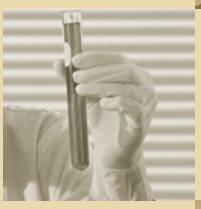
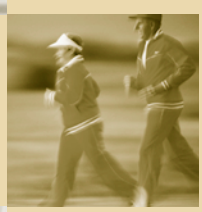






XI. Other Programs Managed by the CDMRP

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

Background

Over the past decade, increased public interest in health care issues has influenced the funding of scientific research. From fiscal year 1995 (FY95) to FY03, Congress has directed the Department of Defense (DOD) to manage numerous targeted research initiatives. As the Executive Agent for these initiatives, the U.S. Army Medical Research and Materiel Command's (USAMRMC's) Office of the Congressionally Directed Medical Research Programs (CDMRP) has managed 29 research programs, 21 of which are characterized by a one-time appropriation and/or are institutionally based programs. Table XI-1 lists these other research programs and the fiscal year that the CDMRP has managed them.

Table XI-1. Other Research Programs Managed by the CDMRP

Program	Fiscal Year*
Advanced Cancer Detection+	97–99
Alcoholism Research	00–03
Arthropod-Borne Infectious Disease Control Research	02
Breast Cancer Imaging Research	03
Cancer Center of Excellence	01–02
Cancer Research	01
Center for Prostate Disease Research	97–03
Children's Hospice Program	03
Coastal Cancer Control[2]	95
Computer-Aided Diagnosis[2]	97
Cooperative DOD/Veterans Affairs (VA) Medical Research	99–00
Defense Women's Health Research	95
Diagnostic and Surgical Breast Imaging	99
Fragile X Research	02
Gallo Cancer Center	00–01, 03
Hepatitis C Research	02
Lung Cancer	00–03
Monoclonal Antibodies Massachusetts Biological Lab	02
Muscular Dystrophy Research	03
Osteoporosis Research	95
Post-Polio Syndrome Research	99–00

* *Fiscal Year that the CDMRP was responsible for managing the listed programs.*

\+ *Award period of performance has been completed or responsibility for managing this program is no longer handled by the CDMRP.*

The goal of the CDMRP in managing these other programs is to fund scientifically meritorious research that addresses the topic areas specified by Congress. For FY02–03, the CDMRP has been responsible for executing or managing 12 institutionally based research programs. FY02–03 awards were made following proposal submission in response to the USAMRMC 99-1 Broad Agency Announcement and an external peer review for scientific merit.

This section contains information on the other programs that the CDMRP has been responsible for managing or executing in FY02–03. Appendix B, Table B-9, summarizes the directions from Congress and the investment strategy for these FY02–03 initiatives.

Alcoholism Research

From FY00 to FY03, Congress appropriated $24.6 million (M) for alcoholism research. The FY00–02 funds have been used to support 17 research projects at the Ernest Gallo Clinic and Research Center in San Francisco, California. These research projects are related to the center's theme of studying neuroscience in models of addiction, particularly alcoholism, and fall into six areas: Invertebrate Biology, Cell and Molecular Biology, Neurophysiology, Mouse Genetics, Behavioral Neuropharmacology, and Behavioral Studies. The Gallo Center's multidisciplinary approach links genetics, physiology, behavioral studies, and molecular and cell biology in model systems and uses coherent team approaches to study the complex problems of alcohol abuse. Two proposals for the FY03 program have been scientifically peer reviewed and awards are currently being negotiated.

Arthropod-Borne Infectious Disease Control Research

In FY02, Congress appropriated $2.5M for "Arthropod-Borne Infectious Disease Control." Arthropod-borne infectious diseases such as malaria, dengue fever, Lyme disease, and West Nile virus can have significant health effects and could have an effect on readiness in overseas deployments. One proposal has been awarded to support studies focused on establishing the molecular basis for vaccines to prevent disease transmission by ticks and mosquitoes in accordance with the directives received from Congress. This program is currently managed by the USAMRMC Infectious Diseases Research Area Directorate.

Breast Cancer Imaging Research

In FY03, Congress appropriated $6M for breast cancer imaging research. The House Appropriations Committee Report No. 107-532 directed the DOD to focus these funds on the development of new imaging techniques aimed at the early detection of breast cancer. Breast cancer imaging by mammography (x-ray examination of internal breast structure) is believed to reduce the number of breast cancer deaths for women ages 40 to 69, especially those over age 50.[1] Concerns about the validity of studies used to establish current mammography screening recommendations have motivated the need for improved methods of breast cancer imaging and screening.[2,3] A total of 23 preproposals have been received. Full proposals are due in October 2003, with subsequent scientific and programmatic review to select proposals for funding completed by December 2003.

Cancer Center of Excellence

In FY01 and FY02, Congress appropriated $1M and $2.1M, respectively, for a Cancer Center of Excellence. In 2003, approximately 1,334,100 individuals in the United States are expected to be diagnosed with some form of cancer and about 556,500 are expected to die of cancer.[4] The FY01–02 funds have been used to support two awards to the University of Notre Dame to identify new cancer-causing genes and novel drugs for cancer therapy and diagnosis. Thus, a research infrastructure has been established and several postdoctoral fellowships have been recruited.

Center for Prostate Disease Research

The Center for Prostate Disease Research (CPDR) received congressional appropriations totaling $37.9M during FY97–02 and $5.7M during FY03.[5] The CPDR was initially established in response to a growing concern over the incidence of prostate cancer and the controversy over treatment choices at the various stages of the disease. The program is administered under the auspices of the Uniformed Services University of the Health Sciences. The CPDR has been devoted to the study and cure of prostate

---

1 *National Cancer Institute, Fact Sheet 5.28.*

2 *Olsen O and Gotzsche P. 2001.* The Lancet *358.1340–1342.*

3 *National Cancer Institute, News from the NCI, February 21, 2002.*

4 *American Cancer Society - Cancer Facts and Figures 2003.*

5 *Congress appropriated funding ($2M) in FY92 to establish the CPDR. The USAMRMC, but not the Congressionally Directed Medical Research Programs, managed $10.25M in FY92-95 appropriations for the CPDR.*

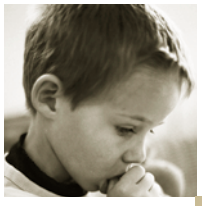
disease and cancer, and comprises three major emphasis programs: The Tri-Service Multicenter Prostate Cancer Database, the Basic Sciences Research Program, and the Clinical Research Center. These programs strive to fight diseases of the prostate as well as fostering training in basic sciences and clinical research.

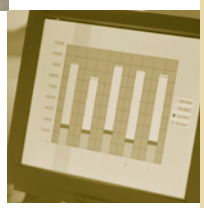
The CPDR Program developed, and is actively maintaining and expanding, the Tri-Service Multicenter Prostate Cancer Database involving nine military treatment sites and numerous military and civilian researchers and support staff. The CPDR Program database maintains relevant prostate disease data on more than 19,000 men treated in military health facilities. The database has resulted in landmark studies of the prostate-specific antigen, including screening for prostate cancer in high-risk African American men.

The CPDR Basic Science Research Program laboratories continue to focus on cutting-edge molecular and cell biology research with a goal to better understand the biology of the disease and develop novel diagnostic and prognostic biomarkers for prostate cancer. The CPDR laboratories, in collaboration with Walter Reed Army Medical Center (WRAMC) and the Armed Forces Institute of Pathology, continue to develop and expand unique bioresources for prostate cancer research, which now include paraffin-embedded whole-mount prostates, OCT[6] embedded frozen tissues, as well as a frozen section slide library and serum bank from over 700 cancer patients. Blood- and bone marrow-derived RNA and DNA from 500 cancer patients and 300 controls have been prepared. The CPDR laboratories have also developed a new DNA and RNA bank from laser capture microdissected normal and tumor cells of 130 patients. Linkage of these biomaterials to well-defined clinicopathologic features, patient demographics, and treatment responses has been providing promising new opportunities in the discovery of prostate cancer-specific biomarkers using genomic and proteomic approaches. Prostate cancer (PC) gene discovery efforts using state-of-the-art global gene expression profiling and positional cloning strategies at CPDR are uncovering novel gene alterations in prostate cancer. The current focus is on the identification of the putative tumor suppressor gene on chromosome 6q16 locus that is frequently deleted in prostate cancer.

The CPDR Clinical Research Center headquartered at the WRAMC has over 20 ongoing clinical trials related to prevention of PC, quality of life for PC patients, and therapy development and evaluation. CPDR is

6 *Tissue-embedding media.*





collaborating with both pharmaceutical companies and academic institutions in conducting these clinical trials and studies. CPDR is also an active participant in several large clinical trial studies sponsored by Cooperative Research Groups such as the Eastern Cooperative Oncology Group and the Cancer and Leukemia Group B.

Over the past year, the CPDR Program has published over 22 peer reviewed manuscripts, 35 abstracts, 2 book chapters, and several publications for patient education.

Children's Hospice Program

In FY03, Congress appropriated $1.5M to establish the Children's Hospice Program at WRAMC. Between 75,000 and 100,000 children die each year in the United States alone, and approximately 1 million children are seriously ill with progressive medical conditions.[7] The Children's Hospice Program demonstration project at WRAMC structures, implements, and provides oversight of a program serving children with life-threatening illnesses, diseases, or conditions who have parents or custodial caregivers serving in the U.S. military (including the Reserve components) or retired from the U.S. military. A full proposal has been scientifically peer reviewed, and the award is currently being negotiated.

Fragile X Research

In FY02, Congress appropriated $1M for Fragile X research. Fragile X Syndrome is a hereditary condition that causes a wide range of mental impairments, as well as a number of physical and behavioral symptoms. It is the most common cause of genetically inherited mental impairment, affecting approximately 1 out of every 2,000 males and 1 out of every 4,000 females.[8] FY02 funds are supporting an intervention study at the Children's Hospital of Pittsburgh aimed at finding effective methods of treatment, both pharmacological and nonpharmacological, for the symptoms and behavioral problems associated with Fragile X Syndrome.

Gallo Cancer Center

In FY00–01, Congress appropriated a total of $7M to provide for the initiation of a cancer center dedicated to prostate cancer research. FY00–01 funds were awarded to the University of Medicine and Dentistry

---

7 *Children's Hospice International website (www.chionline.org).*

8 *The National Fragile X Foundation website, January 2002.*

of New Jersey to support the Dean and Betty Gallo Prostate Cancer Center at the Cancer Institute of New Jersey. The Gallo Prostate Cancer Center contains three programs: the Clinical Science, Population Science, and Basic Science Programs. The Clinical Science Program's goals are to increase translational research, support clinical trials, and encourage a statewide alliance of hospitals. The Population Science Program has a cancer control focus and is currently involved in a study to identify and develop effective means of prostate cancer intervention among different ethnic groups. The Basic Science Program is performing basic research on prostate cancer by examining all steps in the cancer pathway from initiation to progression and advanced disease.

Congress appropriated an additional $1.05M in FY03 for the Gallo Cancer Center. A proposal has been scientifically peer reviewed, and the award is currently being negotiated.

Hepatitis C Research

In FY02, Congress appropriated $3.4M for research on Hepatitis C. Hepatitis C is a disease of the liver caused by the Hepatitis C virus. Nearly 4 million Americans have either an ongoing or previous infection with HCV.[9] Hepatitis C results in an estimated 8,000 to 10,000 deaths annually in the United States.[10] Recent studies show that the incidence of Hepatitis C in U.S. veterans is between 8 and 10 percent, or 4 or 5 times that of the population in general.[11] Funds were awarded to the Uniformed Services University of the Health Sciences to support a multi-disciplinary research project that is looking at immunological, virological, and biochemical correlates of treatment failure for Hepatitis C, as well as a therapeutic clinical trial exploring new treatments.

Lung Cancer Research

From FY00 to FY03, Congress appropriated $24M for the Lung Cancer Program. FY00–02 funds were awarded to the University of Texas M.D. Anderson Cancer Center to explore multiple avenues of research, prevention, diagnosis, and therapy that would yield new treatment options for lung cancer. A proposal for the FY03 program has been scientifically peer reviewed, and the award is currently being negotiated.

---

9 *Centers for Disease Control and Prevention.*

10 *National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health Publication No. 99-4230, Revised December 2000.*

11 *Hepatitis Research Foundation website, January 2002.*

Research highlights for this program include the following:

- The identification of a short protein sequence that when injected into the blood stream inhibits an enzyme in the bronchial arterioles that is involved in cancer invasion and metastasis
- The discovery that expression of a major tumor suppressor gene, PTEN, is lost in nearly one-third of early-stage lung cancers
- The development of a mouse model of lung cancer not only to study the biology of cancer but to test new drugs for the prevention and treatment of it
- Detection of elevated levels of 14 proteins in blood samples from lung cancer patients
- Demonstration that inhibition of phosphatidyl inositol 3-kinase (PI3K) in both lung cancer cells and animal models of lung cancer inhibits lung cancer growth
- Discovery of a deleted region on human chromosome 3p in a portion of non-small cell lung cancer patients

Monoclonal Antibodies, Massachusetts Biological Lab

In FY02, Congress appropriated $1M for "Monoclonal Antibodies, Massachusetts Biological Lab." A proposal was received, and reviewed, and a grant was awarded to the University of Massachusetts Medical Center.

Muscular Dystrophy Research

In FY03, Congress appropriated $3.4M for muscular dystrophy (MD) research. MD is the common name for a group of inherited diseases characterized by progressive muscle weakness and degeneration. Each type of MD has a distinct hereditary pattern, age of onset, and rate of muscle loss. Between 50,000 and 250,000 people are affected by MD each year. There is currently no prevention or cure for any of the forms of MD. However, the future looks promising due to recent advances in gene manipulation and stem cell therapy.[12] Three proposals have been scientifically peer reviewed and are currently in negotiations.

[12] *Muscular Dystrophy Family Foundation, Inc.*