



THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

SEP 14 2005

The Honorable John W. Warner
Chairman, Committee on Armed Services
United States Senate
Washington, DC 20510-6050

Dear Mr. Chairman:

This replies to the request in the House Armed Services Committee Report 108-491 for the Secretary of Defense to review ongoing clinical research efforts within the military departments and to report to the Congressional defense committees any programs that should be added to Department of Defense (DoD) efforts. This report was due February 1, 2005, but additional months of work were required in order to perform the appropriate analysis, and so the report is provided now.

I directed the U.S. Army Medical Research and Materiel Command to prepare the report and to coordinate the response through the Armed Services Biomedical Research Evaluation and Management Committee. A working group was formed with representatives from the Army, Navy, Air Force, and Uniformed Services University of the Health Sciences to conduct the review. The group selected a list of disease categories based on reported high incidence in the active duty population and the current impact on the Military Health System in terms of healthcare cost and workload required to care for DoD beneficiaries. A data call, forwarded through me to the Services in February 2005, was required to perform the review of DoD research programs addressing these disease categories. The Services and DoD components have collected and correlated the data for analysis, formulated recommendations, and prepared the final report. The enclosed report was reviewed and approved by the Armed Services Biomedical Research Development and Management Committee.

I look forward to working with you to strengthen research funding into disease areas that are not presently adequately addressed. My goal is to ensure a fit and healthy force. The report highlights five areas for special consideration. These areas are rehabilitation; head, neck, face, and/or eye injury; post-traumatic stress disorder; substance abuse, alcohol, and/or drug; and respiratory infections, including associated respiratory diseases. We stand ready to explore these priorities further as you debate future programs and priorities.

Thank you for your continued support of the Military Health System.

Sincerely,


William Winkenwerder, Jr., MD

Enclosure:

As stated

cc:

Senator Carl Levin



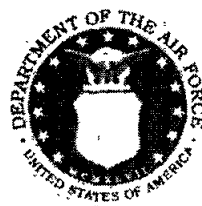
Report on the:

Department of Defense Clinical Research Program Review

August 11, 2005

In response to:

House Armed Services Committee Report 108-491:
Title II - Research, Development, Test & Evaluation (RDT&E) Overview, Army
RDT&E, Items of Special Interest, Clinical Research Programs,
Pages 150-151, May 14, 2004.



From the Department of Defense Clinical Research Program Review Working Group:

A working group consisting of representation from the Army, Navy, Air Force, and Uniformed Services University of the Health Sciences coordinated the Clinical Research Program Review and compiled this report. The following signatures of the primary working group members acknowledge participation in the review process and that the report reflects the outcome of the working group's review but does not reflect final service or Department of Defense opinion.



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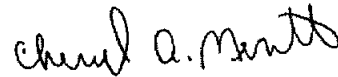
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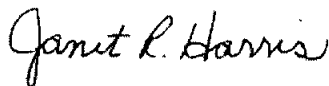
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Executive Summary

E-1 Purpose

House Armed Services Committee (HASC) Report 108-491 requested that the Secretary of Defense review the clinical research efforts within the military departments and report to the congressional defense committees whether any research programs should be added to the Department of Defense's (DoD's) efforts. This DoD Clinical Research Program Review report is provided as requested by HASC Report 108-491.

E-2 Background

The DoD manages one of the largest health care systems in the world and it conducts or manages a vast array of medical research and development projects. The medical research efforts within the DoD are supported and conducted through a variety of mechanisms. Biomedical research (Program 6) is funded and executed through service core research, development, test and evaluation (RDT&E) programs and is based on service operational priorities. Clinical research (Program 8) is funded through the Assistant Secretary of Defense (Health Affairs) (ASD)(HA) and includes but is not limited to programs such as graduate medical education, with funds going to the Uniformed University of the Health Sciences (USUHS) and to the services' medical treatment facilities. Clinical research is also conducted through cooperative agreements with other services and with federal agencies such as the National Institutes of Health, through Congressional Special Interest Programs, and through partnerships with the commercial sector. The research is conducted within DoD research and treatment facilities, as well as in extramural facilities, and includes exploratory basic research through advanced development to U.S. Food and Drug Administration approval and licensure.

The ASD(HA) directed the U.S. Army Medical Research and Materiel Command (USAMRMC) to execute and coordinate the response to HASC Report 108-491 through the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee. To that end, the USAMRMC established a working group of representatives from the Army, Navy, Air Force, and USUHS to conduct the review and provide recommendations regarding the establishment of formal research programs as they relate to military service. For purposes of this report, the working group considered military service to include active duty, Reserve, National Guard, Army, Navy, Air Force, Marine, and other federal uniformed services health care beneficiaries.

E-3 Method Used to Develop Recommendations

For the review, 14 categories of diseases with 43 subcategories were selected from active duty service member and DoD beneficiary databases. These diseases were selected primarily based on their impact on the military health system for active duty service members, consistent with the HASC instruction to consider research on diseases as they relate to military service. Additionally, diabetes and lung cancer were included, as these were specifically mentioned as potential candidates for formal research programs in the HASC report, and mesothelioma was included at the request of the Office of ASD(HA). A data call to the services was initiated February 2005 to obtain the necessary research program data for conducting the review.

To identify missed opportunities to conduct research, the working group first excluded from consideration disease subcategories that had either significant formal programs or a substantial amount of DoD research effort. Next, the remaining disease subcategories were assessed for

inclusion or exclusion based upon three factors: (1) whether the disease subcategories are addressed by current DoD research projects; (2) the level of effort, as defined by numbers of projects and total funding; and (3) the relative level of impact on the military medical system. The following were additional considerations: disparity between the research efforts and the medical system impact data, impact on military readiness, and whether the illness or injury related directly to deployed service in Operation Enduring Freedom (OEF) or Operation Iraqi Freedom (OIF). Finally, a prioritized list of 10 disease subcategories was developed from which the top four were put forward as recommendations of research areas for special consideration.

E-4 Recommendations

Based on the analysis conducted and the primary RDT&E mission to protect and sustain a fit and healthy force, the working group recommended four areas for special consideration, and the area of respiratory infections was added at the request of the ASBREM Committee:

- Rehabilitation
- Head, Neck, Face, and/or Eye Injury
- Post-Traumatic Stress Disorder
- Substance Abuse, Alcohol and/or Drug
- Respiratory Infections, including Associated Respiratory Diseases

Research in these areas will lead to new information and technologies that may benefit service members, their families, and military retirees. Research on diabetes and lung cancer, areas specifically mentioned by the HASC, was reviewed. However, the data for research conducted in the DoD beneficiary population indicate that diabetes ranked second in funds expended for FY03 and FY04. Lung cancer ranked within the top 10 for consideration as it was not studied extensively in military health system beneficiaries and it represents a long-term health care issue for beneficiaries. However, because it ranked 16 in funds expended, lung cancer was not recommended for special consideration.

The following statements should be taken into consideration by Congress and others when using the preceding recommendations for the establishment of formal programs to fight illnesses and injuries as they relate to military service:

- The 14 disease categories and their 43 subcategories do not represent the full spectrum of medically related research conducted or managed by DoD.
- The analysis conducted herein is limited to DoD-conducted and -managed research and does not consider complementary programs being conducted by other research and development entities worldwide including NIH, universities, and the commercial sector.
- The areas for special consideration provided here do not address the specific direction that any new research program should take. Thus, should a requirement for the addition of particular programs be forthcoming, further analysis must be conducted to determine the appropriate direction, approach, and resources for the research program(s), with consideration not to jeopardize existing programs. In particular, consideration should be given to expansion of current outcomes research efforts and their risk mitigation strategies. The clinical end results—outcomes—are important factors in the “real life” situation and quality of life experiences of health care beneficiaries.
- Each service has different research priorities than the recommendations presented herein, and existing programs are vital to the individual service missions. Therefore, these programs should continue to be fully supported.

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1.0 BACKGROUND

1.1 Purpose

House Armed Services Committee (HASC) Report 108-491 requested that the Secretary of Defense review clinical research efforts within the military departments and report to the congressional defense committees whether any research programs should be added to the Department of Defense's (DoD's) efforts. An excerpt of the relevant section of the HASC report is provided in **Appendix 1**. This DoD Clinical Research Program Review report is provided as requested by HASC Report 108-491.

1.2 Scope of DoD Medical Research Efforts

Medical research efforts within the DoD are supported and conducted through a variety of mechanisms. Biomedical research (Program 6) is funded and executed through service core research, development, test and evaluation (RDT&E) programs and is based on service operational priorities. Clinical research (Program 8) is funded through the Assistant Secretary of Defense (Health Affairs) (ASD)(HA) and includes but is not limited to programs such as graduate medical education, with funds going to the Uniformed University of the Health Sciences (USUHS) and to the services' medical treatment facilities. Clinical research is also conducted through cooperative agreements with other services and with federal agencies such as the National Institutes of Health (NIH), through Congressional Special Interest Programs, and through partnerships with the commercial sector. The research is conducted within DoD research and treatment facilities, as well as in extramural facilities, and includes exploratory basic research through advanced development to U.S. Food and Drug Administration (FDA) approval and licensure.

2.0 REVIEW METHODOLOGY

2.1 Tri-service/DoD Working Group

The ASD(HA) directed the U.S. Army Medical Research and Materiel Command (USAMRMC) to execute and coordinate the response to the HASC report request [1] and to coordinate the response through the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee. To that end, the USAMRMC established a working group of representatives from the Army, Navy, Air Force, and USUHS to conduct the review and provide recommendations regarding the establishment of formal research programs as they relate to military service. **Appendix 2** lists the membership of the working group.

2.2 Assumptions

2.2.1 Interpretation of HASC Language

Additional clarification on the intent of the congressional language was obtained from HASC and the Office of Assistant Secretary of Defense (Health Affairs) (OASD(HA)) staff. Guidance from the HASC professional staff was to review the data to "identify those areas of disease research in which there is a cohort of people in the DoD who are affected by the disease and who would, because they are under military control and monitored and treated in a military medical system, provide statistical bases for research in such diseases" [2]. The OASD(HA) provided further guidance that the review should include the clinical investigation programs within the military medical centers. In addition, the working group assumed that Congress was primarily interested in diseases observed within the military health care system that have a large impact (cost, clinical workload, etc.) and not a detailed

look at all diseases observed. The working group interpreted diseases to include illnesses and injuries. Additionally, Congress directed that the establishment of formal programs be considered as they relate to military service. For purposes of this report, the working group considers military service to include active duty, Reserve, National Guard, Army, Navy, Air Force, Marine, and other federal uniformed services health care beneficiaries, as related to their active duty service.

2.2.2 Scope of Review

Although the HASC report language suggested that the review be limited to programs involving clinical research (i.e., human subject research), the working group assumed that a broader scope was of interest to the Committee. This assumption was based on the fact that medical research programs often include a variety of interrelated projects ranging from preclinical studies to clinical trials of potential treatments. Depending on the current stage of knowledge in a disease area, the level of research being conducted may not yet be at the clinical studies stage. Therefore, the review was designed to encompass all research from preclinical to clinical and to consider all research programs under DoD management for a particular disease area.

2.2.3 Definition of Research Project

A significant concern in reporting data on research projects is that the size and scope of all projects either within a service or across the services are not equivalent. Therefore, it was necessary to provide the services with the flexibility in how their data were reported in terms of projects. In some cases, logic dictated reporting of a single large project that involved multiple protocols, whereas other cases required reporting at the level of an individual research protocol or groups of research protocols to provide the necessary information.

2.2.4 Adequacy of Research Level of Effort

An objective determination of the adequacy of the DoD's level of effort (i.e., funding) for research in a particular disease area would be complex. Such a determination would take into consideration factors such as the impact of the disease on the individuals, unit readiness, and the military health system; the goals of the research and progress made; as well as a comparison of DoD to non-DoD research in that area. To assess the DoD's level of effort and contributions to U.S. and worldwide efforts in a disease area, one would need to conduct a review of all current research (DoD and other) on the disease. This type of review was deemed to be outside the intent of the congressional request and time frame given. Rather, it was assumed by the working group that the analysis should be limited to the determinations of whether the DoD has a formal RDT&E or a congressionally directed research program in a disease area, whether the DoD active duty or beneficiary population is being enrolled in clinical trials for a disease area, and the impact of the disease on the military health system.

2.3 Interim Reports

The February 1, 2005 due date to Congress for the report was not feasible for two reasons: It was necessary to solicit data from the organizations within the services and DoD regarding their programs, and the staffing requirements for the services, the ASBREM Committee, and ASD(HA) required additional time. Consistent with the ASD(HA) direction, interim reports were prepared and sent to Congress on January 26 [3] and May 20, 2005 [4].

2.4 Determination of Diseases of Interest

Diseases (i.e., illnesses and injuries) were selected primarily based on their impact on the military health system as measured by effects on active duty service members, consistent with the HASC instruction to consider establishing formal programs as they relate to military service. Various sources of data were considered for determining disease impact and subcategories including the U.S. Army Center for Health Promotion and Preventive Medicine (CHPPM) medical system impact data for service members in 2003 [5]; 2004 inpatient data from the Military Health System Management and Reporting Tool (M2) database Standard Inpatient Data Record (SIDR) and Health Care Service Record (HCSR) for Army, Navy, Air Force, and Marines including active duty, family members, and retirees; and the subject matter expertise of the working group. The CHPPM report [5] was selected as a primary source and used to devise the disease classification scheme because it provided recent published trend data for medical system impact – patient encounters, individuals affected, and hospital bed days.

Four of the major CHPPM categories – signs and symptoms, maternal conditions, oral conditions, and congenital anomalies – were excluded predominately because they were not considered to be specific disease states or were not directly related to military service. Within the remaining CHPPM categories, research project data were separately collected for each of the high-impact subcategories, and combined data for all of the remaining subcategories within the same major category were collected under an “All Other” heading. Additionally, diabetes and lung cancer were included because these subcategories were specifically mentioned as potential candidates for formal research programs in the HASC report, and mesothelioma was included at the request of OASD(HA).

Table 1 provides the list of disease categories and subcategories selected for the data call to the services. **Appendix 3** shows the CHPPM data [5] adjusted to the data call disease subcategories.

Table 1. Diseases/Conditions for Data Call

Category	Subcategory
Diseases of the Circulatory System	Essential Hypertension Ischemic All Others (Excluding Neoplasms)
Injury and Poisoning	Poisoning, Not Chemical or Biological Burn Head, Neck, Face, and/or Eye Injury Rehabilitation All Other Injuries
Diseases of the Musculoskeletal System and Connective Tissue	Back Knee All Others (Excluding Neoplasms)
Diseases of the Respiratory System	Allergic Rhinitis Asthma All Others (Excluding Neoplasms)
Diseases of the Digestive System	Gastroenteritis and Colitis All Others (Excluding Neoplasms)

Table 1. Diseases/Conditions for Data Call (cont.)

Category	Subcategory
Neoplasms	Mesothelioma Lung Cancer, Other Than Mesothelioma Breast Cancer Prostate Cancer Ovarian Cancer Cancers of Blood Forming Tissue (Leukemia, Lymphoma, and Myeloma) All Others
Diseases of the Genitourinary System	All (Excluding Neoplasms)
Endocrine, Nutritional, and Metabolic Diseases and Immunity Disorders	Diabetes Obesity Nutritional Deficiencies All Others (Excluding Neoplasms)
Infectious and Parasitic Diseases	Leishmaniasis Malaria HIV Sexually Transmitted Diseases, Other Than HIV All Others
Diseases of the Nervous System and Sense Organs	Headache All Others (Excluding Neoplasms)
Mental Disorders	Substance Abuse, Alcohol and/or Drug Tobacco Dependence Post-Traumatic Stress Disorder All Others
Diseases of the Skin and Subcutaneous Tissue	All (Excluding Neoplasms)
Blood and Immune System Diseases	All (Excluding Neoplasms)

2.5 Research Program Data Call

2.5.1 Tasking to Services

As data on the research programs' efforts for these disease areas were not available centrally, a data call was issued to the services via an ASD(HA) tasking on February 2, 2005 [6]. Research program data were requested from the following organizations: Army, Navy, Air Force, USUHS, and the Defense Advanced Research Projects Agency.

2.5.2 Research Program Data Collected

The data call obtained information on research projects and protocols addressing the disease subcategories listed in Table 1, including the clinical group under study (if any), funding source, and FY03 and FY04 funding levels. Each of these parameters is discussed in the following sections.

2.5.2.1 Disease Category/Subcategory

Each research project was classified by the respondents with respect to the disease category/subcategory that it addresses and the primary study population. Judgment on the part of respondents was necessary to classify the projects accordingly. Further, the disease categories/subcategories surveyed in the data call do not represent the full spectrum of DoD disease research.

2.5.2.2 Study Group Classification

Research projects were classified by the primary clinical study group population into one of four classifications: Human – Active Duty; Human – All DoD Beneficiaries; Pre-Clinical – Military; and Not Applicable. Human – Active Duty includes clinical studies where the primary subject population consists of active duty military personnel. Human – All DoD Beneficiaries includes clinical studies where the primary subject population consists of DoD health care beneficiaries. This classification includes retired military personnel and family member/dependents of military personnel and may include studies with active duty participants if the primary subject population would not be considered active duty. Pre-Clinical – Military includes all nonhuman (preclinical) studies that are conducted in a military facility. Not Applicable consists of all studies (human or preclinical) that do not fall within one of the other three categories. Examples are extramural research or military research conducted overseas on a non-DoD beneficiary population.

The study group classifications were designed to address the guidance from the HASC professional staff to “identify those areas of disease research in which there is a cohort of people in the DoD who are affected by the disease and who would, because they are under military control and monitored and treated in a military medical system, provide statistical bases for research in such diseases” [2]. The study groups Human – Active Duty and Human – All DoD Beneficiaries are directly relevant to this interpretation of the HASC language. This allowed a determination of the disease states for which enrollment of the DoD population in clinical research studies was occurring.

2.5.2.3 Funding Data

Funding levels were collected for each project for FY03 and FY04 in \$K, the two most recent fiscal years with complete data available. FY05 data were not considered because not all funding allocations had not been made by the services for FY05 at the time of the data call. For some projects, it was necessary for respondents to estimate funding levels. For example, some projects that addressed multiple disease subcategories were split into subprojects for reporting purposes, and per year funding for projects spanning multiple years may not have been readily available. Further, medical treatment facility (MTF) funding data were not reported for clinical investigation programs conducted as part of graduate medical education, as these projects do not receive additional funds but are conducted within the available resources of the MTFs.

In addition, the funding source for each project was categorized as follows: MTF; Cooperative Research and Development Agreement; Congressional Special Interest Programs; Core Research and Development Programs; NIH (any institute); Non-DoD federal institutes, other than NIH; programs in one service/component, funded by another service; commercial sector; and other. This information was not directly relevant to the HASC instruction but allowed for a determination of how the research on each of the diseases was distributed across the different funding mechanisms.

2.5.3 Resolution of Potential Duplicate Reporting

The potential for duplicate reporting of projects by the services was a concern. For example, in one instance in which one service was executing funding that was provided by another service, a project was being conducted at multiple centers. In another example, two similar projects appeared identical because the differentiating factors were not captured by the data call. As such, cross-service duplications were considered as one project, and each instance of a multicenter project was treated as a separate project.

2.6 Analysis for Research Areas of Opportunity within DoD

The working group used a three-phased approach in considering the data collected to identify missed opportunities to conduct research into other vital areas. First, the working group excluded from consideration disease subcategories that had either formal DoD research programs or a significant amount of DoD research effort.

In the second phase, the remaining disease subcategories were assessed for inclusion or exclusion by considering three factors: (1) which disease subcategories are or are not addressed by DoD research projects; (2) the level of effort, as defined by numbers of projects and total funding, for projects where active duty service members and other DoD beneficiaries were actively enrolled in studies in the disease subcategories; and (3) the relative level of impact on the military medical system for the active duty population due to the disease subcategories surveyed (Appendix 3). The following were additional considerations: disparity between the research efforts and the medical system impact data, impact on military readiness, and whether the illness or injury related to deployed service in Operations Enduring and Iraqi Freedom (OEF and OIF).

The third and final phase developed a prioritized list of 10 illness and injury subcategories from those identified in phase two. Consensus agreement of the working group ranked these subcategories based on their priorities (1 to 10) as potential research areas, with those ranked high (1 to 4) to be put forward as a recommendation of research areas for special consideration.

2.7 ASBREM Committee Review of Working Group Recommendations

The recommendations of the working group were coordinated through the ASBREM Committee. The Committee met on August 2, 2005 to consider the recommendations of the working group, and the Committee's comments and recommendations were provided to the ASD (Force Health Protection & Readiness) on August 9, 2005 [7] and are incorporated into this report.

3.0 DOD RESEARCH PROGRAM SUMMARY DATA BY DISEASE SUBCATEGORIES

Table 2 summarizes the data collected on the DoD research programs. For each of the 43 disease subcategory areas, the numbers of projects and FY03 and FY04 funding data (including the total for FY03 and FY04) are presented in the table. Within each of these parameters, the disease subcategories are ranked ("1" representing the highest level of effort). Further, these parameters are presented for both DoD total research projects (all study groups combined) and the subset of projects enrolling the DoD patient population (active duty and DoD beneficiary study groups).

Table 2. Research Program Summary Data for DoD Clinical Research Program Review

Data Call Category/Subcategory	DoD Total Research (Active Duty, DoD Beneficiaries, Preclinical-Military, Not Applicable)								DoD Subject Populations (Active Duty and DoD Beneficiaries)							
	Number of Projects ¹		FY03 Funding		FY04 Funding		Total FY03 and FY04 Funding		Number of Projects ¹		FY03 Funding		FY04 Funding		Total FY03 and FY04 Funding	
	#	Rank ²	\$K	Rank ²	\$K	Rank ²	\$K	Rank ²	#	Rank ²	\$K	Rank ²	\$K	Rank ²	\$K	Rank ²
Diseases of the Circulatory System																
Essential Hypertension	9	29	12	37	170	36	182	37	7	24	0	34	161	30	161	33
Ischemic	35	19	3481	19	9423	15	12904	17	7	24	204	24	0	37	204	32
All Others (Excluding Neoplasms)	81	8	9419	11	10501	13	19920	11	58	8	1247	13	1400	15	2647	15
Injury and Poisoning																
Poisoning, Not Chemical or Biological	1	34	8	38			8	42	0	30	0	34	0	37	0	39
Burn	17	24	191	33	600	33	791	34	13	20	191	25	600	24	791	24
Head, Neck, Face, and/or Eye Injury ³	33	20	17608	7	21172	8	38780	8	19	17	1568	12	3152	11	4720	11
All Other Injuries	70	11	38831	2	31846	6	70677	4	37	12	9104	2	9184	3	18288	3
Rehabilitation	6	31	0	40	2152	24	2152	31	5	26	0	34	311	28	311	29
Diseases of the Musculoskeletal System and Connective Tissue																
Back	12	27	13	36	32	40	45	39	11	21	13	31	32	33	45	35
Knee	20	22	33	35	10	41	43	40	18	18	33	30	10	35	43	36
All Others (excluding Neoplasms)	118	6	5066	17	1300	30	6366	22	92	3	1634	11	403	27	2037	18
Diseases of the Respiratory System																
Allergic Rhinitis	6	31	0	40	41	39	41	41	2	28	0	34	3	36	3	38
Asthma	15	25	1043	27	1170	32	2213	30	14	19	870	16	940	19	1810	20
All Others (Excluding Neoplasms)	52	15	3414	20	3896	21	7310	18	35	13	2978	9	2937	12	5915	9
Respiratory Infections																
Upper Respiratory ⁴	12	27	6991	14	8700	16	15691	15	10	22	6200	4	8700	4	14900	4
All Others	11	28	2	39	86	38	88	38	7	24	2	33	31	34	33	37
Diseases of the Digestive System																
Gastroenteritis and Colitis	13	26	97	34	136	37	233	36	13	20	97	26	136	31	233	30
All Others (Excluding Neoplasms)	62	12	708	28	3863	22	4571	25	59	7	708	18	3863	9	4571	12
Neoplasms																
Mesothelioma	3	33			377	35	377	35	2	28			0	37	0	39
Lung Cancer, Other Than Mesothelioma ⁵	44	17	7420	12	6327	17	13747	16	38	11	12	32	631	23	643	26
Breast Cancer	1100	1	65013	1	61810	1	126823	1	100	2	12521	1	14068	2	26589	1
Prostate Cancer	509	2	31599	5	37695	4	69294	5	76	4	784	17	887	20	1671	21
Ovarian Cancer	77	9	6339	15	10223	14	16562	14	26	15	0	34	3229	10	3229	14
Cancers of Blood Forming Tissue (Leukemia, Lymphoma, Myeloma)	83	7	376	31	2120	25	2496	29	76	4	0	34	701	22	701	25
All Others	211	4	16080	8	20429	9	36509	9	169	1	4280	7	5247	6	9527	6
Diseases of the Genitourinary System																
All (Excluding Neoplasms)	76	10	317	32	5105	19	5422	24	73	5	317	22	871	21	1188	23
Endocrine, Nutritional and Metabolic Diseases and Immunity Disorders																
Diabetes	46	16	11599	10	16878	10	28477	10	24	16	8150	3	15036	1	23186	2
Obesity	19	23	1241	25	5696	18	6937	19	18	18	1241	14	4064	8	5305	10
Nutritional Deficiencies	6	31	1562	23	1330	29	2892	28	5	26	947	15	1195	18	2142	16
All Others (Excluding Neoplasms)	54	14	1524	24	1666	27	3190	26	38	11	60	28	98	32	158	34

Table 2. Research Program Summary Data for DoD Clinical Research Program Review (cont.)

Data Call Category/Subcategory	DoD Total Research (Active Duty, DoD Beneficiaries, Preclinical-Military, Not Applicable)								DoD Subject Populations (Active Duty and DoD Beneficiaries)							
	Number of Projects ¹		FY03 Funding		FY04 Funding		Total FY03 and FY04 Funding		Number of Projects ¹		FY03 Funding		FY04 Funding		Total FY03 and FY04 Funding	
	#	Rank ²	\$K	Rank ²	\$K	Rank ²	\$K	Rank ²	#	Rank ²	\$K	Rank ²	\$K	Rank ²	\$K	Rank ²
Infectious and Parasitic Diseases																
Leishmaniasis ⁵	7	30	1789	22	4697	20	6486	21	1	29					0	39
Malana	15	25	22368	6	27592	7	49960	7	1	29			0	37	0	39
HIV	41	18	14644	9	35756	5	50400	6	30	14	67	27	286	29	353	28
Sexually Transmitted Diseases, Other Than HIV	4	32	696	29	589	34	1285	33	4	27	696	19	589	25	1285	22
All Others	157	5	33063	4	55252	2	88315	2	62	6	37	29	547	26	584	27
Diseases of the Nervous System and Sense Organs																
Headache	7	30	0	40	0	42	0	43	7	24	0	34	0	37	0	39
All Others (Excluding Neoplasms)	250	3	38535	3	48662	3	87197	3	100	2	2513	10	1254	17	3767	13
Mental Disorders																
Substance Abuse, Alcohol and/or Drug ⁷	12	27	3393	21	3380	23	6773	20	4	27	231	23	0	37	231	31
Tobacco Dependence ⁸	9	29	650	30	1276	31	1926	32	8	23	548	20	1269	16	1817	19
Post-Traumatic Stress Disorder ⁹	11	28	5535	16	11404	11	16939	13	6	25	3641	8	4546	7	8187	7
All Others	70	11	7248	13	11269	12	18517	12	48	9	5220	5	8016	5	13236	5
Diseases of the Skin and Subcutaneous Tissue																
All (Excluding Neoplasms)	27	21	4777	18	1583	28	6360	23	26	15	4700	6	1583	14	6283	8
Blood and Immune System Diseases																
All (Excluding Neoplasms)	56	13	1072	26	1963	26	3035	27	47	10	392	21	1728	13	2120	17
Legend																
¹ Variations in service reporting of projects/protocols made it not feasible to count projects by FY ² A ranking of "1" represents highest level for this measure (i.e., greatest number of projects or highest funding). Lowest ranking varies from 30 to 43 by measure due to duplicate values ³ Subsequent to the primary data call, additional information was received on related congressional special interest programs. There were 6 additional head, neck, face, and/or eye injury projects reported (\$2.1M in FY03 and \$2.1M in FY04). Two projects had active duty service members or all DoD beneficiaries as the primary subject population (\$838K and \$838K, FY03 and FY04, respectively) ⁴ Subsequent to the primary data call, additional information was received on related congressional special interest programs. There were 2 additional upper respiratory infection projects reported (\$101K in FY03 and \$298K in FY04). Neither of these projects had active duty service members or all DoD beneficiaries as the primary subject population ⁵ Subsequent to the primary data call, additional information was received on related congressional special interest programs. There were 2 additional lung cancer (other than mesothelioma) projects reported (\$2.8M in FY03 and \$2.8M in FY04). One project had all DoD beneficiaries as the subject population (\$1.6M and \$1.6M, FY03 and FY04, respectively) ⁶ Subsequent to the primary data call, additional information was received on related congressional special interest programs. There was 1 additional leishmaniasis project reported (\$351K in FY03 and \$351K in FY04). This project did not have active duty service members or all DoD beneficiaries as the primary subject population ⁷ Subsequent to the primary data call, additional information was received on related congressional special interest programs. There were 28 substance abuse (alcohol and/or drug) additional projects reported (\$6.3M in FY03 and \$8.3M in FY04). Seven projects had active duty service members or all DoD beneficiaries as the primary subject population (\$1.7M and \$2.3M, FY03 and FY04, respectively) ⁸ Subsequent to the primary data call, additional information was received on related congressional special interest programs. There were 3 additional tobacco dependence projects reported (\$1.2M in FY03 and \$1.2M in FY04). These projects all had active duty service members as the primary subject population. ⁹ Subsequent to the primary data call, additional information was received on related congressional special interest programs. There was 1 additional post-traumatic stress disorder project reported (\$111K in FY03 and \$111K in FY04). This project had all DoD beneficiaries as the primary subject population																

4.0 RESEARCH AREAS OF OPPORTUNITY WITHIN DOD

The following research areas were identified by the working group as potential areas for research programs using the approach described in Section 2.6: (1) Rehabilitation; (2) Head, Neck, Face, and/or Eye Injury; (3) Post-Traumatic Stress Disorder; (4) Substance Abuse, Alcohol and/or Drug; (5) Respiratory Infections; (6) Infectious and Parasitic Diseases – All Others; (7) Diseases of the Digestive System – Gastroenteritis and Colitis; (8) Diseases of the Digestive System – All Others (Excluding Neoplasms); (9) Neoplasms – Lung Cancer, Other Than Mesothelioma; and (10) Tobacco Dependence. **Appendix 4** provides the definitions developed by the working group to establish what each area encompassed for the purpose of this report. These definitions take into account the overall illnesses and injuries, as well as aspects of the conditions that are relevant to the military.

5.0 DISCUSSION

The DoD provides health care services to a very heterogeneous population across the age range from birth to death, from the healthy and able-bodied to the injured, ill, and disabled. These individuals suffer illnesses and injuries similar to those of the general U.S. population, along with “military unique” illnesses and injuries as a result of military service and deployment on combat and other missions. Many federal uniformed service members and their beneficiaries may obtain their health care for many decades within the military health system. Thus, captured within the military health system are longitudinal sets of medical records for individuals and their dependents on illnesses and injuries that impact both the U.S population and military service members. Access to this type of information and the individuals represents a valuable resource to medical research.

The close association between the military medical and research departments offers the researcher access to this valuable data source. Additionally, it provides the opportunity for the population cared for by the military health system to volunteer for and participate in a wide array of medical research efforts contributing to the generalizable medical information to prevent, detect, and treat diseases and injuries. The special scrutiny and the productivity of the clinical research conducted by DoD through its core military research mission and through congressionally directed research projects in the past have led to advances in many areas.

Recognizing the value of the DoD medical research programs, both core and congressionally directed, the HASC report directed the DoD to conduct a comprehensive review of the ongoing clinical research efforts within the military departments. This review was directed to look for diseases that may have been neglected or may present missed opportunities as they relate to military service and provide recommendations for the establishment of formal programs. To identify missed opportunities to conduct research in vital areas, the working group first excluded from consideration disease subcategories that either had significant formal programs or a substantial amount of DoD research effort. Examples of these exclusions include the congressionally funded programs for breast and prostate cancers. Although specifically mentioned by the HASC, diabetes was also excluded because the data (Table 2) indicate that for research conducted in the DoD beneficiary population, diabetes ranked second in funds expended (approximately \$23M, totals for FY03 and FY04) and is currently studied in existing and congressionally directed programs.

The remaining disease subcategories were then evaluated using three factors: (1) which disease subcategories are or are not addressed by DoD research projects, (2) the level of effort, as defined by numbers of projects and total funding, and (3) the relative level of impact on the military medical system. Also considered were disparity between the research efforts and the medical system impact data, impact on military readiness, and the active conflicts in which the United States is currently engaged, OEF and OIF, and the illnesses and injuries sustained in these conflicts. Finally, a prioritized list of 10 illness and injury subcategories was developed from which the top four were put forward as a recommendation of research areas for special consideration. Lung cancer—which, like diabetes, was specifically mentioned by the HASC, was included in the top 10 due to a low level of research efforts involving military beneficiaries; however, the overall DoD research effort was high (Table 2), indicating that lung cancer is already the subject of existing and congressionally directed programs. Four research areas were identified by the working group for special consideration as follows, and respiratory infections area was added at the request of the ASBREM Committee:

- Rehabilitation
- Head, Neck, Face, and/or Eye Injury
- Post-Traumatic Stress Disorder
- Substance Abuse, Alcohol and/or Drug
- Respiratory Infections, including Associated Respiratory Diseases

The following sections describe the rationale for recommending the four research areas for special consideration, their military relevance, and representative examples of ongoing/projected research efforts.

5.1 Rehabilitation

5.1.1 Rationale for Recommendation

Rehabilitation restores physical skills and cognitive abilities as well as psychosocial balance and functioning, facilitating the integration of the individual back into his/her family, duty work environment, and community. Rehabilitation research represents a valuable area of study that may provide opportunities to discover new technologies to prevent and mitigate injury and/or disability that will provide beneficiaries the prospect to regain the highest quality of life. For service members, beneficiaries, and the DoD, the prospect of regaining a person's independence and advancing in their acquired occupation is socially, psychologically, and financially invaluable. A substantial military readiness benefit is achieved by maintaining trained and experienced service members in their jobs, which shifts the responsibility for the care of these service members remaining on active duty from the Department of Veterans Affairs (VA) to the DoD. There is, however, a disparity between the low historical research effort in the area and the high level of current impact that these injuries have on the military, or are likely to have in the future. These factors argue for an expanded research program that will support the potential for discovery and development of technologies for both prevention and treatment.

5.1.2 Relevance to the Military

Historically, rehabilitation has been considered a VA mission as disabled service members leave the military. There is increased interest recently, on both the part of service members and the DoD, in rehabilitation so that injured personnel may mentally and physically maintain their

occupation and continue with the lifestyle and in an environment to which they have become accustomed. Rehabilitation provides an opportunity for those who desire to continue working in areas where they have acquired occupational knowledge and skills to remain in the military community as active duty service members. The recent conflicts have also heightened the awareness of this issue, as advances in personal protective equipment and medical treatment have increased survivability. Service members who would have otherwise died of wounds now have survived but with potential disabilities including amputations, traumatic brain injuries, and hearing loss.

Recently, research efforts have not focused on young, traumatic amputee patients. Researchers have primarily focused on the growing populations of the elderly, diabetics, and patients with peripheral vascular disease in their amputee research. Because of this, the short- and long-term outcomes in young traumatic amputees have not been clearly elucidated. Research will help to define the most effective clinical services, rehabilitative therapy, psychosocial support methods, and prosthetics utilization for this previously high-functioning population.

5.1.3 Representative Research Efforts

In FY04, the DoD had only a few research projects in rehabilitation. Two research projects were conducted using active duty service members and involved the use of simulation technology. Congressional special interest funds supported the Assistive Technology Research Center at the National Rehabilitation Hospital. This initiative funds research that focuses on the timely problems of multi-system trauma secondary to blast and landmine injuries in partnership with Walter Reed Army Medical Center (WRAMC) to identify the ongoing medical, psychological, and social needs and outcomes of these victims. This research focuses on spinal cord and head injuries and amputations and includes victims of stroke, cerebral palsy, and other neurological and orthopedic conditions to develop effective research-based approaches to improve recovery and restore physical function and wellness. This research continues in FY05 without supplemental funding. Other related DoD efforts include epidemiology studies, such as a project focused on the epidemiology of jump landing movements and anterior cruciate ligament injury.

Congressionally directed research also funds the Military Amputee Research Program (MARP). The primary aim of the program is to establish and develop research initiatives that will advance amputee clinical patient care strategies and prosthetic technology used to optimize recovery of persons after traumatic limb loss. The MARP will coordinate and implement multiple research initiatives to develop and maintain a database to track longitudinal amputee patient care, support advances in clinical and rehabilitation strategies, provide traumatic amputee patient care, foster advances in prosthetic technology to optimize patient function, and develop epidemiological studies to model longitudinal trends in patient care and recovery after traumatic limb loss. A unique platform for collaborative research between military/civilian partnerships will allow for the evaluation and implementation of clinical practice initiatives as developed by the MARP. The overall goal of the MARP is to create a national program that combines clinical and technological excellence to generate, develop, and implement innovative initiatives to optimize patient recovery despite traumatic limb loss.

The FY05 investment at WRAMC focuses on advances in prosthetics care for amputee service members. This effort includes advances in assistive technology applied to the amputees and the

development of a database for amputee patient follow-up treatment outcomes and monitoring. The MARP's projected research focus is not solely on rehabilitation strategies, but also on areas such as amputation-related case management studies, prosthetic technology advancements, epidemiological studies, and data mining. The MARP intends to achieve and maintain this focus by funding both intramural (intra-DoD) and extramural (private industry and academia) research efforts in these areas.

5.2 Head, Neck, Face, and/or Eye Injury

5.2.1 Rationale for Recommendation

Approximately 25% of all combat casualties result from penetrating "ballistic" injuries to the head, and nearly 35% of the head injuries manifest as acute brain seizures. These traumas are among the leading cause of death among wounded service members who survive to receive acute medical care. Head and neck injuries have become increasingly prominent in recent operations. Based on the disparity between the low historical research effort in the area and the high level of current interest and potential impact on the military, these types of injuries from the current ongoing engagement in OEF and OIF and future conflicts increase the need for a research program that will support the potential for discovery and development of technologies for both prevention and treatment.

5.2.2 Relevance to the Military

Combat injuries to the head and neck outnumber torso injuries by four to one in recent deployments. The eye and orbit are the most frequently injured regions of the face. The human eye, the most important biological sensor to military operations, is extremely vulnerable to directed energy from military lasers. The need for a far-forward fieldable therapeutic for head trauma would mitigate penetrating head injuries. Design criteria for head and neck protection based on tissue-level brain and spine injury mechanisms are needed. A laser eye injury field therapy kit that can be used by medics is also needed far forward.

5.2.3 Representative Research Efforts

The DoD conducted or managed 33 projects in head, neck, face, and/or eye injury in FY03 and FY04, with a total investment of \$17.6M and \$21.1M, respectively. Only four of these were conducted using active duty service members as primary subjects—three internal DoD projects and one congressional special interest project. Traumatic brain injury is a focus for a significant number of the projects, and a large proportion of the funding is directed toward the Defense and Veterans Head Injury Program, a Congressional Special Interest Program. Other areas of research include head-supported mass, laser eye injury, and vision. Additionally, research supports preventive measures such as the development of transparent, lightweight composites that will be suitable for incorporation into next-generation face shields.

The Defense Brain and Spinal Cord Injury Program (DBSCIP) was set up between the military and the civilian leaders in brain and spinal cord injury research, rehabilitation, and quality-of-life programs. The goals of the DBSCIP are to provide comprehensive, multidisciplinary evaluations and care to active duty military personnel and veterans with brain and spinal cord/column injuries; conduct relevant translational research; find better preventive measures; and provide nationwide education in the area of traumatic brain and spinal cord injury.

Army Program Area H, Neuroprotection Research, has the goal to discover and develop novel therapeutics, diagnostics, and doctrine that will significantly reduce death and residual disability caused by traumatic brain injury. One effort will screen, identify, and conduct preclinical testing of clinically available anti-epileptic drugs that protect against silent brain seizures, including nonconvulsive seizures and spreading depolarizations, secondary to brain injury. The program will conduct studies of cellular and molecular mechanisms of acute and delayed brain injury processes and of functional recovery, with special focus on inflammatory pathways, apoptotic signaling pathways, caspase and calpain pathways, and NF- κ B/IKK proteosome pathways to explore potential means to inhibit the brain injury process. A third effort will conduct preclinical evaluation of neuroprotective compounds in militarily relevant models of brain injury. More specifically, in partnership with the private pharmaceutical sector, i.e., via Material Transfer Agreements or Cooperative Research and Development Agreements, selective neuroprotective targets, such as intracerebral hemorrhage, inflammation, oxidative stress induced by reactive oxygen species, and mitochondria dysfunction are to be studied using comprehensive histological and functional assessments. The ultimate goal is to identify lead neuroprotective compounds for potential clinical development to treat and mitigate brain injury resulting from battlefield brain trauma.

The Army Technology Objective, Warfighter Face and Eye Injury Protection, has the goal to reduce long- and short-term disability due to face and eye injuries. Blunt impact injuries to the face and eye are an emerging threat due to the increased use of head-mounted devices for the service members. The current effort is an epidemiological review and characterization of blunt and penetrating face and eye injuries. This effort will be used to produce a validated, biomedically based tool for assessing risk of face and eye injuries. These models will be utilized by product developers to improve protective and operational equipment for the service members. The Combat Casualty Care Research Program is also funding the development of transparent, lightweight composites that will be suitable for incorporation into next-generation face shields.

Laser eye injuries may cause temporary or permanent visual impairment that can seriously degrade force effectiveness. The Army Technology Objective, Medical Countermeasures for Laser Eye Injury, has the goal to provide a laser eye injury field therapy kit containing comprehensive diagnostic tools and advanced genomic- and proteomic-derived treatments to enable combat medics to rapidly diagnose and treat laser eye injuries on the battlefield. Also, this effort provides updated exposure limits for a new generation of frequency-agile laser systems to enable the development of effective systems that pose reduced risks of injury to the service members who use them. An FY05 congressionally funded DoD project focuses on identifying a panel of natural compounds and biomarkers released for laser eye injury enabling rapid identification of clinical and subclinical laser exposures, developing advanced, agile, multifrequency detecting, prototype eyewear for laser eyewear protection for operators, Homeland Security, and support personnel. This project is also developing new, rugged, field-deployable, handheld, PDA-based "scancorder" medical detector(s). Other DoD projects include functional assessment of laser retinal injury using two metrics of function (visual acuity/contrast sensitivity and multifocal electroretinogram) and the determination of thermal injury using radio frequency radiation.

5.3 Post-Traumatic Stress Disorder

5.3.1 Rationale for Recommendation

Post-traumatic stress disorder (PTSD) is one of the most common, debilitating, and chronic psychological disorders diagnosed among veterans. It is associated with early attrition, impaired social and occupational functioning, increased rate of substance abuse, increased health problems, and higher health care utilization. Based on the disparity between the low historical research effort in the area and the high level of current interest and potential impact on the military, these types of injuries from the current ongoing engagement in OEF and OIF and future conflicts increase the need for a research program that will support the potential for discovery and development of technologies for both prevention and treatment of PTSD.

5.3.2 Relevance to the Military

PTSD incidence for current deployments to OIF and OEF is expected to range from 12% to 20%, with an even higher incidence expected in National Guard Reserve forces and for those Soldiers having multiple deployments. Many who develop PTSD show serious long-term psychosocial consequences such as divorce, job loss, substance use disorders, and poor health. Prospective studies are needed to understand the early course and factors that lead to a chronic course of PTSD.

5.3.3 Representative Research Efforts

PTSD has seen increasing investment, from \$5.5M in FY03 to \$11.4M in FY04, representing 11 projects. The greater part of this investment has been from Congressional Special Interest Programs—\$3.3M and \$8.3M for FY03 and FY04, respectively. Four projects have been conducted using active duty service members, with the most significant being a core program focused on enhancing psychological resilience and preventing psychiatric casualties (\$1.9M and \$2.7M for FY03 and FY04, respectively).

A congressional special interest award, Predictive Tools for PTSD (\$1.0M), has as its goal to conduct a prospective study that will provide detailed information from interviews about the symptomatic course and longitudinal factors for 24 months post-deployment. Knowledge regarding the early course of PTSD and the specific factors and processes that increase risk for chronic PTSD has critical implications for the well-being of service members who served in hazardous deployments. This effort will have direct application to increasing the capability to target individuals who might be at high risk for chronic PTSD and better allocate resources for interventions.

5.4 Substance Abuse, Alcohol and/or Drug

5.4.1 Rationale for Recommendation

Alcohol dependence alone is one of the top four mental health disorders among veterans with war-related accepted mental health disabilities. Based on the disparity between the low historical research effort in the area and the high level of current interest and potential impact on the military, these types of mental health issues from the current ongoing engagement in OEF and OIF and future conflicts increase the need for a research program that will support the potential for discovery and development of technologies for both prevention and treatment of substance

abuse. Further, at the request of the ASBREM Committee, substance abuse research should include research on smoking cessation.

5.4.2 *Relevance to the Military*

Alcohol abuse is a significant concern given the prevalence of problem drinking and related consequences including higher accident rates and decreased productivity for Soldiers. Alcohol disorders affect the youngest male service members disproportionately and more young service members leave military service because of alcoholism and its effects than chronic health conditions. In 1998, 15% of the military were estimated to be heavy drinkers. In the 1990s, alcohol dependence was the second leading cause of hospitalizations of service members; and in 2001, alcohol dependence was the sixth leading cause of ambulatory visits. A 2002 search of the Defense Medical Surveillance System (DMSS) found that 89,341 active duty members of the U.S. Armed Forces were diagnosed with alcohol disorders from 1998 to 2002. Of those service members, nearly two-thirds (64%) had subsequent alcohol-related encounters in a military medical facility within that 4-year period. Drinking alcohol has also been associated with increased risk of accidental death among U.S. Soldiers. Appropriately, DoD has included alcohol disorders among its top priorities for prevention. Military readiness, effectiveness, and retention are negatively affected by alcohol use and abuse. Millions of dollars in military health care costs are spent for alcohol-related injury or disease each year. Alcohol treatment programs have recently strengthened their emphasis on prevention. Innovative approaches that identify at-risk individuals for alcohol abuse from the hospitalization record diagnoses need to be undertaken to reduce alcohol misuse and its negative consequences.

5.4.3 *Representative Research Efforts*

The DoD had 12 active projects in FY03 and FY04, with a total investment of \$3.4M each year for Substance Abuse, Alcohol and/or Drug. Five of these projects were DoD internally funded, with \$245K in FY03, decreasing to only \$15K in FY04. Only one project was conducted using active duty service members—in FY03 for \$231K. The majority of the funding for this area was external; from NIH for a National Institute on Drug Abuse (NIDA)/USUHS study (\$2.3M and \$2.4M for FY03 and FY04, respectively) and congressional special interest projects for genetic and mechanistic studies (\$844K and \$877K, FY03 and FY04, respectively).

During FY05, the DoD has supported (1) alcohol-related research in the areas of mechanisms and effects of alcohol abuse and alcoholism in a variety of models and (2) clinical research into surveillance, prevention, and intervention strategies. The study Preventing the Consequences of Alcohol Abuse: Identification of Soldiers at High Risk for Fatal and Serious Injuries has the goal to improve our understanding of the long-term consequences of alcohol problems on injury risk to prevent further injuries. Individuals at high risk of initial or recurrent injury can be identified in health care databases. Once identified, these service members can be targeted for interventions to reduce both their hazardous drinking and their risk of injury.

6.0 CONCLUSIONS

6.1 Research Areas Recommended for Establishment of Formal Programs

Based on the analysis conducted and the primary RDT&E mission to protect and sustain a fit and healthy force, the working group recommends four areas for special consideration, and the area

of respiratory infections was added at the request of the ASBREM Committee. Research in the following areas will benefit service members, their families, and military retirees affected by these injuries and illnesses:

- Rehabilitation
- Head, Neck, Face, and/or Eye Injury
- Post-Traumatic Stress Disorder
- Substance Abuse, Alcohol and/or Drug
- Respiratory Infections, including Associated Respiratory Diseases

6.2 Considerations for Establishment of Formal Programs and Their Direction

The following should be taken into consideration by Congress and others in the use of the working group's recommendations for the establishment of formal programs to fight these illnesses and injuries:

- The 14 disease categories and their 43 subcategories do not represent the full spectrum of medically related research conducted or managed by the DoD.
- The analysis conducted herein is limited to only DoD-conducted and -managed research and does not consider complementary programs being conducted by other research and development entities worldwide including NIH, universities, and the commercial sector.
- The areas for special consideration provided here do not address the specific direction that any new research program should take. Thus, should a requirement for the addition of particular programs be forthcoming, further analysis must be conducted to determine the appropriate direction, approach, and resources for the research program(s), with consideration not to jeopardize existing programs.
- In addition to the preceding illness-by-illness summary is the critical subject of outcomes research: the analysis of large data sets from actual patient populations to determine which prevention and treatment strategies are most effective. Although this complex subject is being actively addressed both by Defense and civilian medical investigators, further investment unquestionably will improve the effectiveness and efficiency of medical care across all the topics noted above.
- Each service has different research priorities than those recommended by the working group. The existing programs are vital to the individual service missions and should continue to be fully supported.

6.3 Establishment of ASBREM Committee Open Action

Recognizing the value of DoD's clinical research programs and their benefit to military health care system beneficiaries, the ASBREM Committee has established an open action for an annual review of the programs. Specifically, the ASBREM Committee will conduct an annual review of ongoing and planned clinical research into diseases that particularly affect military members, families, and retirees (**Appendix 5**) [8].

7.0 REFERENCES

1. Ellen P. Embry, Deputy Assistant Secretary of Defense, Force Health Protection and Readiness, Office of Assistant Secretary of Defense, Memorandum dated October 25, 2004, for the Commander, U.S. Army Medical Research and Materiel Command, Subject: Clinical Research Program Review Data Call.
2. E-mail communication from Jean Reed, HASC Professional Staffer, to MAJ Richard Starrs, Office, Chief of Legislative Liaison, November 19, 2004.
3. William Winkenwerder, Jr., M.D., Assistant Secretary of Defense, Health Affairs, Interim Reply dated January 26, 2005, to U.S. Senate Committee on Armed Services (John W. Warner and Saxby Chambliss), U.S. Senate Committee on Appropriations (Thad Cochran and Ted Stevens), U.S. House of Representatives Committee on Armed Services (Duncan Hunter and John McHugh), and U.S. House of Representatives Committee on Appropriations (Jerry Lewis and C.W. Bill Young).
4. COL James Romano, Acting Commander, USAMRMC, Action Memo sent May 20, 2005, to Assistant Secretary of Defense (Health Affairs), Subject: Interim Report to Congress, Review of DoD Clinical Research Efforts in Response to HASC Report 108-491.
5. Army Medical Surveillance Activity. Estimates of Absolute and Relative Morbidity Burdens Attributable to Various Illnesses and Injuries, U.S. Armed Forces, 2003. *Medical Surveillance Monthly Report*, 10(2):15-20, April 2004.
6. Ellen P. Embry, Deputy Assistant Secretary of Defense. Force Health Protection and Readiness, Office of Assistant Secretary of Defense. Memorandum dated February 2, 2005, for The Deputy Surgeon General U.S. Army, The Deputy Surgeon General U.S. Navy, The Deputy Surgeon General U.S. Air Force, Vice President for Research USUHS, and Director DARPA, Subject: Clinical Research Program Review Data Call.
7. Robert E. Foster, Ph.D., Acting Chair, Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee, Office of the Director, Defense Research and Engineering, Memorandum dated August 9, 2005, for Deputy Assistant Secretary of Defense (Force Health Protection & Readiness), Subject: Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee Review of Draft Report to Congress, "DoD Clinical Research Program Review."
8. Robert E. Foster, Ph.D., Acting Chair, Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee, Office of the Director, Defense Research and Engineering, Memorandum dated August 9, 2005, for Commander, U.S. Army Medical Research and Materiel Command; Deputy Director for Research and Development, U.S. Navy Bureau of Medicine and Surgery; Director, Human Effectiveness, U.S. Air Force Research Laboratory, Joint Staff Surgeon; President, Uniformed Services University of the Health Sciences; Deputy Assistant to the Secretary of Defense (Chemical and Biological Defense Programs), Subject: Annual Review of DoD Clinical Research Program by the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee.

APPENDICES

Appendix 1 – HASC Report 108-491 Excerpt

The following language is extracted from House Armed Services Committee Report 108-491: Title II - Research, Development, Test & Evaluation (RDT&E) Overview, Army RDT&E, Items of Special Interest, Clinical Research Programs, Pages 150-151, May 14, 2004:

Clinical research programs

The committee understands that the primary federal agency responsible for conducting research into diseases affecting a broad demographic portion of the population is the Department of Health and Human Services. Nonetheless, the Department of Defense (DOD), and in particular the Department of the Army, has at the direction of Congress conducted and managed research for a number of diseases that particularly affect military members, their family members, and military retirees. In fact, the Army provides special scrutiny to these programs, since they are congressionally directed and necessarily involve clinical trials conducted over several years.

While the committee applauds the Department's efforts to manage these programs, the committee is concerned that there may be missed opportunities to conduct research into other vital areas. For example, service members, family members, and military retirees are certainly affected by such serious and increasingly prevalent diseases as lung cancer and diabetes, yet no formal program exists for either.

The committee believes that a comprehensive review of these research programs is necessary so that research can be directed into areas that may have been neglected. Accordingly, the committee directs the Secretary of Defense to review ongoing clinical research efforts within the military departments and report to the congressional defense committees by February 1, 2005, whether any research programs should be added to the DOD's efforts. The committee believes that lung cancer and diabetes are excellent candidates for military sponsored research and urges the Secretary to give every consideration to establishing formal programs to fight these diseases, as they relate to military service.

Appendix 2 – DoD Clinical Research Program Review Working Group Participants

The individuals listed participated with the working group at various stages of the process during the DoD Clinical Research Program Review and preparation of this report.

COL Raj Gupta, Director, Research Plans and Programs, USAMRMC managed the report process and chaired the working group.

COL Kenneth Bertram	Congressionally Directed Medical Research Programs (CDMRP), U.S. Army Medical Research and Materiel Command (USAMRMC)
COL Laura Brosch	Office of Research Protections, USAMRMC
Ms. Julie Buchanan	Azimuth, Supporting CDMRP, USAMRMC
Dr. Richard Drawbaugh	Office of the Assistant Surgeon General, Modernization, U.S. Air Force
Ms. Marianne Elliott	U.S. Navy, Bureau of Medicine and Surgery (BUMED), Human Research Protection Program (HRPP)
Dr. Melissa Gliner	U.S. Army, Office of the Surgeon General (OTSG)
Mr. Joel Glover	Science Applications International Corporation (SAIC), Supporting USAMRMC
COL Mark Gold	U.S. Navy, BUMED
COL Janet Harris	CDMRP, USAMRMC
CAPT Melissa Kaime	CDMRP, USAMRMC
Dr. Steve Kaminsky	Uniformed Services University of the Health Sciences (USUHS)
Dr. Lynn Kitchen	Military Infectious Diseases Research Program (MIDRP), USAMRMC
Lt Col Barbara Larcom	Office of the Assistant Surgeon General, Modernization, U.S. Air Force
Dr. Richard Levine	USUHS
COL Scott Martin	Clinical Investigation Regulatory Office, U.S. Army Medical Department Center & School

Ms. Sheila McFarland	SAIC, Supporting MIDRP, USAMRMC
LTC Mark Mense	Armed Forces Institute of Pathology (AFIP)
Ms. Cheryl Merritt	Telemedicine and Advanced Technology Research Center, USAMRMC
Ms. Remat Mughal	SAIC, Supporting USAMRMC
Dr. Jane Mural	SAIC, Supporting CDMRP, USAMRMC
Mr. James Myers	Baum & Romstedt Technology Research Corporation, Supporting USAMRMC
Mr. Bob Sarvaideo	SAIC, Supporting Combat Casualty Care Research Program, USAMRMC
LTC Harry Slife	Chemical & Biological Defense Program-Medical S&T Office (DTRA), USAMRMC
MAJ Melba Stetz	USAMRMC
Mr. Walt Tinling	USUHS
Dr. Dale Vander Hamm	Allied Technologies and Consulting/Azimuth, Inc., Supporting USAMRMC
Dr. Roy Vigneulle	Anteon Corporation, Supporting Military Operational Medicine Research Program, USAMRMC
CAPT Eileen Villasante	U.S. Navy, BUMED, HRPP
Ms. Pam Winn	U.S. Air Force Surgeon General Office

Appendix 3 – Impact of Selected Diseases in the Active Duty Service Member Population on the Military Health Care System

The Center for Health Promotion and Preventive Medicine (CHPPM) report [5] provides a breakout of medical system impact data – patient encounters, individuals affected, and hospital bed days – for service members in 2003. While this report was used in part as the basis for developing the disease categories/subcategories to be surveyed in the data call, the report did not provide a breakout by the data call categories. Therefore, it was necessary to translate the report data into the data call categories by lumping some of the CHPPM categories under one data call subcategory and excluding other CHPPM categories.

Data Call Category/Subcategory	CHPPM Report Data								
	Medical Encounters ¹			Individuals Affected ²			Hospital Bed Days		
	No	%	Rank ³	No	%	Rank ³	No	%	Rank ³
Diseases of the Circulatory System									
Essential Hypertension	56632	0.98	21	31112	1.00	19	259	0.10	30
Ischemic	9438	0.16	29	3873	0.12	30	2620	1.01	16
All Others (Excluding Neoplasms)	64454	1.11	20	37832	1.21	18	7093	2.73	10
Injury and Poisoning									
Poisoning, Not Chemical or Biological	8023	0.14	31	5863	0.19	28	2617	1.01	17
Burn	*			*			*		
Head, Neck, Face, and/or Eye Injury	152183	2.63	10	76858	2.46	11	15912	6.12	4
All Other Injury	1736487	30.00	1	789533	25.31	1	56055	21.55	2
Rehabilitation	*			*			*		
Diseases of the Musculoskeletal System and Connective Tissue									
Back	68943	1.19	18	30337	0.97	20	2340	0.90	19
Knee	10723	0.19	28	6118	0.20	27	964	0.37	23
All Others (Excluding Neoplasms)	348722	6.03	5	166021	5.32	6	7163	2.75	9
Diseases of the Respiratory System									
Allergic Rhinitis	95338	1.65	14	53467	1.71	14	4	0.00	36
Asthma	36851	0.64	22	18366	0.59	24	802	0.31	26
All Others (Excluding Neoplasms)	84225	1.46	15	58710	1.88	12	4949	1.90	13
Respiratory Infections									
Upper Respiratory	423889	7.32	3	296069	9.49	3	1283	0.49	22
All Others	113864	1.97	12	84792	2.72	9	6796	2.61	12
Diseases of the Digestive System									
Gastroenteritis and Colitis	64733	1.12	19	54449	1.75	13	1715	0.66	20
All Others (Excluding Neoplasms)	145256	2.51	11	84337	2.70	10	22425	8.62	3

CHPPM Report Data									
Data Call Category/Subcategory	Medical Encounters ¹			Individuals Affected ²			Hospital Bed Days		
	No	%	Rank ³	No	%	Rank ³	No	%	Rank ³
Neoplasms									
Mesothelioma	*			*			*		
Lung Cancer, Other Than Mesothelioma	618	0.01	34	99	0.00	35	183	0.07	32
Breast Cancer	2989	0.05	32	364	0.01	32	194	0.07	31
Prostate Cancer	1371	0.02	33	285	0.01	33	303	0.12	29
Ovarian Cancer	164	0.00	36	71	0.00	36	36	0.01	34
Cancers of Blood Forming Tissue (Leukemia, Lymphoma, Myeloma)	8314	0.14	30	1146	0.04	31	2498	0.96	18
All Others	74208	1.28	17	45404	1.46	17	8657	3.33	7
Diseases of the Genitourinary System									
All (Excluding Neoplasms)	221649	3.83	8	136166	4.37	7	9673	3.72	6
Endocrine, Nutritional and Metabolic Diseases and Immunity Disorders									
Diabetes	18953	0.33	25	5258	0.17	29	949	0.36	24
Obesity	30361	0.52	23	19197	0.62	23	163	0.06	33
Nutritional Deficiencies	11083	0.19	27	7604	0.24	26	661	0.25	27
All Others (Excluding Neoplasms)	76142	1.32	16	49186	1.58	16	3201	1.23	15
Infectious and Parasitic Diseases									
Leishmaniasis	*			*			*		
Malaria	383	0.01	35	205	0.01	34	503	0.19	28
HIV	*			*			*		
Sexually Transmitted Diseases, Other Than HIV*	29113	0.50	24	22460	0.72	22	899	0.35	25
All Others	304296	5.26	7	212585	6.82	4	6956	2.67	11
Diseases of the Nervous System and Sense Organs									
Headache	97751	1.69	13	52433	1.68	15	1373	0.53	21
All Others (Excluding Neoplasms)	593715	10.26	2	410693	13.17	2	4656	1.79	14

CHPPM Report Data									
Data Call Category/Subcategory	Medical Encounters ¹			Individuals Affected ²			Hospital Bed Days		
	No	%	Rank ³	No	%	Rank ³	No	%	Rank ³
Mental Disorders									
Substance Abuse, Alcohol and/or Drug	203695	3.52	9	27515	0.88	21	13715	5.27	5
Tobacco Dependence	17075	0.30	26	9307	0.30	25	8	0.00	35
Post-Traumatic Stress Disorder	*			*			*		
All Others	363917	6.29	4	122250	3.92	8	64003	24.61	1
Diseases of the Skin and Subcutaneous Tissue									
All (Excluding Neoplasms)	312273	5.40	6	199116	6.38	5	8464	3.25	8
Blood and Immune System Diseases									
All (Excluding Neoplasms)	*			*			*		
Legend: ¹ Medical encounters: hospitalizations and bed visits. ² Individuals affected: individuals with a hospitalization or ambulatory visit. ³ A ranking of "1" represents highest level of impact for this measure. Lowest ranking is 36. ⁴ May include HIV, as HIV as not separated out in the CHPPM report. * Data not available from the CHPPM report.									

Appendix 4 – Definitions for Disease Subcategories Considered for Potential Research Areas

The following definitions were developed by the working group to establish what each subcategory was considered to encompass for the purpose of this report. These definitions take into account the overall illness and injury, as well as aspects of the conditions that are relevant to the military.

Rehabilitation

Rehabilitation is the care of beneficiaries with musculoskeletal and/or neurological impairment following significant disease or traumatic injury (i.e., traumatic head, neck, and spine injury, amputation, and limb salvage) that restores and maximizes functional independence across the entire spectrum of human activities, from basic self care tasks to recreation, work, and family responsibilities. Rehabilitation restores physical skills and cognitive abilities as well as psychosocial balance and functioning, facilitating the integration of the individual back into his/her family, duty work environment, and community. Rehabilitation can involve recovery following physical and psychological trauma, optimally balancing physical and mental health to achieve functional independence.

Head, Neck, Face, and/or Eye Injury

Head, neck, face, and eye injuries include penetrating (ballistic) injuries, blunt trauma, concussions, and brain injuries from blast overpressure effects. Injuries due to vibration and jolt, such as from vehicles, aircraft, and equipment use are included in this category when affecting the head and neck. Injuries from directed energy, such as laser eye injury and acoustic trauma, and other incapacitating injuries are included.

Post-Traumatic Stress Disorder

Service members, who face the threat of their own death or injury and also witness the death, wounding, and disfigurement of their companions, enemy forces, and civilians, have experienced a heightened physiologic state and a high level of emotion. The intensity of the sensory exposure may lead to heightened levels of arousal, symptoms of dissociation, attempts to avoid emotion, and intrusive recollections of events. The severity and duration of these symptoms will vary among individual service members.

Substance Abuse, Alcohol and/or Drug

Substance abuse-related diseases include alcohol- and/or drug-related conditions such as dependence (alcoholism) and abuse. The definition of alcohol/drug dependence focuses on an interrelated cluster of psychological symptoms, such as craving; physiological signs, such as tolerance and withdrawal; and behavioral indicators, such as the use of alcohol or drugs to relieve withdrawal discomfort. The definition of alcohol or drug abuse includes the concept of “harmful use.” This definition includes health problems related to alcohol and other drug use and implies alcohol/drug use that causes either physical or mental damage in the absence of dependence.

Respiratory Infections

Respiratory infections refer to diseases of the nasopharynx, throat, trachea, and lungs attributed to infections by a variety of microorganisms including viruses, bacteria, and fungi. Respiratory infections are a leading cause of morbidity, hospitalization, and mortality throughout the world and are also the single most common cause of acute illness and physician visits in the United States. The most important causes of acute respiratory illness among service members are adenovirus and influenza. The data call separated out upper respiratory infections; however, for purposes of discussion and recommendations it was determined that one category that included all respiratory infections could be considered. Further, at the request of the ASBREM Committee, respiratory infections is considered to include associated respiratory diseases.

Infectious and Parasitic Diseases – All Others

Naturally occurring infectious diseases excluding potential biological warfare agents have the potential to decimate troop strength, particularly in the tropical and subtropical regions. Target diseases include dengue, bacterial diarrheal diseases, scrub typhus, hantavirus and other lethal viruses, and meningococcal disease. Diseases of current interest—malaria, HIV, and leishmaniasis—were considered as separate categories and are not included in this category.

Diseases of the Digestive System – Gastroenteritis and Colitis

Gastritis is an inflammation of the lining of the stomach. Gastritis can be caused by bacterial or viral infection, autoimmune disorders, or backflow of bile into the stomach (bile reflux). Gastritis can also be caused by irritation from medications (such as aspirin or anti-inflammatory drugs), alcohol, chronic vomiting, excess gastric acid secretion (such as from stress), and eating or drinking caustic or corrosive substances (such as poisons). Gastritis can occur suddenly (acute gastritis) or gradually (chronic gastritis). Viral gastroenteritis is an inflammation of the stomach and intestines caused by a viral infection. Viruses cause 30% to 40% of cases of infectious diarrhea in the United States, and viral gastroenteritis is the second most common illness, after upper respiratory infections. These viruses are often found in contaminated food or drinking water, infectious risks our deployed service members often encounter. The viruses cause about 40% of group-related diarrheal illnesses. Symptoms appear within 4 to 48 hours after exposure to the contaminated food or water. Colitis is an inflammation of the large intestine that is caused by many different disease processes, including acute and chronic infections, primary inflammatory disorders (ulcerative colitis, Crohn's colitis, and lymphocytic and collagenous colitis), lack of blood flow (ischemic colitis), and history of radiation to the large bowel.

Diseases of the Digestive System – All Others (Excluding Neoplasms)

Diseases of the digestive system (excluding gastroenteritis, colitis, and cancer) include hepatitis and other liver diseases and gastroesophageal reflux disease. Hepatitis is inflammation of the liver. The disease can be caused by infections from parasites, bacteria, or viruses (such as Hepatitis A, B, or C); liver damage from alcohol, drugs, or poisonous mushrooms; an overdose of acetaminophen (such as Tylenol[®]), which is rare but can be deadly (more common in regular alcohol drinkers); and immune cells in the body attacking the liver and causing autoimmune hepatitis. Hepatitis may start and resolve quickly (acute hepatitis) or cause long-term disease (chronic hepatitis). In some instances, progressive liver damage, liver failure, or even liver

cancer may result. Gastroesophageal reflux disease (GERD) is when food or liquid travels from the stomach back up into the esophagus (the tube from the mouth to the stomach). This partially digested material is usually acidic and can irritate the esophagus, often causing heartburn and other symptoms.

Lung Cancer, Other Than Mesothelioma

Lung cancer is defined as a disease in which the cells of the lung grow uncontrollably and form tumor(s) in the lungs often leading to metastases in other parts of the body. The general lung cancer types include both non-small cell (the most common form) and small cell lung cancers. Most lung cancers are caused by cigarette smoking, with increased risk of developing lung cancer dependent upon the age at which smoking started and the number of cigarettes smoked per day. Second-hand smoke increases the risk. High levels of pollution and radiation exposure may also increase risk. Mesotheliomas, a rare form of cancer usually caused by inhalation of asbestos fibers, and lung cancers that are not of lung origin (secondary tumors) were excluded from this definition.

Tobacco Dependence

Tobacco use may be in the form of cigarettes, cigars, or smokeless tobacco (chew and snuff). Tobacco use limits physical performance, increases the risk of physical injury during training, is associated with health problems such as lung, head and neck, and esophageal cancer; emphysema; chronic bronchitis; heart disease; asthma; and respiratory infections. Second-hand smoke is associated with lung cancer in adults and sudden infant death syndrome and other illnesses in children.

Appendix 5 – Armed Services Biomedical Research and Management (ASBREM) Committee Open Action for Annual Review of Clinical Research Program



OFFICE OF THE DIRECTOR OF
DEFENSE RESEARCH AND ENGINEERING
3040 DEFENSE PENTAGON
WASHINGTON, DC 20301-3040

August 9, 2005

MEMORANDUM FOR COMMANDER, U.S. ARMY MEDICAL RESEARCH AND
MATERIEL COMMAND
DEPUTY DIRECTOR FOR RESEARCH AND DEVELOPMENT,
U.S. NAVY BUREAU OF MEDICINE AND SURGERY
DIRECTOR, HUMAN EFFECTIVENESS, U.S. AIR FORCE
RESEARCH LABORATORY
JOINT STAFF SURGEON
PRESIDENT, UNIFORMED SERVICES UNIVERSITY OF THE
HEALTH SCIENCES
DEPUTY ASSISTANT TO THE SECRETARY OF DEFENSE
(CHEMICAL AND BIOLOGICAL DEFENSE PROGRAMS)

SUBJECT: Annual Review of DoD Clinical Research Program by the Armed Services
Biomedical Research Evaluation and Management (ASBREM) Committee

The ASBREM Committee met on August 2, 2005, and discussed a draft report to Congress concerning clinical research in the Department. That discussion highlighted the importance of periodically evaluating clinical research priorities to address evolving health threats to U.S. forces. To that end I am establishing an open ASBREM action, as follows:

The ASBREM Committee will conduct an annual review of ongoing and planned clinical research into diseases that particularly affect military members, families and retirees. The review will be conducted so that the Committee can consider the results during the fourth quarter of the fiscal year.

If you have any questions about this action, please contact Bart Kuhn, ASBREM Executive Secretary, at 703-588-7403, or Bart.Kuhn@dod.mil.

Robert L. Foster, PhD
ASBREM Committee Chair (Acting)
Office of the Director,
Defense Research and Engineering

cc:
DASD(TIP&R)



Appendix 6 – Acronym List

ASBREM	Armed Services Biomedical Research Evaluation and Management Committee
ASD(HA)	Assistant Secretary of Defense (Health Affairs)
CDMRP	Congressionally Directed Medical Research Programs
CHPPM	U.S. Army Center for Health Promotion and Preventive Medicine
DBSCIP	Defense Brain and Spinal Cord Injury Program
DoD	Department of Defense
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
HASC	House Armed Services Committee
MARP	Military Amputee Research Program
MIDRP	Military Infectious Diseases Research Program
MTF	Medical Treatment Facility
NIH	National Institutes of Health
OASD(HA)	Office of the ASD(HA)
OEF	Operation Enduring Freedom
OIF	Operation Iraqi Freedom
PTSD	Post Traumatic Stress Disorder
RDT&E	Research, Development, Test, and Evaluation
USAMRMC	U.S. Army Medical Research and Materiel Command
USUHS	Uniformed Services University of the Health Sciences
VA	Department of Veterans Affairs
WRAMC	Walter Reed Army Medical Center