PERSONNEL AND READINESS

UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

The Honorable Richard C. Shelby Chairman Subcommittee on Defense Committee on Appropriations United States Senate Washington, DC 20510

JAN - 7 2021

Dear Mr. Chairman:

The Department's report in response to Senate Report 115–290, page 210, accompanying S. 3159, the Department of Defense Appropriations Bill, 2019 and House Report 115–769, pages 295–296, accompanying H.R. 6157, the Department of Defense Appropriations Bill, 2019, on the status of the Peer-Reviewed Cancer Research Program (PRCRP), is enclosed.

The final report summarizes the Fiscal Year (FY) 2009 - FY 2019 PRCRP research award topics and investments per topic area; discusses relevance of the PRCRP research to Service members and their families; and covers FY 2009 - FY 2018 PRCRP research award outcomes. The FY 2019 PRCRP funded 103 of the 618 full applications received (a 16.7 percent funding rate), which represents 120 separate awards. The Department expects outcomes by the end of the award performance periods, which span two to four years.

Thank you for your continued strong support for our Service members, civilian workforce, and families. I am sending an identical letter to the other congressional defense committees.

Sincerely,

//SIGNED//

Matthew P. Donovan



4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

The Honorable Richard J. Durbin Vice Chairman Subcommittee on Defense Committee on Appropriations United States Senate Washington, DC 20510

JAN - 7 2021

Dear Senator Durbin:

The Department's report in response to Senate Report 115 290, page 210, accompanying S. 3159, the Department of Defense Appropriations Bill, 2019 and House Report 115–769, pages 295 296, accompanying H.R. 6157, the Department of Defense Appropriations Bill, 2019, on the status of the Peer-Reviewed Cancer Research Program (PRCRP), is enclosed.

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4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

JAN - 7 2021

The Honorable Peter J. Visclosky Chairman Subcommittee on Defense Committee on Appropriations U.S. House of Representatives Washington, DC 20515

Dear Mr. Chairman:

The Department's report in response to Senate Report 115 290, page 210, accompanying S. 3159, the Department of Defense Appropriations Bill, 2019 and House Report 115–769, pages 295 296, accompanying H.R. 6157, the Department of Defense Appropriations Bill, 2019, on the status of the Peer-Reviewed Cancer Research Program (PRCRP), is enclosed.

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4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

JAN - 7 2021

The Honorable Ken Calvert Ranking Member Subcommittee on Defense Committee on Appropriations U.S. House of Representatives Washington, DC 20515

Dear Representative Calvert:

The Department's report in response to Senate Report 115 290, page 210, accompanying S. 3159, the Department of Defense Appropriations Bill, 2019 and House Report 115–769, pages 295–296, accompanying H.R. 6157, the Department of Defense Appropriations Bill, 2019, on the status of the Peer-Reviewed Cancer Research Program (PRCRP), is enclosed.

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//SIGNED//

Matthew P. Donovan



4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

JAN - 7 2021

The Honorable Adam Smith Chairman Committee on Armed Services U.S. House of Representatives Washington, DC 20515

Dear Mr. Chairman:

The Department's report in response to Senate Report 115 290, page 210, accompanying S. 3159, the Department of Defense Appropriations Bill, 2019 and House Report 115–769, pages 295 296, accompanying H.R. 6157, the Department of Defense Appropriations Bill, 2019, on the status of the Peer-Reviewed Cancer Research Program (PRCRP), is enclosed.

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Matthew P. Donovan

PERSONNEL AND READINESS

UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

The Honorable William M. "Mac" Thornberry Ranking Member Committee on Armed Services U.S. House of Representatives Washington, DC 20515

JAN - 7 2021

Dear Representative Thornberry:

The Department's report in response to Senate Report 115 290, page 210, accompanying S. 3159, the Department of Defense Appropriations Bill, 2019 and House Report 115–769, pages 295–296, accompanying H.R. 6157, the Department of Defense Appropriations Bill, 2019, on the status of the Peer-Reviewed Cancer Research Program (PRCRP), is enclosed.

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Matthew P. Donovan



4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

The Honorable James M. Inhofe Chairman Committee on Armed Services United States Senate Washington, DC 20510 JAN - 7 2021

Dear Mr. Chairman:

The Department's report in response to Senate Report 115 290, page 210, accompanying S. 3159, the Department of Defense Appropriations Bill, 2019 and House Report 115–769, pages 295–296, accompanying H.R. 6157, the Department of Defense Appropriations Bill, 2019, on the status of the Peer-Reviewed Cancer Research Program (PRCRP), is enclosed.

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Matthew P. Donovan



4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

The Honorable Jack Reed Ranking Member Committee on Armed Services United States Senate Washington, DC 20510

JAN - 7 2021

Dear Senator Reed:

The Department's report in response to Senate Report 115 290, page 210, accompanying S. 3159, the Department of Defense Appropriations Bill, 2019 and House Report 115–769, pages 295–296, accompanying H.R. 6157, the Department of Defense Appropriations Bill, 2019, on the status of the Peer-Reviewed Cancer Research Program (PRCRP), is enclosed.

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//SIGNED//

Matthew P. Donovan

Report to Congressional Defense Committees



Peer-Reviewed Cancer Research Program

January 2021

In Response to: Senate Report 115–290, Page 210, Accompanying S. 3159, the Department of Defense Appropriations Bill, 2019 and House Report 115–769, Pages 295–296, Accompanying H.R. 6157, the Department of Defense Appropriations Bill, 2019

The estimated cost of this report for the Department of Defense (DoD) is approximately \$5,700.00. This includes \$2,700.00 in expenses and \$3,000.00 in DoD labor.

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BACKGROUND AND PURPOSE

Senate Report 115–290, page 210, accompanying S. 3159, the Department of Defense (DoD) Appropriations Bill, 2019 and House Report 115–769, pages 295–296, accompanying H.R. 6157, the DoD Appropriations Bill, 2019, request that the Assistant Secretary of Defense for Health Affairs (ASD(HA)) provide a report no later than 180 days after the enactment of their respective Acts to the congressional defense committees, on the status of the Peer-Reviewed Cancer Research Program (PRCRP). For each research area, the report shall include the funding amount awarded; progress of the research; and relevance of the research to Service members and their families. This fiscal year (FY) 2019 update provides information on actively negotiated awards by the Congressional Directed Medical Research Program. Previous updates for FY 2009–FY 2018 are accessible at: http://cdmrp.army.mil/prcrp/reports/reports/reports.

As directed by the Office of the ASD(HA), the Defense Health Agency DHA J-9, Research and Development Directorate, manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriations. The U.S. Army Medical Research and Development Command provides execution management for the DHP RDT&E PRCRP Congressional Special Interest funds.

FY 2019 PRCRP BACKGROUND AND STATUS

Vision: To advance mission readiness of U.S. military members affected by cancer and to improve quality of life by decreasing the burden of cancer on Service members, their families, and the American public

Mission: To successfully promote high-impact research for cancer prevention, detection, treatment, quality of life and survivorship

BACKGROUND:

Since the PRCRP's inception in FY 2009, Congress has directed its appropriation amount and the different topic areas to be funded (Table 1). Figure 1 shows the percentage of research dollars invested in each topic area from FY 2009–FY 2019.

Each FY, many factors affect the PRCRP investment portfolio, such as whether it includes a specific topic area; the number of applications received for each topic area; the scientific merit of each proposed research project and potential impact of its outcomes; and the appropriation amount with respect to the number of topic areas. The programmatic review considers each topic area to ensure a balanced portfolio with respect to the specific FY topic areas.

Table 1: PRCRP Appropriation and Topic Areas per Fiscal Year

Fiscal Year	Appropriation (Awards)‡	Topic Areas*
2009	\$16M (38)	\$4M, Melanoma and other skin cancers as related to deployments of Service members to areas of high exposure; \$2M, Pediatric brain tumors within the field of childhood cancer research; \$8M, Genetic cancer and its relation to exposure to various environments unique to a military lifestyle; and \$2M, Noninvasive cancer ablation treatment including selective targeting with nanoparticles
2010	\$15M (30)	Melanoma and other skin cancers; Pediatric brain tumors within the field of childhood cancer research; Genetic cancer research and genomic medicine; Kidney cancer; Blood cancer; Colorectal cancer; <i>Listeria</i> vaccine for cancer; and Radiation protection utilizing nanotechnology
2011	\$16M (44)	Melanoma and other skin cancers; Pediatric cancer research; Genetic cancer research; Kidney cancer; Blood cancer; Colorectal cancer; Pancreatic cancer; Mesothelioma; Listeria vaccine for cancer; and Radiation protection utilizing nanotechnology
2012	\$12.8M (27)	Melanoma and other skin cancers; Pediatric brain tumors; Genetic cancer; Pancreatic cancer; Kidney cancer; Blood cancer; Colorectal cancer; Mesothelioma; and <i>Listeria</i> vaccine for cancer
2013	\$15M (27)	Melanoma and other skin cancers; Pediatric brain tumors; Genetic cancer; Pancreatic cancer; Kidney cancer; Blood cancer; Colorectal cancer; Mesothelioma; and Neuroblastoma
2014	\$25M (47)	Blood cancer; Colorectal cancer; Genetic cancer research; Kidney cancer; <i>Listeria</i> vaccine for cancer; Melanoma and other skin cancers; Mesothelioma; Myeloproliferative disorders; Neuroblastoma; Pancreatic cancer; Pediatric brain tumors; and Cancers related to radiation exposure
2015	\$50M (110)	Colorectal cancer; Genetic cancer research; Kidney cancer; <i>Listeria</i> vaccine for cancer; Liver cancer; Melanoma and other skin cancers; Mesothelioma; Myeloproliferative disorders; Neuroblastoma; Pancreatic cancer; and Stomach cancer
2016	\$50M (89)	Bladder cancer; Colorectal cancer; Immunotherapy; Kidney cancer; <i>Listeria</i> vaccine for cancer; Liver cancer; Lymphoma; Melanoma and other skin cancers; Mesothelioma; Myeloproliferative disorders; Neuroblastoma; Pancreatic cancer; Pediatric brain tumors; and Stomach cancer
2017	\$60M (92)	Bladder cancer; Brain cancer; Cancer in children, adolescents, and young adults; Colorectal cancer; Immunotherapy; <i>Listeria</i> -based regimens for cancer; Liver cancer; Lymphoma; Melanoma and other skin cancers; Mesothelioma; Neuroblastoma; Pancreatic cancer; Pediatric brain tumors; and Stomach cancer
2018	\$80M (114)	Adrenal cancer; Bladder cancer; Blood cancers; Brain cancer; Cancer in children, adolescents, and young adults; Colorectal cancer; Immunotherapy; <i>Listeria</i> -based regimens for cancer; Liver cancer; Lymphoma; Melanoma and other skin cancers; Mesothelioma; Myeloma; Neuroblastoma; Pancreatic cancer; Pediatric brain tumors; and Stomach cancer
2019	\$90M (103)	Bladder cancer; Blood cancers; Brain cancer; Cancer in children, adolescents, and young adults; Colorectal cancer; Immunotherapy; <i>Listeria</i> -based vaccines for cancer; Liver cancer; Lymphoma; Mesothelioma; Neuroblastoma; Pancreatic cancer; Pediatric brain tumors; Rare cancers; and Stomach cancer

^{*}Congressional language designates topic areas (as published in the Public Law, Congressional Record, and post-Presidential signature communications for clarification on language).

[‡]Number of awards represents all open, pending closeout, and closed awards, and does not include withdrawals.

Rare Cancers Adrenal Cancer Pediatric Cancer Stomach Cancer 1% 5% Pediatric Brain Tumors Bladder Cancer Pancreatic Cancer Non-Invasive 8% Cancer... Blood Cancers Myleoproliferative Disorders Neuroblastoma Myeloma Brain Cancer 1% Cancers Related to Radiation Mesothelioma Exposure <1% Cancer in Children. Adoescents, and Young Adults Melanoma and Other Skin Cancers Colorectal Cancer 10% Cenetic Cancer Liver Cancer 4% Lymphoma Immunotherapy Kidney Cancer Listerla Vaccine for Cancer

Figure 1: FY 2009-FY 2019 PRCRP Research Investment per Topic Area (Percent of Total Research Dollars)

STATUS:

In November 2019, external panels of experts (including scientists, clinicians, consumers, active duty Service members, and veterans) conducted scientific peer review of the applications received for FY 2019 PRCRP funding. The panels evaluated each application on its technical merit and impact on patient outcomes. The second tier of review, programmatic review (held in January 2020), included discussions by experts in the field, including the FY 2019 Programmatic Panel members for the PRCRP and ad-hoc reviewers (https://cdmrp.army.mil/prcrp/panels/panels). These experts (scientists, clinicians, consumers, active duty Service members, and veterans) assessed the applications based on their respective scientific peer-reviewed ratings, relevance to military health, and compared each peer-reviewed application with the portfolio composition and intent of the published program announcement to ensure a balanced portfolio and alignment with programmatic intent. Following, these experts recommended applications for funding that were scientifically sound and best met the program's interests and goals.

In FY 2019, the PRCRP funded 103 applications (representing 120 separate awards) of the 618 full applications received, for a 16.7 percent funding rate totaling \$80,031,719. For more

information on the award selection process, access the Principal Investigator Information Paper (https://cdmrp.army.mil/prcrp/pdf/W81XWH-19_PRCRP_InformationPaper.pdf). The remainder of the FY 2019 PRCRP appropriation is directed toward administrative and management costs in support of these PRCRP projects and DoD witholds for Small Business Innovation Research/Small Business Technology Transfer Programs, as directed by law.

The PRCRP awarded all FY 2019 research funds by September 30, 2020. The Department expects outcomes by the end of each period of performance, which spans two to four years from the start date of an award. Table 2 shows the FY 2019 total recommended research funding by topic area. Table 3 reports the outcomes for FY 2009–FY 2018 PRCRP awards.

Table 2. FY 2019 Total Research Dollars Invested per Topic Area

Topic Area	Number of Awards	Total Funds (\$M)
Bladder Cancer	10	\$6,179,305
Blood Cancers	11	\$8,178,698
Brain Cancer	12	\$5,647,383
Cancers in Children, Adolescents, and Young Adults	9	\$7,450,867
Colorectal Cancer	14	\$8,435,727
Immunotherapy	10	\$7,581,382
Listeria Vaccine for Cancer*	0	0
Liver Cancer	11	\$7,042,895
Lymphoma	3	\$1,586,149
Mesothelioma	8	\$5,632,698
Neuroblastoma	7	\$4,907,579
Pancreatic Cancer	8	\$5,069,558
Pediatric Brain Tumor	5	\$3,234,982
Rare Cancers	5	\$4,711,460
Stomach Cancer	7	\$4,373,036

^{*}The FY 2019 PRCRP did not receive any applications for Listeria vaccine for cancer. One application funded under the Brain Cancer topic area proposed using Listeria vaccine; recommend funding for this project totaled \$550,491.

Table 3. FY 2009-FY 2018 PRCRP Awards: Reported Outcomes

OUTCOME TYPES	Totals*
Follow-On Funding Obtained (Private and Government)	183
Patent (Provisional and Licensures)	60
Presentation/Abstracts	1,113
Publications	838

^{*}As of July 31, 2020.

MILITARY HEALTH AND CANCER: SERVICE MEMBERS AND THEIR FAMILIES

Congressional language directed that PRCRP-funded research should be relevant to Service members and their families. The PRCRP develops its investment strategy around the requirement to be relevant to military health concerns. The FY 2019 PRCRP addressed these core issues and relevance to military service by *requiring* that all applications address at least one of the FY 2019 PRCRP Relevance to Military Focus Areas, presented in Table 4.

Table 4. FY 2019 Relevance to Military Focus Areas

Environmental Exposures	Environmental/exposure risk factors associated with cancer
Mission Readiness	Gaps in cancer prevention, early detection/diagnosis, prognosis, treatment, and/or survivorship that may affect the general population, but have a particularly profound impact on the health and well-being of military Service members, veterans, and their beneficiaries

ENVIRONMENTAL EXPOSURES

Service members deployed worldwide, both in developed and developing nations, sustain environmental exposures linked to cancer risk. Multiple hazards potentially contribute to the risk of carcinogenesis. Exposures linked to increased cancer risk include, but are not limited to, chemical weapons or storage, ionizing radiation, herbicides, electromagnetic fields, jet fuel, organic materials, biological agents, and ultraviolet radiation (Table 5). The U.S. Department of Veterans Affairs (VA) acknowledged that certain exposures increase cancer risk among Service members and their families (Table 4).

MISSION READINESS

A Service member's cancer diagnosis affects not only the individual Soldier, Airman, Marine, or Sailor, but also his or her entire unit and mission. Each Service member plays a crucial role in mission readiness. Research that improves survival, while minimizing side effects, will have a major impact on mission readiness by enabling an active duty Service member to return to duty. Additionally, mission readiness extends to family members. Service members become affected when a member of their family, or support system, receives a cancer diagnosis. Time off to assist in the care, recovery, and well-being of family members will affect the overall unit force readiness. This may lead to a request for transfer, exceptional status, or even separation. A healthy family unit, free of serious illness, allows the Service member to focus on his or her role and facilitates the overarching military mission.

It is also important to note that the Military Health System (MHS) may cover military beneficiaries and veterans; thus, any improvements within the cancer care spectrum will also decrease the burden of health care on the overall MHS. There are more than 300,000 military beneficiaries with a cancer diagnosis, a prevalence of 4.1 percent, comprised of more than 60 different cancer types [1]. Treatment costs per cancer type differ, with bladder cancer being one of the most expensive treatments (average cost of \$120,000 per patient from the time of diagnosis until death) [2]. The MHS continues to diagnose and treat active duty Service members for a wide variety of cancers [3]. Addressing the key elements of cancer research and

patient care is crucial to the mission of the PRCRP in relation to Service members, their families, veterans, and the American public. The profound impact of cancer research with respect to the military will reduce the burden of cancer on military families and improve force readiness. Furthermore, successful new studies will lead to innovative ways for preventing cancer development; improved diagnostic/detection methods; prognostic information; novel treatments; and better ways to cope with quality of life issues.

Table 5. FY 2019 PRCRP Topic Areas: Cancer Risk and Military Service

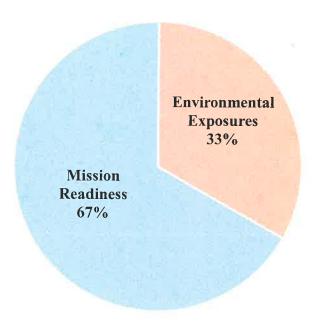
Topic Areas	Relevance to Military Health
Bladder Cancer (refs. 3-6)	Bladder cancer (BCa) is the fourth most common cancer among U.S. Service personnel, affecting over 32,000 Service members since 1995. A majority of U.S. Service members are male (approximately 85 percent), and men outrank women by 3:1 in BCa incidence and mortality. Along with smoking, occupational exposure to chemical carcinogens present in paints and dyes increases BCa risk.
Blood Cancers (Leukemia, Lymphoma, Myeloma) (<u>refs. 7-8</u>)	Exposure to toxic chemicals/herbicides shown to increase risk; the VA acknowledged the association of Agent Orange and other herbicides with blood cancers among veterans. Ionizing radiation exposure has demonstrated correlation with increased risk of blood cancer.
Adult and Pediatric Brain Cancer (Brain Cancer, Neuroblastoma, and Pediatric Brain Tumors) (refs. 9-10)	Adult Brain Cancer: Occupational exposure link (especially electromagnetic fields). Patients with traumatic brain injury are at increased risk of acquiring brain tumors (hazard ratio of 4.67). Pediatric Brain Tumor (PBT)/Neuroblastoma: In all childhood populations, PBT has the highest mortality rates of any childhood cancer; affects mission readiness of Service members with children.
Cancers in Children (0-14 years of age), Adolescents (15-24 years of age) ,Young Adults (25-39 years of age) (refs. 10-11)	Cancers incurred by active duty Service members' support systems (e.g., family members) affect mission readiness: 86 percent of the military are under 39 years of age (adolescents and young adults 15–39 years of age).
Gut Cancers (Colorectal, Liver, Pancreatic, Stomach Cancer) (<u>refs. 12-15</u>)	Colorectal Cancer: Screening of active duty Service members decreases mortality rates. A 2014 report showed that 72 percent of veterans are up to date on age-related screening. Other studies demonstrate a potential implication of infectious diseases with increased mortality rates. Liver Cancer: The veteran population has an increased hazard ratio: increased alcohol use leads to increased risk. Pancreatic Cancer: Direct link to environmental exposures (e.g., herbicides, smoking) may increase odds ratio among veterans. Stomach Cancer: Due to increased exposure to infectious agents (e.g., Helicobacter pylori), veterans may be at increased risk.
Mesothelioma (<u>ref. 16</u>)	Veterans account for more than 33 percent of all cases in the U.S; asbestos exposure is the leading cause.

Table 6 summarizes the different PRCRP Military Health Focus Areas during FY 2014–FY 2019.

Table 6. FY 2014-FY 2019 Military Health Focus Areas - Aggregated

Aggregate Military Health Focus Area	FY 2014–FY 2019 Military Health Focus Area	
Mission Readiness	Gaps in cancer research that impact the health of military beneficiaries	
	Gaps in cancer prevention, early detection/diagnosis, prognosis, treatment, and/or survivorship that may impact mission readiness and the health and well-being of military members, veterans, their beneficiaries, and the general public	
	Gaps in cancer prevention, diagnosis, early detection, or treatment that may have a particularly profound impact on military health	
	Gaps in cancer prevention, early detection/diagnosis, prognosis, treatment, and/or survivorship that have a particularly profound impact on the health and well-being of military Service members, veterans, and their beneficiaries	
Environmental Exposures	,	
	Environmental exposure risk factors associated with cancer	
	Military-relevant risk factors associated with cancer (e.g., ionizing radiation, chemicals, infectious agents, environmental carcinogens)	
	Military-relevant risk factors associated with cancer (e.g., ionizing radiation, chemicals, infectious agents, environmental carcinogens, and stress)	
	Military-relevant environmental risk factors associated with cancer	

Figure 2. PRCRP FY 2014–FY 2019 Investment by Military Health Focus Area (Percent of Research Dollars)



SUMMARY

In FY 2019, the PRCRP published an educational video for the research community regarding military health concerns and cancer effects (https://youtube.com/watch?v=g3TiEf97Ch0). The overarching theme of the PRCRP is to improve the quality of life of Service members, their families, and the American public affected by cancer. This singular idea emphasizes the PRCRP's strategy of funding research on cancers that may develop due to exposures relevant to unique military situations/settings, as well as addressing knowledge gaps in cancer care and research that may have a profound effect on mission readiness and the health and well-being of all military beneficiaries. Through innovative mechanisms, relevance to military health, and targeted investment strategies, the PRCRP answers the need to promote high-impact research for cancer prevention, detection, treatment, and survivorship for Service members, their families, and the American public.

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