Research Advisory Committee on Gulf War Veterans' Illnesses

February 4 2013, Committee Meeting Minutes

Department of Veterans' Affairs
Washington, DC

Research Advisory Committee on Gulf War Veterans' Illnesses
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I hereby certify the following minutes as being an accurate record of what transpired at the February 4th, 2013 meeting of the Research Advisory Committee on Gulf War Veterans' Illnesses.

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/signed/
James H. Binns
Chairman
Research Advisory Committee on Gulf War Veterans' Illnesses

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Attendance Record

Members of the Committee
James Binns, Chairman
Roberta White, Scientific Director
Beatrice Golomb
Anthony Hardie
Marguerite Knox
William Meggs
Jack Melling
James O'Callaghan
Lea Steele

Committee Staff
Kimberly Sullivan
Arpita Husain

Designated Federal Officer
Victor Kalasinsky

VA Office of Research and Development
Robert Jaeger
Victor Kalasinsky

Abbreviations

AChE – Acetylcholinesterase

ALS – Amyotrophic Lateral Sclerosis

CFS – Chronic Fatigue Syndrome

CMI – Chronic Multisymptom Illness

DoD – Department of Defense

GW – Gulf War

GWI – Gulf War Illness

IOM – Institute of Medicine

ORD – Veterans Affairs Office of Research and Development

MS – Multiple Sclerosis

PB – Pyridostigmine Bromide

PTSD – Post-Traumatic Stress Disorder

RAC – Research Advisory Committee on Gulf War Veterans' Illnesses

RFA – Request for Application

VA – Veterans Affairs

VHA – Veterans Health Administration

Meeting of the Research Advisory Committee on Gulf War Veterans' Illnesses

February 4, 2013

Boston University School of Public Health, 715 Albany Street, Boston, MA 02118

THIS MEETING IS A TELECONFERENCE

Agenda

Monday, February 4, 2013

12:30 – 12:35	**Welcome, introductory remarks**	**Mr. Jim Binns, Chairman** **Res Adv Cmte Gulf War Illnesses**
12:35 – 2:30	**Committee Discussion:** **2013 Committee report**	**Mr. Jim Binns, Chairman** **Dr. Roberta White, Scientific Director** **Dr. Kimberly Sullivan, Assoc. Scientific Dir.** **Res Adv Cmte Gulf War Illnesses**
2:30 – 2:45	**Break**	
2:45 – 4:00	**Committee Discussion:** **2013 Committee report**	**Mr. Jim Binns, Chairman** **Dr. Roberta White, Scientific Director** **Dr. Kimberly Sullivan, Assoc. Scientific Dir.** **Res Adv Cmte Gulf War Illnesses**
4:00 – 4:45	**Update of VA Gulf War research** **Portfolio**	**Dr. Victor Kalasinsky** **VA Office of Research and development**
4:45 – 5:15	**Public comment**	
5:15	**Adjourn**	

The February 4th, 2013 meeting of the Research Advisory Committee on Gulf War Veterans' Illnesses (hereinafter referred to as the Committee) was held via teleconference.

Welcome, Introductions & Opening Remarks

Mr. James Binns, Committee Chair

Chairman James Binns called the meeting to order at 12:36 PM. He began by asking Dr. Victor Kalasinsky, the Committee Designated Federal Officer (DFO) if the next Committee meeting planned for June was approved through VA and could still be held as planned. Dr. Kalasinsky replied that he had received positive feedback from the VA travel approval committee and that he was confident that the meeting could be held as planned. Chairman Binns thanked Dr. Kimberly Sullivan, Associate Scientific Director of the Committee, and Dr. Roberta White, Scientific Director of the Committee, for their work in preparing the draft of the 2013 RAC report. He then stated that the main emphasis of the teleconference meeting was to discuss the body of the draft 2013 Committee report.

Dr. White stated that the best way to structure the meeting was to first talk about the overview of the report organization and topics. The Committee members would discuss each individual topic for about thirty minutes and would then discuss the executive summary. She asked the Committee members if they had any comments on the overall structure and report topics to begin the discussion.

Chairman Binns responded that it was a good idea to pair the findings in this report with the 2008 report. He remarked that the executive summary would be strengthened by including the conclusions contained in the body of the topics of the report. He reminded everyone that the Committee's job was not just to report what research had been done on Gulf War Illness (GWI) to date, but also to highlight the Committee's thoughts for future research. He suggested that the Committee could include the draft VA GWI research strategic plan as an appendix section of the 2013 Committee report.

Dr. White asked if the Committee should also include recommendations from the comments on the draft VA GWI research strategic plan. Chairman Binns believed it was a good idea since the draft strategic plan reflected a lot of input, and had generated helpful comments about how to best move forward with GWI research. He stated that the Committee report draft did a great job discussing treatments that were in progress, but it should also contain other recommended treatments that had been discussed in published papers and presentations to the Committee that had not yet been studied in GWI. Chairman Binns mentioned that the Committee should discuss to what extent the two Institute of Medicine (IOM) reports should be mentioned in the Committee report as well. Dr. White responded that the 2010 IOM report had been referenced in the draft Committee report, and that the new IOM report may be included in the treatments chapter in the next draft of the Committee report.

Dr. O'Callaghan said that he liked the content and the bulleted format in the executive summary but had some minor adjustments he wanted to revisit in some of the topic areas. He said that in the mechanisms chapter, there was a mixture of clinical and animal data and he believed that this section needed to be more cohesive when he was switching between the two topics when reading it. Dr. Sullivan responded that it was laid out that way to discuss how mechanistic approaches worked together from the cellular mechanisms to the organ and body system levels.

Dr. Floyd Bloom agreed with many of Dr. O'Callaghan's points and indicated that the Committee needed to emphasize how the new data validated the conclusions from the 2008 report and strengthened them. He added that the report should present the Committee's views on the IOM report as well. Dr. William Meggs also approved of the outline of the report and believed that the conclusions of this report strengthened the conclusions of the 2008 report.

Dr. Lea Steele also agreed with the views of the previous Committee members. She also emphasized that the report should have the Committee's views of the recent IOM reports. She said that the organization of the draft Committee report made sense, but she felt that the content of some of the chapters did not reflect the chapters' respective titles.

The Committee moved their discussion to chapter one of the report, which included epidemiological studies. Dr. Steele wondered why the Haley, Kansas, and Fukuda case definitions were used in the report as opposed to other case definitions. Dr. Sullivan responded that those were the papers that came out since 2008 which included those case definitions of GWI. Dr. Steele responded that it should be stated somewhere in the report that those case definitions were chosen based on studies that came out since 2008. Dr. Beatrice Golomb added that it should be evident to readers that the Kansas definition was relatively specific compared to the Fukuda definition.

Dr. Meggs said that in the original Kansas case definition, there were exclusions such as diabetes and other health problems. As the veterans aged, they developed other medical problems such as depression and diabetes. He said that it was important that case definitions did not start excluding GW veterans because of other intervening medical illnesses in addition to GWI. Dr. Sullivan and Dr. Golomb both agreed with Dr. Meggs and said that it was time to validate a new case definition. Chairman Binns also agreed and said that a new case definition that was relative to new findings since the last report was needed.

Dr. Golomb added that readers that may not be familiar with GWI needed something to orient them towards what the condition was, and adding the commonly used case definitions would achieve that. Chairman Binns responded that in that case, there needed to be an introductory section about GWI in the report draft. Dr. White said that there could be an introductory section added. Dr. Steele added that if the Committee was thinking about adding the VA strategic plan as an appendix, it went into great detail for a need of a new case definition, and went through the pros and cons of each case definition and that could be cited in the draft Committee report.

Dr. Bloom remarked that it needed to be clear in the draft Committee report if there were or were not changes in rates of neurological diseases, such as ALS, amongst GW veterans. Dr. Sullivan thanked Dr. Bloom for his point. Dr. Bloom responded that it was important to say what research was out there regarding ALS.

Dr. Steele agreed with Dr. Bloom that the Committee needed to add what they knew about ALS. She also added that the report draft had included a study of multiple sclerosis (MS) in GW veterans but she believed that there wasn't a study of MS rates in GW veterans. Dr. Sullivan said that Dr. Steele was correct and that the study cited did not specify look at GW veterans as a separate group although it did include them. Dr. Sullivan said that in that study conducted by Dr. Mitchell Wallin, it appeared that it should be possible to specifically look at MS rates in GW veterans, and the Committee would encourage Dr. Wallin to do that in further analyses of his dataset.

Dr. Steele asked if the report should include in the summary of epidemiological studies a paper that did not talk about the rate of ill GW veterans. Dr. Sullivan responded that there were some people that thought that MS rates were higher in GW veterans and she included that paper because it was inconclusive if MS rates were higher or lower in GW veterans. Dr. Steele asked if it included 1991 GW veterans and Dr. Sullivan responded that it did, but the MS rates weren't reported for them separately. Dr. White indicated that there was a paragraph stating that the data in the study needed to be looked at further for MS rates in GW veterans.

Chairman Binns said that Committee member Mr. Anthony Hardie had mentioned at the last Committee meeting that Congress expressly required a prevalence rate study of MS in GW veterans, but it had not been done to date. Dr. Steele believed that the Wallin study did not give any reliable rates of disease since it was service-connected data only. She also asked why the neuroimaging studies and the neuropsychological studies were considered epidemiological studies. Dr. Sullivan said that she and Dr. White thought it made sense to put them in that section since they consisted of cohorts that were compared based on imaging and cognition but they could reconsider that section if the Committee wanted to discuss it. Dr. O'Callaghan suggested that some of the neuroimaging studies could go into the mechanistic section or animal studies sections.

Chairman Binns believed that there needed to be clarification of the discussion of Post-Traumatic Stress Disorder (PTSD) in the report. Dr. Sullivan asked Chairman Binns if it would help to have an introductory area on PTSD. Chairman Binns responded that there needed to be a core point that there were a lot of studies on PTSD in GW veterans and that they showed the rate of PTSD was relatively low compared to other wars.

Dr. Steele remarked that she did not understand the splitting of the PTSD studies into neuroimaging and non-neuroimaging in the report. She also said that in a table in the report that contained PTSD studies, she believed that some of those studies fit better with the clinical

findings. Dr. Meggs also believed that there might be some studies that were not appropriate for the table of PTSD findings.

Dr. White then transitioned to conclusions and recommendations for research for epidemiological studies. Dr. Golomb said that a different spin could be put on the evidence which was that elevated problems were shown with different case definitions, but that the Committee did not know what the optimal case definition was yet. She said that she believed most of the Committee would agree with the first conclusion that standards for a case definition were really important. Dr. Steele agreed with Dr. Golomb and replied that based on the VA strategic plan, there was a need for a case definition for GWI and that an optimal case definition could be created based on current data.

Dr. Jack Melling said that there seemed to be two relevant issues. One issue was whether the Committee agreed that there needed to be a new case definition and the impression among the Committee members was that there did need to be a new case definition. The second issue was, depending on the epidemiological treatment, what the case definition should be. Dr. Sullivan added that with different case definitions, it was very difficult to compare results across studies. She said that maybe one universal definition could be created which then had subparts which would allow comparability across studies. Dr. Golomb indicated that for epidemiological studies, it was important to have a case definition that strongly discriminated between cases and controls, which was different from what was wanted in a clinic setting where one would not be looking for comorbid conditions that could produce similar symptoms. She indicated that the goals for case definitions in treatment trials may be different than the goals of a case definition for epidemiological studies and said there needed to be attention to that distinction.

Chairman Binns said that he believed that the Office of Research and Development (ORD) had contracted with the IOM to develop a new case definition of GWI. He also said that an IOM study that had come out ten days prior to the teleconference meeting contained a working case definition which completely divorced the multisymptom illness definition from Gulf War service.

Dr. White asked if there were any other comments on the rest of the report conclusions. Chairman Binns responded that the conclusion that stated that there was a 25% increased rate of Chronic Multisymptom Illness (CMI) had ambiguous wording. The Committee agreed with this point. Dr. Golomb said that this percentage meant that 25% of the population that had CMI, in excess of the rate in the non-deployed.

Dr. Steele had a comment regarding the conclusion that UK and Iraqi veterans reported similar chronic health effects as US GW veterans. She said there were many studies that looked at UK and US veterans in regards to symptom constellations and believed that there was no need to draw a new conclusion that UK veterans in particular had GWI. She said that this Iraq study might show a parallel in what we see in UK and US veterans, but the information from the one

study was not strong enough to draw a conclusion. Dr. Meggs added that the Committee could clarify the conclusion and indicate that the Iraqi veterans might have had similar exposures.

Dr. Steele and Dr. Golomb remarked that not all of the Iraqi veterans actually had the same exposures. Dr. Sullivan replied that the report did not address the point of having similar exposures because that may not have been the case. She said the intention was to show new studies, and the 2010 IOM report indicated a need for more international studies with regard to chronic illness from the time of the Gulf War. Dr. Golomb did not agree that cultural differences explained higher rates of symptom reporting among UK veterans and believed that it was based on different experiences. Dr. Sullivan said that Dr. Golomb made a good point, and meant to clarify that this was the author's conclusions and not the Committee's conclusions, and that she would work on editing the wording to reflect that distinction.

Chairman Binns suggested that the Committee would need to come up with a better way of phrasing these conclusions that related them to the earlier report. He said that the report could make references to studies in the earlier report and then make note that there were now additional studies. Dr. White and Dr. Sullivan remarked that they could work on that. Dr. Golomb agreed with this idea, and suggested that it should be cited which studies were from the previous report and which studies further strengthened those prior conclusions.

Dr. Steele referenced the conclusion about the cancer registry report showing that most cancers were not elevated in deployed GW veterans compared to non-deployed veterans with the exception of lung cancer. She added that it was recognized from the mortality studies that differences were only found between GW veterans and non-GW veterans when looking at specific exposure subgroups. She said that it is important to put in the conclusions regarding the cancer registry that it did not look into exposure subgroups. She wanted to strengthen the epidemiology section by pointing out the importance of exposure subgroups. Dr. Golomb said that people may want to use different case definitions that focused on individual exposures and Dr. Steele said that could be incorporated in as well.

Chairman Binns said that in regards to the birth defect conclusion, it should be similar to the 2008 language and say that further research was needed in the topic area.

Dr. White asked if people had any further thoughts on the conclusions. Dr. Steele added that she still didn't think neuroimaging and neuropsychological studies belonged in this chapter. Chairman Binns asked if these studies were considered epidemiological and Dr. White said that they could be if a cohort was used which is why they were included. She also added there were some overlap in studies with chapter two and three because there were some congruence in the findings.

Dr. White moved onto recommendations of chapter one and asked if anyone had questions or comments. Dr. Steele said that offering subtyping and/or parallel case definitions of GWI was a good addition. Dr. Steele said she would not use the Haley Syndrome as an example for

subtyping and Dr. Golomb agreed. Chairman Binns suggested that the language regarding case definitions in the strategic plan could be used in the draft report.

Dr. Steele said that what was in the chapter about the National Survey of Gulf War Veterans was not congruent with the recommendations in the report. The language of what the National Survey did and did not provide needed to be more exact. Dr. Sullivan stated that the reasoning behind that recommendation was that the National Survey would be used to study GW veterans again in the future so it needed to be better devised. She suggested that the recommendation could be reworded.

In reference to the recommendation for more research into excess mortality, cancer and neurological disorders in GW veterans, Dr. Steele mentioned that those topics were currently being researched and she felt that a recommendation for them was not necessary. Dr. Sullivan asked if the Committee would want to put a phrase saying that "further" or "continued assessment was needed", or if that recommendation should be eliminated. Dr. Steele said that continued assessment was definitely recommended.

Dr. Golomb asked if a recommendation should include researching exposures in different theatres in regards to the recommendation of further research into birth defects. The Committee agreed that it should be added. Dr. Steele suggested that disease and mortality rates should be separated since those were different studies. Dr. Golomb added that there was discrimination for some exposures between their effect on disease and on mortality rates. Dr. Steele also suggested that all the mortality data from different sources, such as some additional VA data, should be made public.

Dr. Golomb made a comment about the recommendation that diminished CNS functioning was pathognomonic in GWI. She said that it was not pathognomonic, and that diminished CNS functioning meant that the person had GWI.

Dr. White then moved to chapter two and asked the Committee for comments. Dr. Steele said that in the table of contents, chapter two was called etiological investigations but in the text it was called neurotoxicant exposures and she was curious as which title was correct. Dr. White and Dr. Sullivan apologized and indicated that they had changed the title to neurotoxicant exposures and etiological investigations. Dr. Steele indicated that it was confusing to include, in between the research looking into neurotoxicant exposures in Gulf War veterans, other outcomes and other populations and animal models.

Dr. O'Callaghan asked if these agents were referred to as neurotoxicant exposures in the last report. Dr. Steele said that in the previous report there was a category for each type of exposure. Dr. O'Callaghan said that this section may have been a little too defined in terms of labeling all the exposures in chapter two as neurotoxicants in which Dr. Golomb agreed. Dr. Sullivan raised the idea of renaming the chapter as "Toxicant Exposures and Etiological Investigations," to

which Dr. Golomb agreed. Dr. Steele suggested the title "Associations between Deployment Related Exposures and Health Outcomes," to which the Committee agreed.

Dr. Golomb said that it was premature to exclude vaccines from this chapter because studies that had looked at multiple vaccinations had shown a strong elevated risk or odds ratio to GWI, however these were non-US studies. Dr. Sullivan asked Dr. Golomb if there were new papers related to multiple vacations and GWI since 2008. Dr. Steele said there were probably papers since 2008 about multiple vaccinations in other populations. Dr. Sullivan remarked that she understood Dr. Golomb's point, but the report was to emphasize new research since 2008.

Dr. Steele said that the report needed to better differentiate between GW veteran findings and other population findings. She also said that in regards to the sulfur mustard section, there were about two pages on sulfur mustard but little research had come out about that topic since 2008. She said in the only paper that had come out, the writers had speculated a sulfur mustard exposure. She believed there was too much attention to sulfur mustard than the research suggested and that there was not really any new research on sulfur mustard related to GW veterans. Dr. Sullivan remarked that she understood and agreed with Dr. Steele's point, but she was asked by some Committee members to address the topic of sulfur mustard specifically. She stated that the report could be cut back on that section if the Committee felt it appropriate. Dr. Steele also said that there may be more information on Depleted Uranium (DU) than current research suggested.

Dr. White then asked the Committee members for their comments and critiques about each of the chapters and also asked them to send their written edits to her and Dr. Sullivan. She then moved on to discuss the recommendations section of the draft report. She said that with the language regarding toxicant exposures, it went back and forth with the 2008 conclusions and new evidence, but they could reword the section, using language from the 2008 report and embroidering those conclusions with new research since then.

Dr. Steele said that she wouldn't agree that the new evidence would lead her to say that low level sarin is causative for Gulf War Illness. Dr. Steele said that she thought that the link with GWI was still not strong enough in terms of research that had recently come out. Dr. O'Callaghan indicated that the Committee needed to think of the phrasing "caused by exposures." He suggested using the language "associated with" instead, or "linked to exposure". Dr. Sullivan said that in the executive summary, it was written as "contributors" to the development of GWI and maybe that was a better phrasing. She explained that the reason why there was more evidence now than the past about sarin and GWI was because the Chao papers showed specific gray and white matter decrements thus identifying objective brain differences in sarin exposed groups. Dr. Steele asked if findings showed white matter decrements were associated with symptom reporting. Dr. White responded that the research found that white matter decrements were also associated with symptom reporting. Dr. Steele was concerned that recent evidence

wasn't strong enough to say that something was causative. The Committee members agreed to consider the word "associated" instead.

Chairman Binns said that he believed the problem was that there were different levels of evidence for these different levels of exposures. He added that the Committee members needed to look at 2008 as a baseline. He added that in the last report the word "causal" was used, and recent evidence did not suggest anything different. Dr. White added that she believed there was much stronger evidence with sarin and GWI since 2008. Dr. Golomb suggested to change the wording of "possible cause" to "possible contributor" and to indicate that low level sarin exposure contributed to GWI. The Committee all agreed on this point.

Chairman Binns looked at the 2008 report and the language said that low level sarin exposures could not be ruled out. Dr. Sullivan and Dr. Golomb said that the new evidence with sarin and GWI is stronger than what that statement implied. Dr. White said that she and Dr. Sullivan would reword and then see what the Committee thought of the revision. Dr. White then reviewed the conclusions to for chapter two and asked for comments from the Committee.

Dr. Golomb suggested a rewording of a conclusion regarding occupational groups to emphasize that there had been recent further evidence from occupational groups similar to those that occurred in the GW suggesting that understanding the effects of exposures to chemical mixtures was critical. Dr. White asked if occupational groups were mentioned in the last report and Dr. Steele said that they were, but were not used in a conclusion. Dr. Golomb commented on the recommendation regarding genetic research and that the conclusions were not new since 2008. Dr. White suggested a more general conclusion on genetic susceptibility. Dr. Golomb believed that the genetic susceptibility conclusion did not merit its own bullet because it was not new but it could be combined with another conclusion. Chairman Binns said that these conclusions could also be reconciled with the findings from the IOM report. Dr. Golomb suggested that the conclusion be reworded as "Despite our RAC previous findings on PON1 and other genetic invulnerabilities, as well as the recent IOM findings, there had been no new evidence presented on PON1". Dr. Sullivan mentioned that there had been recent PON1 papers on non-GW groups that Dr. Mackenzie-Ross and colleagues had published. Dr. Sullivan and Dr. White said they would take a look to see what recent PON1 papers had come out.

Dr. White moved on to recommendations and asked for comments. Dr. Golomb said she would modify the word neurotoxicants to toxicants. Dr. Steele suggested that the report specify what types of studies the Committee was recommending. Chairman Binns agreed with Dr. Steele's suggestion.

Dr. Sullivan said one of the things they had thought about was whether groups of sarin exposed individuals could be looked at in a cohort over time. She also suggested cohorts of people that were exposed to pesticides, but that study design would be a bit difficult. She asked if these suggestions would be something of interest to the Committee as recommendations.

Dr. Golomb agreed with Dr. Sullivan, and suggested to look at some proximity exposure with Khamisiyah exposed models. Dr. Steele said that a previous study design was done for DU in the last report, but follow-up and comparisons on those cohorts were not conducted so she was concerned that the same thing would happen for these designs. Dr. Sullivan said that there was more of a momentum for sarin because of the recent studies that had been published. Dr. Golomb suggested that Dr. Sullivan look at her study of pesticide applicators, although it could be a small cohort. Dr. Sullivan confirmed that the small cohort would indeed be an issue.

Dr. O'Callaghan indicated that in the following section of the report there were recommendations on types of studies that should be conducted. He suggested that the recommendations in chapter two and the text in chapter three should be compared, to see if the recommendations could be streamlined or merged. He added that the Committee did need to add discrete statements about types of research that were recommended.

Dr. Steele commented about Dr. Sullivan's suggestion of following sarin-exposed cohorts. She added that there was a ton of data about the Khamisiyah plume and that proximity data could be gathered as Dr. Golomb suggested. She said that this would just be looking at subgroups of a sample, and could just use existing data instead of creating a new study design. Dr. Sullivan responded and said that could be done, but they would not get information on biomarkers with that strategy. She added that a lot more information would be received if a developed cohort was followed over time. Dr. Steele hoped that the larger studies, such as the biorepositories, would have sarin-exposed individuals that could be studied over time. Dr. Sullivan agreed with Dr. Steele's suggestion.

Dr. Steele suggested that there could be a recommendation that bigger studies look at subgroups but she was unsure just where it fit in the current outline of the report. Dr. Steele also asked a question regarding the recommendation of further research into mustard gas exposure, and how it could be implemented. Dr. White and Dr. Sullivan both said that they did not have a cohort of mustard gas exposed individuals that they could recommend be followed. Dr. Golomb asked if it was worth making a recommendation then, and Dr. White and Dr. Sullivan replied that it could be removed if the Committee felt that this was an impractical recommendation.

Dr. Meggs said that sulfur mustard seemed to cause a progressive pulmonary disease and skin rashes. He said from a clinical standpoint there could be a way to define and tease out that cohort. Dr. Golomb responded that the Khamisiyah exposed individuals had increased lung cancer and that there were a lot of exposures that could contribute to pulmonary conditions so Dr. Meggs' method might not be very specific. Dr. Meggs replied that what he found unique about the pulmonary disease caused by sulfur mustard was its progressive course. Dr. Golomb replied that most pulmonary diseases had a progressive course. Dr. White replied that it could be possible to conduct the research if there was a defined exposed cohort but it would be difficult to define the cohort by their symptoms. Dr. Sullivan added that she could not think of a marker that

would identify exposed groups specifically. Dr. Golomb concluded that it perhaps should not be a recommendation then.

LTC Marguerite Knox had a comment about the recommendation that "epidemiologic studies are indicated to identify mortality rates, prevalence of neurological disorders (especially ALS, MS, PD) and cancer rates (especially brain cancer)." She indicated that this recommendation was also in chapter one. Dr. Sullivan and Dr. White indicated that in this section it was relevant to toxicant exposures, and it was not related to toxicant exposures in the first chapter. Dr. White asked if the Committee wanted to leave a DU recommendation in the report draft or not. Dr. Steele responded that the DU recommendation would be worthwhile. Dr. Golomb suggested that it could be included in a general longitudinal recommendation that paid attention to specific exposures.

Dr. White then announced a ten minute break.

When the meeting was resumed, the Committee moved on to discuss chapter three. Dr. O'Callaghan remarked that the topics in this chapter, especially in the early parts, served well to express the idea that the report expanded on the key points from the 2008 report, and the emphasis in this section read well.

Dr. Steele asked if Dr. White and Dr. Sullivan could define the term cross-talk pathways. Dr. Sullivan said it meant how different body systems talked to each other. Dr. Steele suggested that the term be defined in the report. As far as the other conclusions, Dr. O'Callaghan said that he had some refinement wording suggestions that he would send to Dr. Sullivan and Dr. White.

Dr. Golomb had a comment in reference to "active pathways for neurotoxicant effects of OP pesticides and sarin that are not the result of AChE inhibition have been recently identified." She suggested adding the phrasing "further active pathways". The Committee agreed with that wording, since there was some prior evidence of these pathways.

Dr. Steele said she would be a bit careful using the term "neuroinflammation" because it referred to respiratory problems triggered by peripheral nerve stimulation of the respiratory tract, while the examples that the report was using was referring to the CNS. Dr. O'Callaghan said that Dr. Steele raised a good point and that the term neuroinflammation should be clearly defined in the report. Dr. Sullivan responded that she believed it was defined, but they could take a look at the wording and define it more clearly. Dr. Steele asked if all the conclusions were based on new studies and Dr. Sullivan confirmed that they were. Dr. Golomb suggested mentioning that these conclusions were reinforcing points from the last RAC report. Dr. Steele asked if there were recent findings related to cholinergic effects. Dr. Sullivan believed that there were a couple of papers and they could revisit that point to make sure that no relevant papers were missed.

Mr. Anthony Hardie, who had joined the conference late, remarked that the role of sulfur mustard in the Brimfield and Haley recent studies were very interesting. He asked if there would

be more sulfur mustard studies recommended in the report. Dr. White responded that these studies were discussed in the last chapter and were discussed prior to his arrival to the meeting.

Dr. White then moved on to the next set of conclusions and indicated that it was written as one paragraph in the report but was easier to view as bullet points on the slide for the Committee members. Dr. O'Callaghan responded that the conclusion needed some refinement. Dr. Golomb suggested further defining cross-talk pathways in the conclusion. She suggested taking out that phrase and replacing it with "pathways that connect". Dr. Golomb had comments on the second part of the paragraph that read "these alterations in body systems correspond with the multi-system symptoms that characterize the illness." She stated that this situation was not always true and suggested that it not be stated in that way. Dr. Sullivan stated that it was not meant to read that it was always true. Dr. Golomb indicated that maybe there would be a way to reword that phrase without saying the word "corresponds", and maybe use the word "complement."

Dr. White then showed a slide which depicted a proposed integrated mechanism of GWI and asked the Committee for their discussion on it. Dr. Bloom thought it was a very helpful model to include. Dr. Sullivan said the purpose of the slide was to show the different areas that were affected in GWI and how they interact with each other. She added the point of this diagram was also to depict the commonalities among all of the multi-symptom and multisystem aspects of GWI.

Dr. Steele said that she liked the idea of a model but she felt like there was a lot of speculation in this model. She approved of the inner boxes of the diagram. She was also curious as to why the last box did not contain "GI Symptoms" as an outcome. Dr. Sullivan said that Dr. Steele was correct, that it should have included "GI Symptoms." Dr. Golomb had comments about the outer arrows of the diagram entitled "proinflammatory cytokine signaling" and "oligodendrocyte, microglial, astrocyte activation." She said that there was a lot of room in the diagram to determine what causes what in the diagram.

Dr. O'Callaghan said that the diagram could be simplified somewhat to incorporate the major themes in the boxes and to cover all the topics in the previous chapters. He said that he would send specific recommendations for this diagram to Dr. Sullivan and Dr. White. Dr. Golomb asked how the diagram would distinguish between systems affected and outcomes in domains like GI and CNS. Dr. Steele said that she would consider GI as a system, and a symptom would be chronic diarrhea. Dr. Sullivan said the diagram did have a symptom for GI but it was cut off. Dr. Steele added that behavioral outcomes did not make sense in the last box and something like memory impairments or concentration difficulties would be better. Dr. Golomb said that she would include sleep, mood, personality and cognition as separate areas that were encompassed within the CNS. Dr. Golomb did not understand what neuroimmune was focused on, and did not know if coagulation underlies any of the symptoms. Dr. Golomb asked if it had to be an underlying mechanism or could it be a parallel consequence. A few Committee members replied that it could be a parallel consequence.

Mr. Hardie suggested that since there were so many symptoms, could the last diagram in the box simply be listed as multiple symptoms. Dr. White and Dr. Sullivan replied that it would not capture all the symptoms to do that. Dr. Golomb suggested collapsing the last two boxes since it was hard to define which were the overarching themes, and in that box define which were causes and which were consequences. Dr. White said that a systems and symptoms box was needed. Dr. Golomb asked if coagulation was a system, and Dr. White and Dr. Sullivan said that it could be called something else or be taken out. Dr. Steele suggested having a list of systems and symptoms, but not linking them directly. Dr. Steele asked if genetic vulnerability should be included, and Dr. Sullivan said that it could be added. Dr. Golomb commented that reactive oxygen species and mitochondrial dysfunction were closely intertwined, but were non-identical and believed that the two terms should be separate in the model.

Dr. White said that they would work on editing the section and went on to discuss the recommendations. Dr. O'Callaghan said that he would send his comments with regard to the recommendations. Dr. Golomb suggested broadening the recommendation on studies assessing biomarkers, since there were a number of more biomarkers than in previous reports. Dr. Sullivan asked Dr. Golomb if she could send her a list of suggested biomarkers. Chairman Binns said that the Committee needed to combine a recommendation with chapter three with recommendations from chapter two and end up with a composite list of biomarkers for readers to understand. Dr. White agreed, and then moved onto chapter four which dealt with treatment trials and asked for comments.

Dr. Golomb asked if acupuncture and acupressure could be collapsed to one topic. Dr. Sullivan responded that it was split up now because they were different studies, but she supposed it could be contained in the same area. Dr. Golomb also commented on the success of using nasal irrigation on veterans that she knew about. These veterans did not need to use any drugs following nasal irrigation treatment.

Chairman Binns thought it would be very helpful to see all the treatment studies that had been funded in this section. He also would like to see some reference to other treatment ideas that seemed reasonable suggested by the literature. He said it would be helpful for researchers to see what other researchers were doing. Dr. Sullivan said that could be added as well as what had been talked about in previous RAC meetings. In terms of the comments on the CPAP procedure, Dr. Golomb indicated that there was no evidence that results with CPAP in GW veterans were any different than other groups with sleep apnea. She indicated it was not really a symptom based treatment for GW veterans, but for people with sleep apnea. Dr. White said that these therapies did not have to be specific for GWI but that they alleviate symptoms that GW veterans had. Dr. Golomb suggested that it was important to specify that CPAP was used on GW veterans with GWI and sleep apnea. Dr. Sullivan said that could certainly be added. Dr. Steele asked if the report should mention the number of treatment studies that had been launched and the number of pilot trials versus clinical trials.

Dr. Steele asked if there were anywhere close to 20 treatment trials and Dr. Sullivan responded that it was close to that number when including ongoing studies that had been recently funded. Dr. Golomb noted that the report should specify ongoing studies. Dr. White agreed and suggested that ongoing studies be labeled as funded studies. Dr. Steele also noted that the chapter did not mention the questions that evaluated treatment in the 2005 National Survey. The data from this survey on specific treatments that the veterans had reported using has never been analyzed. She noted that there was a large data set of veterans self-reporting what treatments they had found helpful and that this data should be analyzed.

Chairman Binns wanted the report to demonstrate which studies were funded through the VA and which through the DoD. Dr. Golomb asked if it would be inappropriate to make a recommendation that the Committee investigated which funding source had followed the recommendations of the Committee reports the best. Chairman Binns noted this had already been happening, but could be looked at again.

Dr. Steele asked if the Committee should recommend larger follow up studies for pilot studies that had already demonstrated preliminary benefits. Dr. Sullivan commented that she was not sure if the research was at that point and would like to see more preliminary studies first. Dr. Golomb mentioned her concern whether there were funds available for larger treatment trial studies. Dr. Sullivan noted that when a treatment study reached a point that it looked reasonable and safe then the NIH or a similar treatment funding organizations could be approached. Chairman Binns also stated that there was a current bill in Congress which would increase funding in the CDRMP if it was adopted. He thought there should be a general recommendation that if a pilot study showed promise, a larger treatment trial should be funded and the organizations would decide who would provide the funding.

Dr. White moved on to chapter five of the report. Chairman Binns stated that there were too many tables and sub analyses and believed it could be covered in summaries instead and offered to submit ideas on that portion of the report.

Dr. White asked what the Committee thought of the conclusions. Dr. Golomb asked if it would be helpful to point out that the funding in the VA had been disproportionally directed towards stress and psychological illness. Chairman Binns stated that he believed that had not happened since 2004. Dr. Sullivan said that they could document funded studies that were not directly related to GWI but noted that they were generally not related to psychological stress and illness. Dr. Steele said that the language in the chapter was not carefully enough worded with respect to GW research and GWI research and commented on the differences between the clarifications.

Chairman Binns suggested that the Committee submit their edits to Dr. Sullivan and White for this chapter. He also noted that he thought the section should reference the Committee's findings in the last year and that recommendations should be based on those findings. He stated that the conclusion would be that the VA reduced their budget in FY13 and Congress has responded by

increasing the funding for CDMRP, which was a positive step forward for GWI research. He thought the language should be more precise regarding the division of labor between VA and CDMRP and when discussing the recommended levels of research funding.

Dr. Steele asked if the VA Gulf War Research Strategic Plan draft should be adopted or mentioned in the report. She stated that the report should discuss the lack of a well-coordinated federal approach to GWI and the strategic plan was a step in that direction. Dr. Steele said no one had seen the new strategic plan, but believed the older one should be mentioned in the report. Chairman Binns agreed with Dr. Steele and said that even if the VA chose not to look at their strategic plan, CDMRP could still use it. It was agreed that the original strategic plan, as of January 31, 2012, would be attached and referred to in the Committee draft report.

Dr. White then initiated the discussion about the executive summary. She noted that the executive summary needed to be reworked since all of the conclusions and recommendations had now been reworked. She said the two main suggestions for the report were that that the summary should follow the same structure, language and conclusions from the 2008 report, and that the summary should pull in all the chapter recommendations. She also noted the IOM report would be included and discussed in the next report draft. The Committee agreed on these changes, and the discussion moved on to Dr. Victor Kalasinsky's presentation.

Update of VA Gulf War Research Portfolio

Dr. Victor Kalasinsky, VA Office of Research and Development (ORD)

Dr. Kalasinsky covered the background on the strategic plan that was discussed during the previous January and June meetings. He stated that after the June meeting, VA ORD had looked over the Committee's recommendations and that it and other VA offices had reviewed the draft strategic plan and made changes. He said that the changes were currently in the approval process at the VA, with the expectation that the strategic plan would be approved in the near future. He noted that annual reviews of the strategic plan would be conducted, allowing the Committee to discuss any possible changes on a regular basis. He hoped that the Committee agreed that VA ORD was making progress.

Dr. Kalasinsky provided an overview of section five of the strategic plan. He said that VA ORD also created a draft implementation plan, which he hoped would help carry out the specific items in the strategic plan. He reiterated that he was waiting for final approval of the strategic plan from the VA.

Dr. Kalasinsky reported that 16 proposal applications were reviewed in March 2012 and that two biomarker projects were recommended for funding. He stated that 15 proposal applications were reviewed in October 2012, and four were recommended for funding. He said that two of the studies were treatment trials, and the other two were biomarker projects. He indicated that

within the month another set of 17 proposals would be reviewed. Dr. Sullivan asked if the Committee could be told about the six studies that were recommended for funding. He reported that he was unable to discuss the four most recent projects which were in the process of IRB approvals and extra review processes. He reported that Dr. Fiona Crawford was funded to investigate proteomics and lipodomics in animals, which would translate to GW veterans' research. He stated that Dr. Michael Falvo from the East Orange VA was also funded to study mitochondrial function.

Dr. Golomb asked when the Committee would be able to learn about the other four studies. Dr. Kalasinsky stated that it depended on the IRB approval, other approval processes and documentation. Dr. Jaeger stated that once a proposal passed merit review, there was a period of several months during which processes such as IRB were taken care of. Dr. Sullivan stated that in the past the Committee was informed almost immediately once it was decided a project was going to be funded. She noted the difficulty in making recommendations when the Committee was unaware of what was already in the process of being funded. She asked if it would be possible to know what is going to be funded or what projects were in the process of being funded.

Mr. Hardie said that as someone who also served on the CDMRP funding panel, it was important to know about funding to ensure that there were no duplicative efforts. Dr. Kalasinsky stated that there was unfortunately not a lot of flexibility because a project that was recommended could potentially not be funded if problems developed with processes. Dr. Golomb stated that the Committee could still be informed of what was recommended, which was what happened in the past. Dr. Sullivan also noted that CDRMP posted what was recommended for funding, and stated that there had been cases in which the project was unable to pass IRB approval.

Dr. Kalasinsky said that he could not release funding information yet, but he would ask if the information could be released sooner. Dr. Jaeger reported that he could not announce any information until the award had actually been obligated at the VA. Dr. Sullivan stated that she understood that it took time, but noted her concern that the Committee was just learning about the projects recommended for funding in March 2012. Dr. Jaeger noted the information, such as titles and abstracts, should also be found on the NIH ERA reporter, which had been in development over the past three years to increase transparency. Dr. Golomb and Dr. Sullivan both noted that the Committee should be directly receiving the information from the VA, and not waiting until the information was posted online for the public. Dr. Jaeger stated that he was not suggesting that, but was discussing another tool available, and that he and Dr. Kalasinsky would ask when the projects from the October 2012 could be released.

Mr. Hardie reported that he was currently looking at a study online that a GW veteran had brought to the public a couple of days previously. The study was entitled "Scalp Application of Red and Near Infrared Light from Light Emitting Diode Therapy (LED) to Improve Thinking and Memory in Veterans with Gulf War Illnesses", with Dr. Margaret Naeser as the Principal

Investigator. He noted his concern that the abstract was online on clinilcaltrials.gov, a public website, prior to the Committee being notified of the study. He assumed that this was one of the October studies that could not be discussed, and said more information on the other studies may be also be available. Dr. Kalasinsky stated that he was unaware that the information had been released. He remarked that after the set of reviews in the current month, the next set of deadlines would be in April and September. Dr. Golomb asked what the RFAs would be for the future deadlines. Dr. Kalasinsky stated that the future RFAs would be for two animal studies, a pilot study, a merit review, and a clinical trial. Dr. Golomb asked if they would be informed of the exact RFAs ahead of time and noted that it was done in the past.

Dr. Kalasinsky then discussed section 5.1 which addressed specific treatments. He stated that three of the four studies that were recommended for funding in the last cycle were treatments. He stated that treatment trial approved in July 2011 was not able to start until October 2012. Dr. Meggs asked what the specific delays were and Dr. Kalasinsky said it was IRB approval and FDA approval. Dr. Jaeger also noted delays in hiring staff for other projects, which could also affect the timeline of a project. Dr. Sullivan clarified that the trial they were discussing that started in October was the rTMS study by Dr. Ashford at the Palo Alto WRIISC center.

Dr. Kalasinsky then discussed section 5.2, databases and surveillance. He noted that VA ORD was planning a meeting with database experts who would be able to offer advice. He also stated that he and Dr. Jaeger met regularly with VA Office of Public Health (OPH), and stated that OPH would like to be included in the June Committee meeting. Dr. Steele confirmed that the meeting with the database experts would include participants knowledgeable about GW and GWI research.

Dr. Kalasinsky then discussed sections 5.3, the creation of a case definition of chronic multisymptom illness in GW Veterans, and stated that it was currently in the contracting process, and was hopeful that information would be available in the near future to report to the Committee. Dr. Steele asked to clarify the contracting process but Dr. Kalasinsky and Dr. Jaeger reported that they were unable to discuss the details.

Mr. Hardie noted that another veteran found information on the procurement action on a federal government public website. Mr. Hardie stated his concerns that members of the Committee were discovering information directly relevant to the Committee via the public record and not from the VA. He stated that the literature review by IOM referenced previously by Dr. Steele was in direct contradiction with the VA strategic plan. Dr. Kalasinsky stated that he was unable to discuss this matter further, and Dr. Golomb voiced her concern that the Committee's charter mandated that plans related to GWI would be reviewed and discussed with the Committee which was not happening. Mr. Hardie asked COL Kent to discuss the lack of transparency with the Secretary's Office. COL Kent stated that there needed to be a discussion addressing what information could be shared at what point with the Committee.

Chairman Binns reported that he received an email from the IOM requesting nominations for Committee members for a case definition study, which required the creation of a report for the VA after ten months. He noted that it was troubling that perhaps even Dr. Kalasinsky and Dr. Jaeger did not know that information and pointed out that the contract was completed at this point. Dr. Kalasinsky said that he was not able to discuss any part of the contracting process. COL Kent said that he would look into the email and see what was happening. Dr. Melling voiced that it would be beneficial for Chairman Binns to have a direct discussion with the VA to prioritize information flow to the Committee.

Dr. Kalasinsky moved on to discuss section 5.4 which dealt with the genetics and genomics portion of the strategic plan. He stated that there were two cooperative studies including the Gulf War Era Cohort and Biorepository in Durham and the Gulf War Veterans' Illnesses Biorepository in Boston. He said the contract for the blood and data collection for the Gulf War Era Cohort was issued in September and the biorepository project in Boston had received outreach efforts and publicity in July 2012. Dr. Kalasinsky also noted that he visited the site in Tucson where the specimens will be stored for the brain biorepository study. Dr. Sullivan commended the effort that Dr. Kalasinsky and his administration had put forth to enlist veterans to sign up for the Gulf War Illness Biorepository. Mr. Hardie agreed with Dr. Sullivan and questioned whether there was any increased recruitment following the public relations effort. Dr. Kalasinsky said that he was not sure if recruitment increased as a direct result of the push for recruitment. Dr. Sullivan commented on the importance of the project and Mr. Hardie agreed stating that he had and would continue to encourage veterans to partake in the project, but he thought that the primary focus should remain on treatments for the living.

Dr. Kalasinsky discussed section 5.5 about biomarkers and noted that two projects from the last two funding cycles had dealt with biomarkers, one of the four being an animal study. He also commented on section 5.6 regarding animal studies, stating that they funded an animal study in March.

He continued to section 5.7 discussing coordination and communication with stakeholders. He stated that VA ORD held a meeting of Gulf War Researchers in September 2012 which involved 43 participants and included presentations by Dr. Dawn Provenzale about the CSP #585 Gulf War Era Cohort and Biorepository, Dr. Christopher Brady about the CSP #501B Gulf War Veterans' Illnesses Biorepository, and Dr. Ronald Przygodzki about the Million Veteran Program. The meeting also included the three directors of the WRIISC who discussed patient care and research. Dr. Steele asked if there were plans to broaden those invited to GW Research meetings to include both federally funded and non-federally funded researchers as discussed in the strategic plan. Dr. Jaeger reported that the intention of the meeting was to get the VA and in-house researchers organized and supported before expanding the meeting to others as Dr. Steele had suggested. Dr. Kalasinsky agreed with Dr. Jaeger and noted that by the end of the day, researchers were discussing collaborations, and noted that 18 participants also reported on their research projects during the meeting. He stated that the meeting allowed the VA to demonstrate

how they were attempting to facilitate GW research including cohorts and funding options. He indicated that the meeting was well received and that similar meetings would be held in the future. Dr. Jaeger added that they also wanted the researchers to be aware that the RFAs were now coming out regularly and hoped that other researchers would be interested in taking advantage of the funding opportunity.

Mr. Hardie found it encouraging that the Committee could already see some positive outcomes from the leadership and support that has formed within the VA. He said that it was not well publicized that the VA had shifted toward seeking treatments and noted that VA would have to continue to back up their actions, but commended them for their current actions. He also stated that he hoped the Secretary's Office at the VA would revive the Gulf War Review newsletter. Dr. Sullivan reported that she would check on the newsletter, but had heard that it would be renewed soon. She stated that the newsletter needed to come out more often than it had been lately, and that the VA might not realize how important it was to the GW veterans.

Dr. Sullivan asked Dr. Kalasinsky if the VA was still planning on working on the consortia funded by CDMRP. Dr. Kalasinsky noted that the VA prepared a brochure on Gulf War Veterans' Illness research, as well as visiting veterans' services organizations, communicating with clinical centers in the VA, communicating regularly with OPH, and setting up teleconferences with researchers as needed. He also noted they had been participating in the monthly Deployment Health Working Group meetings. He stated that he knew the consortium decisions had been made and that they were trying to work them into one or two special RFAs if necessary to encourage VA workers to couple with the consortiums. He said that the VA was also planning on having a joint program review with CDMRP in which they would go over specific programs that had been funded and discover where gaps still existed.

Dr. Kalasinsky then discussed the translation of research into practice in section 5.8. He noted that the VA had been working with OPH to help with provider education issues. He reported on the IOM recommendations for clinical trials and also reported that the annual Gulf War Veterans' Illnesses Task Force report would be posted on the internet soon for the general public. He noted that the VA was in the process of putting together the 2012 annual report for Congress. Dr. Kalasinsky then presented the titles of projects completed in 2011 and 2012, as well as the titles of active research projects. He showed the funding table for GWI, demonstrating that the VA had increased its funding each year with a projection of 7.2 million dollars for 2013 and noted it could potentially be more. Dr. Kalasinsky presented the titles for the new RFAs that would be released including two animal studies and three patient centered studies.

Mr. Hardie stated that he found the funding numbers encouraging and hoped that they continue to increase. Dr. O'Callaghan asked whether any participants at the meeting were unaware of possible funding sources. Dr. Kalasinsky noted some were unaware that the RFAs were issued on a regular basis, and emphasized that they were issued twice a year annually. He stated that the VA has a commitment of 15 million dollars to spend, and noted that it could potentially be

pushed higher if enough proposals are submitted. Dr. Jaeger commented that Dr. Kalasinsky expanded the panel and expertise and noted that he would work with unsuccessful applicants to help prepare them for resubmission.

Dr. Steele asked Dr. Kalasinsky to clarify which studies were classified as GW Research. Dr. Kalasinsky explained that if a study came through an RFA that was not focused on GW veterans, but used GW veterans, than it was filed under the GW research category. Dr. Jaeger added that they had been informing colleagues when they received proposals with a GW focus to ensure that it was reviewed by a panel with the appropriate expertise.

Dr. Sullivan asked for abstracts of all studies currently funded to understand their connection to GWI, because it was unclear for some of the titles. She also asked to get copies of the current RFAs. Mr. Hardie said that it was important to understand why there was a spike in ALS rates and why there appeared to be an increase in MS rates among GW veterans. However, he noted that the main issue was solving the overall problem of symptoms that were affecting GW veterans and he hoped the RFAs were focused on this problem. Dr. Kalasinsky agreed and said that he hoped those types of proposals would increase, but noted that when a good proposal was submitted for other things that affected Gulf War veterans, they too had to be funded. Dr. Jaeger said that he was hopeful the IOM report would inspire people to write more proposals. Dr. Steele and Mr. Hardie voiced their concerns that studies that were not GW specific should not be considered as part of GW funding in the GW research portfolio.

Dr. O'Callaghan thanked Dr. Kalasinsky and Dr. Jaeger for their positive steps in the funding and thanked them for their efforts. He remarked that he was unaware of how quickly a case definition for GWI could be formed, and noted that the most recent IOM report included a working definition. He stated that the definition should link the symptoms to Gulf War service. Dr. Steele stated that the definition should be linked to Gulf War service and not be merged with any other multi-symptom illness. She added that the definition should be evidenced based and consensus driven. Dr. Golomb said that it was problematic to include subsequent veterans in the case definition, because it included illnesses that were known to be due to other mechanisms such as PTSD or traumatic brain injury. She stated that incorporating a broad definition and expanding it to other groups would impair prospects for identifying causes and treatments in a meaningful way. Dr. Bloom agreed that the original syndrome needed to be defined according to the original conditions and exposures that existed in the Gulf War theatre during the conflict, with the idea that it may be broadened later. LTC Knox concurred and Dr. Golomb added that it had to be limited to the 1990-1991 Gulf War veterans, because the VA also defined those deployed to that region later as GW veterans as well. Mr. Hardie commented that the Committee had seen research reports demonstrating that GWI was separate from other diseases such as fibromyalgia, and noted that the IOM definition was too broad to distinguish between different conditions. Chairman Binns suggested that the Committee make a recommendation. The Committee agreed to make a recommendation incorporating the comments that had been made. The recommendation is attached as Appendix B.

Public Comments

MAJ Denise Nichols stated that she was with 28 other veterans who had been listening to the conference. She introduced the first veteran, a veteran's spouse, as Valerie Mulligan. Ms. Mulligan reported that she had been helping her husband for twenty years who had atypical primary progressive multiple sclerosis with autonomic dysfunction. She said that vaccines were catalysts to breaking down the immune system by changing the mitochondria, creating a dysfunction in the autonomic nervous system combined with exposures, stress, poor quality food, poor quality water, and aspartame. She reported that her concerns that were not addressed were how data was collected and questioned why the Committee is not using the WRIISC Center to collect data on the disease process and modalities of treatments that were working with GW veterans. She noted that her second issue was the burning semen syndrome and reproductive issues, which were not mentioned during the meeting. Ms. Mulligan emphasized her belief that vaccinations should be investigated and were the root of the cause of GWI. Dr. Golomb agreed that vaccines contributed to the development of the symptoms, but did not believe they are the sole cause.

MAJ Nichols introduced the next veteran, Maryann Parker. Ms. Parker stated that she was a staff sergeant in the US Air Force and was deployed to Saudi Arabia for one year during Desert Storm. She stated that she received 21 vaccines during deployment and suffered greatly since their administration. She thanked the Committee for their effort and urged them not to eliminate vaccines as a major contributor to the problems experienced. She expressed her disappointment that the VA was an obstacle to veterans' treatment. She noted that GWI should be tied to 1991 service, and should not be lumped with other diseases. Ms. Parker asked for the list of vaccines she received to be released so she could research them if the VA was unwilling, but noted that her shot record was destroyed. She finally noted that she has attended two Gulf War Illness conferences and said that no VA doctors attended either time. She also stated her desire for a study to be conducted on lupus.

MAJ Nichols introduced John Erup as the next speaker. Mr. Erup said that he and his wife suffered from GWI and reported that the change in name of GWI to Chronic Multisymptom Illness was a way for the government to deny the existence of GWI. He said that the research matter was striking down a lot of the illness that pertained to GWI such as MS, which he had been diagnosed with. Mr. Erup reported that he had done extensive research and would like to speak in front of Congress on the issue. He said that everything veterans were exposed to such as pesticides, sarin gas, mustard gas, oil fires, shots, and PB tablets created this type of damage. He said that he had a friend who was wrongly medicated, not been seeing the correct doctors, and currently has two masses in his brain. He finished by stating that he had a Facebook group called Desert Storm Soldiers Exposed that he invited other veterans to visit.

MAJ Nichols reported that communication to the veterans and their family members was very important. She mentioned having the conferences on video or skype for the veterans and

requested that the Committee should meet with the veterans and their families prior to the next in-person meeting. Ms. Nichols asked the Committee to please try and follow the time schedule, even if it required the Committee to break and do the public comments during the scheduled time. She noted that many veterans changed their schedules for the meetings. She mentioned research was needed for eye problems, hearing problem, teeth problems, and bone degeneration. She also noted that infectious agents and biological agents should not be forgotten, stating that they had been neglected and forgotten. She concluded that she hoped the VA would stop calling the disease as chronic multisymptom illness, and that it needed to be called and related to Gulf War service.

Angie McLamb was next to speak and stated that she believed the vaccines should be included in the research, noting that she became ill after the anthrax vaccine. She also asked that women's issues should be studied and felt that spouses should also be included in GWI research.

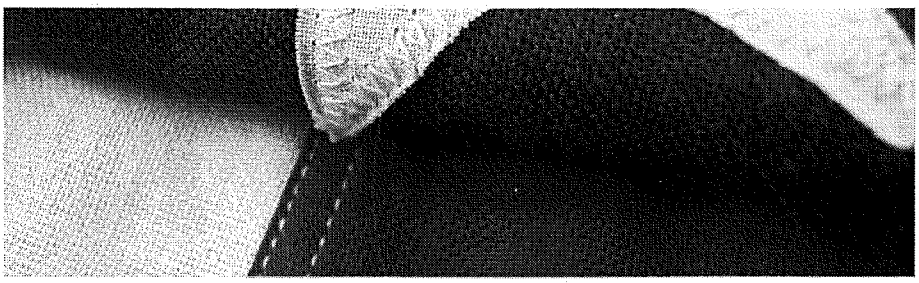
Carol Stum reported that her husband used to be a physician, but gave up his practice and licensure due to his illness. She noted that her husband has continued to deteriorate and stressed the need for answers.

Brian, a Gulf War veteran, asked the VA whether data from the WRIISC was collected and used in research. Dr. Golomb stated that even the IOM report stated that the data used from the WRIISC centers was not being used as effectively as it could be. She stated that there needed to be an operative definition to separate out Gulf War veterans from other service members. She noted that the WRIISC center did not currently have the appropriate data needed to answer these questions.

Dr. Golomb and Dr. Meggs gave their email addresses to the veterans interested in emailing them about vaccine research and information.

Closing Remarks

Chairman Binns thanked MAJ Nichols for organizing the veterans' call-in session. He thanked Drs. Jaeger and Kalasinsky for the work they were doing within the contraints imposed on them. He thanked the Committee members, especially Dr. White and Dr. Sullivan for leading the draft report discussion. Dr. White and Dr. Sullivan thanked the Committee members for reviewing the information and for providing feedback on the report draft. Chairman Binns adjourned the meeting.



GULF WAR RESEARCH PORTFOLIO

VHA OFFICE OF RESEARCH AND DEVELOPMENT / Victor Kalasinsky

February 4, 2013

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

Gulf War Research Strategic Plan - Background

- April, 2011 – Outline of a draft strategic plan was discussed at the Gulf War Steering Committee meeting
- June, 2011 – Draft plan prepared by ORD presented to RACGWVI
- Nine Working Groups of six or more members held teleconferences between Sep and Nov 2011 to recommend changes to draft plan
- Coordinating Committee held teleconferences in Dec 2011 and Jan 2012 to incorporate recommendations of the other groups
- January, 2012 – revised draft plan presented to RACGWVI & NRAC
- June, 2012 – next revision presented to RACGWVI & NRAC
- August, 2012 – draft plan submitted for VA approval
- Conduct annual reviews of the strategic plan

Gulf War Research Strategic Plan (2013-2017)

- **Section 5.0 - Strategic Objectives**
  - 5.1 Symptomatic and Specific Treatments
  - 5.2 Databases and Surveillance
  - 5.3 Case Definition of Chronic Multisymptom Illness in GWVs
  - 5.4 Genetics/Genomics/Systems Biology
  - 5.5 Biomarkers
  - 5.6 Animal Models
  - 5.7 Coordination/Communication with Stakeholders
  - 5.8 Translation of Research into Practice
- **Research topics are listed in RFAs**
- **Implementation Plan**
- **Awaiting final VA approval**

VETERANS HEALTH ADMINISTRATION

Gulf War Research – Requests for Applications (RFAs)

March 2012 Review Panel:

16 applications received; 2 recommended for funding

October 2012 Review Panel:

15 applications received; 4 recommended for funding

February 11, 2013 Review Panel:

17 applications received

2013 Deadlines for Receipt of Applications:

April
September

VETERANS HEALTH ADMINISTRATION

Gulf War Research Strategic Plan (2013-2017)

- **Section 5.0 - Strategic Objectives**
  - 5.1 Symptomatic and Specific Treatments
    - Recommended projects for funding
    - RFAs include complementary and alternative methods
    - Incorporated IOM recommendations for Treatments

VETERANS HEALTH ADMINISTRATION

Gulf War Research Strategic Plan (2013-2017)

- **Section 5.0 - Strategic Objectives**
  - 5.2 Databases and Surveillance
    - Planning a meeting of database experts
    - Meet regularly with OPH regarding surveillance and other activities

VETERANS HEALTH ADMINISTRATION

Gulf War Research Strategic Plan (2013-2017)

- **Section 5.0 - Strategic Objectives**
  - 5.3 Case Definition of Chronic Multisymptom Illness in GWVs
  - – In the Contracting process

VETERANS HEALTH ADMINISTRATION

Gulf War Research Strategic Plan (2013-2017)

- **Section 5.0 - Strategic Objectives**
  - 5.4 Genetics/Genomics/Systems Biology
  - – CSP #585 Gulf War Era Cohort and Biorepository
    - Contract for blood collection issued in Sep 2012
  - – CSP #501B Gulf War Veterans' Illnesses Biorepository
    - Began operations, Jul 2012
    - Site visit to Tucson, Dec 2012

VETERANS HEALTH ADMINISTRATION

Gulf War Research Strategic Plan (2013-2017)

- **Section 5.0 - Strategic Objectives**
  5.5 Biomarkers
  - Recommended projects for funding

VETERANS HEALTH ADMINISTRATION

Gulf War Research Strategic Plan (2013-2017)

- **Section 5.0 - Strategic Objectives**
  5.6 Animal Models
  - Recommended projects for funding

VETERANS HEALTH ADMINISTRATION

Gulf War Research Strategic Plan (2013-2017)

- **Section 5.0 - Strategic Objectives**
  - 5.7 Coordination/Communication with Stakeholders (1)
    - Gulf War Researchers meeting, Sep 2012
    - Prepared a Gulf War Veterans' Illnesses brochure
    - Brief VSO representatives
    - Regular teleconferences with clinical centers
    - Participate in monthly DHWG meetings
    - Meet regularly with OPH

VETERANS HEALTH ADMINISTRATION

Gulf War Research Strategic Plan (2013-2017)

- **Section 5.0 - Strategic Objectives**
  - 5.7 Coordination/Communication with Stakeholders (2)
    - Congressionally-Directed Medical Research Programs
      - Regular in-person meetings and teleconferences
      - DoD-funded consortium proposals
      - Planning Joint Gulf War Program Review
      - DoD presentation at Gulf War Researchers meeting, Sep 2012

VETERANS HEALTH ADMINISTRATION

Gulf War Research Strategic Plan (2013-2017)

- **Section 5.0 - Strategic Objectives**
  - 5.8 Translation of Research into Practice
    - Work with OPH on provider education
    - Incorporated IOM recommendations for Clinical Trials

VETERANS HEALTH ADMINISTRATION

Gulf War Research – Other Activities

- **Gulf War Veterans' Illnesses Task Force (GWVI-TF)**
- **Annual Report to Congress**

VETERANS HEALTH ADMINISTRATION

Recent Gulf War Research Projects

Completed in FY2011:

- Tissue Factor and Gulf War-Associated Chronic Coagulopathies
- Autonomic Functions of Gulf War Veterans with Unexplained Illnesses
- Motor Neuron Function of Gulf War Veterans with Excessive Fatigue
- Genetic Epidemiology of ALS Veterans
- Testing the Feasibility of MC CBT for Veterans with IBS
- A Pilot study of CPAP Adherence Promotion by Peer Buddies with Sleep Apnea
- Transcription factors regulating sensory gene expression and pain pathways

Completed in FY2012:

- Differential Gene Expression in Pathologies Associated with Neuronal Hyperexcitability: Links to Gulf War Illness
- Somatic hypersensitivity in Veterans with IBS
- A randomized controlled trial of a mindfulness based intervention for GW Syndrome
- Imaging Pain Modulation in Gulf War Veterans with Chronic Muscle Pain
- MEG Synchronous Neural Interactions (SNI) in Gulf War Veterans

VETERANS HEALTH ADMINISTRATION

Active Gulf War Research Projects

Active:

- Bacterial Overgrowth Associated with Chronic Multi-Symptom Illness Complex
- Bacterial Host Defense Mechanisms in Polyaromatic Hydrocarbon Carcinogenesis
- Somatic hypersensitivity in Veterans with IBS
- Lipoic Acid Therapy for Experimental Autoimmune Encephalomyelitis
- Multiple Antigenic Peptides to Alter the Course of Autoimmune Disease
- Immunoregulation of Myelin Specific T Lymphocytes
- Central Mechanisms Modulating Visceral Sensitivity
- Evaluation of MEG Synchronous Neural Interaction Test in PTSD
- Neuroprotection and Myelin Repair Mechanisms in Multiple Sclerosis

VETERANS HEALTH ADMINISTRATION

Active Gulf War Research Projects

Active:

- Sleep Neurobiology and Circuitry
- Prevention of Hippocampal Neurodegeneration Due to Age and Apnea
- Epigenetic Mechanisms Relevant to the Pathogenesis of ALS
- Impact of exercise training on pain and brain function in Gulf War Veterans
- Nanoparticle Coupled Antioxidants for Respiratory Illness in Veterans
- Understanding Pain of Gastrointestinal Origin in Women that Serve in OEF/OIF
- Randomized Trial of a Formal Group Program for Fatigue in Multiple Sclerosis
- Memory and Mood Enhancing Therapies for Gulf War Illness
- MEG Synchronous Neural Interactions (SNI) in Gulf War Veterans
- rTMS for the Treatment of Chronic Pain in GW1 Veterans

VETERANS HEALTH ADMINISTRATION

Gulf War Research Funding – DoD, HHS, VA

10-Year (FY 2002-2011) Funding Trends for GW Research in Millions of Dollars

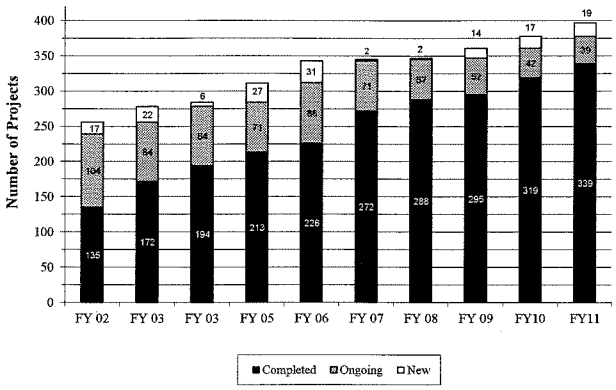
Department	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	Total Costs FY '02-'11
DoD	$ 18.8	$ 16.4	$ 11.1	$ 10.1	$ 10.1	$ 3.4	$ 11.7	$ 10.4	$ 10.2	$ 3.2	$ 105.40
HHS	$ 0.8	$ 1.0	$ 0.5	$ 0.5	$ 0.4	$ 0.4	$ 0.4	$ 0.0	$ 0.0	$ 0.0	$ 4.00
VA	$ 4.5	$ 5.7	$ 7.6	$ 9.5	$ 13.0	$ 22.1	$ 21.9	$ 16.6	$ 13.9	$ 6.0	$ 120.80
TOTAL	$ 24.1	$ 23.1	$ 19.2	$ 20.1	$ 23.5	$ 25.9	$ 34.0	$ 27.0	$ 24.1	$ 9.2	$ 230.20

(DoD estimate for FY 2011 does not include CDMRP funds.)

VETERANS HEALTH ADMINISTRATION

Funded Gulf War Research Projects – DoD, HHS, VA

Cumulative Number of Funded Projects (FY2002 – FY2011)



VETERANS HEALTH ADMINISTRATION

Gulf War Research – Requests for Applications (RFAs)

Biomedical Laboratory Research & Development (BLR&D):

BX-13-011
Award for Research on Gulf War Veterans' Illnesses (GWVI)
BX-13-012
Pilot Projects for Research on Gulf War Veterans' Illnesses (GWVI)

Clinical Science Research & Development (CSR&D):

CX-13-011
Award for Research on Gulf War Veterans' Illnesses (GWVI)
CX-13-012
Pilot Projects for Research on Gulf War Veterans' Illnesses (GWVI)
CX-13-013
Award for Research on Treatments for Gulf War Veterans' Illnesses (GWVI) – (clinical trial)

VETERANS HEALTH ADMINISTRATION

Projected FY2012 ORD Support for Ongoing Gulf War Research Projects (31Jan2013)

FullName	VAMC	Title	Focus	Total FY 2012	Start Date	End Date
Clinical Trials				**$ 542,442**		
Lin, Henry C. (M.D.)	Albuquerque, NM	Bacterial Overgrowth Associated with Chronic Mult-Symptom Illness Complex	Treatment of GW veterans with gastrointestinal symptoms	$ 158,219	04/01/09	03/31/13
Kearney, David J. (M.D.)	Seattle, WA	A randomized controlled trial of a mindfulness based intervention for Gulf War Syndrome	Treatment of GW veterans with gastrointestinal symptoms	$ 112,394	10/01/10	09/30/12
Cook, Dane B. (Ph.D.)	Madison, WI	Impact of Exercise Training on Pain and Brain Function in Gulf War Veterans	Treatment of pain in GW veterans with resistance exercise training	$ 202,910	07/01/11	06/30/16
Bourdette, Dennis N. (M.D.)	Portland, OR	A Randomized Trial of a Formal Group Program for Fatigue in Multiple Sclerosis	Treatment of fatigue in multiple sclerosis patients	$ 68,919	07/01/12	06/30/16
Biomarkers				**$ 3,414,966**		
Fiore, Louis D. (MD)	Boston, MA	VA Gulf War Biorepository (CSP 501)	Gulf War Brain and DNA Bank	$ 561,079	08/01/02	09/30/13
Madison, Roger D. (Ph.D.)	Durham, NC	Differential Gene Expression in Pathologies Associated with Neuronal Hyperexcitability: Links to Gulf War Illness	Identify genes that may be related to neuronal regeneration in Gulf War Veterans	$ 70,250	04/01/03	12/31/11
Cook, Dane B. (Ph.D.)	Madison, WI	Imaging Pain Modulation in Gulf War Veterans with Chronic Muscle Pain	Functional imaging of Gulf War veterans with unexplained musculoskeletal pain	$ 262,184	10/01/08	09/30/12
Provenzale, Dawn (M.D.)	Durham, NC	Gulf War Era Cohort and Biorepository (CSP 585)	Gulf War era repository of blood specimens	$ 1,876,687	04/01/10	09/30/13
Kowall, Neil (M.D.) Christopher Brady (Ph.D.)	Boston, MA	VA Gulf War Veterans' Illnesses Biorepository (CSP 501B)	Gulf War Tissure Bank	$ 237,878	10/01/10	09/30/13
Georgopoulos, Apostolos (M.D.)	Minneapolis, MN	MEG Synchronous Neural Interactions (SNI) in Gulf War Veterans	Diagnosis of mulltisymptom illness in GW Veterans using magnetoencephalography	$ 406,888	10/01/11	09/30/12
Gulf War Veterans Illnesses				**$ 125,170**		
Verne, G. Nicholas (Ph.D.)	Cincinnati, OH	Somatic Hypersensitivity in Veterns with IBS	Evaluation of altered central pain processing in IBS	$ 125,170	04/01/09	03/31/16

* Includes 12.4% administrative overhead*

FullName	VAMC	Title	Focus	Total FY 2012	Start Date	End Date
Model Systems of GW Exposures/Illnesses				**$ 2,397,455**		
Greenwood, Beverley (Ph.D., FACG.)	Oklahoma City, OK	Central Mechanisms Modulating Visceral Sensitivity	Central nervous system control of gastrointestinal pain (IBS)	$ 90,574	10/01/08	03/31/13
Bedlack, Richard (M.D., Ph.D.)	Durham, NC	A Clinical Demonstration of an EEG Brain-Computer Interface for ALS Patients (CSP 567)	New treatment for ALS	$ 26,296	10/01/08	01/01/13
Vandenbark, Arthur A. (Ph.D.)	Portland, OR	Immunoregulation of Myelin Specific T Lymphocytes	New treatment for MS	$ 168,600	01/01/09	12/31/12
Bourdette, Dennis N. (M.D.)	Portland, OR	Lipoic Acid Therapy for Experimental Autoimmune Encephalomyelitis	New treatment for MS	$ 168,600	10/01/09	09/30/13
Hinrichs, David (Ph.D.)	Portland, OR	Multiple Antigenic Peptides to Alter the Course of Autoimmune Disease	New treatment for MS	$ 168,600	04/01/10	03/31/14
Elmets, Craig (M.D.)	Birmingham, AL	Host Defense Mechanisms in Polyaromatic Hydrocarbon Compounds	Mechanisms of toxicity of polyaromatic hydrocarbon pollutants	$ 168,600	10/01/10	09/30/14
Singh, Inderjit (Ph.D.)	Charleston, SC	Neuroprotection and Myelin Repair Mechanisms in Multiple Sclerosis	New treatment for MS	$ 259,707	10/01/10	09/30/14
Shiromani, Priyattam (Ph.D.)	Charleston, SC	Sleep Neurobiology and Circuitry	Control of sleep	$ 303,406	10/01/10	09/30/14
Chase, Michael H,	Vest Los Angeles, C	Prevention of Hippocampal Neurodegeneration due to Age and Apnea	New treatment for neurodegenerative effects of sleep apnea	$ 270,322	01/01/11	12/31/14
Kowall, Neil (M.D.)	Boston, MA	Epigenetic Mechanisms Relevant to the Pathogenesis of ALS	Genetic mechanisms underlying ALS	$ 168,600	01/01/11	12/31/14
Schlosser, Rodney J. (M.D.)	Charleston, SC	Nanoparticle Coupled Antioxidants for Respiratory Illness in Veterans	Nanoparticle (sand) derived respiratory illness	$ 168,600	04/01/11	03/31/15
Greenwood, Beverley (Ph.D., FACG.)	Oklahoma City, OK	Understanding Pain of Gastrointestinal Origin in Women that Serve in OEF/OIF	Central nervous system control of gastrointestinal pain (IBS)	$ 168,600	04/01/11	03/31/15
Shetty, Ashok (Ph.D.)	Durham, NC	Memory and Mood Enhancing Therapies for Gulf War Illness	Development of new therapy for ill Gulf Wat Veterans	$ 266,950	04/01/11	12/31/15
				$ 6,480,033		
				Total Distributed by ORD in FY 2012		

Projected FY2013 ORD Support for Ongoing Gulf War Research Projects (31Jan2013)

FullName	VAMC	Title	Focus	Total FY 2012	Start Date	End Date
Clinical Trials				**$ 661,873**		
Lin, Henry C. (M.D.)	Albuquerque, NM	Bacterial Overgrowth Associated with Chronic Mult-Symptom Illness Complex	Treatment of GW veterans with gastrointestinal symptoms	$ 158,219	04/01/09	03/31/13
Cook, Dane B. (Ph.D.)	Madison, WI	Impact of Exercise Training on Pain and Brain Function in Gulf War Veterans	Treatment of pain in GW veterans with resistance exercise training	$ 202,910	07/01/11	06/30/16
Ashford, J. Wesson (M.D., Ph.D.)	Palo Atlo, CA	rTMS for the Treatment of Chronic Pain in GW1 Veterans	Treatment of chronic pain in GW Veterans using repetitive transcranial magnetic stimulation	$ 231,825	01/01/12	12/31/15
Bourdette, Dennis N. (M.D.)	Portland, OR	A Randomized Trial of a Formal Group Program for Fatigue in Multiple Sclerosis	Treatment of fatigue in multiple sclerosis patients	$ 68,919	07/01/12	06/30/16
Biomarkers				**$ 4,173,525**		
Fiore, Louis D. (MD)	Boston, MA	VA Gulf War Biorepository (CSP 501)	Gulf War Brain and DNA Bank	$ 500,675	08/01/02	09/30/13
Provenzale, Dawn (M.D.)	Durham, NC	Gulf War Era Cohort and Biorepository (CSP 585)	Gulf War era repository of blood specimens	$ 3,175,498	04/01/10	09/30/13
Kowall, Neil (M.D.) Christopher Brady (Ph.D.)	Boston, MA	VA Gulf War Veterans' Illnesses Biorepository (CSP 501B)	Gulf War Tissue Bank	$ 263,848	10/01/10	09/30/13
Georgopoulos, Apostolos (M.D.)	Minneapolis, MN	MEG Synchronous Neural Interactions (SNI) in Gulf War Veterans	Diagnosis of multisymptom illness in GW Veterans using megnetoencephalography	$ 233,504	10/01/11	03/31/13
Gulf War Veterans Illnesses				**$ 197,998**		
Verne, G. Nicholas (Ph.D.)	Cincinnati, OH	Somatic Hypersensitivity in Veterns with IBS	Evaluation of altered central pain processing in IBS	$ 197,998	04/01/09	03/31/16

* Includes 12.4% administrative overhead*

FullName	VAMC	Title	Focus	Total FY 2012	Start Date	End Date
Model Systems of GW Exposures/Illnesses				**$ 2,146,297**		
Greenwood, Beverley (Ph.D., FACG.)	Oklahoma City, OK	Central Mechanisms Modulating Visceral Sensitivity	Central nervous system control of gastrointestinal pain (IBS)	$ 28,682	10/01/08	03/31/13
Bedlack, Richard (M.D., Ph.D.)	Durham, NC	A Clinical Demonstration of an EEG Brain-Computer Interface for ALS Patients (CSP 567)	New treatment for ALS	$ 84,236	10/01/08	01/01/13
Vandenbark, Arthur A. (Ph.D.)	Portland, OR	Immunoregulation of Myelin Specific T Lymphocytes	New treatment for MS	$ 42,150	01/01/09	12/31/12
Bourdette, Dennis N. (M.D.)	Portland, OR	Lipoic Acid Therapy for Experimental Autoimmune Encephalomyelitis	New treatment for MS	$ 168,600	10/01/09	09/30/13
Hinrichs, David (Ph.D.)	Portland, OR	Multiple Antigenic Peptides to Alter the Course of Autoimmune Disease	New treatment for MS	$ 168,600	04/01/10	03/31/14
Elmets, Craig (M.D.)	Birmingham, AL	Host Defense Mechanisms in Polyaromatic Hydrocarbon Compounds	Mechanisms of toxicity of polyaromatic hydrocarbon pollutants	$ 168,600	10/01/10	09/30/14
Singh, Inderjit (Ph.D.)	Charleston, SC	Neuroprotection and Myelin Repair Mechanisms in Multiple Sclerosis	New treatment for MS	$ 259,707	10/01/10	09/30/14
Shiromani, Priyattam (Ph.D.)	Charleston, SC	Sleep Neurobiology and Circuitry	Control of sleep	$ 168,600	10/01/10	09/30/14
Chase, Michael H,	West Los Angeles, C	Prevention of Hippocampal Neurodegeneration due to Age and Apnea	New treatment for neurodegenerative effects of sleep apnea	$ 270,322	01/01/11	12/31/14
Kowall, Neil (M.D.)	Boston, MA	Epigenetic Mechanisms Relevant to the Pathogenesis of ALS	Genetic mechanisms underlying ALS	$ 168,600	01/01/11	12/31/14
Schlosser, Rodney J. (M.D.)	Charleston, SC	Nanoparticle Coupled Antioxidants for Respiratory Illness in Veterans	Nanoparticle (sand) derived respiratory illness	$ 168,600	04/01/11	03/31/15
Greenwood, Beverley (Ph.D., FACG.)	Oklahoma City, OK	Understanding Pain of Gastrointestinal Origin in Women that Serve in OEF/OIF	Central nervous system control of gastrointestinal pain (IBS)	$ 168,600	04/01/11	03/31/15
Shetty, Ashok (Ph.D.)	Durham, NC	Memory and Mood Enhancing Therapies for Gulf War Illness	Development of new therapy for ill Gulf Wat Veterans	$ 281,000	09/30/11	12/31/15
				$ 7,179,693		
				Total Distributed by ORD in FY 2013		

Research Advisory Committee on Gulf War Veterans Illnesses
Recommendation Regarding Gulf War Illness Case Definition
Adopted, February 4, 2013

The Committee recommends that VA ORD sponsor a joint effort with the Gulf War Illness (GWI) Research Program at the Department of Defense's Office of Congressionally Directed Medical Research Programs (CDMRP) to establish an expert consensus and evidence-based case definition for Gulf War illness. This joint effort should include, at minimum: (1) a review of existing literature relevant to case definitions for GWI, (2) in-depth statistical and epidemiologic assessment of the strengths and weaknesses of different case definition approaches using datasets that provide representative data on symptoms and medical conditions affecting 1990-1991 Gulf War era veterans, and (3) final case definition parameters and guidelines developed by an expert consensus panel that includes scientists experienced in GWI research and symptom-based case definitions and veterans affected by GWI.

The Committee emphasizes the importance of establishing a case definition specific to the illness resulting from military service in the 1990-1991 Gulf War, in order to provide homogeneous case groups for research studies. While poorly understood illnesses are known to affect many other populations, the environmental conditions and experiences encountered in the 1991 Gulf War theater are distinct from etiologic factors associated with other symptom-defined conditions, for example, those that follow infection, injury, occupational hazards, as well as ambient cases of unknown etiology. In addition, recent studies have identified a variety of biological differences that distinguish GWI from other multisymptom conditions. Until objective diagnostic tests can be identified for Gulf War illness, it is essential that a symptom-based case definition be established that best characterizes the symptom profile that has been consistently and specifically associated with military service in the 1990-1991 Gulf War.

The Committee strongly urges that the Gulf War illness case definition effort be conducted in cooperation with CDMRP, which supports the majority of federally-funded GWI research. CDMRP is currently sponsoring two large research projects aimed at determining current symptom profiles of Gulf War era veterans, to be used in optimizing a GWI case definition. The Committee also endorses the general process for establishing a GWI case definition outlined in VA's Draft Strategic Plan for Gulf War Illness Research [reviewed by the Committee at meetings held in January and June 2012]. This process provides for a case definition that is both evidence-based and developed by a consensus panel of experts, and will maximize both the scientific value and acceptability of the case definition.