through published manuscripts and presentations at meetings and conferences. Outreach through the Special Populations Program is another partnership emphasized by the CDMRP. The CDMRP fosters partnerships with diverse communities in all phases of its programs with the expectation that this will increase understanding of and reduce the disease disparities among different populations. Partnerships with other funding agencies have also been expanded to develop a common system to classify funded research. A new Common Scientific Outline, jointly developed by the NCI and CDMRP, should facilitate communication among different agencies about ongoing research efforts and areas of emphasis. In addition, the CDMRP has further developed cooperative efforts within the DOD that will encourage small business innovative research. The formation of partnerships is an ongoing process that plays a central role in helping to shape the future of health care to prevent, control, and cure diseases. Section I of this report contains additional information on CDMRP partnerships.

CDMRP Accomplishments

The CDMRP is committed to streamlining its approach to program execution. In order to simplify the award submission, review, and funding process for applicants, new execution processes have been developed and implemented in the past year. In particular, emphasis has been placed on using electronic-based award processes to improve efficiency and save time. CDMRP commitment is also evident in the types of awards that are offered through its programs. Awards are offered to support research that may not be offered by other agencies, build a foundation on which future research can be built, and encourage the next generation of researchers. These flexible approaches have allowed the individual programs within the CDMRP to provide support to areas of highest priority and greatest need. The fruition of these efforts is being realized through the program's scientific achievements.

Scientific Achievements

The research programs within the CDMRP offer unique opportunities in breast cancer, prostate cancer, ovarian cancer, and neurofibromatosis research. Research sponsored by the CDMRP is classified into three major categories: research, infrastructure, and training and recruitment.

—Research Awards

Research awards include an array of diverse mechanisms that encompass most aspects of scientific investigations ranging from basic laboratory questions to clinical applications. The *Idea Award* mechanism encourages innovative perspectives in research. Idea Awards were an early part of the BCRP, and projects funded as Idea Awards are starting to generate exciting results. For example, viruses commonly found in other parts of the body are being used to selectively kill tumor cells, while other viruses are delivering beneficial genes to breast cancer cells. New devices have been developed through Idea Awards to screen for breast cancer cells in ductal fluid and to identify breast cancer patients who have an increased probability for metastases.



Prostate Cancer

A man is diagnosed with prostate cancer every 2 minutes.¹

Congress began appropriating money for support of the PCRCP in FY97. From FY97–00, Congress has appropriated more than \$210M to fund peer-reviewed prostate cancer research to support innovative ideas and technologies aimed at preventing, detecting, treating, and improving the quality of life of men with prostate cancer.

More than 290 awards were made in FY97–99, which led to more than 150 publications, 20 patents or licensures, and 15 clinical trials.

The PCRCP is committed to conquering prostate cancer through research that addresses all men. The PCRCP challenges the scientific community to design innovative prostate cancer research that will foster new directions of exploration, tackle neglected issues, and bring an end to prostate cancer. ♦

¹Based on ACS predictions for 2001 in *CA-A Cancer Journal for Clinicians*, 2001; 51:15–36.

Neurofibromatosis

*Neurofibromatosis type 1 is the most common autosomal dominant disorder of humans appearing in childhood.*¹

The NFRP was established by congressional appropriations in FY96. Since then, the NFRP has promoted research related to enhancing the quality of life for individuals with NF type 1 and type 2 and discovering better ways to diagnose, treat, and eventually cure NF. More than \$52M was appropriated for the NFRP from FY96–00, representing the largest public research funding for NF.²

The FY96–00 NFRP funds emphasized the establishment of innovative multidisciplinary research groups and the translation of basic research into clinical treatments for individuals with NF.

The NFRP is dedicated to research that will improve the health and quality of life for individuals affected by NF and give hope to their families. ♦

¹ *American Journal of Medical Genetics* 1999; 89:7–13.

² The National Neurofibromatosis Foundation, Inc.



Traditional *Investigator-Initiated Awards* were a major emphasis in the FY93–95 BCRP portfolio and have been used more recently by the NFRP to answer basic questions on neurofibromatosis (NF). For example, research toward the understanding of NF type 1 (NF1) has resulted in gaining information about genes that may be involved in the development of leukemia and malignant tumors, factors that may lead to excessive growth of Schwann cells in the brain, and genes that participate in the formation of malignant tumors in these patients. Research concerning NF type 2 (NF2) has linked mutations to NF2 gene function to agents involved in causing cells to become cancerous.

Clinical research remains a goal for all CDMRP programs. Several award mechanisms have been offered to encourage the testing of new drugs that may improve current clinical treatments. For example, the BCRP has offered translational awards that support bringing laboratory research into the clinic. Among the translational awards supported by the BCRP are dietary prevention trials and laser treatment for

breast cancer. Clinical application mechanisms in the PCRCP have shown promising results in work that could have a major impact in the areas of immunotherapy, radiotherapy, and hormonal therapy for prostate cancer treatment.

—Infrastructure Awards

Infrastructure Awards provide support to (1) create or obtain resources for material or data from multiple sources (e.g., tissue repositories), or (2) establish and support centers or consortia. The BCRP, PCRCP, OCRCP, and NFRP have all supported awards to establish infrastructure that focuses on targeted issues. The BCRP initiated several resources in FY93/94. One such resource is a database of computer (digitized) mammograms that can be used by investigators throughout the world. The FY00 BCRP encouraged the use of this database to attract investigators new to the field and to facilitate the proposal review process. In FY97, the OCRCP began supporting multidisciplinary program projects. These awards are already showing promising results that can be applied to the prevention, detection, and treatment of ovarian cancer.

Ovarian Cancer

The chance of living for 5 years after the diagnosis of advanced ovarian cancer is between 20% and 25%.¹

The OCRP was established by a congressional appropriation in FY97. Nearly \$40M was appropriated for the OCRP for FY97–00, supporting innovative, multidisciplinary approaches leading to better understanding, control, prevention, and treatment of ovarian cancer.

The FY97–00 OCRP funds have focused on building the foundation for a broad national multidisciplinary ovarian cancer research enterprise.

The OCRP is a young program dedicated to supporting meritorious research, infrastructure building, and new researchers. ♦

¹ Gilda Radner Familial Ovarian Cancer Registry



—Training and Recruitment Awards

To ensure that the best possible researchers will be available to focus their efforts on a specific disease, *Training and Recruitment Award* mechanisms were supported. The programs of the CDMRP supported the training and mentoring of the next generation of scientists toward an independent, productive career in which creative thinking will produce treatments for human diseases. Other mechanisms assisted established investigators in changing career directions into the research of breast cancer, prostate cancer, ovarian cancer, and neurofibromatosis. During FY93–99, the CDMRP made 874 Training and Recruitment Awards to support individuals from predoctoral through faculty-level positions. The success of the trainees who were supported by the CDMRP is illustrated by some of their research accomplishments. Predoctoral trainees in the BCRP synthesized agents for breast cancer that are more effective than Taxol, and began designing vaccines that target breast cancer cells. In the NFRP, a postdoctoral researcher was instrumental in developing a mouse model to study genes involved in NF1 benign neurofibroma formation. For more information on scientific accomplishments that resulted from research supported through CDMRP awards, see the appropriate program sections in this report (Sections III–VII).



Peer Reviewed Medical Research Program

Addressing issues relevant to military health.

Congress recognized the need for research on issues directly relevant to military health and appropriated \$44.5M for FY99–00 to fund peer-reviewed research focused on defense-related health issues.

In FY99, the PRMRP supported research in alcoholism, chemical weapons treatment, disease management, health care information protection, lung studies, pediatric asthma, and sleep management. Research focusing on the issues directly related to military health will enhance military readiness and ultimately benefit all Americans. ♦

Looking Ahead

Through the combined efforts and passion of many individuals, the world is closer to eradicating breast cancer, conquering prostate cancer, and preventing ovarian cancer. In addition, focused research efforts are bringing the world closer to reducing the impact of neurofibromatosis and solving militarily relevant health issues. However, the solutions to these health crises remain elusive. In response to these needs, Congress has again appropriated more than \$350M in FY01 to support programs managed by the CDMRP. As the 21st century begins, 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 2001,

the CDMRP will move toward advancing health care solutions in areas identified by Congress and the DOD by funding excellent research, recognizing and mobilizing untapped opportunities, creating partnerships, and guarding the public trust. Together we can succeed.

