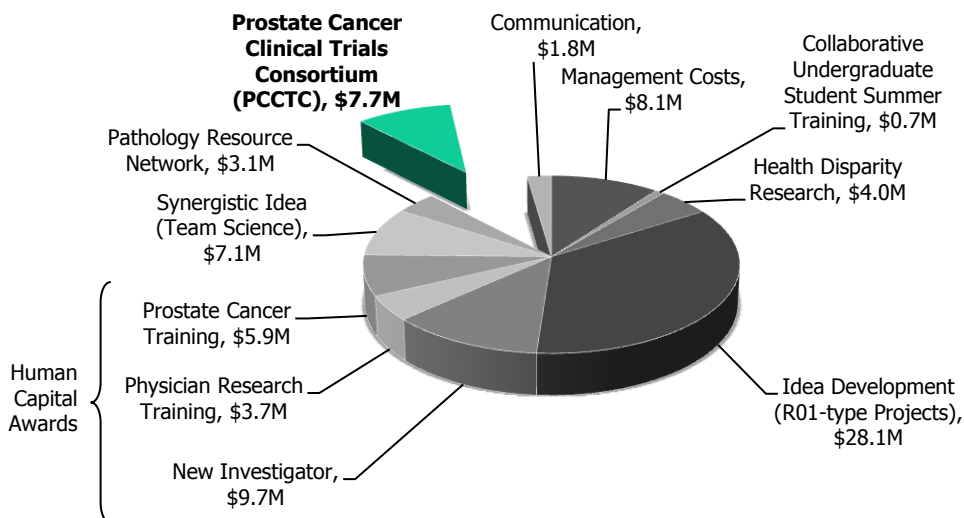


The Department of Defense Prostate Cancer Research Program is America’s leading undiluted support to find and fund the best prostate cancer research. The research funded by DoD PCRP has led to many dramatic improvements in our nation’s prostate health, from decreases in deaths due to prostate cancer to increased life expectancy for men facing terminal diagnoses.

Measurable Results through the World’s Foremost Clinical Trials Network: the Prostate Cancer Clinical Trials Consortium (PCCTC)

- The PCCTC is the world’s most comprehensive “first in man” phase I/II clinical trials group for prostate cancer composed of 13 Centers of Excellence in genitourinary oncology
- Over 20 biotech and pharmaceutical companies have conducted early translational clinical research trials and published their results via the PCCTC

DOD PCRP ESTIMATED ALLOCATION FY2011



- **The Consortium has helped to bring to market 3 new medicines for men with advanced prostate cancer that were approved by the FDA in 2010-11:**
 - PROVENGE® (sipuleucel-T) - Dendreon Corporation
 - XGEVA™ (denosumab) - Amgen Inc
 - ZYTIGA™ (abiraterone acetate) - Johnson & Johnson
- More than 2,700 patients have had access to 83 clinical trials since 2005 through the Consortium
- In 2011, there are 36 active clinical trials spanning treatment for localized disease to castrate-resistant prostate cancer
- The Consortium is currently driving the development of more than five phase III clinical trials programs

In 2011, the PCCTC continues to conduct “first in man” translational research developing new anti-prostate cancer medicines, including the new small molecule drug XL184 (Exelixis), which has a greater than 80% response rate on bone scan, and MDV3100 (Medivation, Inc.), which is on an accelerated track toward approval by the FDA

FACTS AT-A-GLANCE

Many policy-makers propose eliminating the recommended reduced appropriation of \$64 million per year for the Department of Defense Prostate Cancer Research Program (DoD CDMRP PCRP) provided via H.R.2219 for FY12.

The National Cancer Institute’s (NCI) prostate cancer research budget is ~\$294 million per year. The total U.S. budget for translational prostate cancer research = ~\$374 million (based on FY11 DoD PCRP Appropriation of \$80M).

Elimination of entire \$80M DoD PCRP funding = 21% reduction in the U.S. translational prostate cancer research effort in 2012.

Included in the elimination of the \$80 million would be the annual DoD \$7.7 million investment for the infrastructure of the Prostate Cancer Clinical Trials Consortium

The PCCTC supports 100% of early phase I/II clinical trials for prostate cancer research in the U.S.

PCF co-sponsors this program in a public-private partnership, contributing \$3.2 million annually to the PCCTC.

Elimination of the PCCTC = 100% reduction in early phase I/II trials for prostate cancer research.



**Talking Points: Department of Defense (DoD)
 Congressionally Directed Medical Research Program (CDMRP)
 Prostate Cancer Research Program (PCRP)**

**DoD PCRP = Real, Direct Economic Benefits at the Local Level
 Biomedical Research Has a Multiplier Effect on Economic Growth**

Since 1997, when the DoD PCRP was initiated, about \$1.1 billion has been appropriated by Congress and used to fund more than 2,000 prostate cancer research studies across the U.S. Since 2006, this program has been funded at \$80 million per year.

Between FY97-10, the DOD PCRP has funded:

Awards

- 1734 awards to independent investigators
- 595 awards to Young investigators

Career Development

- PCRP has funded the careers of 1231 independent investigators in PCRP history
- PCRP has funded the careers of 547 Young Investigators

DoD Prostate Cancer Research Program (PCRP) Funding by State*

State	All Awards		Currently Funded Only	
	Number of Awards	Total Funds*	Number of Awards	Total Funds*
Alabama	34	\$ 10,320,310	6	\$ 2,076,726
Alaska	0	\$ -	0	\$ -
Arizona	2	\$ 207,330	1	\$ 67,575
Arkansas	9	\$ 3,565,297	2	\$ 207,330
California	361	\$ 145,483,794	102	\$ 45,822,646
Colorado	21	\$ 6,213,610	2	\$ 440,489
Connecticut	9	\$ 3,760,310	4	\$ 1,594,017
Delaware	11	\$ 3,558,449	5	\$ 1,882,575
Florida	33	\$ 12,703,062	7	\$ 1,561,637
Georgia	31	\$ 21,306,848	11	\$ 4,240,075
Hawaii	2	\$ 812,349	0	\$ -
Idaho	0	\$ -	0	\$ -
Illinois	68	\$ 25,036,919	31	\$ 10,274,073
Indiana	23	\$ 11,365,034	5	\$ 1,737,032
Iowa	20	\$ 5,724,902	8	\$ 2,707,726
Kansas	6	\$ 2,619,400	3	\$ 1,417,228
Kentucky	16	\$ 7,469,934	5	\$ 2,073,215
Louisiana	19	\$ 6,149,934	8	\$ 2,779,330
Maine	0	\$ -	0	\$ -
Maryland	118	\$ 43,168,716	39	\$ 15,600,324
Massachusetts	180	\$ 78,792,562	58	\$ 26,817,332
Michigan	123	\$ 48,200,199	44	\$ 17,002,870
Minnesota	35	\$ 16,358,536	8	\$ 2,520,164
Mississippi	2	\$ 474,953	0	\$ -

DoD Prostate Cancer Research Program (PCRP) Funding by State (Continued)*

State	All Awards		Currently Funded Only	
	Number of Awards	Total Funds*	Number of Awards	Total Funds*
Missouri	23	\$ 5,889,557	7	\$ 1,191,600
Montana	0	\$ -	0	\$ -
Nebraska	18	\$ 6,089,342	7	\$ 2,168,193
Nevada	2	\$ 1,512,000	2	\$ 1,512,000
New Hampshire	5	\$ 1,208,787	1	\$ 354,868
New Jersey	26	\$ 9,398,441	9	\$ 3,383,408
New Mexico	9	\$ 1,925,089	1	\$ 99,900
New York	236	\$ 117,594,859	87	\$ 41,040,203
North Carolina	104	\$ 35,950,027	41	\$ 17,042,162
North Dakota	1	\$ 313,256	0	\$ -
Ohio	60	\$ 23,875,554	18	\$ 7,096,535
Oklahoma	4	\$ 1,665,585	3	\$ 1,359,347
Oregon	23	\$ 10,476,170	7	\$ 4,182,630
Pennsylvania	117	\$ 39,346,918	36	\$ 11,814,506
Rhode Island	3	\$ 1,907,190	0	\$ -
South Carolina	12	\$ 4,912,110	6	\$ 2,064,165
South Dakota	3	\$ 729,000	3	\$ 729,000
Tennessee	50	\$ 16,488,452	15	\$ 5,379,728
Texas	217	\$ 76,192,045	77	\$ 28,314,836
Utah	5	\$ 1,778,877	2	\$ 99,606
Vermont	1	\$ 498,382	0	\$ -
Virginia	42	\$ 14,920,835	12	\$ 3,152,981
Washington	65	\$ 21,629,890	21	\$ 7,858,780
West Virginia	1	\$ 108,763	1	\$ 108,763
Wisconsin	46	\$ 16,617,130	12	\$ 5,296,845
Wyoming	0	\$ -	0	\$ -
District of Columbia	50	\$ 16,308,011	10	\$ 2,518,368

* as of 20 May 2011, not all FY10 awards have been made and so some funding amount will increase by 30 Sept 2011

Today, the continued preeminence of the DoD PCRP—and even our position as the leader in biomedical research—is threatened because of the possibility of losing DoD PCRP funding. Most Americans don't know that DoD PCRP is a positive economic force in numerous local communities: most of its \$80 million per year budget funds research that takes place at universities, medical research centers, hospitals, and research institutes in every state in the U.S.

The federal dollars that DoD PCRP sends out into communities equals real, direct economic benefits at the local level, including increased employment; growth opportunities for universities, medical centers, and local companies; and additional economic stimulus for the community. And when DoD PCRP funding is cut, communities across the country suffer too.

The CDMRP is Integral to the Defense Department's Preeminence

- DoD CDMRP programs are positioning the military to work side by side with the academic and private sector to extrapolate the knowledge to understand and create countermeasures for "weaponized" biologic systems. For example, the technology used to create a transgenic animal for cancer research is the basic formula for creating a genetically modified virus or microbe to kill millions.

Why the Department of Defense?

The Department of Defense (DOD) has a track-record of saving lives in the fight against prostate cancer.

Cancer Research is a Defense Department Obligation

- Exposure to Agent Orange doubled the risk of prostate cancer for thousands of American men who served in the military. The DoD PCCTC is the only vehicle through which these men can receive innovative Phase I/II treatment earlier.
- Our uniformed services and our veterans directly benefit from the progress of the program.
- The DoD PCRP is quite simply the gold standard in bench to bedside research. If we do not develop more life-saving new medicines via the PCCTC, we will continue to lose 32,000 men each year.
- Since FY02, DoD PCRP has sponsored the prostate Cancer Project, or PCaP, which seeks to delineate the factors that contribute to the high incidences and disproportionate rates of prostate cancer deaths in African-American versus Caucasian men. The PCaP has accrued more than 2,000 men with newly diagnosed prostate cancer.
- Prostate cancer is more prevalent and more severe in African-Americans; they represent 25% of our Army (vs. 10% of the US population).
- Some believe that "prostate cancer is a disease of old men." But aggressive forms are increasingly striking men in their forties and fifties.
- In a recent study published in May 2011 in *The Journal of Urology*, researched showed that the rate of prostate cancer among active-duty U.S. Air Force members has been several times higher in recent years than it was 20 years ago, a new study finds.
- Researchers found that between 2005 and 2008, the rate of prostate cancer among white active-duty Air Force servicemen was three times higher than it was between 1991 and 1994.
- Among African Americans, the rate rose 11-fold, according to findings published in the *Journal of Urology*.

When lawmakers are making decisions about DOD PCRP funding, first and foremost, they should bear in mind the aforementioned considerable medical accomplishments that have flowed from DOD-supported research (not NIH/NCI-supported research):

- 1) A group of experts annually reviews performance and recommends types of research that will be funded the next year
 - a. This group, the “integration panel” includes physicians, scientists, and consumer advocates (patients) and keeps the program on the cutting-edge of ever-changing scientific priorities
- 2) The Integration Panel reviews all peer-reviewed research applications, builds a portfolio of these applications, and recommends funding
 - a. Why do we care? This unique mechanism allows optimal deployment of precious funds for research
- 3) Areas of research uniquely funded by PCRP
 - a. DNA Vaccines for the treatment of advanced prostate cancer
 - b. Mechanisms of gene fusion formation that drive prostate cancer progression
 - c. Models of prostate cancer useful for testing new experimental treatments
 - d. The use of molecular imaging based on prostate cancer metabolism to better detect small amounts of cancer in patients
 - e. Mechanisms confound the efficacy of immunotherapy have been determined
 - f. New clinical compounds that block the androgen receptor have been discovered
 - g. Nanoparticles have been used to target tumors to enhance visibility by MRA imaging
 - h. PET Imaging software and methodology has been used to help urologists perform more sensitive biopsies of patients
 - i. Many more discoveries that will benefit patients have been achieved during the history of PCRP

In Summary, DOD PCRP funding cuts do more than stifle scientific progress:

- These cuts will have a negative economic impact on jobs in communities across the country.
- These cuts will have a negative impact on the Defense Department’s ability to create countermeasures for “weaponized” biologic systems.
- These cuts will cost us hundreds of thousands of lives.
- These cuts will have a negative impact on our capability to deliver rapidly new treatments to prostate cancer patients.