LEGISLATIVE HEARING ON H.R. 3593, H.R. 4261, H.R. 4281 AND OTHER DRAFT LEGISLATION

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATION

OF THE

COMMITTEE ON VETERANS' AFFAIRS U.S. HOUSE OF REPRESENTATIVES

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CONTENTS

Tuesday, March 25, 2014

	Page
Legislative Hearing on H.R. 3593, H.R. 4261, H.R. 4281 and Other Draft Legislation	1

OPENING STATEMENTS

Hon. Mike Coffman, Chairman, Subcommittee on O&I	1
Hon. Ann Kirkpatrick , Ranking Member	2

WITNESSES

Ms. Stella S. Fiotes, Executive Director, Office of Construction and Facilities Management, Office of Acquisition, Logistics and Construction, Department of Veterans Affairs	6
Prepared Statement	34
Accompanied by:	
Mr. Tom Leney, Executive Director, Office of Small & Disadvantaged Business Utilization, Department of Veterans' Affairs	8
Mr. Gregory Wilshusen, Director, Information Security Issues, U.S. Government Accountability Office	17
Prepared Statement	37
Mr. Raymond Kelly, Director, National Legislative Service, Veterans of Foreign Wars	18
Prepared Statement	53
Ms. Diane Zumatto, National Legislative Director, AMVETS	20
Prepared Statement	55
Mr. James H. Binns, Chairman, Research Advisory Committee of Gulf War Veterans' Illness	21
Prepared Statement	62
Mr. Davy Leghorn, Assistant Director, Veterans Employment and Education Division, The American Legion	23
Prepared Statement	95
Mr. Frank Wilton, Chief Executive Officer, American Association of Tissue Banks	24
Prepared Statement	100

LEGISLATIVE HEARING ON H.R. 3593, H.R. 4261, H.R. 4281 AND OTHER DRAFT LEGISLATION

Tuesday, March 25, 2014

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON VETERANS' AFFAIRS,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATION,
Washington, D.C.

The Subcommittee met, pursuant to notice, at 10:00 a.m., in Room 334, Cannon House Office Building, Hon. Mike Coffman [chairman of the subcommittee] presiding.

Present: Representatives Coffman

OPENING STATEMENT OF CHAIRMAN MIKE COFFMAN

Mr. COFFMAN. Good morning. This hearing will come together.

I want to welcome everyone to today's legislative hearing on H.R. 3593, H.R. 4261, H.R. 4281, and two pieces of draft legislation.

The five bills we will be considering today are the product of extensive investigations conducted by this subcommittee in the course of its oversight duties that have revealed poor judgment, chronic mismanagement, and a general lack of accountability by the Department of Veterans' Affairs. These bills are intended to heighten the protection for our veterans and improve services provided by the VA.

First we will hear about H.R. 3593, the VA Construction Assistance Act of 2013, which ranking member Kirkpatrick and myself introduced on November 13, 2013.

This bill recognizes the tremendous problems associated with VA major construction projects in Aurora, Colorado, New Orleans, Louisiana, and Orlando, Florida, as identified by an O&I investigation and substantiated by GAO report.

According to these findings VA is delayed an average of 35 months with an average cost overrun of $366 million.

This legislation requires the VA to use the Army Corps of Engineers as the special project manager to assist in completing these projects closer to their original budget and completion dates.

Notably this bill is supported by the Veterans of Foreign Wars, the American Legion, and the former secretary of Veterans' Affairs, Jim Nicholson.

Second we will address H.R. 4261, the Gulf War Health Research Reform Act of 2014, which I introduced last week, along with Ranking Member Kirkpatrick and full committee Ranking Member Michaud.

This bill reinstills the independence originally expected of the research advisor committee for gulf war illnesses, which includes overseeing VA's research on gulf war illnesses in order to improve the lives of those suffering as a result of such illnesses.

Third, we will hear about H.R. 4281, the Protecting Business Opportunities for Veterans Act of 2014 sponsored by the Honorable Tim Huelskamp of Kansas.

H.R. 4281 will make tremendous strides and holding accountable the bad actors that attempt to defraud service-disabled veteran-owned small businesses and other veteran-owned small businesses of crucial set asides they receive in business.

Fourth, we will discuss a piece of draft legislation entitled The Biological Implant Tracking and Veterans Safety Act of 2014.

This legislation requires the VA to implement a standard identification protocol for biological implants that is consistent with the FDA's unique identification system. The system must allow for the tracking of implants from donor to recipients.

This bill also requires the VA to procure biological implants only from vendors using the system and only through competitive procurement processes.

Ultimately this legislation will improve VA's ability to prevent the implantation of contaminated tissue and also to notify veterans in cases of FDA recalls.

Finally, we will hear about the draft directive titled The Veteran Information Security Improvement Act of 2014, which is sponsored by the Honorable Jackie Walorski from Indiana.

This IT security directive is designed to assist VA in mitigating known information security weaknesses, and prevent, limit, and detect unauthorized access to its networks and systems.

It also identifies detailed actions and tasks consistent with current federal requirements that should be taken by VA to address this longstanding information security challenges. Once again, I would like to thank all of those in attendance for joining us in our discussion today, and I now recognize Ranking Member Kirkpatrick from Arizona for five minutes to discuss her opening statement.

OPENING STATEMENT OF RANKING MEMBER, ANN KIRKPATRICK

Ms. KIRKPATRICK. Thank you. Thank you, Mr. Chairman for holding this hearing.

Holding hearings on proposed legislation within the jurisdiction of our subcommittee is one of the most important legislative duties we have. These hearings enable us to gather the viewpoints of the Department of Veterans Affairs, veterans groups, and those with specific expertise regarding the matters under consideration.

It is important that we gather these views and thoroughly consider them as we deliberate which bills this subcommittee will forward to the full committee.

We in Congress should never assume we have all the answers. That is important to remember as we consider the often blunt tool of legislation.

If we truly seek the most effective ways to accomplish a policy goal then we must carefully consider the views of stakeholders, in-

cluding those who would enact the policy and those whose lives would be affected by it.

At the end of the day we are all striving to fix problems and improve the services and benefits that VA provides for veterans. This shared priority is a reflection of our nation's commitment to our veterans.

I note that the VA is able to provide comments on only two of the bills before us today. I ask that the VA provide us with its comments regarding the other bills as soon as possible so that we may be able to consider the department's views going forward.

I also ask that all of our witnesses provide us their views on any of the bills that they have not had time to include in their testimony.

I also ask, Mr. Chairman, that in future legislative hearings we try as hard as we can to set the agenda early enough to provide all of our witnesses with the time they need to provide us with their thoughtful views on the bills before us.

There are two bills before us today that I have co-sponsored with the chairman, H.R. 3593, the VA Construction Assistance Act of 2013 and H.R. 4261, the Gulf War Health Research Reform Act of 2014. I especially look forward to hearing from our witnesses regarding these bills.

Again, thank you, Mr. Chairman, for holding this hearing, I look forward to hearing from our witnesses, and I yield back the balance of my time.

Mr. COFFMAN. Thank you, ranking member.

Mr. Huelskamp, you are recognized for five minutes.

Dr. HUELSKAMP. Thank you, Mr. Chairman, I appreciate the opportunity to testify in support of H.R. 4281, the Protecting Business Opportunities for Veterans Act of 2014.

Over the years this committee has heard testimony, received Inspection General reports, and heard reports of numerous businesses who we believe took advantage of set-asides rightfully reserved for service-disabled veteran-owned small businesses.

As a member of this subcommittee as well as the house small business committee I believe the evidence of fraud and abuse of these programs requires stricter oversight and enforcement.

This act would apply to small business concerns owned and controlled by a veteran with a service disability as well as small businesses controlled by veterans who receive federal contracts from the VA.

The bill simply requires that upon receiving a contract with the VA the VA must obtain a certification that the business concerns will comply with the requirements already written into the law, in particular it will address how the recipient of the contract will meet the requirement that 51 percent of the contracted service or work be performed by a veteran-owned business or a service-disabled veteran-owned business.

Those receiving a contract will be required one, to certify to the VA that to meet the specific performance requirements already in law, and two, acknowledge that the certification is subject to the false statement penalty under the U.S. Criminal Code.

Furthermore this legislation will require the Office of Small Business and Disadvantage Business Utilization and the VA's chief

acquisition officer to implement a process to monitor compliance and insure violations are reported to the Office of Inspector General.

The IG is then required to file an annual report to the house and senate VA committees showing the number of small business concerns suspended or debarred from federal contracting and those referred for prosecution for violating the certification requirement.

The intent in this bill simply is to provide law enforcement with the necessary tools to crack down on the contractors who use pass through and other methods to take advantage of set-asides rightfully reserved for veterans.

An affirmative certification at the time of the award constitutes strong evidence of the knowledge and intent to deceive if a contractor is later found to have not been eligible.

Finally the bill is necessary to direct the OSDBU and the VA chief acquisition officer to do what they should be doing all long, that is to monitor and enforce compliance.

The Protecting Business Opportunities for Veterans Act will insure those rightfully deserving of the contracts have access and put in place tougher enforcement mechanisms to insure those wishing to exploit the system are caught and held accountable.

And with that I yield back the balance of my time, Mr. Chairman. Thank you.

Mr. COFFMAN. Thank you, Mr. Huelskamp.

Ms. Walorski, you are now recognized for five minutes.

Ms. WALORSKI. Thank you, Mr. Chairman.

This directive stems from feedback the committee received regarding the members only briefing held on December 3rd, 2013 which the VA, VA's Office of Inspector General, and the Government Accountability Office all attended.

At this briefing the committee provided an overview of VA's information security vulnerabilities using VA's own internal documents and previous testimony for VA Inspector's General.

Recognizing the importance of protecting the personal information of their constituents many members of Congress have asked the committee to take all steps necessary to strengthen IT security within the VA.

In addition to the December briefing the committee held numerous meetings and discussions, sent information security-related letters, and held a hearing in June 2013 to address IT security weaknesses. Unfortunately VA's lack of response, cooperation, and dialogue has been a longstanding issue that continues to this day.

During the December briefing independent information security experts verified HVAC's findings about the VA's critical network vulnerabilities, including the following.

VA's network had been compromised, at least nine times since March 2010.

Within VA's 420,000 computers there were 5 vulnerabilities on at least 95 percent of these computers.

VA employs tens of thousands of outdated operating systems.

Because of VISTA's vulnerabilities VA stated that a data breach to financial, medical, and personal veteran and employee protected information will occur with no way of tracking the source of the breach.

Over the past 20 years VA's independent auditor, Office of Inspector General, and the GAO have all reported persistent weaknesses in the VA's security, placing veterans' personal information in jeopardy.

In fiscal year 2013 the VA's independent auditor reported material weaknesses in IT security for the twelfth year in a row. The VA's Inspector General identified VA's lack of effective information security controls as a major management challenge.

The IG's upcoming FISMA audit provides 35 recommendations for improving VA's information security program. Thirty-two of these recommendations are identical to recommendations included in the previous years' audit.

The GAO has found VA's IT security issues since the late 1990's.

Since 2007 the GAO has found major weaknesses in each of the five major categories of information security controls at the VA.

The number of incidents affecting VA's computer systems and network has risen over the last several years.

The VA system serves as a gateway to many other federal IT systems. Given the goal of integrating electronic health records with the DoD and the eventual future connection of the National Health Care Program securing the VA's IT system is critical.

VA's persistent, decades long IT security weaknesses highlight the need for stronger, more focused action to insure that the VA fully implements a robust security program.

Despite OIG's testimony and the committees' evidentiary documents that originated within the VA itself, VA officials did not concur with our findings from the briefing, including that critical security vulnerabilities do exist and that the domain controller remains compromised.

It is important to understand the critical nature of the security failures we are discussing. Not only do these failures disrupt the daily transactions between the VA and the veterans, but they are incredibly costly.

The VA IT security failure in 2006 that impacted 26 and a half million veterans cost the VA $50 million just to mail out data breach notices.

Given VA and OIT's more than 3.7 billion budget and thousands of employees, these numerous security flaws are unreasonable and irresponsible.

These failures are not due to a lack of resources, they are due to a lack of priorities and proper federal guidance.

I am confident this directive will provide the VA with a clear road map, prevent ambiguity, and take away any guesswork in order to achieve a risk-based approach to address each of these challenges.

The GAO has agreed and stated that if the directive is implemented it will allow VA to refocus its efforts on steps needed to improve the security of its systems and information.

This bill itself establishes an explicit plan of action to resolve VA's IT security weaknesses as identified by the committee, GOA, VA OIG, and others. This plan is taken from a common federal and industry best practices.

Specifically the bill directs the secretary to reclaim, secure, and safeguard VA's network, including their domain controller; defend

workstations from critical security vulnerabilities; upgrade or phase out of unsupported and outdated operating systems; secure web applications from vital vulnerabilities; protect VISTA from anonymous user access; and comply with federal information securities laws, OMB guidance, and NIST standards.

To improve transparency and accountability the bill directs the secretary to submit to the committee a biannual implementation report, including a description of the actions taken by the secretary, to implement and comply with the directive. The VA OIG will also be required to submit to the committee an annual report that includes a comprehensive assessment of VA's execution of the directive.

Finally on a monthly basis the secretary shall submit to the committee reports on any discovered security vulnerabilities.

Thank you, Mr. Chairman, I think our veterans deserve better. Thank you.

Mr. COFFMAN. Thank you, Ms. Walorski.

Our first panel is now at the witness table and I thank you for being here today.

We will hear from Ms. Stella Fiotes, Executive Director of the Office of Construction Facilities Management from the Department of Veterans Affairs. She is accompanied by Mr. Tom Leney, Executive Director of the Office of Small & Disadvantaged Business Utilization of the Department of Veterans Affairs.

Ms. Fiotes, your complete written statement will be made a part of the hearing record, and you are now recognized for five minutes.

STATEMENTS OF STELLA S. FIOTES, EXECUTIVE DIRECTOR, OFFICE OF CONSTRUCTION AND FACILITIES MANAGEMENT, OFFICE OF ACQUISITION, LOGISTICS AND CONSTRUCTION, DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY TOM LENEY, EXECUTIVE DIRECTOR, OFFICE OF SMALL & DISADVANTAGED BUSINESS UTILIZATION, DEPARTMENT OF VETERANS AFFAIRS

STATEMENT OF STELLA S. FIOTES

Ms. FIOTES. Thank you.

Good morning, Mr. Chairman, Ranking Member Kirkpatrick, and other members of the subcommittee. Thank you for the opportunity to be here today to discuss VA's views on pending legislation, including H.R. 3593, the VA Construction Assistance Act of 2013 and a draft bill that concerns compliance with VA's small business programs.

Mr. Chairman, I would like to ask that our written statement be entered for the record.

Mr. Chairman, VA is not testifying on all the bills on the agenda today. Draft bills on gulf war illness research matters and VA IT securities programs were not received in sufficient time to prepare and clear administration views.

I want to insure the subcommittee understands we are not dismissive of these remaining bills or your interest in them, this was purely a matter of having sufficient time to prepare well developed and helpful formal views on complicated subjects.

As noted in our written testimony we will be following up for the record on the remaining bills and we are glad to brief you and your staff at your convenience on the subject matter covered by those bills.

I will speak to H.R. 3593 first.

VA appreciates the strong interest and support from the subcommittee to insure that our major construction projects are delivered successfully.

I would like to make the point that VA has a strong history of delivering facilities to serve veterans. In the past five years VA has delivered 75 major construction projects valued at over $3 billion; however, we also fully acknowledge our challenges on the major construction projects that have been the subject of a great deal of dialogue with you and other stakeholders. We are committed to continuing that dialogue.

VA however does not believe that the approach outlined in the bill will achieve the desired results and thus does not support it.

While there have been challenges with our projects we have taken numerous actions to strengthen and improve the execution of all of VA's ongoing major construction projects and insuring the department's future capital program is delivered on time and within budget.

These include implementing the recommendations from the GAO and the Department's Construction Review Counsel, including the specific actions that would be required in Section III of the bill. Therefore we don't believe Section III of the bill is necessary.

Section IV of the bill would require that VA enter into an agreement with the Army Corps of Engineers to procure a special project manager to oversee VA major construction projects for facilities in Denver, Orlando, and New Orleans.

VA believes the creation of a special project manager would be problematic in the management and supervision of these projects.

The bill raises serious questions about the contractual relationship between the VA and its contractor, potential confusion on the lines of authority the special project manager will have, vis-α-vis, the VA and the Corps, and the affect upon the independent exercise of discretion by the VA contracting officer who is ultimately responsible for managing the contract on behalf of the government.

VA however continues to be open to consultation and collaboration with the Corps or other specialists outside VA.

We continuously evaluate our processes and delivery methods for each lease and for each construction project on its merits and we benchmark industry best practices with several agencies, including the National Institute of Building Sciences, GSA, and the Corps.

When VA determines that the best delivery strategy is to employ another agency such as the Corps this strategy is used. In fact VA and the Corps have a long history of working together to advance VA facility construction and share best practices. Our current discussions with the Corps are a logical evolution of that relationship.

Mr. Chairman, thank you for the opportunity to present views on this bill.

I would like to now turn to my colleague, Tom Leney, who will address the bill regarding service disabled veteran owned small businesses.

[THE PREPARED STATEMENT OF STELLA S. FIOTES APPEARS IN THE APPENDIX]

STATEMENT OF TOM LENEY

Mr. LENEY. Good morning, Mr. Chairman, Ranking Member Kirkpatrick and other members of the subcommittee. Thank you for the opportunity to discuss the draft small business measure that the subcommittee asked us to review.

Mr. Chairman, we understand that H.R. 4281, the Protecting Small Business Opportunities for Veterans Act was just introduced on Friday, March 21st. It differs substantially from the draft that we received earlier and the VA has not had the opportunity to comprehensively review this new text.

You have our views on the original draft bill, I will provide some comments to the subcommittee regarding our preliminary analysis of the version introduced late last week as 4281.

The VA understands the committee's interest in veterans complying with the rules on limitations of subcontracting as the VA procures more dollars and awards from SDVOSB's than the other civilian agencies of the government combined. Unfortunately this draft bill only applies to veteran-owned small businesses that are contracting with the VA.

We think it unfairly singles out veterans and places an unfair burden on those businesses that would not be required of any other small businesses or at any other agency.

Tools exist that we believe can meet the aims of this legislation. For example, monitoring the amount of work passed to subcontractors is required of contracting officers under the current federal acquisition regulation.

In addition the VA has established a subcontracting compliance review program that audits prime contractors to insure compliance with this provision.

We believe processes such as these enable us to achieve the objectives set out in the legislation.

Thank you for the opportunity to testify before the committee today. Ms. Fiotes and I look forward to answering any questions the committee may have.

Mr. COFFMAN. Our thanks to the panel.

Okay. Ms. Fiotes, in Denver VA asked for bids based on the presumption that it would produce a $604 million project for the hospital, but it appears VA has produced potentially a billion dollar incomplete design which they provided eight months after the bid process was completed. How can VA prevent such loss of control in future designs?

Ms. FIOTES. Mr. Chairman, we believe that the project designs we have delivered, albeit somewhat later than originally anticipated, are in fact able to be constructed within the appropriated amount for this project.

Mr. COFFMAN. Ms. Fiotes, you reference the new Las Vegas facility in your testimony as an example of VA completing major construction; however, according to the GAO report Las Vegas was $260 million over budget and 74 months late. So is this representative of VA major construction efficiency, this project?

Ms. FIOTES. Mr. Chairman, in our response to the GAO draft report the VA outlined that it did not agree with the methodology the GAO was using to assess time and cost against these projects, starting at some point in the very early planning stages when the project, and not even the site, were actually defined and then taking that number and that schedule as the basis for comparing to what ultimately happened many years later with a real design and a real site and a real construction project we believe was not an accurate depiction.

So we would argue that the time and the cost should be judged against the appropriated amount by Congress and the time the construction was bid, and in that sense we would state that the project was in fact delivered on time and on budget.

Mr. COFFMAN. So are you saying that this project was delivered on budget and on time, the Las Vegas project?

Ms. FIOTES. Based on the way that we account for time and budget, yes.

Mr. COFFMAN. Wow. Well the GAO obviously differs with you, and I think what was so compelling about the GAO report was that in the report it referenced the Army Corps of Engineers as building the same projects or what it called similar projects for the Department of Defense on budget and on schedule.

Ms. Fiotes, do you believe that contractors submit excessive or unwarranted change orders to drive up cost or cause delays? How does VA manage the change order process?

Ms. FIOTES. Mr. Chairman, the change order process is a very critical process in the duration of the construction of any large complex project, and we recognized, as did some of the GAO reports, that our process was too lengthy and too cumbersome resulting in delays in the execution of the change orders and the payment of those change orders.

We have since addressed those challenges. We have put in place new policies, we have established metrics for the change orders, we have added staff, we have added legal counsel to help us with the review of the change orders, and we are in a much better position now and are processing our change orders at a much better rate than in the past.

We hope within the next several months to be completely caught up with our backlog.

Mr. COFFMAN. So when the GAO report says that these major medical construction projects are delayed an average of 35 months each with an average overrun of $360 million each, you differ with GAO and you say that you can produce accounting standards that erase those delays and erase the amount that is over budget? You can come up with that?

Ms. FIOTES. Mr. Chairman, I didn't reference accounting standards, I just referenced our response to the GAO, which the GAO included in their final report, although they did not agree with our approach.

It is that we measure time from the time a construction project is awarded and not from the time it was conceived, and we measure cost from the time the full amount is appropriated, not from the time the project was conceived. That was the difference be-

tween our evaluation of time and schedule and the GAO's evaluation.

Mr. COFFMAN. Well it is whatever you say it is on any given day.

Ms. KIRKPATRICK. Thank you, Mr. Chairman.

Thank you for your testimony today, and we want to, you know, help to solve this problem and get these construction projects completed so they can serve our veterans.

And my line of question is going to be addressing two things. One is, is basically the construction management and using USACE, and then I also want to talk a little bit about the bid process. So those will be my lines of questioning.

First, has the VA used USACE in managing a major construction project recently?

Ms. FIOTES. Ranking Member Kirkpatrick, we have not used them for major construction projects; however, we have used the Corps for a number of minor construction projects, and more recently in construction projects for our National Cemetery Administration as well.

Ms. KIRKPATRICK. Have you done any quantitative studies between the Corps' overhead and your internal overhead as opposed to—when you use them I mean is there a difference in the overhead costs?

Ms. FIOTES. I don't have those facts before me. We could compare those. I am not sure what the numbers are. I just don't know if we have done that, because those projects, the minor projects are not in my jurisdiction, they are completed by the Veterans Health Administration. But we could certainly get some more information if you would like.

Ms. KIRKPATRICK. Does it make sense to you to use the Army Corps of Engineers in major construction management projects?

Ms. FIOTES. Again, congresswoman, as I said, we evaluate each project on its merits, and if there were a case where we had a major project that we wanted to undertake with the Corps we would have to enter into early discussions with them way before the time that we would award a construction contract to see if that would be an appropriate vehicle to use. And we have done that, as I said, with numerous minor projects.

Ms. KIRKPATRICK. Okay, let me go quickly to the bid process and we may go back to the management.

Although your testimony doesn't address the use of design build versus design bid build the legislation we are proposing requires design build to the extent practical.

Can you enlighten the committee on the advantages and disadvantages of each of the types of bid process, design build versus design bid build?

Ms. FIOTES. Congresswoman, the design build delivery method is a method where the architect and the contractor are awarded one single contract and the contractor has the responsibility to deliver the design as well as the construction of the project.

The traditional design bid build process is where we have a separate contract with an architect engineer to develop a design, 100 percent design, and then go out to bid and hire and award a construction contract to a separate contractor to build the project.

There are advantages and disadvantages to both.

The traditional method allows for a complete design and for input of the user and the facility during the development of the design.

The design build process takes a little bit more of the design out of the control, if you will, of the user and puts it in the hands of the contractor. It is said to save time in some instances. And again, it is a case by case basis.

I will tell you that I have used design build in previous contracts, we have used design build at the VA for certain projects. Traditionally the very complex projects such as the medical centers we are talking about would probably not be the best suited for a design build because it would be very difficult to just describe the performance requirements and then leave the design completely up to somebody independent of the users.

But we have in certain cases where it was just a single more standard type of construction project we have used design build, and we are considering using it in the future as well.

So it is a case by case analysis of the project and what best suits it.

Ms. KIRKPATRICK. One quick last question.

Are change orders treated differently depending on whether it is design build or design bid build?

Ms. FIOTES. Yes, they are.

Ms. KIRKPATRICK. And how is that different?

Ms. FIOTES. In the design bid build process the contractor has bid on 100 percent design documents and therefore any changes from those documents, that happen either because of a government proposed change or because of unforeseen conditions, must be submitted by the contractor to the government for an independent estimate and then an issuance of a change order for the amount that the government deems appropriate for that change.

In a design build process there are fewer opportunities for the discussion between the government and the contractor on change orders because the contractor has taken on some of the risk of changes since he has developed the design as well.

That is not to say that there are not changes and in the design build process when there are changes they are usually much more expensive.

Ms. KIRKPATRICK. Thank you. I have gone over my time.

Thank you for allowing me, Mr. Chairman.

Mr. COFFMAN. Thank you, ranking member.

Dr. Roe, State of Tennessee.

Dr. ROE. Thank you, Mr. Chairman.

And I want to delve in further what Ms. Kirkpatrick was talking about, something I have a lot of experience with having been in the process of building three hospitals, three medical office buildings, schools, public buildings for the City of Johnson City, Tennessee, so I am very familiar with the bid process and change orders.

And literally it should be embarrassing to the VA, this Orlando, I mean I think the cubs are going to win the world series before that hospital is finished in Orlando, Florida, I think that is a possibility. So anything to speed it up, because money spent with what happened down there is not money spent on some other needy project the VA has. So I am going to go with what we did.

Very simply there are two ways. You very well stated out what a design bid build and what design build is, and they both have advantages and disadvantages.

What I like about the design bid build is, is that when we would build a school, for instance, at home we would build in probably about ten percent change order. We knew there were going to some change orders. Once you get started there are things when you have designed it as well as you can with your architect and you had a sealed bid and a qualified contractor bid on it, you know you are going to run across some things in there that weren't anticipated, so we build about ten percent and sometimes you don't.

And what you described is the way it should be done. If you hit something that needs to be changed it comes back, we would vote on it in a city council, approve that change order or not approve it, and go on.

So I think that is a very good way to do it, and to have a—and what we hired—we learned this very early on, we hired our own person to not just have the contractor there, and that is why I think having a supervisor in the Corps of Engineers is a great idea, because you have got a third party who can look after your interests and watch over that project. And we hired someone, the City of Johnson City, a former contractor to do that very thing. They would look over every building structure that we put up, he was there every day several days a week at least looking over and supervising that along with it and working with the contractor, not some adversary, but looking after it, but looking at our interests, the taxpayers and the city people.

So I would think that would be a good thing that you all would want that and to have an objective third party out there like the Corps who is not involved with VA to overlook your project. I think it will slow things down, I think it will make it better for you. I would encourage you to look favorably on that, not unfavorably on that.

Any comments.

Ms. FIOTES. Congressman, thank you for your remarks, and I agree with the way you have laid out the challenges, particularly with the change order process.

We don't believe that the establishment of this special project manager will aid the project because of the complex contractual relationships between the VA and the contractor, the responsibilities of the contracting officer as the arm, if you will, of the government in implementing the contract, and then the uncertainty of the role and the authority of this professional contractor.

Dr. ROE. Well why would it work where I was, because it worked great. I mean we felt like our interests were being looked after on the job site when we had someone there who knew what they were doing who was in the construction business, who could tell us, no, this is not being done. Why would it work there and it wouldn't work at a VA site?

Ms. FIOTES. Well, and I can't comment on the specific contract and the specific project, but I can tell you that we do have numerous project team members and project executives looking out for——

Dr. ROE. Well who was looking after Orlando?

Ms. FIOTES. I am sorry?

Dr. ROE. Who was looking after Orlando and Denver and Las Vegas, these other projects that have not gone exactly like I think anybody wanted them to?

Ms. FIOTES. And I agree that we have run into challenges, and I can't speak anymore about the Orlando challenges because I think we have spoken about those in the past, but I think that the cooperation and the collaboration with the Army Corps of Engineers could be a benefit to the VA and to the project if it is the right type of collaboration.

Dr. ROE. I agree 100 percent, and I think, I am looking at——

Ms. FIOTES. We just don't think that the project manager may be the best vehicle.

Dr. ROE. I think a project manager, someone who is there to look after our interests, the taxpayers, the veterans' interest to make sure this project is done right and to point it to work with the contractor, not as an adversary. We didn't have that relationship with our contractors. And I think you will find it works very well. I am surprised that the VA has a reluctance to do that.

Mr. Chairman, I see my time has expired, I yield back.

Mr. COFFMAN. Thank you, Mr. Roe.

Mr. Walz.

Ms. Walorski.

Ms. WALORSKI. Thank you, Mr. Chairman.

Ms. Fiotes, does the VA make sure that its prime contractors use surety bonds with their subcontractors to insure timely payment?

Ms. FIOTES. Yes, we do, congresswoman.

Ms. WALORSKI. On all projects?

Ms. FIOTES. On all our projects, yes.

Ms. WALORSKI. Thank you, Mr. Chairman, I yield back.

Mr. Coffman. Mr. O'Rourke.

Mr. O'ROURKE. Thank you, Mr. Chairman.

I want to see if I can better understand some of what we are talking about.

And so I understand that you don't agree with the conclusions that the GAO has reached, and when the chairman was asking about the Las Vegas project in particular you talked about a difference in terms of when you begin to measure the costs outlayed and the start of the clock for the construction, not when the idea was conceived, but when the funds were appropriated.

But would you accept I guess the thrust of the argument that projects are taking too long to complete and are too expensive or more expensive than they should be?

Ms. FIOTES. I can't necessarily agree with that. If we look at the projects at the time that they are fully scoped out with their requirements clearly defined with an appropriation that matches the requirements that have been submitted I can't say that we exceed the cost after that point.

But if the project spends too much time trying to get to that point that is a problem, and that challenge we have recognized. We have recognized that when the Construction Review Council, chaired by the Secretary, looked at some of those projects, and we recognize that the early stages of planning needed to be strengthened and we needed to be very clear in defining our requirements

and our scope before we came to Congress asking for money, and we have put that in policy and we no longer submit projects going forward for construction of appropriation lists, we have 35 percent design completed.

That gives us the confidence that we have established the requirements, we know the basics of what the design is going to look like, and we have a substantive budget that we can base our request on.

I don't think that was happening in the past, and some of the projects that we are discussing happened before these policies were put in place.

Mr. O'ROURKE. I appreciate that, and my perspective in my job representing El Paso is the fact that our VA facility—proposed VA facility, which is to be co-located with the active duty military hospital in El Paso, is number 79 on that SCIP list, which lists, all capital projects the VA has yet to construct, and so if—I understand the improvement in the processes that you just described, but if you are unable to acknowledge that the hundreds of millions of dollars in individual projects over what they were initially conceived to be and that the amount of time that we are taking to complete these is a problem and needs a more urgent corrective action to resolve it, it is deeply troubling to me as number 79 on the list for a facility that is desperately needed in El Paso where we are sending folks on a ten-hour round trip to get care that they should be able to receive in the community.

So I hope you understand where I am coming from on this, and I agree with our ranking member who said, you know, we should only with the greatest hesitation move forward on legislation because it is such a blunt instrument, and you are the subject matter expert in this, not me, so I want you to be able to come up with the best possible solution to the problem we have.

But it is hard for me when it doesn't seem like there is an acceptance of the problem or at a minimum a very wide gulf between what you are hearing up here from the folks who represent these communities where we have these large cost and time overruns and then what you are saying, which is, you know, I guess changing—a difference of opinion about when the clock starts. You know, by the time you start the clock on our project we are, you know, a decade plus out from start.

So that is where I am coming from, and it makes me more likely to support this legislation when I don't hear in terms of at least I can understand an admission of the problem and how it is we are going to fix it with the urgency required not only to fix the current problems but to get to those that are, you know, further down the line on that SCIP list.

Ms. FIOTES. Congressman, I don't disagree that our process needed fixing, and that is what I was trying to describe before when I said that we recognize that we were not doing a good job of planning up front and establishing the requirements and nailing down the scope before we came to Congress to ask for an appropriation, and that is what has caused what appears to be a series of cost increases.

The fact that the project started as a shared facility somewhere and ended up being a stand-alone replacement hospital on its own

campus in the span—over the span of several years of course added hundreds of millions of dollars to the cost. That was our fault. We were not doing a good job of planning before we came to the Congress.

We do acknowledge that, and that is the reason that was the number one recommendation from the Construction Review Council and the number one priority to implement it. We would not bring forth projects that were not thoroughly thought through, thoroughly designed, and with a good solid budget before we asked for money.

So no, I did not say that we did not—I just—that we did not have issues, I just said that the way the GAO report presented the cost escalations we did not agree with.

Mr. O'ROURKE. I appreciate that.

My time is expired, but I would love to follow up with your office after this to find out how this impacts not only the projects that we have identified today but those much further down the line, like number 79 on the SCIP list.

Ms. FIOTES. No, we owe you that, congressman, we talked about it last time, we just didn't make it happen yet. We will.

Mr. O'ROURKE. Thank you.

Thank you, Mr. Chairman.

Mr. COFFMAN. Thank you. Dr. Huelskamp.

Dr. HUELSKAMP. Thank you, Mr. Chairman.

Mr. Leney, I appreciate your testimony, I appreciate that you haven't had a full opportunity to review H.R. 4281, but a couple questions just on the program, and I am looking back at the GAO report from last August or over a year ago I guess, longer than that, August 2012, indicating the program remains vulnerable to fraud and abuse. Can you quantify the extent of the abuse by pass through?

Mr. LENEY. Yes, sir. Since the last GAO report we put a lot of effort into making sure that the veterans first program is not vulnerable to fraud and abuse.

We have instituted post verification audits of our eligible firms, we are doing about 100 of those a month. To date we have found less than three percent of the firms that we audit are ineligible; we go on site, look at the firms, look at their documentation, they are unannounced audits. Sometimes veterans do not appreciate the need to do that, but we appreciate the need to insure the integrity of the program, and we have found less than three percent to be ineligible at the time we audit them.

So we think that the process that we use to verify firms is a very solid one, it sets the standard for the federal government, and it has been successful.

This bill however speaks to a different issue, which is the issue of limitations on subcontracting, which is not directly in the purview of my office so I am going to step on a limb a little bit to talk about what contracting officers do.

Contracting officers do monitor the performance of prime contractors and our office of acquisition and logistics and construction has put together a program where we go out and we do a subcontracting review. They also go on site, they look at documentation to determine whether or not prime contractors are both meeting

the small business subcontracting goals and to insure that limitations on subcontracting are met.

Dr. HUELSKAMP. I didn't understand, Mr. Leney, who does that? It is not your office. Who is the office actually falling through on that?

Mr. LENEY. This falls under the office of acquisition and logistics and construction.

Dr. HUELSKAMP. Okay. Have they had a chance to review the bill or any testimony from then, Mr. Chairman?

Mr. LENEY. They have not has a chance—we have not had a chance to discuss the final bill that you presented, but like I say, we do have—we do have a program, because we agree that it is important to insure, particularly the prime contractors, when we provide awards to service-disabled veteran-owned small businesses or any business that—they—or any small business that they comply with the limitations of subcontracting, and that is the reason the VA established that program. So we would do additional reviews.

They do it on a random basis and based on a risk assessment if they determine that there is a concern that a small business is not meeting its subcontracting.

Dr. HUELSKAMP. How would they know if there was a concern if they are not——

Mr. LENEY. If a contracting officer has evidence that this might be going on they can refer a small business to this program and they go out and do an audit.

Dr. HUELSKAMP. Who would make the reference? Who would refer that?

Mr. LENEY. A contracting officer. The contracting officers are the people who have the responsibility to insure that the contract is properly implemented, and so they monitor the work of the prime contractor and they monitor the amount of work that is subcontracted out.

Dr. HUELSKAMP. Well, as I read the OIG report and various other reports that therein is the concern, that you know, you say they monitor it, they have not done that adequately.

More of a concern we have this set aside for veterans and I think the VA should be concerned if there is evidence that the work is not being done as required under the law by veterans, and I think we are going to hear testimony later from veterans' organizations that would expect that to occur.

But as you know the false statements by contractors are already a violation of the law, and this sort of a bill is pretty simple, it just says they have to submit and that they understand that that helps prosecution later on if, and, when it is found that there is some evidence of fraud and abuse in this system.

Again, I know this committee is committed to making certain and certainly the small business committee as well to make certain that the work is done as required under the law, and we just want to provide tools to the prosecutors to make that happen.

With that, Mr. Chairman, I yield back.

Mr. COFFMAN. Thank you, Mr. Huelskamp.

Our thanks to the panel. You are now excused.

I now welcome our second and final panel to the witness table. On this panel, we will hear from Mr. Gregory Wilshusen, Director

of Information and Security Issues for the Government Accountability Office; Mr. Raymond Kelley, Director of National Legislative Service, for the Veterans of Foreign Wars of the United States; Ms. Diane Zumatto, National Legislative Director of AMVETS; Mr. James H. Binns, Chairman of the Research Advisory Committee on Gulf War Veterans' Illnesses; Mr. Davy Leghorn, Assistant Director of the Veterans Employment and Education Division of the American Legion; and Mr. Frank Wilton, Chief Executive Officer of the American Association of Tissue Banks.

Now, all of your complete written statements will be made part of the hearing record. Mr. Wilshusen, you are now recognized for five minutes.

STATEMENT OF GREGORY WILSHUSEN

Mr. WILSHUSEN. Chairman Coffman Chairman Coffman, thank you very much for the opportunity to testify today on this hearing related to some proposal legislation, particularly the one related to information security at the VA.

Before I begin though, I'd like to recognize several members of my team, who were instrumental in developing my written statement. With me today is Tyler Mountjoy and also back at the office, Jeff Knott, Jennifer Franks and Lee McCracken, and these individuals will be involved with our ongoing review of information security at VA.

The use of information technology is critical to VA's ability to carry out its mission of assuring that veterans receive proper health care, benefits, support and memorials. However, without adequate protections, the VA systems and information are vulnerable to exploitation by a wide array of cyber based threats, potentially resulting in, among other things, the compromise of veterans' personal information.

GAO has identified information security as a government wide high risk area since 1997. And the increasing number of security incidents at the VA further underscores the need for the department to implement appropriate security over its systems and information.

Our work has shown that the Department of VA continues to face longstanding challenges in its information security program. From fiscal year 2007 through 2013, we noted that VA has had weaknesses in each of the five major security categories that we track over that period of time in each year, and these include those controls that protect and limit unauthorized access to its systems, controls such as configuration management which are intended to ensure that only authorized programs are in operation and are current and apply appropriate patches, segregation of duties, contingency planning which is also intended to assure that disruptions in service are minimized and prevented to the extent possible, and importantly, security management.

And these are the controls that establish the governance and assure that controls are tested, and known weaknesses are remediated in a current timely manner.

For the twelfth year in a row, the VA IG has identified information security as a material weakness, which is the most significant kind in its audit of the department's financial statements.

In addition, the IG has noted that it is a major management challenge for the department to effectively implement its security program. Our work that dates back to the 1990s show that these weaknesses have been persisting for a very long.

And to help address this, we know that the subcommittee is considering draft legislation which is intended to improve and help VA improve its information security program.

I would like to point out that the draft legislation allows for and provides that the VA implements security objectives, as well some very specific security control activities. In certain instances, the changing technologies, cyber threats and business practices at agencies introduces risks that very specific control activities that may be appropriate today may not be appropriate tomorrow.

And so we suggest that by emphasizing the need for VA to focus on the security objectives, and ensure that the security activities that are identified are implemented on the basis of risk will help to assure that those objectives are being met and could result in VA improving its information security.

Mr. Chairman, that concludes my statement. I'd be happy to answer your questions at the appropriate time.

[THE PREPARED STATEMENT OF GREGORY WILSHUSEN APPEARS IN THE APPENDIX]

Mr. COFFMAN. Mr. Kelly, you are now recognized for five minutes.

STATEMENT OF RAYMOND KELLEY

Mr. KELLEY. Thank you, Mr. Coffman Chairman. On behalf of the men and women of the Veterans of Foreign Wars and our auxiliary, thank you for the opportunity to testify today.

In regards to H.R. 3593, the VA Construction Assistance Act of 2013, it's well documented that the Department of Veterans Affairs struggles to complete major medical facility construction projects on time and on budget.

Currently, VA has an average project delivery delay of 35 months and average costs overrun of more than $300 million. VA is in the process of building three medical centers, each of which has been met with their own unique problems that has caused VA to lose time and money that could've been used on other projects.

VA has a list of major construction projects that will cost more than $20 billion to complete. Every effort must be made to ensure every dollar is used efficiently so VA can close these major construction gaps. H.R. 3593 will help VA achieve these goals.

Section 3 of this bill calls for five specific reforms to VA's major medical facility construction process. They are use medical equipment planners, develop the use of project management plan, peer review project management plans, develop a metrics to monitor change order processing, and use designed-build process when possible.

Using medical equipment planners places the experienced medical expert or equipment expert at the disposal of the architect and the construction contractor. When used properly, the medical

equipment planner can work with the architect during the design phase, and then the construction contractor during the build phase to ensure needed space, physical structure, and electrical support are adequate for the purchased medical equipment, reducing change orders and work stoppages.

Poor communication within VA and between VA and the general contractor has also led to delays and cost overruns. By developing and using project management plans, all parties at the onset of the project will have a clear understanding of the roles and the authorities of each member of the project team. Included in the plan will be a clear guidance on communication, staffing, cost and budget, as well as change order management.

Construction peer excellence reviews are an important aspect to maintaining a high level of construction quality and efficiency. These reviews provide important feedback, a separate set of eyes on the project management plan, to ensure a plan is in place, to make the project come in on time and on budget.

The VFW believes that VA should migrate from a design bid build to a design build model of construction management. A design build project teams the architect and engineer company and the construction contractor under one contract. This method can save VA up to six months of time by putting the design phase and the construction performance metric together. Placing the architect at the lead from the start to finish, and having a prime contractor work side-by-side with the architect, allows the architect to be an advocate for VA.

Also, the architect and the prime contractor can work together early in the design phase, and reduce the number of design errors, and also allow them to identify and modify building plans throughout the project. The VFW agrees with the recommendations allowed in Section 3 of this legislation.

Section 4 calls on VA to enter into an agreement with the Army Corps of Engineers, so the Corps can provide a special project manager to conduct oversight of the construction operations regarding compliance of acquisition regulations, and monitor the relationship of VA and the prime contractor at the three ongoing projects in Denver, Orlando, and New Orleans.

The VFW supports this provision, but it should be a stop gap measure to help VA to quickly complete these three outstanding major construction projects and systems must be put in place to ensure VA can function under a similar guidance without the assistance of the Corps in future projects.

It is important for VA to become more efficient at facility construction. Veterans have expectations that medical facilities will be available when VA first states when the completion date will be.

It is obvious by looking at the number of delays and the cost overruns, that the contracting and building procedures that VA currently use are inadequate and are costing VA millions of dollars more for each project, and causing five or six years' delay on much needed medical facilities.

By passing this legislation, VA will gain better oversight and cost controls and more efficient procedures for future construction projects.

Mr. Chairman, this concludes my testimony and I look forward to any questions you or the committee may have.

[THE PREPARED STATEMENT OF RAYMOND KELLEY APPEARS IN THE APPENDIX]

Mr. COFFMAN. Thank you, Mr. Kelley. Ms. Diane Zumatto, National Legislative Director of AMVETS, you have five minutes.

STATEMENT OF DIANE ZUMATTO

Ms. ZUMATTO. Chairman Coffman, Ranking Member Kirkpatrick and distinguished committee members, while I'm pleased to have the opportunity to sit before you today, I'm simultaneously disheartened that it's because we're dealing with administrative issues rather than making progress towards the understanding and treatment of the scourge that is Gulf War illness.

If we expect to understand Gulf War illness, if we ever expect to develop medically appropriate treatments for it, and if we ever hope to truly improve the quality of life of our Gulf War veterans, then business as usual can no longer be accepted.

Twenty-three years have passed since the end of the Gulf War, and sixteen since Congress first mandated the appointment of a public advisory panel of independent scientists and veterans to advise on federal studies and programs to address the health consequences of the Gulf War.

AMVETS' sole interest in seeing this legislation enacted is the health and therefore the quality of life of our Gulf War veterans. For all these years now, these men and women have suffered and continue to suffer from the often debilitating effects of Gulf War illness. How much longer are they to be expected to wait to get relief from their decades' long pain and distress.

AMVETS believes this legislation, H.R. 4261, the Gulf War Health Research Reform Act of 2014 can be an important part of the solution that Gulf War veterans have been waiting for all these years.

AMVETS fully supports H.R. 4261 which would establish the RAC as an independent committee with authority over budget allocations, staffing levels and expenditures, personnel decisions, processes, procurements, and other administrative and management functions.

This is perhaps the most important provision of the legislation. It would also require that the majority of the RAC members be appointed by the Chairman and ranking members of the House and Senate Veterans Affairs Committees rather than the VA.

This provision means that the RAC will not become just another part of the VA. It will also strengthen the RAC's ability to review, research, and studies, as well as publish reports related to Gulf War illness. The ability of the committee to freely make and publish recommendations, reports, et cetera, increases transparency and positively adds to the body of work on Gulf War illness.

The legislation also expressly a sense of Congress that VA should contract with the Institute of Medicine to conduct several Gulf War studies and reports previously ordered by Congress, which were not conducted or were not conducted in accordance with Congress' direction.

Until the right questions are asked, and the correct studies are conducted and considered, solutions will not be found. It also requires the VA to ensure that research conducted on this disease be referred to as Gulf War illness. It's time for the VA to call this condition by its commonly accepted name.

And with regard to future research, it would require that the Institute of Medicine reports on the health effects of veteran toxic exposures, consider animal, as well as human studies as Congress has previously ordered, to better understand the causes and how best to treat our afflicted veterans.

Since its formal establishment in 2002, the RAC's charter has undergone a series of minor changes, including in April 2014, May 2006, May 2008, and November 2010. Until May of 2013, there had not been any fundamental changes made to the committee's charter. All that changed with a stroke of pen on 17 May 2013, when the independence oversight role and the provision providing the committee with authority over its own staff and budget were eliminated.

With this action, it appears that the RAC has essentially been turned into nothing more than an internal VA advisory committee, operating strictly under VA's authority with little to no connection to the national community.

I'd be happy to answer any further questions.

[THE PREPARED STATEMENT OF DIANE ZUMATTO APPEARS IN THE APPENDIX]

Mr. COFFMAN. Thank you, Ms. Zumatto. Mr. James Binns, Chairman of the Research Advisory Committee on Gulf War Veterans' Illnesses.

STATEMENT OF JAMES H. BINNS

Mr. BINNS. Thank you for the opportunity to testify in support of H.R. 4261.

Since Congress created the Research Advisory Committee on Gulf War Veterans' Illnesses, our members have testified at ten congressional hearings. This is the last time a committee member will freely testify without VA censorship unless this bill becomes law.

Gulf War illness is a serious disease associated with service in the war, affecting 250,000 veterans. It cannot be explained by any psychiatric illness, and likely results from environmental exposures.

Effective treatments can likely be found with the right research. These are the conclusions of the Institute of Medicine. Next month our committee will release a five year report that shows research is making progress. But just as science is turning the corner, career VA and DoD staff have attempted to revolve old fictions, that the same thing happens after every war, due to psychiatric factors.

Because there is no evidence to support this position, they have resorted to manipulating research to provide apparent support. In its recent survey of Gulf War veterans, the VA Office of Public Health included the questions to identify PTSD but not Gulf War illness.

In a medical journal, the heads of the three VA war related illness and injury study centers wrote that the illness quote, has

been documented after armed conflicts since the Civil War, and that a bio psycho-social approach will best benefit the patient. The list goes on.

VA's talking points say that it does not support the notion that some have put forward that these health symptoms arise as a result of PTSD or other mental health issues. But the some who are putting these notions forward are VA staff.

These actions threaten to mislead science down blind allees once again, just as has happened for most of the last 23 years.

Our committee has been charged since its inception with assessing the effectiveness of government research. We complimented early progress under Secretary Shinseki. But when staff launched this campaign, we reported it, and asked the Secretary to investigate and remove those responsible from Gulf War research responsibilities.

Instead, VA removed us. In May of last year, I was notified that the committee's charter had been changed to eliminate its charge to assess the effectiveness of government research, and that the membership of the committee would be replaced over the next year.

Fresh blood is certainly desirable, but two of the three scientists subsequently proposed for membership by VA were stress advocates. One has edited a textbook on stress, and is a member of the American Psychosomatic Society. VA has sought to backtrack, pulling these names, and appointing others, but they have shown where they intend to go, once they are no longer under scrutiny.

VA has attempted to explain the charter changes as necessary to comply with the Federal Advisory Committee Act, or that the Committee's work is an inappropriate oversight. But virtually identical language has been part of five charters signed by four secretaries, including Secretary Shinseki.

All recognized, that an inherent part of advising on future research is to assess the effectiveness of the research already being done.

The clear purpose of the charter change was to stop our committee from reporting on staff efforts to mislead research, and that is exactly the effect that it's having. Attached to my testimony is the draft section on VA's research program which had to be removed from the report our committee will release next month.

In addition, VA has recently stated that committee members may not release reports without written VA approval.

H.R. 4261 gives back to the Research Advisory Committee the responsibilities and independence VA has taken away. Ms. Zumatto has already summarized the terms, so I will proceed to state that this bill is vital to maintain the hope that progress toward effective treatments will continue. But restoring the committee only gets us back to where we were: Advancing science in one area, while the staff pulls it back somewhere else. That is what has happened for most of the last 23 years. If the IOM is correct, and I believe it is, that effective treatments can likely be found with the right research, then Gulf War veterans would likely have effective treatments today but for this staff obstruction.

Unless staff obstruction is removed once and for all, science candidly may never reach this goal. VA leadership has decided to shoot the messenger instead. I urge Congress to go beyond this bill and

pursue a rigorous investigation necessary to end this shameful history and clear the way ahead.

[THE PREPARED STATEMENT OF JAMES H. BINNS APPEARS IN THE APPENDIX]

Mr. COFFMAN. Well, thank you so much for your testimony. I have just got to say, as a Gulf War veteran I want to thank you both, Ms. Zumatto and Mr. Binns, for your attention on this issue. I just think it is so disgraceful how our Gulf War veterans have been treated on this issue.

Mr. Davy Leghorn, Assistant Director of the Veterans Employment and Education Division of the American Legion.

STATEMENT OF DAVY LEGHORN

Mr. LEGHORN. Chairman Coffman, Ranking Member Kirkpatrick and distinguished members of the subcommittee. On behalf of our national commander, Dan Dellinger, and the 2.4 million members of the American Legion, thank you for the opportunity to submit the views of the American Legion regarding the bill to improve the oversight of contracts awarded by the Secretary of Department of Veteran Affairs to veteran owned small businesses.

Many of our veteran small business owners are at a disadvantage when they have to compete with companies that don't actually complete more than 50 percent of the required work of contracts that are specifically set aside for service disabled veteran owned small businesses.

The purpose of a veteran's set aside contract is to bolster the capacity of the veterans small business industrial base, and likewise, for contracts designed for service disabled veteran owned small businesses.

When the majority of this money ends up going to non-qualifying businesses by way of a pass-through company, the good intentions of public law, 109–461 become meaningless. This is why the American Legion passed Resolution 73 which endorses legislative efforts to ensure that contracts awarded pursuant to the veterans first program are awarded to companies that truly are entitled to receive these set asides.

The American Legion advocated for Public Law 106–50, which made all federal agencies stakeholders in supporting veterans entrepreneurship. The American Legion also supported public law 109–461, which provided VA with the authority to set higher agency standards for SDVOSB and VOSB set asides.

VA refers to this program as the Veteran's first contracting program or Vet First. The American Legion has vested interests in and is very protective of the programs we help institute within the federal government. This is why we support legislation that would increase problematic oversight and increased penalties for bad actors who maliciously seek to defraud the federal government.

Regarding a certification of good faith to the Secretary, the American Legion believes that this is a solid step in ensuring our veterans fully understand the rules when bidding on and accepting prime responsibility for federal contracts, and also, understand what the penalties are for making false claims and statements.

However, fraud and abuse is neither rampant nor exclusive to the veterans small business community alone. Other disadvantaged

small business programs have come under scrutiny in the past, yet they are not held to an extra administrative hurdle.

The American Legion is concerned with the message this administrative step sends to the small business community and the public as a whole, and with support, similar scrutiny and administrative safeguards across the federal procurement landscape.

The American Legion understands the intent of this certification, and we caution this committee to ensure that we are not singling out the veterans small business community as the only program that might meet safeguards.

This extra administrative step would be easier for the veterans small business community to accept wholeheartedly if it were instituted among all over disadvantaged small business set aside programs as well.

Again, the American Legion supports this bill but ideally we would prefer to see the same standard being applied, not only with 38 CFR, but extended to 13 CFR as well.

Lastly, regarding the bill's congressional reporting mechanism, the American Legion agrees that an independent entity such as VA's Office of Inspector General or the Small Business Administration should conduct a report on VA's OSDBU's oversight. OSDBU's main role is small business advocacy within the agency. The report in the acquisitions issue that falls outside of OSDBU's purview, so the American Legion would go as far as to recommend that aside from minor aggregate reporting, OSDBU be completely removed from the referral and reporting process and ensuring that the report submitted to Congress is unbiased.

In conclusion, the American Legion believes that the responsibility is upon all the stakeholders to ensure that we become better stewards of the veterans first program. The American Legion will continue to work with the Small Business Administration and the Department of Veteran Affairs to increase contracting opportunities for our veteran small business owners, and to ensure that the money allotted for these set aside contracts stay within our community.

The American Legion appreciates the opportunity to testify today. Again, thank you, Chairman Coffman

[THE PREPARED STATEMENT OF DAVY LEGHORN APPEARS IN THE APPENDIX]

Mr. COFFMAN. Thank you, Mr. Leghorn. Mr. Frank Wilton, Chief Executive Officer of the American Association of Tissue Banks.

STATEMENT OF FRANK WILTON

Mr. Wilton, Chairman Coffman.

This critical legislation directs the Secretary of Veteran Affairs to adopt a standard identification protocol for use in the procurement of biological implants, by building upon the unique device identifier or UDI, this legislation will ensure that biological implants can be appropriately tracked from the donor of the human tissue all the way to the recipient.

This critical capability for track and trace efforts will enhance patient safety, expedite product recalls, and assist with inventory management.

This legislation takes a bold step to expand the application of the concept of the UDI to all tissue products, including those tissue devices which are already covered by the UDI, as well as another product category—certain biological implants, or as termed by the Food & Drug Administration, 361 HCTPs.

While many of the biological implants do have bar codes, by requiring a standardized format as outlined in this legislation, it is easier for the Department of Veteran Affairs' medical facilities to utilize universal bar coding conventions.

As the Secretary of Veteran Affairs opts to adopt the standard identification protocols for tissues, both devices and non-devices, I urge you to ensure the Secretary to provide a menu of options.

Under the UDI final rule, FDA has done just that, by providing for multiple entities called issuing agencies. At this time, FDA has provided for three different issuing agencies: GS1, Health Industry Business Communications Counsel or HIPBCC, and ICCBBA. I hope that this flexibility is maintained within the Department of Veteran Affairs.

However, given that the bill language already suggests that the unique identification system is comparable to the UDI provides, we believe the intent to provide that flexibility is inherent in the legislation.

For those of you unfamiliar with my organization, the American Association of Tissue Banks is a professional, non-profit scientific and educational organization. The association was founded in 1976 by a group of doctors and scientists who had started in 1949, our nation's first tissue bank, the United States Navy Tissue Bank.

It is the only national tissue banking organization in the United States, and its membership totals more than 125 accredited tissue banks and 850 individual members.

These banks recover tissue for more than 30,000 donors and distribute in excess of 2 million allographs for more than 1 million tissue transplant performed annually in the United States.

The vast majority of tissue banks that process tissue maintain AATB accreditation. First published in 1994 and presently in its thirteenth edition, the AATB standards for tissue banking are recognized as the definitive guide for tissue banking. The AATB standards have served as the model for federal and state regulations, as well as several international directives and standards.

Currently, the statutes are regulations in 19 states, reference AATB standards, institutional accreditation or individual certification.

Given the wide acceptance of AATB's standards, I would be remiss if I didn't mention one aspect of the legislation which is disappointing. The current legislation lacks a requirement that biological implants purchased by the VHA be procured from accredited tissue banks and accredited tissue distribution intermediaries.

While I understand that there may be some concern about imposing such a requirement because AATB is a private entity, I would just note that there are other instances in which the VHA has decided that private accreditation is not only appropriate, but required.

Specifically, the VHA requires medical facilities to receive and retain accreditation by the Joint Commission, a private accrediting

agency. Leading medical centers of excellence require AATB accreditation of vendors from whom they procure tissue graphs.

In addition, the American Academy of Orthopaedic Surgeons recommends the use of tissue from banks that are accredited by AATB. By not requiring that vendors adhere to the highest safety standards required by the AATB's accreditation process, I remain concerned about the overall safety and quality of the products provided to our veterans.

I welcome your questions and yield the remainder of my time.

[THE PREPARED STATEMENT OF FRANK WILTON APPEARS IN THE APPENDIX]

Mr. COFFMAN. Thank you for your testimony. Mr. Kelley, what do you believe explains the lengthy delays and overruns in major—in VA major construction projects?

Mr. KELLEY. Unfortunately, I think sometimes politics gets in the way within VA, within the community, within Congress. There is—everybody's got their vision of what it should be, and the ball starts rolling, those visions change along the way to meet the needs of the politics, not necessarily the veterans. And then as that works out, the needs of the veterans are taken into account.

Mr. COFFMAN. Mr. Binns, please briefly describe how VA has interfered, undermined or impeded the work of the RAC.

Mr. BINNS. Well, VA has removed our charters charge to review the effectiveness of government research. That means that you, the Secretary of Veterans Affairs and the public will not know what an independent body of scientists and veterans considers is happening within VA research.

And as you will see from reviewing the draft which had to be removed from our report, which I have attached to our written testimony, that is a serious indictment indeed.

The latest action that has been taken is that each committee member, in the letter inviting them to attend the next meeting, which we were asked to sign, acknowledges that we will not share any information, reports, recommendations produced at the meeting without the written approval of VA. Even the pretense that the committee is independent has been removed.

So you will not ever hear from a RAC chairman in the future, I can assure you, who has not had each and every word of his testimony vetted and written for him or her.

Mr. COFFMAN. Ms. Zumatto, what does autonomy for the RAC accomplish for Gulf War vets?

Ms. ZUMATTO. Well, I think that certainly the more people we have involved in this process and the more—I do not know if I want to say competition, but it should not—this is not something that should be handled by one organization or one agency.

And so having the RAC and having them being able to provide an individual opinion on what the—what is happening in the VA I think is only a positive thing. I think our veterans are going to benefit by having that, having another set of eyes on what is happening.

Mr. COFFMAN. Very well. Mr. Kelley, your testimony mentions cost overruns and adversarial relationships between VA and contractors. There is evidence that such problems occurred in Denver, or in Aurora, and possibly other sites where VA asked for bids

based on the presumption that it would produce in a situation of Aurora, a $600 million project, but it appears VA has produced a project potentially much more expensive than that in terms of its design, which they provided eight months after the bid process was completed.

What should VA do to maintain control of construction designs in the future?

Mr. KELLEY. I think going to the design build model will help. It puts the contractor in the process early on so you do not get an architect who has got a grand design of a beautiful building that might not be practical, and then when the build starts, the contractor has to come in and say, this space is not going to be right, and there is a conflict between the contractor and the architect, which also conflicts with what VA had asked for to begin with, and what the outcome is going to be.

So I think putting those two together at the very beginning of the process, so the architect and the contractor are on the same page, that the outcome will be cheaper. Because you are not running into cost overruns when you bid on a design, and then you realize, well, what we need in here is not going to fit in the design that we have and we have to go back and fix this. Now we have got change orders, we have got design redos that increase time and increase costs.

Mr. COFFMAN. Thank you, Mr. Kelley. Ranking Member Kirkpatrick?

Ms. KIRKPATRICK. Thank you, Mr. Chairman. I join the Chairman in thanking you, Ms. Zumatto and Mr. Binns for your attention and your work on behalf of the Gulf War veterans and keeping the attention focused on the illness.

You have been a great resource to my office, Mr. Binns, and I do not really have any questions, but I just wanted to thank you for being here today and for the work that you are doing.

I want to ask a question about the tissue bar coding, Mr. Wilton. One of the things that we are working on is to keep the same formulary in the Department of Defense as we have in the VA, and we are finding that that is a little more difficult than we thought it might be.

So can you tell me if the Department of Defense uses the bar code that you are proposing for the VA?

Mr. WILTON. I think one of the benefits of this will be that, as it becomes universal, it will be used in all of the health care settings, so not only DoD but VA, but also in other health care settings. So I do not believe they currently do, but we would certainly support the use of it in other settings.

Ms. KIRKPATRICK. Okay. And that is something that we are able to be successful with this legislation that I would like to work with you on because we are having joint meetings between the top positions at the VA with the top positions at the Department of Defense, ultimately with the goal that we will be able to have one good medical record transitioning out of the military into the VA system. So thank you for that.

Mr. WILTON. We would welcome the opportunity to work with your office on that.

Ms. KIRKPATRICK. Thank you. Mr. Leghorn, I recently visited some military bases and, my role was really to talk to military members who are soon transitioning into the VA, and what we could put in place for them while they are still in service to make that transition easier.

And the number one issue was jobs. They said, you know, they were really concerned about where they would find work, how they would find work. So I appreciate your emphasis on hiring vets, but in recent meetings with some of our veterans groups, there is certainly a feeling, and I have not looked into this in terms of, you know, really investigating, but there is a feeling that all of these programs are great, but there is no enforcement, that people are—businesses are really overlooking the programs. There's no teeth in this legislation to make sure that veterans are indeed being given preference.

Has the American Legion done any studies, any research into that?

Mr. LEGHORN. Not that I know of, no.

Ms. KIRKPATRICK. Okay. Is it something that you are hearing that you would agree maybe needs to be done?

Mr. LEGHORN. Absolutely.

Ms. KIRKPATRICK. All right. And let me ask you too, then you are proposing safeguards. Do you think internal safeguards are better than some kind of external oversight in terms of enforcement?

Mr. LEGHORN. In terms of the safeguards that were mentioned in the bill, we feel to a certain extent, it is necessary. We are just concerned about the messaging that it sends to the community, because it is—we are enforcing this safeguard only on the veterans small business community and we are not applying it to everyone else.

Ms. KIRKPATRICK. And the singling, I understand that, that the small business veterans community is being singled out.

Mr. LEGHORN. Yes.

Ms. KIRKPATRICK. And I am concerned about that. I just was trying to bring it into a larger context, but thank you for your testimony.

My last question is for you, Mr. Wilshusen. In your written testimony, you state that emphasizing that specific security related actions should be taken based on risk could help ensure that VA is better able to meet the objectives outlined in the draft bill.

Would including a risk assessment make the specific actions addressed in the bill discretionary rather than mandatory on the VA?

Mr. WILSHUSEN. It would make it based upon the risk because one of the factors that should go into risk management and security controls is the fact that every single control may not be appropriate in every single circumstance. And that according to FISMA, which is the overarching law for information security, agencies are supposed to perform risk assessments, and then design and implement security controls based on the effect or on the results of those assessments to assure that they are able to cause effectively reduce risks to an acceptable level.

Now, there is judgment involved with those risk assessment and which controls should be in place. But federal guidelines specify that there are a number of security controls that should be consid-

ered depending upon the significance or the categorization of the system which relates to the impact that could occur, should the information be compromised.

But it does allow for some leeway because—in terms of determining when a control should be implemented and maybe not. You know, I think what the—many of the specific controls that are identified in the draft bill are based on sound security practices and are consistent with federal guidelines.

But as I mentioned, building it in and to allowing and assuring that those controls are implemented on risk, and are intended to meet the security objectives with and allow some flexibility for those controls and security practice to evolve naturally over time as conditions change.

Because a specific control that may be appropriate in one circumstance, that same control may not be appropriate in another circumstances due to the change in conditions.

Ms. KIRKPATRICK. You know, it makes commonsense to me that the recent flexibility that, you know, Mr. Chairman, I have some concern about there not being some benchmarks to make sure it happens in a timely manner. Thank you very much, I've gone over a little bit, thank you for your indulgence.

Mr. COFFMAN. Dr. Roe.

Dr. ROE. Thank you, Mr. Chairman, just a couple of comments and a couple of quick questions.

Mr. Wilton, if you would on the tissue banking, I agreed with—much what you said. Is there any reason for the VA not to do what is outlined in the draft?

Mr. WILTON. I cannot come up with one, Congressman. I think it makes good sense, and I think that who better to make sure that we are protecting than the men and women who served this country so nobly. So I can come up with none.

Dr. ROE. I agree with you, and I think one of the things that will happen ultimately, it will be unintended on anybody's part, but we have seen where something happens and then there is a delay on notification of the veterans about this particular issue, and I have used these products before and there are tracking systems out there in the private world.

Secondly, just briefly, are there any other accreditation other than what you mentioned, and I think one of the reasons it was left out in the draft legislation and maybe it should be put in, is are there other agencies that accredit not just that one? You said it is a private agency as I understand it, that does that accreditation.

Mr. WILTON. Within the tissue banking profession, we are the only one. And quite frankly, considered the gold standard within health care. Most leading centers of medical excellence, as I mentioned in my testimony, will only source tissue from AATB-accredited banks. So we think again, why would the VA not want to get the best.

Dr. ROE. Okay. Thank you and Mr. Binns, and also, Ms. Zumatto, just a couple of comments.

One of my pet peeves in the practice of medicine over the years was, if we did not know what it was wrong with you, it was either in your head or was a virus, and we did not know. So I think that

basically what we need to do is exactly what you have said, and I think VA somewhat has done that, but to take the RAC, to get the Institute of Medicine to study this like you would any other issue and then come to a conclusion, whatever it is, and whatever the conclusion is.

I could not agree more with that and to put this to bed, and as I want to thank our Chairman for his service at Desert Shield and Desert Storm, and there are many veterans out there that just would like to have an answer to this, an objective answer in an unbiased setting, so just a comment there.

And, Mr. Kelley, just a couple of things. One, I agree and I think the VA did a great job of describing the design build and design bid build. Sometimes what you do if you have a design build process is you eliminate a lot of smaller builders who do not have an architect in house. Most of the design builders are big firms that have an in-house architect, and I can think of many instances in my area where very, very good builders could not bid on a design bid because they just did not—they are not big enough.

And there are situations where it is—I mean, I have seen it in literally hundreds of millions of dollars worth of construction and the design bid build that works fine. And I just want to make that point that that is not the only point to do that, and the VA I think described that extremely well.

And I guess my last question is to Mr. Wilshusen, what should the VA be doing now that they are not doing? I listened very carefully to your testimony and read it, but what—if they were doing something now, what would you say they need to implement right now for security?

Mr. WILSHUSEN. I think it would be to redouble their efforts in resolving and mitigating and taking corrective actions on known vulnerabilities. They have a large number of outstanding security vulnerabilities that have been existing for quite some time.

So taking actions right now to assess the risk of those, identify the most critical ones, and act on that and take corrective action immediately would be something that they should do.

Dr. ROE. Yeah, I think we have noticed—I mean, we know that literally there are people trying to hack into these systems, foreign governments, I mean, we had that testimony right here in this committee, this subcommittee about that, and it is a moving target. I understand how—well, maybe I do not even understand how hard it is it is so complicated.

But I guess the question I would have if they could implement anything now that would be effective, what should they do, because it is at every phase of government has it, private businesses have it, medical records, everything that we do on line is now being—I mean, really is vulnerable.

Mr. WILSHUSEN. Well, it certainly is because what the—with the extensive use of information technologies across the federal governments, VA and other agencies too, if there is inherent risk with the use of those technologies, particularly as it becomes more interconnected with other systems, other organizations, external and internal to each department.

But the one thing that—you know, there is a number of things that agencies and VA needs to do, and one of the first things in

terms if shoring up and making sure, for example, that they take corrective actions to assure that the systems that they operate have the appropriate patches installed, that they implement the appropriate security controls that harden to prevent and limit access to their systems.

But again, it gets back on——

Dr. ROE. Well, do they need legislation to do that or could they just do that now?

Mr. WILSHUSEN. They should be doing it now, but apparently in the VA's case, they may need this legislation, the proposed bill, may help prompt them to refocus their efforts to take the necessary actions to protect their systems.

Dr. ROE. Thank you. I yield back.

Mr. COFFMAN. Thank you, Dr. Roe. Ms. Walorski.

Ms. WALORSKI. Thank you, Mr. Chairman.

Mr. Wilshusen, will the—with all the weaknesses that you have cited in the conversation that you and Dr. Roe just had, has the VA made any improvements to its information security program?

Mr. WILSHUSEN. Well, according to the OIG at VA, the Department has taken steps to implement a continuous monitoring program, as well as to standardize many or several of their security configurations.

And if those are designed and implemented effectively, that could result in some security benefits. But as you may know, we have been asked by this subcommittee to review the weaknesses and vulnerabilities of the Department of VA for—on their information security.

We plan on looking at the extent to which those vulnerabilities continue to exist, the extent to which VA has taken actions to mitigate them, and the extent to which those vulnerabilities help expose veterans' information and to compromise.

And so I will have more on that issue for you later as we complete that particular review. It is—we are just starting it at this point.

Ms. WALORSKI. So this is your first review of their internal security documents?

Mr. WILSHUSEN. Not the first—at the present time, yes.

Ms. WALORSKI. Uh-huh.

Mr. WILSHUSEN. Yes, we—for years, we have reviewed information security at the time.

Ms. WALORSKI. Right.

Mr. WILSHUSEN. But for this particular effort and these vulnerabilities, yes, we are just starting that this year.

Ms. WALORSKI. And given the current federal information and security requirements and VA's known material weaknesses, do you believe that this IT directive can assist VA in addressing those weaknesses if implemented?

Mr. WILSHUSEN. Yes. You know, I think these actions identified in the directive are intended to address known vulnerabilities that exist in VA now. And so to the extent that they take those actions again on a risk based basis, that it should help VA improve its security.

Ms. WALORSKI. And well just to echo Dr. Roe's comment and your comment as well, is legislation needed. I honestly having sat on

this committee think that it is a directive that has to be implemented at this point because there is no voluntary compliance.

So the mere suggestion from Congress asking and asking and asking, and then having your department follow up and the reports continually come back with vulnerabilities, vulnerabilities, vulnerabilities, you know, I mean, it is just my opinion our veterans deserve more.

There are so many people that come in here and testify on so many different issues, and I appreciate all of your testimony today, but when it comes to protecting identities and health care records, and you know, there isn't a day that goes by in the local news and national news where we are not talking about protecting the most important data that we all have, which is our identity, and now in this case, health records, and now we are talking domain controllers and we are asking questions about foreign entities having access.

I just—to me, I just think there is an urgency involved, so I appreciate the work that you do and all of you in your testimony today. Thank you, Mr. Chairman, I yield back.

Mr. COFFMAN. Thank you, Ms. Walorski, Mr. Huelskamp.

Dr. HUELSKAMP. Thank you, Mr. Chairman. Mr. Leghorn, I appreciate your testimony. I appreciate the executive committee on their resolution that endorsed efforts such as these to make certain that the contracts are awarded to companies that are truly entitled to receive these set asides. I think that is very critical. I appreciate your efforts on that, and my office is more than willing to—if you hear of examples and cases that perhaps the VA has not acted on quickly enough, let us know, and we would be happy to look into those as well.

Because I think if we are going to have a program such as this, we can do everything we can to make certain that it goes to veterans. I appreciate that.

I do have one small question for the gentleman from the GAO in reference to apparently twelve years of reports and studies and I congratulate my colleague for introducing the bill, but I will say the testimony we heard in this subcommittee about how vulnerable the system was and is has probably been the most shocking I have heard on this committee in over three years. And I appreciate the efforts and I know my colleague asked the question, do you think they are making progress, and it is not nearly enough.

But do you have any evidence or ability to share that will give us an example of if we compared this to a private sector entity, what standard we're meeting out in the world outside of government, in terms of meeting those security requirements?

Because I vow to my colleagues that I always want to talk about these private companies, and rightly so that are not secure enough with data, and then we have the shocking reports of 20 million veterans and their families and their medical records, financial records were hacked. The VA refused to—actually said it did not occur, and a whistle blower said otherwise.

But is there a standard we can look at, and say here we are compared to the private sector?

Mr. WILSHUSEN. Well, in terms of the information security requirements that federal agencies are to implement, they tend to be as stringent as those perhaps available to the private sector.

You know, one can look at the news media and we have not examined the security controls at very many private sector companies. When we have, we have identified vulnerabilities that also puts those entities' information at risk. But you can look at the papers and just with Target and a number of other companies, there are security breaches across the board.

Many are reported, many are not. It is just emblematic I think of the fact that—and it is required, that agencies, private companies need to protect the information. It is a challenging proposition. There are many things that can be done to help raise the bar in protecting that information. Many of the actions identified in the draft bill are among those types of controls if implemented on a risk based basis.

And—but it is something that is a fact of life in our environment, and it is in large part because agencies—I will not say agencies have not taken it seriously, but you are right, there is much more that needs to be done in order to adequately protect the information that those individuals who provide their sensitive personal information to agencies entrust and deserve.

Dr. HUELSKAMP. All right. I yield back. Thank you, Mr. Chairman.

Mr. COFFMAN. Thank you, Mr. Huelskamp. Thank you. The panel is now excused. I again want to thank everyone for their participation today. The input and feedback provided is an important contribution at this subcommittee—as this subcommittee crafts legislation to improve the quality of service VA provides to our nation's veterans.

With that, I ask unanimous consent, that all members have five legislative days to revise and extend their remarks, and include extraneous materials. With no objection so ordered, this hearing is now adjourned.

[Whereupon, at 11:45 p.m., the subcommittee was adjourned.]

APPENDIX

PREPARED STATEMENT OF MS. STELLA S. FIOTES

Good morning, Mr. Chairman, Ranking Member Kirkpatrick, and other Members of the Subcommittee. Thank you for the opportunity to be here today to provide the Department of Veterans Affairs (VA) views on pending legislation affecting VA's programs, including H.R. 3593, the VA Construction Assistance Act of 2013 and a draft bill regarding the oversight of contracts awarded by VA to small business concerns owned and controlled by Veterans with service-connected disabilities.

Other bills on today's agenda were not received in time for VA to provide testimony here today, but we will be following up with the Subcommittee for the record at a later time. Those bills include H.R. 4261, regarding VA research on Gulf War illness and a draft bill regarding VA's information security programs

Mr. Chairman, accompanying me here today is Mr. Tom Leney, Executive Director for Small and Veteran Business Programs for VA.

H.R. 3593, the VA Construction Assistance Act of 2013

Section three of the bill would institute certain requirements for VA major medical facility projects, including mandates for the use of a medical equipment planner, use of a project management plan, and use of a construction peer excellence review. It would also require development of a metrics program to enable the monitoring of change-order processing time and goals for the change order process consistent with the 'best practices' of other federal agencies.

Section four of the bill would mandate that within 180 days VA enter into an agreement with the U.S. Army Corps of Engineers (USACE) to procure a "special project manager" on a reimbursable basis to oversee three named current VA major construction projects for facilities in Denver, Colorado, Orlando, Florida, and New Orleans, Louisiana. The bill enumerates the duties of the special project manager and requires that plans and progress reports be provided to the House and Senate Committees on Veterans' Affairs. It also establishes that VA provide the special project manager with the requisite information and administrative assistance necessary to carry out their tasks.

VA has a strong history of delivering facilities to serve Veterans. In the past 5 years, VA has delivered 75 major construction projects valued at over $3 billion that include the new medical center complex in Las Vegas, cemeteries, polytrauma rehabilitation centers, spinal cord injury centers, a blind rehabilitation center, and community living centers.

VA appreciates the strong interest and support from the Subcommittee to ensure that our major construction projects, and more specifically the Denver, Colorado, New Orleans, Louisiana, and Orlando, Florida facilities, are delivered successfully. While there have been challenges with these projects, we have taken numerous actions to strengthen and improve our execution of all VA's ongoing major construction projects, including the three projects that H.R. 3593 addresses. For the reasons expressed below, VA does not believe that the approach outlined in the bill will achieve the desired results, and thus does not support it.

VA believes the creation of a special project manager would be problematic in the management and supervision of these projects. Specifically, the special project manager adds more levels of management and may complicate, if not confuse, the project delivery process. The bill raises serious questions about the contractual relationship between the VA and its contractor, the lines of authority the special project manager will have vis-&-vis VA and the U.S. Army Corps of Engineers (USACE), and the effect upon the independent exercise of discretion by the VA contracting officer, who is ultimately responsible for managing the contract on behalf of the Government. The legislation we believe will also lead to increased management and overhead costs associated with funding the special project manager and support team.

VA continuously evaluates its processes and delivery methods for each lease and construction project on its merits, and we benchmark industry best practices with several agencies including the National Institute of Building Sciences, General Services Administration and the USACE. When VA determines that the best delivery strategy is to employ another agency such as the USACE, this strategy is used. VA and the USACE have a long history of working together to advance VA facility construction and share best practices, and our current discussions are a logical evolution of that relationship.

Since 2008, VA has engaged USACE to support maintenance and minor construction projects at more than 70 of our medical facilities. VA engaged USACE to review the contracts for the New Orleans and Denver projects, and they continue to assist in schedule evaluation in Orlando. More recently, USACE is supporting VA in establishing a Project Review Board process, similar to the process used by USACE districts, and supporting the VA National Cemetery Administration in its maintenance and minor construction program.

As outlined in the cited Government Accountability Office (GAO) testimony and April 2013 report, the delays and cost increases on the Denver, New Orleans and Orlando projects occurred in the planning and design phases; each of these projects is now in the construction phase. Last year, VA took aggressive action on the recommendations in the April 2013 GAO report and all recommendations were closed as of September 2013. Their recommendations included the addition of medical planners, the streamlining of the change order process, and clearer definition of roles and responsibilities in the project management.

In addition to closing the GAO recommendations, VA has worked diligently to address and close all of the recommendations identified through the VA's Construction Review Council (CRC), which was established in 2012 and is chaired by the Secretary of Veterans Affairs to serve as the single point of oversight and performance accountability for the VA real property capital asset program. With the personal commitment of the Secretary, and the diligent efforts of senior staff and management, all CRC recommendations have been implemented since October 2013. These recommendations include improvements in the development of requirements, measures aimed at improving design quality, better coordination of funding across the Department to support VA's major construction program, and advances in program management and automation. Through the CRC and the VA Acquisition Program Management Framework that provides for continual project review throughout the project's acquisition life-cycle, VA will continue to drive improvements in the management of VA's real property capital programs.

Our focus across the spectrum of construction project management has led to advancements in our overall construction program. Areas of increased effort include improving requirements definition and acquisition strategies, assessing project risk, assuring timely project and contract administration, partnering with our construction and design contractors, early involvement of the medical equipment planning and procurement teams, and engaging in executive level on-site project reviews. Additionally, the monthly updates provided to the Committees on key projects have increased the transparency in our program.

The way the Department is doing business today has changed significantly since the Orlando, Denver and New Orleans projects were undertaken. The lessons learned and the improvements made have resulted in positive changes and are being applied to help ensure the Department's capital program is delivered on time and within budget.

The costs associated with enactment of this legislation cannot be predicted with specificity, as they will depend on the scope and details of the arrangement mandated to be concluded with the USACE under the bill.

Draft Bill to Amend Title 38, United States Code, to Improve the Oversight of Contracts Awarded by the Secretary of the Department of Veterans Affairs to Small Business Concerns Owned and Controlled by Veterans With Service-Connected Disabilities

Section one of the draft bill proposes to amend subsection (e) of § 8127 to create a second requirement to eligibility for status as a Service-disabled Veteran-owned Small Business (SDVOSB). The newly inserted subsection (2) would provide that SDVOSBs may only be awarded set-aside contracts when, in addition to the requirements of verification, the SDVOSB submits a statement to VA explaining how the concern would meet applicable self-performance requirements to conduct 51 percent of work themselves, identifying employees who will be working on the contract and the work the employees will carry out under the contract, and the percentage of such work as compared to the total amount of work performed under the contract.

The bill would also amend subsection (g) of section 8127 regarding penalties by granting the Secretary authority to make a determination that a SDVOSB did not act in good faith with respect to the performance requirements of the contract regarding the requirement to have their own employees perform at least 51 percent of the work requirements. If that determination is made, the Secretary would retain amounts awarded under the contact in the same manner and amount as if the small business concern failed to comply with approved subcontracting plans, which appears to be a reference to provisions concerning liquidated damages for failure to make a good faith effort to comply with a subcontracting plan, found at 15 U.S.C.

§ 637(d)(4)(F) and 48 CFR § 19.705–7. Lastly, the new statement required by the bill would be subject to the criminal false statements statute, 18 U.S.C. § 1001.

VA shares the Committee's concerns that Veterans perform the required percentages of work on set aside contracts. To that end VA contracting officers monitor the amount of work passed to subcontractors in accordance with the Federal Acquisition Regulations. In addition, VA has established a Subcontracting Compliance Review Program (SCRP) which assesses contractor compliance with limitations on subcontracting requirements, subcontracting commitments, and subcontracting goals included in prime contracts with VA.

We appreciate the Committee's interest in the integrity of these important programs, but for the reasons set forth below, VA does not support the draft bill.

The requirements of this bill would be impractical, as many awardees will not have all the required information (such as names and amount of work to be performed) at the time of bid or offer, or even at the time of award.

We are also unclear whether the bill as drafted would only apply to SDVOSBs, as 38 U.S.C. § 8127 authorizes Veteran-owned Small Business set-asides within VA as well as SDVOSB set-asides.

Finally, VA believes that the provisions of this bill will place an onerous and unfair burden on SDVOSBs that is not placed on any other socioeconomic category of small business.

VA will provide its cost estimate for this bill for the record.

Conclusion

Mr. Chairman, this concludes my statement. Thank you for the opportunity to appear before you today. We would be pleased to respond to questions you or the other Members of the Subcommittee may have.

United States Government Accountability Office

Testimony
Before the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

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INFORMATION SECURITY

VA Needs to Address Long-Standing Challenges

Statement of Gregory C. Wilshusen,
Director, Information Security Issues

GAO-14-469T

Chairman Coffman, Ranking Member Kirkpatrick, and Members of the Subcommittee:

Thank you for inviting me to participate in today's hearing on information security at the Department of Veterans Affairs (VA). In 1997, we first designated information security as a government-wide high-risk issue and continued to do so in the most recent update to our high-risk series.[1] Effective information security is essential to protecting the availability, confidentiality, and integrity of the information residing on federal information systems. Moreover, as we have reported since the 1990s,[2] VA has faced challenges in safeguarding personal information.

My testimony today will discuss long-standing challenges VA has experienced in effectively implementing security controls over its systems and information, as well as comment on a draft bill being considered by the Subcommittee to improve information security at VA. In preparing this testimony, we relied on our previously published work in this area, as well as an analysis of recent VA Office of Inspector General (OIG) and VA reports related to the department's information security program and data from the U.S. Computer Emergency Readiness Team (U.S.CERT) related to reported information security incidents. We also analyzed the draft bill in light of existing federal requirements and best practices for information security. All the work supporting this testimony was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings based on our audit objectives.

Background

VA's mission is to promote the health, welfare, and dignity of all veterans in recognition of their service to the nation by ensuring that they receive medical care, benefits, social support, and memorials. According to VA, its employees maintain the largest integrated health care system in the nation for approximately 6 million patients, provide compensation and benefits for about 4 million veterans and beneficiaries, and maintain about

[1]GAO, *High-Risk Series: An Update*, GAO-13-283 (Washington, D.C.: Feb. 14, 2013).

[2]See the list of related GAO products at the end of this statement.

3 million gravesites at 164 properties. The use of information technology (IT) is crucial to the department's ability to provide these benefits and services, but without adequate protections, VA's systems and information are vulnerable to those with malicious intentions who wish to exploit the information.

Federal Agencies Face an Array of Cyber-Based Threats

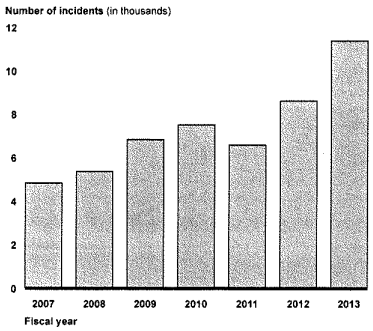
The evolving array of cyber-based threats can jeopardize the confidentiality, integrity, and availability of federal information systems and the information they contain. These threats can be unintentional or intentional. Unintentional threats can be caused by natural disasters; defective equipment; or the actions of careless, inattentive, or untrained employees that inadvertently disrupt systems. Intentional threats include both targeted and untargeted attacks from a variety of sources. These include disgruntled employees, criminal groups, hackers, and foreign nations engaged in espionage and information warfare. Such threat sources vary in terms of the types and capabilities of the actors, their willingness to act, and their motives.

These threat sources make use of various techniques to compromise information or adversely affect computers, software, networks, an organization's operation, an industry, or the Internet itself. Such techniques include, among others, denial-of-service attacks and malicious software codes or programs. The unique nature of cyber-based attacks can vastly enhance their reach and impact, resulting in the loss of sensitive information and damage to economic and national security, the loss of privacy, identity theft, and the compromise of proprietary information or intellectual property. The increasing number of incidents reported by federal agencies has further underscored the need to manage and bolster the security of the government's information systems.

VA Has Reported an Increasing Number of Information Security Incidents

The number of incidents affecting VA's information, computer systems, and networks has generally risen over the last several years. Specifically, in fiscal year 2007, the department reported 4,834 information security incidents to US-CERT; in fiscal year 2013, it reported 11,382 incidents. These included incidents related to unauthorized access, denial-of-service attacks; installation of malicious code; improper usage of computing resources; and scans, probes, and attempted access, among others. Figure 1 shows the overall increase in the total number of incidents VA reported to US-CERT for fiscal year 2007 through 2013.

Figure 1: VA Information Security Incidents Reported to US-CERT, Fiscal Years 2007-2013



Source: US-CERT.

In addition, reports of incidents affecting VA's systems and information highlight the serious impact that inadequate information security can have on, among other things, the confidentiality, integrity, and availability of veterans' personal information. For example:

- According to a VA official, in January 2014 a software defect in VA's eBenefits system improperly allowed users to view the personal information of other veterans. According to this official, this defect potentially allowed almost 5,400 users to view data of over 1,300 veterans and/or their dependents.
- In May 2010, it was reported that VA officials had notified lawmakers of breaches involving the personal data of thousands of veterans, which had resulted from the theft of an unencrypted laptop computer from a VA contractor and a separate incident at a VA facility.[3]

[3]See http://www.federaltimes.com/article/20100514/CONGRESS01/5140301/.

Federal Law and Policies Establish Information Security Responsibilities for Agencies

To help protect against threats to federal systems, the Federal Information Security Management Act of 2002 (FISMA)[4] sets forth a comprehensive framework for ensuring the effectiveness of information security controls over information resources that support federal operations and assets. The framework creates a cycle of risk management activities necessary for an effective security program. In order to ensure the implementation of this framework, FISMA assigns specific responsibilities to agencies, the Office of Management and Budget (OMB), the National Institute of Standards and Technology (NIST), and agency inspectors general.

Specifically, each agency is required to develop, document, and implement an agency-wide information security program and to report annually to OMB, selected congressional committees, and the Comptroller General on the adequacy of its information security policies, procedures, practices, and compliance with requirements. For its part, OMB is required to develop and oversee the implementation of polices, principles, standards, and guidelines on information security in federal agencies. It is also responsible for reviewing, at least annually, and approving or disapproving agency information security programs. NIST's responsibilities include the development of security standards and guidance. Finally, inspectors general are required to evaluate annually the information security program and practices of their agency and submit the results to OMB.

Further, Congress enacted the Veterans Benefits, Health Care, and Information Technology Act of 2006[5] after a serious loss of data earlier that year revealed weaknesses in VA's handling of personal information. Under the act, VA's chief information officer is responsible for establishing, maintaining, and monitoring department-wide information security policies, procedures, control techniques, training, and inspection requirements as elements of the department's information security program. It also reinforced the need for VA to establish and carry out the responsibilities outlined in FISMA, and included provisions to further

[4]FISMA was enacted as title III of the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2946 (Dec. 17, 2002).

[5]Veterans Benefits, Health Care, and Information Technology Act of 2006, Pub. L. No. 109-461, 120 Stat. 3403, 3450 (Dec. 22, 2006). See also GAO, *Privacy: Lessons Learned about Data Breach Notification*, GAO-07-657 (Washington, D.C.: Apr. 30, 2007).

protect veterans and service members from the misuse of their sensitive personal information and to inform Congress regarding security incidents involving the loss of that information.

VA Continues to Face Long-Standing Challenges in Effectively Implementing Its Information Security Program

Information security remains a long-standing challenge for the department. Specifically, VA has consistently had weaknesses in major information security control areas. For fiscal years 2007 through 2013, deficiencies were reported in each of the five major categories of information security controls as defined in our *Federal Information System Controls Audit Manual.*[6]

Table 1: Control Weaknesses for Fiscal Years 2007 – 2013

Security control category	2007	2008	2009	2010	2011	2012	2013
Access control	✓	✓	✓	✓	✓	✓	✓
Configuration management	✓	✓	✓	✓	✓	✓	✓
Segregation of duties	✓	✓	✓	✓	✓	✓	✓
Contingency planning	✓	✓	✓	✓	✓	✓	✓
Security management	✓	✓	✓	✓	✓	✓	✓

Source: GAO analysis based on VA and Inspector General reports.

Access controls ensure that only authorized individuals can read, alter, or delete data.

Configuration management controls provide assurance that only authorized software programs are implemented.

Segregation of duties reduces the risk that one individual can independently perform inappropriate actions without detection.

[6]GAO, *Federal Information System Controls Audit Manual (FISCAM),* GAO-09-232G (Washington, D.C.: February 2009).

Contingency planning includes continuity of operations, which provides for the prevention of significant disruptions of computer-dependent operations.

Security management includes an agency-wide information security program to provide the framework for ensuring that risks are understood and that effective controls are selected and properly implemented.

In fiscal year 2013, for the 12th year in a row, VA's independent auditor reported that inadequate information system controls over financial systems constituted a material weakness.[7] Specifically, the auditor noted that while VA had made improvements in some aspects of its security program, it continued to have control deficiencies in security management, access controls, configuration management, and contingency planning. In particular, the auditor identified significant technical weaknesses in databases, servers, and network devices that support transmitting financial and sensitive information between VA's medical centers, regional offices, and data centers. According to the auditor, this was the result of an inconsistent application of vendor patches that could jeopardize the data integrity and confidentiality of VA's financial and sensitive information.

In addition, the VA OIG reported in 2013 that development of an effective information security program and system security controls continued to be a major management challenge for the department. The OIG noted that VA had taken steps to, for example, establish a program for continuous monitoring and implement standardized security controls across the enterprise. However, the OIG continued to identify weaknesses in the department's security controls and noted that improvements were needed in key controls to prevent unauthorized access, alteration, or destruction of major applications and general support systems.

[7]See U.S. Department of Veterans Affairs, *2013 Performance and Accountability Report* (Washington, D.C.: Dec. 16, 2013). A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented, or detected and corrected, on a timely basis. A deficiency in internal control exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, misstatements on a timely basis.

These more recent findings are consistent with the challenges VA has historically faced in implementing an effective information security program. In a number of products issued beginning in 1998, we have identified wide-ranging, often recurring deficiencies in the department's information security controls.[8] These weaknesses existed, in part, because VA had not fully implemented key components of a comprehensive information security program. The persistence of similar weaknesses over 16 years later indicates the need for stronger, more focused management attention and action to ensure that VA fully implements a robust security program.

In addition, we have recently reported on issues regarding the protection of personally identifiable information (PII) at federal agencies, including VA. In December 2013, we issued a report on our review of agency practices in responding to data breaches involving PII.[9] Specifically, we determined the extent to which selected agencies had developed and implemented policies and procedures for responding to breaches involving PII.

Regarding VA, we found that the department had addressed relevant management and operational practices in its data breach response policies and procedures. In addition, it had implemented its policies and procedures by preparing breach reports and performing risk assessments for cases of data breach. However, VA had not documented the rationale for all its risk determinations, documented the number of individuals affected by breaches, consistently notified individuals affected by high-risk breaches, consistently offered credit monitoring to affected individuals, or consistently documented lessons learned from PII breaches. Accordingly, we recommended that VA take specific steps to address these weaknesses. VA agreed with some, but not all, of these recommendations. We maintained that all our recommendations were warranted.

In January 2014 we reported on selected agencies'—including VA's—compliance with amendments to the Privacy Act of 1974 that addressed

[8]See the related products page at the end of this statement for a list of relevant GAO products dealing with VA's information security.

[9]GAO, *Information Security: Agency Responses to Breaches of Personally Identifiable Information Need to Be More Consistent,* GAO-14-34 (Washington, D.C.: Dec. 9, 2013).

the computerized matching of personal information for purposes of determining eligibility for federal benefits programs.[10] Under these amendments, agencies are required to establish formal agreements with other agencies to share data for computer matching, conduct cost-benefit analyses of such agreements, and establish data integrity boards to review and report on agency computer matching activities.

Specifically regarding VA, we found that the department generally established computer matching agreements for its matching activities and conducted cost-benefit analyses of proposed matching programs. However, the completeness of these analyses varied in that they did not always include key costs and benefits needed to determine the value of a computer matching program. We noted that VA's guidance for developing cost-benefit guidance did not call for including key elements. We recommended that VA revise its guidance on cost-benefit analyses and ensure that its data integrity board review the analyses to make sure they include cost savings information. VA concurred and described steps it would take to implement our recommendations.

Consideration of Proposed Legislation to Improve VA's Information Security

The Subcommittee is considering draft legislation that is intended to improve VA's information security. The draft bill addresses governance of the department's information security program and security controls for the department's information systems. It requires the Secretary of Veterans Affairs to improve the transparency and coordination of the information security program and to ensure the security of the department's critical network infrastructure, computers and servers, operating systems, and web applications, as well as its Veterans Health Information Systems and Technology Architecture system, from vulnerabilities that could affect the confidentiality of veterans' sensitive personal information. For each of these elements of VA's computing environment, the draft bill identifies specific security-related actions and activities that VA is required to perform.

Many of the actions and activities specified in the proposed legislation are sound information security practices and consistent with federal guidelines, if implemented on a risk-based basis. FISMA requires

[10]GAO, *Computer Matching Act: OMB and Selected Agencies Need to Ensure Consistent Implementation*, GAO-14-44 (Washington, D.C.: Jan. 13, 2014).

agencies to implement policies and procedures that are based on risk assessments, cost-effectively reduce information security risks to an acceptable level, and ensure that information security is addressed throughout the life cycle of each agency information system. The provisions in the draft bill may prompt VA to refocus its efforts on actions that are necessary to improve the security over its information systems and information.

In a dynamic environment where innovations in technology and business practices supplant the status quo, control activities that are appropriate today may not be appropriate in the future. Emphasizing that specific security-related actions should be taken based on risk could help ensure that VA is better able to meet the objectives outlined in the draft bill. Doing this would allow for the natural evolution of security practices as circumstances warrant and may also prevent the department from focusing exclusively on performing the specified actions in the draft bill to the detriment of performing other essential security activities.

In summary, VA's history of long-standing challenges in implementing an effective information security program has continued, with the department exhibiting weaknesses in all major categories of security controls in fiscal year 2013. These challenges have been further highlighted by recent determinations that weaknesses in information security have contributed to a material weakness in VA's internal controls over financial reporting and continue to constitute a major management challenge for the department. While the draft legislation being considered by the Subcommittee may prod VA into taking needed corrective actions, emphasizing that these should be taken based on risk can provide the flexibility needed to respond to an ever-changing technology and business environment.

Chairman Coffman, Ranking Member Kirkpatrick, and Members of the Subcommittee, this concludes my statement today. I would be happy to answer any questions you may have.

Contact and Acknowledgments

If you have any questions concerning this statement, please contact Gregory C. Wilshusen at (202) 512-6244 or wilshuseng@gao.gov or Nabajyoti Barkakati at (202) 512-4499 or barkakatin@gao.gov. Other individuals who made key contributions to this statement include Jeffrey L. Knott and Anjalique Lawrence (assistant directors), Jennifer R. Franks, Lee McCracken, and Tyler Mountjoy.

Related GAO Products

Computer Matching Act: OMB and Selected Agencies Need to Ensure Consistent Implementation. GAO-14-44. Washington, D.C.: January 13, 2014.

Information Security: Agency Responses to Breaches of Personally Identifiable Information Need to Be More Consistent. GAO-14-34. Washington, D.C.: December 9, 2013.

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VA Information Systems: The Austin Automation Center Has Made Progress in Improving Information System Controls. AIMD-99-161. Washington, D.C.: June 8, 1999.

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Information Systems: VA Computer Control Weaknesses Increase Risk of Fraud, Misuse, and Improper Disclosure. AIMD-98-175. Washington, D.C.: September 23, 1998.

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GAO Highlights

Highlights of GAO-14-469T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

March 25, 2014

INFORMATION SECURITY

VA Needs to Address Long-Standing Challenges

Why GAO Did This Study

The use of information technology is crucial to VA's ability to carry out its mission of ensuring that veterans receive medical care, benefits, social support, and memorials. However, without adequate security protections, VA's systems and information are vulnerable to exploitation by an array of cyber-based threats, potentially resulting in, among other things, the compromise of veterans' personal information. GAO has identified information security as a government-wide high-risk area since 1997. The number of information security incidents reported by VA has more than doubled over the last several years, further highlighting the importance of securing the department's systems and the information that resides on them.

GAO was asked to provide a statement discussing the challenges VA has experienced in effectively implementing information security, as well as to comment on a recently proposed bill aimed at improving the department's efforts to secure its systems and information. In preparing this statement GAO relied on previously published work as well as a review of recent VA inspector general and other reports related to the department's security program. GAO also analyzed the draft legislation in light of existing federal requirements and best practices for information security.

View GAO-14-469T. For more information, contact Gregory C. Wilshusen at (202) 512-6244 or wilshuseng@gao.gov or Nabajyoti Barkakati at (202) 512-4499 or barkakatin@gao.gov.

What GAO Found

The Department of Veterans Affairs (VA) continues to face long-standing challenges in effectively implementing its information security program. Specifically, from fiscal year 2007 through 2013, VA has consistently had weaknesses in key information security control areas (see table).

Control Weaknesses for Fiscal Years 2007-2013

Security control category	2007	2008	2009	2010	2011	2012	2013
Access control	✓	✓	✓	✓	✓	✓	✓
Configuration management	✓	✓	✓	✓	✓	✓	✓
Segregation of duties	✓	✓	✓	✓	✓	✓	✓
Contingency planning	✓	✓	✓	✓	✓	✓	✓
Security management	✓	✓	✓	✓	✓	✓	✓

Source: GAO analysis based on VA and inspector general reports.

In addition, in fiscal year 2013, the department's independent auditor reported, for the 12th year in a row, that weaknesses in information system controls over financial systems constituted a material weakness. Further, the department's inspector general has identified development of an effective information security program and system security controls as a major management challenge for VA. These findings are consistent with challenges GAO has identified in VA's implementation of its security program going back to the late 1990s. More recently, GAO has reported and made recommendations on issues regarding the protection of personally identifiable information at federal agencies, including VA. These were related to developing and implementing policies and procedures for responding to data breaches, and implementing protections when engaging in computerized matching of data for the purposes of determining individuals' eligibility for federal benefits.

Draft legislation being considered by the Subcommittee addresses the governance of VA's information security program and security controls for the department's systems. It would require the Secretary of VA to improve transparency and coordination of the department's security program and ensure the security of its critical network infrastructure, computers and servers, operating systems, and web applications, as well as its core veterans health information system. Toward this end, the draft legislation prescribes specific security-related actions. Many of the actions and activities specified in the bill are sound information security practices and consistent with federal guidelines. If implemented on a risk-based basis, they could prompt VA to refocus its efforts on steps needed to improve the security of its systems and information. At the same time, the constantly changing nature of technology and business practices introduces the risk that control activities that are appropriate in the department's current environment may not be appropriate in the future. In light of this, emphasizing that actions should be taken on the basis of risk may provide the flexibility needed for security practices to evolve as changing circumstances warrant and help VA meet the security objectives in the draft legislation.

PREPARED STATEMENT OF RAYMOND C. KELLEY

Mr. Chairman and Members of the Subcommittee:

On behalf of the men and women of the Veterans of Foreign Wars of the United States (VFW) and our Auxiliaries, I would like to thank you for the opportunity to testify on today's pending legislation.

H.R. 3593, VA Construction Assistance Act of 2013

It is well documented that the Department of Veterans Affairs (VA) struggles to complete major medical facility construction projects on time and on budget. Currently, VA has an average project delivery delay of 35 months and average cost overruns of more than $300 million.

VA is in the process of building three medical centers, each of which has been met with their own unique problems that have frustrated veterans who live in the communities and rely on the medical service of the VA, and have caused VA to lose time and money that could have been used on other projects. VA has a list of major construction projects that will cost more than $20 billion. Every effort must be made to ensure every dollar is used efficiently, so VA can close these major construction gaps. H.R. 3593 puts recommendations in place that will help VA achieve these goals.

Section 3 of this bill calls for five specific reforms in VA's Major Medical Facility Construction process. These reforms call on the Secretary to:

- Use medical equipment planners from the onset of a major medical facility construction project.
- Develop and use a project management plan to improve communication among all parties involved.
- Put construction projects under peer excellence review.
- Develop a metric to monitor change-order processing times and ensure the process meets other federal department and agency best-practices.
- Use a design-build process when possible.

VA wants to equip its facilities with the most up-to-date equipment. However, procuring medical equipment after the design of the facility inevitably causes building delays while the designs are redrawn, and in some cases demolition and reconstruction have taken place to accommodate the newly purchased medical equipment.

The VFW believes VA would benefit from the use of medical equipment planners. Using these planners, which is an industry practice used by the Army Corps of Engineers and other federal agencies, places an experienced medical equipment expert at the disposal of the architect and construction contractor. When used properly, a medical equipment planner can work with the architect during the design phase and then the construction contractor during the build phase to ensure needed space, physical structure and electrical support are adequate for the purchased medical equipment, reducing change orders, work stoppages, and the demolition of newly built sections of a facility.

Using a medical equipment planner can reduce schedule delays and cost overruns. Using the Orlando facility as an example, issues with the purchase of medical equipment caused cost overruns of more than $10 million and construction had to be suspended until the issues were resolved.

Poor communication within VA and between VA and the general contractor has also led to delays and cost over-runs. There have been cases identified where separate VA officials have provided contradictory orders to the general contractor, where one VA employee authorized the continuation or start of a new phase of building, while another VA employee gave the order not to continue or start a particular phase. This lack of VA project management coordination led to a portion of the Orlando, Florida facility to be built then removed.

By developing and using a project management plan, all parities at the onset of the project will have a clear understanding of the roles and authorities of each member of the project team. Included in the plan will be clear guidance on communication, staffing, cost and budget, as well as change-order management.

Construction peer excellence reviews are an important aspect of maintaining a high level of construction quality and efficiency. When used, these review teams are made up of experts in construction management who travel to project sites to evaluate the performance of the project team. These meetings provide important feedback—a separate set of eyes—on the project management plan to ensure a plan is in place to make the project come in on time and on budget.

VA has historically relied on the design-bid-build project delivery system when entering into contracts to build major medical facility projects. Sixty percent of current VA major medical facility projects use design-bid-build. With this model, an archi-

tect is selected to design a facility, the design documents are used to secure a bid, and then the successful contract bid holder builds the facility.

Design-bid-build projects often encounter disputes between the costumer—VA in this case—and the construction contractor. Because these contracts are generally firm-fixed-price, based on the completed design, the construction contractor is usually responsible for cost overruns, unless VA and the contractor agree on any needed or proposed changes that occur with a change of scope, unforeseen site condition changes or design errors. VA and the contractor negotiate these changes through change orders. This process can become adversarial, because neither party wants to absorb the cost associated with the change, and each change order can add months to the project completion date.

A design-build project teams the architectural/engineering company and the construction contractor under one contract. This method can save VA up to six months of time by putting the design phase and the construction performance metric together. Placing the architect as the lead from start to finish, and having the prime contractor work side-by-side with the architect, allows the architect to be an advocate for VA. Also, the architect and the prime contractor can work together early on in the design phase to reduce the number of design errors, and it also allows them to identify and modify the building plans throughout the project. The VFW agrees with the recommendations outlined in Section 3 of this legislation.

Section 4 provides for a special project manager for the on-going construction projects in Denver, Colorado, Orlando, Florida, and New Orleans, Louisiana. This section calls on VA to enter into an agreement with the Army Corps of Engineers, so the Corps can provide a special project manager to conduct oversight of the construction operations regarding compliance with acquisition regulations, and monitor the relationship of VA and the prime contractor. It will also authorize the Corps to assist in construction related activities, such as change-order requests, and provide guidance on developing best practices in overall project operations.

The VFW supports this provision, but it should be seen as a stop-gap measure to help VA to quickly complete these three outstanding major construction projects, and systems must be put in place to ensure VA can function under similar guidance without the assistance of the Corps on future projects.

It is important for VA to become more efficient at facility construction. Veterans have expectations that medical facilities will be available when VA first states what the completion date will be. It is obvious by looking at the number of delays and cost overruns that the contracting and building procedures that VA currently uses are antiquated and are costing VA millions of dollars more for each project; and causing five to six year delays in much needed medical facilities. By passing this legislation, VA will gain better oversight, cost controls and more efficient procedures for future construction projects.

Mr. Chairman, this concludes my remarks and I look forward to any question you or the Committee may have.

Information Required by Rule XI2(g)(4) of the House of Representatives

Pursuant to Rule XI2(g)(4) of the House of Representatives, VFW has not received any federal grants in Fiscal Year 2013, nor has it received any federal grants in the two previous Fiscal Years.

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TESTIMONY OF

DIANE M. ZUMATTO
AMVETS NATIONAL LEGISLATIVE DIRECTOR

BEFORE THE

HOUSE COMMITTEE ON VETERANS' AFFAIRS, SUBCOMMITTEE

ON OVERSIGHT AND INVESTIGATIONS

U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS
SECOND SESSION

CONCERNING

A LEGISLATIVE HEARING ON:

HR 4261:
GULF WAR HEALTH RESEARCH REFORM ACT OF 2014

EXECUTIVE SUMMARY

AMVETS supports HR 4261, the Gulf War Health Research Reform Act of 2014, which would:

- establish the RAC as an independent committee within the VA with its own budget;
- require the that the majority of the RACs members be appointed by the chairmen and ranking members of the House and Senate Veterans Affairs Committees;
- strengthen the RACs ability to review research and studies as well as publish reports related to Gulf War Illness (GWI);
- expresses the sense of Congress that VA should contract with the Institute of Medicine to conduct several Gulf War studies and reports previously ordered by Congress, which were not conducted or weren't conducted in accordance with Congress' direction;
- require the VA to ensure that research conducted on this disease be referred to as "Gulf War Illness";
- with regard to future research, require that Institute of Medicine (IOM) reports on the health effects of veteran toxic exposures, consider animal as well as human studies, as Congress has previously ordered, to better understand the causes and how best to treat our afflicted veterans

If we ever expect to understand GWI, if we ever expect to develop medically appropriate treatments for it, and if we ever hope to truly improve the quality of life of our Gulf War veterans, then continued research, as well as adequate, on-going funding, is absolutely vital. Our veterans didn't give up while they served overseas; they risked their lives and their health for the good of all American citizens. It's time for this country to hold up its end of the bargain by doing everything possible to take care of the healthcare needs of our Gulf War veterans.

AMVETS believes this legislation can be part of the solution that Gulf War veterans have been waiting 23 years for.

Chairman Coffman, Ranking Member Kirkpatrick and distinguished committee members, while I am pleased to have this opportunity to sit before you today, I am simultaneously disheartened that it is because we're still dealing with administrative issues rather than making progress towards the understanding and treating of the scourge that is Gulf War Illness.

Twenty three years have passed since the end of the Gulf War and sixteen, since Congress first mandated (Public Law 105-368, the Veterans Programs Enhancement Act of 1998) the appointment of a public advisory panel of independent scientists and veterans to advise on federal studies and programs to address the health consequences of the Gulf War. The Research Advisory Committee on Gulf War Veterans' Illnesses (RAC) was originally appointed in 2002 by Secretary of Veterans Affairs Anthony Principi, who directed the committee to, "*provide advice and make recommendations* to the Secretary of the Veteran Affairs on proposed research studies, research plans and research strategies relating to the health consequences of military service in the Southwest Asia theater of operations during the Persian Gulf War."

In the 'Objectives and Scope of Activity' section of the committee's original 2002 charter it is further stipulates that the RAC, ". . .shall review all proposed federal research plans, initiatives, procurements, grant programs, and other activities in support of research projects on Gulf War-associated illnesses and assess the individual projects and the *overall effectiveness of government research* in addressing central questions on the nature, causes and treatments of Gulf War-related illnesses." There can be no doubt that the RAC, in conjunction with the VA, has been charged over the years with important, and in some cases, life or death responsibilities and AMVETS is appreciative of all the work done by both entities.

Research has shown that Gulf War illness is associated with service in the 1991 war; that it affects at least 175,000 veterans; and that it is a physical condition caused by toxic exposures, rather than stress or other psychiatric factors.

Symptoms typically include debilitating fatigue, cognitive and other neurologic symptoms, gastrointestinal problems, skin problems, chronic widespread pain, and persistent headaches or migraines. Gulf War veterans also have elevated rates of ALS, Lou Gehrig's Disease and there is concern that Gulf War Illness could develop into life-threatening neurological disorders as this cohort ages. Unfortunately, at this point in time, there are no effective treatments.
AMVETS' only concerns regarding the subject of this hearing are simply - the health and quality of life of our Gulf War veterans. For more than 20 years now, these men and women have suffered, and continue to suffer, from the often debilitating effects of Gulf War Illness (GWI). How much longer will they be expected to wait to get relief from their decades-long pain and distress?

AMVETS fully supports the concept, purpose and work of the RAC. We believe that their work over the years has been instrumental in helping to:

- shed light on the underlying causes of GWI;
- examine treatment options for those currently afflicted;
- ensure that adequate research funding is requested;
- act as a catalyst, bringing together VA and non-Va researchers;
- consider countermeasures for long-term, low-dose exposures to protect current and future servicemebers; and
- identify additional focus areas for future research.

I would suggest that it is common knowledge that bureaucracies, and VA is among the largest, are not well known for their transparency, creativity or ability to 'think outside the box'; therefore, it makes good sense to have an independent, non-partisan and transparent body, with its own support staff, nothing to lose and no hidden agendas, composed of medical professionals, research experts, veterans and other stakeholders, so prominently involved in this important work.

Additionally, by openly allowing academic subject matter experts and medical professionals to participate in RAC activities, the best and brightest are able to contribute and act as force multipliers towards resolving the problem of GWI.

AMVETS, as one of the authors of the *Independent Budget,* as a member of the Military Coalition (both of whom take strong positions on the issue of GWI) and one of the preeminent, congressionally-chartered veteran service organizations in the country, is extremely disappointed that the VA often appears to be working at cross-purposes with the RAC and has failed to act on recommendations made by the committee in June 2012 and February 2013.

Among the concerns outlined in the 2013 RAC Annual Report:

- VA did not add questions to its national survey of Gulf War veterans that would enable it to determine the prevalence, progression or correlates of the illness;
- VA did not modify the contract for the Institute of Medicine (IOM) treatment report to conform to Congresses intent;
- VA re-set its budgeted Gulf War research spending in FY 2014 to $15 million; however, VA has historically not spent the amount budgeted and the amount spent has included significant numbers of studies not actually directed at Gulf War Veterans;
- VA concluded a contract for the development of a case definition with the IOM through a literature review by a committee with little expertise in the illness,

although this is contrary to standard scientific practice and the IOM has never done a case definition of an illness before;

- In May 2013, VA changed the committee's charter to eliminate its authority "to assess the overall effectiveness of government research to central questions on the nature, causes and treatments for the health consequences of military service . . . during the 1990 – 1991 Gulf War" and
- The charter change also calls for the elimination of the provision granting the committee its own staff, as well as, the replacement of half of the committee members this year and the balance in 2015.

I hope that these concerns and others expressed today indicate why AMVETS supports, HR 4261, the Gulf War Health Research Reform Act of 2014. This concludes my testimony and I'll be happy to answer your questions.

21 March 2014

The Honorable Representative Mike Coffman, Chairman
U.S. House of Representatives
House Committee on Veterans' Affairs
Subcommittee on Oversight and Investigations
335 Cannon House Office Building
Washington, D.C. 20510

Dear Chairman Coffman:

Neither AMVETS nor I have received any federal grants or contracts, during this year or in the last two years, from any agency or program of the federal government.

Sincerely,

Diane M. Zumatto

Diane M. Zumatto
AMVETS National Legislative Director

Biographical Sketch

Diane M. Zumatto of Spotsylvania, VA joined AMVETS as their National Legislative Director in August 2011. Ms. Zumatto, a native New Yorker and the daughter of immigrant parents decided to follow in her family's footsteps by joining the military. Ms. Zumatto is a former Women's Army Corps (WAC) member who was stationed in Germany. Zumatto was married to a CW4 aviator in the Washington Army National Guard and is the mother of four adult children. Ms. Zumatto is extremely proud that two of her children have chosen to follow her footsteps into military service.

Ms. Zumatto has more than 20 years of experience working with a variety of non-profits in increasingly more challenging positions, including: the American Museum of Natural History; the National Federation of Independent Business; the Tacoma-Pierce County Board of Realtors; the Washington State Association of Fire Chiefs; Saint Martin's College; the James Monroe Museum; the Friends of the Wilderness Battlefield and the Enlisted Association of the National Guard of the United States. Diane's non-profit experience is extremely well-rounded as she has variously served in both staff and volunteer positions including as a board member and consultant.

After receiving her B.A. in Historic Preservation from the University of Mary Washington in 2005, Diane decided to diversify her experience by spending some time in the 'for-profit' community. Realizing that her creativity, energy and passion were not being effectively challenged, she left the world of corporate America and returned to non-profit organization.

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Testimony of James Binns
Chairman, Research Advisory Committee on Gulf War Veterans Illnesses
U.S. House of Representatives Committee on Veterans Affairs
Oversight and Investigations Subcommittee
March 25, 2014

Chairman Coffman, Ranking Member Kirkpatrick, and Members of the Committee, I appreciate the opportunity to testify in support of H.R. 4261, the Gulf War Health Research Reform Act of 2014.

Since Congress created the Research Advisory Committee on Gulf War Veterans Illnesses in Public Law 105-368, members of the Research Advisory Committee have testified at ten Congressional hearings. This is the last time a member of the Committee will freely testify to Congress, without VA censorship, unless this bill becomes law.

The title of the 1997 Congressional report which led to the creation of the Committee was "Gulf War Veterans Illnesses: VA, DOD Continue To Resist Strong Evidence Linking Toxic Causes To Chronic Health Effects".

Sixteen years later, that still says it all: "VA, DOD Continue To Resist Strong Evidence Linking Toxic Causes To Chronic Health Effects."

The only difference is that science now knows for certain that Gulf War Illness is a physical disease, that it is associated with service in the war, that it affects an estimated 250,000 U.S. veterans, that it cannot be explained by any psychiatric illness, and that it likely results from environmental exposures.

I am not quoting the Research Advisory Committee. Those are the conclusions of the Institute of Medicine's landmark 2010 report. Our committee agrees but goes further to name the exposures: pyridostigmine bromide pills, pesticides, and very possibly oil well fires, multiple vaccinations, and low level nerve agents released in the destruction of Iraqi facilities.

The Institute of Medicine report also tells us that "effective treatments, cures, and, it is hoped, preventions" can "likely" be found with the right research, and called for a renewed research effort to achieve those goals.

Next month, the Research Advisory Committee will release a five-year report that shows science is making progress. Research is beginning to identify probable underlying mechanisms, promising treatments and biomarkers.

Just as science is turning the corner, however, career VA and DOD staff have pushed back in an attempt to reassert discredited fictions from the 1990's that "the same thing happens after every war" due to psychiatric factors. Because there is not a

shred of scientific evidence to support this position, they have resorted to manipulating research studies and reports to provide apparent support.

In its recent survey of Gulf War veterans, the VA Office of Public Health included the questions necessary to identify PTSD but not Gulf War illness. In the journal Military Medicine, the heads of the three VA War-Related Illness and Injury Study Centers wrote that "chronic multisymptom illness has been documented after armed conflicts since the Civil War" and that a "biopsychosocial approach to the illness ... will most benefit the patient." In a briefing to an Institute of Medicine committee studying treatments for chronic multisymptom illness in Gulf War veterans, the director of the VA Post-Deployment Integrated Care Initiative stated that it is unknown whether the illness is physical or psychiatric. The list goes on.

VA's standard talking point is that it "does not support the notion some have put forward that these health symptoms arise as a result of Post-Traumatic Stress Disorder (PTSD) or other mental health issues." But the "some" who are putting forward this "notion" are VA staff. These actions threaten to mislead science down blind alleys once again, just as has happened for most of the past twenty-three years.

The Research Advisory Committee has been charged since its inception with the responsibility to assess the effectiveness of government research, and we complemented early progress under Secretary Shinseki. But when the tide turned and staff launched its campaign to revive 1990's fictions, the Committee reported it in detail to the Secretary in June 2012 and in testimony to this subcommittee in March 2013. We asked the Secretary to investigate these actions and to remove those responsible from positions of authority over Gulf War research.

Instead, VA removed us. In May 2013, I was notified that the committee's charter had been changed to eliminate its charge to assess the effectiveness of government research and that the membership of the committee would be entirely replaced over the next year.

New blood is certainly desirable, but two of the three scientists subsequently proposed for membership by VA were stress advocates. One has edited a textbook on stress and is a member of the American Psychosomatic Society. The other published an editorial last year which stated that "presupposing a primary, supplementary, or synergistic role for stress in the Gulf War syndrome . . . provides a framework for valid scientific analysis." It is apparent that VA intends to use the Research Advisory Committee itself in its campaign to resurrect these discredited themes.

VA has sought to backtrack on its appointments, pulling these names and appointing others that I and other current members supported. I have heard that VA may be preparing to name its next round of members to reassure skeptics that it is not going to pack the committee. But that is now, while their actions are under scrutiny.

They have shown where they intend to go, once that scrutiny is gone. It is apparent that VA intends to use the committee itself to resurrect these discredited themes.

VA has attempted to explain the charter changes as routine, necessary to comply with the Federal Advisory Committee Act, or that the committee's work constituted improper oversight. But virtually identical language has been part of all previous five charters signed by four VA Secretaries, including Secretary Shinseki in 2010. All recognized that an inherent part of advising on future research is to assess the effectiveness of the research already being done.

The clear purpose of the charter change was to stop the committee from reporting further on VA staff's efforts to mislead research. And that is exactly the effect it is having. Attached to my testimony is the draft section on VA's research program which had to be removed from the report that the committee will release next month. In the future, VA Secretaries and Congressional committees will not have the benefit of this information. In addition, VA has recently stated that committee members may not release reports and recommendations without written VA approval. Not even the pretense that the committee is independent remains.

I urge you to read this section, not only to appreciate in more detail the dangerous campaign now underway, but also to see that it is a balanced assessment, giving credit where credit is due.

Similarly, the legislation before you, H.R. 4261, is a balanced approach to the problems I have discussed. It gives back to the Research Advisory Committee the responsibilities that were taken away last year. It provides for the independent operation of the committee within VA but not subject to VA authority. It provides for nine of the twelve members to be appointed by the chairs and ranking members of the House and Senate Veterans Affairs Committees, and three members by the Secretary of Veterans Affairs. These provisions are based on the bipartisan model of the Advisory Committee on Student Financial Assistance, which has operated successfully within the Department of Education for over twenty years.

The bill also reasserts other appropriate Congressional authority. VA has routinely disregarded laws passed by Congress related to Gulf War research. In some cases, studies ordered by Congress have not been done at all, such as the studies ordered by Congress in 2008 of the prevalence of multiple sclerosis, Parkinson's disease, brain cancer, and other central nervous system abnormalities in Gulf War veterans and in veterans of Post 9/11 operations.

Other studies ordered by Congress have been changed by VA to produce results VA desired rather than what Congress ordered. When Congress ordered VA to contract with the IOM for a review of best treatments by a panel of doctors who treat Gulf War veterans, VA contracted for a literature review by a panel with no Gulf War expertise. The panel was overweighted with specialists in psychosomatic medicine, and the report largely reviewed psychiatric treatments.

When Congress ordered VA to contract with the IOM to review the health effects of toxic substances to which troops were exposed in the war, Congress specified multiple times that the reviews should consider animal as well as human studies. Yet the resulting IOM reviews have excluded animal studies from consideration in their conclusions. Since most studies of toxic substances are necessarily done in animals for ethical reasons, IOM reviews consistently find insufficient evidence that a substance causes health effects. This same standard is now being applied to mislead conclusions regarding the health effects of toxic exposures to veterans of the recent wars in Iraq and Afghanistan.

The bill requires VA to specify that animal studies will be considered, as previously ordered by Congress, in future IOM studies of toxic substances to which veterans were exposed. The bill also states that it is the sense of Congress that Gulf War studies previously ordered by Congress be conducted, or reconducted, in accordance with Congress's prior direction, and that IOM committees studying Gulf War health include three members of the Research Advisory Committee. The bill further provides that it is the sense of Congress that VA should conduct an immediate followup to its national survey of Gulf War veterans to include the questions necessary to identify Gulf War illness.

A complete analysis of the bill's provisions is attached to this testimony.

This bill is essential to maintaining hope that research progress will continue. But restoring the committee only gets us back to where we were, advancing science in one area, while staff pulls it back somewhere else.

That is what has happened for the past twenty-three years. If the IOM is correct, as I believe it is, that effective treatments can likely be found with the right research, then Gulf War veterans would likely have effective treatments today were it not for staff obstruction. Instead, hundreds of millions of dollars have been spent in the name of Gulf War health, with little to show for it until recently.

Gulf War veterans who became ill serving their country consider this history a betrayal, with good reason. Having spent most of my working life in medical technology businesses, I also have never understood its logic. If the concern is to save money, developing treatments for ill veterans is far more cost-effective than paying for benefits and healthcare for the rest of their lives as their conditions further deteriorate.

Similarly, it makes no sense to sabotage this research while current and future American forces remain at risk of similar exposures, as recent events in Syria have emphasized. As a Vietnam veteran and former Principal Deputy Assistant Secretary of Defense, I understand that chemical defenses based on preventative and immediate measures will not be effective in the terrorist settings that American troops and civilians are most likely to face. It is critical that the tragic experience of

Gulf War veterans be used to develop medical countermeasures for longer-term, low-dose exposures.

In summary, this research should continue with every encouragement for excellent reasons. But unless the obstacle of VA and DoD staff obstruction is removed once and for all, science candidly may never reach its goal. This is not easy science. Expecting the research community to find the answers, while it is being misled by bogus studies and reports, is unrealistic.

VA leadership has decided to shoot the messenger instead. I urge Congress to go beyond this bill to pursue the rigorous investigation necessary to end this shameful history and clear the way to success. To continue this flawed process as it has gone on these many years is a cruel hoax on Gulf War veterans and the men and women in uniform today who expect their government will protect them.

Exhibit A

Analysis of H.R. 4261, the Gulf War Illness Research Reform Act of 2014
March 24, 2014

Executive Summary:

Science has firmly established that Gulf War Illness is a serious physical condition caused by toxic exposures during the 1990-91 war. Based on this knowledge, research is finally making significant progress toward understanding the mechanisms underlying the illness and identifying treatments. This research is vital to the health of 175,000 ill Gulf War veterans and to future American forces at risk of similar exposures. Unless legislative action is taken to reassert Congressional authority, however, future research will be misled, and this progress will end.

While proclaiming its interest in Gulf War veterans' health, VA staff is attempting to reassert discredited 1990's government positions that Gulf War veterans have no special health problem -- just "what happens after every war," reflecting psychiatric factors. Since no scientific support for these positions exists, government staff has resorted to manipulating research studies to provide apparent support, including reports of the Institute of Medicine ordered by Congress. The entire scientific community relies on these studies to guide future research. These staff actions thus threaten to terminate the progress being made, and mislead science down blind alleys, as has happened for most of the past twenty-three years.

The Congressionally-mandated Research Advisory Committee on Gulf War Veterans Illnesses has reported on these developments to the Secretary of Veterans Affairs and to Congress. VA's response has been to terminate the independence of the committee, removing its authority to assess the effectiveness of federal research programs, changing its membership, and prohibiting it from releasing reports without written VA approval.

The proposed bill would re-establish appropriate Congressional authority over Gulf War Illness research and enable scientific progress to continue.

- It provides that the Research Advisory Committee on Gulf War Veterans Illnesses will operate independently of VA authority, with nine members appointed by the chairs and ranking members of the House and Senate Veterans Affairs Committees and three members by the Secretary of Veterans Affairs. This model is based on a similar non-partisan advisory committee at the Department of Education, which has operated successfully for over twenty-five years.
- It requires VA to follow previously enacted legislation requiring the Institute of Medicine to consider animal as well as human studies in assessing the health effects of toxic exposures. Most scientific research on toxic substances is necessarily done in animals. This standard relates to the health of veterans of recent wars in Iraq and Afghanistan, as well as Gulf War veterans.
- It declares it to be the sense of Congress that VA conduct other studies that Congress has ordered in accordance with the law, which VA has either materially changed or failed to conduct at all.

The bill is revenue neutral, as the Research Advisory Committee's functions and costs will not change, and the research studies mentioned in the bill are not mandatory and, in any case, relate primarily to studies already ordered by Congress. It has not yet been formally scored.

Why Legislation Is Needed:

The Research Advisory Committee on Gulf War Veterans Illnesses (the "Committee") was created by Public Law 105-368, following a 1997 Congressional report entitled "Gulf War Veterans Illnesses: VA, DOD Continue To Resist Strong Evidence Linking Toxic Causes To Chronic Health Effects." The report concluded: "After 19 months of investigation, the subcommittee finds the status of efforts on Gulf War issues by the Department of Veterans Affairs, the Department of Defense, the Central Intelligence Agency, and the Food and Drug Administration to be irreparably flawed. . . [W]e find current approaches to research, diagnosis and treatment unlikely to yield answers to veterans' life-or-death questions in the foreseeable, or even far distant, future."[i]

The statute provided that the Committee provide "advice to the [Secretary of Veterans Affairs] on proposed research studies, research plans, or research strategies relating to the health consequences of military service in the ... Persian Gulf War."[ii]

The Committee was first appointed in 2002 by Secretary of Veterans Affairs Anthony Principi, who established a charter that provided for the Committee to have its own staff and the authority to assess the effectiveness of government research, reflecting the independent role that Congress intended. Virtually identical provisions were included in subsequent charters signed by Secretary Principi in 2004, Secretary James Nicholson in 2006, Secretary James Peake in 2008, and Secretary Eric Shinseki in 2010. All recognized that an inherent part of advising on future research plans and strategies is to assess the effectiveness of the research plans and strategies currently being implemented.

To date, the Committee has performed its intended role, providing independent advice to the Secretary of Veterans Affairs and to Congress. Members of the Committee have testified before Congress ten times. The Committee's reports and recommendations have gradually led the scientific community to recognize the true scope and nature of Gulf War illness and to direct federal research to the right areas and the goal of identifying treatments. In 2008, the Committee issued a comprehensive report that reviewed the scientific literature and concluded that Gulf War illness is real, affects at least one-fourth of those who served in the war, is not associated with psychiatric illness, and was caused by toxic exposures including pesticides, pyridostigmine bromide pills, and possibly oil well fires, multiple vaccinations, and low-level nerve gas released by the destruction of Iraqi facilities. The Committee is currently preparing an update of that report, to be released in April 2014, which will show that scientific studies since 2008 support and further confirm the conclusions of the 2008 report.

In 2010, building on the work of the Committee, an Institute of Medicine report concluded that the multisymptom illness suffered by Gulf War veterans is a "diagnostic entity," associated with Gulf War service, affecting an estimated 250,000 veterans, which "cannot be reliably ascribed to any known psychiatric disorder," and that "it is likely that Gulf War illness results from an interplay of genetic and environmental factors." The report called for a "renewed research effort with substantial commitment" to identify treatments. The chair of the IOM panel emphasized that "[v]eterans who continue to suffer from these discouraging symptoms deserve the very best that modern science and medicine can offer ... to speed the development of effective treatments, cures, and, it is hoped, preventions... and we believe that ... answers can likely be found."[iii]

The Research Advisory Committee welcomed the IOM report and the progress being made at the DoD Congressionally Directed Medical Research Program (CDMRP) and at VA. In its 2011 annual report, the Committee stated: "It appears likely that for the first time VA will soon have a comprehensive strategic plan to provide the foundation for an effective Gulf War research program."[iv]

However, beginning in 2012, career VA and DoD staff pushed back, attempting to re-establish discredited 1990's positions minimizing the health problems of Gulf War veterans – the same positions that had led Congress to establish the Committee. Since no scientific support for these positions exists,

staff has resorted to manipulating research studies and reports to provide apparent support, including new reports of the Institute of Medicine. These studies and reports address topics fundamental to understanding Gulf War illness, including the number of ill veterans, whether the illness is psychiatric, and whether it is "just what happens after every war." Unless halted, these actions will mislead the future course of Gulf War illness research, terminating progress just as science has finally turned the corner, not only at VA but also at the effective Gulf War Illness research program Congress has established at CDMRP.

VA's standard talking point is that it "does not support the notion that some have put forward that these health symptoms arise as a result of PTSD or other mental health issues." But the "some" who are putting forward this "notion" are VA staff.

In a recent survey of Gulf War veterans, the VA Office of Public Health included the questions to identify PTSD but not Gulf War Illness. In the medical journal Military Medicine, the heads of the three VA War-Related Illness and Injury Study Centers wrote that "chronic multisymptom illness has been documented in armed conflicts since the Civil War" and that a "biopsychosocial approach to the illness . . . will most benefit the patient." In a briefing to an Institute of Medicine committee studying treatments for chronic multisymptom illness in Gulf War veterans, the director of the VA Post-Deployment Integrated Care Initiative stated that it is unknown whether the illness is physical or psychiatric. The list goes on.

The Committee documented such actions in forty-six pages of findings and recommendations issued in June 2012.[v] Two Committee members testified about them at a March 2013 Congressional hearing.[vi] [vii] Rather than fix the problems, VA responded in May 2013 by eliminating the independence of the Committee:

- changing the charter of the Committee to remove its charge to assess the effectiveness of VA Gulf War health research;
- eliminating charter terms providing for the Committee to have its own staff (rather than be staffed by the same personnel whose work it formerly assessed); and
- announcing that the Committee membership would be replaced within one year.[viii]

VA has falsely characterized these changes as routine. While fresh blood is certainly desirable, two of the three scientists subsequently proposed for membership by VA were stress advocates. One has edited a textbook on stress[ix] and belongs to the American Psychosomatic Society.[x] The other published in 2013 that "[p]resupposing a primary, supplementary, or synergistic role for stress in the Gulf War syndrome . . . provides a framework for valid scientific analysis."[xi] VA has sought to backtrack, pulling these names and appointing others. But they have shown where they intend to go, once they are no longer under scrutiny. It is apparent that VA intends to use the Committee itself to resurrect these discredited themes.

VA has attempted to explain the charter changes as necessary to comply with the Federal Advisory Committee Act, or that the Committee's work constitutes improper oversight. As noted above, however, virtually identical language has been part of five charters signed by four VA Secretaries, including Secretary Shinseki in 2010.[xii] All have recognized that an inherent part of advising on future research is to assess the effectiveness of the research already being done.

The clear purpose of the charter change was to stop the Committee from reporting further on VA staff's efforts to mislead research. And that is exactly the effect it is having. The draft section on VA's research program (which had appeared in earlier committee reports) had to be removed from the report that the committee will release next month.[xiii] In the future, VA Secretaries and Congressional committees will not have the benefit of this information.

In addition, VA has recently stated that committee members may not release reports and recommendations without written VA approval. Not even the pretense that the committee is independent remains.

This bill would give back to the Committee the responsibilities and independence that Congress intended and that it exercised prior to May 2013. It also reasserts other appropriate Congressional authority. VA has routinely disregarded laws passed by Congress related to Gulf War research. In some cases, studies ordered by Congress have not been done at all, while others have been changed to produce results VA desired.

Provisions of the Bill:

1. The bill would amend the statute that created the Committee to return to the Committee the functions that it historically performed prior to May 2013, including those that VA has taken away. These provisions come largely from prior charters.

a. The Committee shall provide advice to the Secretary of Veterans Affairs and to the House and Senate Veterans Affairs Committees on proposed research studies, research plans, or research strategies related to the health consequences of military service during the Gulf War.

b. The Committee does not conduct research or review individual research proposals prior to funding.

c. The guiding principle for the Committee is the premise that the fundamental goal of Gulf War health-related research is to ultimately improve the health of ill Gulf War veterans, and the choice and success of research efforts shall be judged accordingly.

d. The Committee shall assess the effectiveness of federal research to answer central questions on the nature, causes, and treatments for the health consequences of Gulf War service.

e. The Committee has its own staff, up to four people, rather than relying for staff support on the VA personnel whose work it is responsible to assess. This staff support may be contracted out to a university.

2. The bill provides that the Committee shall continue to function under the Federal Advisory Committee Act within the Department of Veterans Affairs, but independent of Department of Veterans Affairs control. Nine of its members shall be appointed by the chairs and ranking members of the Senate and House Veterans Affairs Committees, and three members by the Secretary of Veterans Affairs. Its budget will be set by Congress within the VA budget, at the same level as the current historical level, it is anticipated. These provisions follow the model of the non-partisan Advisory Committee on Student Financial Assistance, which has operated successfully for over twenty years within, but independent of, the Department of Education.[xiv]

a. The Committee will have independent control over its budget, personnel decisions, and other management functions. These provisions are drawn from the Advisory Committee on Student Financial Assistance authorizing statute.[xv]

b. Committee reports shall be submitted to the House and Senate Veterans Affairs committees, the Secretary of Veterans Affairs, and the head of any other federal department conducting Gulf War health research.

c. Reports shall be approved by the Committee meeting in public session prior to submission.

d. Reports shall not be subject to review or approval by the Secretary of Veterans Affairs, but proposed recommendations may be submitted to the Secretary for thirty days for comment.

e. Members will include scientists, doctors, and veterans, as at present.

f. Members will be appointed, in rotation, by the chairs and ranking members of the House and Senate Veterans Affairs Committees and the Secretary of Veterans Affairs.

g. The chairman is appointed jointly by the chairs of the House and Senate Veterans Affairs Committees.

h. The initial membership will include ten members who currently serve on the Committee and two new members chosen through the initial rotation selections. Members will serve three-year terms, except that the initial group will be given one, two, or three-year terms, so that the terms will be staggered. Members will be eligible to be reappointed for one additional term (other than current members who have already served more than three years).

3. The Committee will sunset two years after submitting a report signed by nine of its members that the Department of Veterans Affairs and the Department of Defense are each carrying out an effective research program related to the health consequences of 1990-91 Gulf War service, provided that no report to the contrary has been issued in the interim.

4. The bill would also require VA to follow certain standards regarding Gulf War research.

a. Any research conducted or funded by VA shall refer to the multisymptom illness that afflicts an estimated one-fourth of Gulf War veterans as "Gulf War Illness."

VA's unwillingness even to put a name on Gulf War Illness undermines any serious research effort to solve it. While the scientific community and CDMRP consistently use the term "Gulf War illness," VA refuses to adopt this term. Instead, VA continues to use terms such as "medically unexplained illnesses" or "undiagnosed illnesses" that suggest the condition has not been validated or that Gulf War veterans' complex of symptoms does not constitute a common disease. The VA Gulf War website is entitled "Gulf War Veterans Medically Unexplained Illnesses," explaining: "We prefer not to use the term 'Gulf War Syndrome' [or Gulf War illness] when referring to medically unexplained symptoms reported by Gulf War Veterans. Why? Because symptoms vary widely."[xvi] In fact, the IOM has concluded that the illness is a "diagnostic entity."[xvii] In March 2014, the IOM recommended that VA use the term "Gulf War Illness."[xviii]

Terms like "chronic multisymptom illness" are also unsatisfactory, because, while the term was originated by a CDC researcher to refer to Gulf War illness,[xix] it has morphed into an umbrella phrase covering a wide range of illnesses such as chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome, etc. While there is some similarity between Gulf War Illness and these illnesses, research has also shown substantial differences. Effective research requires segregating one illness from another.

b. Any Gulf War illness research conducted or funded by VA shall use the case definition recommended by the Committee.

c. Any study ordered from the Institute of Medicine related to the health of Gulf War and other veterans to determine if a potentially toxic exposure is associated with adverse health effects shall use a standard that considers animal studies to the same extent as human studies, as previously ordered by Congress. (See below.)

4. The bill would not require, but would declare it to be the sense of Congress that VA should contract with the Institute of Medicine to conduct several Gulf War studies and reports previously ordered by Congress, which either have not been conducted or were not conducted in accordance with Congress's direction. VA's refusal to follow these laws is part of VA staff's efforts to mischaracterize the health problems of Gulf War veterans.

a. Public Law 111-275, Section 805, required VA to contract with the IOM for a "comprehensive review of the best treatments for chronic multisymptom illness in Gulf War veterans."[xx] VA converted this review into a restatement of discredited fictions that the illness is psychiatric.

The statute directed that the contract provide that the IOM "shall convene a group of medical professionals who are experienced in treating individuals who served as members of the Armed Forces in the Southwest Asia Theater of Operations of the Persian Gulf War during 1990 or 1991 and who have been diagnosed with chronic multisymptom illness or another health condition related to chemical and environmental exposures that may have occurred during such service."

Congress knew that there was virtually no published literature regarding treatments for Gulf War illness, but reasonably thought that doctors with experience in treating these veterans would have practical experience in using different therapies and would know what has been helpful to their patients, although it might not have been formally studied.

VA ignored this express direction and instead contracted with the IOM for a literature review by a committee with no experience in treating Gulf War veterans. The committee was heavily weighted with specialists in somatic medicine and stress,[xxi] although the comprehensive IOM review eighteen months before had concluded that "the excess of unexplained medical symptoms reported by deployed Gulf War veterans cannot be ascribed to any known psychiatric disorder."[xxii] Two VA staff members and four others (reportedly suggested by VA and DoD staff) briefed the committee that the illness is, or may be, psychiatric. VA instructed the IOM committee to review published literature "concerning treatment of populations with a similar constellation of symptoms."

Following this guidance, the committee found only three Gulf War treatment studies. It reviewed treatment literature for twelve other illnesses, six of them psychiatric. Its report devotes sixteen pages to discussing these psychiatric illnesses and forty-eight pages to psychotherapies. Rather than the valuable treatment experience of Gulf War veterans' doctors, as Congress intended, the resulting report is a restatement of government positions from the 1990's that have since been discredited by science: that this "unexplained" illness is psychosomatic, that the same thing happens after every war, that ill Gulf War veterans do not have common symptom clusters, and that "clinicians should approach [the illness] with 'a person-centered model of care … that helps patients understand that the word psychosomatic is not pejorative.'"

The bill would also declare it the sense of Congress that this report not be used for research or other purposes by VA.

b. Public Law 110-389, Section 804, required that VA contract with the IOM "to conduct a comprehensive epidemiological study … [to] identify the incidence and prevalence of diagnosed neurological diseases, including multiple sclerosis, Parkinson's disease, and brain cancers, as well as central nervous system abnormalities that are difficult to precisely diagnose" in 1991 Gulf War veterans, in Post 9/11 Global Operations veterans, and in non-deployed comparison groups. VA has never contracted for this study.

At the Research Advisory Committee on Gulf War Veterans Illnesses meeting on January 7, 2014, the head of the VA Office of Public Health, Dr. Victoria Davies, acknowledged that VA has not ordered the study. She stated that the IOM has told VA that conducting the study is not feasible.

None of Committee scientists agreed with this statement. It could possibly be argued that it would be difficult to study the prevalence of "central nervous system abnormalities that are difficult to diagnose," but determining the prevalence of multiple sclerosis, Parkinson's disease, and brain cancer is straightforward epidemiology.

Dr. Davies also stated that VA had covered the same ground elsewhere, referring to a multiple sclerosis study by Dr. Michael Wallin. However, while the study is entitled "The Gulf War era multiple sclerosis cohort," it actually covers veterans from 1990 to 2007, and provides data only on the incidence of MS by race, sex, and service for that entire period -- nothing on the prevalence among those who served in the Gulf War or among those who served in Post 9/11 operations compared to their non-deployed counterparts.[xxiii] Dr. Davies confirmed that VA has done no studies of the prevalence of Parkinson's disease or brain cancer in Gulf War or Post 9/11 operations veterans.

c. Public Law 105-277 and Public Law 105-368 require that VA contract with the Institute of Medicine for reports reviewing the scientific literature concerning thirty-three "toxic agents, environmental or wartime hazards, or preventative medicines or vaccines associated with Gulf War service ... [to] determine ..."whether a statistical association exists between exposure to the agent . . . and the illness ...[and] the increased risk of the illness among human or animal populations exposed to the agent ..."[xxiv]

The purpose of these reports is to provide the basis for a determination by the Secretary of Veterans Affairs as to whether exposure to an agent warrants a presumption of service connection, which would entitle a veteran with the illness to receive health care and other benefits. The statutes further require that the Secretary of Veterans Affairs consider "the exposure in humans or animals" to an agent and "the occurrence of a diagnosed or undiagnosed illness in humans or animals".[xxv]

Congress thus repeatedly provided that the scientific information to be considered included studies of both humans and animals. Most studies of toxic substances are necessarily done in animals, as it would be unethical to test them in humans.

However, VA did not require the IOM to consider animal studies in these determinations, and the IOM has not considered them. Indeed, the IOM deliberately has gone out of its way not to consider them. The first IOM Gulf War report stated that it was applying the same standard that was used in the Agent Orange report that had found an association between Agent Orange and the illnesses of Vietnam veterans, because that standard had "gained wide acceptance for more than a decade by Congress, government agencies, researchers, and veteran groups."[xxvi]

The standard used in the Agent Orange report was: "a positive association has been observed between [the agent] and a health outcome in studies in which chance, bias, and confounding could be ruled out ..."[xxvii] In the first Gulf War report, however, the standard was quietly changed to "...a health outcome in *human* studies in which chance, bias, and confounding could be ruled out." [emphasis added][xxviii] This corrupted standard has been applied in all subsequent IOM Gulf War reports.

With relatively few human studies to consider, IOM Gulf War committees have consistently found insufficient evidence of an association between each of the thirty-three toxic agents and illness, and the Secretary has never made a determination of service connection. VA has never directed the IOM to consider animal studies as required by Congress.[xxix]

IOM representatives have responded that IOM Gulf War reports mention animal studies, and that their standard provides for animal studies to be taken into account in determining whether an association is

biologically plausible. However, under the IOM formula, biological plausibility only comes into play if an association has already been found, and the corrupted standard requires that an association first be found based only on human studies.

This corrupted standard is now being used in IOM reports on the health effects of exposures to veterans of the recent wars in Iraq and Afghanistan. Following reports of illnesses among troops stationed downwind from burn pits where toxic waste was incinerated, VA ordered an IOM report on the long-term health consequences of exposure to burn pits. Stating that it was "[f]ollowing the methods and criteria used by other IOM committees that have prepared reports for the Gulf War and Health Series and the Veterans and Agent Orange Series,"[xxx] the IOM committee in 2011 applied the standard limiting consideration to human studies, and found limited or insufficient evidence of an association between the exposures and illness.

The corrupted standard, using only human studies, was also used in the IOM report on the Long-Term Effect of Blast Exposures released on February 13, 2014.[xxxi]

VA and IOM's failure to follow Public Laws 105-277 and 105-368 thus continues to impact veterans of recent conflicts as well as Gulf War veterans.

5. The bill would also declare it to be the sense of Congress that IOM Gulf War committees should include at least three members of the Research Advisory Committee (in view of the inappropriate memberships of recent IOM Gulf War committees), [xxxii] that VA notify Congress if any federal employee or contractor seeks to influence an IOM Gulf War report other than toward a scientifically objective outcome, and that VA consult with the Research Advisory Committee regarding the scope of work and charge for any future Institute of Medicine contract related to the health of Gulf War veterans.

6. The bill would also declare it to be the sense of Congress that VA should conduct an additional followup to its recent survey of Gulf War era veterans to ask the questions about their symptoms necessary to determine if they have Gulf War illness according to leading current case definitions.

The survey sent out in April 2012 asked two pages of questions on recent stressful events and worries, nine questions on alcohol use, and the seventeen questions necessary to define PTSD, but not the questions necessary to define Gulf War illness. The Committee repeatedly asked that the questions necessary to define Gulf War illness be included. Committee members pointed out that "[t]he draft . . . does not provide for assessment of Gulf War illness by any case definition. Using this instrument, the OPH survey cannot determine the prevalence, progression, or correlates of this illness. . . [I]t is unthinkable that the largest national study of Gulf War veterans would not provide the data required to evaluate the signature problem of the 1991 Gulf War."[xxxiii]

The former principal investigator of the survey, then a senior epidemiologist in the VA Office of Public Health, testified to a Congressional committee that his superiors lied to the VA Chief of Staff to get him to approve sending the survey out without the symptom questions."[xxxiv]

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[i] http://www.gpo.gov/fdsys/pkg/CRPT-105hrpt388/pdf/CRPT-105hrpt388.pdf, pp. 1-2
[ii] http://www1.va.gov/RAC-GWVI/Committee_Documents.asp
[iii] IOM, Gulf War and Health, Vol. 8 (2010), pp. x, 109, 204, 210, 260-262.

[iv] http://www1.va.gov/RAC-GWVI/2011annualreport.pdf
[v] http://www1.va.gov/RAC-GWVI/docs/Committee_Documents/CommitteeDocJune2012.pdf
[vi] https://veterans.house.gov/witness-testimony/dr-lea-steele-0
[vii] https://veterans.house.gov/witness-testimony/mr-anthony-hardie-0
[viii] http://www.scribd.com/doc/150957737/Riojas-Letter-to-RAC-Chair-05-16-2013; http://www.scribd.com/doc/150958154/LETTER-RAC-Chair-Binns-to-Riojas-Re-RAC-Charter-05-29-2013
[ix] http://www.wiley.com/WileyCDA/WileyTitle/productCd-3527609067.html
[x] http://www.memphis.edu/provost/pdfs/arnetz-cv.pdf
[xi] Freeman, R., Objective Evidence of Autonomic Disfunction and the Role of Stress in the Gulf War Syndrome, JAMA Neurol. 2013;70(2):158-159 (page 159)
[xii] http://www1.va.gov/RAC-GWVI/Committee_Documents.asp
[xiii] http://www.scribd.com/doc/210906186/RAC-Annual-Report-2013-Feb-26-2014
[xiv] http://www2.ed.gov/about/bdscomm/list/acsfa/edlite-index.html
[xv] http://www2.ed.gov/about/bdscomm/list/acsfa/authleg.pdf
[xvi] http://www.publichealth.va.gov/exposures/gulfwar/medically-unexplained-illness.asp
[xvii] IOM, Gulf War and Health, Vol. 8 (2010), p. 204
[xviii] http://books.nap.edu/openbook.php?record_id=18623&page=11
[xix] IOM, Gulf War and Health, Vol. 10, p. 21
[xx] Veterans Benefits Act of 2010, Sec. 805, http://library.clerk.house.gov/reference-files/PPL_111_275_VeteransBenefitsAct_2010.pdf
http://www7.nationalacademies.org/ocga/laws/PL111_275.asp
[xxi] http://www.scribd.com/doc/150949964/WHITE-PAPER-IOM-CMI-Panel-Membership-Analysis
[xxii] IOM, Gulf War and Health, Vol. 8 (2010), p. 109
[xxiii] http://www.ncbi.nlm.nih.gov/pubmed/22628389
[xxiv] 38 USC Sec. 1117, note Sec. 1603 (e)
[xxv] 38 USC Sec. 1118 (b)(1)(B)
[xxvi] IOM, Gulf War and Health, Volume I, p. 83
[xxvii] IOM, Veterans and Agent Orange: 1996 Update, p. 97
[xxviii] IOM, Gulf War and Health: Volume I, p. 83
[xxix] A full legal analysis of the failure of VA and IOM to follow this law can be found at http://archives.veterans.house.gov/hearings/Testimony.aspx?TID=2125&Newsid=2169&Name=%20James%20H.%20Binns
[xxx] IOM, Long-term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan (2011), p. 6. http://books.nap.edu/openbook.php?record_id=13209&page=6
[xxxi] IOM, Long-term Effects of Blast Exposures http://books.nap.edu/openbook.php?record_id=18253&page=22
[xxxii] http://www.scribd.com/doc/150949964/WHITE-PAPER-IOM-CMI-Panel-Membership-Analysis
[xxxiii] http://www1.va.gov/RAC-GWVI/docs/Committee_Documents/CommitteeDocJune2012.pdf, Appendix C
[xxxiv] http://veterans.house.gov/witness-testimony/dr-steven-s-coughlin

Exhibit B

The Committee's 2008 report and other Committee findings and recommendations have assessed federal Gulf War research programs pursuant to the Committee's chartered role to "assess the overall effectiveness of government research to answer central questions on the nature, causes, and treatments for health consequences of military service . . . during the 1990-1991 Gulf War." Because of the recent charter change to eliminate this responsibility, this subject will not be addressed in the 2009-2013 update report. The following document was prepared by Committee chairman James Binns as a draft section of the update report for the Committee to consider in the event the charter change was rescinded. Since the charter change was not rescinded, the section was removed from the draft report and from consideration by the Committee. However, it is based on previous findings and recommendations by the Committee.

Federal Research Programs that Address the Health of 1990-1991 Gulf War Veterans

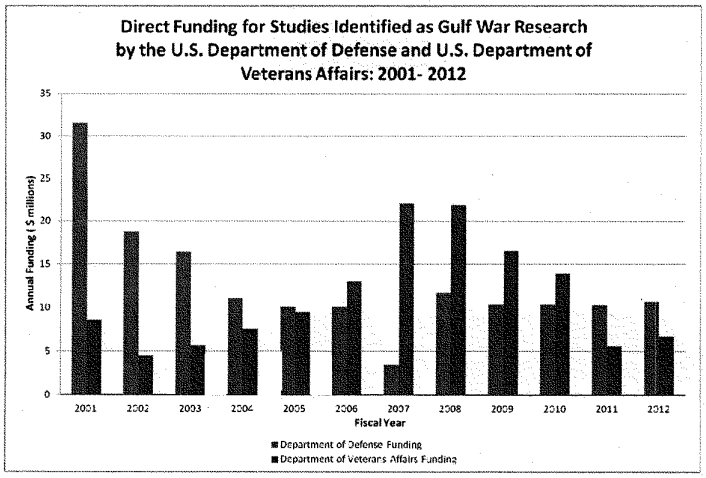
As evidenced throughout this report, important progress has been made in improving the understanding of Gulf War illness. Research is beginning to identify probable underlying mechanisms, promising treatments and biomarkers.

Highly qualified new investigators from prestigious institutions have entered the field, inspired by the 2010 Institute of Medicine committee's belief that "treatments, cures, and, it is hoped, preventions" can "likely" be found with the right research. [IOM 2010] Experienced Gulf War illness investigators "believe, based on recent progress, that these successes are possible, and within sight." [Lea Steele Testimony, 2013]

Regrettably, VA policy has recently reverted to positions similar to those established in the 1990's, when the government asserted that Gulf War veterans had no unusual health problems. Since no scientific support for these positions exists, misleading studies and reports have been generated to justify them. These studies and reports address topics fundamental to understanding Gulf War illness, including the number of ill veterans, whether the illness is psychiatric, whether it is "just what happens after every war," and the case definition of the illness to be used in future research. Unless halted, these actions will mislead the future course of Gulf War illness research, at VA and elsewhere, terminating progress just as science has finally turned the corner.

Federal Gulf War research since 2008 has been conducted by the Department of Veterans Affairs and the Department of Defense.

The following graph shows direct funding for studies identified as Gulf War research by the Department of Defense and the Department of Veterans Affairs from 2001 through 2012.



Gulf War Research at the Department of Defense Congressionally Directed Medical Research Programs

The Department of Defense provided the largest share of Gulf War research funding in the initial decade following the war. However, DoD funding declined from over $30 million in FY2001 to less than $4 million in FY2007 as funding of new projects stopped following the onset of new wars in Iraq and Afghanistan. [Deployment Health Working Group Research Subcommittee 2004, Deployment Health Working Group Research Subcommittee 2005, Deployment Health Working Group Research Subcommittee 2006 Deployment Health Working Group Research Subcommittee 2006 Deployment Health Working Group Research Subcommittee 2007, RAC Report 2004]

Recognizing the continued military importance of Gulf War illness research to current and future forces at risk of similar exposures, Congress appropriated $5 million for new DoD Gulf War illness research in FY2006, which was assigned to the Office of Congressionally Directed Medical Research Programs (CDMRP) of the US Army Medical Research and Materiel Command. Congressional language provided that the funds be used for research that provided insights into the biological mechanisms that underlie Gulf War illness and for studies to evaluate promising treatments and diagnostic biomarkers. [Harris, 1997, Kucinich, 2005]

The CDMRP program began by defining a mission, establishing priorities, and enlisting the input and guidance of experts in the subject and of Gulf War veterans. Ill veterans were placed on the panels that determine the kinds of research proposals the program solicits, and which proposals the program will fund. All proposals are evaluated for scientific merit, but final funding decisions are based on the relevance of the study to program priorities.

CDMRP funding is available on an openly competed, peer-reviewed basis to any investigator, public or private, government or academic. In contrast, VA research programs are only open to VA doctors, which limits the pool of potential researchers and study topics in a new and specialized field like Gulf War illness.

Interest in Gulf War illness in the scientific research community increased following the release of the RAC report in November 2008 and IOM report in April 2010. Congress maintained funding at the $8-10 million level from FY2009 through FY2012.

In 2011, CDMRP-funded researchers at the University of California, San Diego, reported on the first successful medication study in the history of Gulf War illness research. Preliminary results from a pilot study of the supplement CoQ10, one of the treatment studies funded in the first year of the program, showed significant improvement in one of the most serious Gulf War illness symptoms, fatigue with exertion, and positive improvement in all symptoms.

In 2012 and 2013, positive preliminary results were reported in two additional treatment pilot studies, as other studies funded in the early years of the program began to be completed. Georgetown University scientists reported that Gulf War veterans randomized to receive L-carnosine therapy showed a significant improvement in the digit symbol substitution cognitive task. The L-carnosine group also showed reduced irritable bowel syndrome-associated diarrhea [Baraniuk, 2013]. Researchers from Harvard Medical School and the New England School of Acupuncture found that Gulf War veterans reported a significant improvement in quality of life and pain on self-report measures after acupuncture treatment. A pilot study of the drug mifepristone proved largely unsuccessful.

From its founding in FY2006 through FY2012, the CDMRP program has funded 57 projects, including 18 treatment studies, 11 clinical studies in humans and 7 preclinical studies in animal models. [Lea Steele Testimony, 2013]. The remaining studies were studies of diagnostic biomarkers and studies of mechanisms underlying the illness to identify targets for treatments.

Nine studies have been awarded to investigators from the Department of Veterans Affairs.

The CDMRP program has also funded two multi-site "consortia," teams of researchers from different institutions who have developed coordinated Gulf War illness research projects, addressing the full spectrum of treatment identification, beginning with animal models. The consortia were also chosen through competitive proposals.

One hundred percent of these CDMRP projects directly relate to Gulf War illness.

In 2012, after the Department of Veterans Affairs reduced its own FY2013 budget for Gulf War research from $15 to $5 million, Congress voted to increase CDMRP GWI funding by $10 million to a total of $20 million, recognizing the success of the program and the need to maintain overall federal research levels. Due to the sequester process, the actual amount that ultimately reached CDMRP was about $15.6 million. The program committed the additional FY2013 funds to an innovative multicenter treatment solicitation.

Gulf War research at the Department of Veterans Affairs

From FY2007 through FY2009, Department of Veterans Affairs Gulf War research was largely conducted by the University of Texas Southwestern Medical Center (UTSW) in Dallas. Congressional legislation in 2006 directed VA to establish a Gulf War illness research center at UTSW, funded for five years at a $15 million annual level [Brown, 2006]. A memorandum of understanding to establish this "Gulf War Illness and Chemical Exposure Research Program" was agreed upon between VA and UTSW. [REFERENCE]

This Committee closely reviewed the UTSW program, holding at least one meeting each year in Dallas during this period. The Committee submitted findings and recommendations [cite to RAC recommendations regarding UTSW] as with other VA research programs, and was critical where appropriate, but appreciated the program leadership's willingness to engage in open dialogue and to make changes in response to Committee comments and recommendations. The Committee welcomed the program's unambiguous focus on Gulf War illness.

In recent years, UTSW has published numerous papers reflecting the work of the program. These studies have made significant contributions to the understanding of Gulf War illness, including the extent and type of autonomic nervous system injury [Haley 2013], the extent and site of brain injury and new magnetic resonance spectroscopy techniques to study brain injury, [Gopinath 2012; Li, 2011; Liu, 2011] and research on the prevalence of Gulf War illness [Iannacchione, 2011].

In August 2009, VA cancelled the balance of the UTSW contract, citing a VA inspector general's report. The report concluded that UTSW had "failed to comply with the terms of the contract related to data ownership and secrecy." However, the report also concluded that VA's "use of . . . contracting authority was inappropriate and . . . resulted in multiple problems with contract administration. . . Since VA management chose not to pursue grant authorization, they opted to misuse Federal government regulations and policy." [Office of the Inspector General, 2009]

The VA press release announcing the termination of the contract stated: "Research into the illnesses suffered by Gulf War Veterans remains a priority for VA. . . The decision not to continue the contract means VA's research program will be able to redirect funds to support additional research into GWVI." [VA Press Release 2009]

The following table shows research officially reported as Gulf War research to Congress by VA from FY2008 through FY2012. During this period, reported VA Gulf War research has declined from $21.6 million to $6.7 million.

Table 1. Reported VA Gulf War Illness Research Expenditures from 2008-2012

Focus of VA Gulf War Research Studies†	**2008 Funding*** (% of 2008 funds)	**2009 Funding*** (% of 2009 funds)	**2010 Funding*** (% of 2010 funds)	**2011 Funding*** (% of 2011 funds)	**2012 Funding*** (% of 2012 funds)
Gulf War Illness, Effect of Gulf War Exposures	$17,535,709** (81%)	$8,687,878** (56%)	$3,761,795** (27%)	$1,290,581 (23%)	$3,874,737 (58%)
Other health problems specific to Gulf War Veterans	$767,379 (3%)	$651,989 (4%)	$353,309 (3%)	$242,775 (4%)	$168,600 (2%)
General research on ALS in veterans of all eras	$2,494,074 (12%)	$5,664,976 (36%)	$2,954,873 (22%)	$1,862,572 (33%)	$618,840 (9%)
Other general research in veterans of all eras	$849,885 (4%)	$653,172 (4%)	$6,620,240 (48%)	$2,321,025 (40%)	$2,060,779 (31%)
Total VA Gulf War Research Funding, by Year	$21,647,047 (100%)	$ 15,658,015 (100%)	$13,690,217 (100%)	$ 5,716,953 (100%)	$6,722,956 (100%)

*Direct costs, as reported in Deployment Health Working Group Annual Report to Congress for each year

†Research focus of individual projects categorized by Research Advisory Committee on Gulf War Veterans' Illnesses

** Including $15,000,000 in 2008, $7,000,000 in 2009, and $2,300,000 in 2010 spent on the University of Texas Southwestern program

As the table shows, much of this research was focused on studies involving veterans of all eras rather than the particular health problems of Gulf War veterans, especially Gulf War illness.

Virtually all VA research regarding ALS has been reported as Gulf War research, although it relates to veterans of all eras. The reported "VA Gulf War Biorepository Trust," for example, funded at $5.7 million in FY2009, was an ALS brain bank with one Gulf War brain out of 61 as of 2010.

Many general VA research projects in veterans of all eras regarding multiple sclerosis, pain, gastrointestinal problems, and medical imaging have similarly been reported as Gulf War research. Examples include a $5.1 million grant toward the purchase of a 7-tesla MRI scanner for general imaging research, for which there was no pending Gulf War study, and a 2011 study of gastrointestinal pain in women who served in Iraq and Afghanistan during the past decade.

VA Gulf War research includes a mix of investigator-initiated studies, chosen through competitive review, and central office-initiated studies, where central office officials determine in advance the research subject and the individuals chosen to execute it. The central office-initiated studies are often the larger dollar projects, such as the ALS brain bank and MRI scanner noted above.

Achievements of VA Gulf War researchers during this period have included many of the studies cited in this report. A notable example was the 2010 publication by Dr. Han Kang and colleagues of a survey of 30,000 Gulf War era veterans, conducted in 2005, which found that 37% of deployed veterans have multisymptom illness (compared to a rate of 12% in non-deployed veterans of the same era), confirming smaller studies by earlier investigators regarding the excess rate of illness in Gulf War veterans. [J Occup Environ Med. 2009 Apr;51(4):401-10. doi: 10.1097/JOM.0b013e3181a2feeb.
Health of US veterans of 1991 Gulf War: a follow-up survey in 10 years. Kang HK, Li B, Mahan CM, Eisen SA, Engel CC.] The 2011 study of Continuous Positive Airway Pressure by Dr. Mohammad Amin, showing statistically significant improvement in some symptoms of Gulf War illness in veterans with GWI and sleep disordered breathing, was one of the first successful Gulf War illness treatment pilot studies. [Amin, 2011]

Additional VA Programs Relevant to Gulf War Research

Prior to the release of the 2008 RAC report, VA programs regarding care, benefits, and public information reflected 1990's government positions that Gulf War veterans had no serious health problem -- just "what happens after every war", due to stress or other psychological factors, affecting relatively few veterans.

As discussed in that report, VA's clinical training program taught doctors that "discussing chronic illness with a Gulf War veteran or a woman with a silicone breast implant is a different matter from discussing it with the average patient." [2008 report, p. 304] There was "no unique Gulf War syndrome."[2008 RAC report, p. 41-42.] "[M]ost have health problems similar to those experienced by veterans of other eras. . . [M]ost of the symptoms reported by veterans in VA registry examinations were found to be caused by conventional illnesses." [2008 RAC report, p. 304] The approval rate for benefits claims based on "undiagnosed illness" was 26% (compared to 87% for disability claims overall). [2008 RAC report, p. 306]

Following the release of the 2008 report, over the period from 2009-2011, VA significantly improved its programs toward bringing them in line with current research knowledge.

<u>2009-2011</u>

2010 Institute of Medicine report. The 2008 RAC report was released in November 2008. Before the new Administration took office in January, VA staff initiated a new IOM report to compare the findings of the IOM with the findings of the RAC report. The VA charged the IOM to update a 2006 IOM report

regarding scientific literature on the prevalence of cancer, neurodegenerative diseases, birth defects, and psychiatric conditions in Gulf War veterans. [reference VA charge described at http://www.iom.edu/Activities/Veterans/GulfWarHealth2009.aspx]

This limited review would have found nothing to substantiate the findings of the RAC report regarding Gulf War illness, since the review would not have addressed undiagnosed illnesses like GWI. The RAC report had described how previous IOM Gulf War reports had been "skewed and limited" by VA's direction. [2008 RAC report, p. 55] The new report would have been another example of VA shaping the conclusions of IOM reports by limiting the information considered.

However, the Research Advisory Committee alerted the Secretary's Office, and Secretary Eric Shinseki asked the IOM to invite the Research Advisory Committee to make a presentation to the IOM committee tasked with the report. In April 2009, three RAC committee members briefed the IOM committee on the scientific findings of the RAC report, as well as the history regarding VA's direction of IOM Gulf War reports. The IOM committee subsequently decided to disregard the limiting instructions of VA staff and conduct a fresh comprehensive review of the literature regarding Gulf War veterans' health. When its report was completed in April 2010, it largely reached the same conclusions as the 2008 RAC report, as described above.

Gulf War Task Force. VA Chief of Staff John Gingrich, who served as a battalion commander during the Gulf War and had witnessed members of his command become ill, established and chaired an internal VA "Gulf War Task Force" of representatives from all relevant VA offices. The task force prepared a report on needed changes in VA programs based on the findings of the RAC report. [reference: http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1858] Secretary Shinseki announced the release of the initial report of the task force in February 2010 as " the first step in a still-unfolding comprehensive plan of how VA will treat and compensate veterans of the Gulf War era." [cite to http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1858]

VA disability benefits in relation to Gulf War research. A training letter sent by the VA Compensation and Pension Service to all VA regional offices the same month provided new scientifically and legally accurate guidelines to use in determining if a Gulf War veteran who suffers from an "undiagnosed illness" qualifies for health coverage and other benefits. The letter also instructed the offices to re-evaluate past claims to apply the new standard.

The letter acknowledged the connection to environmental hazards in "undiagnosed illness" or "chronic multisymptom illness": "Because military personnel continue to operate in Southwest Asia and continue to be exposed to potential environmental hazards, including some not experienced during the initial 1990-1991 Gulf War, C&P Service has determined that an adjustment to the regulation is in order." [cite to http://www.ngwrc.org/docs/VAtl10-01.pdf]

Information on Gulf War research provided to VA clinicians. VA revised its training for doctors. The VA online training course, "Caring for Gulf War I Veterans," released in July 2011, acknowledged that Gulf War illness is not psychological: "What we do know is that chronic multisymptom illness is real and cannot be reliably ascribed to any known psychiatric disorder. Specifically, it cannot be ascribed to somatiform disorder, PTSD (Post-Traumatic Stress Disorder), or depression." [cite to http://www.publichealth.va.gov/docs/vhi/caring-for-gulf-war-veterans-vhi.pdf page 40]

Gulf War Research Strategic Plan. In mid-2011, the VA Office of Research and Development agreed to a proposal put forward by Dr. Maximillian Buja, chairman of its Gulf War Steering Committee (GWSC), to prepare a Gulf War strategic research plan using working groups of VA staff and outside advisors. (The GWSC was an entity ORD had established, made up of three RAC members and four

other outside advisors, including Dr. Buja, a former Dean of the University of Texas Health Science Center at Houston.) The RAC had frequently recommended that VA develop a strategic plan to guide its Gulf War research program.

The topics to be considered by the strategic plan were divided among ten working groups. The outside advisors named to the working groups included members of the RAC, members of the VA National Research Advisory Council (NRAC), and others. Ten members of the RAC and its associate scientific director volunteered to serve on the working groups, with five members serving on two working groups.

In addition to ORD personnel serving on the working groups, ORD provided staff support. The working groups met frequently during the fall of 2011 under the leadership of Dr. Buja. Working together, VA staff and RAC members were able to find common ground, and the other outside advisors provided fresh perspectives. The plan acknowledged the reality of Gulf War illness and VA's commitment to implement the 2010 IOM recommendation for "a renewed research effort with substantial commitment to well-organized efforts to better identify and treat multisymptom illness in Gulf War veterans. . . to alleviate their suffering as rapidly and completely as possible." [1]A new era of cooperation and productivity appeared to have arrived for VA Gulf War research. The bureaucratic resistance that had held up research progress for twenty years appeared to be removed.

The December 2011 annual report of the RAC stated: "It appears likely that for the first time VA will soon have a comprehensive strategic plan to provide the foundation for an effective Gulf War research program." [cite to http://www.va.gov/RAC-GWVI/2011annualreport.pdf]

The draft strategic plan, incorporating the inputs of the working groups, and of a leadership group that coordinated the inputs, was presented to a meeting of the RAC on January 31-February 1, 2012. Several NRAC members who had participated in the working groups were present. The discussion at the meeting was generally constructive and enthusiastic. As noted in the recommendations following the meeting, there was agreement between ORD and the RAC that the plan required the participation of other VA offices involved in research besides ORD, notably the Office of Public Health. [cite to http://www.va.gov/RAC-GWVI/docs/Committee_Documents/strategic_plan_recs.pdf]

2012-2013

This period of progress came to an end in early 2012, as VA policy reverted to positions similar to those established in the 1990's. Since no scientific support for these positions exists, misleading studies and reports have been initiated to justify them. These studies and reports address topics fundamental to understanding Gulf War illness, including the number of ill veterans, whether the illness is psychiatric, whether it is "just what happens after every war," and the case definition of the illness to be used in future research. Unless halted, these actions will mislead the future course of Gulf War illness research, at VA and elsewhere, terminating progress just as science has finally turned the corner.

National Survey of Gulf War Era Veterans. Once a decade, the VA Office of Public Health conducts a survey of 30,000 Gulf War and Gulf War era veterans, which is the basic data source on the health of this group. The survey sent out in April 2012 asks two pages of questions on recent stressful events and worries, nine questions on alcohol use, and the seventeen questions necessary to define PTSD, but not the questions necessary to define Gulf War illness.

The Research Advisory Committee repeatedly asked that the questions necessary to define Gulf War illness be included. Committee members pointed out that "[t]he draft . . . does not provide for assessment

of Gulf War illness by any case definition. Using this instrument, the OPH survey cannot determine the prevalence, progression, or correlates of this illness. . . [I]t is unthinkable that the largest national study of Gulf War veterans would not provide the data required to evaluate the signature problem of the 1991 Gulf War."[ii] They provided a suggested symptom inventory of less than two pages.

VA staff commented that no symptom inventory was included in the previous (2005) version of the survey, and that sound scientific practice required using the same questions from the 2005 survey so answers could be compared. In fact, however, the original 1995 version of the survey included a symptom inventory, which was dropped in 2005.

Committee members also pointed out that the 1995 survey "identified significantly excess rates of birth defects and adverse pregnancy outcomes in 1991 Gulf War veterans." However, "these problems were not followed up in the 2005 survey, and are not included in the current survey."

VA Chief of Staff John Gingrich approved the study after considering these comments and those of OPH staff. The principal investigator of the survey, a senior epidemiologist in the Office of Public Health, subsequently testified to a Congressional committee that his superiors intentionally misled Mr. Gingrich to get him to approve the study without the changes.

"They falsely stated that putting the study on hold long enough to revise the questionnaire would cost the Government $1,000,000, delay the study for a year or longer, and potentially result in contract default. None of this was true. But as a result, the Chief of Staff ordered the survey to proceed without the changes."[iii]

The Office of Public Health has subsequently advised the Committee that it is conducting a sub-study associated with the survey in which the medical records of veterans will be compared to their self-reported medical conditions.[iv] Since there is no diagnostic code for multisymptom illness, it is virtually certain that the medical records review will show substantially less than the self-reported amount.

Institute of Medicine treatment report launch. In February and April, two VA staff members and four other individuals reportedly suggested by VA staff, briefed a new IOM committee that Gulf War illness is, or may be, a psychiatric problem.

The new IOM committee was commissioned in response to Congressional legislation ordering VA to contract with the IOM for a study of the best treatments for Gulf War chronic multisymptom illness.[v] Knowing that there was virtually no scientific literature on treatments (because of the lack of treatment studies prior to the creation of the CDMRP program), Congress specified that the IOM convene a panel of medical practitioners with expertise in treating Gulf War veterans.[vi] Congress knew these doctors would have practical experience in trying different approaches and know what therapies had been helpful to their patients, although they might not have been formally studied.

VA ignored the law and contracted for a literature review by a committee with no Gulf War health experience.

The speakers who briefed the committee on the nature of chronic multisymptom illness[vii] were figures associated with government positions in the 1990's and early 2000's. Two spoke on "Chronic Stress and Its Role in Emotional, Somatic, and Cognitive Symptoms" and "Vulnerability, Stress Exposure and Depression." A third featured a slide on the ""Overlap Between Chronic Multisymptom Illnesses and Psychiatric Disorders." The director of the DoD Deployment Health Clinical Center highlighted "stress, PTSD, or somatization" as the likely causes of Gulf War Veterans Illnesses. A staff member from the

VA Center for Implementing Evidence-Based Practice, discussed the "SAD triad: somatization, anxiety, and depression."[viii]

The director of the VA Post-Deployment Integrated Care Initiative, speaking on "VA Approaches to the Management of Chronic Multi-Symptom Illness in Gulf War I Veterans," presented data from an eleven-year-old study showing that VA doctors do not know if Gulf War multisymptom illness is mostly a physical or mostly a mental disorder.[ix] As noted above, the current VA physician training guidelines state: "What we do know is that chronic multisymptom illness is real and cannot reliably be ascribed to any known psychiatric disorder."[x] The speaker did not mention the current guidelines, although he served on the committee that wrote them.[xi]

Given that the IOM's own comprehensive 2010 report had concluded that Gulf War illness "cannot be reliably ascribed to any known psychiatric disorder" (2010 IOM report, p. 109), the selection of these six individuals to provide scientific background for a committee with no experience in Gulf War illness was striking. A former senior VA epidemiologist subsequently testified to Congress that the chief scientist of the VA Office of Public Health identified the first five speakers that the IOM should invite.[xii] Only one invited speaker provided a view of the illness consistent with current scientific knowledge.

The membership of the treatment committee itself was also striking. The fifteen members included no one with the clinical experience that Congress had specified, four with special interests in somatic and psychosomatic medicine, one specialist in anxiety and traumatic stress, one expert in risk communication, and a professor of psychiatry.[xiii]

Rather than focus the committee, as Congress desired, on "chronic multisymptom illness or another health condition related to chemical and environmental exposures,"[xiv] VA instructed the committee to review "all published peer-reviewed literature concerning treatment of populations with a similar constellation of symptoms."[xv]

Given this broad assignment, the content of the briefings, and the makeup of the committee, it became clear that its review would focus on psychiatric literature, notwithstanding the unambiguous conclusion of the previous IOM report that the illness was not psychiatric.

Public information. VA public information materials were revised to reflect old positions. The 2012 annual report of the Office of Research and Development characterized VA's Gulf War research program as "investigating whether service in the Gulf War is linked to illnesses Gulf War veterans have experienced." Other VA research programs were described in the annual report in terms of solving veterans' health problems, not whether service-related problems exist.

The scientific literature, the Research Advisory Committee, and the Institute of Medicine had long ago concluded that service in the Gulf War is linked to veterans' illnesses. As stated by the IOM in 2010, "the committee concludes that there is sufficient evidence of association between deployment to [the] Gulf War and chronic multisymptom illness."[xvi]

The VA Office of Public Health website adopted the same inaccurate language to characterize the VA Gulf War research program.

Gulf War Research Strategic Plan. The plan developed over five months by working groups of VA staff and outside advisors was dramatically scaled back to reflect previous practices.

Two weeks following the RAC meeting at which the strategic research plan was reviewed, VA submitted to Congress its proposed budget for FY2013, cutting Gulf War illness research two-thirds compared to the FY2012 budget, from $15 to $4.9 million.[xvii] While actual expenditures in FY2012 were far below $15 million, as discussed above, VA staff had explained this shortfall as an inability to find good research to fund, and the intention of the strategic plan was to design an effective $15 million annual program. However, it became apparent that VA did not intend to fund this program.

Four months later VA revealed a revised version of the plan following unilateral changes by VA staff. The changes transformed the plan from a focused strategy to execute the IOM's 2010 call for "a renewed research effort . . . to better identify and treat multisymptom illness in Gulf War veterans" into a bland justification of VA's old policy of reporting research on various problems affecting veterans of all eras as Gulf War research. The changes further eliminated the urgency, commitment, and specificity built into the working group's draft. Except where the plan quoted from outside sources, any mention of "Gulf War illness," or other terminology suggesting an illness related particularly to the Gulf War, was removed.

June 2012 Research Advisory Committee findings and recommendations. At its first meeting following this sea change in VA policy, the Research Advisory Committee prepared a detailed review of the revisions to the strategic plan and the other actions described above. It noted the divergence of these actions from the policy of the Secretary and the intent of Congress. It observed, however, that "[t]hese actions repeat the pattern of the last twenty years, as has been documented in Congressional reports over this period. (See, for example, "Gulf War Veterans Illnesses: VA, DOD Continue To Resist Strong Evidence Linking Toxic Causes To Chronic Health Effects, Nov. 1997)"

"Given the current state of scientific knowledge, they are particularly stark today: the refusal to implement the recommendation of the Institute of Medicine, the policy of the Secretary, and the law; the misrepresentation of scientific knowledge regarding Gulf War veterans' health and of the effort being made to address it; the failure to acknowledge that the central health problem of this war even exists."

The Committee concluded that it had "no confidence in the ability or demonstrated intention of VA staff to formulate and execute an effective VA Gulf War illness research program." It acknowledged "the credible work conducted by many individual researchers, and the positive intentions of some staff members" but recommended that the actions outlined "be thoroughly investigated to identify the individuals responsible and that appropriate action be taken to remove them from positions of authority and influence over Gulf War illness research."[xviii]

Institute of Medicine treatment report outcome. The IOM Treatment committee presented its report in January 2013. As expected, its literature review found that "[o]nly three [treatment] studies were conducted in military or veteran populations."[xix] Given its assignment from VA and the background provided by the briefers, it proceeded to consider treatment literature for twelve other diseases, six of them psychiatric, including somatic-symptom disorder, depression, anxiety, PTSD, substance use and addictive disorders, and self-harm.

In its review of drug interventions, for example, the committee considered nine clinical studies. "Only one study involved [a] veteran population," it reported. "[I]t was the only study to use a nonpsychopharmacologic intervention. . . The other eight studies enrolled people from the general population, most of them female, who had somatoform disorder."[xx]

Overall, the report devotes forty-eight pages to psychotherapies in its discussion of treatments for chronic multisymptom illness. It counsels doctors treating Gulf war veterans: "[C]linicians should approach CMI with 'a person-centered model of care . . . that helps patients understand that the word psychosomatic is not pejorative.'" [xxi](p. 17)

It claims that the same problems happen after every war: "Throughout modern history, many soldiers returning from combat have experienced postcombat illnesses. . . that cannot now be attributed to any diagnosable pathophysiologic entity or disease."[xxii]

It characterizes such illnesses as psychosomatic: "Many soldiers who have postcombat illnesses have long-term unexplained symptoms that cannot now be attributed to any diagnosable pathophysiologic entity or disease; such symptoms are referred to as medically unexplained."[xxiii] "Among the many terms used in the literature to label . . . somatic presentations, . . . [current] descriptive terms [include] medically unexplained symptoms. . ."[xxiv]

This language sharply contrasts with the findings of the 2010 IOM report: "[S]tudies of somatoform disorder in Gulf War veterans … do not support the hypothesis that their medically explained symptoms results from this disorder."[xxv]

Indeed, wherever the treatment report purports to address actual Gulf War research, it is inaccurate. (The treatment committee did not review all Gulf War health literature as the 2010 IOM committee had done, only the handful of treatment studies.) It states, for example: "Research has identified no symptom clusters, or syndromes."[xxvi] In fact, the 2008 RAC Report includes a table of eight such studies covering five symptom clusters, and the text discussed many more.[xxvii]

Because VA's instruction to the committee ignored Congress's focus on "health condition[s] related to chemical and environmental exposures,"[xxviii] the committee considered no illnesses related to environmental exposures. It never mentions the 2010 IOM report observation that "it is likely that Gulf War illness results from an interplay of genetic and environmental factors."[xxix] Rather, it dismisses the idea: "The focus on toxicants may be attributed, at least in part, to 'a general fear of toxins spread as a result of modern industrial life.'" [xxx]

In summary, by contracting for a literature review by a committee without Gulf War expertise, misleading the committee to believe that the illness is or may be psychiatric, and directing the committee to consider a broad range of illnesses including psychiatric conditions, VA guided the treatment committee to produce a report that re-asserted all the former positions from the 1990's. The report bears no resemblance to Congress's intention in ordering it or to current scientific knowledge.

The statute requires that the findings of the report "be disseminated throughout the Department of Veterans Affairs."[xxxi]

Case definition of the illness. An entire section of the Gulf War research strategic plan was devoted to the need and process for developing a case definition for Gulf War multisymptom illness. One working group focused exclusively on this section, illustrating the importance of the subject.

The process customarily used in medical science to define an illness are: 1) the appointment of a consensus panel of experts in that illness and 2) a rigorous analysis to determine which possible definition elements best fit the accumulated research data. This process was accordingly recommended by the working group: "The case definition should be developed by a consensus panel of experts in the field,

utilizing analytic results from a comprehensive evaluation of available data resources."[xxxii]

Different case definitions have been used over the years, and the benefits of having a uniform case definition were discussed. However, the wrong case definition would misdirect future Gulf War health research, not only at VA, but throughout the scientific community.

The January 2013 IOM treatment report, for example, developed its own "working case definition": "the presence of a spectrum of chronic symptoms experienced for 6 months or longer in at least two of six categories – fatigue, mood and cognition, musculoskeletal, gastrointestinal, respiratory, and neurologic – that may overlap with but are not fully captured by known syndromes (such as IBS, CFS, and fibromyalgia) or other diagnoses." (p. 23)

The definition was not developed using research data and did not involve the consensus, or even the input, of experts in the field. It would expand the scope of the illness to include all populations and any unexplained condition involving two of the common symptom areas listed, divorcing the concept of chronic multisymptom illness from Gulf War service.

Note that this is a radical change. The term "chronic multisymptom illness" was originated by a CDC researcher to describe the disease of Gulf War veterans.[xxxiii] Note also that the treatment report ignored the definition provided by Congress, which linked the illness to Gulf War service.[xxxiv]

Absent the connection to Gulf War service, the definition encompasses most unexplained chronic health problems, whether physical or mental. By including all populations and many conditions, the chance of identifying an effective treatment that works on the underlying mechanism of Gulf War multisymptom illness would be reduced dramatically. Gulf War veterans and their doctors would be forever limited to addressing only the most general symptoms and coping skills.

In late 2012, VA assigned the development of a case definition for "chronic multisymptom illness as it pertains to the 1990-1991 Gulf War Veteran population" to the IOM. Contrary to usual good practice, VA's charge to the IOM called for a literature review, not a comprehensive data analysis. VA staff informed the Committee that the contract was in process in February 2013.[xxxv]

The Committee recommended that VA instead "sponsor a joint effort with the Gulf War Illness research program at CDMRP to establish an expert consensus and evidence-based case definition for Gulf War illness." The Committee "emphasize[d] 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 homogenous groups for research studies. While poorly understood illnesses are known to affect 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. 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."[xxxvi]

March 2013 Congressional testimony. Two members of the Research Advisory Committee provided testimony on the recent findings and recommendations of the Committee to a hearing of the House Veterans Affairs Committee Subcommittee on Oversight and Investigations on March 13, 2013. It was the ninth Congressional hearing where Committee members have testified.

VA's response. VA's response to the June 2012 and February 2013 recommendations of the Research Advisory Committee has been as follows.

VA did not add the questions necessary to identify Gulf War illness by any existing case definition to the national survey of Gulf War era veterans. The survey results will not be able to determine the prevalence, progression, or correlates of the illness, and are likely to underreport it. Initial results are expected in mid-2014.

VA did not modify the contract for the IOM treatment report to conform to Congress's intent. The report has been completed. Although the IOM committee did not review any Gulf War scientific literature beyond the three treatment studies, the report reasserts government positions from the 1990's that the health problems of Gulf War veterans are no different from what happens after every war, that they are due to psychiatric/psychosomatic factors, and that there is no evidence of a common pattern in their symptoms. The report puts the weight of the IOM behind these findings, although they bear no resemblance to current scientific knowledge. The statute requires that the findings of the report "be disseminated throughout the Department of Veterans Affairs."[xxxvii]

VA re-set its budgeted Gulf War research spending in FY2014 to $15 million and has made a number of edits to its website and to the Gulf War strategic plan. However, VA has historically not spent the amount budgeted, and the amount spent has included significant numbers of studies not actually directed at Gulf War veterans.

The VA Gulf War website remains titled "Gulf War Veterans' Medically Unexplained Illnesses".[xxxviii] The strategic plan similarly continues to employ terminology that does not acknowledge that Gulf War veterans have any special health problem. The term "chronic multisymptom illness" has been expanded from a term to describe the multisymptom condition of Gulf War veterans to any illness with multiple symptoms, from irritable bowel syndrome to fibromyalgia. While there are similarities among these conditions, research has found important differences, too,[xxxix] and the key to understanding them lies in segregating them in research studies, while lumping them together eliminates that possibility.

VA proceeded to conclude the contract for the development of a case definition with the IOM through a literature review by a committee with little expertise in the illness, although this is contrary to usual scientific practice. The IOM has never done a case definition of an illness before.[xl]

Similar to the treatment report, VA's direction to the IOM requires it to consider "published peer-reviewed literature concerning case definitions for other populations with a similar constellation of symptoms."

Also similar to the treatment report, the members appointed to the committee reflect a heavy representation of psychiatric views. The group initially chosen had only three individuals out of fourteen with Gulf War illness research or clinical experience. Two of those three have published papers expressing the view that psychological fear of toxic exposures causes veterans' illnesses. Others include a past president of the Academy of Psychosomatic Medicine, a psychologist who favors a mental health approach to treating multisymptom conditions, and a specialist in the health consequences of psychosocial stress. The members also include three who have previously served on IOM committees that found no connection between toxic exposures and illness, including one member of the 2013 treatment committee.[xli]

The IOM invited members of the Research Advisory Committee and several Gulf War veterans to address the case definition panel in the open session of the case definition committee's first meeting on June 26, 2013.[xlii] Several expressed concern that the IOM committee was not qualified to establish a Gulf War illness case definition. The IOM subsequently appointed three new members to the committee. One has experience conducting Gulf War health research, but two of the three are specialists in psychometrics and psychiatry biostatistics, respectively, with no Gulf War health experience.[xliii]

The working case definition developed by the treatment committee was discussed in a closed session at the first meeting of the case definition committee.[xliv] A case definition similar to the working definition would determine that future Gulf War illness research would be conducted in a vague, unbounded universe of "chronic multisymptom illness" of whatever origin, losing any chance to identify underlying mechanisms, specific diagnostic tests, and effective treatments. The case definition committee's report is expected in the Spring of 2014.

Military Medicine editorial. The predictable outcome of the studies and reports described above will be a further shift of VA policy toward 1990's positions. VA has already begun to signal where it is headed. In July 2013, the chief scientist of the VA Office of Public Health, joined by the heads of the three VA War Related Illness and Injury Study Centers, published an editorial in the journal Military Medicine on the "Care of Veterans With Chronic Multisymtom Illness."[xlv]

The editorial begins by stating that "CMI has been documented after armed conflicts since the Civil War and unfortunately has surfaced again as Veterans return from the theaters of operation in Afghanistan and Iraq." The Gulf War is not even mentioned.

The authors assume that the problem is at least partly psychiatric. A "biopsychosocial approach to the illness . . . will most benefit the patient." An advantage of clinical team care is that "someone will ask a question about the 'other' factors affecting the patient." "Since the psychosocial issues often form barriers to effective management, being aware of them helps the team resolve problems."

Eliminating oversight. VA's most significant response to the Research Advisory Committee's findings and recommendations was to change the charter of the Committee to eliminate its oversight function over VA and other government research.

In May 2013, VA changed the Committee's charter to eliminate its authority "to assess the overall effectiveness of government research to answer central questions on the nature, causes, and treatments for the health consequences of military service . . . during the 1990-1991 Gulf War."

The principle "that the fundamental goal of Gulf War health-related government research . . . is to ultimately improve the health of ill Gulf War veterans, and that the choice and success of research efforts shall be judged accordingly" was also eliminated.

VA further eliminated the charter provisions granting the Committee its own staff. While not implemented as yet, this change means that the Committee will in the future be staffed by the same VA personnel whose programs it formerly reviewed.

VA also announced that half the membership of the Committee would be replaced immediately, and the remaining half in one year. VA stated that the changes were being made because the Committee had been operating outside its research oversight role, but the changes made eliminated its research oversight role, and no example of the Committee acting outside that role was provided.[xlvi]

These provisions have been included in all previous charters of the Committee since its formation in 2002. Indeed, the oversight function was the primary reason why Congress created the Committee. Congress had no confidence in the commitment of the executive branch to address the health problems of Gulf War veterans. The Congressional report which led to the law establishing the Committee, "Gulf War Veterans Illnesses: VA, DOD Continue To Resist Strong Evidence Linking Toxic Causes To Chronic Health Effects," stated its position clearly:

> "After 19 months of investigation, the subcommittee finds the status of efforts on Gulf War issues by the Department of Veterans Affairs, the Department of Defense, the Central Intelligence Agency, and the Food and Drug Administration to be irreparably flawed. . . [W]e find current approaches to research, diagnosis and treatment unlikely to yield answers to veterans' life-or-death questions in the foreseeable, or even far distant, future."

For twelve years, this Committee has exercised the responsibilities assigned to it by Congress and by four VA Secretaries. Long restricted by bureaucratic agendas, science is finally making progress. The prospect of finding answers to the diagnosis and treatment of Gulf War illness is now likely, provided good research continues. It is time to applaud and support the scientists working to improve the health of Gulf War veterans and to protect the health of current and future American servicemen and women at risk of similar exposures. It is unconscionable that the greatest obstacle these scientists face is the renewed effort of government staff to shape research to mask the problem rather than to solve it. Until this subject is addressed, once and for all, the need for an independent research advisory committee will continue, and progress will be far slower than it should, and could, be.

Recommendations:

The Committee commends the effective Gulf War illness research program that has been created at the Department of Defense Congressionally Directed Medical Research Program and recommends that Congress authorize and appropriate $20 million annually for five years to support openly-competed, peer-reviewed studies focused on identifying:

1) effective treatments for Gulf War illness,
2) objective measures that distinguish ill from healthy veterans, and
3) underlying biological mechanisms potentially amenable to treatment.

The Committee reiterates the findings and recommendations previously expressed regarding the Department of Veterans Affairs Gulf War research program in June 2012[xlvii], February 2013[xlviii], and June 2013[xlix].

The Committee recommends that the relationship between the Department of Veterans Affairs and the Institute of Medicine regarding Gulf War health research be investigated and reformed, including:

1) Reviewing the informal and formal input of VA and DoD staff into IOM report processes and content;

2) Reviewing the process for selecting IOM committee members and background speakers;

3) Re-conducting those IOM Gulf War and Health reports not conducted in accordance with the statutes mandating the reports, including:

a) The report on the best treatments for chronic multisymptom illness in Gulf War veterans required by Public Law 111-275, Section 805, which was not conducted in accordance with the provision of the statute requiring that the committee preparing the report be comprised of "medical professionals who are experienced in treating [Gulf War veterans] who have beem diagnosed with chronic multisymptom illness or another health condition related to

chemical and environmental exposures that may have occurred during such service." (Gulf War and Health, Treatment for Chronic Multisymptom Illness, 2013);

b) The report on the prevalence of "multiple sclerosis, Parkinson's disease, and brain cancers, as well as central nervous system abnormalities that are difficult to precisely diagnose" in Gulf War and recent Iraq/Afghanistan war veterans, required by Public Law 110-389, Section 804, which has never been conducted;[i] and

c) The reports on the health effects of thirty-three "toxic agents, environmental or wartime hazards, or preventive medicines or vaccines associated with Gulf War service" required by Public Law 105-277 and Public Law 105-368, which were not conducted in accordance with the provisions of the statutes requiring that studies in animals, as well as humans, be considered in determining whether a statistical association exists between exposure to a substance and illness (Gulf War and Health Vol. 1 (2000), Vol. 2 (2003), Vol. 3 (2005), Updated Literature Review of Sarin (2004); Updated Literature Review of Depleted Uranium (2008)).[ii]

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[i] 2010 IOM report, pp. 260-261

[ii] See Appendix C.

[iii] Cite to Coughlin testimony,

[iv] Presentation of Dr. Victoria Davey, June 18, 2013, http://www.va.gov/RAC-GWVI/June2013MeetingMinutesFinal_NoSig.pdf

[v] Veterans Benefits Act of 2010, Sec. 805(a)
http://www7.nationalacademies.org/ocga/laws/PL111_275.asp

[vi] Veterans Benefits Act of 2010, Sec. 805(b)

[vii] Four other speakers addressed different topics such as complementary/alternative medicine and information technology.
http://iom.edu/~/media/Files/Activity%20Files/Veterans/GulfWarCMITreatment/Meeitng%202%20Agenda/public%20agenda.pdf
[viii] See presentations of Drs. Dusek, Kendler, Clauw, Engel, and Kroenke at http://iom.edu/Activities/Veterans/GulfWarMultisymptom/2012-FEB-29.aspx
[ix] See presentation of Dr. Hunt, http://iom.edu/Activities/Veterans/GulfWarMultisymptom/2012-APR-12.aspx
[x] http://www.publichealth.va.gov/docs/vhi/caring-for-gulf-war-veterans-vhi.pdf, p. 40
[xi] Ibid, p. iii
[xii] http://veterans.house.gov/witness-testimony/dr-steven-s-coughlin
[xiii] http://www.scribd.com/doc/150949964/WHITE-PAPER-IOM-CMI-Panel-Membership-Analysis
[xiv] Veterans Benefits Act of 2010, Sec. 805(b)
[xv] IOM treatment report p. 14
[xvi] 2010 IOM report, p. 210

[xvii] [cite to http://www.va.gov/budget/docs/summary/Fy2013_Volume_II-Medical_Programs_Information_Technology.pdf page 3A-5]
[xviii] http://www.va.gov/RAC-GWVI/docs/Committee_Documents/CommitteeDocJune2012.pdf
[xix] Treatment report, p.86
[xx] Ibid, p. 32
[xxi] Treatment report, p. 17
[xxiixxii] Ibid, p. 11
[xxiii] Ibid, p. 11
[xxiv] Ibid, p. 100
[xxv] 2010 IOM report, p. 109
[xxvi] Ibid, p. 15
[xxvii] 2008 RAC report, p. 28.

[xxviii] Veterans Benefits Act of 2010, Section 805(b), see footnote 2.

[xxix] 2008 RAC report, p. 261.

[xxx] Treatment report, p. 13
[xxxi] Veterans Benefits Act of 2010, Sec. 805(a)
[xxxii] Gulf War Research Strategic Plan, January 23, 2012 draft, Sec. 5.3.1
[xxxiii] IOM treatment report, p. 21

[xxxiv] Veterans Benefits Act of 2010, Section 805(e)(1)
[xxxv] Minutes, meeting of the Research Advisory Committee, February 4, 2013, http://www.va.gov/RAC-GWVI/FebMeetingMinutes.pdf
[xxxvi] Recommendation Regarding Gulf War Illness Case Definition, adopted February 4, 2013, http://www.va.gov/RAC-GWVI/CommitteeRecommendation.pdf
[xxxvii] Veterans Benefits Act of 2010, Sec. 805(a)
[xxxviii] http://www.publichealth.va.gov/exposures/gulfwar/medically-unexplained-illness.asp

[xxxix] 2008 RAC report, pp. 280-288
[xl] http://www.forbes.com/sites/rebeccaruiz/2013/06/28/inside-the-effort-to-define-gulf-war-illness/
[xli] http://www.scribd.com/doc/150949964/WHITE-PAPER-IOM-CMI-Panel-Membership-Analysis
[xlii] http://www8.nationalacademies.org/cp/meetingview.aspx?MeetingID=6711&MeetingNo=1
[xliii] Biographies of Drs. Cook and Leoutsakos, http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49546
[xliv] http://www8.nationalacademies.org/cp/meetingview.aspx?MeetingID=6711&MeetingNo=1 (click on "Closed Session Summary")
[xlv] http://www.warrelatedillness.va.gov/WARRELATEDILLNESS/research/articles/2013-LangeG-wriisc-multidisciplinary-care-of-veterans-with-cmi.pdf
[xlvi] Statement of Chief of Staff Jose Riojas, June 17, 2013, http://www.va.gov/RAC-GWVI/June2013MeetingMinutesFinal_NoSig.pdf, p. 10
[xlvii] http://www.va.gov/RAC-GWVI/docs/Committee_Documents/CommitteeDocJune2012.pdf
[xlviii] http://www.va.gov/RAC-GWVI/CommitteeRecommendation.pdf
[xlix] http://www.va.gov/RAC-GWVI/RACrecsJune2013_7_30.pdf
[l] Public Law 110-389, Section 804; www.va.gov/RAC-GWVI/docs/Committee_Documents/CommitteeDocJune2012.pdf, Appendix E
[li] James H. Binns, testimony, U.S. House of Representatives, Committee on Veterans Affairs, Subcommittee on Oversight and Investigations, July 30, 2009, http://archives.veterans.house.gov/hearings/Testimony.aspx?TID=2125&Newsid=2169&Name=%20James%20H.%20Binns

STATEMENT OF
DAVY LEGHORN, ASSISTANT DIRECTOR OF THE VETERAN EDUCATION AND EMPLOYMENT COMMISSION OF THE AMERICAN LEGION
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES
ON
PENDING LEGISLATION

MARCH 25, 2014

Chairman Coffman, Ranking Member Kirkpatrick and distinguished Members of the Subcommittee, on behalf of Commander Dellinger and the 2.4 million members of The American Legion, I thank you and your colleagues for the work you do in support of our service members and veterans as well as their families. The hard work of this Subcommittee in creating significant legislation has left a positive impact on our military and veterans' community.

Bio Implant Draft Legislation

To amend title 38, United States Code, to direct the Secretary of Veterans Affairs to develop or acquire a standard identification protocol for use in the procurement of biological implants by the Department of Veterans Affairs, and for other purposes.

In testimony before this subcommittee The American Legion previously raised concerns about the lack of a robust tracking system in the Veterans Health Administration (VHA). The Department of Veterans Affairs (VA) Office of the Inspector General (OIG) conducted an audit in 2012 and made recommendations regarding VA's management of their prosthetics supply inventory[1]. In VHA's response, they indicated that they would work to develop a plan to replace the Prosthetic Inventory Package (PIP) and the Generic Inventory Package (GIP) with a more comprehensive system. The target completion date is March 30, 2015. In the interim, VHA indicated they were working on a VA OI&T patch (VistA Prosthetics patch 101) which was 95 percent completed.

While reaching this goal by 2015 is indeed laudable, 2015 is rapidly becoming a critical year for VA to meet strategic goals including the elimination of veteran homelessness and the disability claims backlog, The American Legion would like to see a more detailed timeline implementing these changes and improvements for veterans. Reports through System Worth Saving Task Force visits and contact with VHA employees indicate responsibility for entering serial numbers of implant devices is manual, not automated, and is inconsistently implemented.

Although VHA claims to work to a standard of "removing recalled products from inventory within 24 hours of a recall", there is still no clear policy on how veterans who have already

[1] VAOIG Report 11-00312-127 "Audit of Prosthetics Supply Inventory Management

received implants are tracked. It is not enough to cut off the problem at the source, attention must be paid to veterans who are already downstream in the process. Without consistent tracking of implants, including positive identification by serial number and other identifying factors, uncertainty remains as to how veterans are served in the case of recalls. The American Legion noted we would like to see a more comprehensive procedure and policy clearly delineated by Central Office to ensure consistency in all Veterans Integrated Service Networks (VISNs)[2].

The analysis of the current inadequacy of the tracking system for bio-implants derives directly from The American Legion's System Worth Saving Task Force reports. The System Worth Saving Task Force was established to examine the State of VA Medical Facilities by resolution in 2004[3]. This annual report, provided to members of Congress and the veterans' community is a vital resource as the primary third party analysis of the quality of VA facilities.

The American Legion supports the passage of this legislation.

Gulf War Health Research Reform Act of 2014

To improve the research of Gulf War Illness, the Research Advisory Committee on Gulf War Veterans' Illnesses, and for other purposes.

The American Legion has long encouraged the Department of Veterans Affairs (VA) to devote appropriate resources towards finding effective medical treatments for the unexplained physical symptoms of Gulf War veterans[4]. Part of appropriate resources requires robust scientific research, and The American Legion has supported the implementation of reasonable recommendations in reports of the Institute of Medicine (IOM), as well as the Research Advisory Committee (RAC) on Gulf War Illnesses.

The recent, highly publicized struggles between VA officials and RAC members over the past year have been cause for concern. A healthy, working relationship between all parties, and the free exchange of scientifically valid information, is vital to a better understanding of the health issues resultant from deployment in the Gulf War theater of operations over the past two decades.

While this legislation aims to address some of the issues between VA officials and the RAC that led to the discord last year, The American Legion still has two primary concerns as to whether this is the appropriate vehicle to resolve the issue. It is unclear from the legislation whether this bill would actually resolve the differences between the scientists and the VA officials, and it is unclear whether it serves the ultimate goal of focus on veteran health. Because of these outstanding questions, The American Legion feels this bill falls outside the scope of what can be supported by existing resolutions.

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[2] Testimony of Roscoe Butler before the HVAC Subcommittee on Oversight and Investigation – JAN 15, 2015
[3] Resolution 206 "Annual State of VA Medical Facilities Report" AUG 2004
[4] Resolution 104 "Gulf War Illness" AUG 2012

Solving the impasse between the RAC and VA is a complex issue, with many moving pieces that will require careful deliberation by the Commissions of The American Legion to determine which course of action best suits the needs of veterans. As this will require a specific resolution targeting a solution, The American Legion cannot support the bill at this time.

The American Legion cannot support the passage of this legislation at this time.

Psychotropic Medication Draft Legislation

To amend title 38, United States Code, to provide for special rules relating to the informed consent of veterans who are prescribed psychotropic medication by health care professionals employed by the Department of Veterans Affairs.

This legislation aims to address deficiencies in the current consent regulations for prescription drugs for veterans. The American Legion has focused close scrutiny on the struggles of veterans returning from the wars in Afghanistan and Iraq as they cope with psychological disorders such as Posttraumatic Stress Disorder (PTSD). As a result The American Legion established the TBI and PTSD Committee in 2010 comprised of American Legion Past National Commanders, Commission Chairmen, respected academic figures, and national American Legion staff. The committee is focused on investigating existing science and procedures as well as alternative methods for treating TBI and PTSD that are not being employed by the Department of Defense (DOD) and VA for the purpose of determining if such alternative treatments are practical and efficacious.

During a three year study the committee met with leading authorities in the DOD, VA, academia, veterans, private sector mental health experts, and caregivers about treatments and therapies veterans have received or are currently receiving for their TBI and PTSD symptoms. As a result of the study, the committee released their findings and recommendations in a report titled *"The War Within*[5]*." "The War Within"* report highlights these treatments and therapies and also identifies findings and recommendations to the DOD and VA.

The War Within recognized problems with over-reliance on prescription medication and exhorted VA and the DOD to examine alternative therapies either in addition to or in lieu of some of the more traditional therapies.

The scope of this bill and its attention to prescription drugs however, is outside the scope of the resolutions of The American Legion, or the findings of the report. The American Legion *does* endorse the examination of alternative therapies to psychological disorders, but does not have a specific position on this piece of legislation.

The American Legion has no position on this legislation.

[5] http://legion.org/documents/legion/pdf/american-legion-war-within.pdf

Small Business Draft Legislation

To amend title 38, United States Code, to improve the oversight of contracts awarded by the Secretary of Veterans Affairs to small business concerns owned and controlled by veterans.

At its Fall 2013 meeting, The American Legion's National Executive Committee passed Resolution 73: *Support Verification Improvements for Veterans' Business Within the Department of Veterans Affairs and the Department of Defense*, which endorses legislative efforts to ensure that contracts awarded pursuant to the Veterans First Program are awarded to companies that truly are entitled to receive these set-asides. The American Legion has long been an advocate and strong supporter of a robust veteran and service disabled business owner contracting program. Businesses that prey on veterans by using their preferred contracting status pervert the system and rob opportunities from healthy veteran businesses that are prepared to perform a majority of the actual contract work. Companies that act as pass-thrus degrade the integrity and undermine the veteran contracting program. While The American Legion has not found this to be an alarming problem, we are saddened when we hear of even one situation where the preferred status of a Service Disabled Veteran Owned Company has been purchased by a no qualifying company for the purpose of securing contracts that have been specifically set aside for veterans. We believe that veterans would benefit from an added reminder of their responsibilities when it comes to accepting a contract that has been designated as a Service Disabled Veteran, or Veteran Owned Small Business Contract, and would like to continue to work with this committee to serve and protect the veteran business community.

The American Legion supports the passage of this legislation.

Information Technology Security Draft Legislation

To improve the information security of the Department of Veterans Affairs by establishing an integrated information security program, and for other purposes.

The American Legion is a grassroots organization that derives its operational mandate from resolutions passed by the membership in regular meetings. There are no resolutions that specifically address the content of this legislation.

The American Legion has no position on this legislation.

H.R. 3593: The VA Construction Assistance Act of 2013

To amend title 38, United States Code, to improve the construction of major medical facilities, and for other purposes.

When American Legion National Commander Dellinger testified before a joint session of Congress on September 10th 2013, Congressman Coffman referred to the Commander's construction background and asked Commander Dellinger if he would please offer his comments, based on his personal experience in the construction industry, about construction challenges that VA was facing in Colorado and other areas. Commander Dellinger responded,

"Maybe the VA should get out of the construction business, and do what they do best – take care of our veterans."

Since September, American Legion leaders and staff have been researching and reviewing possible policy changes regarding VA's major construction and leasing programs, and will be presenting our findings and recommendations to our voting members during our upcoming meeting in March 2014. It will be at this meeting that The American Legion will decide whether or not to develop and pass a resolution regarding the VA construction program.

As part of our research and investigation, The American Legion met with senior officials from the Army Corps of Engineers, The VA Office of Acquisition, Logistics & Construction (OALC), and the VA Office of Construction and Facilities Management to assess the viability of diversifying VA's construction management responsibilities.

During our evaluation, we found that The Army Corps of Engineers:

- Is adequately suited to undertake the long-term mission of managing VA's construction portfolio
- Has a track record that is equal to or better than the federal industry standard regarding on-time, on-budget construction projects
- Would report directly to VA and not replace OALC
- Has worked on VA construction projects in the past
- Routinely builds hospitals for the Department of Defense

The Corps is not without its criticisms, however most of the criticisms suffered by the Army Corps of Engineers involve their Civil Construction arm and the amount of money Congress has dedicated to disaster relief, beach erosion and other civil engineering projects, not their construction projects. One note regarding this organization is that, there is more transparency and ready access to information regarding overhead expenses and actual costs than with private firms as the Government Accountability Office has an entire collection of assessments and evaluations of the Army Corps of Engineers ready for public review. Information about Army Corps can also be found at the Congressional Budget Office, the Congressional Research Service, as well as other federal research activities and offices.

It is also important to note that inserting the Army Corps of Engineers into the VA construction program would not reduce VA's authority or oversight in any way, as VA would always maintain the role of "customer" in any future relationship. Another advantage is the advocacy role that Army Corps assumes on behalf of VA. In the event of cost overruns not covered by the reserve fund, Army Corps takes on the responsibility of representing VA before Congress to request additional appropriated funds needed to complete the project.

The failures in Florida, Louisiana, Colorado and Nevada with major construction projects have made it clear that VA needs help. The Army Corps of Engineers has a proven track record of managing projects of this nature. This legislation would provide a helpful bridge. Efforts to exhort the VA to pursue this path on their own have not proven successful. The Congress needs to act, and pass this legislation to help get the VA construction program back on track.

STATEMENT OF FRANK WILTON
CHIEF EXECUTIVE OFFICER
AMERICAN ASSOCIATION OF TISSUE BANKS
MCLEAN, VA

FOR PRESENTATION BEFORE THE
HOUSE COMMITTEE ON VETERANS' AFFAIRS
LEGISLATIVE HEARING
MARCH 25, 2014

Chairman Coffman, Ranking Member Kirkpatrick, Distinguished Members of the House Committee on Veterans' Affairs Subcommittee on Oversight and Investigations:

Thank you for the opportunity to come before you today in support of the "Biological Implant Tracking and Veteran Safety Act of 2014." This critical legislation directs the Secretary of Veterans Affairs to adopt a standard identification protocol for use in the procurement of biological implants by the Department of Veterans Affairs. By building upon the past success of the implementation of the Unique Device Identifier or UDI, this legislation will ensure that biological implants used within the Department can be appropriately tracked from the donor of the human tissue all the way to the recipient. This critical capability for "track and trace" efforts will enhance patient safety, expedite product recalls when necessary, and assist with inventory management.

This legislation takes a bold step to expand the application of the concept of the UDI to all tissue products, including those tissue-devices (which are already covered by the UDI), as well as another product category: certain biological implants or, as termed by the Food and Drug Administration (FDA), 361 human cells, tissues, and cellular and tissue-based products or HCT/Ps. While many of the biological implants do have company specific bar coding information, by requiring a standardized format for those bar codes, as outlined in this legislation, it is easier for the Department of Veterans Affairs medical facilities to utilize universal bar coding conventions and to realize the full benefit of a unique identification system. Finally, by applying a system which has been developed for devices to biological implants, such a solution should also be applicable to other health care settings and other health care systems (such as the Department of Defense health care system or the private sector).

As the Secretary of Veterans Affairs opts to adopt the standard identification protocol for tissues (both devices and non-devices), I urge you to ensure that the Secretary provide a menu of options for such adoption. Under the UDI final rule, FDA has done just that be providing for multiple entities called issuing agencies. At this time, FDA has provided for three different issuing agencies: (1) GS1, (2) Health Industry Business Communications Council (HIBCC), and (3) ICCBBA. I hope that this flexibility is maintained within the Department of Veterans Affairs. However, given that the bill language already suggests that the unique identification system is comparable to what the UDI provides, we believe the intent to provide that flexibility is inherent in the legislation.

For those of you unfamiliar with my organization, the American Association of Tissue Banks (AATB) is a professional, non-profit, scientific and educational organization. It is the only national tissue banking organization in the United States, and its membership totals **more than 125 accredited tissue banks and approximately 850 individual members**. These banks recover tissue from more than **30,000 donors** and distribute in excess of **two million allografts for more than one million tissue transplants performed annually in the U.S**. The vast majority of tissue banks that process tissue maintain AATB accreditation,

and the AATB estimates that only 5-10% of the allografts distributed are from tissue donors who were not determined to be suitable by the medical director of an AATB-accredited tissue bank. The AATB does not have a similar estimation for tissue distributed by tissue distribution intermediaries.

The Association was founded in 1976 by a group of doctors and scientists who had started in 1949 our nation's first tissue bank, the United States Navy Tissue Bank. Recognizing the increasing use of human tissue for transplant, these individuals saw the need for a national organization to develop standards, promote ethics and increase donations.

Since its beginning, the AATB has been dedicated to improving and saving lives by promoting the safety, quality and availability of donated human tissue. To fulfill that mission, the **AATB publishes standards and guidance documents, accredits tissue banks, and** certifies personnel. The Association also interacts with regulatory agencies and health authorities, and conducts educational meetings.

First published in 1984 and presently in its 13th edition, the AATB's *Standards for Tissue Banking* are recognized in both the United States and around the world as the **definitive guide for tissue banking**. These Standards are the only private tissue-banking standards published in the United States, and they are the most comprehensive and detailed tissue-banking standards in the world. As such, the **AATB's Standards have served as the model for federal and state regulations as well as several international directives and standards.** Currently, the statutes and/or regulations of 19 states (i.e., California, Connecticut, District of Columbia, Florida, Georgia, Idaho, Illinois, Kentucky, Maryland, Montana, New Jersey, North Carolina, Ohio, Oklahoma, Pennsylvania, Texas, Utah, Virginia, and Wisconsin) reference AATB's Standards, institutional accreditation, or individual certification. And, these Standards are the basis of our accreditation process.

Human tissue is used in a wide variety of medical procedures in the VHA facilities, ranging from wound care management to hernia repair to orthopedic procedures, among many others. Human tissue is also used in a wide array of dental services, such as bone augmentation and gum tissue grafting procedures. In fact, according to a report for this committee, biologics accounted for approximately $75 million in VHA acquisitions in fiscal year 2013. Recently, human tissue "track and trace" concerns have been raised with the VHA, both at the agency and Congressional level. A recent report by the Government Accountability Office (GAO), prepared for this Committee, noted that one Veterans Affairs Medical Center (VAMC) had a high percentage of purchases missing serial numbers or lot numbers (16 percent in the first three quarters of fiscal year 2013).[1] I'm hopeful that this legislation will appropriately address this outstanding concern, without providing an undue burden on the health care system. For this and many other reasons, I am here in support of this critical legislation.

However, I would be remiss if I didn't mention one aspect of the legislation which is disappointing: The current legislation lacks a requirement that biological implants purchased by the VHA be procured from accredited tissue banks and accredited tissue distribution intermediaries. While I understand that some of you may be concerned about imposing such a requirement because we are a private entity, I would just note that there are other instances in which the VHA has decided that private accreditation is not only appropriate but required. Specifically, the VHA requires medical facilities to receive and retain accreditation by the Joint Commission, a private accrediting agency. Leading medical centers of excellence require AATB accreditation of vendors from whom they procure tissue grafts. In addition, the American Academy of Orthopaedic Surgeons (AAOS) recommends the use of tissue from banks that are

[1] http://www.gao.gov/assets/670/660105.pdf

accredited by the AATB.[2] By not requiring that FSS contractors adhere to the highest safety standards required by the AATB's accreditation process, I remain concerned about the overall safety and quality of the products provided to our veterans.

I welcome your questions.

I yield back my time.

[2]http://www.aaos.org/about/papers/advistmt/1011.asp

ONE PAGE SUMMARY OF FRANK WILTON'S STATEMENT

Thank you for the opportunity to come before you today in support of the "Biological Implant Tracking and Veteran Safety Act of 2014." This critical legislation directs the Secretary of Veterans Affairs to adopt a standard identification protocol for use in the procurement of biological implants by the Department of Veterans Affairs. By building upon the past success of the implementation of the Unique Device Identifier or UDI, this legislation will ensure that biological implants used within the Department can be appropriately tracked from the donor of the human tissue all the way to the recipient. This critical capability for "track and trace" efforts will enhance patient safety, expedite product recalls when necessary, and assist with inventory management.

As the Secretary of Veterans Affairs opts to adopt the standard identification protocol for tissues (both devices and non-devices), I urge you to ensure that the Secretary provide a menu of options for such adoption. Under the UDI final rule, FDA has done just that be providing for multiple entities called issuing agencies. At this time, FDA has provided for three different issuing agencies: (1) GS1, (2) Health Industry Business Communications Council (HIBCC), and (3) ICCBBA. **I hope that the flexibility provided by the FDA with respect to issuing agencies is maintained by the Department of Veterans Affairs.** However, given that the bill language already suggests that the unique identification system is comparable to what the UDI provides, we believe the intent to provide that flexibility is inherent in the legislation.

The American Association of Tissue Banks (AATB) is a professional, non-profit, scientific and educational organization. AATB was founded in 1976 by a group of doctors and scientists who had started in 1949 our nation's first tissue bank, the United States Navy Tissue Bank. It is the only national tissue banking organization in the United States, and its membership totals **more than 125 accredited tissue banks and approximately 850 individual members**. These banks recover tissue from more than **30,000 donors** and distribute in excess of **two million allografts for more than one million tissue transplants performed annually in the U.S**.

One aspect of the legislation which is disappointing to AATB: The current legislation lacks a requirement that biological implants purchased by the VHA be procured from accredited tissue banks and accredited tissue distribution intermediaries. While I understand that some of you may be concerned about imposing such a requirement because we are a private entity, I would just note that there are other instances in which the VHA has decided that private accreditation is not only appropriate but required. Specifically, the VHA requires medical facilities to receive and retain accreditation by the Joint Commission, a private accrediting agency. Leading medical centers of excellence require AATB accreditation of vendors from whom they procure tissue grafts. In addition, the American Academy of Orthopaedic Surgeons (AAOS) recommends the use of tissue from banks that are accredited by the AATB.[1] **By not requiring that Federal Supply Schedule (FSS) contactors adhere to the highest safety standards required by the AATB's accreditation process, I remain concerned about the overall safety and quality of the products provided to our veterans.**

Please review AATB's full written testimony for additional information.

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[1]http://www.aaos.org/about/papers/advistmt/1011.asp

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