

**TOXIC EXPOSURE: EXAMINING THE
VA'S PRESUMPTIVE DISABILITY
DECISION-MAKING PROCESS**

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS

UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

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SEPTEMBER 25, 2019
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TOXIC EXPOSURE: EXAMINING THE VA'S PRE-SUMPTIVE DISABILITY DECISION-MAKING PROCESS

WEDNESDAY, SEPTEMBER 25, 2019

U.S. SENATE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 10 a.m., in room 418, Russell Senate Office Building, Hon. Johnny Isakson, Chairman of the Committee, presiding.

Present: Senators Isakson, Moran, Boozman, Cassidy, Rounds, Tillis, Sullivan, Blackburn, Tester, Brown, Blumenthal, Hirono, Manchin, and Sinema.

**OPENING STATEMENT OF HON. JOHNNY ISAKSON, CHAIRMAN,
U.S. SENATOR FROM GEORGIA**

Chairman ISAKSON. Good morning. We are glad to have you here at the Veterans' Affairs Committee for this hearing today, which is a very important hearing. It has been scheduled twice before and was postponed for other problems. One was the principal author could not be here for the hearing, on his bill, and we did not want to do that. The other cancellation was because of conflicts—problems with our whole calendar on the day and we had to pull it off the calendar because of other votes that preceded it.

But, today we do not have any competition. We have competition but it is not any good competition, so we are going to have our hearing and hopefully we are going to have good attendance.

This is a very important hearing issue that is bubbling up from time to time in our military, and it is an issue that is not covered greatly, because it is an issue of more modern warfare than some of the old stuff. I think it is important that we hear everything that is going on and what the Department of Veterans Affairs is doing, and what problems veterans who have been conflicted with, associated with toxic waste and toxic fire pits, have endured.

We are in the process of beginning to gather facts, and I want to point out today something I have never said before. The high level of toxic exposure issues with claims and benefits never occurred to me until we started working on the Blue Water Navy legislation. As you know, we passed Blue Water Navy, what, a month ago, Jon?

Senator TESTER. Yes.

Chairman ISAKSON. We have had been working on Blue Water Navy for, I guess, ever since you have been Ranking Member and

I have been Chairman—four years anyway—to include Blue Water Navy benefits for those who did not serve on land, but served at sea in the Vietnam War. That expanded payments for presumed illness due to Agent Orange exposure. It might be from Agent Orange, while it could be from something else.

We have to be very careful in the future when we start gathering facts to make certain we take into account facts, and clarify indirect cause and effect. We want to find out exactly what is causing illnesses and diseases, exactly where the problems may or may not be, and hear from the Department of Veterans Affairs about exactly what it would take for us to do the research and what to do with the findings. Then, if we did have a cause for action, how long it would take us and how far we would have to go in substantiating that cause of action for veterans.

We have got a long way to go before we have any legislation, but it is time to start looking at this very important topic. In Iraq and Afghanistan, there have been lot of incidences of burn pits, which is only exacerbated by the terrain and atmosphere, and those countries are already classified as austere living conditions. So, you have the waste that comes from a burn pit affecting soldiers who are fighting today, and that is something that causes a big problem.

We are going to gather all the facts we can. We will make sure our soldiers get what they are entitled to and what they have earned for representing our country. I want to see to it that we get all the facts on the table so we don't have a rush to judgment without something that isn't scientifically founded. The only thing we need to rush to do is what is right by veterans because we know it is, and that is what we plan on doing at this hearing today.

Before I introduce our guests I want to introduce Ranking Member Jon Tester from Montana for his comments.

**OPENING STATEMENT OF HON. JON TESTER, RANKING
MEMBER, U.S. SENATOR FROM MONTANA**

Senator TESTER. Well, thank you, Mr. Chairman.

I want to thank the folks on both panels who are going to be testifying today. I appreciate you taking time out of your schedules to be here to testify before us on a very critically important issue.

Before we get to business I also want to take a moment and recognize Bobby Daniels, a Blue Water Navy veteran from Missouri. Bobby, it is good to have you in the crowd. I know this is an issue that you have been working on for some time, and we appreciate your service, so thank you, sir. [Applause.]

I also want to say a few things about the fellow to my left, who said he would be returning back home to Georgia at the end of this year. There are going to be a lot of things said about Johnny Isakson over the next 3 to 4 months, but the fact is that serving with Johnny on this Committee has been an honor of a lifetime for me. He is an example of what the U.S. Senate should be—civility, bipartisanship, and decency—and one that we should all try to emulate.

Johnny is everything that you could ask for in a colleague, in a friend, and he has been the best damn advocate for veterans in this country that they could ever ask for. We have accomplished a lot

under Johnny's chairmanship, from the MISSION Act to the Forever GI bill, to the Appeals Modernization, and, yes, to the Blue Water Navy Veterans Act.

That is why we are here today, not just to talk about the process, but to talk about fulfilling this Nation's promises to our veterans.

When folks sign up for the military, there are promises made, and the cost of fulfilling those promises are the costs of war. In terms of Agent Orange exposure we are talking about an aging Vietnam veterans' population, a population that often returned home to protests in angry and divided communities. They did not return home to parades or other appreciation from a grateful Nation. This population has suffered for far too long from health conditions caused by service to a government, and far too frequently that government refused to acknowledge the true extent of their sacrifice.

So, now is the time. The time has passed to wait for those veterans' families to wait for three medical conditions—hypothyroidism, bladder cancer, Parkinson's-type syndromes or Parkinsonism. The National Academy suggests that those are associated with Agent Orange. In the case of the fourth condition, hypertension, their view of the studies have shown there is a positive association between that and Agent Orange.

Yet, in all four of these cases, Vietnam veterans continue to wait for VA bureaucracy to unravel itself from the red tape and issue a decision on whether to extend presumptive exposure. There is absolutely nothing stopping the Secretary from making a decision on these four conditions right now.

Meanwhile, those Vietnam veterans who served offshore, their wait continues. Despite the court ordering the Department to finally acknowledge Blue Water Navy veterans' exposure to Agent Orange and other herbicides, the VA continues to slow-walk processing claims for these veterans, and the VA must do right by these Blue Water Navy veterans; quite frankly, lift the stay and the wait, and begin processing their claims today, because the fact is the VA is outliving these veterans and that is simply not right.

We are at a point where our newest generation of veterans is losing faith in this government because the VA bureaucracy has not prioritized or appropriately addressed the health outcomes of veterans exposed to harmful toxins while in service. For the Gulf War veterans, their health has worsened in comparison to their non-deployed counterparts, and the VA must work harder to figure out why this is.

While I understand the National Academy is undertaking a comprehensive review of the health effects of airborne hazards from burn pits, veterans are understandably frustrated with the pace of progress in examining their exposures. Moving forward, we must develop a better process for recognizing health outcomes caused by toxic and environmental exposures. Veterans and their families cannot wait decades for determinations that their military exposures caused their illness. We need a simpler, quicker process.

At Secretary Wilkie's confirmation, he said that a veteran should not have to employ a team of lawyers to get their benefits to the care that they are entitled, and I know he sincerely believes that. I agree with him. But, it is my opinion that the VA could make this

progress much less adversarial if it stopped employing armies of lawyers to find ways to deny care or benefits to veterans and start hiring additional docs and claims processors to provide more timely care to their veterans.

Yet, the VA is not the only government agency that bears fault here. The Department of Defense must do a better job mitigating the damage done by environmental hazards, by working to prevent them in the first place. It needs to more accurately record the exposure our troops come in contact with and make sure our troops' medical records document these exposures.

I have worked closely with Senators Blackburn and Blumenthal on the OATH Act, which would require such documentation. It would help veterans establish that contact with toxic occurred so that they have more easily fileable claims for exposure, just as it helps the VA with diagnosis and treatment.

The Joint Economic Council exists to improve coordination between the DOD and the VA and ultimately improve outcomes for servicemembers and veterans. Why is common-sense legislation like the OATH Act even necessary when the highest levels of the DOD and VA are supposed to be looking into these issues routinely?

To that end, I would like to see the JEC take a harder look at how the DOD and VA can work collaboratively to ensure that the VA has the information that it needs to substantiate the claims so that veterans do not have to hire a team of lawyers, as referenced by the Secretary.

Making a decision on science should not take more than 3 years. Following a court decision should not take 9 months. And not learning from decades of mistakes and allowing our newest generation of veterans to experience the same hold-ups as the Vietnam veterans have is a failure in and of itself.

Mr. Chairman, I cannot thank you enough for calling this hearing today. It is one of the most important hearings I think we are going to have this year in the VA Committee. Thank you.

Chairman ISAKSON. Well, thank you, Jon, and thank you for your kind remarks about me, but I want to tell everybody, one fact to keep in mind. In the past 2 years, all the legislation we have passed, making changes, all of them that have been made—new GI bill, everything—there was one dissenting vote from a Committee Member on one vote. So, we have 100 percent votes for everything we did, except for one time we had one no vote yet we had 14 yes votes on that bill. So, we are a team, we are not individuals up here. We are ready to work on problems and get them solved. I appreciate your help along the way. We had a good Committee all the way through.

Now for our panel today. Our first panel is Dr. Patricia Hastings, Chief Consultant, Post-Deployment Health, VA; accompanied by Dr. Drew Helmer, Director of War-Related Illness and Injury Study Center. Then, Dr. Terry Rauch, Acting Deputy Assistant Secretary of Defense for Health Readiness, Policy, and Oversight.

Dr. Hastings, you are first.

STATEMENT OF PATRICIA HASTINGS, M.D., CHIEF CONSULTANT, POST DEPLOYMENT HEALTH, U.S. DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY DREW HELMER, M.D., DIRECTOR, WAR RELATED ILLNESS AND INJURY STUDY CENTER (WRIISC)

Dr. HASTINGS. Thank you very much.

Chairman ISAKSON. I will interrupt for 1 second. You have got up to 5 minutes.

Dr. HASTINGS. OK. Chairman Isakson, Ranking Member Tester, and Members of the Committee, I really want to thank you for having this meeting. I want to thank you for allowing the VA to talk about what we do in regard to military environmental exposures and how we take care of veterans.

I am a 30-year veteran at retirement. I decided that I would come to the VA to continue to serve veterans. I am joined today by Dr. Drew Helmer. He is the previous director of the War-Related Illness and Injury Study Center at East Orange, NJ, and last month he was selected to be the Deputy Director at the Center for Quality Innovations, Effectiveness, and Safety at the Houston Medical Center in Houston, TX.

I am a board certified emergency medicine physician with a degree in public health, and I am very happy to continue serving.

Post Deployment Health Services (PDHS) is the oversight for military environmental exposures, and we know how critical this is for veterans. Exposures are the reason that my office exists. We have four programs in Post Deployment Health Services. These are the Pre-9/11 programs, the Post-9/11 Era Programs, and here we have subject matter experts that look at how to develop policy that is effective and works for the veterans.

Epidemiology looks at the science, does some original research, and informs policy for the VA. The War-Related Illness and Injury Study Center, that I just spoke about, does research, education, very extensive education, and also sees the most difficult cases in the VA, those veterans that are hard to diagnose and hard to make a treatment plan for.

At the War Related Illness and Injury Study Center in New Jersey there is the Airborne Hazards Open Burn Pit Center of Excellence, and I think you know about that because you have supported it vigorously. Your support has accelerated research for veterans and care for veterans, and I would like to sincerely say thank you.

VA does recognize that environmental exposures during deployment may be associated with immediate and delayed adverse outcomes, and the greatest challenge there is getting the work done. VA cares for 9.6 million veterans. A third of these veterans report that they may have had an exposure to an environmental hazard, and a quarter of those veterans are concerned that they may have an adverse health outcome.

We have teams that are addressing this. We have epidemiologists. We have physiologists. We have internists. We have pulmonologists. We work with the other Federal agencies. We work very closely with the DOD. We work with the National Academy of Medicine. We work with CDC, VBA, all of these in support of veterans.

When a disability is determined to be due to an in-service exposure, whether it is through a presumption or direct proof of exposure, VBA is there to help veterans with compensation.

In certain circumstances, VA does presume that a disability was caused by military service, and presumption can take the place of some other forms of proof. They are established by Congress or by the Secretary after review of the science by the subject matter experts, and in the VA we use external agencies as well as the internal subject matter experts. One of the greatest challenges with the presumption process is that good science does take time, and we are working very hard to get things done.

In the absence of a presumption, however, we do encourage the veteran to turn in a claim which can be looked at on an individual basis if they believe that their service has harmed their health.

A central question that does remain unanswered, in many cases, is what aspect of the deployment is causing the ill health? We see that right now with airborne hazards. Is it the dust? Is it the burn pits? Is it an infectious process? Is it blast over pressure or a combination of all those things? VA is working with DOD and our other partners to find the answers.

An exciting new opportunity to improve understanding is ILER. I think most of you know about the Individual Longitudinal Exposure Record. If you match ILER with the electronic health record, and we have the ability to do big data, we have a very powerful tool that can look at large or small cohorts very quickly and get you the answers that you seek for care of veterans. We hold scientific exchanges with the DOD. We have the Airborne Hazards Symposium, toxic-embedded fragments studies, the July Environmental Health Conference. All of these have taken place in the last 6 months. We publish our research findings in peer-reviewed journals.

In conclusion, sir, VA is committed to the health and well-being of veterans. My office is dedicated to that specifically. To this end, your continued support, as has been, is essential.

Mr. Chairman, this concludes my testimony. My colleague and I are prepared to answer your questions.

[The prepared statement of Dr. Hastings follows:]

PREPARED STATEMENT OF DR. PATRICIA R. HASTINGS, CHIEF CONSULTANT, POST DEPLOYMENT HEALTH SERVICES, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS (VA)

CHAIRMAN ISAKSON, RANKING MEMBER TESTER, AND MEMBERS OF THE COMMITTEE, Thank you for the opportunity to discuss the ongoing processes, research, and actions that VA uses to identify illnesses and care for Veterans who may have an illness associated with environmental health hazards during military service. I am joined by Dr. Drew Helmer, Deputy Director of the Center for Innovations in Quality, Effectiveness, and Safety at the VA Medical Center in Houston, Texas, and immediate past Director of the War Related Illness and Injury Study Center (WRIISC) at the VA New Jersey Health Care System in East Orange, New Jersey.

POST DEPLOYMENT HEALTH SERVICES

Post Deployment Health Services (PDHS) oversees health-related concerns of relevance to Veterans and their occupational and environmental exposure.

PDHS consists of four programs: Pre-9/11 and Post-9/11 Era Environmental Health Programs—addressing military environmental concerns from conflicts as well as garrison exposures; Epidemiology—providing research and scientific review to inform policy; and WRIISC located at three sites. WRIISC provides research, edu-

cation, and medical consultation for cases that are difficult to diagnose or treat. WRIISC NJ houses the congressionally-mandated Airborne Hazards and Burn Pits Center of Excellence. Your support has accelerated Airborne Hazards research and Veteran care. Thank you.

VA recognizes that environmental exposures during deployment may be associated with both immediate and delayed adverse health consequences. There are over 18 million Veterans in the United States, and VA cares for approximately 9.6 million of them. Exposures are a major concern of Veterans and why PDHS exits. One in three Veterans report a possible exposure to environmental hazards and one in four report health concerns due to deployment exposures. PDHS oversees VA's efforts to mitigate health effects of exposures and to provide care for the associated adverse health outcomes when necessary. When a disability is determined to be due to an in-service exposure, whether through direct proof or because the disability is eligible for presumptive service connection, the Veterans Benefits Administration (VBA) provides disability compensation. The teams addressing exposure concerns are diverse: epidemiologists, physiologists, pulmonologists, internists, other medical specialties, bench researchers, VBA, Department of Defense (DOD), and academia.

THE PRESUMPTIVE PROCESS

In certain circumstances, VA presumes that certain disabilities were caused by military service and subsequently awards disability compensation to a veteran. The presumption of service connection takes the place of some of the proof elements that apply in an ordinary direct service connection claim, such as proof of exposure or a causal link between the in-service exposure and subsequent disability, otherwise known as the nexus requirement. The first presumptions were established in 1921, with more added through the decades.

The way VA currently handles decisions on claims based on illness asserted to be due to in-service exposure is through presumption or a direct causation analysis. Both of these methods can be complicated by a lack of contemporaneous proof of what happened to a given person in service. I will discuss a better method of documenting exposure and health outcomes in a moment. It is called the Longitudinal Exposure Record (ILER).

Presumptions are established by Congress or by the Secretary after review of the science by subject matter experts (SME). VA uses external agencies such as the National Academy of Science, Engineering, and Medicine, the National Institutes of Health, and the Agency for Toxic Substance Disease Registry, as well as its own experts for these reviews. The greatest challenge with the presumption policy-making process is that it usually takes time to conduct the research to link military service to an illness for presumptive service connection. In the absence of a presumption, however, the Veteran can submit a claim for a condition that they believe was caused or exacerbated by their military experience. Other challenges are: establishing a dividing line for exposure; addressing attributable risk; advances in medical science; the relationship to service; delayed diagnosis; and incomplete or unavailable records.

Military exposures research is challenging. Exposure information can be difficult to obtain. Individual exposure levels can vary tremendously even for Veterans deployed to the same geography or conflict. Details, such as the timing of deployment, exact locality, occupation, and actual assigned duties, can affect the presence or absence and extent of an exposure.

Most literature on chemical and toxin exposures comes from occupational health providing some objective data about health risk and outcomes through analogy. Occupational exposures in civilian settings are managed proactively and systematically with a host of controls to include elimination, substitution, administrative controls, and personal protective equipment. Military Servicemembers in high-tempo operations or high-pressure environments often do not have the luxury of such controls.

Researchers use scientific methods to detect causal associations between exposures and disease. Theoretically, the best method is a randomized clinical trial, but this is generally unethical for exposure research. Therefore, other techniques must be used such as animal and in vitro toxicity studies, observational studies, and case control studies. A disadvantage of these studies is the inability to make firm conclusions based on one study.

A central question that remains unanswered in many cases is: What aspect of the deployment experience is contributing to poor health outcomes? In the matter of airborne hazards, is it the particulate matter, burn pits themselves, blast overpressure, an infectious agent, or a combination of exposures? VA and DOD continue working alongside academia to find these answers.

As mentioned above, an exciting opportunity to improve our understanding and management of exposure-related health concerns comes from the new Individual ILER. VA and DOD are working jointly to improve real-time exposure monitoring and to capture these data in ILER. Initial Operational Capability for the ILER is scheduled for release on October 1, 2019. The ILER identifies a Servicemember's deployments by date, location, and known toxic exposures. ILER will improve care, benefits, and research.

A STRATEGIC VISION ON RESEARCH TO ENHANCE COLLABORATION BETWEEN VA AND
DOD

In the Deployment Health Working Group, VA and DOD SMEs meet monthly to discuss and plan joint actions regarding deployment-related exposures and their possible association with subsequent adverse health conditions. VA and DOD also hold scientific exchanges for a variety of different exposures: in March 2019, the Airborne Hazards Symposium; in April 2019, a review of chelation interventions regarding toxic embedded fragments; and, in July 2019, the Environmental Health Conference.

In order to improve evaluation and care of Veterans, PDHS/WRIISC has a robust educational program aimed at improving VHA and private sector providers' knowledge about deployment-related health concerns. WRIISC delivers monthly continuing education accredited Webinars for VHA providers and has eLearning modules available online and on demand. SMEs present and lead workshops to discuss exposure issues at professional and scientific meetings. We publish our research findings in peer-reviewed journals to improve clinical practice. All these education and dissemination activities contribute to raising the standard of care to improve Veterans' health and function.

CONCLUSION

VA is committed to the health and well-being of Veterans and is dedicated to working with our Interagency and academic partners to investigate potential adverse health effects associated with exposure during deployment.

To this end, your continued support is essential. Mr. Chairman, this concludes my testimony. My colleague and I are prepared to answer any questions.

Chairman ISAKSON. Thank you very much for your testimony.

Our next witness is Dr. Helmer of Veterans Affairs. Dr. Helmer. Oh, you're the—

Mr. RAUCH. I am the second.

Chairman ISAKSON. You are the second?

Mr. RAUCH. Dr. Rauch, for the DOD.

Chairman ISAKSON. OK, Dr. Rauch. I am sorry. We will take your expert testimony, and then he can correct it after I introduce him.

Mr. RAUCH. My pleasure.

STATEMENT OF TERRY M. RAUCH, Ph.D., ACTING DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH READINESS POLICY AND OVERSIGHT, U.S. DEPARTMENT OF DEFENSE

Mr. RAUCH. Chairman Isakson, Ranking Member Tester, and Members of the Committee, thank you for the opportunity to discuss the Department's process for exposure monitoring, identifying illnesses that are potentially associated with exposures during military service, and our collaboration with the VA.

I spent 27 years on active duty in the Army, some of that time working on this topic in the deployed and garrison environment. The Department has a longstanding collaborative relationship with the VA, focused on a continuum of care for servicemembers and veterans. We collaborate extensively on occupational and environmental exposures, including the exchange of individual exposure information, health effects research to determine possible linkage

of exposures to illnesses, exposure-related registries, and outreach and education to our servicemembers, veterans, and their health care providers.

The Department's current process for assessing garrison- and deployment-related health hazards informs our commanders of the health risk to their personnel, so that they, along with their public health and safety professionals, can make necessary operational decisions to mitigate the health risk and protect the health of the force.

The health risk assessment process also informs health care provided to individuals and provides information to the VA to support the determination of claims for veterans. The Department and VA have several processes in place to share exposure-related information on servicemembers and veterans. These processes include, but are not limited to, the service treatment record, the newly developed electronic Individual Longitudinal Exposure Record, known as ILER, establishment of specific exposure registries, and collaborative meetings, sharing research findings on the health effects of environmental exposures in military environments.

The DOD and VA have collaborated on the establishment of several exposure-related registries as a means to provide event-related exposure information to the servicemember and veteran, health care providers, researchers, claims adjudicators, and others. Existing exposure registries include Agent Orange, Gulf War Illness, Ionizing Radiation, Depleted Uranium, Toxic Embedded Fragments, Operation Tomodachi, and the Airborne Hazards and Open Burn Pit Registry.

Moreover, past, current, and emerging exposures of concern are deliberated with the intent of developing recommendations to inform policy decisions, updating of exposure and health effects knowledge, supporting joint project development, critical information-sharing, and health risk communication.

The Department has, and will continue to, collaborate with the VA and other Federal agencies, academia, and others on epidemiological and health-related research to gain a better understanding of the potential long-term health outcomes associated with exposures and to translate our research findings to improve the health care of our servicemembers and veterans.

The Department is grateful for the unwavering congressional support that has enabled collaborative actions, focused on the health and readiness of servicemembers, the health of veterans, and the provision of high-quality care to servicemembers, veterans, and their families.

Thank you again for the opportunity to be here with my VA colleagues. I look forward to your questions.

[The prepared statement of Mr. Rauch follows:]

PREPARED STATEMENT OF TERRY M. RAUCH, PH.D., ACTING DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS) HEALTH READINESS POLICY AND OVERSIGHT, U.S. DEPARTMENT OF DEFENSE

CHAIRMAN ISAKSON, RANKING MEMBER TESTER, AND MEMBERS OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS, I am pleased to represent the Office of the Secretary of Defense and have the opportunity to discuss the current Department of Defense (DOD) process to identify illnesses that are associated with occupational and environmental health hazards during military service and possible modifications to the process to address future exposure linked illnesses.

The Department's current process for assessing health hazards informs our commanders of the health risk to their personnel so that the commanders can make necessary operational decisions to manage that health risk, protect the health of the force, and preserve mission readiness. The health risk assessment process also informs: (1) the occupational medicine community of the need for medical surveillance examinations to monitor for adverse health effects and further risk management actions; (2) DOD clinicians providing health care to their patients of exposures that may be causing reported symptoms; and (3) Department of Veterans Affairs (VA) to assist in claims determinations and for health care to veterans.

The Department applies these processes for exposures in routine operations and deployed military operations, for the Military Services and Defense Agencies, for exposures to chemicals used by the worker, physical hazards, and from the ambient environment (commonly called "environmental health hazards"), and for military Servicemembers and civilian employees.

These processes are established as DOD policies in DOD Instruction (DODI) 6055.01, "Safety and Occupational Health (SOH) Program;" DODI 6055.05, "Occupational and Environmental Health (OEH);" DODI 6055.20, "Assessment of Significant Long-Term Health Risks From Past Environmental Exposures on Military Installations;" DODI 4715.19, "Use of Open-Air Burn Pits in Contingency Operations;" DODI 6490.03, "Deployment Health;" and DOD Manual 6055.05-M, "Occupational Medical Examinations and Surveillance Manual." The Military Services, Defense Agencies, and Geographic Combatant Commands develop implementing instructions to carry out these policies.

Current policies are based on knowledge of the current science for health effects and the exposures that would cause those health effects. The Department has policy and procedures to review and analyze health literature and regulatory actions to identify the need to update health risk assessment procedures (reference: DODI 4715.18, "Emerging Chemicals (ECs) of Environmental Concern"). These procedures have led DOD to begin updating health risk assessment procedures for lead, trichloroethylene, and chromium compounds. "Most recently, the DOD exposure community of interest has begun reviewing and analyzing continuous exposure to blast overpressure by servicemembers in the operational and training environments to determine potential health effects on the brain, in accordance with Public Law 115-91.

Using lead as an example, the Department policy has followed the Occupational Safety and Health Administration (OSHA) lead standard for exposure and medical surveillance of military and civilian employees. A growing body of knowledge—confirmed by an independent assessment by the National Academies of Science Committee on Toxicology—found that the OSHA lead standard may not sufficiently protect against the latest findings of significant health effects. The Department updated DOD Manual 6055.05-M for medical surveillance and for medical removal of individuals with elevated blood lead levels from environments that put the individual at risk, and plans to issue policy in DODI 6055.01 with new health standards for allowable levels for inhalation of lead dust and fumes. The health risk procedures in DODI 6055.05 will apply to the new health standards. The Department will collaborate with the VA for health risk assessments of additional exposures of concern using the current DOD procedures for emerging chemicals.

The Department and VA have several processes in place to share exposure-related information on Servicemembers and veterans. These processes include, but are not limited to: (1) making the Servicemember's Service Treatment Record (STR) available within 30 days of separation from service, (2) the newly developed electronic DOD/VA Individual Longitudinal Exposure Record (ILER); (3) establishment of specific exposure registries; and (4) collaboration meetings.

The STR includes the Separation History and Physical Examination and any clinical evaluation and/or treatment associated with exposures during military service. The STR is maintained for 100 years after the date of separation of the member from the Armed Forces. DOD makes electronic copies of the STR available to the Department of Veterans Affairs within 30 days of separation from service.

The first-ever ILER project recognizes the Department's commitment to establishing a permanent record of exposures. The ILER is a composite record of an individual's potential and documented exposures from garrison or deployment activities, from initial entry to discharge or retirement from military service. The ILER will be made accessible to DOD and VA medical providers, epidemiologists, and researchers, as well as to VA claims and disability adjudicators. The ILER will enhance medical evaluation and treatment; support epidemiological investigations and research to better understand potential and actual health outcomes; inform health risk mitigation strategies; and provide easily accessible exposure information when needed to DOD and VA medical and administrative offices. Release of the Initial

Operational Capability version of the ILER is set for 1 October 2019, followed by spiral development rollout to Full Operational Capability over the next four years. The ILER will serve as a data culling repository for existing DOD exposure systems and provide a single access point for exposure information.

The DOD and VA have collaborated on the establishment of several exposure-related registries as a means to provide event-related exposure information to the Servicemember and veteran, healthcare providers, researchers, claims adjudicators, and others. Existing exposure registries include the following: Agent Orange, Gulf War Illness, Ionizing Radiation, Depleted Uranium Registry, Toxic Embedded Fragments, Operation Tomodachi, and the Airborne Hazards and Open Burn Pit Registry.

The DOD and VA have a long-standing collaboration on these processes through Joint Airborne Hazards Symposia focused exposure health effects research, outreach and education and the DOD/VA Deployment Health WG formed to focus on occupational and environmental exposures affecting the health of servicemembers and veterans.

Past, current and emerging exposures of concern are deliberated with the intent of developing recommendations to inform policy decisions, updating of exposure and health effects knowledge, and supporting joint project development (such as the ILER), critical information sharing, and health risk communication.

The Department has and will continue to collaborate with the VA, other Federal agencies, academia and others on epidemiological and health-related research focused on full and better understanding of potential long-term health outcomes associated with garrison and deployment-related occupational and environmental exposures, and to translate this research into prevention, diagnosis and treatment to better care for our Servicemembers and veterans.

The Department is grateful for the consistent Congressional support that has enabled collaborative actions focused on the health and readiness of Servicemembers, the health of veterans, and the provision of high-quality care to Servicemembers, veterans and their families.

Chairman ISAKSON. Thank you very much, Doctor. We are glad to have you here today. I will ask the first questions and then go to Jon, and then we will go to Mr. Rounds and other Members as they come here today.

On the identification of illnesses, the work that you have to finally determine whether there is a presumption of association or not, how long a process is that; or is that a process to which there is a discipline and a rule of order, or does it depend on what the accusation is or what the illness is?

Dr. Rauch, do you have anything on that?

Mr. RAUCH. Well, our process starts from the ground up, where we have preventive medicine units in the deployed and garrison environment that routinely collect surveillance data, environmental health, occupational health data. That data is then captured into databases. It is evaluated. It is reported to the commander. The commander has the ultimate decision to mitigate risk, which he or she sees from those environmental and occupational health assessments.

Those are done routinely, and as a matter of fact, in some environments they are done routinely daily.

Chairman ISAKSON. More of the things that you investigate are things that you initiate in the Department itself rather than things that are brought to you by a veteran. Is that right? Would that be a correct assumption?

Mr. RAUCH. Yes, that would be correct.

Chairman ISAKSON. Very good. Dr. Helmer, I had a call 2 weeks ago from a veteran, whom I know very well, so I know his credibility. In fact, he was an elected official after his service in Vietnam and a very successful person in our community. He has ter-

minal liver cancer, and he called me and said that it is a liver cancer that is not covered by—I do not remember what the name of the cancer is. This is just a what-if question. It is a liver cancer for which there is no benefit paid from the Veterans Administration. There is some caregiver money but there is not any direct benefit paid.

Is every benefit that is paid for an illness or a condition or a situation like cancer, is that determined broadly or is that determined individually in the Department by the disease?

Dr. HELMER. I think the answer is that it is a combination, and that for the presumed service-connected conditions they are defined more explicitly and often have limits, in terms of what is covered, depending on the language that is used, either in the Secretary's language or in the congressional language.

As Dr. Hastings mentioned, every veteran can file a claim for service connection on an individual basis, and that determination is made on a case-by-case basis, weighing both the evidence of the actual connection, the nexus to the military service, as well as the evidence supporting the association between perhaps an exposure and that health condition.

Chairman ISAKSON. Do you know if there is a process in the Veterans Administration whereby someone can bring a request for a benefit for something that is not covered and is handled on an individual basis?

Dr. HELMER. And it is handled on an individual basis?

Chairman ISAKSON. Is there a process for that? I am not looking for one. I just want to know if there was one.

Dr. HELMER. I will refer to Dr. Hastings.

Dr. HASTINGS. Sir, that would be the claims process, and if any veteran has a condition that has caused a disability which they believe is related to their military service, it will be evaluated on an individual basis. In fact, that is how most VA claims are handled. It does not require a presumption.

[The information requested during the hearing follows:]

RESPONSE TO REQUEST ARISING DURING THE HEARING BY HON. JOHNNY ISAKSON TO PATRICIA R. HASTINGS, M.D., CHIEF CONSULTANT, POST-DEPLOYMENT HEALTH, U.S. DEPARTMENT OF VETERANS AFFAIRS

Question. Do you know if there is a process in the Veterans Administration whereby someone can bring a request for a benefit for something that is not covered and is handled on an individual basis?

Response. The Department of Veterans Affairs (VA) has an existing process where Veterans can claim conditions that are not presumptively associated with their military service. For any condition that a Veteran believes is related to their military service, the Veteran can submit a claim for disability benefits; this can be done by mail, in-person, or online. For conditions that are not considered presumptively associated with their military service, service connection may still be granted if there is evidence that the disability was due to or caused by disease, injury, or event in military service.

Chairman ISAKSON. If a condition is determined for one individual veteran and the Department pays benefits, then another veteran comes in with the same condition, do they automatically get the benefit or do they have to go through the same process as the first one did?

Dr. HASTINGS. They would be going through the same process.

Chairman ISAKSON. Does that happen very often?

Dr. HASTINGS. I can ask the VBA how often it happens, and I would be very happy to get the information for you and brief you back on it.

[The information requested during the hearing follows:]

RESPONSE TO REQUEST ARISING DURING THE HEARING BY HON. JOHNNY ISAKSON TO PATRICIA R. HASTINGS, M.D., CHIEF CONSULTANT, POST-DEPLOYMENT HEALTH, U.S. DEPARTMENT OF VETERANS AFFAIRS

Question. If a condition is determined for one individual veteran and the Department pays benefits, and another veteran comes in with the same condition, do they automatically get the benefit, or do they have to go through the same process as the first one did?

Response. Entitlement to disability compensation benefits is not automatic, unless established through presumption. Veterans go through the same process and each claimed condition is adjudicated on an individual basis, (i.e., considering factors such as exposure time and duration, medical history, manifestation period for symptoms, etc.).

Chairman ISAKSON. I want you to be very careful when you answer this question. This is the last one I am going to ask. There is a process whereby you could get a piece of legislation passed in the Congress on citizenship or on legality or on immigration, and handle a single case with one bill, if somebody wants it done. Would that be the case—do you know of any case within the Veterans Administration where a Senator or a Representative has introduced a bill that directed the VA to cover one individual incident or disease?

Dr. HASTINGS. I do not know of any, but I will go to VBA and ask if there have been any.

[The information requested during the hearing follows:]

RESPONSE TO REQUEST ARISING DURING THE HEARING BY HON. JOHNNY ISAKSON TO PATRICIA R. HASTINGS, M.D., CHIEF CONSULTANT, POST-DEPLOYMENT HEALTH, U.S. DEPARTMENT OF VETERANS AFFAIRS

Question. I want you to be very careful when you answer this question. This is the last one I am going to ask. There is a process whereby you could get a piece of legislation passed in the Congress on citizenship or on legality or on immigration, and handle a single case with one bill, if somebody wants it done. Would that be the case—do you know of any case within the Veterans Administration where a Senator or a Representative has introduced a bill that directed the VA to cover one individual incident or disease?

Response. VBA is unaware of any legislation that provides benefits for an individual person (single case) based on toxic exposures. However, Congress has previously passed laws to address specific exposure incidents. For example, under title 38 United States Code (U.S.C.) section 1112, Veterans located in Hiroshima or Nagasaki, Japan, during August 6, 1945, and ending on July 1, 1946, are considered radiation-exposed Veterans. Radiation-exposed Veterans are entitled to the presumption of service connection for certain diseases listed in 38 U.S.C. §1112(c)(2). Similarly, the Camp Lejeune Families Act of 2012 dealt with specific exposure to environmental hazards for persons residing or working at the U.S. Marine Corps Base Camp Lejeune, North Carolina.

Chairman ISAKSON. That was a good answer. Thank you. I appreciate it.

Dr. Rauch? No, you have already—who is next? Dr. Helmer, right? I am trying to avoid you.

Dr. HELMER. Well, if I can just tag onto what Dr. Rauch said about the VHA, and you were asking do we ever go to the DOD and ask about service-connected conditions, or conditions of concern. I would say we do. As a matter of fact, on a clinical level, at the War-Related Illness and Injury Study Center, we have very

close collaborations with our counterparts over in the DOD. We will routinely ask them about an exposure that a veteran brings to us. So, on a one-on-one basis we certainly have that opportunity, as well as the more formal arrangements that were mentioned.

Chairman ISAKSON. Thank you very much. OK, next is Senator Tester.

Senator TESTER. Thank you, Mr. Chairman.

Dr. Hastings, thank you for being here. Thank you all for being here. As I said in my opening remarks, I think it is time to end the way veterans, Blue Water Navy veterans, wait and for the VA to start making sure these guys and gals get the benefits that they have earned. I recognized Bobby Daniels in my opening statement. Bobby Daniels has just applied for a—recently applied for a second mortgage on his house to pay for his medical bills. It is my belief that these medical bills would be paid for if the blanket stay was lifted.

Do you believe that the VA will reverse course on its blanket stay? I think they say it is going to be stayed until January 2020. Do you think there is any potential that it could lift its blanket earlier than that, and start processing claims?

Dr. HASTINGS. I know that right now VBA is getting ready for the increased claims, doing the training. I do not know that they would be able to do it any earlier. But, they have hired more people, they are training them, and veterans certainly can put in a claim at this time. The adjudication process will take place as quickly as possible.

Senator TESTER. So, it is not an issue of recognizing that things like hypertension or bladder cancer are now to be covered, but it is more an issue of infrastructure within the VA?

Dr. HASTINGS. It is the preparation in the VBA to make sure that they can process all the claims that will be coming on.

Senator TESTER. OK. So I—and you just have to help me with this. This is just a straight-up, honest question that I do not get. Isn't it the VBA's business to allocate benefits? I mean, isn't that what they are set up for?

Dr. HASTINGS. That is what VBA is set up for, to make sure that they take care of the veterans with regards to claims.

Senator TESTER. I got you. So, why—I understand it is more numbers, but it looks to me like the process is already set up, ready to go. You just add the four presumptives on and you are rocking and rolling.

Dr. HASTINGS. The presumptives are a separate issue, and those are with leadership and in coordination, right now, for the decisions to be made.

With regards to Blue Water Navy, one of the things that they also are doing, since it is within 12 miles, there is a process by which they are taking the ships' logs from the archives, they are having them scanned in and put into a computer program. Ships used to make sure where they were in the ocean three time a day.

Senator TESTER. I got you. So—and this may not be in your bailiwick, but it would appear to me that they know already where some of those ships were. Why not lift the stay on those, at least? I mean, I am not sure that you need to know 100 percent to be able to start giving out benefits.

Dr. HASTINGS. With regards to the ships, I would have to ask VBA if they have any ships that they have already delineated, but I know they are scanning in 65 million pages of the ships' logs, in order to—

Senator TESTER. Yeah. I got that. I question whether there are 65 million pages of ship logs in relation to the Vietnam War, but maybe there is. I just—I think they are making it more complicated than it needs to be.

As far as these presumptives go, is the research done on these presumptives now done because of the court cases and because of our actions here in Congress, or is there still work being done on those presumptives as applied to Agent Orange exposure?

Dr. HASTINGS. There is still work that is being done on the presumptives. We are still researching the issues that face the Vietnam veterans.

Senator TESTER. OK. Is that going to have any impact upon benefits, that research?

Dr. HASTINGS. I believe that it may. We are still looking at the issues that face veterans. We are looking at intergenerational effects. We are looking at other disease processes, not simply the bladder cancer—

Senator TESTER. I got you. All right. So, over and beyond what the court decision said, you are looking at potential impact, generational impacts, and others.

Dr. HASTINGS. We have veterans that have many concerns that they expressed to us, and we do look at those individually—

Senator TESTER. OK.

Dr. HASTINGS [continuing]. And on a population basis.

Senator TESTER. Because it appears to me, with the court case and with the action that Congress has taken, that it is pretty much as soon as you get the infrastructure built, the benefits should go out. Am I misreading that?

Dr. HASTINGS. I do not believe so, sir.

Senator TESTER. OK. Good. I am out of time but hopefully we will have another round of questions. Thank you, Mr. Chairman.

Chairman ISAKSON. Senator Rounds.

HON. MIKE ROUNDS, U.S. SENATOR FROM SOUTH DAKOTA

Senator ROUNDS. Thank you, Mr. Chairman. Let me begin by just adding my thoughts with regard to having the privilege of serving with you, Mr. Chairman. I think the Ranking Member, Mr. Tester, has done a very nice job of indicating how strongly we feel about your service to our country, your service within the U.S. Senate, and as Chairman of this Committee, the work that you have done for veterans. We have been honored to be a part of this process with you.

It would seem to me that there is a concept here that perhaps the VA and this Committee has tried to put together, with regard to the issue of disability and the issue of whether or not there is a connection between service-related injuries, disabilities, and so forth, and a simplified process of taking care of those veterans. I can't count the number of times that I have stood in front of groups and said "thank you for your service," or the number of times that

we have said we want to make sure that everything which you are entitled to, as a member, or as a former member, that you receive.

Yet, when we get down to the paperwork of it, the legalese of it, it seems like we continue to find these reasons why we cannot get it done on a timely basis, and in some cases, there are reasons why we do not get it done at all, whether it be making payments for emergency room visits to veterans, which clearly should have been taken care of. It all comes back down to money, and it comes back down to where the money is going to go, inside the VA or outside the VA.

Right now we are talking about what the DOD does and what the VA does. Are they consistent and are they focused with a culture of finding a way to take care of an injured veteran long-term.

It starts with whether or not—and this may seem unusual, but we put men and women in harm's way, and we should find a way to take care of their health, if possible, to do everything we can to protect them. That means more than simply issuing the appropriate equipment, whether it be jackets, whether it be the right type of clothing, whether it be the right type of armaments. It also means protecting them from environmental issues as well, wherever possible.

Dr. Rauch, what alternatives has DOD taken to reduce the likelihood of servicemembers being exposed to toxic materials, and is this integrated into logistical planning or, if not, is there an initiative to do so?

Mr. RAUCH. Thank you for the question, Senator. We, in the Department, have initiated an aggressive research agenda to do just that, research and develop technologies for the servicemember in the deployed environment, to sense and characterize the environment and potential exposures that he or she will be subject to, to sense, record, document, and analyze. Now that is a vision. It is a research program to research technologies. We are putting money against it, and we have an initiative to pursue that.

Senator ROUNDS. OK. But, have we deployed any qualified medical service officers, or have any of them been assigned to pre-deployment or post-deployment planning cells, perhaps with an eye toward citing infrastructure, to reduce exposure to toxic elements? It seems to me that we have known about these issues for more than 20 years now, and it would seem that there would be something in the works besides just the research.

Is any action being taken today to try to—with regard to burn pits, or with regard to exposures to chemicals, to where there are actual medical personnel who have been assigned to any of these facilities or any locations around the world today?

Mr. RAUCH. Every deployed force has some organic medical element to support that deployed unit, and that medical element will consist of medical professionals, to include a preventive medicine team.

Senator ROUNDS. Do they have the ability to make recommendations, to limit exposure to those areas where they feel there is a risk involved?

Mr. RAUCH. The preventive medicine unit or team will make recommendations to the commander on the group, to identify health hazards and recommend mitigation of those health hazards. At the

end of the day, the commander on the group is going to make a decision based upon the mission he or she has to do.

Senator ROUNDS. Thank you.

Thank you, Mr. Chairman. My time has expired.

Chairman ISAKSON. Thank you, Senator Rounds.

Senator Hirono.

HON. MAZIE K. HIRONO, U.S. SENATOR FROM HAWAII

Senator HIRONO. Thank you, Mr. Chairman.

Dr. Hastings, I think I heard you say that most of the veterans who file claims to have coverage for their medical conditions are decided on an individual basis. On this there is a presumption that applies for their medical condition. Is that correct?

Dr. HASTINGS. Right.

Senator HIRONO. So, I want to know, since most of the veterans have to come to you on a case-by-case basis and there is no presumption, what is the burden of proof on them to show that there is a connection between service and illness?

Dr. HASTINGS. It would vary by the illness, but I would be very happy to get the information from VBA or arrange for them to give you a briefing.

Senator HIRONO. Well, give me an example. What is—because I think that it is quite a high burden for the veteran to show the connection, is it not?

Dr. HASTINGS. We would want medical records that could be reviewed. In many cases it will talk about their medical condition, and if it does have a relation to an exposure, that will be adjudicated. It is very easy to look at someone who has a back injury and say here is an x-ray. It is harder to look at these things with toxic exposures, but there is literature that we use. We—

Senator HIRONO. I am not talking about the existence of a symptom or the injury, but it is the connection that is a barrier that the veteran faces, isn't it, that it is service-related?

Dr. HASTINGS. That is one of the things they would need to show that they were near—in the example of airborne hazards, that they were in a certain location that had burn pits.

Senator HIRONO. Yeah, but who—and what the burden of proof is is often very—it is an indicator of what the result will be. I am very concerned that there is requirement that the veterans produce a whole slew of evidence to support their claim, and that this makes it really hard for them. So, I would like to know, in this review process I realize all the claims are different, but, you know, what is the average length of time for a veteran to come and ask for a decision regarding their claim and their decision?

Dr. HASTINGS. I do not know the length of time from VBA. I am very happy to take that back. But, I do agree with you.

[The information requested during the hearing follows:]

RESPONSE TO REQUEST ARISING DURING THE HEARING BY HON. MAZIE K. HIRONO TO PATRICIA R. HASTINGS, M.D., CHIEF CONSULTANT, POST-DEPLOYMENT HEALTH, U.S. DEPARTMENT OF VETERANS AFFAIRS

Question. I want to know, since most of the veterans have to come to you on a case-by-case basis and no presumption, what is the burden of proof on them to show that there is a connection between service and illness? So, I would like to know, this review process I realize all the claims are different, but, you know, what is the aver-

age length of time for a veteran to come and ask for a decision regarding their claim and their decision?

Response. The requirements to establish disability compensation for these types of claims are the same as any other claim. The evidence must show the following:

- (1) A current disability
- (2) An event, injury, or disease in service, and
- (3) Link or nexus between disability and service.

VA does not have data on the average length of time between in-service exposures to environmental hazards, and a subsequent filing of a claim. Please note that many Veterans continue to serve actively in the military for years following exposure to environmental hazards and some Veterans could be exposed to environmental hazards more than once in their career. However, as of December 8, 2019, the average number of days a claim is pending a decision on entitlement to disability compensation is approximately 81 days.

Dr. HASTINGS. One of the things that is a game-changer, as we talked about, is ILER. It will take some of the burden of proof—

Senator HIRONO. What is that?

Dr. HASTINGS. The Individual Longitudinal Exposure Record.

Senator HIRONO. Uh-huh.

Dr. HASTINGS. This will take some of the burden of proof off the veteran, it will make research easier, it will make VBA and the claims process easier, and it will improve medical care.

Senator HIRONO. So, when was this process instituted?

Dr. HASTINGS. Well, it actually is going to go live 1 October. We have already had some of the physicians and the researchers look at it already and use it, what we have had. It has been very well accepted. It will be able to match a servicemember with a location, a time and date, and the monitoring that went on there. And as I was saying before, in my testimony, if you can link this to the electronic health record and we can manipulate big data, it will make a huge difference for research claims and care.

Senator HIRONO. Is this available for Vietnam veterans, for example, or is it a timeframe that goes back not so long?

Dr. HASTINGS. No. The timeframe is really from when we had the computerized records, so it is 2000 forward. But even though it—

Senator HIRONO. 2000?

Dr. HASTINGS [continuing]. Is going forward, it will help us inform some of our decisions from the past.

Senator HIRONO. So, my point is that we should do everything we can to enable the veteran to meet his or her burden without making that burden so hard that their claims are routinely denied. I think there are so many barriers to them having their claims sustained that I am glad you have something in place. I am sorry that it took this long.

Regarding—he already asked about the four new illnesses or conditions connected to Agent Orange, and you said you are still reviewing it. I mean, what is the timeframe for the VA to say, OK, that is going to be a presumption for these four new illnesses?

Dr. HASTINGS. The review of the National Academy report was given to the leadership in mid-summer. It is with the leadership right now and undergoing a coordination with the other Federal agencies.

Senator HIRONO. You are supposed to do it within—this is also supposed to happen within 60 days of the report from the National Academy of Medicine, isn't it?

Dr. HASTINGS. We do have a directive, which is called 0215, which does describe how we will review the external reports from the National Academy, and we did follow that. If anyone would like a copy of that, I can certainly provide it.

Senator HIRONO. Well, we know that there are years-long delays in the VA attending to these situations.

I have a question about PFAs as it relates to the testing that you are doing. So, it is a class of chemicals, as you know, used in fire-fighting, et cetera, very toxic. And my understanding is that the DOD has been testing drinking or ground water on or around hundreds of military sites for PFA contamination.

Dr. Rauch, has the DOD tested the water at military sites in Hawaii for this chemical?

Mr. RAUCH. Senator, I know that we have tested numerous military installations. I will get back to you with regard to a specific installation in Hawaii.

Senator HIRONO. OK. And, if you did do such testing, of course you will tell me what locations and if any contamination was found, and if there was not any testing on any of the military sites in Hawaii, why not. OK. Because we have a lot of military sites in Hawaii.

Mr. RAUCH. I will provide a detailed answer.

[Responses were not received within the Committee's timeframe for publication.]

Senator HIRONO. Thank you. Thank you, Mr. Chairman.
Chairman ISAKSON. Senator Boozman.

HON. JOHN BOOZMAN, U.S. SENATOR FROM ARKANSAS

Senator BOOZMAN. Thank you, Mr. Chairman. We certainly appreciate you. You are not going anywhere, though, for a while. We need you around here to keep Senator Tester under control. [Laughter.]

That is a big job.

But, thank you for holding the hearing, both of you all. This is an area that I believe that everybody on the Committee is working on some project or working in unison. As most of you know, Senator Tester and I sponsored a bill in the last two Congresses to provide a way for veterans who served in Thailand to get benefits and health care. I believe that they would be left behind by the current limitations on the presumption of toxic exposure to Agent Orange. It was an Arkansas veteran, Bill Rhodes, who first brought this policy inequity to my attention. Mr. Rhodes served in Thailand and was exposed to toxic chemicals, and now suffers from an Agent Orange-related illness and cannot get the VA to consider his claim for benefits.

The VA currently limits service-connected benefits to veterans whose duties placed them on or near the perimeters of military bases. The VA says that only those veterans might have been exposed to the harmful effects of toxic chemicals.

The current policy further limits the possibility of exposure to veterans who served in security-related military occupational specialties. This limitation arbitrarily, I believe, disqualifies veterans who may have otherwise been exposed to toxic chemicals during their service in Thailand by transiting through the perimeter or by

the toxin moving through air or water to other parts of the base. With the Thailand Toxic Exposure bill, S. 1381, Senator Tester and I seek to eliminate the barrier for veterans.

For my colleagues on the Committee, most of you probably received letters in the bright orange envelopes like these. Mr. Rhodes and his fellow Thailand veterans and their families have started a letter-writing campaign to make sure that we keep them at the top of our minds as we make policy. I appreciate their support. I understand their urgencies and hope that we can fix this soon.

So, Dr. Hastings, within the VA's Post-Deployment Health Services, the environmental health program makes policy recommendations for health outcomes related to military exposure for Agent Orange, among other things. Let me ask you two or three things, you know, altogether, and then you can think about it.

How often do you all look at your current policy to recommend updates, like to those currently limiting benefits for Thailand service? Is there any process to review claims data from claims approved, denied, and pending, to identify trends that may warrant a review of presumption policy?

For example, let's say there were a number of claims from veterans who had served in the interior of a Thailand-based location not covered by the VA's current presumption. If those claims contain medical diagnosis of something like amyloidosis, you know, one of these things that seems to be directly related to Agent Orange, are you aware of a process that would identify that trend and trigger a view policy?

Then, finally, when you recommend policy changes, who in the Department ultimately determines whether to implement your recommendations?

Dr. HASTINGS. Yes, sir. Thank you very much. I would like to just comment on the Agent Orange locations, if I might. GAO asked for a report to be done by DOD and VA. DOD went to the archives and to the original manifest, et cetera. We do have a new Agent Orange list that we have just received from the DOD and we are looking at it right now. It is with my office and with VBA, and we hope to post that soon.

You asked about looking at current policy and benefits review. We review it every 2 years. It has been with the National Academy of Medicine reports. We have 11 reports that they have given us, so we have had a review every 2 years. My office also looks at trends in between times with the registry. We look at some of the health outcomes. Recently, we were concerned about cholangiocarcinoma. There have been questions about brain cancers before. We do look at it in the interim, also.

With regards to claims pending, we do look at those, for example, with the Airborne Hazards Registry. We look at the top 10 items that go in, and I routinely screen those to see if there are any things that we might be missing or that we need to look at further.

Further, we do take our registry, the Airborne Hazards Registry, and if people want to go online to see what the top complaints are, what the issues are, we have dataminated that registry and it is available for people to look at. We want to be as open and transparent as possible.

With regards to policy changes, those are submitted to the leadership of VA. They do recognize that my office has the subject matter experts, and if they have further questions they will work with us. But, our policies have mainly been in the area of the exams for the veterans and how to document those for the VA, and some care.

Senator BOOZMAN. We appreciate it, appreciate your hard work, and look forward to working with you. But I would be interested in following up, and maybe we can get together, as to if there are trends that you have identified in regard to, you know, just the military police that worked in the area. It is very restrictive right now. So, this is not asking that we do everybody, but it is asking that those that can build a case, that have a disease directly related to, you know, to Agent Orange, that they are able to prosecute that.

Thank you very much.

Thank you, Mr. Chairman.

Chairman ISAKSON. Thank you, Senator Boozman.

Before we go to Senator Sinema I want to interrupt to make a statement, if I can, for the record, and for all of you that are here. It is because Senator Manchin is here and he may leave before I get to him, which, if he does I wanted him to hear it.

You know, we had a lot of problems at the Veterans Administration with the timeliness of their follow-through on problems. I mean, they were quick to tell us about things they were doing good but they weren't quick to tell us about where they had problems. Then, we all of a sudden read about them on the front page of the newspaper, which got a lot of us upset; so we started working on ways to get that information out. I want to commend the VA on how forthright they have been in almost all cases, about bringing the bad news as well as the good news to us in a timely fashion. It is important if we have a problem that we address the problem so it does not happen again.

The reason I bring this up when Senator Manchin is in line to talk, Senator Manchin brought a problem in West Virginia to our attention, as well as the other Senator from West Virginia, which we jumped on when we got it, but when we got it was a lot later than we should have gotten it. I want to commend the Senators from West Virginia for their bringing it to our attention.

Senator Manchin called me at home. I was almost in bed when he called me. I did not mind to get out of bed for Senator Manchin at all, but it is—at my age, that's tough. So, we got to respond to it, and we are responding now. This is a situation that is going to probably include criminal charges as well as other things. So, whatever it is, it is going to take a while, but it has already been too long as far as the people affected by the charge or concern.

So, we jumped on that late. We are jumping on it with both feet now and we are going to get to it as quick as we can. I am working with the West Virginia Senators to see to it we do.

At the same time, I made a statement 2 weeks ago, on the floor of the Senate, about how proud I was of the VA for sending us the good news and the bad news contemporaneously, so that we were not having problems anymore with people finding out things after the fact. Lo and behold, I got home to Atlanta the same day and there was a big story about ants on the body of a man who died

in the VA's care, at a senior facility in Atlanta. I just felt like my statement would have been considered wrong to have made it, because it was the same day that it happened and was uncovered.

So, I wanted to say we got the VA on that as well, and because of the accountability law that we passed in this Committee, people on the—not on the West Virginia case, because that is a potential criminal case, but on the Atlanta case, for violations of the care, the standard of care—we have eight people that are gone. We are going to see that that accountability takes places.

I want to you to know it is not just the good things we talk about, but it is also when we have a problem we jump on it. The VA is jumping on it now. We are making sure people are held accountable, and I just wanted to make sure that got in before Joe had to leave, or something else. So, that is all I have. We are bragging about the good things but we are also bringing the bad things to attention, and we are going after them just as fast as the headlines for the good things.

Now Senator Sinema. it is your turn.

HON. KYRSTEN SINEMA, U.S. SENATOR FROM ARIZONA

Senator SINEMA. Well, first, Mr. Chairman, let me thank you for the work of this Committee and for your leadership. You know, as we all know, I live in Arizona. Before coming to the Senate I served in Congressional District 9, which is home to the Phoenix VA, where we know many of the previous scandals came to light, unfortunately well after many of the individuals did not receive the care that they deserved and that they needed.

So, I want to thank you for your leadership on this Committee and ensuring that we are taking care of our veterans all around the country. Thanks.

I want to thank our witnesses for being here today. You know, my team of military and veteran case workers support Arizona veterans every day on a range of needs, including support with disability compensation claims. I can tell you that based on those calls and their work, the issue of presumptive conditions and the frustration with how slow the process can be to recognize presumptive conditions impacts veterans and their families every day.

And, while it is important to consider the process, I wanted to remind us about the people who depend on the process to work for them. Mr. Grau is a Vietnam veteran who served in the U.S. Navy from 1967 to 1971, and deployed to Vietnam. He came home from Vietnam 50 years ago, and to this day he still dreams about his experiences in Vietnam. For 40 years after returning home, he did not pursue his VA benefits because he felt that no one wanted to hear about his nightmares and the trauma that he brought back with him from his service in Vietnam.

He now has an 80 percent disability rating, which includes PTSD and Parkinson's disease. He was recently diagnosed with precancerous cells in his prostate and will soon be applying again to recognize service-connected diabetes as a presumptive condition. He began the disability compensation process 10 years ago, and it has taken 10 years, including the help of my office, for VA to recognize his service-connected disabilities. His work continues as VA adds

additional presumptive conditions to recognize his already obvious illnesses.

As new presumptive conditions arise, he goes through the formal process of telling VA what he has known for years, that many of his health problems are connected to his service and that the country owes him care and compensation for those injuries and illnesses.

So, in sharing this story, Mr. Grau told my staff that he was willing to risk his life for this country, but he did not realize he would also have to fight for his right to treatment. He said when the U.S. called upon him and his compatriots to serve, they stepped up without pause. They did not wait 10 years to serve, but he is still waiting for much of his benefits and care.

The men and women who served and continue to serve this country do so with an understanding that we will take care of them in return, and we cannot forget all that they and their families have given in service to our country. So, our priority must be about fulfilling our promise to care for them.

For Doctors Rauch and Hastings, throughout our military history, the U.S. servicemembers have been exposed to chemicals and hazards that have had a negative impact on their health, and they have faced unreasonable obstacles in receiving care for the injuries and illnesses that have resulted from those exposures.

While I understand the need for research to inform the process, one cannot cast aside the suffering that servicemembers and veterans who are waiting for the U.S. Government to fulfill its promise to care for those who have borne the battle.

What lessons have been learned in navigating Agent Orange and other exposures to inform the process moving forward for current and future generations of our servicemembers and veterans?

Dr. HASTINGS. Thank you very much. I agree with you that many things have taken too long, and ILER—I go back to the Individual Longitudinal Exposure Record—is one of the lessons learned. We need to be able to match a person with a location, a time, and the exposure.

We have also learned, from the Agent Orange experience, that we need to constantly, during conflict, look at what are those exposures people may have and start studying them right away, and we have done that with airborne hazards. We appreciate the support that this Committee has given us with the Airborne Hazards Open Burn Pit Center of Excellence, that will be able to look at research much more quickly. The electronic health record will make a huge difference because of the transmission of data between the two groups, but we do have the ability to transfer now. This will make it more seamless.

One of the things we need to get good with, in the VA and in my office, in particular, is the manipulation of big data, so we can look at the groups, whether they be a small group, like the Sulphur fires at Al-Mishraq, or a much larger issue like the burn pits. We have learned a lot with the Vietnam experience. We are carrying it over into the burn pits experience.

Mr. RAUCH. I will just add to Dr. Hastings' comment. I agree with you also. We have a duty in the Department of Defense, when we put servicemembers in harm's way, and we do, in some pretty

tough environments, we have an obligation to take care of them. We have an obligation to protect them. And, we have an obligation to sponsor research and technologies to put into our force that deploys to be able to protect them, and at least capture the environment and the exposures that they are deployed into, for a matter of record, and for a matter of care.

Senator SINEMA. In 2008, the National Academy of Sciences published a report that reviewed the presumptive disability decision-making process for veterans, and they offered 19 recommendations on the topic, and 12 were specifically addressed to VA and DOD. A number of these recommendations are geared toward developing and executing improved surveillance strategies, exposure monitoring, medical treatment, tracking, all of which would allow for a more proactive monitoring of exposures and health status of veterans.

How have the DOD and VA effectively addressed the need to keep better record and proactively monitor this data so that servicemembers and veterans who are showing health impacts from these exposures do not have to wait decades for the research to catch up?

Dr. HASTINGS. Senator, I do have a copy of that book, and I agree with you. It had some excellent points in it. That was probably the nidus for a number of things in the DOD and the VA, but most notably the Individual Longitudinal Exposure Record. It also made it apparent that we needed to do coordination, so we meet with the deployment health working group every month, and, in fact, I meet with them tomorrow afternoon. We talk about research, we talk about trends.

Two years ago we were at—actually, two and one-half years ago we were talking about the perfluorinated compounds and the importance of studying that, so we have been working with EPA since that time.

I absolutely agree with you. The ability to share the data, the ability to manipulate the data, is going to be critical, and that is going to improve care, research, and the claims process for veterans.

Senator SINEMA. Thank you. Mr. Chairman, I have exceeded my time. Thank you.

Chairman ISAKSON. Thank you.

Senator Cassidy.

HON. BILL CASSIDY, U.S. SENATOR FROM LOUISIANA

Senator CASSIDY. Thank you. Mr. Rauch, a lot of my questions were set up by Senator Sinema. But, if DOD is not collecting the data, nothing the VA does is going to be of scientific worth. It will be presumptions, and presumptions are based upon assumptions, and assumptions can be manipulated.

So can you go into detail how, if somebody is in Iraq—I saw a picture in the *New York Times* once of them around something which was clearly chemical weapons; they were not known to be there but they found them. How would you then document something which was not a planned exposure, like a burn pit, but rather an incidental exposure, and how would that be filed in a way in

which subsequent investigators would be able to use the information?

Mr. RAUCH. Thank you for the question, Senator. The documentation really begins with the assessment, occupational health, and environmental assessment that is really done by the preventive medicine units that are deployed with—

Senator CASSIDY. I am thinking of a forward—I have limited time so I do not mean to interrupt. I am on the front lines. I am ahead of the support personnel in pursuit of an enemy when we come upon something which could be a toxic exposure. The enlisted man may not know—or woman—may not know that it is, but nonetheless it is. And, later on it is discovered by people coming behind that, indeed it is.

I guess I am not quite sure, in that dynamic situation, how this is being captured.

Mr. RAUCH. Well, it is being captured because even in the forward deployed units you still have organic medical preventive medicine detachments with those forward—

Senator CASSIDY. I do not mean to be incredulous, but we are going to have an MPH—and I do not mean to be rude, but I truly do find that we are going to have somebody with master's of public health adjoining somebody with—going after bad guys, who are moving forward very quickly. And we can imagine, in that situation, that they would come up on multiple situations which would require an assessment. So, you would have to have redundancy in terms of your ability to track and trace, if you will.

Because that does not seem logistically feasible to me, but is that the current plan?

Mr. RAUCH. Well, our ability to capture exposure information to far forward forces is really dependent upon our preventive medicine units that are in support of those far forward forces, and they move right along with those far forward forces.

Senator CASSIDY. I do not see—in all fairness, I do not see how, in the battle zone, that is going to be practical, because you would have to have a fair number of folks, presuming that the squad may end up being dispersed—I keep on think of what if in Fallujah, in Fallujah a firefight every street, with snipers all around, but you stumble upon chemical weapons. Again, I do not mean to challenge you. I know this sounds rude, and I apologize for that. But, I do find this—I am not quite sure how it works.

I think Dr. Hastings just gave you a note, so Dr. Hastings, if you have something, again, I am just trying to understand this.

Dr. HASTINGS. Like passing notes in school, it is bad.

Senator CASSIDY. No, no, no. I am OK with that, because I just want answers.

Dr. HASTINGS. Absolutely. Some of it is done after the fact, and I have two examples, if I might. One is Qarmat Ali, the water treatment plant outside Basra, that had the hexavalent chromium—if anyone remembers that was the chemical in the Erin Brockovich movie. There were about 800 servicemembers that were exposed to that. It was noted during the time that they were there. We have their names. We are following up with them with letters and chest x-rays.

Senator CASSIDY. So, let me ask you, when the soldier is on the battlefield, is their GPS location tracked so that if, at a later point, you can see that there was exposure to something, such as that?

Dr. HASTINGS. They do track the location of the units.

Senator CASSIDY. And of the—would you be confident that the members of the unit would stay sufficiently together that if the unit were in a location, all would be in that location?

Dr. HASTINGS. Some individuals may leave—this is speaking from my time in the military, when I was deployed to Iraq. Some of it would be self-reporting. But, we also have chemical weapons agents. There were some servicemembers exposed to chemical weapons agents. We looked at their medical records, and, in fact, Dr. Helmer has put a note in all of their medical records in the VA, so that we can track them. And this was a combination between the DOD and the VA.

Senator CASSIDY. One more thing, because I am out of time. That would go to location but not to intensity of exposure. Correct?

Dr. HASTINGS. The intensity of exposure was examined not only were they seen at the time of the occurrence but they were looked at later at Walter Reed Army Medical Center, actually, Walter Reed National Military Medical Center now, and did get a screening exam, an exam which was transmitted to the VA. We are now caring for those individuals.

Senator CASSIDY. No. I mean, there can be a threshold effect of exposure. A little bit of sunlight is not bad, but too much sunlight gives you melanoma. And so—but I am over time and I will stop there. Thank you very much.

Chairman ISAKSON. Senator Manchin.

HON. JOE MANCHIN III, U.S. SENATOR FROM WEST VIRGINIA

Senator MANCHIN. Thank you, Mr. Chairman, and I am going to follow up on what you had mentioned. I want to thank you and Senator Tester for being so attentive to a horrible situation, and I can report what I know, that has been publicly made, and I think you all know a little bit about it, in Clarksburg, WV. We know that we had at least two of our veterans murdered, and maybe more. It is a horrible, horrible situation.

Let me tell you something that is even more disturbing. The people in charge—the people in charge at that VA hospital—and the VA hospital has had a good record of doing great jobs and doing good work—they did not know—did not know; this is the head doctor in charge, and the head of nursing—so they didn't know. But, the inspector general was able to find, in an investigation that was done very quickly, that almost 9 months before they even said they knew, which the inspector general found very expediently that somebody knew something, that there were some concerns 9 months prior to that.

Nothing adds up here. Nothing makes any sense. We are in a— it is a homicide, and it is going to be horrible when we find out the details. We do not know if it is one person of interest or more. We do not know.

What I also did not know is how the VA controls its medication on the floors; I mean, who has control of that, who has access to it. Then, I also did not know this. I did not know that basically in-

sulin—this is hypoglycemia, in all these cases—that insulin can be purchased in any pharmacy, without any prescription, and you can get a syringe to administer it. There are so many fallacies in all of this.

We are going to need all hands on deck. Our veterans deserve better than this, and to have this horrible, horrible atrocity on these veterans is something that is unexplainable. You can imagine the fear that we have. Operations are being canceled. They are afraid of getting services, and things on and on and on.

Hopefully—and I want to thank you again, both of you, for being attentive to this. We need to get to the bottom as quick as possible. The inspector general—it has been over a year now, this has been under investigation—I mean, the northern prosecuting attorney, U.S. attorney is on top of this, and I have all the confidence in him, because his father is a veteran and also uses the hospitals and clinics.

I just want you all to be aware, and I hope you are looking through all your operations, all the operations, throughout the hospitals and clinics throughout this country.

On another note here, I know we were talking; I know Senator Cassidy was talking about, as am I, about the veterans who served in Iraq and Afghanistan after 9/11. They were exposed to large-scale use of open-air pits to dispose of waste during combat operations. The burn pits exposed our servicemembers to toxic chemicals, like benzene, arsenic, freon, sulfuric acid, which have had all sorts of impact on otherwise healthy veterans. That is why many are calling burn pits this generation's Agent Orange.

That is why I am working on a bill with Senator Sullivan to provide presumption of exposure, not presumption of benefits, for veterans who served in an area with burn pits. Our bill would make it easier for veterans to prove their exposure to toxic burn pits.

My question would be, we cannot take as long on burn pits as we did on Agent Orange to take care of our veterans. What are the VA and DOD doing in accelerating research into the health impacts of these chemicals?

Dr. HASTINGS. Sir, I will go ahead and start, then I am sure that Dr. Rauch would probably have something to add.

We work with the DOD very closely on research. We also work with our academic institutions. We have Airborne Hazard Symposium that takes place each year. DOD ran it last year and we will be running it this year. We do invite the VSOs to that. We have over 50 research projects right now with the DOD in regard to the toxic substances. We have SME exchanges. We do conferences together. We publish our information in the peer-reviewed journals. And this is not only beneficial to the veterans and the active-duty servicemembers but also to the civilian community that are also affected by toxic hazards at other—

Senator MANCHIN. Let me just, if I may, interrupt real quick.

Dr. HASTINGS. Certainly.

Senator MANCHIN. You know, we know about Agent Orange. We did not know until well after, many, many years after the exposure that Agent Orange even, had not a direct but incidental exposure. So, we know what effects it is having now. The burn pits we know

because it has been reported and all the different types of toxic material that are being disposed of identified.

Are we looking at other ways our servicemembers are being exposed to toxic chemicals that could have an effect? Are we doing that in a proactive way or are we just waiting until we have these devastating effects to their health?

Dr. HASTINGS. We are looking very proactively. We learned a lot from Agent Orange. That is the unfortunate reality. We are looking at burn pits proactively. We are actually looking at the health effects right now with the National Academy. They are doing a report that we will have next October. We know that intergenerational effects are of concern to veterans also. We just had an intergenerational effects report that came to us from the National Academy.

We want the answers to come more quickly. We are datamining the registry. We are actively pursuing the electronic health record and the Individual Longitudinal Exposure Record, because that really will make a difference with looking at exposures, and even in some cases of very small exposures.

Dr. HELMER. Could I just add to that?

Senator MANCHIN. Please.

Dr. HELMER. I was the Director at the War-Related Illness and Injury Study Center and I would like to just say that the Burn Pit Center of Excellence that is based there is really doing exactly what Dr. Hastings said. We are taking advantage of some of the data that have already been gathered, and ILER is going to make that even better.

But, as of right now we have 185,000 veterans and servicemembers who have participated in the Burn Pit Registry, and because it is the modern registry where the data are online, it is pretty instantaneous that we get access to the information, from the veteran themselves, which we can link to the electronic medical record and actually do this cross-match through the big data activities, to see what is going on.

So, we generate reports on a quarterly basis and more often.

Senator MANCHIN. I know about the reports. I am asking, are we being proactive in looking at other exposure, exposures that our servicemembers might have that we do not—we are not even looking at at this point in time? We have only seen, you know, post, if you will, what happened with Agent Orange, now what happens with burn pits. Is there something else besides Agent Orange and burn pits we should be looking at, that we are exposing our servicemembers to?

Dr. HELMER. On the VA side, certainly as a clinician I get that information, and as the War-Related Illness and Injury Study Center, people are referred to us, we take that information and we share it with our colleagues in Central Office, and it is shared with the DOD through the Defense Health Working Group. But, we are not able to do the assessments in real time, in terms of the exposures.

Chairman ISAKSON. Thank you, Senator Manchin.
Senator Sullivan.

HON. DAN SULLIVAN, U.S. SENATOR FROM ALASKA

Senator SULLIVAN. Thank you, Mr. Chairman, and I want to thank Senator Manchin. We have—

Senator BROWN. [Off microphone.]

Senator SULLIVAN. Yeah, I think we go—thank you. So, I want to thank Senator Manchin for the work. His questions are going to be similar to mine, because what we are trying to do with our bill is get this right, get this right in terms of how we do it, but we are going to need your help. And there are lessons learned, right, from previous examples of toxic exposure.

I also want to just thank the Chairman here. And, you know, in light of his announcement that he is going to retire at the end of year, I just want to thank him, in this Committee, on the great leadership that he has provided all of us for all of our veterans. A true champion of our veterans. I think when you see how much impactful legislation this Committee gets done, it is, in large measure, due to the distinguished Senator from Georgia. So, I am honored to serve with him. Thank you, Mr. Chairman.

Let me follow up. Again, it is more process. We are always talking process, and I think it is important for legislation. But, we have got to remember that there are people at the end of the process chain, and I know you guys all know that.

Let me just ask a couple of questions that are going to help us refine this kind of legislation and work with all of you to get it right. How does DOD assist a servicemember who is deployed at a site with a known burn pit but does not have it in their health records? So, that is kind of a big gap in how can we or the Department of Defense or VA try to address that gap?

Mr. RAUCH. Well, thank you, Senator, for the question. At the deployed site, as I explained in some previous remarks, there are preventative medicine assessment teams that do health hazard and occupational health assessments. If a servicemember presents a complaint to the medical unit while they are deployed, that is documented. It is in their medical record. And then as we explained a little while ago, now that medical record is going to be linked to ILLER, which is a long-term environmental health exposure record.

Senator SULLIVAN. But, if you have a soldier, a Marine who is like, "Well, wait. I was in Bagram. I know there is—and my medical record does not indicate this." Is there a way to fix that?

Mr. RAUCH. Certainly. I mean, the servicemember can present to their provider, and the provider can so indicate those symptoms in the servicemember's record. Also, the provider, if it is primary care, can refer that servicemember in to occupational health.

Senator SULLIVAN. OK. Let me ask Dr. Hastings, according to the VA, from 2007 through 2018, there were 11,500 burn pit claims lodged with the VA. Out of those, over 9,000, or 80 percent, were denied. My staff has been working with your staff on trying to get a little granularity on why the majority of these claims were denied.

Can you go into a little bit more detail from your perspective? I know they are individual cases, but that is a pretty high number. Maybe you could submit for the record, to the Committee here, in a little bit more detail than you have with a minute left in my

questioning on why you think that pretty high majority of claims is denied, at least at this juncture.

Dr. HASTINGS. Sir, I would be very happy to go ahead and get that information for you on the number of claims that are covered and not covered. If it would not be inappropriate, I would also like to just answer your other question just a little bit—

Senator SULLIVAN. Sure.

Dr. HASTINGS [continuing]. In regard to—

Senator SULLIVAN. Do you have an answer to my first question?

Dr. HASTINGS. Your first question—

Senator SULLIVAN. Eighty percent—

Dr. HASTINGS. I do not. I would have to look at what the reasons were. I know that in the top 10 reasons that people put in a burn pit claim, some of them do not seem like they would be related to burn pits—

Senator SULLIVAN. OK.

Dr. HASTINGS [continuing]. But, I do not have the medical records and review. Some are complaining of irritable bowel syndrome. Some people are complaining of migraines. The sinusitis and the breathing problems, those are pretty easy to connect. Some of the others that would be harder to connect would be things that were not associated with the respiratory system. I would be very happy to talk to VBA and get that information for you.

Senator SULLIVAN. Good. That would be helpful.

[The information requested during the hearing follows:]

RESPONSE TO REQUEST ARISING DURING THE HEARING BY HON. DAN SULLIVAN TO PATRICIA R. HASTINGS, M.D., CHIEF CONSULTANT, POST-DEPLOYMENT HEALTH, U.S. DEPARTMENT OF VETERANS AFFAIRS

Question. OK. Let me ask Dr. Hastings, according to the VA, from 2007 through 2018, there were 11,500 burn pit claims lodged with the VA. Out of those, over 9,000, or 80 percent, were denied. My staff has been working with your staff on trying to get a little granularity on why the majority of these claims were denied. But can you go into a little bit more detail from your perspective? I know it is individual ones, but that is a pretty high number. And maybe you could submit, for the record, to the Committee here, in a little bit more detail than you have, with a minute left and my questioning on why you think that pretty high majority of claims is denied, at least at this juncture.

Response. The most common reason for denying burn pit related claims is that the Veteran's record did not contain evidence that the claimed condition was incurred in or caused by military service. The second most common reason is that there was no evidence that the Veteran had a current diagnosis showing the presence of the condition they were claiming.

Senator SULLIVAN. On the other one?

Dr. HASTINGS. On the other one, everyone goes through a post-deployment health assessment when they come back. I have gone through several of those. I did them for my co-servicemembers as their physician, and I also had someone else do them for me. We also have the feed from the Defense Manpower Data Center, so we know where people were.

Now, there are times that they would be sent out of area, but for the most part we know where people were. Frankly, in most cases, we do believe the servicemember or the veteran. In fact, I know of stories where there were no records of the person being in Vietnam because they flew from Korea. All we asked for was a picture of them in front of their aircraft at the Osan Air Base. So, in the ma-

majority of cases, we do believe the information that is given to us by the veteran.

Senator SULLIVAN. Great. Thank you. Thank you, Mr. Chairman. Chairman ISAKSON. Thanks, Senator Sullivan. Before I go to Senator Brown I want to say that while he was a little bit late, there is something we need to take care of. Senator Brown is the reason this hearing is taking place today. He and Senator Tester and a few others have insisted on us dealing with toxic exposure and getting that information for us. So, even though he was a little bit late he did not need to apologize for that. He told me yesterday he would be. He is appropriately here now and I want to introduce him with the appropriate credit for what he did.

HON. SHERROD BROWN, U.S. SENATOR FROM OHIO

Senator BROWN. Thank you, Senator Isakson. Thanks to you and Senator Tester for this hearing, and your Staff—Pat, Leslie, Adam, Simon, J.C., and Tony, and my staff, Anne and Drew. This is such an important hearing and I appreciate all of you being here.

Senator Tester, Senator Isakson, and I—Senator Moran came a little bit later—we have been on this Committee for 13 years now. I have known Johnny longer, but Jon and I are with him for 13 years. And, the question is always, “Why isn’t the VA taking better care of these awful illnesses and diseases?” The question never seems to be, “Why do we pursue stupid wars in Vietnam and Iraq?” So, now I worry, with Iran and the tough talk and the escalation on both sides, where this leads.

Sitting on this Committee really makes you, I think, understand the cost of war, and what Senator Sinema said about this constituent of hers waking up and still thinking about Vietnam five decades later ought to be a lesson to our policymakers and President on making some of the decisions they have had on if we go to war with Iran—three big, stupid wars in a row.

Dr. Hastings, on March 26, not you but VA officials told this Committee that within 90 days the Department would make a decision on expanding the list of Agent Orange presumptive diseases to include bladder cancer, hypothyroidism, Parkinson’s-like symptoms, and hypertension. March 26th—April, May—June 26th was the 90 days. Now it has been 183 days. You just told the Committee the decision is within leadership. It might be a commentary on your leadership, but when is this going to be made?

Dr. HASTINGS. It is in leadership and it is in coordination with other Federal agencies. So, I am as hopeful for a decision soon as you are.

Senator BROWN. Can you do anything about more than hope? Can you accelerate this? I mean, it has been twice the 90 days that your superiors came in here and promised. I assume they are your superiors.

Dr. HASTINGS. Pretty much everybody is my superior.

Senator BROWN. I do not think so, but—

Dr. HASTINGS. I can absolutely find out where it is in the process with the external coordination, and I would be very happy to get that information and give you that brief.

Senator BROWN. OK. I mean, every day we wait on presumptive eligibility is more people fighting with the VA, more of your re-

sources, processing these, with less certitude, and probably more men and women dying from one of these illnesses.

I will shift to burn pits. Since forces deployed to Afghanistan and Iraq, DOD has known that burn pits, similar to Dow Chemical and probably DOD knowing about Agent Orange, DOD has known that burn pits released toxic blooms into the air. There are memos, one dating back to 2006, near the beginning of the Iraq war or soon after, containing phrases like “an acute health hazard for individuals,” another phrase, “possibility for chronic health hazards associated with smoke,” another, “the known carcinogens and respiratory sensitizers released from the atmosphere present both an acute and a chronic health hazard to our troops and our local population.”

But, the burn pits continued, the size of football fields, is my understanding. Air quality testing in Bagram airfield found that air samples were considered, “unhealthy by EPA standards.”

Dr. Rauch, walk me through the Department’s thinking here. If we have weekly air sample data from burn pits that routinely show particulate matter exceeding EPA health standards, DOD shared that raw data with VA or outside experts to build a comprehensive picture of what our servicemembers, civilians, contractors in the local populations were exposed to. So, walk me through this. What is the problem?

Mr. RAUCH. Well, the Department’s position is in response, really, to, I believe it was on the House side that requested a report from the Department, which is due February, on alternatives to burn pit—technology alternatives to burn pits in the deployed environment.

That report is still ongoing, in terms of the analysis and the proposed solutions, but the Department is moving away from open burn pits—

Senator BROWN. As they should have. But, let me boil it down. DOD shared that information with VA years and years ago. Am I correct?

Mr. RAUCH. Well, I—we share information with the VA all the time. I can’t say it was years and years ago.

Senator BROWN. OK. I would really like to know some of those comments made, that I quoted, and other data from DOD, I would like to know when, in fact, that was shared with the VA, first point, and if you would get that to us—

Mr. RAUCH. I will.

[Responses were not received within the Committee’s timeframe for publication.]

Senator BROWN [continuing]. At some point. You know, I would like to know what local population were exposed to. That is really important. We go into these war zones. We leave behind lots of things, some toxic, sometimes a better life for people. But, sometimes—you get it.

And last, Dr. Hastings, has VA established a presumption of eligibility of service connection and list of diseases associated with exposure? Senator Manchin asked about, you know, it took us a long time, but we learned something from Agent Orange. We were too slow. Elected officials were too slow. VA, we were all too slow. DOD knew more than they told us, all those things.

But, we know that burn pits—exposure to burn pits is a very serious thing, resulting in illness and sometimes death. Are we going to do a presumption of service connection and list diseases on burn pits? If we are, when, and why not yet?

Dr. HASTINGS. I do not know if we will be required to do a presumption for burn pits. We are getting a lot more information—
Senator BROWN. What do you mean, required?

Dr. HASTINGS. I do not know if a presumption will be necessary. We may be able to do it on an individual basis. If we do have a presumption that comes out, I believe we would look at it after the National Academy Report that we will get in October of next year.

I would like to ask my colleague, Dr. Helmer, who was previously at the War-Related Illness and Injury Study Center at the Airborne Hazard and Open Burn Pit Center of Excellence if he has any comments in regard to that.

Dr. HELMER. I think you are seeing a real flourishing of information and scientific, high-quality research that is coming out about what might be associated with, let's start with the unexplained shortness of breath and decreased exercise tolerance that many of our veterans have reported since their deployment to Iraq or Afghanistan.

I think at this point there are multiple potential causes, the burn pit smoke being one of them. The ambient air quality was actually highlighted by the National Academy's report in 2011 as maybe the most likely source of the problem for those servicemembers. And our own work, more recently, has actually highlighted the possibility of blast over pressure as being a contributing factor, at least in some individuals experiencing shortness of breath.

I think there is a lot of good science that is being done, and we are getting a better understanding of what the causal factors might be. So, I would just—you know, before a presumption is determined, perhaps, we should understand a little better about why.

Senator BROWN. Thank you. I see that. My time is way over, but I want to make three real quick comments.

First of all, there seems to be a lack of urgency in all of this, as people get sick and die, in far too many cases, and every time we wait to add names to the presumption list, to the Agent Orange presumptive eligibility list, every time we talk about this with burn pits, another day goes by in people's lives. That is one point.

Dr. Hastings, you used the word "requirement." Well, there is no requirement. Congress should pass a requirement, but you can move on a requirement of beginning to compile which diseases should, in fact, be on this list.

And third, that you made a statement—and you do not need to respond now. It is just that I am over time—but you made a statement that the VA—that we do not know if we need presumptive eligibility, that we can handle each one individually—and that is the whole point. If we handle each one it just slows everything down. That is what we tried to do with Agent Orange for, I don't know, two decades, or whatever, until Congress and the VA and the public and the DAV and the VFW and The American Legion and Polish American Vets had all figured this out, that we need presumptive eligibility.

So, those are just my three assertions that I hope you take into account. Thank you, Mr. Chairman.

Chairman ISAKSON. Thank you, Senator Brown.
Senator Moran.

HON. JERRY MORAN, U.S. SENATOR FROM KANSAS

Senator MORAN. Mr. Chairman, thank you. It is a pleasing thing to me that it is not Senator Tester who is departing the Committee but you, because I could not find anything nice to say about Senator Tester. [Laughter.]

But, if you say that, I will believe it. I would take this moment to thank you for your leadership on this Committee and your love, care, and compassion for the U.S. Senate, for the citizens of Georgia, and, most particularly in this instance, for the veterans of America.

I have been in a number of settings where you have received accolades, toasts, and cheers, pats on the back and cheers, a lot about who you are as a person, a man who was interested in bipartisanship, a person who cares about this institution for its well-being and the well-being of America, your willingness to, in addition to working across the aisle, trying to find right answers and treating people with respect. Those are things that ought to be able to be said about every person in public life, and, unfortunately, it is more rare than it should be.

So, for you and the way you treat people and the role model that you provide for those of us who serve in public service, I thank you for that. I cannot imagine that one would want to be known more than being a good person, but I would add to that there is not a veteran in this country who has not benefited by what you have done on their behalf. So, I commend you for that and I respect you for that. Should Senator Tester retire or be defeated, I will work on something to say about him as well.

I appreciate you having this hearing and the leadership that many around the table have led on toxic exposure. My particular interest was piqued in 2014, when I attended a conference in Wichita, KS, hosted by the Vietnam Veterans of American, on toxic exposure. I visited with veterans who certainly experienced the consequences of that exposure themselves.

What captured my attention even more than that was the realization, the belief, the recognition that there are those who are the children and grandchildren of those veterans who, it is believed, are experiencing consequences from their mother, father, or their grandparents' exposure to toxic substances. We set out to try to do something to find out what the nature of the relationship is between toxic exposure for a veteran, for a military man or woman, and those who follow them, their children and grandchildren.

My guess is that most every service man or woman recognizes that they are creating risks for themselves, but what a tremendous burden it must be to recognize that something you did, in service to your country, has a consequence to those in your family who are yet to be born.

So, I will save my questions for the second panel. I am interested in the scientific nature of the study that has been completed.

Senator Blumenthal and I teamed up on this issue. We introduced legislation that would require a scientific study, review and assessment conducted by the National Academy of Sciences, regarding the toxicological and epidemiological research on descendants of individuals with toxic exposure. I am interested in hearing more about what the results from the National Academy of Sciences is, so that we can set the stage to care for those who, through no actions of their own, now may be suffering from the actions of the patriotic service of their parents and grandparents.

Senator Tester and I, we teamed up to try to get legislation passed, which we were successful, that declassifies records of veterans exposed to toxins, so they can better pursue their claims. One of the things I learned in those conversations with those veterans that day in Wichita was that we cannot often prove our case to the Department of Veterans Affairs because of the places that were served, the circumstances we served under, the records simply are not available.

So, that bill is part of NDAA, which a year or so ago became law, and I needed to follow up and make certain that there is a consequence to the law changing and that veterans have greater access to those records.

And, I would suggest to this panel that we are spending a lot of money on information services. The DOD, in my view, ought to be able to collect—it is a bit of what Senator Sullivan was talking about—ought to be able to collect information when that military man or woman returns and enters into the care of the VA. That is the moment—as you tell your personal history and your medical history, that is the point at which that service man and woman ought to be able to tell their story.

But, I also would say that with the new electronic health records that we have underway, that could be the place to capture the exposure information and track conditions, not only of that military man or woman, and soon to be veteran, but also their family members, as well.

I would recommend to the VA, if you are not specifically looking at electronic medical records, that ought to be an awfully good place to start as we presumably are on a path that puts the Department of Defense and the Department of Veterans Affairs in the same system.

Mr. Chairman, thank you for the opportunity to make those remarks, and I will save my questions for Panel 2.

Chairman ISAKSON. Thank you, Senator Moran.
Senator Blumenthal.

**HON. RICHARD BLUMENTHAL,
U.S. SENATOR FROM CONNECTICUT**

Senator BLUMENTHAL. Thank you, Mr. Chairman. I want to thank both you and the Ranking member for holding this year. I apologize that I was at other hearings, so missed the first panel, but I just want to—I am sorry—I missed the beginning of the testimony from the first panel.

I want to really second, as strongly as possible, the point made by Senator Tester, that the VA seems to be needless staying and delaying the Blue Water Navy veteran Vietnam claims. The date

is now January 1, 2020. The VA had been issuing claims decision since April 2019.

I do not need to go over the history of the Blue Water Navy veterans, but I am proud of the work that we have done, on a bipartisan basis, over the past several years, to pass the Blue Water Navy Act. And I am deeply disappointed—in fact, I am angry, like a number of my colleagues, that the VA chose to stay all these claims until the last possible minute, rather than work to grant them as soon as possible.

So, I hope that the VA can address this issue and move forward without hiding behind their lawyers. I have nothing against lawyers. I am one myself. But, the VA has no excuse for failing to move forward on these claims.

I am also concerned, and I have been very proud to team with my colleague, Senator Moran, on the issue of burn pits, airborne hazards, and other toxins and poisons on the battlefield. Many of us have a personal stake in this issue, having family members who have served there. I am concerned that the DOD continues to use open burn pits when we know there are serious medical consequences for our troops. We have got millions of servicemembers deployed to areas in which the DOD's own tests show the air is not safe to breathe, and we are, in effect, repeating mistakes that we made in the past with our Agent Orange veterans.

I know Senator Sullivan asked you, Dr. Rauch, about this topic, but can you specify what DOD reporting requirements are for exposure to burn pits? Does the DOD keep records of detailed information, that would allow the VA and veterans to establish a claim for disability?

Mr. RAUCH. Thank you, Senator, for the question. First of all, the Department's position is to move away from burn pits and replace them with alternative technologies. The documentation of ambient air quality surrounding burn pits and the deployed environment is collected by area air monitoring, which is done daily by the preventive medicine that is organic to the unit attached to that area. So the ambient air quality is assessed 24/7, as well as other environmental hazards in that area.

Senator BLUMENTHAL. So, a veteran could establish the connection between the disability and that service connection?

Mr. RAUCH. Well, the veteran—so I am talking about air monitoring in an area. So, now we are talking about an individual in that area, and once again, determining what the rate or degree of exposure is difficult. I can just tell you that the Department is not there on—

Senator BLUMENTHAL. Could the DOD establish better measures?

Mr. RAUCH. Absolutely. Absolutely.

Senator BLUMENTHAL. Do you think that it will?

Mr. RAUCH. We will. We have a research effort to develop technologies—it is probably going to be wearable—for the individual, that would characterize and capture the exposures at a point in time to that individual servicemember. This is research, so it is not going to happen tomorrow, but it is an active research effort that we are spending money on.

Senator BLUMENTHAL. Dr. Hastings, can you explain why the VA has stayed every single claim under the Blue Water Navy Act?

Dr. HASTINGS. I know that the VBA is getting ready for January, but I cannot tell you why there is a stay.

Senator BLUMENTHAL. You cannot tell us why?

Dr. HASTINGS. I do not know.

Senator BLUMENTHAL. Well, I would like to ask you to respond in writing.

Dr. HASTINGS. I absolutely will, sir.

[The information requested during the hearing follows:]

RESPONSE TO REQUEST ARISING DURING THE HEARING BY HON. RICHARD BLUMENTHAL TO PATRICIA R. HASTINGS, M.D., CHIEF CONSULTANT, POST-DEPLOYMENT HEALTH, U.S. DEPARTMENT OF VETERANS AFFAIRS

Question. Dr. Hastings, can you explain why the VA has stayed every single claim under the Blue Water Navy Act?

Response. VBA is working to ensure that the proper resources are in place to meet the needs of all claimants whose claims have been stayed, as authorized by the Blue Water Navy Vietnam Veterans Act of 2019. In addition to claims based on service in the offshore waters of the Republic of Vietnam, the claims affected by the stay include all claims based on service along the Korean DMZ between September 1, 1967, and August 31, 1971, as well as claims for spina bifida based on exposure in Thailand.

Although some claimants with service along the Korean DMZ may have been eligible for benefits prior to the passage of the law, VA has elected to stay all claims specifically allowed by the Act. This has been necessary to ensure that VA processes and adjudicates all affected claims in an accurate and consistent fashion by carefully implementing the Act as Congress intended. VA is using this time until January 1, 2020, to build tools and procedures for claims adjudication and to develop evidence for the claims to appropriately identify qualifying service. VA continues to process all claims which the Act did not expressly allow to be stayed.

Senator BLUMENTHAL. Thank you. My time has expired. Thank you, Mr. Chairman.

Chairman ISAKSON. Thank you.

Senator Tillis.

HON. THOM TILLIS, U.S. SENATOR FROM NORTH CAROLINA

Senator TILLIS. Thank you, Mr. Chairman. I want to associate myself with the comments made by Senator Moran about you and your role-model behavior. I will only take one exception to something that Senator Moran said. "Senator Tester, I like your hair." [Laughter.]

That is a place to build on.

Thank you all for being here. I want to go back. It was not a question I had intended to ask, but I think it is very important, since we have the DOD and the VA represented here. One thing that I am very interested in and excited about, is having more compatible electronic health records going forward.

Dr. Rauch, as we move forward and we collect more information, I think we need to understand the situation that we find ourselves in sometimes when burn pits are used today. These are very dangerous situations where they are trying to do the best to get out of a dangerous situation. It is clearly not a preferred technique, and I know we are looking for other ones. So, while we still have these practices in place, we have to capture more information, have more insight into how individuals were exposed.

I am particularly interested in making sure that once we capture that data it becomes a part of the lifetime record for that soldier when they move into veteran status, so that, over time, we may be

able to predict a risk before any symptoms manifest themselves. So, that is the idea future state of fully-interactive, integrated electronic health records, and I think the research that you say that you are working on may be an indicator that we need to make sure ultimately finds itself into the man or woman who is serving at the time of exposure.

Ms. Hastings, I had a question for you on the family member program, specifically around some of the toxic substances that you may know that we worked a fair amount on the toxic substances issue down at Camp Lejeune. And I believe the number is right, that we have about 300 family members who may have been exposed to toxic substances that seem to be linked in utero, but they are having a difficult time getting care.

So, what do we need to do, if it is not within the VA's authorities, to step up that family member care? What should we be looking at, as a matter of policies that we should consider for congressional action?

Dr. HASTINGS. Sir, I am very active in the Camp Lejeune Community Assistance panel meetings, and, in fact, they had one here in D.C. the 13th and 14th, which I did attend. They are run by the Agency for Toxic Substance Diseases Registry. If there was a child in utero, and had a specified relationship with the veteran on Camp Lejeune—

Senator TILLIS. In the time period in question?

Dr. HASTINGS [continuing]. In the time period in question, they are covered for those 15 covered conditions. And the community program, the Community Care Program, run out of Denver, I routinely talk with them if there are problems. Whether they are financial or medical reviews, we help them with them. If you have a specific case, I am very happy to take that forward to the Community Care group, because I do also get individual requests from people. I had one yesterday. I am very willing to run the traps and help people.

Senator TILLIS. It may very well be that once they go through the traps they are in a good place. Some of it seems to be getting them to the point to where I guess they present a sufficient case. We will go back—I do not do casework in committee hearings, but we will go back to any specific cases. But, the main thing, much the same way that we went through some of the presumptions, you know, we got to, I think, a much better place in terms of the presumptions a couple of years ago. But, it is sort of giving them the benefit of the doubt, if a significant part of the information that they present looks like they should be qualified for support. So, we will deal with that outside of the Committee.

The other question that I did have for you, though, was this idea—and I saw this when we were going through the Camp Lejeune discussion, about some of the additional presumptions. Do you think that there is a value in us having—as more information is available, more scientific data is available—that we have more frequent reviews of presumptions and update these? It took a lot of time and effort for us to get where we ultimately got, under the Ensminger Act and some of the other VA decisions. But, what more could we do to just make this a recurring, iterative process, not episodic?

Dr. HASTINGS. I just agreed, at this last Community Assistance panel meeting, to talk with the Agency for Toxic Substance Disease Registry and have another meeting to review the new scientific literature. I did review much of the research that they have just completed. I have my epidemiologists working on that right now.

Senator TILLIS. Thank you very much. Thank you, Mr. Chair.

Chairman ISAKSON. Thank you, Senator. Before I introduce Panel 2 I want to turn the gavel over to Senator Tester, who has agreed to finish the balance of the hearing, which I appreciate very much. I have a previous commitment that I have to finish with.

I want to say, though, that this is the best participation for any meeting we have had. Almost every Member of the Committee, at one time or another, was in asking questions, and our panel did an excellent job and I want to thank both of you for your time.

I will ask Panel 2 to move forward and Panel 1 may move out.

Senator TESTER. Can I just say one thing?

Chairman ISAKSON. Before that, Senator Tester has a comment.

Senator TESTER. I appreciate you guys' testimony and I really appreciate your work, when you talk about the studies that you are doing. Ultimately, decisions have to be made.

I think Senator Brown touched on this. I often think that there is an adversarial relationship between the VA and the veterans. I don't think that is you guys' intent, but the truth is we have got folks out there that are dying, that were put in positions that got them that way.

I am a farmer. I could get hit by a tractor and get killed any time. That is my choice. These folks were put in positions—and you folks; you are probably all military, right, at one time or another—were put in positions that you had no control over. We have an obligation to deal with these folks in a timely manner.

You do good work. We need to make sure that your work results in decisions, not just reports. Again, I just want to thank you for being here today.

Dr. HASTINGS. Thank you, sir.

Dr. HELMER. Thank you.

Chairman ISAKSON. Panel number 2, please come forward.

[Pause.]

Senator Tester [presiding]. First of all, I want to welcome the second panel. This is going to be a very, very brief introduction, and forgive me for that. You all deserve a longer one.

I want to first introduce Dr. David Butler, Director of the Office of Military and Veterans Health, the National Academies of Sciences, Engineering, and Medicine. Thank you for being here, David. We have got Mr. Shane L. Liermann, who is familiar to all of us. He is DAV Deputy National Legislative Director for Benefits. Thank you for being here, Shane. And, we have Dr. Robert Miller, from Vanderbilt University Medical Center. We appreciate you making the trek up, Robert. Thank you.

We will let you start, Dr. Butler. You have got 5 minutes, and the remainder of your testimony will be put in the record.

**STATEMENT OF DAVID BUTLER, Ph.D., DIRECTOR, OFFICE OF
MILITARY AND VETERANS HEALTH, HEALTH AND MEDICINE
DIVISION, THE NATIONAL ACADEMIES OF SCIENCES, ENGI-
NEERING, AND MEDICINE**

Mr. BUTLER. Thank you, Ranking Member Tester, and Members of the Committee, for the opportunity to testify today. As you mentioned, my name is Dr. David Butler. I serve as a Scholar in the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine, and director of its Office of Military and Veterans Health.

The National Academies have a long history of advising the Federal Government on the health effects of military service in general, and on the effects of in-theater exposures resulting from military activities, in particular. We have also, when requested, offered perspectives on the decisionmaking processes used by the Department of Veterans Affairs in their determination of whether a particular health problem in a veteran may be associated with their military service.

The most recent report addressing this issue as it relates to toxic exposures is entitled "Improving the Presumptive Disability Decision-Making Process for Veterans," which was released in 2008. The study committee formed to research and write that report was charged with describing the process for how presumptive decisions are made for veterans who have health conditions arising from military service and proposing a scientific framework for making such presumptive decisions in the future.

To address its charge, the study committee conducted a thorough review of relevant research and met with a full range of involved stakeholders, including Congress, the VA, veteran service organizations, and individual veterans. It attempted to capture how VA's presumptive disability determination approach works and completed a set of case studies to identify lessons learned that would be useful in proposing new approaches.

The study committee also considered how information obtained on the health of veterans and how exposures during military service can be linked to health consequences via scientific investigation. Substantial attention was paid to how information can best be synthesized to determine if a particular exposure is associated with a risk to health.

This assessment led the study committee to recommend an approach to assure that the presumptive disability decisionmaking process is based on the best possible scientific evidence.

That approach comprised the following components: an open process for nominating exposures and health conditions for review, involving all stakeholders in the process; a revised process for evaluating scientific information on whether a given exposure causes a health condition in veterans, including a revised set of categories to assess the strength of evidence for an association, and estimate the number of exposed veterans whose health condition might be attributed to their military exposure; a consistent and transparent presumptive disability determination process by the VA; a system for tracking exposures of military personnel and for monitoring the health conditions of all military personnel while in service and

after separation; and an organizational structure to support this process.

To support the implementation of the study's recommendations, it suggested the creation of two panels. One was an advisory committee to the VA that would assemble, consider, and give priority to exposures and health conditions proposed for possible presumptive evaluation. Nominations for presumptions could come from veterans or other stakeholders, as well as from health tracking, surveillance, and research.

The second panel was a scientific review board, an independent body that would evaluate the strength of evidence that links a health condition to a military exposure, and then estimates the fraction of exposed veterans whose health condition could be attributed to their military exposure. The scientific review board's reports and recommendations would then go to VA for its consideration.

The VA would use explicit criteria to render a decision with regard to whether a presumption would be established. In addition, the scientific review board would monitor information on the health of veterans as it accumulates over time in DOD and VA tracking systems, and nominate new exposures for health conditions for evaluation, as appropriate.

The report suggested that this framework be considered as a model to guide the evolution of the current process. It observed that the ability to implement changes would be improved by the provision of appropriate resources for all the participants in the presumptive disability decision-making process.

The study committee recognized that action by Congress would be needed to implement all of the components of its proposed approach, but noted that some changes could be carried out without legislative action. They concluded that veterans deserve to have an improved system where decisions about disability compensation and related benefits are based on the best possible documentation and evidence.

Thank you.

[The prepared statement of Mr. Butler follows:]

PREPARED STATEMENT OF DAVID A. BUTLER, PH.D., SCHOLAR | DIRECTOR, OFFICE OF MILITARY AND VETERANS HEALTH, NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE

CHAIRMAN ISAKSON, RANKING MEMBER TESTER AND MEMBERS OF THE COMMITTEE, Thank you for the opportunity to testify today. My name is Dr. David Butler and I serve as a Scholar in the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine and as Director of its Office of Military and Veterans Health.

The National Academy of Sciences was created more than 150 years ago through a congressional charter signed by Abraham Lincoln in order to serve as an independent, authoritative body outside the government that could advise the Nation on matters pertaining to science and technology. Every year, approximately 6,000 Academies members and volunteers serve pro bono on our consensus study committees or convening activities. We do not advocate for specific policy positions. Rather, we enlist the best available expertise across disciplines to examine the evidence, reach consensus, and identify a path forward. Our reports, proceedings and other publications are available via the web in PDF form without charge.

The National Academies have a long history of advising the Federal Government on the health effects of military service in general and on the effects of in-theater exposures resulting from military activities in particular. The Office of Military and Veterans Health that I direct includes the Medical Follow-up Agency, which was es-

tablished after World War II and which maintains a collection of epidemiologic data on over 100 study populations of former military personnel. I have included a list of recent National Academies reports related to military and veterans health issues in the materials submitted for the Committee's attention.

The National Academies have also, when requested, offered perspectives on the decisionmaking processes used by the Department of Veterans Affairs (VA) in their determination of whether a particular health problem in a veteran may be associated with their military service. The most recent report addressing this issue as it relates to toxic exposures—*Improving the Presumptive Disability Decision-making Process for Veterans*—was released in 2008. The study committee formed to research and write that report was a multidisciplinary group of 16 people who covered the broad range of expertise needed to take on this important, but very challenging topic. A copy of the summary of the report and a list of the people who were involved in its writing is attached to my testimony.

That study committee was charged with describing the current process for how presumptive decisions are made for veterans who have health conditions arising from military service and with proposing a scientific framework for making such presumptive decisions in the future. Presumptions are made in order to reach decisions in the face of unavailable or incomplete information. They address the gaps in evidence that introduce uncertainty in decisionmaking. Presumptions have been made with regard to exposure and the association between exposure and outcome. In trying to assess whether a particular health problem in veterans can be linked to their exposures in the military, a presumption might be needed because of missing information on exposures of the veterans to the agent of concern or because of uncertainty as to whether the exposure increases risk for the health condition. A presumption might also be made with regard to the link between an exposure and risk for a disease, while the evidence is still uncertain or accumulating as to whether the exposure causes the disease.

Presumptions regarding service connections have long been made; in fact, the first were established in 1921. More recently, a number of presumptions have been made with regard to the consequences of herbicide (generically referred to as "Agent Orange") exposure during service in Vietnam and the health risks resulting from a series of exposures experienced by military personnel involved in the Persian Gulf conflicts.

To address its charge, the 2008 National Academies committee met with the full range of involved stakeholders, including Congress, the VA, Veterans Service Organizations, and individual veterans. The Department of Defense (DOD) gave the study committee information about its current activities and its plans to track exposures and health conditions of personnel. The Committee attempted to formally capture how the current approach works and completed a series of case studies to identify "lessons learned" that would be useful in proposing a new approach. The Committee also considered how information is obtained on the health of veterans and how exposures during military service can be linked to any health consequences via scientific investigation. It gave substantial attention to how information can best be synthesized to determine if an exposure is associated with a risk to health and whether the association is causal.

The present approach to presumptive disability decisionmaking largely flows from the Agent Orange Act of 1991, which started a model for decisionmaking that is still in place. In that law, Congress asked the VA to contract with an independent organization—the National Academies—to review the scientific evidence regarding wartime exposure to herbicides in Vietnam. Subsequently, we have produced reports evaluating the potential association between wartime exposure and health outcomes in Vietnam veterans (the *Veterans and Agent Orange* series) and a variety of exposures and health outcomes related to service in the Gulf conflicts (the *Gulf War and Health* series). The National Academies provides its reports to the VA, which then acts through its own internal decisionmaking process to determine if a presumption is to be made.

The case studies conducted by the 2008 study committee probed deeply into this process. The case studies pointed to a number of difficulties that the Committee said needed to be addressed in any future approach:

- Lack of information on exposures received by military personnel and inadequate surveillance of veterans for service-related illnesses.
- Gaps in information because of secrecy.
- Varying approaches to synthesizing evidence on the health consequences of military service.
- In the instance of wartime exposures to herbicides in Vietnam, classification of evidence for association but not for causation.

- A failure to quantify the effect of the exposure during military service, particularly for diseases with other risk factors and causes.
- A general lack of transparency of the presumptive disability decisionmaking process.

The study committee discussed in great depth the optimum approach to establishing a scientific foundation for presumptive disability decisionmaking, including the methods used to determine if exposure to some factor increases risk for disease. This assessment and the findings of the case studies led to a number of observations and recommendations to improve the process:

- Congress could provide a clearer and more consistent charge on how much evidence is needed to make a presumption. There should be clarity as to whether the finding of an association in one or more studies is sufficient or the evidence should support causation.
- Due to lack of clarity and consistency in congressional language and VA's charges to the Committees, National Academies committees have taken somewhat varying approaches since 1991 in reviewing the scientific evidence, and in forming their opinions on the possibility that exposures during military service contributed to causing a health condition. Future National Academies committees could improve their review and classification of scientific evidence if they were given clear and consistent charges and followed uniform evaluation procedures.
- The internal processes by which the VA makes its presumptive decisions following receipt of a National Academies report have been unclear. VA should adopt transparent and consistent approaches for making these decisions.
- Adequate exposure data and health condition information for military personnel (both individuals and groups) usually have not been available from DOD in the past. Such information is one of the most critical pieces of evidence for improving the determination of links between exposures and health conditions. Approaches are needed to assure that such information is systematically collected in an ongoing fashion.

All of these improvements are feasible over the longer term and, the Committee said, are needed to ensure that the presumptive disability decisionmaking process for veterans is based on the best possible scientific evidence. Decisions about disability compensation and related benefits such as medical care for veterans should be based on the best possible documentation and evidence of their military exposures as well as on the best possible information. A fresh approach could do much to improve the current process. The study committee's recommended approach had several parts:

- an open process for nominating exposures and health conditions for review, involving all stakeholders in this process;
- a revised process for evaluating scientific information on whether a given exposure causes a health condition in veterans, including a revised set of categories to assess the strength of the evidence for association and an estimate of the numbers of exposed veterans whose health condition can be attributed to their military exposure;
- a consistent and transparent decisionmaking process by the VA;
- a system for tracking the exposures of military personnel (including chemical, biological, infectious, physical and psychological stressors), and for monitoring the health conditions of all military personnel while in service and after separation; and
- an organizational structure to support this process.

To support the study committee's recommendations, it suggested the creation of two panels. One was an Advisory Committee (advisory to VA), that would assemble, consider and give priority to the exposures and health conditions proposed for possible presumptive evaluation. Nominations for presumptions could come from veterans and other stakeholders as well as from health tracking, surveillance and research. The second panel would be a Science Review Board, an independent body that would evaluate the strength of the evidence (based on causation) which links a health condition to a military exposure and then estimates the fraction of exposed veterans whose health condition could be attributed to their military exposure. The Science Review Board's report and recommendations would go to the VA for its consideration. The VA would use explicit criteria to render a decision by the VA Secretary with regard to whether a presumption would be established. In addition, the Science Review Board would monitor information on the health of veterans as it accumulates over time in the DOD and VA tracking systems, and nominate new exposures or health conditions for evaluation as appropriate.

The study committee recommends that the following principles be adopted in establishing this new approach:

1. Stakeholder inclusiveness

2. Evidence-based decisions
3. Transparent process
4. Flexibility
5. Consistency
6. Causation, not just association, as the target for decisionmaking.

The last principle needs further discussion, as it departs from the current approach. In proposing causation as the target, the study committee had concern that the approach of relying on association, particularly if based on findings of one study, could lead to “false-positive” presumptions. The Committee calls for a broad interpretation of evidence to judge whether a factor causes a disease in order to assure that relevant findings from laboratory studies are adequately considered. The report also recommends that benefits be considered when there is at least a 50% likelihood of a causal relationship, and does not call for full certainty on the part of the Science Review Board.

The report suggested that this framework be considered as the model to guide the evolution of the current approach. While some aspects of the approach may appear challenging or infeasible at present, feasibility would be improved by the provision of appropriate resources to all of the participants in the presumptive disability decisionmaking process for veterans and future methodological developments. Veterans deserve to have these improvements accomplished as soon as possible.

The study committee recognized that action by Congress would be needed to implement its proposed approach. The Committee’s report notes that legislation to create the two panels would be needed and Congress would also need to act to ensure that needed resources were available to create and sustain exposure and health tracking for service personnel and veterans. Many of the changes proposed by the National Academies could be carried out even as steps were taken to move the DOD and VA toward implementing the full model recommended. They concluded that veterans deserve to have an improved system as soon as possible.

Thank you for the opportunity to testify. I would be happy to address any questions that you might have.

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Ensuring the Readiness of the Military Medical Workforce for Future Combat
Operations
Assessment of the Care and Use of Dogs in Biomedical Research Funded by or
Conducted at the U.S. Department of Veterans Affairs

Revised September 20, 2019

Senator TESTER. Thank you.
Shane?

STATEMENT OF SHANE L. LIERMANN, DEPUTY NATIONAL LEGISLATIVE DIRECTOR FOR BENEFITS, DISABLED AMERICAN VETERANS

Mr. LIERMANN. Ranking Member Tester, Members of the Committee, thank you for inviting DAV to testify at today's hearing on toxic exposures and the presumptive decisionmaking process.

At the outset, I want to thank Mr. Bobby Daniels, a Blue Water Navy veteran, and Mrs. Claudia Holt, wife of Frank Holt, a Blue Water Navy veteran who passed away this May. They proudly stood with us and others yesterday, in front of the Capitol, to call on the President to lift the stay and put an end to their wait.

Bobby Daniels, who is with us today, has terminal prostate cancer. He is fearful and angry that his wife of 56 years, Judy, may not receive survivor benefits after he is gone. Claudia Holt, who has applied for survivor benefits, is worried about how she will pay

her bills and whether or not she will lose her home. But, because of the blanket stay, both of them are forced to continue waiting.

That is why today's hearing on the future of presumptive decisionmaking process is so important, so we can prevent these types of injustices from ever happening again.

You have my full written testimony, but in my oral remarks I will highlight three of our key recommendations. First, we recommend to statutorily require future studies on all toxic exposures. Not all of the established presumptive processes have requirements for future studies for reviewing and potentially adding new diseases to each presumptive disease list. Only Persian Gulf water illnesses and Agent Orange exposures have required continued studies. Therefore, in order to ensure we utilize all scientific analysis and research for toxic exposures, we recommend that any new presumptive process have a requirement for new studies every 2 years.

Second, we recommend to add time requirements for decisions and actions by the Secretary. The statutory provisions for Agent Orange and Persian Gulf illnesses that require timely decisions and actions by the Secretary, on the recommendations from the National Academies, have expired.

The lack of statutory mandate unfortunately has resulted in no action by the VA, on the National Academies recommendations on three presumptive diseases from 2016—bladder cancer, hypothyroidism, and Parkinson's-like syndromes, as well as one from 2018, hypertension. All of these diseases are associated with Agent Orange exposure, and in our view all four should be added.

Veterans with terminal diseases such as bladder cancer do not have the time to wait for the Secretary to decide. Regardless of whether the Secretary decides to add the diseases or not, veterans deserve timely action.

Third, we recommend to establish a concession of exposure for burn pits. The common denominator for all presumptive processes is something called the concession of exposure to a specific toxin or environmental hazard. There are requirements that must be met to concede the toxic exposure prior to establishing if a presumptive process applies to that veteran.

For example, the presumptive processes for mustard gas, radiation, Persian Gulf illnesses, Agent Orange, and Camp Lejeune contaminated water all have a concession of exposure built into the presumptions.

We are proposing to concede the exposure without establishing a presumptive process for burn pits. A concession of exposure would still require a veteran to provide a diagnosis of a current illness. However, by conceding veterans who served in areas of active burn pits, were exposed to chemicals and toxins, to include those already recognized in VA's adjudication manual, the veteran would not have to provide proof of their personal evidence of that exposure.

This would still require veterans to have a medical opinion linking the condition to the exposure. However, by conceding their exposure to the known toxins, a physician, VA or private, will now be able to provide a medical opinion, with the scientific rationale, as the toxins of exposure are now known. To be clear, this proposal would not create a list of diseases for burn pit exposures.

We are currently working with Senator Sullivan and Senator Manchin to draft legislation that would address the need for a concession of exposure for burn pits. They are both committed to providing an avenue for burn pit veterans to establish entitlement to benefits and VA health care. We look forward to their introduction of the bill in the near future.

This concludes my testimony. I would be pleased to answer any questions you or Members of the Committee may have.

[The prepared statement of Mr. Liermann follows:]

PREPARED STATEMENT OF SHANE L. LIERMANN, DEPUTY NATIONAL LEGISLATIVE
DIRECTOR FOR BENEFITS, DISABLED AMERICAN VETERANS

CHAIRMAN ISAKSON, RANKING MEMBER TESTER, AND MEMBERS OF THE COMMITTEE: Thank you for inviting DAV (Disabled American Veterans) to testify at today's hearing on "Toxic Exposures: Examining the Presumptive Disability Decision-Making Process."

DAV is a congressionally chartered national veterans' service organization of more than one million wartime veterans, all of whom were injured or made ill while serving on behalf of this Nation. To fulfill our service mission to America's injured and ill veterans and the families who care for them, DAV directly employs a corps of National Service Officers (NSOs), all of whom are themselves wartime service-connected disabled veterans, at VA regional offices (VARO) as well as other VA facilities throughout the Nation. Together with our chapter, department, transition and county veteran service officers, DAV has over 4,000 accredited representatives on the front lines providing free claims and appeals services to our Nation's veterans, their families and survivors. We represent over one million veterans and survivors, more than any other veterans' service organization (VSO). This provides us with an expert understanding and direct knowledge in navigating the VA claims and appeals process.

Mr. Chairman, the men and women who serve are often placed in situations that have long-term health effects that will impact their individual functioning, provide industrial impairments and require physical rehabilitation and future health care. Combat wounds, illnesses, and invisible wounds will stay with them long after service. Our nation has a sacred obligation to care for those who bore the burden of battle. When these men and women are subjected to toxins and environmental hazards, our sense of duty to them must be heightened as many of the illnesses and diseases due to these toxic exposures may not be identifiable for years, even decades after they have completed their patriotic service.

Although there has been some significant progress achieved over the past two decades for veterans who suffered illness due to toxic and environmental exposures, there are still too many who have yet to receive the full recognition, health care and benefits our Nation owes to them. Notwithstanding numerous laws and regulations governing how VA makes presumptive decisions, there are still gaps and breakdowns that have left some veterans, particularly Vietnam veterans, waiting. Throughout this testimony we will refer to the numerous studies and reports from the National Academy of Sciences, to include the National Academy of Medicine formerly known as the Institute of Medicine. From this point we will refer to them collectively as the National Academies.

While reform of the presumptive decisionmaking process is critical, it cannot be done overnight. There are, however, two actions that the Administration can take immediately related to Agent Orange (AO) presumptions that would provide greater justice and support to Vietnam veterans.

First, the Secretary can accept the recommendations of the National Academies to add four new conditions to the Agent Orange presumptive list. In 2016, the National Academies recommended that Bladder Cancer, Hypothyroidism and "Parkinson-like symptoms" be included. In December 2018, the National Academies found that there was "sufficient evidence" linking Agent Orange and Hypertension, strengthening their prior recommendation, and again calling for it to be included on the AO presumption list.

As I will explain in greater detail below, although the landmark Agent Orange Act of 1991 required VA to make decisions on National Academies' recommendations within 60 days, that law was allowed to expire in 2015. As a result, despite clear scientific and medical evidence, veterans continue to wait for a decision on these four recommended presumptives.

Second, the President can overrule Secretary Wilkie to end the blanket stay on Blue Water Navy claims, rather than waiting until January to begin processing them.

Mr. Chairman, we do not believe that Congress intended, nor that the law requires, VA to stay every pending Blue Water Navy claim. But that is exactly what VA has done. Despite the U.S. Court of Appeals for the Federal Circuit decision in *Procopio v. Wilkie* in January, and subsequent passage of the Blue Water Navy Vietnam Veterans Act in June, there are thousands of sick and dying veterans, as well as surviving spouses, who must continue to wait and wonder if their claims for health care and benefits will be granted. Two of those people are here with us today.

BOBBY AND JUDY DANIELS

Robert "Bobby" Daniels, from Missouri, served in the Navy from 1960 to 1964, including service onboard the USS Lexington, an Aircraft Carrier deployed to Vietnam. It was there, while serving as a Machinist's Mate that he was exposed to Agent Orange in the offshore waters. Bobby says that he has the ship logs to prove it.

In 2011, Bobby was diagnosed with prostate cancer and diabetes, diseases that many of his former shipmates have also suffered from. Unfortunately, since 1997, VA has not provided the Agent Orange presumption of exposure for Blue Water Navy veterans like Bobby who served only in the waters offshore Vietnam without ever setting foot on the land. As he began this new battle, Bobby was blessed to have his wife of more than 50 years, Judy, a former school teacher, by his side. Over the years, Bobby and Judy have struggled through tough times together, including taking out a second mortgage to help pay for his medical expenses. Last year Bobby was told that his prostate cancer had reached a terminal stage with no cure possible. Although he had not previously sought benefits due to his prostate cancer or diabetes, he was now worried about how his wife would get by after he was gone, and filed new claims in January and February of this year so that his wife might be eligible for survivor benefits.

When the *Procopio* decision was rendered in January ruling that the Agent Orange Act of 1991 was clearly intended to include all those who served in the waters offshore, Bobby had new hope that he might finally get long overdue recognition and support from VA. He had accepted that his journey is almost over; he is now focused on getting survivor benefits for his wife Judy after he is gone.

When Congress passed, and the President signed the Blue Water Navy Vietnam Veterans Act on June 26, Bobby and Judy, like so many others, celebrated what they thought would finally bring them some measure of justice and support. But just five days later, the Secretary issued a blanket stay on all Blue Water claims until January 1, 2020. Bobby said this blow felt like getting hit in the mouth with a sledgehammer.

Today, Bobby and Judy continue to wait for VA to review and decide his claims, not knowing if or when they might get a decision. And Bobby, who may not make it to the new year, remains fearful and angry that his wife, Judy, may not receive the survivor benefits she would be entitled to as a result of his Agent Orange-related conditions.

FRANK AND CLAUDIA HOLT

Frank Holt served in the Navy from November 1960 to November 1964, including service onboard the USS Prichett during the Vietnam War. While serving off the coast of Vietnam, he claimed he was exposed to Agent Orange and was never the same since. For the past two decades, Frank suffered from numerous illnesses, including lung cancer, a disease presumptively linked to Agent Orange. Frank was lucky to have his wife Claudia, a nurse by profession, at his side throughout his health struggles. But like Bobby Daniels and other Blue Water Navy veterans, Frank's claims for health care and benefits due to prostate cancer were denied.

Sadly, on May 13 of this year, months after the *Procopio* decision was rendered, Frank Holt died. Following his death, Claudia applied for survivor benefits, based on the *Procopio* decision and the new law. But because of the blanket stay issued by the Secretary on July 1, Claudia must continue to wait until at least January before VA will even look at her claim.

Claudia, who is 78 years old and in mourning, is worried about how she will pay her bills, whether or not she'll lose her home, and how she'll keep food on the table and the lights on overhead. Claudia drove almost three hours to be here so that she could represent for her husband who never got his justice, as well as other Blue Water Navy veterans and their spouses who continue to wait.

My colleagues and I have heard from dozens of others who, like Bobby Daniels, Frank Holt and their spouses Judy and Claudia, continue waiting, wondering if they can hold on until January when VA plans to finally begin looking at their claims. It's time to end their wait.

For this reason, DAV, together with other leading veterans organizations, including the Veterans of Foreign Wars (VFW), Vietnam Veterans of America (VVA), Paralyzed Veterans of America (PVA), AMVETS, Fleet Reserve Association (FRA), Military Officers of America (MOAA) and Blinded Veterans Association (BVA), joined with Senator Tester and House Chairman Takano yesterday, to call on President Trump to end the wait for Blue Water Navy Vietnam veterans by lifting the stay.

That is also why we believe today's hearing on the future of presumptive decision-making is so important, to prevent these types of injustices from happening in the future. Our testimony will address the known toxic exposures with resultant presumptive service-connected process, how the current processes are inconsistent and present our recommendations to improve and reform the future of the presumptive decisionmaking process.

Known Military Toxic Exposures and Presumptive Service Connection

In discussing the future of the presumptive-decisionmaking process, we must examine the history and impact of chemical and toxic exposures thrust upon our military servicemembers. In all of the instances noted below, the U.S. Government or Department of Defense (DOD), exposed military servicemembers to toxins without being fully aware of the immediate or long-term health effects.

Mustard Gas and Lewisite Exposure

During World War II (WWII), both the Axis and Allies produced millions of tons of chemical weapons and had made massive preparations for their use. The U.S. established secret research programs to develop better chemical and toxic weapons and better methods of protecting against these poisons. At the end of WWII, over 60,000 U.S. servicemembers had been used as human test subjects. At least 4,000 of these active military servicemembers had participated in tests conducted with high concentrations of mustard agents or Lewisite in gas chambers or in field exercises over contaminated ground areas. The U.S. servicemembers were intentionally exposed to mustard agents or Lewisite, from mild (a drop of agent on the arm in "patch" tests) to quite severe (repeated gas chamber trials, sometimes without protective clothing).

All servicemembers in the chamber and field tests, and some in the patch tests, were told at the time that they should never reveal the nature of the experiments. Attention was drawn to these experiments when some of the veterans began to seek benefits from VA for health problems they believed were caused by their exposures to mustard gas and lewisite. Two factors complicated these cases. First, there were often no records or documentation available of a veteran's individual participation in the testing programs. Second, there was a great deal of uncertainty about which health problems were in fact the result of mustard agent or Lewisite exposure.

Not until 1991, over 70 years from the use in WWI and over 50 years from the secret testing in WWII, did the VA provide guidelines for establishing claims related to these exposures. That same year the VA requested a study from the National Institute of Medicine (IOM), currently the National Academy of Medicine. On July 31, 1992, VA published a final regulation, 38 CFR §3.316, authorizing service connection in claims from veterans who underwent full-body exposure to mustard gas during field or chamber experiments. The report, "Veterans at Risk: The Health Effects of Mustard Gas and Lewisite" was issued in 1993 and prompted an updates to the regulatory provision in 1993 and 1994. We would like to point out that this presumptive, when established in 1992, excluded WWI veterans exposed to mustard gas.

Radiation Exposure

Some of the first atomic veterans were servicemembers who were sent to Hiroshima and Nagasaki to assist in clean-up. Approximately 255,000 troops were involved in the occupation of Hiroshima and Nagasaki. From 1946 to 1962, the United States conducted about 200 atmospheric nuclear tests. Approximately 400,000 servicemembers were present during these atmospheric tests, whether as witnesses to the tests themselves or as post-test cleanup crews. Sworn to secrecy, many of these servicemembers never told anyone of what they witnessed. If they told anyone that they were involved in these nuclear tests, they could have been fined up to \$10,000 and tried for treason.

On October 24, 1984, the Veterans' Dioxin and Radiation Exposure Compensation Standards Act was enacted to ensure compensation to veterans and their survivors for disabilities or deaths related to exposure to ionizing radiation during atmos-

pheric nuclear testing or the occupation of Hiroshima and Nagasaki. The law instructed VA to prescribe regulations setting forth specific guidelines, standards, and criteria for adjudicating compensation claims based on radiation exposure.

On September 25, 1985, VA published 38 C.F.R. § 3.311b (now designated § 3.311) to implement the radiation provisions of Pub. L. No. 98-542. This regulation contains standards and criteria under which service connection is to be considered for diseases first appearing after service in radiation-exposed veterans.

Effective May 1, 1988, 38 U.S.C. § 1112(c) provided compensation on a presumptive basis for radiation-exposed veterans who developed one of 13 specified diseases to a degree of 10 percent or more within 40 years following participation in a radiation risk activity. The presumptive period for one of the 13 diseases, leukemia, was set at 30 years.

In 1994, the Advisory Committee on Human Radiation Experiments was created to investigate the US government's role in radiation experiments on US service-members and American civilians from 1944 to 1974. The Committee found the U.S. Government had conducted human experimentation that included injection of radioisotopes and intentional releases of radioactive gases into the environment. The Committee discovered that the government, scientists, and officials involved did not follow any procedures to obtain consent from the subjects in these experiments.

Agent Orange Presumptive

The U.S. program, code-named Operation Ranch Hand, sprayed more than 20 million gallons of various herbicides over Vietnam, Cambodia and Laos from 1961 to 1971. The purpose was to strip the thick jungle canopy that could conceal opposition forces, to destroy crops that those forces might depend on, and to clear tall grasses and bushes from the perimeters of US base camps and outlying fire-support bases. At the time of the spraying, 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD), the most toxic form of dioxin, was an unintended contaminant generated during the production of 2,4,5-T and so was present in Agent Orange as well as some other formulations sprayed in Vietnam.

After their service, many Vietnam veterans were developing multiple illnesses and fatal diseases. It was not until Veterans' Dioxin and Radiation Exposure Compensation Standards Act of 1984 that VA recognized presumptive service connection for an illness related to Agent Orange. As we will outline later in this testimony, it took many years of legislation, regulations and court battles to establish exposure to this deadly toxin. Because 20 million gallons were sprayed, VA has ultimately conceded exposure for those who served in Vietnam and the waters offshore.

Persian Gulf War and Undiagnosed Illnesses

In response to the invasion of Kuwait by Iraq in August 1990, the United States led a coalition of 34 countries in Operation Desert Shield in the Persian Gulf. This was followed by Operation Desert Storm, which began in January 1991 with an air offensive and a 4-day ground war; the war ended with a cease-fire in April 1991. Almost 700,000 U.S. troops were deployed to the Persian Gulf region during the height of the buildup.

The U.S. military engaged in further conflicts in the Middle East following the terrorist attacks of September 11, 2001. Operation Enduring Freedom began in October 2001 with troops stationed in and around Afghanistan. Operation Iraqi Freedom began in March 2003 with the invasion of Iraq, and it ended on August 31, 2010. Operation New Dawn, whose goal was to reduce the number of U.S. military personnel in Iraq, was initiated in September 2010 and ended in December 2011. However, there is still a U.S. military presence in Iraq.

As noted by the National Academy of Medicine report, "Gulf War and Health: Volume 11: Generational Health Effects of Serving in the Gulf War" (2018), veterans who served in the 1990—1991 Gulf War and Post-9/11 were subjected to a variety of exposures during deployment that have been associated with health effects in veterans and other exposed populations. These exposures include burning oil fields, pesticides, nerve agents, depleted uranium, burn pits, particulate matter, vaccinations and many other environmental hazards.

The Persian Gulf War Veterans Acts of 1998, codified at 38 U.S.C. § 1118, was established to associate the numerous health effects known as Persian Gulf Illnesses. It also established a requirement for continual research and studies from the National Academies.

Airborne Hazards and Open Burn Pits

Veterans who served in Southwest Asia during the first Persian Gulf as well as those serving in those locations, including Afghanistan after 9/11, have been exposed to the large scale use of burn pits.

DOD has acknowledged the vast use of burn pits to dispose of nearly all forms of waste. Several studies have indicated that veterans were exposed to burned waste products including, but not limited to: plastics, metal/aluminum cans, rubber, chemicals (such as paints, solvents), petroleum and lubricant products, munitions and other unexploded ordnance, wood waste, medical and human waste, and incomplete combustion by-products. The pits did not effectively burn the volume of waste generated, and smoke from the burn pit blew over bases and penetrated all living areas/quarters.

DOD has performed air sampling at Joint Base Balad, Iraq and Camp Lemonnier, Djibouti. Most of the air samples have not shown individual chemicals that exceed military exposure guidelines. The air sampling performed at Balad and discussed in an unclassified 2008 assessment tested and detected all of the following: (1) Particulate matter; (2) Polycyclic Aromatic Hydrocarbons (PAH); (3) Volatile Organic Compounds; and (4) Toxic Organic Halogenated Dioxins and Furans (dioxins).

The VA launched the Airborne Hazards and Open Burn Pit Registry in June 2014 to allow eligible veterans and servicemembers to document their exposures and report health concerns through an online questionnaire. To date, the VA has not created any presumption associate with exposure to airborne hazards and open burn pits.

Contaminated Water

From the 1950s through the 1980s, people living or working at the U.S. Marine Corps Base Camp Lejeune, North Carolina, were exposed to drinking water contaminated with industrial solvents, benzene, and other chemicals. The Caring for Camp Lejeune Families Act of 2012, recognized exposure and treatment for veterans and families members for 15 specific diseases.

In 2017, by regulation, the Secretary established 8 presumptive diseases for active duty, reservists, and National Guard members who were stationed at Camp Lejeune for 30 aggregate days. However, this does not include any requirements for future studies to consider adding any potential new diseases in the future.

As of August 2017, DOD has identified 401 military sites that could be contaminated with the toxic compounds known as per-and polyfluoroalkyl substances (PFAS). PFAS are found at high levels in a concentrate for a firefighting foam which has leaked into groundwater and contaminated drinking water. Currently, there are no presumptive illnesses, diseases or conditions established. Recently VA contracted with the National Academies to undertake a study on PFAS.

DIFFERENCES IN CURRENT PRESUMPTIVE PROCESSES

To best understand the current presumptive decisionmaking process, we must look at the overall presumptive processes for toxic exposures. The presumptive processes and the presumptive decisionmaking process are not consistent among all of the different types of exposures; it varies from exposure to exposure. Which means that not all presumptive processes are the same when it comes to establishing concession of exposure, or in adding new diseases linked to the exposure, or requirements for additional studies, or requirements from the Secretary to act on adding new diseases linked to exposure.

Some of these inconsistencies or differences can be traced back to the ways each of the presumptive processes based on each specific exposure is established. There are two paths to establish new presumptive exposure processes; Congress by statute and the Secretary of Veterans Affairs by regulation via the formal rulemaking process.

Differences with Presumptive Exposure by Regulation

The presumptive exposures based on mustard gas and Camp Lejeune contaminated water were established by the Secretary via Federal rulemaking and not based on congressional action. Neither of these regulatory presumptive processes have requirements for additional studies to address potentially new diseases linked to the toxic exposures. There is not a specific process in play, for these exposures, that regulates the addition of new diseases or any requirements on the Secretary to define their responses. However, new diseases for these exposures can be added by statute or Federal rulemaking, but again, there are no specific controls or requirements in doing so.

Differences with Conceding Exposure

The current presumptive process for exposure to radiation was established by Congress and further defined by VA regulation per formal rulemaking. There are inconsistencies with the concession of exposure for radiation exposure. The statute clearly states that a radiation-exposed veteran is one who participated in radiation-

risk activities. It further provides a list of radiogenic diseases that will be service-connected if they become manifested in a radiation-exposed veteran.

VA regulation 38 CFR §3.311 states that dose estimates for all radiation-exposed veterans, which is not required by the statute, must be conducted to estimate the dose of radiation. The dose estimates are provided by the Defense Threat Reduction Agency. Once they provide their estimate, it is given to a physician with subject matter expertise for an opinion if the estimated dose amount caused the radiation-exposed veteran's radiogenic diseases. This is the only presumptive process that requires estimation of dose of exposure and then a medical opinion if the known diseases are related to the exposure. This places a higher burden of proof on radiation exposed veterans for a presumptive disease than any other presumptive process within the VA. It is more akin to the direct service connection process than an actual presumptive process.

In 2000, the Government Accountability Office (GAO) released a report on the DOD's dose reconstruction program, which established the estimated amount of radiation a veteran could have been exposed to. The report determined that there should be an independent review board that would examine the program, because many of the atomic veterans questioned the program's validity. As a result, Congress mandated an independent review.

The Defense Threat Reduction Agency tasked the National Research Council to conduct the review. In 2003, The Board on Radiation Effects Research, under the auspices of the National Research Council, released its report. It found that while the estimated average dose was valid, estimated individual exposure was uncertain, because many veterans at the time of exposure were not wearing film badges that would collect radiation data. It was determined that methods to estimate "inhaled radioactive materials involve many assumptions that are subject to error" due to a lack of data.

By contrast, the current Agent Orange presumptive process includes requirements for exposure based on the Agent Orange Act of 1991. The Secretary has conceded exposure to the toxin for those who served in the Air Force and a part of Operation Ranch Hand. This concession of exposure was added via 38 CFR §3.307. The VA has also conceded exposure to Agent Orange for those who served on eight specific Royal Thai Air Forces Bases during the Vietnam Era. However, this was not added by statute or formal rulemaking; it was added via VA's M21-1 adjudication manual. It restricts exposure to Agent Orange to only those who served on the perimeter of the bases.

Until the recent passage of the Blue Water Navy Vietnam Veterans Act, concession of exposure to Agent Orange for those who served on the Korean Demilitarized Zone was only available by the Secretary previously adding it via Federal rulemaking. The men and women who served in the waters offshore of Vietnam were conceded as being exposed to Agent Orange in 1991. However in 1997, a VA General Counsel Opinion determined only veterans who physically served in Vietnam were exposed to Agent Orange, excluding Blue Water Navy veterans. The Blue Water Navy Vietnam Veterans Act of 2019 has conceded their exposure.

Differences with Future Studies Required

Not all of the presumptives have requirements for future studies to be conducted for reviewing and potentially adding new diseases to the established presumptive diseases lists. There are no requirements for future studies of mustard gas; Camp Lejeune contaminated water, and radiogenic diseases. However, statutes require continued studies and the National Academies recommendations on diseases related to Agent Orange and exposures to toxins in the Persian Gulf. Both respective laws require studies to be conducted by the National Academies. We are concerned that those presumptive processes without required future studies will not provide current information on the toxic exposures and any advances or changes in science that can relate additional diseases or illness to that exposure. These are further evident of the overall differences in the presumptive decisionmaking process overall.

Time-Required Actions by the VA Secretary on Recommendations

When the Agent Orange Act of 1991 was passed into law, it contained requirements for action by the Secretary when a report and recommendations from the National Academies was received. It noted the Secretary not later than 60 days after the date on which the Secretary receives a report, shall determine whether a presumption of service connection is warranted for each disease covered by the report. If the Secretary determines that such a presumption is warranted, the Secretary, not later than 60 days after making the determination, shall issue proposed regulations setting forth the Secretary's determination. If the Secretary determined that a presumption of service connection is not warranted, the Secretary, not later than

60 days after making the determination, shall publish in the *Federal Register* a notice of that determination. The notice shall include an explanation of the scientific basis for that determination. It further added that not later than 90 days after the date on which the Secretary issues any proposed regulations under this subsection, the Secretary shall issue final regulations.

This section of the statute included a date to discontinue this requirement. It was reauthorized several times; however, this part of the Agent Orange Act, 38 U.S.C. § 1116, expired on October 1, 2015. This means, the Secretary no longer has a required timeframe for actions on recommended diseases to be added as a presumptive to Agent Orange. The lack of the time-required action is having a negative impact on veterans and their families.

The National Academies “Veterans and Agent Orange” update was published in 2016. The Committee concluded that there was compelling evidence for adding bladder cancer and hypothyroid conditions as presumptive diseases. Further, the study clarified that Vietnam veterans with “Parkinson-like symptoms,” but without a formal diagnosis of Parkinson’s disease, should be considered under the presumption that Parkinson’s disease and the veterans’ are service-connected. On November 1, 2017, the VA issued a press release noting they were exploring these new presumptive conditions related to Agent Orange.

In December 2018, the National Academies issued a report noting there was sufficient evidence of a relationship between hypertension and Agent Orange and recommended for it to be added to the presumptive list. In March 2019, at a congressional hearing, Dr. Stone, Executive in Charge of the Veterans Health Administration (VHA) indicated that an answer on these presumptives could be released within 90 days. To date, there has been no action or responses from the VA in reference to a decision on adding these four presumptive diseases.

The Persian Gulf War Veterans Act of 1998, codified at 38 U.S.C. § 1118, originally had these same types of time-required actions by the Secretary. However, those requirements expired on October 1, 2011, as the date was not reauthorized for the future. All of this means there are no current time requirements on the Secretary to act on recommendations made by the National Academies in reference to additional diseases related to toxic exposures.

Causation vs Association

As noted in the many reports from the National Academies, there is a distinction between causation and association of a disease to the specific exposures. There is debate over which requirement should drive the presumptive decisionmaking process, or whether both should be included.

Regardless of the outcomes from a report or study indicating causation or association, we would like to note, the ultimate decision for adding the presumptive disease lies with the Secretary, as well as Congress, which also has the authority to add diseases, as was the case with radiation-exposed veterans. As noted below, there are differences in the presumptive statutory language and the recommendations by veterans, the VA, and the National Academies.

The Veterans’ Dioxin and Radiation Exposure Compensation Standards Act of 1984 used language of both association and causation in describing the evidence required for presumptions. VA interpreted the law as requiring a certain threshold of evidence for causation, and as a result denied presumptions between Agent Orange and all diseases except Chloracne. Veterans filed a lawsuit against the VA and as determined by district court in *Nehmer v US Veterans Administration*, 1989, the Act was ambiguous and interpreted congressional intent as establishing a threshold of evidence for an association.

The Agent Orange Act of 1991, 38 U.S.C. § 1116, originally stated that each additional disease that the Secretary determines in regulations warrants a presumption of service connection by reason of having positive association with exposure to a herbicide agent. Unfortunately, this requirement of association was not carried forward and ended on October 1, 2015. However, each subsequent report from the National Academies provides their assessments based on this original requirement of association.

In “Veterans at Risk: The Health Effects of Mustard Gas and Lewisite,” issued in 1993, the study only focused on findings of a causal relationship and did not provide any comments or recommendations on diseases that may have an association vs causation. However, since this presumptive was established by regulation, there is no language or directions in reference to ongoing studies or any requirement of causation vs. association.

The Persian Gulf War Veterans Act of 1998, 38 U.S.C. § 1118, notes that the Secretary determines if illnesses or diseases warrant a presumption of service connection by reason of having a positive association with exposure to a biological, chem-

ical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine. The plain text of the law notes association and not causation.

In the National Academies report, “Improving the Presumptive Disability Decision-Making Process,” 2008, it made recommendations of causation over association. However, in the National Academies “Veterans and Agent Orange” update 2016; it discussed this question of whether the Committee should be considering statistical association rather than causality. The Committee believed that the categorization of strength of evidence on association is consistent with the previous court ruling.

Classification Scheme used by the National Academies

The National Academies “Veterans and Agent Orange” reports originally created and provided the four different classifications for associations of diseases to Agent Orange exposure as follows:

Sufficient Evidence of an Association

Epidemiologic evidence is sufficient to conclude that there is a positive association. That is, a positive association has been observed between exposure to herbicides and the outcome in studies in which chance, bias, and confounding could be ruled out with reasonable confidence. For example, if several small studies that are free of bias and confounding show an association that is consistent in magnitude and direction, then there could be sufficient evidence of an association.

Limited or Suggestive Evidence of an Association

Epidemiologic evidence suggests an association between exposure to herbicides and the outcome, but a firm conclusion is limited because chance, bias, and confounding could not be ruled out with confidence. For example, a well-conducted study with strong findings in accordance with less compelling results from studies of populations with similar exposures could constitute such evidence.

Inadequate or Insufficient Evidence to Determine an Association

The available epidemiologic studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association. For example, studies fail to control for confounding, have inadequate exposure assessment, or fail to address latency.

Limited or Suggestive Evidence of No Association

Several adequate studies, which cover the full range of human exposure, are consistent in not showing a positive association between any magnitude of exposure to a component of the herbicides of interest and the outcome. A conclusion of “no association” is inevitably limited to the conditions, exposures, and length of observation covered by the available studies.

The Gulf War and Health reports issued by the National Academies have used five classifications of association that they noted, “gained wide acceptance by Congress, government agencies (particularly VA), researchers, and veterans groups.” They present a common message: the validity of an association is likely to vary to the extent to which common sources of spurious associations can be ruled out as the reason for the observed association. The one additional category provided by these reports is:

Sufficient Evidence of a Causal Relationship

Evidence is sufficient to conclude that a causal relationship exists between being deployed to the Gulf War and a health outcome. The evidence fulfills the criteria for sufficient evidence of a causal association in which chance, bias, and confounding can be ruled out with reasonable confidence. The association is supported by several of the other considerations such as strength of association, dose—response relationship, temporal relationship, and biologic plausibility.

It is important to note, that of all the diseases that have ever been recommended to be added to any of the presumptives lists, no diseases classified as Inadequate or Insufficient Evidence to Determine an Association or Limited or Suggestive Evidence of No Association have been added as a presumptive disease.

RECOMMENDATIONS FOR MOVING FORWARD

While considering the future of the presumptive-decisionmaking process, we must look at all aspects of the presumptive process as well as other ways for the men and women who served to establish entitlement to their earned benefits. Below are

DAV's recommendations moving forward for strengthening and reforming the presumptive-decisionmaking process.

1. Improve DOD Recordkeeping, Data Collection and Information Sharing with VA.

In reference to the lack of information regarding exposures while on active duty, the National Academies noted, "It is too late for Vietnam veterans and other more recently deployed veterans, but DOD should prepare the way for addressing the issue of delayed service related health conditions in a more coherent and better documented fashion for future veterans. The compilation of rosters of individuals sent on various deployments is a rudimentary starting point for any subsequent epidemiologic investigations. Documentation of medical procedures such as vaccinations should also be maintained for such cohorts."

As noted throughout our testimony and the many reports from the National Academies, there is a fundamental lack of exposure data for servicemembers to include troop locations, vaccinations, and other relevant information.

DAV supports S. 1680, the "Servicemember's Occupational and Environmental Transparency Health Act" or the "OATH Act," as this takes steps to avoid the lack of medical data and exposure information for future generations of veterans. We also support the ongoing efforts to improve the data collection for the VA's Airborne Hazards and Burn Pit Registry as noted by S. 191, the Burn Pits Accountability Act, and S. 554, the Burn Pit Registry Enhancement Act, as well as the inclusions in the pending National Defense Authorization Act of 2020.

As we look to create better record keeping and data of exposures for future veterans, we must reconcile the poor record keeping for past generations trying to establish their exposure to toxins. As noted, veterans exposed to mustard gas, radiation-risk veterans, veterans exposed to Agent Orange, Persian Gulf veterans, and those serving today, have difficulty establishing their exposures, due in part to poor DOD record keeping, especially during periods of war.

2. Establish Concession of Exposure.

One of the common denominators for all presumptive processes is the concession of exposure to a specific toxin or environmental hazard. There are requirements that must be met to concede the toxic exposure prior to establishing if the presumptive process applies and thus the granting of association for diseases, illnesses and conditions.

When veterans have been exposed to toxins and current science and medical evidence fails to provide diseases or illnesses, they cannot use the presumptive process to establish service connection for their illnesses. So prior to the establishment of a presumptive process or disease list, the concession of exposure can provide an avenue to establish service connection for access to VA benefits and VA health care.

For example, *The Independent Budget Veterans Agenda* for the 116th Congress notes that a Concession of Exposure can provide veterans exposed to open air burn pits a means to establish service connection as there is currently not a presumptive process for burn pit exposure. Without a presumptive process, veterans exposed to burn pits with associated diseases and illnesses must establish service connection by the means of direct service connection, which requires three components:

1. A current diagnosis of a disease;
2. Evidence of in-service injury, illness, treatment or exposure; and
3. A medical opinion linking the current diagnosis to that in-service event.

VA has reported that since 2007, 80 percent of claims for illnesses and diseases related to burn pits have been denied, mostly as the veteran does not have a medical opinion linking the illness to the claimed exposure. Again, there are few, if any, records to establish a veteran's exposure to and specific toxin from burn pits.

A Concession of Exposure would still require a veteran to provide a diagnosis of a current condition, however, by conceding veterans who served in areas of active burn pits were exposed to certain chemicals and toxins, including those recognized in VA's M21-1, adjudication manual, the veteran would not have to provide personal evidence of exposure. This will still require veterans to have a medical opinion linking the condition to the exposure. By conceding their exposure to the known toxins, a physician will now have a better ability to provide a medical opinion as the toxins of exposure are known.

A Concession of Exposure can provide benefits to veterans before a presumptive process is established or even if one is not created. For example, in April the National Academies started a 21-month study for VA on the long-term health effects of burn pits. If this report does not identify any diseases associated to burn pits, veterans will still have the ability to establish entitlement to service connection on a direct basis by Concession of Exposure and an independent medical exam.

We are currently working with Senators Sullivan and Manchin to draft legislation that would address the need for a Concession of Exposure for veterans exposed to burn pits. They are both committed to providing an avenue for veterans exposed to burn pits to establish entitlement to benefits and VA health care. We look forward to their introduction of the bill in the near future.

3. Approve Legislation or Regulations Requiring VA to Apply the Court's Holdings in *Combee* Whenever Applicable.

Currently when the VA adjudicates a claim that associates a disease to a toxic exposure, but the disease is not one of the recognized presumptive diseases, it is usually denied. One of the most common reasons for this denial is that the disease is not listed as a presumptive. However, there is a means for this type of claim to be established based on direct service connection, as determined by the U.S. Court of Federal Appeals. In their decision of *Combee v. Brown*, 34 F.3d 1039, 1042 (Fed. Cir. 1994); they held that notwithstanding the presumption provisions, a claimant is not precluded from establishing service connection with proof of direct causation.

While this precedent has existed since 1994, most VA regional offices fail to apply this legal standard. When a veteran provides evidence of the disease, has a concession of the exposure, and even with an opinion with scientific and medical rationale linking the disease to the exposure, it is denied. These denials are then appealed to the Board of Veterans' Appeals and in many cases are granted by the Board based on the holdings of *Combee*.

Many claims based on a toxic exposure for a disease not recognized as a presumptive can be resolved quickly based on *Combee* and would not add to the backlog of pending appeals.

4. Statutorily Require Future Studies on Toxic Exposures.

Not all of the presumptives have requirements for future studies to be conducted for reviewing and potentially adding new diseases to the established presumptive diseases lists. Only Persian Gulf War Illnesses and Agent Orange associated diseases have statutorily required continuing studies. As noted in the numerous studies and reports from the National Academies, additional scientific research and new medical processes continue to change. Therefore in order to ensure that diseases are properly associated with toxic exposures, any new presumptive processes should have a requirement for new studies every two years.

5. Time Requirement for Action from the Secretary.

As noted above, the statutory provisions that required the Secretary to respond and take actions on the recommendations from the National Academies have expired. While Congress has the ability to reauthorize the law, or directly add presumptions, no such action has been taken in recent years. This lack of statutory mandate, unfortunately, has resulted in no action by VA on the recommendations on three presumptive diseases from 2016 and one from 2018. Veterans with these diseases, such as bladder cancer, do not have the time to wait for the Secretary to decide on action. These veterans with terminal illnesses are left with no action from the Secretary. These situations need to be avoided in the future. Regardless of whether the Secretary decides to implement the diseases or not, veterans deserve action. A future presumptive decisionmaking process must include timely action.

We recommend inclusion of the language previously found in 38 U.S.C. §§ 1116 and 1118. We recommend including, "the Secretary not later than 60 days after the date on which the Secretary receives a report from the National Academies, shall determine whether a presumption of service connection is warranted for each disease covered by the report. If the Secretary determines that such a presumption is warranted, the Secretary, not later than 60 days after making the determination, shall issue proposed regulations setting forth the Secretary's determination. If the Secretary determined that a presumption of service connection is not warranted, the Secretary, not later than 60 days after making the determination, shall publish in the *Federal Register* a notice of that determination. The notice shall include an explanation of the scientific basis for that determination. It further added that not later than 90 days after the date on which the Secretary issues any proposed regulations under this subsection, the Secretary shall issue final regulations."

6. Association of Diseases to Exposure.

As noted in the many reports from the National Academies, there is a distinction between causation and association of a disease to the specific exposures. The debate of which requirement should be included in the presumptive decisionmaking process is noted throughout.

We recommend that the studies from the National Academies continue the use of statistical association between an exposure and a disease or illness. There is judi-

cial precedent as noted by the Court in *Nehmer v US Veterans Administration*, 1989. The Court held, “the legislative history, and prior VA and congressional practice, support our finding that Congress intended that the Administrator predicate service connection upon a finding of a significant statistical association between dioxin exposure and various diseases. We hold that the VA erred by requiring proof of a causal relationship. [712 F. Supp. 1404, 1989].

The National Academies discussed this question of whether they should be considering statistical association rather than causality as has been debated. It is believed that the categorization of strength of evidence on association is consistent with that court ruling. However, we do realize that due consideration should be given to causation as in certain situations it can provide a path to adding a presumptive disease when the statistical analysis for association is not yet available.

It is important to note that in each National Academies report they make their recommendations on adding diseases to the presumptive lists. This is based on their compiled research, studies, statistical analysis and most importantly, their professional expertise. Veterans rely on the scientific community to make these recommendations. As they have the expertise, we believe VA and Congress should follow their recommendations based on the merits, medical evaluations, and scientific value.

7. Classifications of Scientific Association.

We have discussed and explained the currently used classifications for scientific association between exposures and the identified diseases. We propose the below classification of associations to be used for future studies:

Sufficient: The scientific analysis and evidence is sufficient to conclude that an association exists between the exposure and the disease.

Equipose and Above: The scientific analysis and evidence is sufficient to conclude that an association is at least as likely as not. 38 U.S.C. §5107 notes that if the evidence is in equipose, the benefit of the doubt is resolved in the veteran’s favor, thus the presumptive would be established. This would replace the “limited but suggestive” classification.

Below Equipose: The scientific analysis and evidence is not sufficient to conclude that an association is at least as likely as not.

Against: The scientific analysis and evidence suggests a lack of an association.

In discussion for future presumptive decisionmaking, we should consider adding a requirement on the Secretary when it comes to adding a disease to the presumptive list from our recommendations above. As there is no current time requirements on the Secretary to act on recommendations and much debate over these issues, requiring any disease as noted above being classified as sufficient association, would require the Secretary to add to the presumptive list unless there is clear and convincing scientific evidence to the contrary.

In conclusion, we have discussed the known toxic exposures with resultant presumptive service-connected process, how the current processes are inconsistent and our recommendations to improve and influence the future of the presumptive decisionmaking process. Changes to the presumptive processes will have monumental impacts on the men and women exposed to toxins in their military service. We offer our assistance and want to participate in these ongoing conversations and debates to ensure that veterans and their families are able to access all of their VA benefits and VA health care, now and into the future.

Mr. Chairman, this concludes my testimony on behalf of DAV. I would be happy to answer any questions you or other Members of the Committee may have.

Senator TESTER. Thank you, Shane.
Robert?

STATEMENT OF ROBERT MILLER, M.D., VANDERBILT UNIVERSITY MEDICAL CENTER

Dr. MILLER. Chairman Isakson, Ranking Member Tester, and Committee, thank you for allowing me to present today.

I began seeing soldiers with unexplained shortness of breath in 2004, following their deployments in support of Operation Iraqi Freedom. All were physically fit at the time of deployment but were quite short of breath on return. They were incapable of completing their two-mile runs within regulation time, which meant that they

no longer met Army physical fitness standards. Ft. Campbell referred dozens of similarly affected soldiers to Vanderbilt University Medical Center, and as a result we became leaders in evaluating and understanding this condition.

The soldiers referred underwent standard testing, including chest radiographs, pulmonary function testing, and exercise studies, all of which were normal, and therefore failed to explain their exercise limitation. This led us to perform surgical lung biopsies, which consistently exhibited characteristics of toxic inhalation. Most of the biopsies demonstrated a condition known as constrictive bronchiolitis affecting the small airways, but there were multiple other pathologic features demonstrating toxic inhalation.

You may wonder why the earlier studies failed to detect these changes, and the answer is that diseases affecting the small airways are frequently missed with non-invasive tests and are diagnosed only with biopsy, something that has been known for over 40 years.

Performing surgical biopsies in patients with normal preexisting testing was unconventional, but the stories of these deployers were striking. All of them faced dismissal from the military with a label of “unexplained shortness of breath,” which does not qualify as a diagnosis and therefore does not meet the standard for disability. The biopsies established a connection between the expositors of deployment, and their symptoms, as a result. The results of our initial 80 patients were published in the *New England Journal of Medicine* in August 2011.

Vanderbilt University has now evaluated over 250 deployers with unexplained shortness of breath. Approximately 100 of them have had surgical lung biopsies, all of which are abnormal. Other major academic centers have reported similar biopsy results. The DOD STAMPEDE trial reported that standard clinical evaluations fail to explain respiratory complaints of over 40 percent of patients presenting with shortness of breath. These patients were similar to the patients that we saw at Vanderbilt, but they did not undergo biopsy.

A large number of deployers report respiratory symptoms associated with deployment. Some of them are easily assessed and meet criteria for straightforward diagnoses, such as asthma, sinusitis, allergic rhinitis. But, the patients referred to Vanderbilt were more complicated, and they had been dismissed by clinicians who had limited experience with this presentation, and who misinterpreted their normal preoperative evaluations. The absence of a diagnosis was unsettling to those veterans who were affected.

This brings us to the two issues that I would like to raise related to unexplained respiratory symptoms following deployment. The first is how to best medically evaluate those with this presentation. While surgical biopsies may explain symptoms, performing them on a routine basis is not practical. They are invasive and expensive. They may, however, provide clarity for veterans whose symptoms are unrelenting and severe enough to end their military service and whose symptoms may have been dismissed by previous providers.

The DOD and VA should consider designating Centers of Excellence to evaluate deployers with unexplained shortness of breath.

These centers would establish standard protocols for evaluating these respiratory symptoms, and determine who may need surgical lung biopsy and who may be eligible for a presumptive diagnosis of deployment-related lung injury.

The second issue relates to disability benefits for deployers who have been diagnosed with a deployment-related lung disease. As noted earlier, Vanderbilt has performed surgical lung biopsies in over 100 deployers. Those who were actively serving were medically boarded out of the military with inconsistent ratings. Those who applied for VA benefits were usually denied a rating, due to their normal pulmonary function tests. The current VA standard does not allow a disability rating for veterans with biopsies showing inhalation lung injury when pulmonary function tests are normal. This is inconsistent with the report from the U.S. Defense Health Board, which states that pulmonary function testing usually fails to detect small airways disease.

Patients with deployment-related airways disease represent a unique group of veterans. While this injury may not be as noticeable as loss of limb, respiratory disorders are associated with lifetime limitation.

It has been 10 years since I first presented our preliminary data to this Committee. I hope that it is evident that this issue is not a transient one for our veterans and that too many of them with this disorder feel that they are not receiving proper health care or appropriate disability benefits.

Thank you, and I would be glad to answer any questions.
[The prepared statement of Dr. Miller follows:]

PREPARED STATEMENT OF ROBERT F. MILLER, M.D., PATRICIA AND RODES HART
PROFESSOR OF MEDICINE, VANDERBILT UNIVERSITY MEDICAL CENTER

“DISABLING RESPIRATORY ILLNESSES FOLLOWING DEPLOYMENT”

CHAIRMAN ISAKSON, RANKING MEMBER TESTER, AND MEMBERS OF THE COMMITTEE, Thank you for the opportunity to testify today. My comments today relate to a cohort of United States servicemembers with permanent respiratory impairment following service in Iraq and Afghanistan. I am here to advocate for improved respiratory evaluations and disability benefits for those affected.

BACKGROUND

I began seeing soldiers with unexplained shortness of breath in 2004 following their deployments in support of Operation Iraqi Freedom. All were physically fit at the time of deployment but were quite short of breath on return. They were incapable of completing their two-mile runs within regulation time which meant that they no longer met Army physical fitness standards. Ft. Campbell referred dozens of similarly affected soldiers to Vanderbilt University Medical Center and as a result we became leaders in evaluating and understanding this condition.

The soldiers referred underwent standard testing, including chest radiographs, pulmonary function testing and exercise studies, all of which were normal or near normal and therefore failed to explain their exercise limitation. This led us to perform surgical lung biopsies, which consistently exhibited characteristics of toxic inhalation. Most of the biopsies demonstrated a condition known as constrictive bronchiolitis affecting the small airways, but there were multiple other pathologic features consistent with toxic inhalation. You may wonder why the earlier studies failed to detect these changes. The answer is that diseases affecting the small airways are frequently missed with non-invasive tests and are diagnosed only with biopsy.

Performing surgical biopsies in patients with normal pre-operative testing was unconventional but the stories of these deployers were striking. All faced dismissal from the military with a label of “unexplained shortness of breath,” which does not qualify as a diagnosis and therefore does not meet a standard for disability. The bi-

opsies established a connection between the symptoms of deployers and a shared history of exposures in Iraq and Afghanistan. The results of our initial eighty patients were published in the *New England Journal of Medicine* in August 2011.¹

Vanderbilt University Medical Center has now evaluated over 250 deployers with unexplained shortness of breath. Approximately 100 of them have had surgical lung biopsies, all of which were abnormal. Other major academic centers have reported similar biopsy results.² The DOD STAMPEDE study reported that standard clinical evaluations fail to explain respiratory complaints over 40% of the time.³ The patients in this study were very similar to those studied at Vanderbilt, but none of them underwent biopsy.

Almost three million servicemembers have been deployed to central and southwest Asia since 2001. Many of those deployed report frequent and complex hazardous inhalational exposures. The DOD surveyed multiple sites in Iraq and Afghanistan and consistently found airborne particulate matter levels (PM_{2.5}) well above safe standards as established by both DOD and EPA.⁴ Elevated particulate matter is considered a standard for assessing air quality and is associated with increased risk for pulmonary and cardiovascular diseases.⁵ The sources contributing to elevated particulate levels came from a combination of geologic dusts, and human sources such as burning waste, local industry, battle field smoke and vehicle exhaust. The National Academy of Sciences has emphasized the importance of considering the health effects associated with high particulate matter exposure in Iraq and Afghanistan.⁶

A large number of deployers report respiratory symptoms associated with deployment.^{7,8} Some of them are easily assessed and meet criteria for straight forward diagnoses such as allergic rhinitis, sinusitis and asthma.⁹ However, many of the patients referred to Vanderbilt had been dismissed by other clinicians who had limited experience with this presentation and misinterpreted initial normal testing results. The absence of a diagnosis was unsettling to those affected. They required sophisticated diagnostic evaluations by professionals with knowledge of their exposures and the spectrum of illnesses encountered with such exposures.

RECOMMENDATION

This brings us to the two issues that I would like to raise related to unexplained respiratory symptoms post-deployment. The first is how to best medically evaluate those with this presentation. While surgical biopsies may explain symptoms, performing biopsies on a routine basis is not practical; they are invasive and expensive. They may, however, provide clarity for Veterans whose symptoms are unrelenting and severe enough to end their military service and whose symptoms may have been dismissed by previous providers.

The DOD and VA should consider designating Centers of Excellence to evaluate deployers with unexplained shortness of breath. These centers would establish standard protocols for evaluating disabling respiratory symptoms, determine who may need surgical lung biopsy and who may be eligible for a presumptive diagnosis

¹King MS, Eisenberg R, Newman JH, Tolle JJ, Harrell FE Jr, Ninan M, Miller RF, et al. Constrictive bronchiolitis in soldiers returning from Iraq and Afghanistan. *N Engl J Med*. 2011;365:222–230.

²Garshick E, Miller R, et al. Respiratory Health after Military Service in Southwest Asia and Afghanistan: An Official American Thoracic Society Workshop Report. *Ann Am Thoracic Soc*. 2019 16(8):937–946.

³Morris MJ, Dodson DW, Lucero PF, Haislip GD, Gallup RA, Nicholson KL, et al. Study of Active Duty Military for Pulmonary Disease Related to Environmental Deployment Exposures (STAMPEDE). *Am J Respir Crit Care Med*. 2014;190:77–84.

⁴National Research Council. Review of the Department of Defense enhanced particulate matter surveillance program report. Appendix D—Final report of the Department of Defense enhanced particulate matter surveillance program. Washington, DC: National Academies Press; 2010.

⁵Brook RD, Rajagopalan S, Pope CA 3rd, et al. Particulate matter air pollution and cardiovascular disease: an update to the scientific statement from the American Heart Association. *Circulation*. 2010;121(21):2331–2378.

⁶Institute of Medicine, Board on the Health of Select Populations, Committee on the Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan. Long-term health consequences of exposure to burn pits in Iraq and Afghanistan. Washington, DC: National Academies Press; 2011.

⁷Rivera AC, Powell TM, Boyko EJ, Lee RU, Faix DJ, Luxton DD, et al.; Millennium Cohort Study Team. New-onset asthma and combat deployment: findings from the Millennium Cohort Study. *Am J Epidemiol*. 2018;187:2136–2144.

⁸Falvo MJ, Osinubi OY, Sotolongo AM, Helmer DA. Airborne hazards exposure and respiratory health of Iraq and Afghanistan veterans. *Epid Rev*. 2015;37:116–130.

⁹Kreffit SD, Meehan R, Rose CS. Emerging spectrum of deployment-related respiratory diseases. *Curr Opin Pulm Med*. 2015;21(2):185–92.

of deployment related lung injury. Centers of Excellence would provide leadership in the area of research to identify and mitigate the causes of lung injury for this group of service members.

The second issue relates to disability benefits for deployers who have been diagnosed with a deployment related lung disease. As noted earlier, Vanderbilt has performed surgical lung biopsies in over 100 deployers. Those who were actively serving were medically boarded out of the military with inconsistent disability ratings (10%–100%). Those who applied for VA disability benefits were usually denied a rating due to their normal pulmonary function tests. The current VA standard does not allow a disability rating for Veterans with biopsies showing inhalation related lung injury when pulmonary function tests are normal. This is inconsistent with the report from the US Defense Health Board, which states that pulmonary function testing usually fails to detect small airways disease.¹⁰

I have seen several patients who received one rating from the DOD only to have it downgraded by the VA. I have seen patients who have received a rating for constrictive bronchiolitis only to have their rating reduced at a later date without explanation. This is despite that fact that this condition does not resolve spontaneously and has no known effective treatment. We need to re-define the disability criteria for our servicemembers and Veterans with deployment related respiratory disease.

Patients with deployment related airways disease represent a unique group of Veterans. While this injury may not be as noticeable as loss of limb, respiratory disorders are associated with lifetime limitation. It has been 10 years since I first presented our preliminary data to this Committee. I hope that it is evident that this issue is not a transient one for our Veterans and that too many of them with this disorder feel that they are not receiving proper health care and appropriate disability benefits.

Thank you for your attention and I would be glad to answer any questions.

Senator TESTER. Thank you, Dr. Miller.

Senator Moran.

Senator MORAN. Mr. Chairman, or Mr. Ranking Member, thank you. Thank you for your service on this Committee.

Dr. Butler, I have questions for you, but I thank all of you for being here, and I took seriously the testimony that you presented.

Dr. Butler, in November of last year, the National Academy of Sciences published the Gulf War and Health, Volume 11, Generational Health Effects of Serving in the Gulf War. This report concluded that there is, “a substantial dearth of information,” on the generational effects of toxic exposure. Also within that report, the National Academy prioritized the collection, storage, and maintenance of a comprehensive baseline and longitudinal data, and biospecimens from veterans, their partners, and their descendants, in order to develop an effective, successful health monitoring and research program.

The Department of Defense and the Department of Veterans Affairs continued to develop that, an Individual Longitudinal Exposure Record. My questions to you—well, first of all, I learned in our efforts to have research completed that would demonstrate whether or not there is a medical-scientific connection between generations, that before that was possible we had to demonstrate that there was not sufficient evidence in that regard existing. So, your study, Dr. Butler, at the National Academy of Sciences, was very important as a step in determining that connection.

So, my question is, I just want you to expand upon that report, your findings, and if you have any sense of whether the cooperation between the Department of Defense and Veterans Affairs is on its

¹⁰United States Defense Health Board Report: Deployment Pulmonary Health, Feb 11, 2015.

path toward getting the necessary data about the necessary facts about the occurrences.

Mr. BUTLER. Thank you for the question. The Gulf War and Health Update 11 Report not only looked at the existing evidence regarding possible reproductive effects of exposures, but also put together a comprehensive research plan that could be followed that would allow VA to make more informed decisions about this in the future. The report is still a relatively new one. As Dr. Hastings mentioned, and Dr. Rauch, the ILLER system that is about to come on line is going to provide an important new source of information on exposures and getting a handle on exposure assessment, which is typically the poorest part of the information set that is available for making decisions like this. It is going to be really important in the future for getting a better handle on outcomes that might be related, not only to reproductive and generational effects, but all the other effects.

Senator MORAN. Do you have a sense—you know, I have heard and read the testimony of the Department—do you have a sense that that process is—which is soon to be completed and available, utilized—is it the right process? You are comfortable with the direction they are going, or have you not analyzed that?

Mr. BUTLER. The National Academies has not yet analyzed it. The extensive research plan that was put forward as part of the Gulf War and Health Report does provide a roadmap in the future for getting information specific to reproductive and generational effects.

Senator MORAN. Do you have the sense your roadmap is being followed?

Mr. BUTLER. We do not have specific information on what is being done at the moment.

Senator MORAN. Thank you, Doctor. Thank you.

Senator TESTER. Senator Brown.

Senator BROWN. Thank you, Senator Tester.

Before I start I would like to acknowledge my constituents, Susan Zeier, who has joined us. She has been a driving force behind this hearing. Senator Isakson and Senator Tester commented earlier this hearing was done because of a push from people in Ohio and elsewhere. She has made countless visits with Burn Pits 360. We are also joined by Paul McMillan, who is an activist in Ohio. Thank you for joining us. They have made these visits to ensure that we acknowledge what has been done for our servicemembers in finding an approach that provides the kind of help that all of them have earned.

I would like to submit a statement for the record that she prepared, with information we gathered from Ohio veterans.

Senator TESTER. Without objection.

[The Zeier letter and attachments appear in the Appendix.]

Senator BROWN. Thank you. Also, Ms. Zeier is training a service dog for someone, so thank you for that.

Dr. Miller—thank you for your testimony, all three of you—you have treated servicemembers exposed to sulfur mine fire burn pits, other environmental exposures. Walk me through examples of what you have seen while treating patients, and in your clinical opinion,

do you think DOD and VA have the protocols in place to correctly diagnose these respiratory illnesses?

Dr. MILLER. There are probably two phases to what we have seen. Early on, in 2004, we saw a free flow of patients from Fort Campbell who returned from 1 year of service in Iraq with unexplained shortness of breath. There was good cooperation at that time. That is when we made our original find of constrictive bronchiolitis.

Over time, these servicemembers have become more complicated. They are farther out from service. We are not seeing as many direct referrals from Fort Campbell as we used to. A lot of them have seen other providers who are not familiar with this, or—

Senator BROWN. They stopped referring veterans to specialists?

Dr. MILLER. They stopped referring to Vanderbilt and other academic institutions and chose to refer to DOD facilities.

Senator BROWN. Are they getting the care they should?

Dr. MILLER. I think that if you were to go to one of the centers that they were referring to you would get a different evaluation than you might get with us or with other academic medical centers. We felt like we were able to characterize those patients who were ultimately diagnosed with deployment-related lung disease. They had a consistent pattern of exercise limitation, and despite their pulmonary function tests and exercise studies being normal, we were willing to take this a step further and get them a diagnosis with lung biopsies. I would say that except in rare circumstances, the DOD facilities did not do that.

Senator BROWN. Thank you. Mr. Liermann, thank you for being in front of this Committee again. The first panel I asked a similar question, why do you think, given what we know about air quality tests and DOD recordkeeping, DOD and VA, have not been more forward-leaning to develop a process, a presumption or otherwise to provide health care and disability for servicemembers and veterans exposed to burn pits?

You ended by suggesting that one step Congress should take to apply pressure would be to reinstate the timeline by which VA needs to act after receiving a National Academies report. Senator Hill and I introduced a bill last year, which obviously did not pass.

Why is it important to reinstate that requirement?

Mr. LIERMANN. Thank you, Senator. Without that requirement we are in the situation we are right now where we have three additional diseases that have not been added for almost 3 years, yet were recommended. That requirement that there be some sort of action within the timeframe, good, better, indifferent is going to get a decision, and at the very least veterans need to have a decision. That way we know other avenues to proceed for service connection if it is not going to be as a presumptive disease.

Senator BROWN. OK. Thank you. Thank you, Mr. Chairman.

Senator TESTER. Thank you, Senator Brown.

Senator Tillis.

Senator TILLIS. Thank you, Senator Tester, and thank you all for being here. You know, one question I wanted to ask Dr. Miller, you alluded to the idea of centers of excellence in your opening statement, and it really relates somewhat to the discussion you just had

with Senator Brown on some of the referrals going to facilities that may or may not have the same level of expertise.

So, in your mind, waving a wand, what would a good network of centers of excellence look like? And I would assume that that would be in and out of the DOD or VA.

Dr. MILLER. I think it could be in or out of DOD and VA, but I think that for patients with unexplained shortness of breath, which are the large number of patients with respiratory disorders, there is an unfamiliarity that you can be ill, that you can have toxic inhalation with a normal x-ray and pulmonary function test.

There is also an unwillingness to take it to the next level, to either do a lung biopsy or to say, "You have the characteristics of people who have been diagnosed with deployment-related lung disease, and we think that you meet those criteria."

So, you need the expertise, but you also need the willingness to take it to that level.

Senator TILLIS. Some of that may require us to do a better job of educating servicemembers who were in potential at-risk situations to understand what they may be going through and getting advice or engaging experts in the area. That is more a matter of increasing awareness and engagement on the part of the servicemember?

Dr. MILLER. It is more about increasing awareness among providers. The typical person that I am seeing now is somebody who has seen multiple providers, some of them in the private world, some of them through DOD, some of them through VA. The DOD and VA providers frequently are aware of what we have done at Vanderbilt or has been done at National Jewish Health in Colorado, but they do not take it to the level that we do. Then, the servicemembers leave with a diagnosis that, "We are sorry that you are short of breath. Your x-rays and pulmonary function tests are normal."

Senator TILLIS. You mentioned that the referrals reduced to Vanderbilt in favor of, I guess, DOD Health. Do you know why that happened? Is there any speculation on why that happened?

Dr. MILLER. I think you would have to ask them.

Senator TILLIS. We will.

Dr. MILLER. I think that they were uncomfortable with the idea that we would do lung biopsies on somebody who had normal x-rays and pulmonary function tests. I will tell you that that is a leap for me, as a clinician, to have made that diagnosis, and it is one that when I see patients I tell them that it is unconventional. But, in this group of patients, it has a very high yield.

Senator TILLIS. Thank you. Mr. Butler, I want to go back and follow up on a question I asked of Dr. Hastings on the first panel, and that has to do with what the National Academies specifically can do to review some of the other conditions affecting dependents and family members. I referred to some of the exposures in utero. What more do you think we can do there?

Mr. BUTLER. Well, as I mentioned, the Gulf War and Health 11 Report put forward a comprehensive research protocol that could be followed to get more information in this area. The National Academies is an institution and does not conduct primary research, which is to say we do not research data on individual veterans or

groups of veterans directly, but we do review the literature. It is a challenging area to do research in, but it is one that is very important and that the Committee who wrote the Gulf War and Health 11 Report thought deserved greater attention.

Senator TILLIS. Mr. Liermann, it is good to see you back. Just a real quick question that also relates to a question I asked of the prior panel, which has to do with—I think you are familiar with the fact that Senator Burr co-introduced the Janey Ensminger Act, and we have worked hard to make sure the VA is changing some of their presumptions. We have made some progress over time.

But, what do you think that we need to do, either what the VA can do or what more we need to do to make sure that we are constantly reassessing the data, constantly challenging the presumptions and making sure we are giving the care to as many people as we can?

Mr. LIERMANN. Thank you, Senator. I believe one of the big things we can do is require additional studies, have additional research, because as things change and more information is gathered we are going to know more commonalities between different diseases and different disabilities.

So, by providing that research every 2 years, and having that available for the scientific community to go through, to glean and find that key information, is really a key part of this. Because, if we do not continue to do those types of things—for example, for Agent Orange-exposed veterans—we would not continue to find these additional diseases that are associated with their exposure. So, studies and research, and I would say, at the minimum of 2 years, would go a long way.

Senator TILLIS. Thank you very much. Thank you, Senator Tester.

Senator TESTER. Yes.

Senator Blackburn.

**STATEMENT OF HON. MARSHA BLACKBURN,
U.S. SENATOR FROM TENNESSEE**

Senator BLACKBURN. Thank you.

Dr. Miller, I appreciate so much that you are here, and, of course, representing our great State of Tennessee. I have heard a bit about your work at Vanderbilt, and the fact that I have two military retirees and veterans that are a part of our team and they had been deployed in the Gulf. I have heard many stories, as I have talked with those Fort Campbell families, about the crud that they bring back with them from those early days in Iraq and Afghanistan.

We will be following up with you on some more specifics. I know the lung biopsies are painful. It is not a simple procedure. Yet, we want to make certain that the best treatment possible is available for our men and women in uniform. Indeed, we have heard so many stories about the shortness of breath issue, which seems to be unexplainable in an otherwise completely healthy individual. Mr. Liermann, you spoke to the toxins and the inhalation of them.

So, it does concern us and as someone who in 2003—a group of women went in to visit the 101st. There were six female Members of the House that went in, and I was in that group. We saw first-

hand some of the particulate that seemed to be floating through the air and ever-present. So, living in that and inhaling it is something that does leave that residual effect. We want to make certain that things are well cared for.

We have just had votes called and we are going to need to scoot to the floor, but, Dr. Miller—and I think I am going to ask you to do this as a written response, just in the interest of time. So, what I would like to have from you is a little bit of a deeper dive, when you talk about the differences in the DOD testing and what Vanderbilt has done. It is also so curious to me when there is research work that is being done with the VA located on Vandy's campus. It seems as if more would be available for these veterans, and we appreciate that you have targeted this area.

So, if you would talk a little bit about these exams, the center of excellence type of concept, what DOD does, and where they end the process and how that is not the fullness of what ought to be the process, to get to the bottom of this. I would appreciate that.

With that, Mr. Chairman, I am going to yield back. I thank each of you for your attention to the issue. And, Dr. Miller, I especially thank you for your willingness to come and speak before us today.

I yield back.

Senator TESTER. Yes, thank you, Senator Blackburn. I want to also thank Dr. Hastings and Dr. Helmer for sticking around here for the second panel. I appreciate you wanting to hear what these folks have to say. And, I don't know if Dr. Rauch—I did not pick him out in the crowd—if he is here I thank him also.

I am going to start with you, Dr. Butler. As requested by the VA, the National Academies have convened a committee to review, evaluate, and summarize available scientific and medical literature regarding respiratory health effects and exposure to airborne hazards. Can you summarize the process for performing this study?

Mr. BUTLER. Yes. This is a study that is ongoing. We have assembled an expert panel of—

Senator TESTER. When did it start?

Mr. BUTLER. It started at the beginning of this year. We are going to be holding a meeting next Thursday and Friday, a workshop, where we will be gathering information for the committee's consideration. That is a public event and one that will be broadcast over the Web.

We are also in the middle of a large-scale literature review of all of the information that has been published on this topic. We will be assembling that literature review, the additional information, including a presentation from one of Dr. Miller's colleagues from Vanderbilt. We will be preparing a report that will be completed in late spring of next year.

Senator TESTER. Late spring of next year? OK. That report will go to the VA, correct?

Mr. BUTLER. It will, and it will also be made public and will be capable of being downloaded for free from the internet.

Senator TESTER. Yeah, and typically—and I do not know if you can answer this question, and if you cannot you do not have to—but typically, how long does it take the VA to make a decision after you have forwarded information to them?

Mr. BUTLER. That would depend on the particular report that we are doing.

Senator TESTER. I am assuming these reports are pretty comprehensive?

Mr. BUTLER. We try to make them as comprehensive as possible, yes.

Senator TESTER. OK. Are there any ongoing studies right now that have been requested of the National Academies over and above this?

Mr. BUTLER. Aside from this study, we are completing a study on the effect of exposure to anti-malarial agents—

Senator TESTER. OK.

Mr. BUTLER [continuing]. And that will also come out in 2020.

Senator TESTER. OK. All right.

Dr. Miller, you have seen a number of servicemen. There is a study you did—it may be a number of years ago now—where you conducted research on 100 veterans who had, I believe, shortness of breath, and you performed biopsies on those. Were all 100 percent abnormal?

First of all, did all 100 veterans have shortness of breath?

Dr. MILLER. All of them did. Our original study was 80 patients. We have now seen 250 with shortness of breath, and we have done biopsies on a little over 100. All of the biopsies are abnormal.

Senator TESTER. OK.

Dr. MILLER. All of them are patterns of toxic inhalation.

Senator TESTER. I got you. How do you choose the 100? Was it random or was it the worst-case scenarios?

Dr. MILLER. Some of them had other explanations for their shortness of breath. They might have asthma. Some of them had too many comorbid conditions to undergo biopsy, and some of them did not want biopsies.

Senator TESTER. OK. So, as I am sitting here listening to your testimony and you do a biopsy on the 100 veterans who have shortness of breath and it all comes back bad news, and then the VA does not use you anymore, it tends to put red flags up for me, because potentially it makes me think they do not want to hear the bad news. Do you look at it the same way?

Dr. MILLER. Between 2004 and 2009, we worked very closely with the DOD, and we had people come down and define the protocol that we used with Fort Campbell. I felt like that we were working well together.

Senator TESTER. Yeah, to supplant DOD. Yeah, keep going.

Dr. MILLER. Then, it changed. It changed when our data became more nationally known. There was a large consensus conference in Denver where we presented our data, which was the first time that a lot of them had seen our data. That is when things changed.

Over time, many VA facilities have been willing to take the same approach that we do. For example, the VA in Nashville, the VA in Denver do a lot of biopsies.

The big problem with the VA has been in the disability rating—

Senator TESTER. Oh yeah.

Dr. MILLER [continuing]. And that has been—I guess there were two issues. One is their willingness to say that someone's unex-

plained shortness of breath was deployment-related, or to do a biopsy, and the other is that for those that were diagnosed they would not give them a disability rating, despite significant exercise limitations.

Senator TESTER. OK. Really quick, going back to Dr. Butler, you are gleaning information from a lot of different sources, including places like Vanderbilt. Correct?

Mr. BUTLER. That is correct. As I mentioned, one of Dr. Miller's colleagues will be giving us a presentation.

Senator TESTER. Right. And when is the last time you did any research that the DOD requested?

Dr. MILLER. The DOD has not requested any from us. We get a few patients—

Senator TESTER. In how many years—10?

Dr. MILLER. It has probably been 10.

Senator TESTER. OK. The information that you are gleaning, Dr. Butler, is it 10-year-old information, or are you getting all your information from the DOD over the last 5 years?

Mr. BUTLER. We try to get the most recent information available from all sources.

Senator TESTER. I got you, but is that information only available from the DOD now?

Mr. BUTLER. No. It is also available from academic researchers. We also ask the service organizations and veterans.

Senator TESTER. OK. Sounds good, and thank you.

Shane, do you believe the VA is capable of rewarding claims of some Blue Water veterans right now?

Mr. LIERMANN. Absolutely.

Senator TESTER. So, why is it important that at least they take a look at some of them? In your testimony that we heard yesterday you actually listed off some that they should be considering. Why is that important?

Mr. LIERMANN. When you take a look at veterans like Bobby, who is here with us today, who is terminal and dying from his condition, yet they will not take any action on his care, that is one of the very important reasons why they should at least look at those cases now. And then—this was touched on earlier, Senator, and I just wanted to expand on it a little bit—

Senator TESTER. Yeah. Go ahead.

Mr. LIERMANN [continuing]. There are certain pieces where the VA already knows where the ship was. They do not have to reconstruct hundreds of thousands of millions of pages of documents to prove it.

Senator TESTER. Bingo.

Mr. LIERMANN. For example, Da Nang Harbor. For years, if a veteran served on a ship in Da Nang Harbor but never went ashore, they were not considered in country. They already have all of that information on those veterans. There is enough information for them right now to make decisions on cases. Will a lot of them have to be developed more? Absolutely. But, do they have enough now they can make decisions on? Yes.

Senator TESTER. Gotcha.

I want to thank all three of you for your testimony and the work that you do. I very much appreciate it. Keep up the good work.

I would just say that Members have 5 days to submit additional statements or questions for the record. With that we will adjourn this hearing. Thank you all.

[Whereupon, at 12:32 p.m., the Committee was adjourned.]

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. JON TESTER TO PATRICIA R. HASTINGS, M.D., CHIEF CONSULTANT, POST-DEPLOYMENT HEALTH, U.S. DEPARTMENT OF VETERANS AFFAIRS

PRESUMPTIVE SERVICE CONNECTION

Question 1. The 2008 NAS report on “Improving the Presumptive Disability Decision-Making Process for Veterans” made 6 recommendations specific to VA to improve the process. What is the status of implementing these recommendations?

Response. Please see the following VA responses to the 2008 National Academy of Sciences (NAS) Report on Improving the Presumptive Disability Decision-Making Process for Veterans Recommendations 3,4,5,6,7, and 8:¹

- *Recommendation 3:* VA should develop and publish a formal process for consideration of disability presumptions that is uniform and transparent and clearly sets forth all evidence considered and the reasons for the decisions reached.

Response. Following release of the Institute of Medicine (IOM) report, Veterans and Agent Orange, Update 2008, VA established the Agent Orange Update 2008 Task Force. In the past, similar VA Task Forces were established to consider previous IOM committee reports upon their completion. The 2008 Task Force, chaired by the VA Acting Under Secretary for Health and including the VA Under Secretary for Benefits, the VA General Counsel, and the VA Acting Assistant Secretary for Policy and Planning, was supported by a work group. The work group was chaired by the Director of Regulatory and Policy Management and consisted of representatives from the Office of Public Health and Environmental Hazards, Veterans Benefits Administration (VBA), Office of General Counsel, Patient Care Services, and Office of Policy and Planning. The work group included experts in disability compensation, health care, occupational and environmental medicine, neurology, cardiovascular disease, and hypertension, and on VA’s legal requirements under the relevant statutes. The work group received a briefing by the NAS Committee Chair about the new report on July 21, 2009, which provided an opportunity to hear about the report and to ask questions. The work group met three times (July 27, 2009, August 13, 2009, and September 2, 2009) to discuss possible VA responses, and prepared a report for consideration by the VA Task Force, which then had responsibility for making relevant recommendations to the Secretary.

Independent of recommendations based on reports from IOM, the Secretary has general authority under 38 United States Code (U.S.C.) § 501(a)(1) to issue regulations governing “the nature and extent of proof and evidence and the method of taking and furnishing them in order to establish the right to benefits” under laws administered by VA. Pursuant to this authority, the Secretary may establish regulatory presumptions of service connection, if warranted by evidence, on grounds other than those specified in 38 U.S.C. § 1116(b)(2).

Currently, VA follows VA Directive 0215, Management of Institute of Medicine Reports (Attachment 1), when considering whether to establish new service connection presumptions for additional medical conditions. To make recommendations to the Secretary of Veterans Affairs, VA uses several levels of workgroups and a leadership governance process that spans from the technical (subject matter expert (SME)) level through VA leadership.

These deliberative efforts require VA to collaborate, internally and externally, with stakeholders, medical experts, scientific researchers, and Federal agencies in order to study the debilitating effects of diseases and injuries on Veterans who have been exposed to or impacted by various toxins and chemicals during events in military service.

¹ <https://www.nap.edu/catalog/12662/veterans-and-agent-orange-update-2008>.

**Department of Veterans Affairs
Washington, DC 20420**

**VA DIRECTIVE 0215
Transmittal Sheet
May 2, 2016**

Management of Institute of Medicine Reports

1. REASON FOR ISSUE. This directive establishes Departmental policy which delineates responsibilities for addressing National Academy of Sciences (NAS) Institute of Medicine (IOM) reports.

2. SUMMARY OF CONTENTS/MAJOR CHANGES. This directive sets forth policies, roles, and responsibilities for managing VA's IOM Task Force, Strategic Work Group, and Technical Work Groups (TWGs).

3. RESPONSIBLE OFFICE. Deputy Assistant Secretary for Policy (008A), Office of Policy and Planning (008).

4. RELATED HANDBOOK. None.

5. RESCISSION. None.

CERTIFIED BY:

/s/
LaVerne H. Council
Assistant Secretary for
Information and Technology

**BY DIRECTION OF THE SECRETARY
OF VETERANS AFFAIRS:**

/s/
Linda Schwartz
Assistant Secretary for
Policy and Planning

Distribution: Electronic Only

May 2, 2016

VA DIRECTIVE 0215

Management of Institute of Medicine Reports

- 1. PURPOSE.** This directive establishes Departmental policy that delineates responsibilities for addressing National Academy of Sciences (NAS) Institute of Medicine (IOM) reports.
- 2. BACKGROUND.** Over recent years, legislation, such as the Agent Orange Act of 1991, Pub. L. 102-4, 105 Stat. 11 (codified in part at 38 U.S.C. § 1116) and the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1998, Pub. L. 105-277, 112 Stat. 2681, Title XVI—Service Connection for Persian Gulf War Illnesses (codified in part at 38 U.S.C. § 1118), has been enacted that directs VA to contract with NAS to evaluate available scientific evidence concerning Veterans' issues and publish related reports. These scientific reviews are typically conducted by NAS's Institute of Medicine.
- 3. POLICY.** It is VA policy that IOM reports prepared as a result of legislative mandate are managed by the VA IOM Task Force (IOMTF) to facilitate coordination and collaboration across the Department and ensure that mandated requirements are met.
 - a.** The IOMTF reviews and evaluates IOM reports and develops and presents related findings, recommendations, and/or responses to SECVA. See Appendix A for IOMTF membership. This body meets or is briefed quarterly.
 - b.** The executive agent for IOMTF is the Deputy Assistant Secretary for Policy, Office of Policy and Planning (OPP). The executive agent is responsible for managing IOMTF activities; managing communications within the IOMTF and the IOM Strategic Work Group (SWG); coordinating meetings and briefings; and coordinating Department review and concurrence of recommendations and responses.
 - c.** Under the direction of the IOMTF, the IOM SWG serves as the permanent body to monitor VA's review of, and responses to, IOM reports; provides advice and guidance to the Technical Work Groups (TWGs); and provides updates to IOMTF as needed. SWG will consist of members from across the Department, and will be assigned by their respective offices. This body meets monthly. See Appendix A for IOM SWG membership.
 - d.** Under the direction of SWG, TWGs are formed to review IOM reports and develop any related findings, recommendations, and/or responses for IOMTF review, consideration, and approval. Members of TWGs will be determined based on the subject matter of the relevant IOM report. TWGs meet as needed.

4. RESPONSIBILITIES.**a. VA's IOM Task Force (IOMTF):**

- (1) Reviews and approves/disapproves TWG findings and recommendations that have been developed in response to IOM reports;
- (2) Meets quarterly or is briefed quarterly on the status of, and issues related to, IOM studies;
- (3) Provides direction and guidance to SWG and TWGs;
- (4) Presents IOMTF findings, recommendations, and responses to IOM reports for SECVA approval/disapproval;
- (5) Establishes the policies and processes for IOMTF and its sub-groups.

b. The IOM Strategic Work Group (SWG):

- (1) Reviews TWGs' findings, recommendations, and responses for IOMTF approval;
- (2) Provides advice and guidance to, and facilitates kick-off meetings of TWGs;
- (3) Provides updates to IOMTF on IOM study status and issues.

c. IOM Technical Work Groups (TWGs):

- (1) Review and evaluate IOM reports and develop related findings, recommendations, and/or responses;
- (2) Participate in IOMTF and SWG meetings to provide status updates;
- (3) Brief IOMTF on findings, recommendations, and/or responses to IOM reports;
- (4) Assist IOMTF in presenting findings, recommendations, and/or responses to IOM reports to SECVA.

d. Executive Agent:

- (1) Manages IOMTF activities;
- (2) Manages communications between IOMTF and SWG;
- (3) Coordinates IOMTF meetings and briefings;

May 2, 2016

VA DIRECTIVE 0215

(4) Coordinates Department review and concurrence of IOMTF recommendations and responses;

(5) Implements IOMTF administrative policies and processes

5. REFERENCES.

- a. 38 USC Chapter 11
- b. VA Framework for IOM Engagement and Reporting (OPP/VHA 2014)
- c. VA's IOM Engagement and Reporting Process (OPP/VHA 2014)
- d. VA IOM Process Roles and Responsibilities (OPP/VHA 2014)

Please contact OPP or the Veterans Health Administration for a copy of the above-referenced documents.

6. DEFINITIONS.

- a. **Department, VA.** Generic references to the entire Department of Veterans Affairs, which includes VA Central Office and all field facilities.
- b. **SECVA.** The Secretary of Veterans Affairs.

May 2, 2016

VA DIRECTIVE 0215
APPENDIX A**Membership****VA's IOM Task Force:**

Assistant Secretary for Policy and Planning (Chair);
 Under Secretary for Health;
 Under Secretary for Benefits;
 General Counsel;
 Deputy Assistant Secretary for Policy (Executive Agent).

VA's IOM Task Force's Strategic Work Group:

Veterans Health Administration (Chair);
 Veterans Benefits Administration;
 Office of Policy and Planning;
 Office of General Counsel;
 Office of the Secretary of Veterans Affairs;
 Office of Congressional and Legislative Affairs;
 Office of Public Affairs.

A-1

• *Recommendation 4:* The Committee recommends that the goal of the presumptive disability decisionmaking process be to ensure compensation for veterans whose diseases are caused by military service and that this goal must serve as the foundation for the work of the Science Review Board. The Committee recommends that the Science Review Board implement its proposed two-step process.

Response. Since 2008, VA has established a Secretary-level Advisory Committee for Disability Claims to advise and review VBA's overall disability claims process—including adding presumptive disabilities to the VA Schedule for Rating Disabilities (VASRD). This advisory committee is routinely kept apprised of the status of

VASRD rulemaking and intermittently participates in the pre-decisional review of materials related to military exposures.

VA already had an established organizational structure which collectively scrutinized the validity of presumptive service-related conditions and makes recommendations to the Secretary of Veterans Affairs, considering an evidence-based approach to creating new service connection presumptions. As part of VA's Office of Patient Care Services, the Office of Post Deployment Health is primarily responsible for administering programs related to environmental and occupational exposures of U.S. Veterans during military service, including Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF), Gulf War, Vietnam, World War II, and atomic Veterans. The Office of Post Deployment Health also maintains several registries based on these exposures. Together, with VBA Compensation Service, these VA offices convene regularly to discuss military exposures and the pertinent new literature that may pertain to and may be associated with diseases and disabilities Veterans experience due to military exposure incidents.

- *Recommendation 5:* The Committee recommends that the Science Review Board use the proposed four-level classification scheme, as follows, in the first step of its evaluation. The Committee recommends that a standard be adopted for "causal effect" such that if there is at least as much evidence in favor of the exposure having a causal effect on the frequency or severity of disease as there is evidence against, then a service-connected presumption will be considered.

Response. The Academies typically use the following four-level scheme employed in the Veterans and Agent Orange series: 1) Sufficient Evidence of an Association; 2) Limited or Suggestive Evidence of an Association; 3) Inadequate or Insufficient Evidence to Determine an Association; and 4) Limited or Suggestive Evidence of No Association.

VA formalized the process for scientific review of literature reviewed by NAS in VA Directive 0215. Consistent with the suggested two-step process underlying Recommendation 5 for the Committee's proposed Scientific Review Board, VA assembles a Technical Work Group (TWG) of SMEs to provide an objective critique and scientific review of the NAS recommendations for VA leadership.

The Directive 0215 TWG is empaneled to review recommendations and considers the classification scheme used by the NAS Committee report. Causation is a higher standard that epidemiological studies are not often able to achieve. Where evidence of causation is presented, VA would consider it in support of establishing a presumption, regardless of the levels of evidence employed by NAS.

- *Recommendation 6:* The Committee recommends that a broad spectrum of evidence, including epidemiologic, animal, and mechanistic data, be considered when evaluating causation.

Response. Epidemiologic, animal, and mechanistic studies all contribute to scientific understanding and VA decisionmaking. Well-designed human epidemiologic studies may be given greater weight because of the more direct demonstration of effect of exposure on human disease. VA carefully considers all available scientific evidence to examine the relationship between exposure and disease prior to recommending presumptions. National Academy Committees develop criteria for literature to be reviewed in response to the VA charge to the Committee. Either the charge to the Committee or deliberative Committee decisionmaking directs the scope of literature under NAS review.

- *Recommendation 7:* When the causal evidence is at Equipose and Above or Sufficient, the Committee recommends that an estimate also be made of the size of the causal effect among those exposed.

Response. There are limitations to causal inference from observational data commonly found in human studies. The scientific community, including VA in policymaking, relies on standard estimations of risk—relative risk, odds ratios, hazard ratios, standardized mortality rates, etc. Determining the magnitude of causal effect is often limited in human studies of exposure and disease because of the imprecise measures of exposure that are employed and ethical issues in research design. As science advances, techniques for exposure measurement and systematic collection of exposure data are developed, estimation of causal effect may become possible.

- *Recommendation 8:* The Committee recommends that, as the second part of the two-step evaluation, the relative risk and exposure prevalence be used to estimate an attributable fraction for the disease in the military setting (i.e., service-attributable fraction).

Response. VA considers scientific literature that includes measures of attributable risk, when available. Unfortunately, estimates of the fraction of disease prevalence due to military service or magnitude of risk associated with military exposure are often not available. VA and the Department of Defense (DOD) have been developing the Individual Longitudinal Exposure Record (ILER). ILER may allow better esti-

mates of exposure and more precise application of measures of attributable risk as related to specific military exposures or experiences.

Question 1a. Would VA need any new statutory authorities from Congress to implement any of the remaining NAS recommendations?

Response. No.

Question 1b. As it pertains to providing presumptive benefits, what is the standard VA process for implementing recommendations from the National Academy of Sciences, including timelines for completion each step of the process?

Response. When specified in statute, VA must follow certain procedures, as VA did with the now-expired provisions of the Agent Orange Act of 1991. Otherwise, VA generally relies on the guidance of VA Directive 0215 for reviewing the recommendations presented by the National Academies of Sciences, Engineering, and Medicine (NASEM)—formerly IOM. This policy provides the framework for developing guidance for decisionmaking by the Secretary of Veterans Affairs and any subordinate required actions.

Question 1c. When VA decides makes a decision on NAS recommendations, where can Congress or the public go to get the rationale behind those decisions?

Response. The final reports issued by NASEM remain the authoritative review of the literature used for decisionmaking. If VA makes official decisions based on NASEM's recommendations, the House, and Senate Committees on Veterans' Affairs (HVAC and SVAC) are formally notified by letter from the Secretary of Veterans Affairs explaining the decisions made. In some instances, such as where VA's decision involves rulemaking, notice of proposed or final action or regulation would be published in the *Federal Register* with an explanation for the decision.

Question 1d. Does VA need any additional authorities to make the process for adding new presumptive conditions be more productive and transparent?

Response. No.

BURN PITS

Question 2. The VA reported that 184,795 individuals have enrolled in the Airborne Hazards and Open Burn Pit Registry as of August 30, 2019. How does the population of enrolled individuals compare to the number of individuals who have served at burn pit locations?

Response. The eligible population is estimated to be 3 million. The number of participants in VA's Airborne Hazards and Open Burn Pits Registry (AHOBPR) continues to grow by at least 500 people a week. It is open to any Veteran or Servicemember who served in the Southwest Asia (SWA) theater of operations on or after August 2, 1990. Consistent with 38 CFR § 3.317(e)(2), the SWA theater of operations refers to Iraq, Kuwait, Saudi Arabia, the neutral zone between Iraq and Saudi Arabia, Bahrain, Qatar, the United Arab Emirates, Oman, the Gulf of Aden, the Gulf of Oman, the Persian Gulf, the Arabian Sea, the Red Sea, and the airspace above these locations. In addition, VA expanded participation in the Airborne Hazards and Burn Pits Center of Excellence (AHBPCE) to include individuals who served in Afghanistan or Djibouti on or after September 11, 2001.

VA and DOD continue their respective and mutual efforts to increase participation numbers using targeted mailings, social media, videos, and the VA Public Health Web site. These efforts are coordinated through the monthly VA/DOD Deployment Health Working Group. In addition, DOD covers and highlights VA Environmental Health programs, to include AHOBPR, during its Transition Assistance Program (TAP), which is held for separating/discharged Servicemembers to inform them of both DOD and VA benefits available to them.

Question 2a. Of the enrolled individuals, how many have opted to participate in a medical evaluation?

Response. There are 159,566 Servicemembers and Veterans who are eligible for the AHOBPR examination. Approximately 60 percent of eligible Veteran-participants request a registry exam. Regarding Veterans, of those who have completed AHOBPR's online questionnaire and requested a VA AHOBPR health examination, 9,303 have been completed the health examination. DOD Active Duty participant numbers are 25,229. VA has implemented multiple education efforts to continue to improve exam completion numbers. This resulted in a 35 percent increase in exam numbers from Fiscal Year (FY) 2018 to FY 2019. These efforts will continue through FY 2020 and into the future.

Question 2b. What actions has the VA taken to increase awareness of the availability of the registry and medical evaluations to eligible veterans and current servicemembers?

Response. VA has contracted with DCG Communications to conduct focus-group interviews with over 100 Veterans and Servicemembers to better understand barriers to registering for the AHOBPR and for completing requested in-person registry examinations. The results of these focus groups, once analyzed, will help inform VA's enhanced outreach campaign targeted at individuals eligible to participate in the registry. It is projected that this outreach campaign will begin once all preparatory steps have been completed in the Fall of 2020.

VA has produced fact sheets on the topic, including an overview of the registry, steps for completing the optional in-person registry (in English and Spanish), fact sheets for VA providers performing the registry examination, quarterly fact sheets displaying the number of participants by location, and biannual fact sheets summarizing registry findings. VA released newsletters with information about the registry, including articles in past issues of the annual Gulf War Newsletter and Post-9/11 Vet Newsletter (retired in 2019 and 2018, respectively) and the new biannual Military Exposures & Your Health newsletter for Veterans with service in 1990 through the present. The first Military Exposures & Your Health newsletter, released in September 2019, contains two articles about the registry. VA also has several blog posts on the registry, an article on MyHealthVet, social media postings and email announcements, and a VHA Facebook chat on the registry.

In addition, VA meets with Veterans Service Organizations (VSO) periodically to discuss AHOBPR operations to include outreach and barriers to participation. A meeting with the Veterans of Foreign Wars resulted in the organization sending out a message to its members to ensure the accuracy of their AHOBPR contact information. VSOs with a specific focus on Airborne Hazards are invited to the annual VA/DOD Airborne Hazards Symposium.

VA has produced two videos on the AHOBPR registry that are available to Servicemembers and Veterans. One video provides an overview of the registry and the other focuses on steps to complete an in-person exam, if requested, and it explains how participating in the registry may contribute to VA research efforts aimed at studying possible relationships between long-term respiratory disease and/or other health conditions and possible in-service AHOBPR-related exposures.

Find materials on the registry, including the videos, on VA's Web page <https://www.publichealth.va.gov/exposures/burnpits/registry.asp>.

Question 2c. What efforts are underway at VA to improve the registry?

Response. In 2017, NASEM (NAM or National Academy of Science Engineering and Medicine) published a report titled "Assessment of the Department of Veterans Affairs Airborne Hazard and Open Burn Pit Registry." VA has completed 5 of the 9 recommendations. Two will be addressed with a future contract and two (research and improved clinical exams) are ongoing projects. As per the Congressional law regarding the AHOBPR Registry, another review is due 5 years after the first review. It has been commissioned and is expected in February 2022.

In addition, VA's contract with DCG Communications, discussed previously, should help VA better understand and address barriers to participation and help identify possible incentives VA can undertake to increase participation.

Major improvements to the online questionnaire must be programmed in coordination with VA information technology contracting projects. Improvements requested for this contract cycle include allowing registry participants to add new deployment information during their military time. VA is also working to improve its software capability to better process and schedule requested in-person registry examinations.

VA conducts yearly training at the Environmental Health Coordinators and Clinicians (EHCC) Conference for VA Medical Center (VAMC) EHCCs from across the Nation. VA has quarterly phone conferences with each Veterans Integrated Service Network (VISN) to update VA EHCCs.

Question 2d. Does VA need new authorities to make any appropriate changes to the Burn Pit Registry to increase its usefulness?

Response. No.

Question 2e. What are the most recent policy guidance documents that VA released related to both the disability criteria and treatment of deployment related respiratory conditions?

Response. VBA's Compensation Adjudication Procedures Manual contains guidance on processing claims for service connection for disabilities resulting from exposure to specific environmental hazards.

For Veterans enrolled in VA's health care system, the treatment of respiratory conditions that may be related to Airborne Hazards, such as asthma, sinusitis, or other medical conditions, are the same regardless of the underlying cause. Hence, there is no need for a specific or separate VHA policy related to the treatment of

the AHOBP-participant cohort. As to the registry, in August 2019, VA published a policy on administering AHOBPR, VA Directive 1307, AIRBORNE HAZARDS AND OPEN BURN PIT REGISTRY (AHOBPR). Please see Attachment 2.

ATTACHMENT 2

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1307
Transmittal Sheet
August 19, 2019

AIRBORNE HAZARDS AND OPEN BURN PIT REGISTRY (AHOBPR)

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive sets forth clinical and administrative policies for the VHA Airborne Hazards Open Burn Pit Registry (AHOBPR). The AHOBPR is established for eligible Veterans and Servicemembers who may have been exposed to airborne hazards, such as open burn pits, during qualifying military service.

2. SUMMARY OF CONTENT: This VHA directive establishes required processes and procedures for the AHOBPR and associated health examination. Refer to Appendix A for clinical guidance on the conduct of AHOBPR health examinations.

3. RELATED ISSUE: VHA Directive 1325, Gulf War Registry, dated June 1, 2017, VHA Directive 1303, Evaluation Protocol for Veterans with Potential Exposure to Depleted Uranium (DU), dated April 6, 2017, VHA Directive 1303.01, Screening and Evaluation Protocol for Veterans with Embedded Fragments who Served in Iraq and/or Afghanistan post-September 11, 2001, dated April 6, 2017.

4. RESPONSIBLE OFFICE: The VHA Office of Post Deployment Health Services (10P4Q) is responsible for the contents of this directive. Questions may be referred to 202-266-4695 or by email at: vabumpiter@va.gov.

5. RESCISSION: None.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of August 31, 2024. This VHA directive will continue to serve as national VHA policy until it recertified or rescinded.

**BY DIRECTION OF THE OFFICE OF THE
UNDER SECRETARY FOR HEALTH:**

/s/ Lucille B. Beck, PhD.
Deputy Under Secretary for Health
for Policy and Services

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publications Distribution List on August 19, 2019.

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AIRBORNE HAZARDS OPEN BURN PIT REGISTRY (AHOBPR)**1. PURPOSE**

a. This Veterans Health Administration (VHA) directive sets forth administrative and clinical policy and responsibilities for the Airborne Hazards and Open Burn Pit Registry (AHOBPR). Participation in the AHOBPR is voluntary; however, participation allows eligible Veterans and Servicemembers to document their exposures and report health concerns through an online self-assessment questionnaire. Veterans, and Servicemembers can use the Registry questionnaire to report exposure(s) to airborne hazards (such as smoke from burn pits, oil-well fires, or pollution during deployment) and open burn pits that they experienced during service defined in paragraph 2.a as well as any other in-service exposures and associated health concerns.

b. Provided they have completed the on-line self-assessment questionnaire, AHOBPR participants, may also request an in-person, no-cost registry health examination. This is entirely optional and done only at the request of the AHOBPR participant. Specifically, Veterans enrolled in the Department of Veterans Affairs (VA) health care system may request an AHOBPR health examination from their closest facility. The facility may utilize primary care provider or Patient Aligned Care Team to complete these exams. Veterans not enrolled in VA's health care system who have completed the self-assessment questionnaire may contact a VA Environmental Health Coordinator to schedule it. Active duty Servicemembers are to contact their local serving military hospital or medical treatment facility to obtain the examination.

c. AHOBPR data includes information necessary to ascertain and monitor the health effects of the exposure of members of the Armed Forces to toxic airborne chemicals and fumes caused by open burn pits. This data can be used to identify areas of needed scientific study and clinical investigation. Research findings are translated into clinical practice, if and as appropriate, to improve VA treatment programs and to address, more generally, Servicemembers' concerns about potentially harmful toxic exposures they may experience during deployment. **AUTHORITY:** Title 38 United States Code (U.S.C. 527; Public. Law (Pub. L.) 112-260 section 201; and Pub. L. 102-585 (1992).

2. BACKGROUND

a. Section 201 of Pub. L. 112-260 (2013) required VA to establish and maintain an open burn pit Registry for certain eligible individuals who may have been exposed to toxic airborne chemicals and fumes caused by open burn pits. Having expanded the group of eligible individuals beyond those described in the law, the AHOBPR includes individuals who may have been exposed to open burn pits, toxic airborne chemicals and fumes, and other airborne hazards such as particulate matter (PM), while serving as a member of the Armed Forces in one or more of the locations in the Southwest Asia (SWA) theater of operations on or after August 2, 1990 to present. Consistent with 38 Code of Federal Regulation (CFR) 3.317(e)(2), the SWA theater of operations refers to Iraq, Kuwait, Saudi Arabia, the neutral zone between Iraq and Saudi Arabia, Bahrain, Qatar, the United Arab Emirates, Oman, the Gulf of Aden, the Gulf of Oman, the

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Persian Gulf, the Arabian Sea, the Red Sea, and the airspace above these locations. VA further expanded participation to include individuals who served in Afghanistan or Djibouti on or after September 11, 2001.

b. High levels of ambient particulate matter (PM) were identified as a potential threat to respiratory health early in Operation Iraqi Freedom (OIF). Sampling conducted by preventive medicine personnel deployed to the United States Central Command (USCENTCOM) area of operation typically demonstrated levels of PM (sometimes referred to as particle pollution in public communications) above those considered healthy by the U.S. Environmental Protection Agency's National Ambient Air Quality Standards. Generally, the major contributor to PM in the SWA theater of operations was re-suspension of dust and soil from the desert floor. Open-air burn pits were used frequently during Operation Enduring Freedom (OEF), OIF, and Operation New Dawn (OND) before incinerators became the norm.

c. A 2011 Institute of Medicine (IOM) Report on Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan determined that there is limited/suggestive evidence of an association between exposures to combustion products and reduced pulmonary function in these populations. The evidence for the association between the development of specific respiratory diseases and exposure to combustion products was found to be inadequate or insufficient. Currently, it is unknown if reduced pulmonary function is a consequence of exposure to PM, or if combustion products are a risk factor for the development of clinical disease later in life.

d. To clarify this uncertainty, studies are either in progress or planned to determine the prevalence and risk factors which may contribute to respiratory disease after exposure during service to airborne hazards and open burn pits. VA and Department of Defense (DoD) are supporting additional research to further understand potential long-term health effects of airborne hazards. This research is focused not only on possible associations between these exposures and respiratory disease but also with other diseases such as cancer, gastrointestinal disease, etc. Studies also focus on any potential effects that may result from combined exposure to both open burn pits and the general environment of the SWA theater of operations, to determine if such combined exposure may put one at risk of disease. As the Departments' respective AHOBPR-related research is using current AHOBPR data aligned with the registry's current design parameters, participation will not be further expanded to other regions or theaters of operations; it is necessarily limited to those who served in the currently listed locations during the qualifying time-period(s).

3. DEFINITIONS

a. **Open Burn Pits.** For purposes of this directive, an 'open burn pit' is an area of land located in any of the places listed in paragraph 2.a of this directive to which a person eligible for inclusion in the AHOBPR must have deployed that is designated by the Secretary of Defense to be used for disposing solid waste by burning in the outdoor air; and does not contain a commercially manufactured incinerator or other equipment specifically designed and manufactured for the burning of solid waste.

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- b. **Operation Enduring Freedom (OEF).** For the purposes of the AHOBPR, OEF is defined as service in Afghanistan after September 11, 2001.
- c. **Operation Iraqi Freedom (OIF).** For the purposes of the AHOBPR, OIF began in March of 2003, when the U.S. and coalition forces moved into Iraq from Kuwait. OIF continued until August 2010.
- d. **Operation New Dawn (OND).** For the purposes of the AHOBPR, OND began in August of 2010, in Iraq and ended in December 2011.
- e. **Particulate Matter (PM).** Particulate Matter are airborne particles with a fine particle mass and a diameter of less than 2.5 µm-micrometers (PM2.5).
- f. **Servicemember.** For the purposes of the AHOBPR, a Servicemember is a person who is serving on active duty in one of the following branches of the U.S. Armed Forces: Army, Marine Corps, Navy, Air Force, National Guard, or the Coast Guard.
- g. **User Validated Data (Deployment).** User validated data is deployment and demographic data, provided from DoD sources, that the user confirms as accurate, revises, or augments.

4. POLICY

It is VHA policy that all eligible Veterans have an opportunity to participate in the AHOBPR and, if requested after completion of the AHOBPR's on-line self-assessment questionnaire, receive an in-person, no-cost AHOBPR health examination.

NOTE: *AHOBPR laboratory studies/tests and the optional in-person health examinations, to include diagnoses, are for registry purposes only (i.e., they do not constitute examinations for purposes of treatment). Nor do they qualify as compensation and pension examinations or fitness for duty examinations. Referrals for further diagnoses will be made as necessary.*

NOTE: *If the need for follow-up medical care is identified or recommended as a result of the Veteran's participation in the AHOBPR, then, the Veteran, if enrolled, will be referred to their treating VA primary care provider or specialist for recommended medical follow-up. If not enrolled, the participant will be advised to seek appropriate medical follow-up (at non-VA expense) with their own health care provider in the community.*

5. RESPONSIBILITIES

- a. **Under Secretary of Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.
- b. **Deputy Under Secretary of Health for Operations and Management.** The Deputy Under Secretary of Health for Operations and Management is responsible for overseeing the development and maintenance of VHA programs and policies concerning the AHOBPR.

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c. **Chief Consultant, Post Deployment Health Services (PDHS)**. The Chief Consultant, PDHS has the responsibility to develop, coordinate, and monitor VHA activities relating to the AHOBPR. These activities are used to answer congressional and Veteran Service Organization requests and to improve the health of Veterans. This data is used to better understand the potential health effects of airborne hazards and open burn pit exposure. The analysis of the collected data will be used to update policy as needed.

d. **Veterans Integrated Service Network (VISN) Director**. The VISN Director, or designee, is responsible for:

(1) Designating one VISN Lead Environmental Health (EH) Clinician and one VISN Lead EH Coordinator.

(2) Notifying the Chief Consultant, PDHS of changes in either the VISN EH Clinician or the VISN Lead EH Coordinator at VHA10P4QPostDeploymentAction@va.gov. The notification must be made within 10-business days of the change and include the new name, title, mail routing symbol, and commercial telephone and fax numbers with area code.

e. **VISN Lead Environmental Health (EH) Clinician**. The VISN EH Clinician is responsible for:

(1) Disseminating clinical program information forwarded from the Chief Consultant, PDHS to appropriate VA medical facility staff.

(2) Providing quality assurance of environmental health clinical work (interviews, physical exams, records review) as directed by the Chief Consultant, PDHS.

(3) Responding to inquiries from VA medical facility EH Clinicians within 5-business days or forwarding them to PDHS for response.

(4) Notifying the Chief Consultant, PDHS of changes in the EH Clinician at any VA medical facility in the VISN within 10-business days and include the new name, title, mail routing symbol, and commercial telephone and fax numbers with area code. This information must be submitted to PDHS by emailing VHA10P4QPostDeploymentAction@va.gov.

f. **VISN Lead Environmental Health Coordinator**. The VISN Lead EH Coordinator is responsible for:

(1) Disseminating administrative information from the Chief Consultant, PDHS to appropriate staff.

(2) Responding to inquiries from VA medical facility EH Coordinators within 5-business days or forwarding them to PDHS for response.

(3) Notifying the Chief Consultant, PDHS of changes in the Lead EH Coordinator at any VA medical facility in the VISN within 10-business days of the change to include the

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new name, title, mail routing symbol, and commercial telephone and fax numbers with area code. This information must be submitted to PDHS by emailing VHA10P4QPostDeploymentAction@va.gov.

(4) In addition to disseminating information described in the law, ensuring the distribution of up-to-date information to Veterans, VA medical facility staff (e.g., at staff conferences or grand rounds), Veterans organizations, community groups and other interested parties.

(5) Providing oversight of all AHOBPR programs in the VISN and improving them through coordination with facilities' lead environmental health coordinators.

g. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Designating one or more VA medical facility EH Clinician(s) and one VA medical facility EH Coordinator and alternate and ensuring proper training consistent with assigned duties.

(2) Notifying the VISN EH Coordinator of changes in medical facility EH Coordinators and notifying the VISN EH Clinician of changes in medical facility EH Clinicians at their respective facilities and/or satellite clinics. The notification must be made within 10-business days of the change and include the new name, title, mail routing symbol, and commercial telephone and fax numbers with area code. This information must be submitted to PDHS by emailing VHA10P4QPostDeploymentAction@va.gov.

(3) Ensuring that AHOBPR health examinations are conducted within 90-calendar days from the date the Veteran-participant requests. If the VA medical facility fails to meet this appointment scheduling time standard, the VA medical facility Director must explore all alternatives (e.g., referrals to other VA medical facilities or additional staff hours to perform these examinations) to bring the VA medical facility into compliance with this standard. If these alternative measures have been explored but their use would still not meet the standard, then an exemption must be requested by emailing PDHS at VHA10P4QPostDeploymentAction@va.gov.

(4) Ensuring that EH Clinicians possess appropriate clinical training in possible and known health effects associated with military occupational and environmental exposures. This can be met by a combination of formal professional training, certifications, and continuing education, such as Veterans Health Initiative (VHI) modules.

(5) Ensuring requested AHOBPR health examinations are completed in accordance with requirements. These examinations are a VHA core service meaning that they are not available in the community. Moreover, non-VA health care providers are unable to access the Veterans AHOBPR questionnaire and examination template (Patch 39). Registry exams are unable to be completed and documented to the record if sent to community care. **NOTE:** See references, section c, for more information on core services.

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(6) Ensuring these examinations are conducted only within VA medical facilities (and not performed by outside providers as these providers are unable to access the Veteran's Registry Questionnaire or the examination template). **NOTE:** *Standard release of information requests can be submitted to obtain the results of these examinations.*

(7) Overseeing that the Post Examination letter is sent to the Veteran within two weeks of the initial appointment. This process is facilitated by the VA medical facility Lead EH Coordinator. **NOTE:** *See Appendix C for additional information.*

h. **VA Medical Facility Lead Environmental Health (EH) Clinician.** The VA medical facility Lead EH Clinician is responsible for:

- (1) Serving in an advisory capacity for the AHOBPR's clinical management.
- (2) Engaging primary care services at the VA medical facility level to ensure primary care teams are aware of the AHOBPR and EH Clinician subject matter expertise.
- (3) Referring a Veteran who is enrolled in VA's health care system to their treating VA primary care provider, if follow up treatment is recommended or needed. Recommending Veterans not enrolled to seek (at non-VA expense) appropriate follow up with their personal medical providers in the community.

NOTE: *The cost of all laboratory studies/tests conducted as part of the AHOBPR health examination are covered by the AHOBPR. The scope of the AHOBPR health examination may include testing and examinations beyond the initial examination. For instance, a participant who wheezes on AHOBPR examination may be sent for Pulmonary Function Tests and given a consult to pulmonary as part of the AHOBPR laboratory studies/tests and health examination. Because the examination is not conducted for purposes of treatment, any conditions suspected or identified on testing or, if applicable, examination, are to be followed up as discussed above in paragraph 4.*

- (4) Advising the Veteran or primary care provider of all aspects of the AHOBPR health examination, including its purpose and limitations.
- (5) Performing the AHOBPR health examination for all Veterans who request it. The examination needs to be done only once, with future care and exams provided from their primary care provider.
- (6) Completing or assisting other primary care providers to complete requirements to include recording the encounter using the Airborne Hazards and Open Burn Pit Registry Clinical Template as covered in the Initial Basic Health Examination section below.
- (7) Signing the Post Examination follow up letter to the Veteran. This letter explains the results of AHOBPR laboratory studies/tests and the AHOBPR health examination.
- (8) Ensuring that VA medical facility staff members are familiar with clinical applications of the AHOBPR.

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i. **VA Medical Facility Lead Environmental Health (EH) Coordinator.** The VA medical facility Lead EH Coordinator is responsible for:

- (1) Completing initial and ongoing training concerning the AHOBPR.
- (2) Providing assistance to Veterans, as needed, to access the online AHOBPR questionnaire and, if requested, to schedule the optional health-examination with the facility's EH clinician or a primary care provider, as applicable.
- (3) Engaging primary care services and VA medical facility staff, as needed to ensure awareness of the AHOBPR.
- (4) Assisting enrolled Veterans with scheduling appointments with appropriate VA providers for medical follow-up of any abnormalities found on testing or examination.
NOTE: It remains, however, the Veteran's (or surrogate's) decision whether to pursue recommended medical follow-up. Preparing and obtaining the VA medical facility lead EH Clinician's signature on the Post Examination letter and mailing the letter to the Veteran.

6. REPORTING REQUIREMENTS

- a. **Registry National Clinical Template.** Completion of the AHOBPR Clinical Template satisfies the central Registry reporting requirements.
- b. **Clinical Reminders Patch 39 Airborne Hazards Open/Burn Pit.** If the template patch is not currently accessible through CPRS, users can contact the VA medical facility site clinical applications coordinator (CAC) for assistance and installation.

7. TRAINING

a. The following training is required for all clinicians performing AHOBPR health examinations. The two modules will take about 1.5 hours to complete.

(1) Employee Education System VHA Train, <https://www.train.org/vha/welcome>.

NOTE: This is an internal VA web site that is not available to the public.

(a) Course ID: 1070234, WRIISC Mod 1 - Assessing Deployment Related Environmental Exposures; and

(b) Course ID: 1070422, WRIISC Mod 2 -Airborne Hazards.

NOTE: These courses are available to outside agencies.

(2) VA Talent Management System 2.0, <https://www.tms.va.gov/SecureAuth35/>.

NOTE: This is an internal VA web site that is not available to the public.

(a) Course ID: 33195, Module 1: Assessing Deployment Related Environmental Exposures; and

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(b) Course ID: 33405, WRIISC MOD 2: Airborne Hazards.

b. In addition, training is available for technicians through annual conference, and monthly meetings. Training is also available upon request through skype to learn about using the AHOBPR.

c. Additional training is being developed by post deployment health services (10P4Q) to educate primary care providers on completion of AHOBPR examinations.

NOTE: *It is the responsibility of the national program office to own, develop, and make available all training products and this responsibility cannot be delegated down to the VISN or facilities.*

8. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

9. REFERENCES

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APPENDIX A**CLINICAL GUIDANCE FOR PROVIDERS DURING EXAMINATION RELATED TO
AIRBORNE HAZARDS AND OPEN BURN PIT EXPOSURES****1. PURPOSE**

a. The following outline represents a focused, thorough examination of a Veteran who requests an examination after completing the Airborne Hazards and Open Burn Pit Registry (AHOBPR) Self-Assessment. This guidance may also be useful for encounters where deployment health concerns are expressed, regardless of whether the Veteran is participating in the Registry.

b. Before the encounter, review the clinically relevant summary for the patient through the provider portal- <https://vaww.ahobpr.registries.aac.va.gov/RegistrantSearch.aspx>. **NOTE:** *This is an internal VA Web site that is not available to the public.*

2. HISTORY

a. Explore the primary health concerns of the Veteran in the context of exposure to deployment-related airborne hazards and open burn pits. Health concerns that are not central to airborne hazards and open burn pits can be addressed in the past medical history (comorbid diagnoses or conditions) or review of systems (symptoms).

(1) Chief complaint;

(2) History of present illness;

(3) Relevant deployment history, including environmental and occupational exposure concerns;

(4) Past medical history;

(5) Social history;

(6) Tobacco use history;

(7) Other illicit or recreational substance use;

(8) Family history, including birth defects in children;

(9) Medication reconciliation, as per your facility standards; and

(10) Review of systems.

b. Physical Examination: Document pertinent positive and negative findings in each of the following body systems. A more extensive physical examination may be performed if clinically indicated:

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- (1) Vital signs (respiratory rate, O2 Sat, pulse, blood pressure, height, weight, temperature);
- (2) Ear, nose and throat (e.g., conjunctivitis, nasal mucosa/septum, oropharynx);
- (3) Lymphadenopathy (e.g., cervical, axillary, submandibular, posterior auricular occipital);
- (4) Chest/Pulmonary (e.g., lung sounds, cyanosis, clubbing, habitus);
- (5) Cardiovascular (e.g., heart sounds/borders/position, pulses, edema);
- (6) Abdomen (e.g., organomegaly, tenderness); and
- (7) Other findings on physical examination.

c. Diagnostic examination to date: Review and summarize pertinent positive and negative results from these and other relevant diagnostic tests and examinations (ordered as necessary).

- (1) Chest radiograph – posterior/anterior and lateral;
- (2) Computed tomography (CT) chest;
- (3) Arterial blood gas;
- (4) Complete blood count with differential;
- (5) Spirometry/pulmonary function tests;
- (6) Echocardiogram;
- (7) Pulmonary consult;
- (8) Ear, nose and throat consult; and
- (9) Biopsy or other tissue obtained.

d. Overall assessment and recommendations based on available information: Synthesize findings and formulate a concise assessment. Consider an appropriate differential diagnosis to explain patient-reported symptoms and dysfunction. Use objective findings from examination to prioritize the list of possible diagnoses according to likelihood of presence and urgency. Develop a plan for additional work up and follow up, as appropriate.

- (1) Assessment plan may include:
 - (a) Vocal cord dysfunction assessment;

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- (b) Respiratory muscle strength;
- (c) Other related specialty consult results; and
- (d) Other testing.

e. Overall Registry assessment and recommendations: Overall assessment and recommendations must be based on available information. Synthesize findings and formulate a concise assessment. Consider appropriate differential diagnoses to explain patient-reported symptoms and dysfunction. Use objective findings from examination to prioritize the list of possible diagnoses according to the likelihood of presence and urgency.

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APPENDIX B**ADMINISTRATIVE GUIDANCE FOR OPTIONAL IN-PERSON HEALTH
EXAMINATION**

1. Veterans do not need to be enrolled in VA's health care system to be eligible to participate in the Airborne Hazards and Open Burn Pits Registry or to obtain the optional in-person Registry-related health examination. Veterans and Servicemembers can participate by accessing the following link:
<https://veteran.mobilehealth.va.gov/AHBurnPitRegistry/>.

2. If enrolled in VA's health care system, the Veteran may request a Registry health examination from the Patient Aligned Care Team (PACT), primary care provides, or Environmental Health (EH) Clinician.

3. If not enrolled in VA's health care system, the Veteran may request a Registry health examination from their local VA medical facility. If a Veteran receives this examination but has no VA medical record, then the VA medical facility must ensure an individual record is established for the Veteran in VA's current electronic health record.

4. EH appointments are facilitated through the EH Coordinator that serves each VA medical facility. Follow the link at: <http://www.publichealth.va.gov/exposures/index.asp> for a list of EH Coordinators and contact information. **NOTE:** Completion of the on-line questionnaire is required to be considered a participant in the Registry and to request the voluntary face-to-face Registry health examination.

5. Participation in the on-line Registry is required to obtain the in-person clinical examination. After completing the Registry self-assessment questionnaire, Veterans and Servicemembers may request an in-person and no-cost medical examination for health concerns and conditions that may be related to environmental airborne hazards and open burn pits.

a. Active-duty Servicemembers may also participate in the Registry through completing the on-line questionnaire. They may also request a voluntary medical examination from their local military treatment facility (MTF), after they have completed the Registry self-assessment questionnaire. When contacting the MTF, active-duty Servicemembers should state they are calling for an appointment specifically to address health concerns related to the Registry exposures. Active duty Servicemembers are encouraged to complete the Registry as well as not to delay seeking medical care for medical concerns.

b. The clinical examination includes a health care provider's review and discussion of the self-assessment results with the Veteran-participant. The goal of the face-to-face medical examination is to address any concerns, questions, or symptoms Veterans may have regarding airborne hazards and open burn pits. The medical encounter includes a basic initial examination. Depending on those results, further consultation or specialty examination may be justified and the provision of such will be considered part of the

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Registry medical examination. Any consults or specialty examination results will be forwarded to the Veteran's primary care provider, whether VA or civilian in the Post Examination follow-up letter.

c. Providers can access the clinically relevant summary results at the Airborne Hazards and Open Burn Pit Registry Clinical Portal: <https://vaww.ahobpr.registries.aac.va.gov>. **NOTE:** *This is an internal VA web site that is not available to the public.*

6. Veterans may receive this evaluation via tele-medicine especially if the Veteran or servicemember cannot travel to the site of the examining physician. The Veteran will need to travel to a VA site with telemedicine capability and consent to a telemedicine encounter.

NOTE: *Participants can return to the secure Registry web-application to obtain a copy of their questionnaire to share with non-VA providers.*

d. **Basic Medical Examination**

(1) As part of the Registry program, Veteran participants are eligible for an in-person Registry medical examination at no cost to discuss concerns and be evaluated for symptoms possibly related to airborne hazards and open burn pit exposures, during deployments. To facilitate Registry discussions, providers may refer to Appendix A, Guidance for Providers during Initial Encounter Related to Airborne Hazards and Open Burn Pit Exposures. Appendix A highlights ways to interpret a Veteran's responses. The standardized clinical template is available in the CPRS. Clinicians can access this template to record the Registry medical encounter via Clinical Reminders Patch 39 "Airborne Hazards Open/Burn Pit" template. If the template patch is not available currently within your access to CPRS, please contact your site's clinical applications coordinator (CAC) for assistance and installation.

(2) The basic examination includes:

(a) Medical, occupational, and environmental history with an emphasis on exposures to airborne hazards and burn pits and PM (e.g., pollution, blowing sand, and dust);

(b) History of personal habits including smoking; and

(c) Physical examination focusing on the respiratory system with pulse oximetry.

(3) The following additional tests may be appropriate for those with respiratory symptoms, this list is not all inclusive, other tests may be ordered as the clinician deems appropriate:

(a) Spirometry testing;

(b) Posterior-anterior PA and lateral chest radiograph; and

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(c) Complete blood count, especially in menstruating women.

e. **Required Use of Relevant DoD medical data.**

VA providers may want to review medical information about active duty deployment. This information may be available using the Joint Legacy Viewer. Encounters for the post deployment health assessment and post deployment health reassessment may be helpful. These assessments should be done within 30 days of return from deployment and again at 90-180 days. These data points will have information about environmental exposures.

f. **Health Risk Communication.**

Health risk communication is an approach to communication which emphasizes the importance of trust, perception of possible harm, and uncertainty, and is a useful paradigm for conversations about possible health effects from deployment-related exposures. Guidance and educational products on these issues are available through the Office of Public Health Web site at: <http://www.publichealth.va.gov>.

g. **Medical Enrollment & Claims.**

The Registry medical examination does not constitute medical treatment or, on that basis, make participants eligible for VA treatment of any conditions identified as a result of the Registry examination. Participants who are not enrolled in VA's health care system should be encouraged to enroll in order to receive any needed follow-up treatment of conditions identified based on the questionnaire and/or optional medical examination. Veterans who wish to enroll may be directed to the eligibility staff at local VA medical facilities, or the VA Health Resource Centers at 1-877-222-8387, or online at: <http://www.va.gov/healthbenefits>. Veterans who prefer to receive their health care outside of the VA health care system should likewise be encouraged to follow-up, as needed, with their private provider.

h. **Copayments Not Applicable to Registry Health Examinations**

(a) Consistent with law, regulations, and policies, Copayments will not be assessed Veteran participation in the Registry, which includes any related Registry-authorized examination(s).

(b) If follow up care is desired with the VA related to the results of the Registry examination, Veterans may incur copayments related to those services.

(c) The Veteran may consider applying for care within the VA following proper enrollment procedures.

(d) Use the Stop Code below to avoid copayment.

i. **Stop Code**

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The Stop Code for the environmental health/Registry exams must be used for the Registry Exam. The current code is 499.

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APPENDIX C**POST-EXAMINATION PROCEDURES FOR LETTERS**

1. Letters are to be mailed to the Veteran within two weeks of the initial examination appointment. If the Veteran is referred to a specialty clinic, the letter can be sent after a diagnosis is made. Since specialty referrals may take time, efforts should be made to keep the Veteran informed and to not be lost to closing out the burn pit process. It is a requirement that the Veteran receives a letter closing out the registry exam. **NOTE:** *This is facilitated by the VA medical facility lead Environmental Health Coordinator.*

2. A copy of this dated and signed letter must be filed and/or scanned into the Veteran's health record.

3. It is essential that this letter be written in language that can be easily understood by the Veteran and includes the following:

(a) If the Veteran who was examined has no detectable medical problems, the follow-up letter needs to indicate and suggest that the Veteran contact the nearest VA medical facility if health problems appear later.

(b) If it is determined upon examination that the Veteran does have medical problems, it is not necessary to specify the problems in the letter; however, the Veteran must be advised if the recent examination indicated a health condition or problem which may require further examination and/or treatment.

(c) If the Veteran is eligible for VA medical treatment, the letter needs to so advise and recommend that the Veteran seek follow-up medical care at a VA medical facility.

(d) If the Veteran is not eligible for treatment, the letter needs to recommend that the Veteran seek appropriate medical care elsewhere.

4. The medical examination does not automatically initiate a claim for VA benefits. For information relating to claims, refer the Veteran to the nearest VA medical facility or regional office (RO).

5. Sample letters are available in the Airborne Hazards Open Burn Pit Toolbox:
<https://vaww.publichealth.va.gov/exposures/airborne-hazards-burn-pit-registry.asp>.

Question 2f. How often does VA review and update that guidance?

Response. VHA policies are active for 5 years, although they remain in effect until rescinded, re-issued, or replaced. VA Directive 1307 technically expires on August 31, 2024. Nevertheless, policy amendments may occur before a formal expiration date, if and as needed.

Question 2g. What criteria does the VA consider in determining whether a regulatory presumptive service connection is warranted for airborne hazard and burn pit exposed veterans?

Response. Currently, there are no presumptive service-connected diseases for Airborne Hazards exposures. Any Veteran who believes their illness or injury is the result of military service is encouraged to submit a claim. The NASEM report on Medical Effects of Airborne Hazards and Open Burn Pits is expected in May 2020.

Presumptive determinations are based on scientific evidence of an association between a toxic exposure of adequate dose and duration to cause harm and a defined health condition.

Question 2h. What is the position of the VA on the establishment of a regulatory presumptive service connection between exposures to open burn pit emissions during military service? And the subsequent development of certain diseases or illnesses?

Response. Currently, there is insufficient scientific evidence to create presumptive service connection between exposure to Airborne Hazards associated with open burn pit emissions and disease.

VA commissioned an updated NASEM review of health outcomes that may be related to Airborne Hazards. The report on this review is due in Spring 2020. The previous NASEM report was completed in 2011.

VA also continues to work on original Airborne Hazards research with DOD and academia.

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. BERNIE SANDERS TO PATRICIA R. HASTINGS, M.D., CHIEF CONSULTANT, POST-DEPLOYMENT HEALTH, U.S. DEPARTMENT OF VETERANS AFFAIRS

Question 1. Dr. Hastings, what are some of the major roadblocks that our veterans keep facing when they file a claim for an illness that could be connected to toxic exposure, and how is VA mitigating these roadblocks?

Response. Military environmental exposures and indeed in-depth environmental exposure training are not taught in medical school. There are about 150 EH Coordinators at VAMCs to assist Veterans. PDHS provides an annual conference covering environmental exposures. PDHS also provides Webinars, a robust Web site and monthly calls to EHCCs. Creation of more clinics with additional specialty training could better serve Veterans potentially exposed to environmental exposure with increased access and services.

Additionally, VA has encountered a lack of documented exposure and verification of exposure. VA is continually coordinating with DOD to continue developing avenues to assist Veterans in verifying potential exposures to environmental hazards. In order to mitigate these risks, VA continues to obtain all military service records to substantiate the Veteran's claim, as well as other relevant evidence, to include lay evidence. VA is statutorily obligated to assist Veterans in obtaining evidence in support of their claims, which also includes medical examinations for purposes of completing their disability claims, when necessary.

Question 2. Dr. Hastings, are all VA facilities equipped to help veterans who have been exposed to toxic chemicals?

Response. VA health care providers are more than equipped to provide examinations and referrals for specialty care, as needed, for health problems which may be related to patients' self-reported or verified in-service exposure(s) to Airborne Hazards or toxic chemicals. Within each VISN there is a cadre of lead EH clinicians who have specialized knowledge and direct communication with a network of similarly trained colleagues to provide support for questions regarding environmental exposures or unique clinical presentations. Further, at each VAMC there is a designated EHCC; however, these staff may have other clinical non-EH assigned duties and responsibilities, as well.

VA health care providers are provided training opportunities in environmental exposure assessment. This includes the annual EHCC Conference, monthly EH Webinars, bi-monthly VISN EH Lead phone conferences, quarterly VISN EHCC phone conferences, and on demand e-learning.

Question 2a. If not, what percentage of VA facilities are so equipped? And if not, are there plans to ensure all VA facilities are so equipped?

Response. See response to Question 2.

Question 3. Dr. Hastings, what is the extent of the collaboration between the DOD and the VA that helps our Veterans receive the treatment that they need for exposure to toxic chemicals?

Response. DOD and VA meet monthly at the PDHS Working Group.

Question 3a: To be more specific, does the DOD provide in a timely and efficient manner, information on burn pits and other environmental hazards to the VA to speed up the claims process for our Veterans?

Response. DOD provides the Periodic Occupational Environmental Monitoring System (POEMS) data, which is very helpful in evaluation of locations and any monitoring that may have been performed. The ILER will improve the sharing of available environmental exposure data between DOD and VA. A specifically identified end user of the ILER, and thus a driver for ILER functionality, is the VA claims adjudicator.

Question 3b. If yes, has that been helpful in reducing waiting times for our Veterans in regard to their claims?

Response. Generally, DOD provides most information in a timely manner, but of late there have been delays in the receipt of Defense Manpower Data base Center (DMDC) direct feed. This, in turn, delays our ability to enter eligible individuals in the AHOBPR because VA must manually enter their eligibility data. DOD and VA are working with the DMDC to more efficiently authenticate AHOBPR eligibility for veterans and Servicemembers.

Question 4. Dr. Hastings, during your testimony you alluded to the fact the Veterans Benefit Administration faces a staffing infrastructure issue when processing the incoming claims related to toxic exposure. How many more permanent staff members does VBA need to process these claims in a timely manner, and how can Congress help you reach that goal?

Response. The infrastructure that was being discussed was related to increasing the staffing and training needed for processing of Blue Water Navy claims.

Beyond the additional resource request VBA has submitted regarding Public Law 116-23 (Blue Water Navy) that is effective January 1, 2020, VBA is sufficiently staffed to process all claims, including toxic exposure claims.

Question 5. Dr. Hastings, during your testimony you mentioned the new ILER system for identifying veterans who may have been exposed to toxic chemicals during their service. How long until veterans can expect to hear from this new system if they were exposed?

Response. ILER is at Initial Operating Capability (IOC) as of 30 September 2019. Fully Operating Capability will be developed through FY 2023. ILER is at Initial Operating Capability (IOC) as of 30 September 2019. Fully Operating Capability will be developed through FY 2023. It will be available for clinicians to use for evaluation of Veterans' exposure related concerns during FY 2020. VA is working with DOD to implement a plan for provider access and training. We anticipate that most clinicians will have ILER access in Winter 2020. ILER has direct deployment information from about 2000 on from the Defense Manpower Data Center (DMDC).

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. SHERROD BROWN TO PATRICIA R. HASTINGS, M.D., CHIEF CONSULTANT, POST-DEPLOYMENT HEALTH, U.S. DEPARTMENT OF VETERANS AFFAIRS

Question 1. Dr. Hastings, prior to this hearing I asked Ohio veterans to detail any environmental or toxic exposure they experienced during service. The majority of veterans who wrote in said they had been exposed to Agent Orange. One of those veterans has bladder cancer. You said the decision to expand the list of Agent Orange presumptive diseases to include bladder cancer, hypothyroidism, Parkinson's-like symptoms, and hypertension is with leadership and the interagency. What recommendation did VA make to the interagency?

Response. This is still in deliberation.

Question 1a. What questions or concerns did OMB relay back to VA leadership?

Response. This is still in deliberation.

Question 1b. When can Congress expect the administration to move forward with a regulation?

Response. This is still in deliberation.

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. RICHARD BLUMENTHAL
TO PATRICIA R. HASTINGS, M.D., CHIEF CONSULTANT, POST-DEPLOYMENT HEALTH,
U.S. DEPARTMENT OF VETERANS AFFAIRS

VA STAY OF ALL BLUE WATER NAVY CLAIMS

Question 1. Why has VA stayed every single claim under the Blue Water Navy Act?

Response. The Blue Water Navy Vietnam Veterans Act of 2019 (Act), Public Law 116-23 that was signed into law on June 25, 2019, and goes into effect on January 1, 2020, gave the Secretary of Veterans Affairs the discretionary authority to issue a stay of pending claims in order to prepare for implementation of the Act. This authority was exercised on July 1, 2019, based on reasoned judgment that it was in the best interest of Veterans and the VA adjudication system as a whole.

As HVAC recognized, the *Procopio v. Wilkie* court decision did not define the term “territorial sea.” *H.R. Rep. No. 116-58, at 11 (May 10, 2019)*. Although some claimants may have been eligible for benefits under the *Procopio* ruling, the stay became necessary to ensure that VA will process and adjudicate all Blue Water Navy claims in an accurate and orderly fashion by carefully implementing the “broad and comprehensive” definition of service in the Republic of Vietnam that Congress intended. VA is also working to ensure that the proper resources are in place to meet the needs of the Blue Water Navy Veteran community and all Veterans filing for disability compensation and survivors claiming Dependency Indemnity and Compensation. In addition, VA is using this time, until January 1, 2020, to build tools for claims adjudication and to develop evidence for the claims to appropriately identify those who served offshore of Vietnam. Once these issues are addressed, VA will begin processing these claims based on the date that the law goes into full effect.

Although VA stayed the issuance of decisions until the new law becomes effective on January 1, 2020, VA is authorized to effectuate Board of Veterans’ Appeals decisions, issued before July 1, 2019, directing a grant of benefits; VA is currently effectuating those granted benefits. Also, VA continues to concede herbicide exposure and award service connection under existing rules and procedures. These include Veterans who are shown to have served in or visited the country of Vietnam (“boots on ground”) and those who served on vessels on the inland waterways of Vietnam.

Question 1a. How will the Individual Longitudinal Exposure Record (ILER) allow VA to adjudicate claims such as these more quickly?

Response. The ILER will not include records of exposure from the Vietnam era, thus will not be useful in adjudicating Blue Water Navy claims (see below). The ILER will include environmental exposure information that will assist VA in researching and describing military and deployment related exposures for those who have served after 2000. At Full Operating Capability, ILER is intended to provide information about location of service and known recognized exposure hazards. In addition to service location there may be environmental or personal sampling data about specific agents or toxic chemicals, as well as qualitative reports addressing specific situational and environmental conditions at a particular time or place of concern. Records in ILER will be available to claims adjudicators and health care providers in real-time as they work with Veterans to develop claims files or provide care.

Because of the specific requirements of the law, VA will not rely upon ILER for purposes of adjudicating Blue Water Navy claims. In identifying vessels that traveled within 12 nautical miles seaward from the Vietnam water demarcation line as defined by the law, VA has collaborated with the National Archives Records Administration and the Naval History and Heritage to scan and transcribe deck logs for the eligible ships over a 10-year timeframe. The data will then be populated into an electronic repository, which will be utilized by claims processors to determine whether a ship operated in the offshore waters during the prescribed timeframe.

BURN PITS AND AIRBORNE HAZARDS

Question 2. Will servicemembers have access to data from ILER and other DOD records when they are trying to show a disability caused by exposure to burn pits?

Response. Yes, Veterans will be able to see and have copies of their respective individual summary ILER data. The amount of summary data available will improve over time as the ILER is developed from Initial Operating Capability to Full Operating Capability.

AGENT ORANGE

Question 3. Why has the VA not added bladder cancer, hypothyroidism, hypertension, and Parkinson-like symptoms as presumptive disabilities, since the National Academy of Sciences recommended it in 2016?

Response. This is still in deliberation.

Question 3a. In a January 17th letter, Secretary Wilkie indicated a decision on these conditions could be expected summer 2019. During a March 26th hearing, Dr. Richard Stone of the Veterans Health Administration stated that a decision could be expected within the next 90 days. Why have these decisions been delayed?

Response. This is still in deliberation.

PALOMARES RADIATION

Question 4. Secretary Wilkie committed to using a scientifically valid dose estimate methodology to evaluate Palomares veterans' radiation exposure in June 2018. Over a year later, the VA continues to use the Air Force's flawed methodology. Why has the VA continued to use this faulty methodology, and when will it reform its methodology to provide the benefit of the doubt for Palomares veterans as required by law?

Response. The Air Force Medical Service contracted out a "re-look" of exposure and biological monitoring data using the most up-to-date methods for estimation of plutonium intake and committed dose (total dose integrated over a 50-year period following intake). That effort, completed in 2001, confirmed the overall conclusions from 1968 that adverse health effects would not be expected for responders to the accident, but offered three recommendations on actions that might be taken to improve the estimates of plutonium intake and committed doses, and provide further explanation of the discrepancy between the initial high bioassay (urinalysis) results and exposure estimates from environmental sampling.

The methodology used is not flawed (VA and USAF). The question around the radiation doses comes from a number of contaminated samples that were excluded from the initial analyses. The original Labat-Anderson report and the USAF (most recently as 2014) have addressed the issue in detail. Most of the Veterans who participated had no dose or a dose that was barely above the lowest limit of detection. As a result of the most recent USAF communication to VBA, we have used the highest calculated doses for individual Veteran claims, which does indeed give benefit of doubt to the Veteran.

Question 4a. Around 1,600 servicemembers participated in the Palomares clean-up, nearly all of them airmen from a nearby U.S. Air Force base. Some servicemembers have since passed away, many due to illnesses arising from radiation exposure at Palomares. How many Palomares veterans are still alive today?

Response. VA received a Defense Threat Reduction Agency (DTRA) file of individuals who served at the Palomares location. There were 1465 unique observations. After making attempts to fill in missing data for social security numbers (SSN), which is required to complete a search for causes of mortality, there remained 273 records with no SSN. [Many of these 273 had Spanish surnames and may have been Spanish citizens.] This leaves a list of 1192 persons with a valid SSN. Of the list of 1192 with a valid SSN, 923 (60 percent) have been previously submitted to the National Centers of Disease Control, National Death Index (NDI). The most recent search of mortality records through 2016 shows that for the period captured by the National Death index (1979-2016) VA searched 923 records and identified 450 deaths. As of the fourth quarter of FY 2019 there remain ~269 Palomares Veterans who have not yet been searched in the NDI.

VA is developing the submission list for the NDI search for the 2018 mortality file. This submission will include the entire list of 1192 Palomares Veterans who have a valid SSN and should provide an accurate count of vital status through calendar year 2018.

Question 4b. How many Palomares veterans have applied for benefits connected to their radiation exposure at Palomares?

Response. VA does not track, at the corporate level, every specific exposure location, such as Palomares, for claims for service connection based on radiation exposure. Therefore, VA cannot accurately identify the number of Veterans who participated in the Palomares clean-up efforts and have applied for benefits.

Question 5. If the Palomares Veterans Act of 2019 (S. 1896) were passed into law as it is currently written, what is the expected cost and maximum cost to the VA?

Response. Without data on the number of living Palomares Veterans or data on previous claims, VA is unable to provide accurate benefits costs projections. Cost estimates would need to be developed by VHA Forecasting. PDHS has requested data

on the Palomares Veterans in order to look at health outcomes. Any Veteran may submit a claim for any illness that they believe was caused by military service. Claims involving radiation are reviewed by a health physicist in VA's Post Deployment Health Services.

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. MAZIE K. HIRONO TO PATRICIA R. HASTINGS, M.D., CHIEF CONSULTANT, POST-DEPLOYMENT HEALTH, U.S. DEPARTMENT OF VETERANS AFFAIRS

BLUE WATER NAVY VETERANS

Question 1. Earlier this year, Congress passed and the President signed legislation to establish presumptive eligibility for Blue Water Navy Veterans, a policy I have long supported. However, the VA has decided to implement a stay on all claims until January 1, 2020. I continue to hear from veterans in my state, asking when they will be able to access these benefits. These veterans have already waited a long time. How does the VA justify making them wait even longer to seek relief?

Response. The Blue Water Navy Vietnam Veterans Act of 2019 (Act), Public Law 116-23 that was signed into law on June 25, 2019, and goes into effect on January 1, 2020, gave the Secretary of Veterans Affairs the discretionary authority to issue a stay of pending claims in order to prepare for implementation of the Act. This authority was exercised on July 1, 2019, based on reasoned judgment that it was in the best interest of Veterans and the VA adjudication system as a whole.

As HVAC recognized, the *Procopio v. Wilkie* court decision did not define the term "territorial sea." H.R. Rep. No. 116-58, at 11 (May 10, 2019). Although some claimants may have been eligible for benefits under the Procopio ruling, the stay became necessary to ensure that VA will process and adjudicate all Blue Water Navy claims in an accurate and orderly fashion by carefully implementing the "broad and comprehensive" definition of service in the Republic of Vietnam that Congress intended. VA is also working to ensure that the proper resources are in place to meet the needs of the Blue Water Navy Veteran community and all Veterans filing for disability compensation and survivors claiming Dependency Indemnity and Compensation. In addition, VA is using this time, until January 1, 2020, to build tools for claims adjudication and to develop evidence for the claims to appropriately identify those who served offshore of Vietnam. Once these issues are addressed, VA will begin processing these claims based on the date that the law goes into full effect.

Although VA stayed the issuance of decisions until the new law becomes effective on January 1, 2020, VA is authorized to effectuate Board of Veterans' Appeals decisions, issued before July 1, 2019, directing a grant of benefits; VA is currently effectuating those granted benefits. Also, VA continues to concede herbicide exposure and award service connection under existing rules and procedures. These include Veterans who are shown to have served in or visited the country of Vietnam ("boots on ground") and those who served on vessels on the inland waterways of Vietnam.

BURN PITS

Question 2. In talking with veterans in my state, I hear warnings that burn pits will be this generation's Agent Orange. We have an obligation to our service-members and veterans to ensure this generation does not have to wait decades for care and benefits needed to address illnesses caused by their service. What action is the VA taking now to ensure veterans exposed to burn pits can be properly diagnosed, treated, and cared for?

Response. For Veterans enrolled in VA's health care system, treatment of their conditions is the same regardless of etiology. For example, asthma treatment is the same for all causes of asthma. Generally stated, applicable standards of care dictate what is necessary and appropriate treatment, not possible disease etiologies.

Veterans' primary care teams can, as part of their care, complete a clinical evaluation of symptoms and concerns related to Veterans' self-reported burn pit smoke exposure(s). As clinically indicated, Veterans are referred for necessary diagnostic testing and specialty care within the VHA system of care, or, if eligible, to needed specialty care in the community.

For enrollees with difficult-to-diagnose or poorly controlled symptoms, a clinical referral can also be made to AHBPCE at the War-Related Illness and Injury Study Center (WRIISC-NJ). In addition, AHBPCE is reaching out to AHOBPR Veteran-participants who appear to have high priority conditions. AHBPCE is inviting these individuals to come to AHBPCE for a comprehensive in-person clinical evaluation to facilitate their diagnosis and management, and to learn more about the health conditions being experienced by this cohort of Veterans.

As noted, for Veterans who are not enrolled in VA's health care system but who are eligible to participate in the AHOBPR, once they have completed the online AHOBPR questionnaire, they may request an optional in-person registry medical examination at no cost. This examination is not, however, for treatment purposes and does not serve as a basis for either enrollment in VA's health care system or service-connection for purposes of VBA-administered benefits. The VA clinician performing the registry examination uses a standardized medical note template to ensure complete assessment and capture of the registry-required clinical data. Necessary tests and specialty care can also be provided at no cost as part of the registry examination.

Question 2a. What are the barriers facing the VA in meeting this mission?

Response. There are about 300 EHCCs system-wide; they are typically aligned under Primary Care Services. VHA has considered, and will continue to consider, the merits of having large VAMCs operate independent EH programs and clinics with their own dedicated EH staff. For now, due to resources and other reasons, establishing independent EH programs and clinics at these facilities remains an individual VAMC decision.

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. JOE MANCHIN III TO
PATRICIA R. HASTINGS, M.D., CHIEF CONSULTANT, POST-DEPLOYMENT HEALTH,
U.S. DEPARTMENT OF VETERANS AFFAIRS

Question 1. As part of legislation created by Congress, the new Airborne Hazards and Burn Pits Center of Excellence was stood up in May at the VA's War-related Illness and Injury Center in East Orange, New Jersey. From what we know, respiratory issues will make up a large part of its research, since the most obvious immediate impact of burn pits is on the respiratory system. However, similar to what we say with Agent Orange it's likely that there are far more conditions that should be studied. What is the timeline for what conditions will be studied and when?

Response. Please see Attachment 3 for a list of ongoing research projects.

ATTACHMENT 3: COMPLETED, ONGOING, AND PLANNED POST-DEPLOYMENT HEALTH STUDIES IN HUMANS

Completed, Ongoing, and Planned Post-Deployment Health Studies in Humans

Completed, Ongoing and Planned Post-Deployment Health Studies in Humans

| Agency | Study Name and Brief Summary | Study Population | Study Design | Information Collected | Status |
|--------|---|---|--|--|---|
| VA OPH | <p>National Health Study for a New Generation of U.S. Veterans (NewGen)</p> <p>Research Aims</p> <ol style="list-style-type: none"> 1. Do veterans of OIF/OEF have an increased prevalence of health problems and behavioral risk factors following deployment in combat theaters relative to non-deployed veterans? 2. Are some health problems among deployed veterans associated with a specific exposure or experience in combat theaters? | <p>-30,000 OIF/OEF Veterans and 30,000 Veterans who served elsewhere during same period (October 2001-June 2008)</p> <ul style="list-style-type: none"> -representative of each branch -representative for component -oversample women for 20% | <ul style="list-style-type: none"> -Prospective Cohort -Three follow up surveys over ten years. -Self Report Survey -Medical records review of 1,000 subjects | <ul style="list-style-type: none"> -Health Risk Behaviors (ETOH, HIV, sexual behavior, helmet use, seatbelt use, smoking, speeding) -Health Conditions (anxiety, asthma, cancer, depression, chronic disease, CVD, IBS, PTSD, TBI, pain, migraines) -General Health (functional status, general health perception, pregnancy outcomes, reproductive health) -Health Care Utilization (doctor visits, hospitalizations, prescription drug use, CAM, VA facility use) -Potential Exposures (accidents, blasts, burn pits, chemicals, dust/sand, falls, head injury, MST, smoke, vaccinations) | <p>-Active -22,000 participated in first wave.</p> <p>Barth, SK, Dursa, EK, Peterson, MR, Schneiderman A. Prevalence of Respiratory Diseases Among Veterans of Operation Enduring Freedom and Operation Iraqi Freedom: Results From the National Health Study for a New Generation of U.S. Veterans. <i>Mil Med</i> 2014; 179: 241-245.</p> <p>Yoon, FB, Jang D, Sukash A, Kress AM, Barth SK, Mahan CM, Coughlin SS, Dursa EK, Schneiderman AI. 2013. Adjustments for misclassification of deployment status in a population based health study of Operation Enduring Freedom and Operation Iraqi Freedom Veterans. In <i>ISM Proceedings: Mental Health Statistics section</i>. Alexandria, VA: American Statistical Association. 1596-2008.</p> <p>Barth SK, Dursa EK, Bossarte R, Schneiderman A. Lifetime Prevalence of Respiratory Diseases and Exposures Among Veterans of Operation Enduring Freedom and Operation Iraqi Freedom Veterans: Results From the National Health Study for a New Generation of U.S. Veterans. <i>J Occup Environ Med</i>. 2016 Dec;58(12):1175-1180.</p> <p>Cypel YS, Hamlett-Berry K, Barth SK, Christofferson DE, Dawey VJ, Eber S, Schneiderman AI, Bossarte RM. Cigarette Smoking and Sociodemographic, Military, and Health Characteristics of Operation Enduring Freedom and Operation Iraqi Freedom Veterans: 2009-2011 National Health Study for a New Generation of US Veterans. <i>Public Health Rep</i>. 2016 Sep;131(5):714-727.</p> |

Completed, Ongoing, and Planned Post-Deployment Health Studies in Humans

| Agency | Study Name and Brief Summary | Study Population | Study Design | Information Collected | Status |
|--------|--------------------------------------|---|---|--|--|
| VA ORD | <p>Million Veteran Program (MVP)</p> | <p>1,000,000 Veterans (ideally) -Volunteer -Active duty military recruitment starting in 2017 with invitations to 202,000 individuals enrolled in DoD Millennium Cohort Study</p> | <p>-Prospective cohort -Retrospective cohort (assuming access to past medical records)</p> | <p>-Demographics (race, ethnicity, ancestry, education, marital status, income) -Family information (structure, vital status of biological family members, family medical history) -Medical history (CV, ID, MH, GI, neurological, and musculoskeletal) -Functional health status (SF-12) -Frequency of physical activity -ETOH and tobacco consumption -History of military service (period of service, location, exposure to selected deployment related agents) -Physical features -Healthcare utilization (hospitalizations, prescription use, VA usage) -Biological specimen (blood) -Past medical records -Access to future medical records</p> | <p>Currently enrolling, with goal of one million. Over 700,000 veterans enrolled as of January 2019. Studies of genetic contribution to many diseases underway, including PTSD, substance abuse, cardiovascular disease, kidney disease, etc. No analyses of respiratory diseases, to date.</p> |

Completed, Ongoing, and Planned Post-Deployment Health Studies in Humans

| Agency | Study Name and Brief Summary | Study Population | Study Design | Information Collected | Status |
|--------|--|--|--|--|---|
| VA ORD | <p>CSP #595: Respiratory Health and Deployment to Iraq and Afghanistan</p> <p>Objective: Assess association of deployment and airborne exposures during deployment with current measures of respiratory health</p> | <p>Population based sample of VA and non-VA users</p> <p>Six sites will enroll a cohort of 5000.</p> <p>PI, Eric Garshick</p> | <p>Cross-sectional study of deployed and non-deployed Veterans</p> | <p>Estimate individual-level particulate-matter (PM) exposure while deployed, using validated spatial-temporal mapping of air quality</p> <p>Assess relationships between PM exposure and respiratory health assessed by spirometry and respiratory symptoms</p> | <p>Project is funded for 5/2016 – 9/2022</p> <p>Recruitment started in 2016 at 6 sites: Atlanta, Boston, Houston, Minneapolis, San Diego, Seattle</p> <p>As of DEC 2018, 612 Veterans (12%) enrolled out of 5000 planned</p> <p>Testing anticipated through 10/2022, then data analysis through 10/2023</p> |
| VA ORD | <p>Project Numbers DHI 09-237 and HSR5-329-10W</p> <p>Validating and Identifying Complex Comorbidity Clusters in OEF/OIF Veterans</p> | <p>OBJECTIVES:</p> <p>Objective 1. Identify comorbidity clusters among OEF/OIF veterans at baseline and describe trajectories (stable vs. deterioration) over 3 years.</p> <p>Objective 2. Identify risk factors for trajectories of deterioration vs. stability.</p> <p>Objective 3. Compare VA health care utilization for individuals with stable comorbidity trajectories vs. those who exhibit patterns of deterioration, and trajectories within each initial comorbidity cluster.</p> | <p>Cohort study that will combine data from VA national data repositories</p> <p>Approximately 2,000 OEF-OIF VA patients</p> | <p>Examines the prevalence of respiratory diagnoses in OEF/OIF/VN Veterans between F102-F111.</p> | <p>Completed. (10/2010 - 9/2015)</p> <p>Findings of increasing healthcare utilization for respiratory conditions over time suggests that there may be chronic effects of exposures, in light of concern for the impact of environmental exposures in OEF/OIF/VN. Smoking was significantly associated with all forms of respiratory conditions.</p> <p>Findings also suggest pulmonary screening in those with symptoms may help to identify and treat chronic pulmonary disease early, and may alter the disease trajectory.</p> <p>Publication: Pugh MJ, Jaramillo CA, Leung KW, Favero P, Fleming N, Mortensen E, Amuan ME, Wang CP, Eapen B, Restrepo M, Morris MI. <u>Increasing Prevalence of Chronic Lung Disease in Veterans of the Wars in Iraq and Afghanistan.</u> <i>Mill Med.</i> 2016 May;181(5):476-81</p> |

Completed, Ongoing, and Planned Post-Deployment Health Studies in Humans

| Agency | Study Name and Brief Summary | Study Population | Study Design | Information Collected | Status |
|--------------------------|---|--|--------------|--|--|
| VA ORD, NJ WRIISC | 1121RX001079-01 Effects of Deployment Exposures on Cardiopulmonary and Autonomic Function (PI: Falvo MJ) Research Aims: 1 – Evaluate cardiopulmonary function (i.e. exercise gas exchange and spirometry) in deployed OEF/OIF Veterans versus those deployed elsewhere. 2- Determine whether deployment-related exposures alter cardiovascular autonomic control. | OEF/OIF/OND Veterans | Case-control | Physiological Assessments: 1 – Exercise Challenge 2 – Spirometry 3 – Autonomic battery Questionnaires: 1 – Health history 2 – Deployment history 3 – Exposure history (DARE) 4 – Symptoms | Data Acquisition Completed 9/2015. Manuscripts in review. ClinicalTrials.gov Updated (link) Conference Abstracts: Klein JC, Ndirangu D, Chen YC, Condon MR, Falvo MJ. Cardioventilatory Impairments in Deployed Post-9/11 Veterans: 3645 Board# 84 June 4, 9. <i>Medicine & Science in Sports & Exercise</i> . 2016 May 1;48(5S):1013. Salcedo P, Jiao X, Chen Y, Klein JC, Ndirangu D, Condon MR, Falvo MJ. Post-exercise changes in endothelin-1 in military veterans with respiratory complaints. <i>The FASEB Journal</i> . 2016 Apr;30(1_supplement):954-12. Chen Y, Klein J, Ndirangu D, Condon M, Falvo M. Is P53 Activated in Response to Airborne Hazards Exposure in Deployed Military?. <i>The FASEB Journal</i> . 2015 Apr;29(1_supplement):977-14. Klein JC, Ndirangu DS, Chen Y, Condon MR, Falvo MJ. Bronchial Responsiveness Is More Frequent in Veterans With Longer Deployments: 2944 Board# 259 May 29, 2. <i>Medicine & Science in Sports & Exercise</i> . 2015 May 1;47(5S):808. Chen Y, Klein J, Ndirangu D, Smith W, Falvo M. Deployment length and its correlation with spirometric variables in deployed veterans (882.1). <i>The FASEB Journal</i> . 2014 Apr;28(1_supplement):882-1 Active accrual, data analysis |
| VA PDHS, NJ WRIISC | Airborne Hazards Exposure and Cardiorespiratory Health of Veterans. (PI: Falvo MJ) Retrospective Cohort Study Research Aims: To describe and compare cardio-respiratory health of deployed Veterans, and | OEF/OIF/OND Veterans referred to the NJ WRIISC | | Physiological Assessments: 1 – Pulmonary Function Testing 2 – Cardiopulmonary Exercise 3 – Forced Oscillometry 4 – Methacholine Challenge Questionnaires: 1 – Health history 2 – Deployment history 3 – Exposure history 4 – Symptoms | Publications: Falvo MJ, Abraham JH, Osmubi OY, Klein JC, Sotolongo AM, Ndirangu D, Patrick-Deluca LA, Helmer DA. Bronchodilator Responsiveness and Airflow Limitation Are Associated With Deployment Length in Iraq and Afghanistan Veterans. <i>J Occup Environ Med</i> . 2016 Apr;58(4):325-8. Falvo MJ, Helmer DA, Klein JC, Osmubi OY, Ndirangu D, Patrick-Deluca LA, Sotolongo AM. Isolated diffusing capacity reduction is a common clinical presentation in deployed Iraq and Afghanistan veterans with deployment-related environmental exposures. <i>Clin Respir J</i> . 2018 Feb;12(2):795-798. |

Completed, Ongoing, and Planned Post-Deployment Health Studies in Humans

| Agency | Study Name and Brief Summary | Study Population | Study Design | Information Collected | Status |
|--------|---|------------------|--------------|-----------------------|---|
| | <p>determine the relationship between airborne hazards exposure and symptoms with cardiorespiratory health.</p> | | | | <p>Burtzo RP, Sotolongo AM, Helmer DA, Klein-Adams JC, Osinubi OY, Beriman AR, Ortiz-Pacheco R, Falvo MJ. Forced oscillation technique in veterans with preserved spirometry and chronic respiratory symptoms. <i>Respir Physiol Neurobiol</i> 2019 Feb;260:8-16</p> <p>Conference Abstracts: Klein-Adams JC, Sotolongo AM, Ndirangu D, Eager N, Falvo MJ. Exercise Ventilatory Limitation To Exercise In Dyspneic Iraq And Afghanistan Veterans: 1003 Board# 264 May 30 2. <i>Medicine & Science in Sports & Exercise</i>. 2018 May 1;50(5S):237.</p> <p>Sotolongo AM, Falvo MJ, Jani N, Klein-Adams JC, Osinubi OY, Ndirangu N, Eager N, Helmer DA. Lung capacity and compliance are reduced in Iraq and Afghanistan veterans with blast exposure. <i>Am J Respir Crit Care Med</i> 2018;197:A6080</p> <p>Falvo MJ, Helmer DA, Guo G, Wold LE, Eager N, Klein-Adams JC, Ndirangu N, Sotolongo AM. Liver function enzymes are elevated in deployed Iraq and Afghanistan Veterans and associated with pulmonary function. <i>Am J Respir Crit Care Med</i> 2018;197:A6083</p> <p>Ndirangu D, Sotolongo AM, Klein JC, Helmer DA, Osinubi OY, Patrick-DelLuca LA, Eager N, Falvo MJ. Assessment of Respiratory Symptoms in Iraq and Afghanistan Veterans using FeNO. <i>Am J Respir Crit Care Med</i> 2017;195:A2539.</p> <p>Klein JC, Sotolongo A, Ndirangu D, Osinubi OY, Helmer DA, Patrick-DelLuca L, Eager N, Falvo MJ. Abnormal Gas Exchange in Dyspneic Veterans with Normal Spirometry. 3659 Board# 106 June 3 800 AM-930 AM. <i>Medicine & Science in Sports & Exercise</i>. 2017 May 1;49(5S):1047.</p> <p>Falvo MJ, Helmer DA, Osinubi OY, Klein JC, Ndirangu D, Zhang NJ, Eager NA, Sotolongo AM. Airway reactance is an independent predictor of exercise capacity in dyspneic patients. <i>Am J Respir Crit Care Med</i> 2017;195:A3886.</p> <p>Falvo MJ, Litke DR, Helmer DA, Osinubi OY, Klein JC, Ndirangu D, Patrick-DelLuca L, Sotolongo AM. Effect of Comorbid Lower Respiratory Symptoms and PTSD on Pulmonary Function and Physical Health Status in Deployed Veterans. <i>Am J Respir Crit Care Med</i> 2016;193:A5424.</p> |

Completed, Ongoing, and Planned Post-Deployment Health Studies in Humans

| Agency | Study Name and Brief Summary | Study Population | Study Design | Information Collected | Status |
|--------|---|----------------------|--|--|--|
| VA ORD | 1101CX001515-01 Pulmonary vascular dysfunction after deployment-related exposures. (PI: Falvo MJ) | OEF/OIF/OND Veterans | Case-control with longitudinal follow-up | Physiological Assessments: 1 – Pulmonary Function Testing 2 – Cardiopulmonary Exercise 3 – Forced Oscillometry 4 – Exercise Echocardiography 5 – Vascular Reactivity 6 – Vascular Injury Biomarkers Questionnaires: 1 – Health history 2 – Deployment history 3 – Exposure history 4 – Symptoms | Scicolongo AM, Klein IC, Osinubi OY, Helmer DA, Ndirangu DS, Chua JB, Patrick-Deluca L, Falvo MJ. Forced oscillation technique to assess reversibility in Iraq/Afghanistan Veterans. <i>Am J Respir Crit Care Med</i> 2015;191:A1726 Falvo MJ, Scicolongo AM, Osinubi OY, Klein IC, Ndirangu DS, Patrick-Deluca L, Helmer DA. Gas Exchange is Impaired in Iraq/Afghanistan Veterans and Related to Deployment Length. <i>Am J Respir Crit Care Med</i> 2015;191:A1730 Falvo MJ, Osinubi O, Klein IC, Patrick-Deluca LA, Smith WA, Helmer DA. Late Prevalence of Pulmonary Function Abnormalities in Iraq/Afghanistan Veterans. <i>Am J Respir Crit Care Med</i> 2014; 189: A6496. Smith WA, Klein IC, Osinubi O, Helmer DA, Ndirangu DS, Patrick-Deluca L, Falvo MJ. Cardiopulmonary exercise testing in deployed veterans with respiratory symptoms and airborne hazards exposure concerns. <i>Am J Respir Crit Care Med</i> 2014; 189: A6500. Falvo MJ, Teichman RA, Blatt MW, Orrico J, Patrick-Deluca LA, Helmer DA. Bronchodilator Responsiveness in Iraq/Afghanistan Veterans Despite Normal Baseline Spirometry. <i>Am J Respir Crit Care Med</i> 2013;A6090. Period of Performance: April 2018 to March 2022 Recruiting patients |

Non-Human and Toxicological Studies, Funded by DoD and VA

Non-Human and Toxicological Studies, Funded by DoD and VA

| Agency | Study Name and Brief Summary | Study Population | Study Design | Information Collected | Status |
|--------|---|------------------|--------------|---|---|
| VA ORD | 5I01BX002221-04 CARBON BLACK INDUCED ACTIVATION OF LUNG APCs PI, David Corry | Mice | Toxicology | Inhalation of smoke through tobacco smoking and other smoke exposures is known to cause lung disease, but why smoke causes such injury is not known. We have discovered that a common substance in smoke, termed carbon black, causes lung diseases such as emphysema. This application is important because it will reveal how carbon black causes harmful lung inflammation and suggest new ways to treat smoke-related lung disease. | Completed, 1 July 2013 to 30 June 2017 Publications: Nanoparticulate carbon black in cigarette smoke induces DNA cleavage and Th17-mediated emphysema. You R, Lu W, Shan M, Berlin I W, Samuel E, Marciano DC, Sun Z, Sikkema WK, Yuan X, Song L, Hendrix AY, Tour JM, Corry DB, Kheradmand F. <i>Elife</i> . 2015 Oct 5;4:e09623. |
| VA ORD | 5I01BX002622-02 MECHANISMS OF CIGARETTE SMOKE-INDUCED ACUTE LUNG INJURY PI, Sharon Rounds | Mice | Toxicology | Cigarette smoking contributes to the leading causes of death in the US, including lung and cardiovascular diseases. Cigarette smoking is common among Veterans. Among the lung disorders associated with cigarette smoking is acute lung injury that results from injury to cells lining the lung blood vessels. The goal of the proposed studies is to determine whether acrolein, a major component of cigarette smoking, is the cause of lung blood vessel injury and acute lung injury associated with smoking. Since acrolein is also a constituent of "burn pit" smoke, these studies are also relevant to occupational exposures among OEF/OIF Veterans. | Ongoing, 1 July 2015 to 30 June 2019 Publications: Cigarette smoke alters lung vascular permeability and endothelial barrier function (2017 Grover Conference Series), Rounds S, Lu Q, Pulm Circ. 2018. Double-hit mouse model of cigarette smoke priming for acute lung injury. Sakhatskyy P, Wang Z, Borgas D, Lomas-Neira J, Chen Y, Avala A, Rounds S, Lu Q. <i>Am J Physiol Lung Cell Mol Physiol</i> . 2017 Jan 1;312(1):156-167. Alda-1 Protects Against Acrolein-Induced Acute Lung Injury and Endothelial Barrier Dysfunction. Lu Q, Mundy M, Chambers E, Lange T, Newton J, Borgas D, Yao H, Choudhary G, Basak R, Oldham M, Rounds S. <i>Am J Respir Cell Mol Biol</i> . 2017. |

Non-Human and Toxicological Studies, Funded by DoD and VA

| Agency | Study Name and Brief Summary | Study Population | Study Design | Information Collected | Status |
|--------|---|--|---|---|--|
| VA ORD | PULM-022-10F Nanoparticle Coupled Antioxidants for Respiratory Illness in Veterans PI: Rodney Schlosser The hypothesis is that smoke and DEP exposure experienced by OEF/OIF Veterans impacts HSNec-APC communication. | Mice and human sinonasal epithelial cells (HSNECs) | Toxicology | Inhibition of PM and DEP-induced inflammation after treatment with antioxidant-linked nanoparticles (NPs) made of poly(lactic acid). The hypothesis is that the inflammatory response can be ameliorated through the use of antioxidant nanoparticles targeted at the respiratory epithelium. PM is particulate matter; DEP is diesel exhaust particulate | Completed. (4/1/2011 - 3/31/2015) Publication: Impact of tobacco smoke on upper airway dendritic cell accumulation and regulation by sinonasal epithelial cells. Mulligan JCLZ, O'Connell BPI, Pasquini WI, Mulligan RMI, Smith SJ, Soler ZM1, Atkinson C3,4, Schlosser RJ. Int Forum Allergy Rhinol. 7:777-785. 2017. |
| VA ORD | Project Number SPLD-002-12F Targeting HSC-derived Circulating Fibroblasts Precursors in Pulmonary Fibrosis PI: Amanda Larue The hypothesis is that HSC-derived CFPs are critical to progression of PF and can be targeted to inhibit fibrotic progression. | Mice | Using a silica model of PF that mimics particulate exposure in Gulf War Veterans, this study will determine if CFPs increase in circulation with PF and traffic to the fibrotic lung. | Objective: Determine the extent to which silica in desert sand can induce the production of fibroblast precursors for pulmonary fibrosis. This will be tested using a novel clonal HSC cell transplantation method, in conjunction with a silica instillation PF model in three diseases and/or response to therapy. | Completed. (10/2013 - 9/2017) Publication: Role of a novel immune modulating DDR2-expressing population in silica-induced pulmonary fibrosis. McDonald JT, Johnson SD, Russell DL, Young MR, LaRue AC. PLoS One. 2017. |

Question 1a. When will the center study other health issues like cancer, auto-immune diseases, endocrine system issues, and cognitive dysfunction? What resources do you need to accelerate this research?

Response. VA's Office of Research and Development (ORD) routinely solicits additional investigator proposals to conduct research related to toxic exposures and respiratory hazards. ORD and VA Post Deployment Health Services (PDHS) review disease trends to assess for new disease(s) which might be increasing in the affected community and suggest need for greater attention by clinicians and researchers.

The initial focus of the AHOBPCE is on unexplained dyspnea and decreased exercise tolerance. In addition, the team has begun looking at the AHOBPR data in conjunction with the VHA electronic medical record data and diagnoses to detect other

conditions. Two other conditions are currently being studied—pancreatic cancer and sarcoidosis. Other conditions will be added as we follow trends in the registry. Additional capacity and capabilities in analyzing large data sets more thoroughly and in real time would accelerate discovery and translation of findings into the public view. ILER will enhance these activities with additional information about deployment-related exposures.

Question 2. Other than the Center of Excellence, what is the VA doing to study all relevant health issues due to open air burn pits?

Response. NASEM is conducting a review of all the literature through an expert panel on AHOBP to answer this question and others related to burn pits. We anticipate the report to be released Spring 2020.

Question 2a. Can you share with us a master list of health issues being studied, by whom, and when?

Response. VA and DOD work together and with academia on issues related to Airborne Hazards. Please see the attached list (Attachment 3) and the following subset:

1. The Study of Active Duty Military for Pulmonary Disease Related to Environmental Deployment Exposure (STAMPEDE) Michael J. Morris, MD (DOD)
2. Service and Health Among Deployed Veterans study Eric Garshick, MD (VA)
3. The Millennium Cohort Study by Rudolph P. Rull, Ph.D., MPH (DOD)
4. National Health Study for a New Generation of U.S. Veterans (New Gen) and Comparative Health Assessment Interview (CHAI) studies Aaron Schneiderman, Ph.D., MPH, RN (VA)
5. Effects of Deployment Exposures on Cardiopulmonary and Autonomic Function (AirHzds) study Michael J. Falvo, Ph.D. (VA)
6. The Gulf War Era Cohort and Biorepository Wu, MD, R. Ryanne MHS (VA)

Question 3. How many Veterans who have applied for benefits through BVA for Burn Pit related conditions have been approved/denied?

Response. Veterans do not apply for benefits through the Board of Veterans' Appeals; Veterans can only appeal to the Board.

VA is able to provide data for Veterans who applied for service-connected disability benefits through the Veterans Benefits Administration for Burn Pit related conditions. As of November 1, 2019, 11,799 Veterans had their claims completed for disabilities based on exposure to burn pits. From that number, 2,629 Veterans have been awarded service connection for a medical condition related to burn pit exposure.

Question 3a. What are the leading causes for being denied?

Response. The Board is unable to readily track the specific Burn Pit related decision outcomes; however, these are tracked within VBA which shows the most common reason for denials of burn pit related claims is that the claimed condition was not incurred during or caused by military service.

The second most common reason is that there was no current diagnosis associated with the claimed condition.

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. JON TESTER TO TERRY M. RAUCH, PH.D., ACTING DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH READINESS POLICY AND OVERSIGHT, U.S. DEPARTMENT OF DEFENSE

INDIVIDUAL LONGITUDINAL EXPOSURE RECORD (ILER)

Question 1. What challenges or opportunities have been identified during the ILER pilot program?

Response. One challenge in implementing the ILER program is the declassification of location data for deployed Servicemembers. To associate exposure assessments conducted in specific deployment locations, the date and location of each deployed Servicemember is needed. A large amount of location data was declassified to support development of the ILER Pilot and recent release of the ILER Initial Operational Capability. DOD is working with each Service classification authority to determine an automated process for routinely declassifying these data. The biggest opportunity for ILER is the ability to build occupational and environmental exposure profiles for each Servicemember to ensure proper, appropriate, and sufficient medical care is available to meet the Servicemember needs into the future, to support exposure epidemiological studies, and to assist the Veteran with adjudication of claims related to exposures and health outcomes.

Question 2. How will those challenges or opportunities be used to inform the future deployment of the ILER?

Response. The challenges identified will influence development by improving our planning and enhancing our ability to establish agreements and data sharing policies. It has also made us more able to develop a technology agnostic data exchange standard and improving processes that should drastically reduce the time required to bring in new data sets. As ILER capabilities are developed, more types and sources of exposure data will be integrated into the individual Servicemember exposure profiles, providing a more comprehensive assessment of military service-related exposures. This will provide a ready resource for assessing multiple chemical exposures that is not possible today.

Question 3. How will the ILER be interoperable or integrated with Military Health System (MHS) Genesis and the VA's Electronic Health Record (EHR) modernization solution?

Response. Requirements for this are being defined. The current requirements (which we are funded for) are for interoperability where ILER would have an interface to the EHR and correlate medical encounter and health data relevant to the exposure incidents. The EHR vendor and DOD/VA Interoperability Office are scheduled to include ILER integration into their development timeline. Current and short term efforts include providing read-only access, using Joint Legacy Viewer (JLV), for individual exposure summaries.

Question 4. What is the current timeline to full deployment of the ILER? Do you anticipate further delays, or additional costs with deploying ILER?

Response. Current timeline is to reach Full Operating Capability (FOC) deployment not later than September 30, 2023. There are some key efforts that allow us to progress toward FOC, including integrating thirty data sources identified as the most valuable, most relevant, and highest priority. Unanticipated data quality and availability challenges will determine delays to FOC or additional costs for complete deployment.

Question 5. DOD continues to utilize several methods and recordkeeping systems to document certain environmental and occupational exposures to servicemembers. Before the ILER is fully deployed, are there any efforts to improve this process as an interim solution?

Response. There are a variety of possible mechanisms that currently exist for informing Servicemembers when the results of an exposure assessment show an increased health risk. These are all contemporaneous, in that the personnel exposed at the time are most likely to get this information. The Armed Forces Health Surveillance Branch (AFHSB) is tasked to coordinate health surveillance activities with each Service's public health division so that information about increased threats to health are communicated to the Combatant Commanders. Each Service has their own mechanism for sharing that information with their respective Servicemembers. The AFHSB also has registries for known exposure events that allow for direct communication with participating Servicemembers if new medical or health information becomes available.

Question 6. Will servicemembers and veterans have access to their ILER data?

Response. Yes, when ILER is fully deployed and integrated with the new DOD electronic health record. Otherwise, Servicemembers can request their ILER data through their medical providers.

Question 7. If I'm a servicemember or veteran that served on a base where it turns out that the air is full of contaminants that I didn't know about, how would I find out about that exposure, aside from the manifestation of a health condition?

Response. Exposures that potentially increase their risk for illness or disease will be identified, much like a public health assessment, so that actions can be taken to reduce the risk. Currently, DOD implements outreach programs to Servicemembers and veterans, in coordination with the VA, when there is an established/known exposure. When ILER is fully implemented, Servicemembers will be informed of their exposures when they visit their military care provider or when they have access to their EHR.

Question 8. Who is responsible for the outreach to servicemembers when we do identify dangerous exposures?

Response. The primary persons responsible for outreach to Servicemembers regarding dangerous exposures include commanders, supervisors, medical staff and environmental health/industrial hygiene specialists at installation and unit level; healthcare providers, including primary care and specialty care providers via the Medical Treatment Facility network; and Service Public Health organizations.

EXPOSURE TO BURN PITS

Question 9. In June 2018, the Government Accountability Office (GAO) reported that the VA planned to work with DOD to update their Airborne Hazards Joint Action Plan by the third quarter of FY 2018.⁹¹ Could you please describe the process for working with the VA to update the Action Plan, including the selection of research priorities to better understand the potential health risks associated with exposures to burn pit emissions?

Response. DOD and VA scientists work together on an interagency committee, called the DOD/VA Deployment Health Work Group (DHWG). This group wrote the initial Joint Action Plan on Airborne Hazards. DHWG scientists update the Plan periodically to incorporate new agency practices and new scientific information. For example, the Plan was updated when VA established the VA Open Burn Pits Registry. DHWG scientists periodically review the new research on the potential health risks associated with exposures to burn pit emissions. They consider published results from clinical studies and epidemiological studies. They identify research questions for which there are large gaps in understanding, based on the currently available results. The scientists make recommendations that those research gaps should be considered for future research priorities.

Question 10. Has DOD established policies to assess the pulmonary health condition of servicemembers before they are deployed to locations with known airborne hazards?

Response. Current DOD policies require annual periodic health assessments, and pre-/post-deployment health assessments that establish Servicemembers' general health status, which includes pulmonary health conditions. Follow on pre- and post-deployment health assessments do assess pulmonary type conditions. These individual health assessments include questionnaires, medical provider reviews, and specialty referrals (if indicated) addressing individual Servicemember concerns about deployment environmental exposures and potentially related health issues. These policies and assessments provide guidance on conducting periodic health risk assessments at deployment sites, including monitoring emissions from operational burn pits and other airborne hazards. These assessments are used to inform decisions that mitigate health risks, document potential exposures, inform medical care, and to compile publically-available Periodic Occupational and Environmental Monitoring Summary (POEMS) reports for geographically-associated forward operating bases in Iraq, Afghanistan and other operational areas. Furthermore, the policies direct pre- and post-deployment health assessments for deployed Servicemembers; an annual periodic health assessment for all Servicemembers; and upon separation or retirement from military service, a separation history and physical exam to facilitate the transfer of care from the DOD to the VA.

Question 11. How many servicemembers has DOD had to medically retire for conditions related to Airborne Hazards and/or burn pit exposure?

Response. Additional time is required to assess the available data necessary to provide an accurate answer.

Question 12. How many servicemembers have been medically discharged since 2001 for pulmonary conditions or explained shortness of breath?

Response. Additional time is required to assess the available data necessary to provide an accurate answer.

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. BERNARD SANDERS TO TERRY M. RAUCH, PH.D., ACTING DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH READINESS POLICY AND OVERSIGHT, U.S. DEPARTMENT OF DEFENSE

BEST PRACTICES FOR MITIGATING ENVIRONMENTAL HAZARDS

Question 13. Dr. Rauch, what are some of the best practices that the DOD has discovered to be most effective to mitigate the damage done by environmental hazards such as burn pits? Does DOD have plans to expand these best practices to all burn pit sites? If not, why not?

Response. DOD has implemented guidance, DOD Instruction 4715.19, Use of Open-Air Burn Pits in Contingency Operations, November 13, 2018, for the Military Departments and Combatant Commanders to determine the need for burning any trash, health risk assessments when trash burning is operationally required, procedures for safely operating the burn pit, and the proper collection and disposal of the ashes. The guidance also requires congressional notification if the burn pit must be operated for an extended period of time.

ELIMINATION OF BURN PITS

Question 14. Dr. Rauch, do you believe that the DOD should push out policies directed to specific units that will ultimately lead to the elimination of burn pit usage?

Response. Current policy and guidance is adequate to meet our current operational requirements. As new waste disposal technology is developed, DOD will make adjustments that do not impact operational readiness and force security.

RESEARCH AND DEVELOPMENT

Question 15. Dr. Rauch, has DOD allocated enough resources to research and development on this burn pit exposure? If so, what is the status on some of the conclusions drawn from these types of research? If not, what can this Committee do in order to guarantee the reduction or elimination of burn pits and other environmentally harmful practices?

Response. DOD and VA have funded and continue to fund many studies on the potential health effects of exposure to airborne hazards during deployments, including burn pit emissions, sand storms, and other sources of air pollution. This includes personnel who were deployed during Operation Iraqi Freedom and Operation Enduring Freedom. Many human health studies have been published, and some long-term follow-up studies are continuing. These include in-depth clinical studies, as well as very large epidemiological studies. The National Academy of Sciences, Engineering and Medicine (NASEM), an independent scientific organization, published a long, comprehensive review of the health effects of airborne hazards in theater in 2011, titled: "Long-term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan." While the NASEM report concluded there was insufficient evidence of long-term health risks associated with burn pit exposure, the report found that negative health effects (particularly respiratory) were plausible due to particulate matter, albeit burn pits were likely one of many factors. The reviewed literature provided limited but suggestive evidence of decreased pulmonary function associated with combustion products. However, there was insufficient evidence of an association between exposure to combustion products and cancer, respiratory disease, circulatory disease, neurologic disease, or adverse reproductive and developmental outcomes in the populations studied. The VA commissioned and updated NASEM review of health outcomes that may be related to airborne hazards. The report, "Medical Effects of Airborne Hazards and Open Burn Pits" is expected to be published in May 2020. On the basis of the available peer-reviewed published research, we do know that military personnel deployed to Iraq and Afghanistan appear to experience elevated rates of acute upper respiratory symptoms during deployment and may be at greater risk for post-deployment respiratory symptoms and respiratory illnesses. DOD has and will continue to collaborate with the VA, other Federal agencies, academia and others on epidemiological and health-related research focused on full understanding of potential long-term health outcomes associated with burn pit and other complex airborne exposures during deployments.

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. SHERROD BROWN TO
TERRY M. RAUCH, PH.D., ACTING DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR
HEALTH READINESS POLICY AND OVERSIGHT, U.S. DEPARTMENT OF DEFENSE

BURN PIT AIR SAMPLE DATA

Question 16. Dr. Rauch, if DOD has weekly air sample data from burn pits that routinely show particulate matter exceeding EPA health standards, has DOD shared that raw data with VA, or outside experts to build a comprehensive picture of what our servicemembers, civilians, contractors, and the local populations were exposed to? And if not, why not?

Response. Military Department deployed preventive medicine teams conduct periodic exposure monitoring, including monitoring of airborne exposures, at contingency locations per DOD policy for deployment health and use of open-air burn pits. The exposure monitoring analytical results are used to construct health risk assessments, Occupational and Environmental Health Site Assessments (OEHSA), Periodic Occupational and Environmental Monitoring Summaries (POEMS), and Incident Reports, which are entered into the Defense Occupational and Environmental Health Readiness System (DOEHRS). DOEHRS data is available to VA. A significant improvement over the past year is the development and fielding of the Individual Longitudinal Exposure Record (ILER) which will now be a primary means to share individual exposure data between DOD and VA. DOD also provides health surveillance information to the VA upon request through sharing agreements. Shar-

ing information requires specific conditions to be satisfied to protect sensitive health information from being released. When outside experts request DOD exposure information, the request may include an institutional review board-approved protocol that ensures that the any information covered under the Privacy Act is necessary and protected.

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. RICHARD BLUMENTHAL TO TERRY M. RAUCH, PH.D., ACTING DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH READINESS POLICY AND OVERSIGHT, U.S. DEPARTMENT OF DEFENSE

BURN PITS AND AIRBORNE HAZARDS

Question 17. What is DOD doing to mitigate the effects of burn pits and airborne hazards to our servicemembers? How often is air quality in deployed locations tested, and what equipment is used to test it?

Response. DOD recognizes and is concerned about the potential acute and chronic health effects of burn pits and other airborne hazards to Servicemembers and Veterans. Achieving a reduction in the use of burn pits, improved exposure monitoring and documentation of ambient air conditions, and health risk mitigation are the primary focus areas at the operational level. Collaborative and targeted research to better understand potential health effects from exposures and better inform health care is also a primary focus area of the Department. Specific initiatives focused on protecting the health of our Servicemembers include: o Recently issued updated policies and procedures, including Deployment Health, that details extensive pre-, during, and post-deployment health activities, and Use of Open-Air Burn Pits that requires additional monitoring and health risk assessments. o Routine monitoring, health risk assessments, and mitigation of environmental exposures from all sources, including airborne exposures from burn pits and other pollution sources: completed and electronically logged over 1,000 deployment-related Occupational and Environmental Health Site Assessments (OEHSA) of base camps, and 139 Periodic Occupational and Environmental Monitoring Summaries (POEMS). o Reduced use of burn pits to 14 sites (as of Oct 2019 reports) via use of landfills, contracted hauling of waste off the operating base, and incinerators. o Periodic health assessments (PHA), pre- and post-deployment health assessments, and mental health assessments: this comprehensive health assessment, coupled with other as needed specific medical evaluations, allows for multiple Servicemember and healthcare provider interactions to evaluate exposure concerns, and treat any resulting medical conditions. o Medical research to enhance our understanding of health effects from exposures to burn pits and other airborne hazards: the DOD and VA have funded and continue to fund studies on the potential health effects of exposure to airborne hazards during deployment. Many human health studies have been published and some long-term follow up studies are continuing. o Health risk communications to Servicemembers and their providers: an ongoing effort to continuously communicate known and potential health risks, including mitigation of hazards, in the garrison, training and deployed environments. DODI 9490.03, Deployment Health, requires a Periodic Occupational and Environmental Monitoring Summary (POEMS) to be conducted annually at the direction of the Combatant Commander. Any environmental sampling conducted as part of a POEMS is done using approved EPA methods. Occupational and Environmental Health Site Assessments (OEHSA) are conducted as needed to “identify and provide recommendations to manage OEH threats and their sources at a particular deployment site (e.g., base camp, airbase, forward operating base (FOB)) with complete or potentially complete exposure pathways to a current or future deployed population.” Any air quality sampling conducted as part of a POEMS is done using approved sampling and analytical methods that includes the equipment. Data collected to support a POEMS or OEHSA are entered into the Defense Occupational and Environmental Health Exposure Readiness System (DOEHRS), the DOD system of record for recording occupational and environmental health monitoring data.

Question 18. Going forward, how will DOD ensure that ILER is actually used to document airborne exposures? Will servicemembers have access to data from ILER and other DOD records when they are trying to show a disability caused by exposure to burn pits? How would servicemembers access classified data and records from DOD to prove exposure?

Response. The primary emphasis will be implementing installation and deployed occupational and environmental health policy that directs periodic and incident exposure monitoring. Monitoring includes entering exposure measurements and risk assessments into the into DOEHRS. DOEHRS is and will be the primary exposure

data source extracted to populate the ILER and present the information to designated users. Yes, when ILER is fully deployed and integrated with the new DOD electronic health record. Otherwise Servicemembers can request their ILER data or their medical records from their medical providers or from their medical treatment facilities, respectively. Due to security and classification concerns and policies, access continues to be a challenge that DOD is addressing with the Military Departments and Combatant Commanders who control the classification of data for specified operations, and potential

PALOMARES RADIATION

Question 19. Will DOD commit to looking into the Palomares exposures, and establishing a more accurate scientific methodology for determining how much radiation these veterans were exposed to?

Response. The Department is committed to looking into possible exposures of Servicemembers to radiation and airborne hazard exposures. DOD is also committed to medical research to enhance our understanding of health effects from exposures and continue to fund studies on the potential health effects of exposure.

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. MAZIE K. HIRONO TO TERRY M. RAUCH, PH.D., ACTING DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH READINESS POLICY AND OVERSIGHT, U.S. DEPARTMENT OF DEFENSE

TESTING FOR PFAS CONTAMINATION

Question 20. PFAS, a class of chemicals used in firefighting foam and flame retardant clothing, are highly toxic and very persistent. I understand the Department of Defense (DOD) has tested drinking or groundwater on or around hundreds of military sites for PFAS contamination. Has DOD tested the water at military sites in Hawaii? If so, did you find contamination? If not, when do you expect that testing to occur?

Response. In June 2016, DOD directed the Military Departments to test for PFOS/PFOA where DOD supplies drinking water to the installation. No installations in Hawaii tested above the Lifetime Health Advisory (LHA) established by the Environmental Protection Agency.

PREVENTING EXPOSURES

Question 21. What is DOD doing to prevent exposing our servicemembers to toxins? Are you taking proactive steps to ensure that our military understands the immediate and long-term health impacts of potential occupational and environmental exposures before we expose troops?

Response. DOD Instruction 6490.03, "Deployment Health" requires Periodic Occupational and Environmental Monitoring Summary (POEMS) to be conducted annually at the direction of the Combatant Commander. Any environmental sampling conducted as part of a POEMS is done using approved EPA methods. Occupational and Environmental Health Site Assessments (OEHSA) are conducted as needed to "identify and provide recommendations to manage OEH threats and their sources at a particular deployment site (e.g., base camp, airbase, forward operating base (FOB)) with complete or potentially complete exposure pathways to a current or future deployed population." Any air quality sampling conducted as part of a POEMS is done using approved sampling and analytical methods that includes the equipment. Data collected to support a POEMS or OEHSA are entered into the Defense Occupational and Environmental Health Readiness System (DOEHRIS).

BURN PITS

Question 22. In talking with veterans in my state, I hear warnings that burn pits will be this generation's Agent Orange. We have an obligation to our servicemembers and veterans to ensure this generation does not have to wait decades for care and benefits needed to address illnesses caused by their service. What actions is the DOD taking now to ensure servicemembers exposed to burn pits can be properly diagnosed, treated, and cared for? What are the barriers facing the DOD in meeting this mission?

Response. In 2016, DOD implemented a policy requiring every Servicemember to have an annual periodic health assessment that includes questions about exposures during deployments and any respiratory system health issues. The medical provider can use this assessment as a tool to arrange any follow-up medical tests or examinations to address any respiratory system health complaints or concerns. Service-

members also complete post-deployment health assessments that provide several opportunities for the Servicemember to discuss their overall health and specific health concerns.

A P P E N D I X

PREPARED STATEMENT OF THE AMERICAN LEGION

CHAIRMAN ISAKSON, RANKING MEMBER TESTER, AND DISTINGUISHED MEMBERS OF THE COMMITTEE; On behalf of National Commander James W. “Bill” Oxford, and the nearly 2 million members of The American Legion, thank you for inviting The American Legion to submit the following testimony on “Toxic Exposure and Examining the Presumptive Disability Decision-Making Process.”

The American Legion has long been at the forefront of advocacy for veterans who have been exposed to environmental hazards such as Agent Orange, Gulf War-related hazards, ionizing radiation, the various chemicals and agents used during Project Shipboard Hazard and Defense (SHAD), and contaminated groundwater at Camp Lejeune. The American Legion continues to urge the study of all environmental hazards and their long-term effects they have on our servicemembers, veterans, and their families.

The effects of the often dangerous environments in which servicemembers operate is a top concern of The American Legion, as thousands of veterans who are or have been exposed to various toxins are often left behind when it comes to vital treatments and benefits. The American Legion remains committed to ensuring that all veterans who served in areas of exposure receive recognition and treatment for conditions linked to environmental exposures.

To this end, The American Legion has been meeting with the newly formed veteran and military toxic exposure working group called the Toxic Exposure in the American Military (TEAM) coalition, which includes 15+ Veteran Service Organizations (VSO) and Military Service Organizations (MSO) all addressing toxic exposure issues. Currently, the members of TEAM include, Wounded Warrior Project, BurnPit360, Cease Fire Campaign, Hunter Seven, Iraq and Afghanistan Veterans of America, Military Officers Association of America, Tragedy Assistance Program for Survivors, Veteran Warriors, Vietnam Veterans of America, Enlisted Association of the National Guard of the United States, California Communities Against Toxics, National Veterans Legal Services Program, Vets First, and the Dixon Center.

Our advocacy also includes the filing of an October 15, 2018 amicus brief in the case of *Procopio v. Wilkie*. On January 29, 2019, the U.S. Court of Appeals for the Federal Circuit handed a major victory for Blue Water Navy veterans in their long fight for Department of Veterans Affairs (VA) benefits to treat illnesses linked to exposure to Agent Orange during the Vietnam War.¹

Procopio presented two issues for the full Federal Circuit to consider:

1. Does the definition of “Vietnam” in 38 U.S.C. §1116 include the territorial waters? (i.e., Should blue-water Navy veterans be presumed to have been exposed to Agent Orange and awarded benefits for conditions presumptively related to exposure?)

2. What is the interaction between the Chevron canon that courts defer to agencies in interpreting statutes and the Gardner canon that veterans benefits statutes are to be liberally construed in favor of veterans? (i.e.—When a veterans benefits statute is unclear, do the courts generally have to accept VA’s interpretation of what it says?)

The Procopio decision rested on the plain meaning of Congress’s words in the 1991 Agent Orange Act, specifically “the Republic of Vietnam.” According to international law, “the Republic of Vietnam” includes the territorial waters within twelve nautical miles of the coast. This reasoning convinced most of the judges; however, our brief alternatively argued that the pro-claimant canon would result in granting the presumption of service connection.

Because the court resolved the case without addressing our alternative argument, this testimony will rehearse some of the argument and considerations in our amicus brief on the second issue, which has bearing on the topic being considered by the

¹*Procopio v. Wilkie*, 913 F.3d 1371, 1387 (Fed. Cir. 2019)

Committee in this hearing. The American Legion encourages Congress to review the amicus brief recognizing that court decisions commonly interpret congressional language.²

SUMMARY OF AMICUS BRIEF ARGUMENT

In our brief, The American Legion joined Navy veteran Alfred Procopio Jr. in urging the Court to reverse the judgment of the lower court. It supported his argument that the intent of Congress is clear in this matter. However, it believes that the simple application of the principle of veteran-friendly interpretation of step one of the traditional analysis from *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842 (1984), misstates the long-established relationship between Congress and the VA on veterans issues and downplays the interpretive principle that the Supreme Court reaffirmed after *Chevron* in cases such as *King v. St. Vincent's Hospital*, 502 U.S. 215 (1991), and *Brown v. Gardner*, 513 U.S. 115 (1994).

The American Legion agreed that the application of proper deference resolves any lingering doubt as to the interpretive issue here. However, this particular application of the *Gardner* principle to a question of the scope of substantive entitlement serves an important role in counterbalancing the null hypothesis of science that typically works against veterans whose disabilities are related to service in hidden and complex ways. These are often difficult to understand on the timescales that flesh-and-blood veterans experience the employment impairment and mortality that the system was intended to compensate.

Belatedly awarding benefits to Americans who served in Vietnam is small consolation to those who have lived a lifetime without proper compensation. The practical application of resolving interpretive doubt in favor of veterans often means erring on the side of supporting disabled veterans in need while their lives can still be changed, instead of waiting for a scientific consensus that might arrive—if ever—only after those who have borne the battle are no longer around to be cared for.

THE NULL HYPOTHESIS OF SCIENCE

One of the hallmarks of modern veteran disabilities is that invisible injuries can occur unnoticed, and often take years or decades to manifest as observable conditions. The general problem of caring for those harmed by exposures is a perpetual issue that will require constant attention due to the lack of knowledge about the conditions at the time of exposure. Despite advances in medicine and the ability to leverage big data, answers to complex issues of causation are still difficult to generate.

The null hypothesis in science often creates a gap in which veterans go uncompensated for decades while evidence is developed to prove an association between their conditions and harmful exposures in service. The most difficult foe for veterans is not uncaring government bureaucrats but the remorseless law of science known as the null hypothesis. This is the baseline assumption that two observed facts have no relationship to each other until a proper application of the scientific method provides reliable evidence of a relationship.

The development of this baseline was critical to overcoming ancient superstitions and developing the scientific method as a reliable way to generate knowledge. Nonetheless, when applied to the problem of providing benefits to veterans who were exposed to harmful agents in service, the result is that the award of benefits often lags decades behind the experiences of veterans and survivors who are affected by service but cannot successfully prove causation.

Inevitably, whenever a new type of exposure affects veterans, some are at the front edge and develop problems first. Based upon their experience in service, they might have an intuition about why they became sick. Typically, the first complaints are rejected based upon a “lack of evidence” to support their suspicions. For example, it was 1977 when VA received the first claim asserting a condition was caused by Agent Orange. However, that was only the beginning of a decades-long struggle to obtain recognition of the harms caused by the use of herbicides. As of 1988, VA recognized only the skin condition chloracne as related to Agent Orange and—even though it had received 150,000 claims for conditions related to Agent Orange exposure—it had not granted a single one.³ Many of those most severely poisoned never

² http://www.vetlawyers.com/wp-content/uploads/2019/09/Procopio_Legion_Amicus_Brief_2018-10-15-1.pdf

³ See *Gerald Nicosia, Home to War: A History of the Vietnam Veterans' Movement* 475 (2001); see also *Diseases Associated with Exposure to Contaminants in the Water Supply at Camp Lejeune*, 82 Fed. Reg. 4,173 (Jan. 13, 2017) (recognizing service connection for conditions caused

lived to see their claims vindicated. Many others have now suffered for years without compensation.

Typically, benefits are not retroactive prior to the filing of a claim, but even when large retroactive awards occur they still do not allow veterans to relive the years when they struggled without compensation. For example, veterans cannot retroactively choose to send their children to college without compensation. Veterans make endless choices about employment, retirement, health care treatment, and living circumstances that cannot be reversed decades later. Even when lost income is fully replaced, a lost lifetime of opportunity cannot be.

The application of *Gardner* to issues such as this one serves—at least in a small way—to mitigate the effects of the null hypothesis. Initially, it always operates to cause the system to err on the side of denying benefits. However, once evidence becomes sufficient to generate action by Congress, liberally interpreting benefits is an appropriate way of erring on the side of compensation when the system has a long history of going in the opposite direction.

In fact, there is no guarantee that science will ever be able to fully resolve the uncertainties involved in any issue.⁴ Therefore, some approach is required to deal with scientific uncertainty, recognizing that any approach carries a risk that it might be someday be judged as wanting in retrospect. Consistent with *Gardner* and the history of interpreting veterans benefits statutes, the proper approach is to resolve lingering uncertainty in favor of veterans, within the bounds of the benefits authorized by Congress, rather than wait for certainty that might never come while veterans continue to suffer and die.

Additionally, rare conditions present additional difficulties. As Judge Newman lamented in her dissent in *Bastien v. Shinseki*, 599 F.3d 1301 (Fed. Cir. 2010), the system is ill-equipped to handle rare conditions for which it is unlikely that there will ever be enough data to determine causation with scientific certainty, *id.* at 1307–08 (Newman, J., dissenting). Combining all these uncertainties into a single, binary determination under the benefit of the doubt is a problem has never been squarely addressed. The correlation between the rare lung disease obliterative or constrictive bronchiolitis and exposure to open air burn pits used in Iraq and Afghanistan is just one example of where causation may not have been determined as yet, but the volume of correlative evidence is fairly clear and mounting as veterans of the last 18 years of war are beginning to seek help.⁵ If VA would empirically study the sample of veterans who have self-identified as having exposure symptoms in its own Airborne Hazards and Burn Pit Registry (with 165,000 registered thus far), perhaps causation and trends could be identified from the collected data.

Fortunately, the veterans benefits system is not based upon the scientific gold standard of ninety-five-percent confidence that an observed effect is real and not simply a random variation within a small sample. The paternalistic system is willing to act in the face of more uncertainty than that with which scientists are comfortable. Courts cannot change the standards established by Congress, they can apply interpretive doubt liberally in favor of veterans, as a partial bridge over the gap between differences in how the legal and the scientific worlds handle uncertainty. This dynamic, specifically the way in which the laws it writes are interpreted, is something Congress must consider as the presumptive disability decision-making process is reviewed.

CONCLUSION

In 2017, Secretary Shulkin was considering recommending “bladder cancer, hypothyroidism and Parkinson-like symptoms” to the list of presumptive conditions linked to Agent Orange exposure as a result of a recently released Institute of Medicine study.⁶ The consideration of adding these conditions, some of which have not yet been implemented, comes nearly 50 years after the initial exposure and has re-

by exposure to contaminated water for the more than three decades between August 1, 1953, to December 31, 1987).

⁴ See, e.g., INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, GULF WAR AND HEALTH, TREATMENT FOR CHRONIC MULTISYMPTOM ILLNESS 1 (2010). (“Despite considerable efforts by researchers in the United States and elsewhere, there is no consensus among physicians, researchers, and others as to the cause of C[hronic] M[ultisymptom] I[llness]. There is a growing belief that no specific causal factor or agent will be identified.” (emphasis added)).

⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3296566/>

⁶ <https://www.stripes.com/news/veterans/shulkin-will-decide-whether-to-add-more-conditions-to-agent-orange-list-by-nov-1-1.481353>

sulted in some veterans suffering with these conditions for decades without the proper compensation.

The American Legion has been the leading advocate for veterans exposed to Agent Orange since the first file was claimed in 1977. When VA failed to conduct congressionally-mandated studies, The American Legion commissioned its own study, not once, but twice.⁷ For over 40 years, Legionnaires have tirelessly advocated on behalf of those that were exposed to these herbicides, to include filing lawsuits in Federal District Court.⁸ We are proud to have contributed to the efforts to pass the long overdue Blue Water Navy Act this past summer, but it is imperative that we do not put the current generation of servicemembers and veterans through an equally painful process.

We call on VA to empirically study the sample of 165,000 registrants of the Airborne Hazards and Burn Pit Registry, all of whom served on or after 9/11, during operations Desert Shield and Desert Storm, or in the Southwest Asia theater of operations after August 2, 1990, and were deployed to a base or station where open burn pits were used or where possible exposures to toxic substances occurred. It also makes sense to separate these eras of war in order to accurately assess causation and trends in hazardous exposures.

As Congress considers implementing new procedures to deal with contemporary toxic exposure issues like burn pits, it is crucial that the lessons of previous generations are taken into consideration. Due to the retrospective and ambiguous nature of this process, it is imperative that the presumptive disability decisionmaking processes, no matter what form they take, err on the side of the veteran.

The American Legion is thankful for the invitation to submit this statement for the record and stand ready to assist when needed on these issues and any others that may arise. For additional information regarding this testimony, please contact Senior Legislative Associate Mr. Jeffrey Steele at (202) 861-2700 or jsteele@legion.org.

⁷This study was known as The American Legion-Columbia University Vietnam Veteran Health Study. Approximately 12,000 members were surveyed to better understand, among other things, the impacts of herbicides exposure.

⁸<https://www.nytimes.com/1990/08/02/us/american-legion-to-sue-us-over-agent-orange.html>

PREPARED STATEMENT OF DR. THOMAS ZAMPIERI, PRESIDENT AND CHAIRMAN,
BLINDED VETERANS ASSOCIATION



Hon. Johnny Isakson
Chairman
Senate Committee
On Veterans Affairs
Russell 131
Washington D.C.

Hon. Jon Tester
Ranking Member
Senate Committee
On Veterans Affairs
Hart 311
Washington D.C.

September 23, 2019,
Re: Sept. 25 Hearing On Impact of Toxic Exposures on Veterans

Dear Senators Isakson and Tester,

I am writing on behalf of the Blinded Veterans Association. The members and national officers of our organization look forward to the hearing planned for September 25 to consider the adequacy of the VA's process for determining which illnesses and medical conditions will be presumed result from toxic exposures during military service. This is a timely issue for our nation's veterans and their families. We wish to thank you and the other members of the Senate Committee on Veterans Affairs for looking into this matter. We would also like to call your attention to one area where we believe VA's current process is failing veterans in alarming numbers.

There is growing evidence that appears to demonstrate a link between exposure to toxic substances such as Agent Orange and the development of eye cancers. VHA has been very reticent to release data on the prevalence of such cancers among veterans enrolled in VA's healthcare system, but the available data indicates that between 2007 and 2010, Vietnam era veterans exposed to toxic substances during their service in the Armed Forces have been diagnosed with a particular form of eye cancer known as Choroidal Melanoma (CM) at the rate of 2,000 per year. While CM is the most common primary malignant intraocular tumor and the second most common type of primary malignant melanoma in the body, it is still very rare in the general civilian population, with occurrences of only 5-6 per one million people. Demographic reports in the U.S. indicated there was a total of 1,000 new cases of eye cancer diagnosed in 2010. If Vietnam Era Veterans developed eye cancer at the same rate as the general population there should have been about 115 veterans diagnosed with this form of cancer. However, among veterans within the VA system in 2007, there were just fewer than 2,000. In 2008, there were just over 2,000 cases diagnosed, about 2,200 in 2009, and about 1,550 cases in 2010.

Family members of veterans impacted by this form of eye cancer often waited years for VBA decisions and appeals, for a review of possible links between CM and exposure to toxic substances. Furthermore, VA didn't respond to BVA's requests for more data on the rates of diagnoses of eye cancers among enrolled veterans from 2000 to 2017 while denying claims of those with this form of eye cancer. We feel that the processes must include reviews by

independent outside medical epidemiological experts in making decisions on if probably toxic exposure caused a cancer pattern to emerge.

VHA's lack of responsiveness has led us to question the objectivity of the VA's process. We urge you and the other members of your committee to thoroughly scrutinize this process and insist that it be evidence-driven; rigorously applying accepted standards of evaluation. We further encourage the committee to examine how VHA determines which medical conditions to review for potential links to toxic exposures working with Academy of Science. BVA would like to see further cooperative research by VA, DoD, and the National Eye Institute into the particular potential correlation described at the beginning of this letter. We urge both the members of the Senate Committee on Veterans Affairs and the Veterans Health Administration to further support evidence-driven research on Agent Orange and other toxic substances that our servicemen and women have been exposed to and the medical side effects of such exposure. Thank you very much for your consideration of our concerns and for your continuing efforts to ensure that our nation's veterans get the medical care and benefits they need and deserve.

Respectfully,
Dr. Thomas Zampieri
President and Chairman

**BURN PITS 360
STATEMENT FOR THE RECORD
BEFORE THE SENATE COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE**

**FOR A SEPTEMBER 25, 2019 HEARING ENTITLED:
"TOXIC EXPOSURE: EXAMINING THE VA'S PRESUMPTIVE DISABILITY
DECISION-MAKING PROCESS"**

Thank you, Chairman Isakson, Ranking Member Tester and distinguished members of the Subcommittee for this opportunity to submit a statement for the record.

For the past decade, Burn Pits 360 has been at the forefront of the issues resulting from toxic exposure, advocating for the families of the forgotten and those battling life-threatening illnesses. They stand with us here today and many of their personal stories are included in Appendix A, which we encourage you to review with the care that they deserve. The most important question is how is DOD and VA jointly addressing this delay and deny tactic? We must address the immediate needs and wellbeing of our active duty, veterans, caregivers and widows? Failing to do so is risking the safety and national security of the country and denying them the right to life.

Burn Pits 360 is a 501(c)(3) non-profit veterans organization located in Robstown, Texas. Our mission is to advocate for veterans, active duty service members, and families affected by deployment-related toxic exposures through research, education, outreach and advocacy. Burn Pits 360 created and maintains an independent burn pits exposure registry, which we will discuss in more detail below.

Our organization's impact has included helping to provide impetus to legislation creating the Airborne Hazards and Open Burn Pit Registry (AHOBPR) signed into law in 2013, P.L. 112-260, which also directed a longitudinal burn pits exposure study to be jointly conducted by the U.S. Departments of Defense (DoD) and Veterans Affairs (VA). Recently Burn Pits 360 was also successful in Texas where Governor Abbott signed a law for the creation of the Texas State Burn Pit Registry that will track mortality and health effects.

Our work is extensive, we participated in the open comment period for registry revisions submitted to the VA Office of Public Health (OPH), resulting in the addition of constrictive bronchiolitis (CB) to the registry. We presented our registry data to the National Academy of Sciences, Engineering, and Medicine (NASEM) committee created under the 2013 legislation, which resulted in an insightful scientific publication online in 2015 and in a peer reviewed medical journal in 2017.¹ We have presented key statements to the Defense Health Board and have actively participated in every VA/DOD AHOBPR Burn Pit Symposium.

¹ Szema, Anthony et al, "Proposed Iraq/Afghanistan War-Lung Injury (IAW-LI) Clinical Practice Recommendations: National Academy of Sciences' Burn Pits Workshop," *Am J Mens Health*, 2017 Nov; 11(6): 1653-1663.
<https://dx.doi.org/10.1177%2F1557988315619005>

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Recently we have had the honor of collaborating our efforts with several allies including Wounded Warrior Project, IAVA, Vietnam Veterans of America, The Dixon Center, Veterans for Common Sense and several others. We are most honored to have the support of the 9/11 advocates from the Fealgood Foundation and actor & comedian Jon Stewart who recently partnered with us in an effort to release an important Public Service Announcement on burn pits. Here is link to the PSA <https://youtu.be/3s3nHo4szE8>

Burn Pits 360 continues to work with Veterans, Active Duty Service Members, Congress, VA, DOD, Veteran Service Organizations and community stake holders to address the immediate needs of the survivors and their families. For almost a decade Burn Pits 360 has developed a strong platform of awareness and outreach through several initiatives including: a new website, independent registry, pod casts, Burn Pit town hall meetings, newsletters, state advocacy pilot program and a national public service announcement campaign. We will continue to collect voluntary self-reported data from our independent burn pit registry to assist us in developing legislation and policies to address the immediate needs of our warriors and their families. We cannot continue to grant one individual a burn pit claim as an instrumentality of war injury and dismiss another claim as a psychosomatic condition.

Burn Pits and Health Consequences

During the OEF and OIF wars, government contractors and the military burned up to 227 metric tons of hazardous waste per day at forward operating bases using jet fuel as an accelerant. This involved the burning of plastics, medical waste including human body parts, expired pharmaceutical drugs, chemicals including paint and solvents, petroleum products, and unexploded ordnance, which according to some reports may have also included Iraqi chemical warfare agents.

Additionally, some of the burn pits were reportedly built on top of soil contaminated by chemical warfare agents.² Due to the unacceptable risk posed by these burn pits to our service members, their use was eventually mostly banned, except under narrow circumstances, in 2010. Tens of thousands of service members have been exposed to toxic chemicals and microfine, highly respirable and dangerous particulates from burn pits and they continue to suffer serious, disabling health consequences upon their return.

The wars in Iraq and Afghanistan exposed U.S. service women and men to an unprecedented array of airborne health hazards including from open-air burning in vast burn pits; shock waves and toxic particulates from improvised explosive devices (IEDs), including vehicle-borne improvised explosive devices (VBIED) and those containing chemical warfare agents; and hazardous microfine sand particles.³ Service members with new-onset, post-deployment

² Walker, Lauren, "US military burn pits built on chemical weapons facilities tied to soldiers' illness," *The Guardian (UK)*, February 16, 2016. <https://www.theguardian.com/us-news/2016/feb/16/us-military-burn-pits-chemical-weapons-cancer-illness-iraq-afghanistan-veterans>

³ Szema, Anthony et al, "Iraq dust is respirable, sharp, and metal-laden and induces lung inflammation with fibrosis in mice via IL-2 upregulation and depletion of regulatory T cells," *J Occup Environ Med.* 2014 Mar;56(3):243-51. <https://dx.doi.org/10.1097/JOM.000000000000119>

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respiratory symptoms from these hazards have been labeled as having **Iraq/Afghanistan War-Lung Injury (IAW-LI)**,⁴ a term we will also use throughout this document.

Burn Pits Health Consequences Led to Creation of Burn Pits 360's National Registry

In 2010, Burn Pits 360 created a national burn pits exposure registry, joining forces with other affected families who were united by the need to prove a correlation between the veterans' toxic exposures during their deployments and the post-deployment illnesses (that in some cases were resulting in death) that had since plagued them. Burn Pits 360 continues to manage this registry, which has since grown to about 6,000 participants. The registry allows participants to later report a decline in health function, and their survivors to record mortality information including the cause of death.

Here is some of what we now know:

- Air sampling data indicate that smoke from these burn pits contained toxic chemicals associated with cancers, lung diseases, cardiovascular disease, kidney disease, neurological disorders, and more.
- The Burn Pits 360 national registry confirms that the array of devastating health conditions being suffered by exposed veterans include rare forms of cancer, pulmonary diseases, neurological disorders, and many other otherwise-unexplained diseases and symptoms. (See Appendix A, Cancer data from BP 360 Registry)
- There are over 100 death entry submissions in the Burn Pits 360 registry, including from rare cancers – and from suicide.
- Both active duty and veterans are facing a high rate of denials for burn pit service-connected claims.
- Burn Pits 360's registry data demonstrates the national failure to adequately prevent, diagnose, treat, and compensate burn pit-exposed service members and veterans.

Recommendations For The Committee

The current lack of clear understanding on the health impacts of these exposures should not circumvent our national obligation to assist every affected military service member, veteran and widow. As we explore the current processes, modifications to the process and how to better utilize the Burn Pit registry data to support future research we will focus on the following 4 areas:

- 1) **Identifying Illness & Establishing evidence-based clinical practice guidelines and specialized healthcare model** for Iraq Afghanistan War-Lung Injury and comorbid conditions;

⁴ Szema, Anthony et al, "Proposed Iraq/Afghanistan War-Lung Injury (IAW-LI) Clinical Practice Recommendations: National Academy of Sciences' Burn Pits Workshop," *Am J Mens Health*, 2017 Nov; 11(6): 1653-1663. <https://dx.doi.org/10.1177%2F1557988315619005>

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- 2) **Improving VA and DOD disability compensation claims process**, including establishing presumption of service-connection for debilitating symptoms and diseases that have been linked to toxic chemicals.
- 3) **Improving the VA's burn pit registry** so that it can be an effective research tool for monitoring and identifying the health consequences of toxic exposure;
- 4) **Conducting more and better research** into the health consequences of toxic exposures and to develop effective treatments;

1) Identifying Illness & Establishing evidence-based clinical practice guidelines

According to a recent search of VA's website that appears to list and link to all of the existing VA/DoD Clinical Practice Guidelines, Currently VA and DoD have not yet developed evidence-based Clinical Practice Guidelines (CPG's) for health care providers to understand how to identify, evaluate, treat, and refer patients with IAW-LI or other conditions that may be associated with exposure to burn pits.⁵ At least one other VA/DoD CPG has come under harsh fire in a 2013 hearing before this Committee for not being evidence-based, and worse.⁶

There remains an unmet need of adequately educating primary care clinicians in the evaluation and treatment of burn pit related physical illness, including in DOD, VA, and civilian healthcare environments. There also remains an unmet need of describing evidence-based treatment recommendations for IAW-LI (including post-exertional shortness of breath and diagnosed respiratory conditions), toxic brain injury, and all disease and illnesses associated with deployment toxic exposures including from burn pits.

More importantly, the current process fails to assist the veteran in identifying their own illnesses. Because of the VA's dereliction of duty to this matter for the last fifteen years; it is our generation's Agent Orange.

Recommendation. Congress should mandate that VA create evidence-based clinical practice guidelines for IAW-LI that are appropriate for DOD, VA, and private healthcare providers to be able to identify, evaluate, treat, and refer patients with conditions that may be associated with exposure to burn pits including Iraq Afghanistan War-Lung Injury and comorbid cancers, respiratory, and other diagnosed diseases.

⁵ U.S. Department of Veterans Affairs website, retrieved June 5, 2018: <https://www.healthquality.va.gov>

⁶ U.S. House Committee on Veterans' Affairs, "Persian Gulf War: An Assessment of Health Outcomes on the 25th Anniversary," <https://veterans.house.gov/calendar/eventsingle.aspx?EventID=1104>

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VA & DOD Clinical Care: Establishing a Specialized Health Care Program

Develop deployment related toxic exposure specialty clinics within every VA and DOD healthcare systems led by physicians with a background in epidemiology and toxic exposure. The WRIISC Center model is not ideal for veterans unable to travel due to financial hardship and illness. Currently veterans are being misdiagnosed and symptoms are being dismissed as psychosomatic and not for the true illnesses they are suffering from.

Recommendation. We ask that Congress query VA leadership: Will VA commit to establishing specialty clinics at every CBOC , VA/DOD healthcare facility and develop a healthcare model to help identify life-saving treatments?

2. Improving VA and DOD Burn Pit Compensation Process

At the 2019 VA/DOD Burn Pit Symposium the Veterans Benefits Administration provided the group Key National Statistics as of 2/1/19.

- National Pending Claims Inventory
-324,093 Compensation Claims (1,523 claims based on Burn Pit Exposure)
- Total # Veterans Claiming Disabilities Based on Burn Pit Exposure (since June 2007)
-10,588 Veterans
- Total # Veterans Granted Compensation Based on Burn Pit Exposure (since June 2007)
-2,360 Veterans
- Total # Veterans Denied Compensation Based on Burn Pit Exposure (since June 2007)
-8,228 Veterans

Recommendation We urge the Committee to investigate the Veterans Benefits Administration about how the VA is handling burn pit claims. The disclosure of the information requested supplement the research done, filling in missing information that will allow us a better understanding of the health effects of burn pits.

1. What data did the VA use to arrive at its number (10,588) of total burn pit related claims? Please provide a copy and explanation of the data used to arrive at this number.
2. How did VA arrive at the number (2,360) of burn pit related claims wherein VA states it awarded benefits? Does the number (2,360) represent just the burn pit related issues granted in said claims, or does it represent “any” award of benefits, burn pit related or not, out of the total number in question one? Please provide a copy and explanation of this data.
3. Out of the number of claims VA states were granted (2,360), how many of the veterans who had their claims granted developed symptoms or received diagnoses while still serving in the military?

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4. VA had no claims adjudication policy on burn pit related claims, or any other OIF/OEF exposure related claims, prior to issuing VBA Training Letter 10-03 in April 2010. The policy states:

Employees involved in the development of these claims must choose the appropriate Special Issue identifier on the MAP-D Contentions screen. Currently, the only identifier pertaining to exposure claims is “Environmental Hazard in Gulf War,” which is only appropriate for exposure within Southwest Asia.

If these instructions were released in April 2010, and even then, the only identifier for such claims was the same identifier used for claims for the first Gulf War, then how did VA identify the number of post 9/11 burn pit-specific claims from 2007, especially when VA’s own policy document in 2010 states it did not have that capability?

5. How many Veterans’ claims with service *after* September 2001 in Iraq/Afghanistan were tracked with the special issue identifier “Environmental Hazards in Gulf War”?
6. The portion of VA Training Letter 10-03 pertaining to constrictive bronchiolitis states the following:

Regional office personnel may have a difficult time rating disabilities in this population. In most cases, the affected soldiers are comfortable at rest and are able to perform the activities of daily living. They have normal or near normal pulmonary function tests, but, at the same time, become short of breath on slight physical exertion, cannot meet physical training requirements, and are considered unfit for deployment. This unique circumstance challenges those who must determine a disability rating. Pulmonary function testing is the usual standard for rating respiratory disabilities. Therefore, rating authorities should utilize an appropriate analogous code (such as 6600-6604) since the condition does not have its own diagnostic code, and consider extra-scheduler ratings in such cases when there is evidence that a Veteran’s employment is affected.

Of the claimants *granted* service connection for constrictive bronchiolitis, how many were referred to Compensation Service for an extra-scheduler evaluation and what training is in place for regional personnel to rate disabilities with this population?

7. Since VA has acknowledged, near 10 years ago, that it does not have rating criteria for constrictive bronchiolitis, what progress, if any, has been made toward developing rating criteria for this disability?
8. How many Veterans with service after September 2001 who served in Iraq and/or Afghanistan have been issued a rating decision wherein VA coded (on the rating decision code sheet) a 6600 series diagnostic code?
1. Among those, how many were granted and how many were denied? Among those, both granted and denied, please provide a breakdown of which of the 6600 series codes were use.
 2. How many were coded under an “analogous” diagnostic code?

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9. Out of the 8,228 burn pit claims granted and denied, how many of those were claims for death benefits?

VA's Compensation and Pension Manual, M21-1MR, provides guidance for adjudicating claims resulting from various toxic exposures. The relevant section, entitled, "Service Connection for Disabilities Resulting from Exposure to Other Specific Environmental Hazards,"⁷ at least partially governs VA's burn pits exposure-related compensation claims. Relevant identified hazards include "large pit burns throughout Iraq, Afghanistan, and Djibouti on the Horn of Africa" and "particulate matter in Iraq and Afghanistan."

VA Training Letter 10-03, identified in the manual, provides more specific policy guidance on processing burn pit claims.

Additionally, after the 1991 Gulf War, Congress enacted statutory directives at 38 U.S.C. § 1117, which addressed a range of disabilities in veterans who served in Southwest Asia. VA then promulgated its regulations at 38 C.F.R. § 3.317. Although rarely applied correctly by VA, the law provides for presumptive service connection for a "qualifying chronic disability." A qualifying chronic disability means a chronic disability resulting from "an undiagnosed illness" (UDX) or "a medically unexplained chronic multi-symptom illness [CMI] that is defined by a cluster of signs or symptoms, such as: (1) chronic fatigue syndrome; (2) fibromyalgia; (3) functional gastrointestinal disorders" [including irritable bowel syndrome (IBS)]. If a veteran's disability pattern is either one of these, then VA must grant service connection based on § 3.317. Veterans with burn pit exposure who served in the Southwest Asia theatre of operations (which does not include Afghanistan or Djibouti) anytime from August 1991 to the present may also qualify to have their claims adjudicated under these provisions.

VA and DOD should have little problem establishing exposure in burn pit cases because nearly every forward operating base (FOB) in Iraq, Afghanistan, and Djibouti had a burn pit. Given the widespread nature of the burn pits, and the inability of military personnel records to identify all duty locations, VA adjudicators are generally supposed to accept the veteran's lay statement of burn pit exposure as sufficient to establish the occurrence of such exposure if the Veteran served in Iraq or Afghanistan.

VA Claims: Medical Diagnosis and Adjudication Practices

At times, VBA staff have exhibited confusion about relevant diagnosis for veterans with burn pits exposures. Confounding burn pit claims with Gulf War Illness claims, they have returned documentation explaining that service-connection could not be granted because the veteran did not have an undiagnosed illness (UDX) or a medically unexplained chronic multi symptom

⁷ U.S. Department of Veterans Affairs, Veterans Benefits Administration, M21-1MR, Part IV, Subpart ii, Chapter 2, Section C, Topic 12, "Service Connection for Disabilities Resulting from Exposure to Other Specific Environmental Hazards."
https://www.benefits.va.gov/WARMS/docs/admin21/m21_1/mr/part3/subptiii/ch05/pt03_sp03_ch05_secj.doc

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illness (CMI). These are complex regulations that VA has systemically failed in correctly applying to the appropriate cases.

Burn Pit related claims are not the same claims as under the Persian Gulf War regulations. Claims based on the Gulf War regulations are granted, if at all, on a legal presumption that the disability is related to service in Southwest Asia. Whereas, claims based on OIF/OEF exposures, such as burn pits, are granted, if at all on a direct basis (i.e., event or exposure during service; diagnosed disability; and, a medical nexus between the two.)

There are times, however, when VA claims staff appropriately apply both sets of rules. A good example is when a veteran who served in Iraq after September 11, 2001 files a service connection claim for a disability that could satisfy the “qualifying chronic disability” requirements of 38 C.F.R. § 3.317 but is also a disability that may be directly related to exposures in Iraq after September 11, 2001, such as burn pits. In such a case, VA should consider both sets of rules separately and then grant the veteran’s claim under whichever is of greatest benefit to the veteran.

Recommendation. The Committee should request detailed information from VA on the gaps and overlaps between the application of these two types of claims adjudication processes for veterans with burn pits exposure and resultant disability.

VA Claims: Adjudication Issues

Most disability claims require a medical examination from a VA practitioner or contracted VA examiner. In burn pit claims, these so-called Compensation and Pension (C&P) exams are very important because VA has not yet acknowledged a medical nexus between burn pit exposure and the disabilities burn pit veterans are experiencing. Often, the veteran’s only chance to show a medical link between their symptoms and contact with burn pit emission is a medical opinion issued by one of these C&P examiners.

This makes it all the more troubling that VBA staff so routinely fail to follow VA guidance on requesting C&P exams for burn pit exposure claims. When they do follow the guidance, the only training C&P examiners receive on burn pit emissions is a one-page “fact sheet” produced by VBA when it issued Training Letter 10-03.

VBA staff also frequently neglect to send the minimalist fact sheet required for all C&P exam requests pursuant to VBA’s M-21 procedural manual. This leaves examiners with little to no information about which chemicals have been detected in burn pits emissions, how burn pits were operated, and other potentially critical medical information.

Most examination reports serve little more purpose than to reveal the person conducting the examination has no experience in burn-pit related claims or are simply not aware they even exist. The status quo answer in response to requests for VA medical opinions is quickly becoming that VA has not found the particular veteran’s disease process is caused by service in Southwest Asia.

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Such opinions rarely acknowledge the claim is even burn pit related, much less provide any analysis on the chemicals produced by the burn pits in relation to the veteran's disability.

If a veteran files a disability claim within a year of their separation from service, a C&P exam is generally ordered for all claims. A year or more after a Veteran's separation, C&P exams are ordered if the claim meets a certain threshold of evidence. VBA usually manages to verify exposure and thus request an exam in burn pit cases. But confusion about burn pit claims has led to mistakes that could prevent or delay the ordering of a C&P exam. Or, if the wrong type of exam is ordered, a second exam may need to be requested. Veterans often have to wait months to get an exam due to the longstanding backlog of disability claims.

In developing for a medical nexus between burn pit exposure and the veteran's diagnosis, VBA staff have ordered medical examinations for the wrong condition (often Gulf War Illness related). Or, when claims staff ordered the correct exam, they have requested medical opinions from examiners who, by VA's own standards, are unqualified to give them—for example, physicians assistants (PAs).

Inadequacy of training on burn pits exposure and Gulf War claims appears to be a deciding factor in the negative outcomes veterans are experiencing with these claims. This inadequate training appears to extend from VHA and contractor medical examiners to VBA claims adjudication staff.

These errors and confusion in the development process have led to unnecessarily long wait times for veterans suffering from often debilitating, and sometimes life-threatening, disabilities resulting from their burn pits exposures.

Recommendation. Congress should make necessary statutory changes to ensure appropriate outcomes for burn pits exposure claims, including mandatory training (and ensuring the appropriateness of that training) for VHA and contractor medical examiners and VBA claims adjudication staff.

Establishing presumptions of service-connection

Among the serious diagnosed medical conditions identified in service members with IAW-LI is an extremely rare, irreversible, and often fatal respiratory disease called constrictive bronchiolitis (CB) and sometimes also called bronchiolitis obliterans (OB). The medical literature reveals CB/OB to be caused by occupational exposure to diacetyl ("popcorn lung"), in Iranian survivors of Iraqi sulfur mustard (mustard gas) attacks during the 1981-88 Iran-Iraq war, and in OIF/OEF veterans.

Currently, CB/OB can only be identified by a highly invasive lung biopsy conducted under general anesthesia, though medical research is currently underway in the Congressionally Directed Medical Research Program (CDMRP) that if successful would allow for non-invasive diagnostic methods.

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Biopsies have been performed on numerous OEF/OIF Veterans whose worsening breathing problems including shortness of breath, especially following even limited exertion, could not be diagnosed by traditional tests, such as x-rays, CT scans, MRIs, or pulmonary function testing. Lung biopsies have returned a positive diagnosis for CB/OB in approximately 90 percent of these cases.

There are several issues of concern here. First, we are hearing from veterans that VA is not currently service-connecting their CB/OB without a confirmatory biopsy.

And, even with such confirmation, VA often denies service-connection on the basis of lack of proof of in-service causation. For veterans without a confirmatory biopsy of CB/OB, it is nearly impossible for them to get VA (or DoD) to provide one.

And, veterans returning without a formal CB diagnosis but with debilitating post-deployment respiratory and other chronic symptoms, which for many veterans developed while they were still deployed, far too often are denied by VA for service-connection.

In short, VA's requirements for these debilitating post-deployment respiratory conditions are nearly impossible for most veterans to meet, despite their serious disability. By contrast, the U.S. Social Security Administration (SSA) has added CB as a Compassionate Allowance after medical research identified the disease as causally related to environmental toxins, including burn pits, in Iraq and Afghanistan. Not so with VA.

Additionally, many of Burn Pits 360's members and constituents have been diagnosed with unexplained cancers, including an array of leukemias, brain cancers, and other cancers. Many of these veterans are young. Many have died, without compensation or appropriate VA assistance for themselves or their survivors.

Recommendations. We ask that Congress pass H.R. 1005, The Burn Pits Veterans Revision Act of 2019, adding a diagnostic code and evaluation criteria for the war lung disease Obliterative Bronchiolitis and amend Title 38, United States Code, to:

- A.) Provide a presumption of service-connection for VA compensation for symptom-based respiratory disability in veterans exposed with presumed exposure to these airborne hazards;**
- B.) Provide a presumption of service-connection in cases where the veteran has been given a diagnosis of CB/OB or other debilitating respiratory diseases, including chronic obstructive pulmonary disease (COPD), post-exertional asthma, pulmonary fibrosis, and other diagnosed respiratory conditions;**
- C.) Provide a presumption of service-connection in cases where the veteran has developed any of the array of post-deployment cancers that we have identified in these veterans.**

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3) Improving the VA's Burn Pit Registry & Burn Pit Exam

As noted earlier, in 2013, DOD and VA were directed by Congress to set up a registry to collect information from service members who may have been exposed to toxic chemicals and fumes caused by open air burn pits and other airborne hazards. The resulting Airborne Hazards and Open Burn Pit Registry (AHOBPR) to date has 178,654 registrants who completed and submitted the registry questionnaire.⁸

And, on February 28, 2017, the NASEM committee mandated in P.L. 112-220 (the Committee on the Assessment of the Department of Veterans Affairs Airborne Hazards and Open Burn Pit Registry) released its final report, entitled, "Assessment of the Department of Veterans Affairs Airborne Hazards and Open Burn Pit Registry." Several key points emerged that we will mention shortly.

First, with a total of over 3.5 million eligible personnel, participation in the VA's registry is far below expectations. Without a drastic increase in registration, it is difficult to see how the VA's registry can provide an accurate assessment of the health effects of open-air burn pits on our service members and veterans.

Currently, there is no way for a service member or veteran to report a decline in health. If registrants initially register as having no ill effects from the burn pits but are subsequently diagnosed with a disease or illness, they cannot later add that information to the VA registry. This limits the long-term effectiveness of using the VA registry to assess the impact of toxic burn pits on our service members' health over an extended period of their lives and to conduct longitudinal studies regarding the health effects associated with burn pit exposures.

We are also concerned with the participation rate in the **VA Registry's Burn Pit Exam**, the initial in-person medical evaluation. As we understand it, the evaluation's intent is to have a VA practitioner systematically assess a service member or veteran for symptoms related to their toxic exposures. This would allow for the creation of a fuller picture of the patient's health than can be obtained through the self-reported survey alone. However, according to a presentation given by Stephanie Eber and Susan Santos of the VA, as of April 2017, *only 2.8 percent* of registry participants have undergone this exam.

Another serious shortfall of the VA registry is that it does not allow family members to register the death of registry participants, especially important when there is reason to believe the death was a result of toxic exposure from burn pits. Without tracking the mortality rate through methods such as allowing surviving family members to report deaths and the cause of death, the registry's ability to establish mortality rates related to conditions and diseases associated with toxic exposure is precluded. We recommend Congress pass H.R. 1001, the Family Member access to Burn Pit Registry Act, which will direct the Secretary of Veterans Affairs to provide a

⁸ U.S. Department of Veterans Affairs website, retrieved June 5, 2018, <https://www.publichealth.va.gov/exposures/burnpits/registry.asp> Registrants completed and submitted the registry questionnaire between April 25, 2014 and May 1, 2018, including from OIF, OEF, Operation New Dawn, Djibouti since 9/11, and Southwest Asia since August 1990.

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process by which a family member of a deceased individual who is eligible for the Department of Veteran Affairs burn pit registry may register for such registry on behalf of the deceased individual.

Most significantly, the NASEM committee on the assessment of VA's registry stated in its final report: "On the basis of its evaluation of the data, the committee concluded that the exposure data are of insufficient quality or reliability to make them useful in anything other than the most general assessments of exposure potential."⁹

The Committee concluded:

Attributes inherent to registries that rely on voluntary participation and self-reported information make them fundamentally unsuitable for addressing the question of whether burn pit exposures have caused health problems. Addressing the issues identified by the committee would, though, improve the AH&OBP Registry's utility as a means of generating a roster of concerned individuals and creating a record of self-reported exposures and health concerns.

All parties—service members, veterans, and their families; VA; Congress; and other concerned people—would benefit from having a realistic understanding of the strengths and limitations of registry data so that they can make best use of them and, if desired, conduct the kind of investigations that might yield salient health information and improve health care for those affected.¹⁰

Previously, the website stated, "A workgroup of VA subject matter experts is reviewing the report's nine recommendations to determine ways to improve the health status and medical care of veterans." To date, we are not yet aware of improvements to the VA's registry recommended either by the NASEM report or the researchers' recommendations published online in 2015 and in a medical journal two years ago.¹¹

Recommendation. We encourage the Committee to seek answers from the VA for the following important questions, and legislating or otherwise ensuring changes as may be appropriate based on VA's responses:

1. Thousands of veterans who were exposed to toxic smoke from burn pits in Afghanistan and Iraq are coming home and developing serious illnesses like constrictive bronchiolitis, other respiratory conditions, and cancers. Is it VA's position that prolonged exposure to toxic chemicals from open air burning can have lasting negative health consequences?

⁹ National Academy of Science, Engineering, and Medicine (NASEM), Committee on the Assessment of the Department of Veterans Affairs Airborne Hazards and Open Burn Pit Registry, "Report Highlights," February 28, 2017. <http://www.nationalacademies.org/hmd/reports/2017/assessment-of-the-va-airborne-hazards-and-open-burn-pit-registry.aspx>

¹⁰ NASEM 2017

¹¹ Szema et al, 2017

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2. The VA has not seriously researched the consequences of burn pit exposure. Congress mandated that VA implement the Registry to monitor health conditions affecting veterans and service members who were exposed to toxic smoke from burn pits and other hazards. But, according to a 2017 report from the National Academy of Sciences, the registry is fatally flawed and ineffective as a way to investigate the true health consequences of burn pits. Will VA commit to reforming the burn pits registry to make it a genuinely useful tool for documenting the true health consequences of burn pits?
3. Who is on the “workgroup of VA subject matter experts” that was reviewing the nine recommendations? What records reflect their work in response to the 2017 National Academy of Sciences report, including their recommendations or determinations?
4. What records reflect the improvements that the VA is considering to the Registry based on the recommendations of the 2017 report?
5. What records exist regarding concerns about the burn pit registry, including concerns from individual veterans and Veteran Service Organizations regarding the registry?
6. What outreach methods are in place to ensure that service members deployed to Iraq and Afghanistan post-9/11 are aware of the registry and are encouraged to register if they believe they have been exposed to toxic matter through open air burn pits?
7. What factors explain the discrepancy between the numbers of service members potentially exposed, versus the number of registrants to the burn pits registry?
8. What is the VA’s strategy to increase participation in the registry?
9. Does the VA regularly communicate with registrants?
10. How is the VA gathering data, if at all, to assess change or decline in health among service members, to support a longitudinal assessment? Why would the VA not support including an option for updated reporting in the registry?
11. How is the VA gathering mortality data, if at all, associated with toxic exposures through burn pits? Why would the VA not support including an option for reporting deaths in the registry?
12. What factors explain the low participation rate of registrants with the associated exam?

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13. Has the VA adopted a strategy to increase the participation rate in the initial Burn Pit exam? Why has there only been 6 million combined dollars allocated to DOD and VA for outreach?
14. Is there a uniform protocol in place that practitioners who administer the exam are following? If yes, what is the protocol and has it proven effective in recognizing common warning signs and symptoms indicating toxic exposure?
15. What protocol does the VA have in place to ensure that its practitioners are equipped to detect and treat medical issues associated with toxic exposure among registry participants VA examines?

Recommendation. To encourage full Registry participation, Congress should offer Veteran Service Organizations grant funding to execute effective national outreach campaigns to their constituents.

3. Active Burn Pits

In the April 2019 DOD Open Burn Pit Report to Congress reported that we have 9 active burn pits in operation, 7 U.S. Forces and 2 Contractor operated. DOD stated in the report several times that “no location has more than 500 personnel assigned” implying that this amount of personnel shouldn’t generate high volumes of trash resulting in a less toxic environment. According to the 2011 NAM report each soldier generates 8-10lbs of waste per day. A soldier on a 6 -month tour will generate around 1800 lbs. of waste and a soldier on a 12-month tour generates 3600 lbs. of waste. In 12 months, that is 1,800,000 lbs. of waste for 500 personnel.

Another statement made is that the small locations do not generate waste streams that require incinerators and that large logistics do generate enough waste suitable for incinerator use but according to DOD open burning remains an alternative to protect troops from disease. So, the excuse of not using the safety of incinerators goes from significant funding to the amount of trash generated.

According to the VA Office of Public Health, the active burn pit sites are quite different and may represent a different composition of airborne hazards than the area currently covered by the AHOBPR. The VA denied our request to add the 9 active burn pit sites to the VA Registry. As of today, service members being exposed to toxic chemicals cannot register.

4) Conducting More and Better Research

The VA was directed under P.L. 112-260 to contract for an independent scientific report that would contain the following:¹²

¹² PUBLIC LAW 112-260—JAN. 10, 2013 126 STAT. 2423 – SEC. 201. ESTABLISHMENT OF OPEN BURN PIT REGISTRY.

(b) REPORT TO CONGRESS.—

(1) REPORTS BY INDEPENDENT SCIENTIFIC ORGANIZATION.— The Secretary of Veterans Affairs shall enter into an agreement with an independent scientific organization to prepare reports as follows:

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- An assessment of the effectiveness of actions taken by the Secretaries to collect and maintain information on the health effects of exposure to toxic airborne chemicals and fumes caused by open burn pits.
- Recommendations to improve the collection and maintenance of such information.
- Using established and previously published epidemiological studies, recommendations regarding the most effective and prudent means of addressing the medical needs of eligible individuals with respect to conditions that are likely to result from exposure to open burn pits.

Certainly VA has not yet determined the “most effective and prudent means of addressing the medical needs of eligible individuals with respect to conditions that are likely to result from exposure to open burn pits.”

Recommendation. We encourage the Committee to provide continued oversight with regards to the status of this report and the implementation of its recommendations.

According to VA’s website, NASEM’s 2011 report, Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan, “found limited but suggestive evidence of a link between exposure to combustion products and *reduced lung function* in various cohorts similar to deployed Service members, such as firefighters and incinerator workers. This finding focused on pulmonary (lung) function, not respiratory disease, and noted that further studies are required. There is little current scientific evidence on long-term health consequences of reduced lung function.”¹³

VA goes on to say, “VA and the Department of Defense will conduct a long-term study that will follow Veterans for decades looking at their exposures and health issues to determine the impact of deployment to Iraq and Afghanistan. Read the February 4, 2013 notice in the Federal Register to learn more.”

It has been more than five years since VA announced it planned to conduct this long-term study. VA has had ample opportunity to conduct it.

(A) Not later than two years after the date on which the registry under subsection (a) is established, an initial report containing the following:

(i) An assessment of the effectiveness of actions taken by the Secretaries to collect and maintain information on the health effects of exposure to toxic airborne chemicals and fumes caused by open burn pits.

(ii) Recommendations to improve the collection and maintenance of such information.

(iii) Using established and previously published epidemiological studies, recommendations regarding the most effective and prudent means of addressing the medical needs of eligible individuals with respect to conditions that are likely to result from exposure to open burn pits.

(B) Not later than five years after completing the initial report described in subparagraph (A), a follow-up report containing the following:

(i) An update to the initial report described in subparagraph (A).

(ii) An assessment of whether and to what degree the content of the registry established under subsection (a) is current and scientifically up-to-date.

(2) SUBMITTAL TO CONGRESS.—

(A) INITIAL REPORT.—Not later than two years after the date on which the registry under subsection (a) is established, the Secretary of Veterans Affairs shall submit to Congress the initial report prepared under paragraph (1)(A).

(B) FOLLOW-UP REPORT.—Not later than five years after submitting the report under subparagraph (A), the Secretary of Veterans Affairs shall submit to Congress the follow-up report prepared under paragraph (1)(B).

<https://www.gpo.gov/fdsys/pkg/PLAW-112publ260/pdf/PLAW-112publ260.pdf>

¹³ U.S. Department of Veterans Affairs website, retrieved June 4, 2018:

<https://www.publichealth.va.gov/exposures/burnpits/health-effects-studies.asp>

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Recommendation. We urge Congress to mandate an independent epidemiologic research study – outside of VA, which has already had ample opportunity to do so – that will help to more formally identify the association between inhaling toxic chemicals from burn pit smoke and resultant health conditions and deaths.

Such research should include determining the incidence and prevalence of IAW-LI and other potentially related health conditions in: (1) military service members and veterans currently in treatment for post-burn pit exposure health complaints; (2) Iraqi local populations similarly exposed to U.S. burn pits (see appendix C); (3) healthy control populations of Iraq and Afghanistan War deployed and non-deployed era service members/veterans.

Recommendation. We encourage the Committee to seek answers from the DOD and VA for the following important questions, and legislating or otherwise ensuring changes as may be appropriate based on VA's responses:

1. Which specific office(s), working group(s) or people are assessing the adequacy and effectiveness of data gathering and surveillance of the health consequences of burn pits?
2. Does VA have any unpublished studies, reports, or similar documents regarding health effects of burn pits?
3. How does VA review, assess, and assimilate studies into (i) its assessment of the long-term health consequences of burn pits and (ii) its screening for potential burn-pit related disease and (iii) its treatment for burn-pit related disease?
4. What records exist that would reflect VA's assessment of such studies (including, potentially, internal correspondence, memos, etc.)
5. What internal assessments, memos, or other documents underlie the VA's determination that "At this time, research does not show evidence of long-term health problems from exposure to burn pits."
6. Which specific office (or which officials) are involved in internal reassessment or reevaluation of VA's determination that there is currently no evidence of long-term health problems? What records exist that would reflect any such ongoing assessment or evaluation?
7. The VA's "fact sheet" on burn pits, which describes ongoing research into the health effects of burn pits and the inconclusive nature of prior research. The last time we reviewed it, that fact sheet was last updated in November 2013 and only referred to studies from 2009 and 2011. Which specific office (or which officials) are involved in reassessing the statements in that fact sheet in light of more recent research? What records exist that would reflect potential reassessments or updates of the fact sheet?

DOD-CDMRP Burn Pit Exposure Medical Research

As many of the members of this Committee know from past hearings on another toxic exposure issue, Gulf War Illness, many ill Gulf War veterans are encouraged by ongoing treatment research directed by Congress, including by many of you and other leaders and Members of the House Veterans' Affairs Committee. Specifically, that treatment research is being done by the

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Gulf War Illness Research Program (GWIRP), part of the Congressionally Directed Medical Research Program (CDMRP) that is funded under the Department of Defense (DOD) health budget.

Like the GWIRP, many of the health research programs within the CDMRP are standalone programs. However, others are congressionally designated topic areas within broader programs like the CDMRP's Peer Reviewed Medical Research Program (PRMRP). The specific topic areas to be pursued are determined by Congress each year through annual Defense appropriations.

For Fiscal Year 2018, there are several medical research topic areas in the CDMRP-PRMRP that remain of strong interest to veterans affected by burn pit exposure, including: Acute Lung Injury; Burn Pit Exposure; Constrictive Bronchiolitis; Lung Injury; Metals Toxicology; Mitochondrial Disease; Pulmonary Fibrosis; and Respiratory Health. We are grateful to Congress for including all of these research topic areas, particularly the restoration of the Burn Pits Exposure topic area.

CDMRP is important for this treatment-focused research for several reasons. First, CDMRP has the ability to fund any qualified research team, not just those employed by the funding agency. By contrast, VA's medical research program is solely intramural and open only to VA-employed researchers. Much of the valuable medical research related to burn pits exposure has been led by researchers at independent, academic medical centers including Vanderbilt University, Stony Brook University, the Deployment-Related Lung Disease Center at National Jewish Health, and others.

Second, CDMRP includes in all levels of planning, proposal review, and funding decisions the active participation of consumer reviewers – patients (or their caregivers) who are actually affected by the disease. This is of critical importance. VA offers no opportunity for similar involvement in research decision-making by the patients who are ultimately affected by such decisions.

Finally, CDMRP has already shown its effectiveness with regards to other complex post-deployment, toxic exposure health conditions including traumatic brain injury (TBI) and Gulf War Illness (GWI), including through its emphasis on collaboration, treatment focus, and effective two-tiered peer review.

Recommendation. We encourage Members of the Committee work to create a Congressionally directed standalone Burn Pits Exposure Research Program (BPERP) within the Congressionally Directed Medical Research Program (CDMRP), modeled after the successes of other CDMRPs including the treatment-focused Gulf War Illness Research Program, as follows:

A standalone burn pits exposure CDMRP would ideally be laser-focused on improving the health and lives of veterans suffering the negative health effects of burn pit exposures and on learning all that is possible from their health experiences to help future veterans similarly exposed. Like the existing standalone CDMRPs, the proposed Burn Pits Exposure Research Program would have its own dedicated staff, focused exclusively on advancing the Congressional directives

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related to this burn pit exposure medical research program. Ideally, it would be focused on several major areas to more rapidly improve the health and lives of veterans affected by burn pits exposure:

- **Accelerating the development of treatments and their clinical translation** for Iraq/Afghanistan War Lung Injury (IAW-LI) and comorbid associated conditions
- **Improving scientific understanding of the pathobiology resulting from burn pit exposures**, including in both affected veterans and in animal models of burn pit exposures, and including research priorities to identify biomarkers of exposure, biomarkers of exposure effect, and biomarkers of illness – all critical in improving the definition and diagnosis, disease monitoring, and monitoring of the effectiveness of tested treatments of veterans affected by burn pit exposure
- **Assessing comorbidities**, including the incidence, prevalence, early detection and diagnosis, treatments for, and any unique factors related to burn pits exposed veterans': constrictive bronchiolitis (CB/OB), pulmonary fibrosis, sarcoidosis, chronic obstructive pulmonary disease (COPD), post-exertional asthmas, and other respiratory diseases; cancers including lung cancer, leukemia, glioblastoma and other brain cancers, renal cancer, and other cancers
- **Identifying force health protection prevention measures** to prevent future burn pit exposures, and to provide early assistance to future military service members exposed to burn pits
- Using other CDMRP successes as a model, investing appropriated medical research funding to **develop a collaborative, inter-institutional, interdisciplinary burn pits exposure research consortium**, while investing other appropriated medical research funding to support focused medical research in the areas described above

We would be pleased to work early next year with any Members interested in creating, on a bipartisan, bicameral basis, a cosigned request for fiscal year 2020 funding to create such a Burn Pits Exposure Research Program.

APPENDICES

Appendix A: Burn Pits 360 Registry Cancer Data

Appendix B: Physician Disability Claims Statements

Appendix C: Dr. Savabiasfahani Iraqi Population Study

Appendix D: Personal Testimonies

Appendix E: Photos

APPENDIX A: Burn Pits 360 Registry Cancer Data

As of March, 2019, at least 506 veterans and others who were exposed to toxic smoke from the burn pits in Iraq and Afghanistan have reported to Burn Pits 360 what they believe to be service related cancers that they are now receiving treatment for.

THE TOP 10 CANCERS SO FAR ARE

| | |
|---|--|
|  Skin (139) |  Soft Tissue Sarcoma (42) |
|  Lymphoma (116) |  Lung (39) |
|  Brain (97) |  Testicular (39) |
|  Esophageal (45) |  Prostate (34) |
|  Leukemia (42) |  Blood (31) |

The Veteran's Administration maintains that their research does not show evidence of long-term health problems from exposure to burn pits.



www.burnpits360.org

Appendix B: Physician Disability Claims Statements

VANDERBILT UNIVERSITY  MEDICAL CENTER

Hillsboro Medical Group at Vanderbilt

November 12, 2015

To: Congresswoman Elizabeth Esty
 Captain Leroy Torres, Ret
 Rosie Torres

Re: Veterans Administration Compensation Code for Constrictive Bronchiolitis

I am writing to support adding constrictive bronchiolitis to the VA compensation code. This is an otherwise rare pulmonary condition that has been linked to service in Iraq and Afghanistan. The current code does not allow compensation for the typical patient with this service-connected illness.

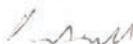
I began seeing Ft. Campbell soldiers with constrictive bronchiolitis in 2005. The typical service member deployed as an elite athlete and returned from deployment incapable of completing a two mile run. In most cases, their inability to meet the Army's physical fitness standard ended their eligibility to remain in the armed forces. Service members with constrictive bronchiolitis typically experience exercise limitation, chest tightness and cough. Despite these symptoms and severely abnormal biopsies, they usually have normal x-rays, CT scans and pulmonary function testing. These findings have been widely accepted by academia and have been published in the *New England Journal of Medicine* (July, 2011). The United States' Defense Health Board Deployment Pulmonary Health Report agrees that constrictive bronchiolitis among service members is a medical condition which is usually missed by routine x-rays, CT scans and pulmonary function testing.

The current VA Compensation Code requires abnormal x-rays, pulmonary function testing or cardiopulmonary exercise testing to provide a disability rating for a service member or veteran. The system fails to provide compensation for the vast number of veterans diagnosed with constrictive bronchiolitis.

I am writing to support legislation that would change the code to allow service members with constrictive bronchiolitis an appropriate rating even in the setting of their having normal non-invasive studies. This condition is very rare and is clearly related to deployment exposures. It is not fair to dismiss this diagnosis which is what is done with the current Veterans Administration Compensation Code.

Thank you for your consideration.

Sincerely,



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 Associate Professor of Medicine

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DEPARTMENT OF VETERANS AFFAIRS
G. V. "Sonny" Montgomery
Veterans Affairs Medical Center
Jackson, MS 39216

January 27, 2016

Dear Senator,

Many veterans of the wars in Iraq and Afghanistan are returning home disabled from a respiratory condition known as constrictive bronchiolitis. This disease affects young, non-smoking men and women and presents as slowly progressive shortness of breath. In its mildest form it limits exercise capacity, and in its more severe form affects daily life sometimes requiring supplemental oxygen 24 hours a day.

I serve veterans as a pulmonologist at the VA Medical Center in Jackson, Mississippi where I am confronting this disease daily. Currently, there are over 100 patients seen at our hospital with this condition confirmed or suspected. The medical community needs your support for research dollars to learn more about this disease and possible treatments. We also need constrictive bronchiolitis listed as a presumptive service connected disease as it is clearly related to airborne exposures suffered in the theater of OEF/OIF. Thank you for your support in this matter and I would be happy to answer any questions you may have.

Sincerely,

Allyn Harris, M.D.
Assistant Professor
Division of Pulmonary/Critical Care
G.V. Sonny Montgomery VA Medical Center
Jackson, MS
abond@umc.edu

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Main Health Campus
1400 Jackson St.
Denver, CO 80206

303.388.4461
800.423.8891

njhealth.org

To Congressional Staff

06.01.2018

Regarding: Small Airway Injury Due to Deployment Related Lung Disease (DRLD), Airborne Hazard exposures and VA Disability Evaluation Criteria

Background

Over 2.5 million US service men and woman have honorably served in Iraq and Afghanistan in support of OIF and OEF since 2001. Forty percent of those returning from service rely on VA providers and a significant number of those seeking care have experienced respiratory symptoms and diseases associated with deployment. While the specific cause(s) for deployment related lung disease (DRLD) have not been proven, there are many significant exposures which have been implicated. The air quality in those regions is poor due to; high levels of ambient air particulates, industrial air pollution, combat operations and open air burn pits used for disposing of medical waste, metals, plastics, electronics and other combustible products (1). The first incinerators were not placed in Iraq until 2009. These activities contribute to high levels of air particulate matter (PM_{2.5}), an exposure which is linked to several cardiovascular and pulmonary disorders (2). The Department of Defense has consistently documented airborne PM_{2.5} concentrations throughout Iraq and Afghanistan that exceed US Military Exposure Guidelines (3). These high levels of particulate matter carry toxins, noxious agents and microbes that can lodge in the small airways of the lung and result in diseases such as asthma, constrictive bronchiolitis, emphysema and other disorders (4).

Both DOD and civilian academic medical centers have described respiratory diseases associated with military deployment. The Millennium Cohort Study, which surveyed 46,000 deployers, reported a higher incidence of respiratory symptoms in deployers compared to non-deployers. Other studies have shown an increased incidence of asthma, eosinophilic pneumonia, constrictive bronchiolitis, granulomatous lung disease and emphysema in deployers, many of whom were never smokers (5-10). Unfortunately, the magnitude of the problem is not quantified as there are no longitudinal studies to adequately determine the long-term health consequences of veterans exposed to inhalation hazards due to OIF and OEF deployments.

There are a number of unique challenges in diagnosing lung diseases following deployment to Southwest Asia, particularly for those diseases affecting the small airways of the lungs. Non-invasive studies such as pulmonary function testing (PFTs), high resolution computed tomography (HRCT) and cardiopulmonary exercise testing (CPET) are normal in some patients. For many, the only definitive diagnostic test has been surgical lung biopsy. This disparity between non-invasive testing and more invasive lung biopsy is well-recognized in patients

The leading respiratory hospital in the nation.

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suffering from small airways disease such as constrictive bronchiolitis and was acknowledged by the United States Defense Health Board in its 2014 study on (DRLD) (11-12). One large DOD facility, which did not pursue video-assisted thorascopic surgical lung biopsies (VATS), was unable to identify the cause of respiratory symptoms in 40% of their deployers (13). Symptomatic deployers may face discharge from military service because they are unable to pass mandatory fitness testing (8).

In summary, a substantial number of service members have returned from OIF and OEF with respiratory diseases that are both unique to deployment and difficult to diagnose. This group of veterans requires specialty care which is not consistently found throughout the VA system. Moreover, the current VA disability guidelines do not adequately address some of the respiratory disability issues affecting service men and women returning from OIF and OEF.

Recommendations

1. The diagnosis of deployment-related lung disease (DRLD) requires specialized pulmonary evaluation and testing, which may include metabolic exercise testing, complete pulmonary function testing, high resolution chest CT scans that are interpreted by thoracic radiologists and sometimes surgical lung biopsy. Since these capabilities are not available at most VA medical centers, the VA should encourage providers to refer veterans suffering from these complex exposure related pulmonary disorders using the “VA Choice” option to academic or tertiary referral centers with expertise in DRLD.
2. The current VA disability criteria for DRLD and, specifically, small airways disease should be revised (14). Current clinical disability guidelines requiring resting PFTS and oxygen saturation testing for bronchitis, asthma and COPD are not sufficient for assessing small airway injury due to Southwest Asia inhalation exposures.

Richard Meehan, MD
CAPT, MC, USN (ret)
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Social Security Official Social Security Website

Program Operations Manual System (POMS)

Effective Dates: 08/21/2012 - Present

DI 23022.840 Obliterative Bronchiolitis

COMPASSIONATE ALLOWANCE INFORMATION

OBLITERATIVE BRONCHIOLITIS

TN 7 (08-12)

DESCRIPTION

Bronchiolitis Obliterans; Constrictive Bronchiolitis

Obliterative Bronchiolitis (OB) is a rare, irreversible, life-threatening form of interstitial lung disease that occurs when the small airway branches of the lungs (bronchioles) are compressed and narrowed by scar tissue (fibrosis) and inflammation. Extensive scarring results in decreased lung function. Causes of OB include collagen vascular disease, organ transplant rejection, viral infections, drug reactions, prematurity complications, rheumatoid arthritis, oral emergency medicines (for example, activated charcoal), exposure to toxic fumes (for example, diacetyl, sulfur dioxide, ammonia, chlorine, mustard gas, ozone), and idiopathic (no known cause). Symptoms of OB include coughing (usually without phlegm), shortness of breath on exertion, wheezing, fever, night sweats, weight loss, frequent or persistent eye, nose, and throat or skin irritation.

OB is not the same disorder as **bronchiolitis obliterans organizing pneumonia (BOOP)**, which is a treatable disorder with a favorable prognosis. OB is also a distinctly different disorder than pediatric bronchiolitis, which is a very common childhood respiratory illness with a good prognosis.

DIAGNOSTIC TESTING, PHYSICAL FINDINGS, AND ICD-9-CM CODING

ONSET AND PROGRESSION

Diagnostic testing: OB can only be definitely diagnosed by a lung biopsy. Other diagnostic testing for OB includes lung volume assessments and chest x-ray with evidence of hyperinflation; and high resolution computerized tomography (CT) of the chest at full inspiration and expiration showing evidence of heterogeneous air trapping, mosaic attenuation, bronchial wall thickening, cylindrical bronchiectasis, or scattered ground glass opacities. Spirometry may show airway obstruction or restriction that is generally unresponsive to bronchodilators. OB can only be definitely diagnosed by a lung biopsy.

ICD-9: 491.8

The progression of OB varies from person to person with symptoms starting either gradually or suddenly. Two to eight weeks after a respiratory illness or exposure to toxic fumes, dry cough, shortness of breath (especially on exertion), fatigue, and wheezing may occur. Severe cases often require a lung transplant. Post-lung transplantation, OB continues to be a major life-threatening complication, affecting up to 50-60% of people who survive five years after transplantation.

There is currently no cure for OB. Bronchodilators, inhaled corticosteroids, oxygen supplementation, and, in the case of lung transplantation, immunosuppressants, are prescribed to control symptoms. Response to treatment is generally poor.

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long. On some nights, we were even able to see the flames change different colors based on what they were burning. (Different colors mean different types of heavy metals.) I can recall on many occasions, I would have upper respiratory infections and I also treated many people in my unit for the same. I was the medic. It was like this day in and day out.

On some occasions, I even lit bum pits on fire using jet fuel and a flare to get it going, so we could dispose of our trash while out in the field. To paint the best picture, this is every day life in Iraq, for over 365 days.

After returning home from the War, I remember coughing up so much black stuff in the first six months. I thought nothing of it other than we are finally in clean air and it was my body getting rid of the toxins of war. To my surprise, that was just the beginning of my medical issues to come later. The year was 2014 and I was training for a triathlon and remaining fit for work, as I was a plain-clothes officer for the US Government. I went for a run one day, and couldn't breathe the next. Over the course of two years, I finally underwent an open lung biopsy to diagnosis Obliterative Bronchiolitis. This disease is more commonly known as Constrictive Bronchiolitis and, it is terminal. I continue to progress to the point where I am on oxygen 24/7 and can no longer do my job. I was medically retired and now I focus my energy on school and remaining as healthy as possible. If it were not for these Pits, I would still be able to have my career and my health.

GOLD STAR FAMILIES**Staff Sgt. David L. Thomas (Colorado)**

David was diagnosed with Stage IV lung cancer that metastasized to the brain in April 2013. "He was given a prognosis of six to 18 months survival rate," Thomas said. "What I was most disappointed about at that moment was the fact that I was selling Beth (his wife) and our children short. Second was the fact that I would no longer be here serving in the U.S. Army doing what was the most important thing: overseeing the safety of my family and our great country via my service.

"I saw a doctor in January 2013, and was told I had an upper respiratory infection or the flu," Thomas said.

"I did not receive any diagnostic testing such as a chest X-ray or lung function test. I was given an antibiotic and sent on my way." After diagnostic testing, Thomas was informed that he had a nodule in his medial left lobe, and additional doctor visits and testing were conducted. "I also learned that I had actually had lung cancer for more than two years, including during my last deployment to Afghanistan." Upon learning of his cancer, Thomas began to research what could have caused it. "I began to uncover the research and studies on Iraq Afghanistan War Lung disease, and the devastating effects of the 'bum pits' on service members and civilians who have served overseas," Thomas said. "Through my research I learned that IAWL is a chronic pulmonary condition that will affect one in seven service members who have served overseas. While Veterans Affairs and the services have not officially recognized IAWL or the effects of the burn pits, there are a lot of people suffering and awareness of IAWL needs to be brought to the public's attention."

"Eventually, through fundraising, we hope that the foundation has enough funds to provide basic testing for veterans or active duty service members who might need to determine if they have IAWL," Thomas said.

"In many ways, through my foundation, my last mission is to bring awareness to IAWL and those who are suffering." Elizabeth said that her husband is her hero. "David kept saying, 'I'm never going to deploy again. I need to be able to. It's my job,'" she said.

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SFC Fred Slape (Texas)

My name is Diane Slape, I am the widow of SFC Frederick T Slape, Retired US Army. When we retired in 2012, I was certain War Zone dangers were behind us. In late August 2015, days after we'd sent our daughter to her first year of college and started building our Forever Home, Fred went to his routine VA Drs appointment. Just to be told again "your White Blood Cell count is elevated, you need to stop smoking." But this time was different, The VA called to tell Fred, they were concerned about the results, to call for a lab appointment, one he couldn't get until October. Despite my 43yr old husband's overall good health, according to his Oncologist Team, Fred died 9 weeks after he was diagnosed with Stage 4 Adenocarcinoma of the Brain & Lung lymph nodes, a disease that usually strikes 70-80yr old people. Most Veterans exposed to the Toxic Burn Pits, who are diagnosed with cancer, aren't living past 18-24 months, due to the aggressive nature.

In August 2015, Fred still showed no symptoms, then 2 days of sporadic headaches along with seriously impaired vision, an MRI discovered the mass in Fred's brain. As if we had expected it, when the Dr told us of the brain mass – Fred & I looked at each other and said "Burn Pits". After 5 days in the hospital, every infectious disease test known to man, and a CAT scan, they discovered the mass in his chest. Many asked Why didn't we go to the VA? My husband said chuckling "What? And Die there?" After reviewing 3 years of lab results, the VA Drs should have been concerned about Fred's blood work since 2012. Being Retirees, we had Tricare coverage too, as well as VA access. Most non-retired veterans do not have the Tricare option, leading to possibly better care.

In the remaining 5 weeks of Fred's life, he would have 1 round of the most intense 3 day chemo treatment, his first and only seizure, brain surgery to remove an aggressively growing brain tumor, during the 2 wk recovery from surgery, He had chest radiation & a stomach tube inserted, just in case the radiation closed off his esophagus. During this recovery period, 4 new inoperable tumors were growing quite rapidly inside Fred's brain. 1 very large one in the Temporal lobe where the initial one was removed, 1 in the Frontal lobe that tripled in size and 2 in the cerebellum, never seen before in all the CAT Scans previously. 3 days later Fred had started brain radiation, which hospitalized him the next day. Oncologists informed us the chest/brain radiation, as well as the 1 round of Chemo had no effect on the cancer in his chest or brain. We opted for 1 more round of brain radiation, which rapidly led to Fred's death 2 days later. Please help so that Fred's young soldiers, who are 20 & 30 yrs old and currently healthy, do not struggle or suffer as Fred did, but without Healthcare that is specific to their exposures & services for their families.

Colonel Mc Cracken (Georgia)

Dear Mr. Vice President,

I am so very sorry for the loss of your son, Beau. My husband, USA Colonel David A. McCracken served an active duty tour at Victory Base Complex (VBC), Baghdad, Iraq in 2007. My husband also died of glioblastoma multiform on September 2, 2011 after an 11-month battle. A year after his death, it was brought to my attention that exposure to toxic chemicals from the open-air burn pits were an attributing factor to his cancer.

My husband was also mentioned in the book, "The Burn Pits, the Poisoning of America's Soldiers" by Joseph Hickman, page 126. As you know, grief is a powerful emotion and I make a choice everyday to

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ensure that my journey is one of healing and hope. I can't imagine the pain associated with the loss of a child. I can only see and experience this loss from my own perspective and that of my children.

I have researched, spoken of and supported efforts regarding the effects of these burn pit toxins. I do this so that my children will see that this effort is a worthy one. It can be exhausting, frustrating straight through to my soul. I've spent more restless nights than I like relentlessly learning and researching this issue with limited return on this particular 'investment'.

It is a special breed of people who take up the calling to serve. I will continue the fight with my small voice to keep my husband's memory alive and to show my children that where there is a passion to make things right, change can be affected.

My husband, a 45-year-old in perfect health returned coughing and complaining of headaches. I watched his health decline rapidly as I'm sure you have witnessed as well. If anything, I want my husband's death to mean something. Some small thing. Not an 'agent of change' but an 'angel of change'. Sir, my spirit was renewed with your words during your recent interview with PBS. It is my greatest hope that you are able to embrace - with similar passion - an outlook of support that brings awareness to the effects of burn pits on our loved ones. I have long felt that I didn't want David's death to be simply a memory, but a catalyst for change and action. I have every hope that you feel the same.

Please continue this fight. Continue to engage and bring awareness to this issue.

Signed with hope and renewed spirit,
Tammy J. McCracken
Proud Wife of deceased USA Colonel David A. McCracken

Timothy Johnson

Dear Vice President,

First off I was so very saddened to hear of your sons diagnosis and eventual passing. I too am a parent whose son has died because of brain cancer.

I am writing in regards to the burn pits in Iraq and their link to cancers. My son Sgt. Timothy Lee Johnson of the USMC died of glioblastoma multiform at the age of 35. He was a bomb dog handler deployed to Iraq. Upon his diagnosis he was deemed 100% disabled service connected with the VA. He had a wonderful doctor who believed the exposure to these toxins were the contributing factor in his cancer.

My hope is more investigation and subsequent help to victims will take place.

I am glad to hear more safety and equipment is now in place.

I have attached the memorial from His funeral. The photo is him with his dog in Iraq. I believe there are thousands of other veterans who have suffered many illnesses and cancers because of the exposure to the burn pit toxins. I believe many have not come forward not realizing they are sick because of their exposure.

May the word continue to be declared so they too can get the medical care they need. Sincerely,

A hurting mom, Donna Johnson

P.S. If this letter can be added to many more of those whose lives and loves were lost.

Major Kevin Wilkins (Eustis, Florida)

Dear Vice President

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I do not want to take up much of your time, so this letter to you will be short and to the point.

My husband, USAF Major Kevin E. Wilkins, RN., served an active duty tour at the Balad Air Force Base, Balad, Iraq in 2006 where your son Beau was also stationed. My husband died of a glioblastoma brain tumor in 2008 after exposure to the toxic chemicals from the open-air burn pit at that base. (He was also mentioned in the book, "Burn Pits" by Joseph Hickman on page 32). I won't go into the effect his death had on my 2 children and me because you already know the pain.

VP Biden, you can help by talking about the effects these burn pits have had on you, Beau's wife and the entire family. I know you promised Beau that you would run for President, but I believe that standing up for Beau in the light of what has happened to him and many other soldier's and their families, is so much greater than being President of the United States. Everything happens for a reason, and I believe it is your calling to help the many other soldiers who are still alive but fighting to live.

If you would like to see the work I have been doing to try to help other families whose soldiers have been exposed to the toxic chemicals, please Google "Jill Wilkins Burn Pits" and you will see the media coverage I have been involved in including CNN.

Very Sincerely,

Jill R. Wilkins

Proud Wife of deceased USAF Major Kevin E. Wilkins, RN

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APPENDIX E: Photos

(Brian Alvarado & his daughter Rihanna)



(Ret. SSG Will Thompson, double lung transplant)



Burn Pits 360 Testimony – September 25, 2019



FALLEN HEROES

| | | | | |
|---|---|---|--|---|
| Sgt. Jeff Wells | SGT. Brandon Matic | SGT Amanda Downing | MAJ Kevin Wilkins | MSGT John Charleston |
|  |  |  |  |  |
| SPINDLE CELL CARCINOMA | ESOPHAGEAL CANCER | AML LEUKEMIA | BRAIN TUMOR | PANCREATIC CANCER |
| Aaron S. Barnes | SSG Steven Ochs | SPC. Dominick Liguori | COL David McCracken | SFC Fred Slape |
|  |  |  |  |  |
| RENAL CANCER | AML LEUKEMIA | SARCOIDOSIS | GLIOBLASTOMA | ADENOCARCINOMA |
| TSGT. Jessica Sweet | CSM James W. Hubbard | Danielle Nienjadio | SSG. Matthew Bumpus | SPC. Anthony Rounds |
|  |  |  |  |  |
| AML LEUKEMIA | LEUKEMIA | AML LEUKEMIA | AML LEUKEMIA | LEUKEMIA |

The War That Followed Us Home

WWW.BURNPITS360.ORG

These are the faces of America's fallen heroes who lost the battle to toxic wounds of war after serving in the post 9/11 wars. Every one of these warriors died as a result of an instrumentality of war and each one leaves behind a legacy of heroism and honor. Their families are their voices and we will stand in solidarity alongside their families. Our mission is to bring awareness and accountability so that war heroes suffering from these invisible wounds of war will be granted specialized health care, benefits and compensation. No longer will any service member, veteran, or their families be ignored to feel they are alone in this fight. We will fight to protect those still undiagnosed, suffering and those who earned the right not to be forgotten.





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I want my kids to know the
value of friendship... the
value of hard work... the
value of doing something
meaningful... the importance
of family... courage and
determination... steadfast
morals



PREPARED STATEMENT OF JONATHAN M. SAMET, MD, MS, DEAN AND PROFESSOR,
 COLORADO SCHOOL OF PUBLIC HEALTH, AURORA, CO

BACKGROUND

I write to provide comments for the September 25, 2019 Senate Veterans' Affairs Committee Hearing titled, "Toxic Exposure: Examining the VA's Presumptive Disability Decision-Making Process." I presently hold the position of Dean and Professor at the Colorado School of Public Health. These comments are written based on my perspective from serving as Chair of the Institute of Medicine's (IOM) 2008 report: "Improving the Presumptive Disability Decision-Making Process for Veterans." I have included two summaries from that report with my testimony: a general summary written for the public and the report's Executive Summary and the full report can be found at the following link (<https://doi.org/10.17226/11908>).

Presumptions are made to cover gaps in information; as documented in the IOM report, presumptions have long been necessary in providing benefits to veterans, e.g., presumed exposure to Agent Orange during the Vietnam conflict based on time period, activities, and location of service. In 2004, Congress established the Veterans' Disability Benefits Commission (the Commission), which was charged with "studying the benefits provided to compensate and assist veterans for disabilities attributable to military service." The Commission identified the presumptive disability decisionmaking process (PDDM) as a topic needing assessment and asked the IOM to establish a committee for this purpose that would be funded by the Veterans Administration (VA). The resulting committee, the Committee on Evaluation of the Presumptive Disability Decision-Making Process for Veterans (the Committee), was given the charge below:

- Describe and evaluate the current model used to recognize diseases that are subject to service connection on a presumptive basis.
- If appropriate, propose a scientific framework that would justify recognizing or not recognizing conditions as presumptive.

To meet this charge, the IOM assembled an appropriately multidisciplinary 14-member committee that included subject matter experts, statisticians, epidemiologists, toxicologists, clinicians, exposure scientists, and policy experts. Committee members also held knowledge of the Department of Defense (DOD) and VA's approach to disability compensation. The Committee's approach was multifaceted: collection of information through open meetings involving the VA, DOD, Veterans groups and others; the completion of 10 case-studies related to PDDM to gather "lessons learned" to guide the development of the Committee's recommendations; committee deliberations on evidence, causation, and decisionmaking; and the elaboration of the Committee's recommended approach. The resulting report was 372 pages in length with over 400 pages of supporting materials including the case studies.

FINDINGS

Here, I focus on some of the key findings that provided the basis for the Committee's recommended approach. With regard to the first element of the charge, the Committee characterized the current approach through its 10 case studies, input from the VA and particularly responses to questions from the Committee, and review of other materials. In spite of its efforts, the Committee could not fully assess all aspects of the extant approach, in part because VA would not reveal all aspects of its pre-decisional processes. This lack of transparency on the part of the VA clouded understanding of the current model.

Nonetheless, the Committee did offer a diagram representing its understanding of the approach followed by VA (see Figure S-1). The diagram captures the key actors (Congress, VA, and the IOM through its role with Agent Orange and other exposures) and stakeholders. The paths for stakeholder input are not specifically defined and various channels are used. Most importantly, the Committee was unable to fully characterize the principles underlying decisionmaking by the VA with regard to presumptions (i.e., the right side of Figure S-1).

In the Committee's proposed model, the ambiguities of Figure S-1, reflecting the current approach, are replaced by a fully specified and evidence-based process (captured in Figure S-2). Quoting the IOM report, "The Committee's recommended approach for the future (Figure S-2) has multiple new elements: a process for proposing exposures and illnesses for review; a systematic evidence review process incorporating a new evidence classification scheme and quantification of the extent of disease attributable to an exposure; a transparent decisionmaking process by VA; and an organizational structure to support the process. The Committee also calls for

comprehensive tracking of exposures of military personnel and monitoring of their health while in service and subsequently.”

The Committee also offered six principles as foundational to its model: (1) stakeholder inclusiveness; (2) evidence-based decisions; (3) transparent process; (4) flexibility; (5) consistency; and (6) using causation, not just association, as the basis for decisionmaking. These principles addressed limitations of the existing approach and were seen as critical to remedying its lack of transparency. In particular, the Committee offered a schema for classifying the strength of evidence for causation that would provide a consistent basis for making causal judgments.

The Committee also proposed two new and permanent entities: the Advisory Committee, serving in an advisory capacity to the VA and the Science Review Board, independent of VA. Quoting the report: “The Advisory Committee would consider the exposures and illnesses that might be a basis for presumptions and recommend to the VA Secretary exposures and illnesses needing further consideration. It would also consider research needs and assist VA with strategic research planning. The Science Review Board would evaluate the evidence for causation and, if warranted, estimate the service-attributable fraction of disease in veterans. One critical element in the deliberations of the Science Review Board would be evidence from monitoring the exposures and health of the veterans.” The Committee saw the potential for carrying out health surveillance of veterans in relation to their exposure history.

GENERAL COMMITTEE RECOMMENDATIONS

Quoting the report: “Based on its evaluation of the current process for establishing presumptive disability decisions and its consideration of alternatives, the Committee has specific recommendations for an approach that would build stronger scientific evidence into the decisionmaking process and, at the same time, be even more responsive and open to veterans. We propose a transformation of the current presumptive disability decisionmaking process. We recognize that considerable time would be needed to implement some of these recommendations as would additional investment to create systems needed to track exposures and health status of currently serving military service personnel and veterans. Progress depends on greater research capacity and improvements in the evaluation and utilization of scientific evidence in making compensation decisions. We find that there are elements of the current process that could be changed quickly and we recommend that VA consider prompt action as it moves toward implementation of a new approach.” The specific recommendations are appended to this testimony, organized by the body to which they are directed.

FINAL COMMENTS

Subsequent to its release, the report of the Committee on Evaluation of the Presumptive Disability Decision-Making Process for Veterans received little attention. While this lack of attention might reflect the institutional and political context of the time and an unwillingness to consider a needed overhaul of compensation for veterans, the conceptual flaws and inconsistencies of the extant system merited consideration and still do. In calling for an evidence-based and transparent replacement to the opaque and not well documented processes of the VA, the Committee did offer an alternative approach. The principles underlying that approach should be the starting point for a transition away from making presumptions to cover evidence gaps that can be filled.

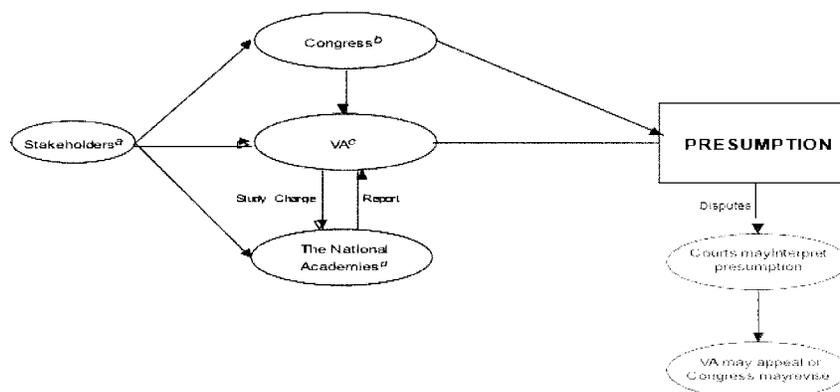


FIGURE S-1 Roles of the participants involved in the presumptive disability decisionmaking process for veterans.

(a) Stakeholders include (but are not limited to) veterans service organizations (VSOs), veterans, advisory groups, Federal agencies, and the general public; these stakeholders provide input into the presumptive process by communicating with Congress, VA, and independent organizations (e.g., the National Academies).

(b) Congress has created many presumptions itself; in 1921, Congress also empowered the VA Secretary to create regulatory presumptions; on several occasions in the past, Congress has directed VA to contract with an independent organization (e.g., the National Academies) to conduct studies and then use the organization's report in its deliberations of granting or not granting regulatory presumptions.

(c) VA can establish regulatory presumptions; VA sometimes contracts with the National Academies to conduct studies and uses the organization's report in its deliberations of granting or not granting regulatory presumptions.

(d) The National Academies (Institute of Medicine and National Research Council) submit reports to VA based on requests and study charges from VA.

Source: Institute of Medicine 2008. *Improving the Presumptive Disability Decision-Making Process for Veterans*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/11908>.

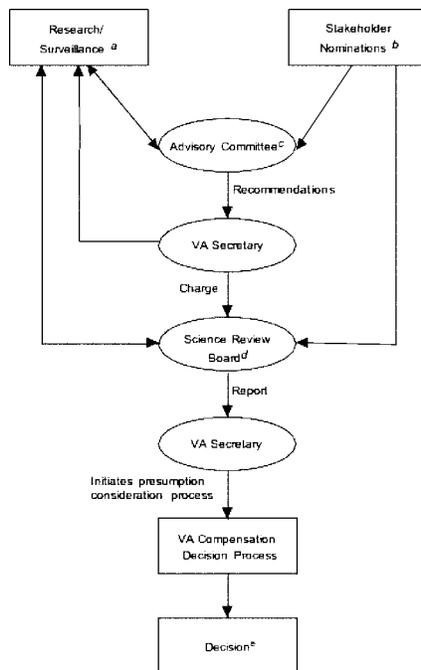


FIGURE S-2 Proposed framework for future presumptive disability decisionmaking process for veterans.

- (a) Includes research for classified or secret activities, exposures, etc.
 (b) Includes veterans, Veterans Service Organizations, Federal agencies, scientists, general public, etc.
 (c) This Committee screens stakeholders' proposals and research in support of evaluating evidence for presumptions and makes recommendations to the VA Secretary when full evidence review or additional research is appropriate.
 (d) The board conducts a two-step evidence review process (see report text for further detail).
 (e) Final presumptive disability compensation decisions are made by the Secretary, Department of Veterans Affairs, unless legislated by Congress.

Source: Institute of Medicine 2008. *Improving the Presumptive Disability Decision-Making Process for Veterans*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/11908>.

SPECIFIC RECOMMENDATIONS

Congress

Recommendation 1. Congress should create a formal advisory committee (Advisory Committee) to VA to consider and advise the VA Secretary on disability-related questions requiring scientific research and review to assist in the consideration of possible presumptions.

Recommendation 2. Congress should authorize a permanent independent review body (Science Review Board) operating with a well-defined process that will use evaluation criteria as outlined in this Committee's recommendations to evaluate scientific evidence for VA's use in considering future service-connected presumptions.

Department of Veterans Affairs

Recommendation 3. VA should develop and publish a formal process for consideration of disability presumptions that is uniform and transparent and clearly sets forth all evidence considered and the reasons for the decisions reached.

Science Review Board

The recommendations that follow are directed toward the proposed, future Science Review Board, the entity to be established in the Committee's proposed approach.

Recommendation 4. The Committee recommends that the goal of the presumptive disability decisionmaking process be to ensure compensation for veterans whose diseases are caused by military service and that this goal must serve as the foundation for the work of the Science Review Board. The Committee recommends that the Science Review Board implement its proposed two-step process.

Recommendation 5. The Committee recommends that the Science Review Board use the proposed four-level classification scheme, as follows, in the first step of its evaluation. The Committee recommends that a standard be adopted for “causal effect” such that if there is at least as much evidence in favor of the exposure having a causal effect on the frequency or severity of disease as there is evidence against, then a service-connected presumption will be considered.

1. *Sufficient:* The evidence is sufficient to conclude that a causal relationship exists.

2. *Equipose and Above:* The evidence is sufficient to conclude that a causal relationship is at least as likely as not, but not sufficient to conclude that a causal relationship exists.

3. *Below Equipose:* The evidence is not sufficient to conclude that a causal relationship is at least as likely as not, or is not sufficient to make a scientifically informed judgment.

4. *Against:* The evidence suggests the lack of a causal relationship.

Recommendation 6. The Committee recommends that a broad spectrum of evidence, including epidemiologic, animal, and mechanistic data, be considered when evaluating causation.

Recommendation 7. When the causal evidence is at Equipose and Above or Sufficient, the Committee recommends that an estimate also be made of the size of the causal effect among those exposed.

Recommendation 8. The Committee recommends that, as the second part of the two-step evaluation, the relative risk and exposure prevalence be used to estimate an attributable fraction for the disease in the military setting (i.e., service-attributable fraction).

Department of Defense and Department of Veterans Affairs

The following recommendations are intended to improve the evidence on exposures and health status of veterans:

Recommendation 9. Inventory research related to the health of veterans, including research funded by DOD and VA, and research funded by the National Institutes of Health and other organizations.

Recommendation 10. Develop a strategic plan for research on the health of veterans, particularly those returning from conflicts in the Gulf and Afghanistan.

Recommendation 11. Develop a plan for augmenting research capability within DOD and VA to more systematically generate evidence on the health of veterans.

Recommendation 12. Assess the potential for enhancing research through record linkage using DOD and VA administrative and health record databases.

Recommendation 13. Conduct a critical evaluation of Gulf War troop tracking and environmental exposure monitoring data so that improvements can be made in this key DOD strategy for characterizing exposures during deployment.

Recommendation 14. Establish registries of Servicemembers and veterans based on exposure, deployment, and disease histories.

Recommendation 15. Develop a plan for an overall integrated surveillance strategy for the health of Servicemembers and veterans.

Recommendation 16. Improve the data linkage between the electronic health record data systems used by DOD and VA—including capabilities for handling individual Servicemember exposure information that is included as part of the individual’s health record.

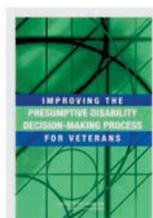
Recommendation 17. Ensure implementation of the DOD strategy for improved exposure assessment and exposure data collection.

Recommendation 18. Develop a data interface that allows VA to access the electronic exposure data systems used by DOD.

Recommendation 19. DOD and VA should establish and implement mechanisms to identify, monitor, track, and medically treat individuals involved in research and other activities that have been classified and are secret.

ATTACHMENTS: A GENERAL SUMMARY (WRITTEN FOR THE PUBLIC) AND
THE REPORT'S EXECUTIVE SUMMARYThe National
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This PDF is available at <http://nap.edu/11908>SHARE    Improving the Presumptive Disability Decision-Making Process
for Veterans (2008)

DETAILS

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GENERAL SUMMARY

The United States has long recognized and honored the service and sacrifices of its military and veterans. Veterans who have been injured by their service (whether their injury appears during service or afterwards) are owed appropriate health care and disability compensation. For some medical conditions that develop after military service, the scientific information needed to connect the health conditions to the circumstances of service may be incomplete. When information is incomplete, Congress or the Department of Veterans Affairs (VA) may need to make a “presumption” of service connection so that a group of veterans can be appropriately compensated. The missing information may be about the specific exposures of the veterans, or there may be incomplete scientific evidence as to whether an exposure during serv-

ice causes the health condition of concern. For example, when the exposures of military personnel in Vietnam to Agent Orange could not be clearly documented, a presumption was established that all those who set foot on Vietnam soil were exposed to Agent Orange.

The Institute of Medicine (IOM) Committee was charged with reviewing and describing how presumptions have been made in the past and, if needed, to make recommendations for an improved scientific framework that could be used in the future for determining if a presumption should be made. The Committee was asked to consider and describe the processes of all participants in the current presumptive disability decisionmaking process for veterans. The Committee was not asked to offer an opinion about past presumptive decisions or to suggest specific future presumptions. The Committee heard from a range of groups that figure into this decisionmaking process, including past and present staffers from Congress, the VA, the IOM, veterans service organizations, and individual veterans. The Department of Defense (DOD) briefed the Committee about its current activities and plans to better track the exposures and health conditions of military personnel. The Committee further documented the current process by developing case studies around exposures and health conditions for which presumptions had been made. The Committee also reviewed general methods by which scientists, as well as government and other organizations, evaluate scientific evidence in order to determine if a specific exposure causes a health condition.

The history of presumptions is a fascinating and complex story. In 1921 Congress empowered the VA Administrator (now Secretary) to establish presumptions of service connection for veterans. Only Congress and VA have the authority to establish presumptions for veterans. Since 1921, nearly 150 health outcomes have been service-connected on a presumptive basis by Congress and VA. This process has evolved over the years. The current process for making presumptions can be traced to the Agent Orange Act of 1991 (Public Law 102-4, 102d Cong., 2d Sess.), an act that established a model for decisionmaking by VA that still stands today. In the 1991 Act, Congress asked VA to contract with an independent organization to review the scientific evidence on Agent Orange. VA turned to the IOM of the National Academy of Sciences to carry out these reviews. Subsequently, VA turned to IOM for issues arising from the 1990 Gulf War. Based on the work of a committee, IOM provides VA with reports that describe the strength of evidence that links agents of concern with specific health conditions. VA uses IOM reports and other information in an internal decision-making process to decide whether a presumption will be made.

The Committee carefully studied the current approach to presumptive disability decisionmaking and examined a number of specific case examples. This assessment led to a number of recommendations to improve the process:

- As the case studies demonstrated, Congress could provide a clearer and more consistent charge on how much evidence is needed to make a presumption. There should be clarity as to whether the finding of an association in one or more studies is sufficient or the evidence should support causation.
- Due to lack of clarity and consistency in congressional language and VA's charges to the Committees, IOM committees have taken somewhat varying approaches since 1991 in reviewing the scientific evidence and in forming their opinions on the possibility that exposures during military service contributed to causing a health condition. Future committees could improve their review and classification of scientific evidence if they were given clear and consistent charges and followed uniform evaluation procedures.
- The internal processes by which the VA makes its presumptive decisions following receipt of an IOM report have been unclear. VA should adopt transparent and consistent approaches for making these decisions.
- Complete exposure data and health condition information for military personnel (both individuals and groups) usually have not been available from DOD in the past. Such information is one of the most critical pieces of evidence for improving the determination of links between exposures and health conditions.

All of these improvements are feasible over the longer term and are needed to ensure that the presumptive disability decisionmaking process for veterans is based on the best possible scientific evidence. Decisions about disability compensation and related benefits (e.g., medical care) for veterans should be based on the best possible documentation and evidence of their military exposures as well as on the best possible information on any health conditions caused by these exposures. While it is impossible to provide certainty in every case, a fresh approach could do much to improve the current process. The Committee's recommended approach (Figure GS-1) has several parts:

- An open process for nominating exposures and health conditions for review; involving all stakeholders in this process is critical
- A revised process for evaluating scientific information on whether a given exposure causes a health condition in veterans; this includes a new set of categories to assess the strength of the evidence for causation, and an estimate of the numbers of exposed veterans whose health condition can be attributed to their military exposure
- A consistent and transparent decisionmaking process by VA
- A system for tracking the exposures of military personnel (including chemical, biological, infectious, physical, and psychological stressors), and for monitoring the health conditions of all military personnel while in service and after separation
- An organizational structure to support this process

To support the Committee's recommendations, we suggest the creation of two panels. One is an Advisory Committee (advisory to VA), that would assemble, consider, and give priority to the exposures and health conditions proposed for possible presumptive evaluation. Nominations for presumptions could come from veterans and other stakeholders as well as from health tracking, surveillance, and research. The second panel would be a Science Review Board, an independent body, which would evaluate the strength of the evidence (based on causation) that links a health condition to a military exposure and then estimates the fraction of exposed veterans whose health condition could be attributed to their military exposure. The Science Review Board's report and recommendations would go to VA for its consideration. VA would use explicit criteria to render a decision by the VA Secretary with regard to whether a presumption would be established. In addition, the Science Review Board would monitor information on the health of veterans as it accumulates over time in the DOD and VA tracking systems, and nominate new exposures or health conditions for evaluation as appropriate.

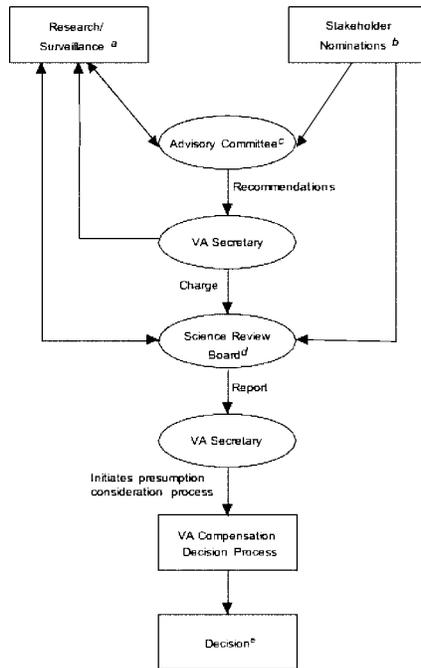


FIGURE GS-1 Proposed framework for future presumptive disability decisionmaking process for veterans.

(a) Includes research for classified or secret activities, exposures, etc.
 (b) Includes veterans, Veterans Service Organizations, Federal agencies, scientists, general public, etc.

(c) This Committee screens stakeholders' proposals and research in support of evaluating evidence for presumptions and makes recommendations to the VA Secretary when full evidence review or additional research is appropriate.

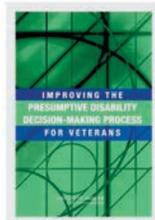
(d) The board conducts a two-step evidence review process (see report text for further detail).

(e) Final presumptive disability compensation decisions are made by the Secretary, Department of Veterans Affairs, unless legislated by Congress.

This Committee recommends that the following principles be adopted in establishing this new approach:

1. Stakeholder inclusiveness
2. Evidence-based decisions
3. Transparent process
4. Flexibility
5. Consistency
6. Causation, not just association, as the target for decisionmaking

The Committee suggests that its framework be considered as the model to guide the evolution of the current approach. While some aspects of the approach may appear challenging or infeasible at present, feasibility would be improved with the full implementation of the Committee's recommendations, provision of appropriate resources to all of the participants in the presumptive disability decisionmaking process for veterans, and future methodological developments. DOD and VA have already been discussing various aspects of improving exposure and health tracking and how the two agencies can share data and information with each other. Veterans deserve to have these improvements accomplished as soon as possible.

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DETAILS

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SUMMARY

INTRODUCTION

The United States has long recognized and honored military veterans' service and sacrifices. Veterans injured by their service, becoming ill while in service, or having an illness after discharge as a long-term consequence of their service have been given healthcare coverage and disability compensation. As the complexity of exposures during combat has increased, the list of service-connected illnesses has grown. The Department of Veterans Affairs (VA) now provides disability compensation to approximately 2.6 million veterans for 7.7 million disabilities annually, expending approximately \$24 billion for this purpose (VBA, 2006, pp. 19, 24, 27).

Disability compensation for military veterans requires that there be a service connection. A medical illness or injury that occurred while a member was in military service is considered service-connected whether caused by or aggravated by an expo-

sure or event during service or simply occurring coincidentally with military service. However, if a medical condition appears after the period of military service and it is presumed to be caused by or aggravated by an exposure or an event that occurred during military service, then veterans may receive compensation based on that presumption (Pamperin, 2006).

In making a decision to provide compensation, VA needs to determine whether the illness of concern can generally be caused by exposures received during service and whether the illness in a specific claimant was caused by the exposure. The answer to the general question of causality comes from a careful review of all available scientific information, while the answer to the question of causation in a specific person hinges on knowledge of the exposure received by that individual and of other factors that may be relevant. If the scientific evidence is incomplete, there may be uncertainty on the question of causation generally; if there is limited or no information on exposure of individual claimants or if other factors also contribute to disease causation, there may be uncertainty on the question of individual causation.

To provide benefits to veterans in the face of these two broad types of uncertainty, Congress and VA make presumptive decisions that bridge gaps in the evidence related to causation and to exposure. Presumptions may relieve the veteran of persuading VA that the exposure produced the adverse health outcome and of proving that an exposure occurred during military service (Pamperin, 2006). Once a medical condition is service-connected through presumptions, and the veteran can document military service consistent with having received the given exposure, the veteran only has to show the basic fact that he or she suffers from the condition in order to receive a disability payment and eligibility for medical care (Zeglin, 2006).

In 2004, Congress established the Veterans' Disability Benefits Commission (the Commission), which was charged with "studying the benefits provided to compensate and assist veterans for disabilities attributable to military service" (VDBC, 2006, p. 1; as found in Appendix A). The Commission identified the presumptive disability decisionmaking process as a topic needing assessment and asked the Institute of Medicine (IOM) to establish a committee for this purpose that would be funded by VA. The resulting committee, the Committee on Evaluation of the Presumptive Disability Decision-Making Process for Veterans (the Committee), was given the following charge by VA:

- Describe and evaluate the current model used to recognize diseases that are subject to service connection on a presumptive basis.
- If appropriate, propose a scientific framework that would justify recognizing or not recognizing conditions as presumptive.

The Commission further elaborated the charge, asking the Committee to "help ensure that future veterans are granted service connection under a presumptive basis based on the best scientific evidence available" (VDBC, 2006, p. 4; as found in Appendix A). The Commission asked the Committee to "evaluate the current model used to determine diseases that qualify for service connection on a presumptive basis, and if appropriate, propose improvements in the model" (VDBC, 2006, p. 1; as found in Appendix A). The Commission emphasized that "having a method of granting service connection quickly and fairly based on a presumption is of critical importance to our disabled veterans and their surviving spouses" and that "ensuring that future presumption processes reflect the then current medical knowledge about the causal relationship would benefit the entire veteran community" (VDBC, 2006, p. 4; as found in Appendix A). The Commission's summary statement further commented that "[t]o the extent possible, suggestions that will avoid the necessity for many future presumptions by ensuring that exposure of servicemembers is documented and scientific evidence is made available would be important" (VDBC, 2006, p. 4; as found in Appendix A).

IOM appointed a 14-member committee that covered the broad scientific and medical areas of general, occupational, and psychiatric medicine; biostatistics; epidemiology; toxicology; industrial hygiene; and exposure and risk assessment. The Committee's members also brought expertise in law, philosophy, causal decisionmaking, and policy as well as knowledge of the Department of Defense (DOD) and VA's approach to disability compensation.

THE COMMITTEE'S APPROACH TO ITS CHARGE

In fulfilling its charge, the Committee first investigated and attempted to characterize Congress' and VA's recent approach to presumptive disability decisionmaking, and then developed a conceptual framework for a new, more evidence-based process. It then constructed a way to move forward that builds on the framework and addresses deficiencies of the current process.

The Committee held three open meetings to gather information on the current presumptive disability decisionmaking process. The Committee heard from past and present congressional staff members, representatives of VA, DOD, IOM, various stakeholder groups (e.g., veteran service organizations [VSOs]) and the general public. Committee members also participated in conference calls with DOD experts on medical surveillance and exposure data collection and exposure assessment systems.

The Committee reviewed extensive background information including: documents provided by the Commission, public laws and supporting House and Senate reports, *Federal Register* notices, VA documents (e.g., cost estimates, a white paper on VA's decisionmaking processes [found in Appendix G]), and responses by VA to written questions from the Committee), DOD documents, and past IOM reports commissioned by DOD and VA. The Committee conducted 10 case study reviews—Mental Disorders' Presumptions, Multiple Sclerosis Presumption, Prisoners of War Presumptions, Amputees and Cardiovascular Disease Presumption, Radiation Presumptions, Mustard Gas and Lewisite Presumptions, Gulf War Presumptions, Agent Orange and Prostate Cancer Presumption, Agent Orange and Type 2 Diabetes Presumption, and Spina Bifida Program (not a presumption but a VA program area)—that cover a wide variety of circumstances for which presumptions have been established by Congress and VA since 1921. The case studies were a foundation for the Committee's efforts in understanding past practices of all participants in the presumptive disability decisionmaking process (see Appendix I).

The Committee also researched and considered capabilities and limitations of the exposure data and health outcome information available to DOD and VA for exposure assessment, surveillance, and research purposes. The Committee examined whether DOD and VA have a strategic research plan and vision for the necessary interface between the agencies, as well as with other, relevant research organizations.

The Committee considered the use of scientific evidence in guiding the process for making presumptive decisions that affect the compensation of veterans. Drawing upon the Committee members' expertise in epidemiology, medicine, toxicology, biostatistics, and causal decisionmaking, the Committee covered the evaluation of evidence for inferring association and causation as well as methods for quantifying the contribution of an agent to disease causation in populations and extending this quantification to individuals. Using this framework, the Committee developed an evidence-based approach for making future decisions with regard to presumptions.

THE PRESUMPTIVE DISABILITY DECISION-MAKING PROCESS FOR VETERANS

In 1921 Congress empowered the VA Administrator (now Secretary) to establish presumptions of service connection for veterans. Only Congress and the VA Secretary have the authority to establish presumptions. Over time, presumptions have been made to relieve veterans of the burden to prove that disability or illness was caused by a specific exposure that occurred during military service (e.g., Prisoners of War). Since 1921, nearly 150 health outcomes have been service-connected on a presumptive basis (see Appendix F). In February 2006, Congress codified all regulatory presumptions that VA had put in place to that time.

The current presumptive disability decisionmaking process for veterans involves several steps and several organizations. The process involves input from many parties—Congress, VA, the National Academies, and stakeholders (e.g., VSOs, advisory committees, and individual veterans) (Figure S-1). Congress has made presumptions itself. In the current model, Congress or stakeholders acting through Congress may call on VA to assess whether a presumption is needed. The VA turns to IOM for completion of a review of the scientific evidence. The findings of that evaluation are considered by VA in its presumptive disability decisionmaking process. Decisions made in the courts have also influenced the current presumptive process.

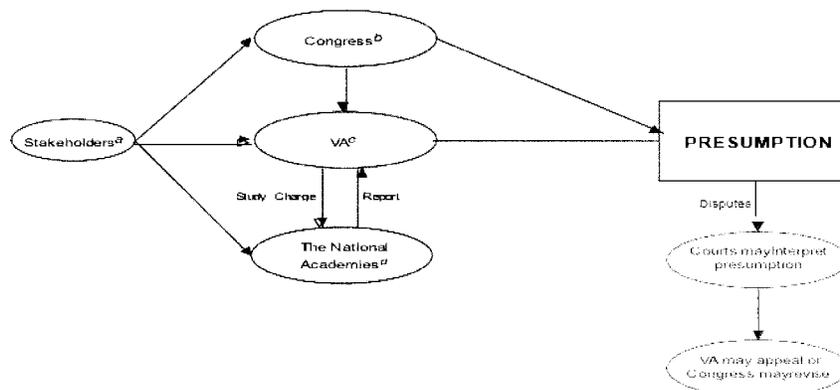


FIGURE S-1 Roles of the participants involved in the presumptive disability decisionmaking process for veterans.

(a) Stakeholders include (but are not limited to) veterans service organizations (VSOs), veterans, advisory groups, Federal agencies, and the general public; these stakeholders provide input into the presumptive process by communicating with Congress, VA, and independent organizations (e.g., the National Academies).

(b) Congress has created many presumptions itself; in 1921, Congress also empowered the VA Secretary to create regulatory presumptions; on several occasions in the past, Congress has directed VA to contract with an independent organization (e.g., the National Academies) to conduct studies and then use the organization's report in its deliberations of granting or not granting regulatory presumptions.

(c) VA can establish regulatory presumptions; VA sometimes contracts with the National Academies to conduct studies and uses the organization's report in its deliberations of granting or not granting regulatory presumptions.

(d) The National Academies (Institute of Medicine and National Research Council) submit reports to VA based on requests and study charges from VA.

Three major legislative actions by Congress have influenced the recent presumptive decisions—the Radiation Exposed Veterans Compensation Act of 1988 (Public Law 100-321, 100th Cong., 2d Sess.), the Agent Orange Act of 1991 (Public Law 102-4, 102d Cong., 1st Sess.), and the Persian Gulf War Acts of 1995 (Veterans' Benefits Improvement Act of 1994, Public Law 103-446, 103d Cong., 2d Sess.) and 1998 (Making Omnibus Consolidated and Emergency Appropriations for the Fiscal Year Ending September 30, 1999, and for Other Purposes, Public Law 105-277, 105th Cong., 2d Sess.). The concept of "at least as likely as not" with regard to exposure potential was introduced for radiation exposures and its use has since been continued. The Agent Orange Act (Public Law 102-4, 102d Cong., 1st Sess.) grew out of events following the Vietnam War, and its language expresses substantial and significant elements of the presumptive story. The presumptions put in place by Congress for Gulf War illnesses represent the first time that Congress produced a list of health outcomes that it defined as "undiagnosed illnesses" (Veterans Education and Benefits Expansion Act of 2001, Public Law 107-103, 107th Cong., 1st Sess.).

When Congress enacted the Agent Orange Act of 1991 (Public Law 102-4, 102d Cong., 1st Sess.), it started a model for a decisionmaking process that is still in place. Congress asked VA to contract with an independent organization—VA contracted with IOM—to review the scientific evidence for Agent Orange. Since 1994, IOM has produced biennial reports on Agent Orange for VA to use as it considers making presumptive decisions (IOM, 1994, 1996, 1999, 2001, 2003b, 2005b). IOM has also delivered five volumes on the Gulf War (IOM, 2000a, 2003a, 2005a, 2006, 2007). Congress requires VA to respond after receiving an IOM report with a determination as to whether VA will make a service connection for particular health outcomes on a presumptive basis. VA has described its internal decisionmaking processes to the Committee in a general fashion, and the Committee has reviewed VA's *Federal Register* notices and documents (see Chapter 3). However, it remains unclear to the Committee how VA makes particular determinations with regard to weighing strength of evidence for causation and exposure potential in making its presumptive decisions.

Analysis of the Agent Orange and Gulf War case studies (see Appendix I) shows important similarities and differences relevant to the over-all presumptive process. One difference is that Agent Orange is a single product (actually a mixture of compounds that contains the contaminant dioxin), extensively researched for associated health outcomes, whereas the health consequences of the Gulf War are unlikely to be the result of any single agent. Military service men and women may have received a number of health-relevant exposures during service in the Persian Gulf, complicating the development of evidence reviews. For Agent Orange, there is one exposure of concern and a more constrained set of health indicators. There have been some differences in approaches of Agent Orange and Gulf War committees. The IOM Agent Orange reports (IOM, 1994, 1996, 1999, 2001, 2003b, 2005b) did not explicitly include a causal category in their evaluations whereas recent Gulf War reports (IOM, 2000a, 2003a, 2005a, 2006, 2007) did include a category for evidence sufficient to infer causation when characterizing the strength of evidence for agents evaluated. For neither set of reports does VA describe in its *Federal Register* notices how it accounted for exposure potential or magnitude in making its presumptive decisions.

FINDINGS OF CASE STUDIES

The case studies offered a diverse set of lessons learned and indicated elements of the current process that need to be addressed. In carrying out the case studies, this Committee had the opportunity to retrospectively examine the work of IOM committees as they grappled with the challenge of using uncertain evidence and of VA staff as they used the findings of IOM committees to make decisions about presumptions. The case studies demonstrate that the process has acted to serve the interests of veterans in many instances. Congress and VA have repeatedly acted to maximize the sensitivity of presumptive decisions so as to assure that no veteran who might have been affected is denied compensation. On the other hand, in maximizing sensitivity of presumptive disability decisionmaking, substantial numbers of veterans whose illnesses may or may not have been actually service related are nonetheless compensated. There are both financial and nonfinancial costs to such decisions.

The case studies illustrate the use of presumptions to cover gaps in evidence, gaps that exist in part because of lack of information on exposures received by military personnel and inadequate surveillance of veterans for service-related illnesses. Secrecy is a particularly troubling source of incomplete information, as illustrated by the veterans who participated in studies of mustard gas and lewisite. Research carried out directly on the health of veterans has proved useful in some instances, leading to a decision, for example, on granting disability compensation for cardiovascular disease in amputees. But the research has not been systematic, and in the example of cardiovascular disease in amputees no further evidence relevant to a presumption made in 1979 has been collected. Research on radiation risks in veterans has been severely constrained by a lack of dose information, and the studies on radiation-exposed veterans have not been highly informative.

Across the case studies, the Committee found variable approaches to synthesizing evidence on the health consequences of military service. The inferential target of scientific evidence reviews has not been consistent and varied between causation (e.g., mustard gas and lewisite, Gulf War) and association alone (e.g., Agent Orange). The more recent IOM Agent Orange reports have emphasized findings of observational studies on association and interpretation that might have been enhanced by placing the findings within a biological framework strengthened by greater attention to other lines of evidence. In the Agent Orange case studies, the category “limited/suggestive” for classifying evidence for association has been used for a broad range of evidence from indicating the mere possibility of an association to showing that an association is possibly causal. The “limited/suggestive” evidence of association—on which the VA’s presumptive decisions to compensate type 2 diabetes and prostate cancer were made—may be below the level of certainty needed to support causation absent strong mechanistic understanding or to meet the congressional language of “if the credible evidence for the association is equal to or outweighs the credible evidence against the association,” which the Committee refers to “at least as likely as not.”

Both prostate cancer and type 2 diabetes illustrate situations in which the contribution of military exposures should be assessed against a background of disease risk that has other strong determinants: age in the case of prostate cancer and family history and obesity in the case of type 2 diabetes, as indicated by the IOM committee in its report (IOM, 2000b). For both type 2 diabetes and prostate cancer, the magnitude of the relative risks observed for pesticide exposure implies that the con-

tribution of military exposures is likely to be small in comparison to those of the other contributing factors. In such circumstances, an estimation of the proportion of cases attributable to military exposures could be helpful to the VA in considering whether or not to presumptively service-connect disabilities. The Committee recognizes that development of such estimations is a complicated process dependent on acquiring better exposure data, which may not be available for some period of time.

In the case studies, the Committee's analyses were based on the very general information provided by VA about its internal decisionmaking processes. The case studies and VA's decision to withhold documents related to specific decisions from the Committee did make clear, however, that these processes are not fully transparent. VA believes that access to predecisional documents by outside sources could stifle candid staff discussions on issues. Once IOM carries out its reviews and provides VA with reports documenting the extent of evidence available on associations, the internal processes of VA that follow are not fully open to scrutiny. This closed process could reduce trust of veterans in the presumptive disability decisionmaking process and may hinder efforts to optimize the use of scientific evidence. The Committee also found inconsistency in the decisionmaking process.

SCIENTIFIC FOUNDATION FOR PRESUMPTIVE DISABILITY DECISION MAKING

In developing a future approach for presumptive disability decisionmaking, the Committee first gave extensive consideration to causal inference and the processes used to make causal judgments. In other words, the Committee considered how scientific evidence is used to determine if exposure causes some disease. These determinations are generally made by expert committees that examine all relevant evidence for strengths and weaknesses and then synthesize the evidence to make a summary judgment. The Committee defines "exposure" in a broad manner to include chemical, biological, infectious, physical, and psychological stressors. The Committee recognizes that psychological stressors may be particularly difficult to describe, let alone measure and quantify.

The Committee then considered the quantification of the contribution of a particular exposure to disease causation. This second issue addresses the question of how much of the observed disease in a group, in both absolute and relative terms, is caused by the exposure.

Provision of compensation to veterans on a presumptive basis, or to any other group that has been injured, requires a general decision as to whether the agent or exposure of concern has the potential to cause the condition or disease for which compensation is to be provided in at least some individuals, and a specific decision as to whether the agent or exposure has caused the condition or disease in a particular individual. The determination of causation in general is based in a review and evaluation of all relevant evidence including (1) data on exposures of military personnel during service; (2) evidence on risks for disease coming from observational (epidemiologic) studies of military personnel; (3) other relevant epidemiologic evidence, including findings from studies of nonmilitary populations exposed to the agent of interest or similar agents; and (4) findings relevant to plausibility from experimental and laboratory research. The determination of causation in a particular case is based first on the general determination as to whether the exposure can cause disease, then on information about the exposures of the individual being evaluated for compensation, and on any other relevant information about the individual.

The Committee considered the properties of a decisionmaking process, recognizing the possibility of two types of systematic errors: making a decision to compensate when the exposure has not caused the illness (false positive) and to not compensate when the exposure has actually caused the illness (false negative). The Committee recommends that any decision process consider the tradeoff between these two errors and attempt to optimize both the sensitivity (i.e., minimize the false negatives) and the specificity (i.e., minimize the false positives). Generally, higher sensitivity cannot be achieved without lower specificity. These errors have costs. False positive errors result in the expenditure of funds for cases of disease not caused by military service while false negative errors leave deserving veterans uncompensated. The appropriate balancing of these costs also needs consideration.

The Committee considered ways to classify evidence, reaching the conclusion that a broader and more inclusive evidence review process is needed. It found that IOM reviews could be enhanced if a broader array of epidemiologic and other evidence (e.g., animal and mechanistic data) was considered. The Committee also found that the target of inference had varied from causation (e.g., mustard gas and lewisite, Gulf War) to association (e.g., Agent Orange). Consequently, the Committee recommends that categories of evidence for reviews be established to make clear those

relationships that are at least as likely as not to be causal. The Committee has concluded that a categorization of evidence is needed that gives a scientifically coherent rendering of the language employed by Congress in calling for review of available scientific evidence. The Committee proposes a four-level hierarchy that classifies the strength of evidence for causation, not just association, and that incorporates the concept of equipoise: that is, whether the weight of scientific evidence makes causation at least as likely as not in the judgment of the reviewing group.

The Committee also gave consideration to the quantification of the burden of disease attributable to an exposure. This quantification would be made to provide an evaluation of the numbers of veterans to be compensated, but it would not be a component of the evidence evaluation for causation. For the purpose of quantification, the attributable risk, termed the service-attributable fraction, can be calculated if the needed information is available on the relative risk of disease among exposed individuals. For those exposures meeting the necessary level of evidence for compensation, the Committee recommends that the service-attributable fraction should be estimated overall and for subgroups of veterans, perhaps grouped by level of exposure, if the requisite data are available. Until more complete exposure information becomes available in the future, such calculations may not be possible for all conditions for which presumptions are made.

COMMITTEE'S RECOMMENDED APPROACH FOR THE FUTURE

Overview

The Committee's recommended approach for the future (Figure S-2) has multiple new elements: a process for proposing exposures and illnesses for review; a systematic evidence review process incorporating a new evidence classification scheme and quantification of the extent of disease attributable to an exposure; a transparent decisionmaking process by VA; and an organizational structure to support the process. The Committee also calls for comprehensive tracking of exposures of military personnel and monitoring of their health while in service and subsequently.

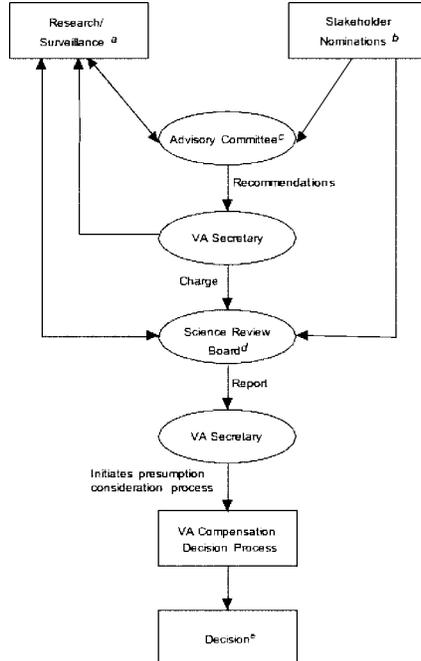


FIGURE S-2 Proposed framework for future presumptive disability decisionmaking process for veterans.

(a) Includes research for classified or secret activities, exposures, etc.

(b) Includes veterans, Veterans Service Organizations, Federal agencies, scientists, general public, etc.

(c) This Committee screens stakeholders' proposals and research in support of evaluating evidence for presumptions and makes recommendations to the VA Secretary when full evidence review or additional research is appropriate.

(d) The board conducts a two-step evidence review process (see report text for further detail).

(e) Final presumptive disability compensation decisions are made by the Secretary, Department of Veterans Affairs, unless legislated by Congress.

Organizational Structure

The Committee recommends the creation by Congress of two new permanent boards: the Advisory Committee, serving in an advisory capacity to VA, and the Science Review Board (independent from VA). The Advisory Committee would consider the exposures and illnesses that might be a basis for presumptions and recommend to the VA Secretary exposures and illnesses needing further consideration. It would also consider research needs and assist VA with strategic research planning. The Science Review Board would evaluate the evidence for causation and, if warranted, estimate the service-attributable fraction of disease in veterans. One critical element in the deliberations of the Science Review Board would be evidence from monitoring the exposures and health of the veterans. The Science Review Board would provide VA with input for its presumptive decisions, including a summary report of the available scientific evidence in a standardized classification scheme.

Congress and VA may find alternative processes to achieve the overall objective of the Committee's recommendations: an evidence-based approach to making presumptive disability decisions. The Committee recognizes that specific elements of its proposal (e.g., the call for carrying out exposure assessments and making exposure estimates) are not yet fully practicable and would take time to develop and implement. However, future methodologic developments should enhance the feasibility of some of the challenging elements of this proposal. The Committee believes that this proposal can significantly improve the presumptive disability decisionmaking process for veterans and, therefore, the process for implementing it should begin without delay.

Underlying Principles

VA's decision to make a presumption may involve weighing difficult and incomplete scientific evidence, in the context of veterans' concerns and society's obligations to the affected veterans, and potential costs. Although the potential complexity of the decisionmaking process may make a complete codification difficult, the underlying principles can be clearly expressed. The Committee suggests the following six principles as a foundation for its proposed framework: (1) stakeholder inclusiveness; (2) evidence-based decisions; (3) transparent process; (4) flexibility; (5) consistency; and (6) using causation, not just association, as the basis for decisionmaking. Flexibility and consistency are not contradictory constructs here. Flexibility refers to the ability to be adaptable through time in evaluating scientific evidence, and consistency refers to being consistent in the process of evaluating evidence and making consistent decisions based on a comparable level of certainty based on the scientific evidence.

Proposals to Review for Potential Presumption

In this process, conditions and causative agents or circumstances would be proposed for review based on evidence of a connection between the condition and military service and evidence that a sizable or well-defined group of veterans is likely to be affected. The possibility of a need for a presumption might arise from surveillance of veterans or active military personnel, laboratory research discoveries, or findings from studies of exposed workers. The process would be open, with proposals accepted from any source (e.g., veterans, veterans' families, VSOs, VA, DOD, other governmental bodies, researchers, the general public). Proposals accepted by the VA Secretary would be sent to the Science Review Board for full, comprehensive scientific evaluation.

Science Review Board

The Committee recommends a two-step process for scientific evaluation by the Science Review Board. The first step would involve a systematic review of all relevant data to decide the strength of evidence for causation, using one of four categories:

1. *Sufficient*: The evidence is sufficient to conclude that a causal relationship exists.

2. *Equipoise and Above*: The evidence is sufficient to conclude that a causal relationship is at least as likely as not, but not sufficient to conclude that a causal relationship exists.

3. *Below Equipoise*: The evidence is not sufficient to conclude that a causal relationship is at least as likely as not, or is not sufficient to make a scientifically informed judgment.

4. *Against*: The evidence suggests the lack of a causal relationship.

If the evidence for causation were categorized as Sufficient or at Equipoise and Above, then we anticipate that VA would consider a presumptive service connection based upon causal evidence categorization and its consideration of the service-attributable fraction if available (to be estimated in the second step of the process, described below). As is current VA policy, if the evidence is at Equipoise, the benefit of the doubt would be given to the veteran. If the evidence were categorized as Against, then we anticipate that VA would not consider a presumptive service-connection. If, however, the evidence were categorized as Below Equipoise, then we anticipate that VA would, after carefully considering the prospects and recommendations for future research, decide on an appropriate timeframe for the subsequent scientific review of the evidence, with the expectation that the evidence would then be sufficient to resolve matters either for or against the causal claim at that time. Such information would be considered by the Advisory Committee serving in its capacity as overseer of the overall process and advisor to the VA Secretary.

If the VA Secretary were to decide that a presumption would not be established for evidence categorized as Below Equipoise or, for other reasons, for evidence categorized as Equipoise and Above, then during the period of further evidence development and gathering and prior to the subsequent scientific review of the evidence, VA should consider providing some support to potentially affected veterans, such as providing provisional access to medical care.

As evidence accumulates, the balance might move to strengthen or to weaken the case for causality. Importantly, the Science Review Board should be free to upgrade the level of evidence, to downgrade the level of evidence, or to leave it as the same categorization. For evidence that has reached the classification of Sufficient, we would not anticipate a potential lowering of the classification, if the original determination was correctly made and based on sound scientific evidence.

If the strength of the evidence reaches Sufficient or Equipoise and Above, then the evaluation would move to step two, the calculation of the service-attributable fraction of disease when required data and information are available. This calculation is independent of the classification of the strength of evidence for causation, and the magnitude of the service-attributable fraction is not considered in the application of the four-level schema for categorizing evidence. Rather, the service-attributable fraction would be of value for decisionmaking, giving an understanding of the scope of the population to be covered by a presumption.

In step two, the Science Review Board would consider the extent of exposure among veterans and subgroups of veterans, as well as dose- response relationships. When such information is available, the board would estimate the service-attributable fraction and its related uncertainty. The purpose of step two is to convey the impact of the exposure on veterans as a whole for the purpose of decisionmaking and planning, but not to serve inappropriately as an estimate of probability of causation for individuals. Some exposures may contribute greatly to the disease burden of veterans, while other exposure (even with a known causal effect) may have a small impact overall. This additional information would be useful to VA in its decisionmaking as to whether a presumption should be made for the veteran population in general, for subgroups, or not at all. In the absence of service-attributable fraction data, as will likely occur for many exposures over the short term, we assume the VA would consider presumptions on the information contained in step one.

Expanding the Evidence Base

In the Committee's view, the best scientific decisions about presumptions can be made only with comprehensive exposure and health surveillance of military personnel. Data collection should begin on entry into the military and continue through discharge, and when harmful exposures are suspected surveillance should be extended indefinitely. Surveillance refers to the ongoing collection, analysis, and use of data relevant to the health of a population. Elements of a surveillance system are already in place, but fall short of what is required. A fully functioning surveillance system would track military exposures and health outcomes, during military service and after discharge, and maintain a repository of data and biological specimens so that emerging and unanticipated questions could be retrospectively addressed. The system needs to be seamless in following military personnel, including

National Guard and reservists, from active duty as they transition and become civilians.

This surveillance system should also track job and deployment history for each Servicemember through the period of service, with exposure assessment and monitoring for a range of job categories. Information on disease risk factors more generally could also be tracked. Use of personal biological samples for individual monitoring also holds promise.

Assessing exposures relevant to the neuropsychiatric disorders that are frequent among veterans of recent and current combats is particularly problematic. Documentation of stress is requisite to the diagnosis of Post Traumatic Stress Disorder (PTSD), but approaches for capturing exposures to such stressors and to the circumstances of combat have not yet been developed and put into place. Research is needed for this purpose that builds on existing approaches so that data become available over the long-term.

In addition to surveillance, the Committee recommends an effort to coordinate and focus research on the health effects of military exposures. Associations identified in the surveillance data might need follow-up through more focused epidemiologic studies or exposure assessments. Toxicological research might be indicated to explore the mechanistic basis for an association between an exposure and a health condition.

VA Procedures

Ultimately, the decision regarding which proposed topics for potential presumptions deserve full evaluation resides with VA. In the Committee's proposed process, VA also receives scientific input from the Science Review Board. We recommend that VA establish a uniform and transparent process for making decisions regarding presumptions following receipt of evidence reviews. VA should establish procedures with input from the many stakeholders, and a clear, evidence-based rationale should be offered for all decisions. The Committee's recommendations are aimed at providing a sound scientific framework for the presumptive disability decisionmaking process. The Committee clearly recognizes that there are social, economic, political, and legal factors beyond the scope of scientific evidence that may influence the presumptive disability decisionmaking process for veterans and the presumptive decisions that are established by Congress and VA.

Scientific evidence is not static, and it often is less than certain. Given that the scientific basis for presumptive decisions will change over time, the Committee recommends that VA should be able to adjust future decisions when such change is scientifically justified. This does not mean that the Committee recommends that benefits previously granted should be terminated. The Committee is aware that disabled veterans and their families are often dependent on such payments and that it could create a hardship to remove them, a matter that VA disability policy recognizes in other situations.

SPECIFIC RECOMMENDATIONS

Based on its evaluation of the current process for establishing presumptive disability decisions and its consideration of alternatives, the Committee has specific recommendations for an approach that would build stronger scientific evidence into the decisionmaking process and, at the same time, be even more responsive and open to veterans. We propose a transformation of the current presumptive disability decisionmaking process. We recognize that considerable time would be needed to implement some of these recommendations as would additional investment to create systems needed to track exposures and health status of currently serving military service personnel and veterans. Progress depends on greater research capacity and improvements in the evaluation and utilization of scientific evidence in making compensation decisions. We find that there are elements of the current process that could be changed quickly and we recommend that VA consider prompt action as it moves toward implementation of a new approach. The recommendations that follow are based around the Committee's proposed framework for making presumptive decisions. We list the recommendations in relation to the appropriate body.

Congress

Recommendation 1. Congress should create a formal advisory committee (Advisory Committee) to VA to consider and advise the VA Secretary on disability-related questions requiring scientific research and review to assist in the consideration of possible presumptions.

Recommendation 2. Congress should authorize a permanent independent review body (Science Review Board) operating with a well-defined process that will use

evaluation criteria as outlined in this Committee's recommendations to evaluate scientific evidence for VA's use in considering future service-connected presumptions.

Department of Veterans Affairs

Recommendation 3. VA should develop and publish a formal process for consideration of disability presumptions that is uniform and transparent and clearly sets forth all evidence considered and the reasons for the decisions reached.

Science Review Board

The recommendations that follow are directed toward the proposed, future Science Review Board, the entity to be established in the Committee's proposed approach.

Recommendation 4. The Committee recommends that the goal of the presumptive disability decisionmaking process be to ensure compensation for veterans whose diseases are caused by military service and that this goal must serve as the foundation for the work of the Science Review Board. The Committee recommends that the Science Review Board implement its proposed two-step process.

Recommendation 5. The Committee recommends that the Science Review Board use the proposed four-level classification scheme, as follows, in the first step of its evaluation. The Committee recommends that a standard be adopted for "causal effect" such that if there is at least as much evidence in favor of the exposure having a causal effect on the frequency or severity of disease as there is evidence against, then a service-connected presumption will be considered.

1. *Sufficient:* The evidence is sufficient to conclude that a causal relationship exists.

2. *Equipose and Above:* The evidence is sufficient to conclude that a causal relationship is at least as likely as not, but not sufficient to conclude that a causal relationship exists.

3. *Below Equipose:* The evidence is not sufficient to conclude that a causal relationship is at least as likely as not, or is not sufficient to make a scientifically informed judgment.

4. *Against:* The evidence suggests the lack of a causal relationship.

Recommendation 6. The Committee recommends that a broad spectrum of evidence, including epidemiologic, animal, and mechanistic data, be considered when evaluating causation.

Recommendation 7. When the causal evidence is at Equipose and Above or Sufficient, the Committee recommends that an estimate also be made of the size of the causal effect among those exposed.

Recommendation 8. The Committee recommends that, as the second part of the two-step evaluation, the relative risk and exposure prevalence be used to estimate an attributable fraction for the disease in the military setting (i.e., service-attributable fraction).

Department of Defense and Department of Veterans Affairs

The following recommendations are intended to improve the evidence on exposures and health status of veterans:

Recommendation 9. Inventory research related to the health of veterans, including research funded by DOD and VA, and research funded by the National Institutes of Health and other organizations.

Recommendation 10. Develop a strategic plan for research on the health of veterans, particularly those returning from conflicts in the Gulf and Afghanistan.

Recommendation 11. Develop a plan for augmenting research capability within DOD and VA to more systematically generate evidence on the health of veterans.

Recommendation 12. Assess the potential for enhancing research through record linkage using DOD and VA administrative and health record databases.

Recommendation 13. Conduct a critical evaluation of Gulf War troop tracking and environmental exposure monitoring data so that improvements can be made in this key DOD strategy for characterizing exposures during deployment.

Recommendation 14. Establish registries of Servicemembers and veterans based on exposure, deployment, and disease histories.

Recommendation 15. Develop a plan for an overall integrated surveillance strategy for the health of Servicemembers and veterans.

Recommendation 16. Improve the data linkage between the electronic health record data systems used by DOD and VA—including capabilities for handling individual Servicemember exposure information that is included as part of the individual's health record.

Recommendation 17. Ensure implementation of the DOD strategy for improved exposure assessment and exposure data collection.

Recommendation 18. Develop a data interface that allows VA to access the electronic exposure data systems used by DOD.

Recommendation 19. DOD and VA should establish and implement mechanisms to identify, monitor, track, and medically treat individuals involved in research and other activities that have been classified and are secret.

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PREPARED STATEMENT OF TOM PORTER, VICE PRESIDENT, GOVERNMENT AFFAIRS,
IRAQ AND AFGHANISTAN VETERANS OF AMERICA

CHAIRMAN ISAKSON, RANKING MEMBER TESTER, AND MEMBERS OF THE COMMITTEE: On behalf of Iraq and Afghanistan Veterans of America (IAVA) and our more than 425,000 members, thank you for the opportunity to share our views, data, and experiences on the matter of burn pits and airborne toxins.

I am submitting this testimony not only as an IAVA advocate, but also as a veteran of Operation Enduring Freedom who was exposed to a variety of airborne toxins from burn pits and other sources. I was deployed to Afghanistan and Kuwait between 2010 and 2011, and was exposed to burn pits and airborne toxins at multiple locations. Prior to that deployment, I had zero breathing problems and completely healthy lungs. In the first couple of weeks after I arrived in Kabul, where the air is particularly bad, my lungs had a severe reaction and became infected. I used medication to control the symptoms over the next year. However, after re-deploying home, I stopped the medication and the symptoms returned. I was subsequently diagnosed with asthma as a result of my deployment.

Exposure to burn pits, which were used by the military to destroy medical and human waste, chemicals, paint, metal/aluminum cans, unexploded ordnance, petroleum and lubricant products, plastics, rubber, wood, and other waste, has been widespread.

Three million American servicemembers have deployed to the conflicts in Iraq and Afghanistan, and we suspect the vast majority may have had some exposure to toxins from burn pits. Exposure was not just limited to those servicemembers who were working at the burn pits. Toxins launched into the air by burn pits could, and did, reach servicemembers located on the same base, even if they were not directly next to the burn pit site. Search for the “Poo Pond Song” on YouTube and you will hear one soldier’s humorous take on the enormous lake of human waste that tens of thousands of international servicemembers lived, worked, and ate around at our formerly large base at Kandahar, Afghanistan. The real health-related consequences of having lived near this waste disposal system, however, are no laughing matter.

The many servicemembers who have served in Kabul, as I did, lived in an enormous city with open sewers and whose population routinely burns dry animal dung to keep warm. There were burn pits there as well. Our military serving there are now suffering the impacts from breathing airborne feces for extended periods of time.

This is to say nothing of the other toxic chemicals and fine particulates our men and women in uniform were exposed to every day. Our friends around the veteran space, especially those who served in Vietnam, know all too well how detrimental toxic exposures and environmental hazards can be. Inspired by their struggle, at Iraq and Afghanistan Veterans of America we don’t want burn pits to be the “Agent Orange of our generation.”

Many Iraq and Afghanistan veterans have personal stories related to the U.S. government’s process for disposing of human waste. One of our members, Christina Thundathil, a U.S. Army veteran, told us of her own experience during her deployment to Balad, Iraq. Although her specialty was in food preparation, her job in Balad was to drag full bins from port-o-johns daily, douse the contents with jet fuel, light them on fire, stir them with her e-tool (shovel), and then repeat until she had a brick she could bury in the desert. She’s severely injured because of these exposures, and she desperately needs a cure for her ills. Christina is just one example of the many veterans who are currently suffering.

THE NEED FOR PUBLIC EDUCATION

Little is understood about the long-term effects of exposure to burn pits and other airborne hazards. As our presence in Iraq and Afghanistan has largely faded from most Americans’ consciousness, the country must remain focused on investing in the system of care for veterans and their families.

Year after year, we have seen an upward trend in the number of members reporting symptoms associated with burn pit exposure. Eighty-two percent of IAVA members who responded to our latest survey report being exposed to burn pits during their deployment; over 84% of those exposed report that they may be or are already suffering from associated symptoms.

In response to our members’ concerns, IAVA launched a campaign last year to educate Americans about burn pits and airborne toxic exposures and the devastating potential impact they could be having on the health and welfare of millions of Post-9/11 veterans and their families.

To see the enormous extent of veteran interest in this issue, you only need to look at the comments section of any related online news article. These veterans need help now.

WE NEED TO GET VETERANS REGISTERED—PASS THE BURN PITS ACCOUNTABILITY ACT

The Department of Veterans Affairs has an “Airborne Hazards and Open Burn Pit Registry,” which helps VA “collect, analyze, and report on health conditions that may be related to environmental exposures experienced during deployment.” Although established in 2014, only 185,000 have completed the registry questionnaire. VA estimates that 3.5 million veterans are eligible to register. However, the latest numbers indicate that only 1.7% of eligible post-9/11 veterans have done so. In our annual survey we found that only 48% of IAVA members who self-identified as having been exposed have registered. That number is an increase from the previous year, which is a good sign, but much more work needs to be done.

The Burn Pit Registry is not well-known and is underutilized. The result is that the data on these exposures is not being collected at the levels needed to fully inform the next steps. Legislation signed into law last year (Public Law 115-929) sponsored by Sen. Amy Klobuchar and backed by IAVA resulted in the designation

of the Airborne Hazards and Burn Pits Center of Excellence in May 2019. The Center conducts clinical and translational research related to airborne hazards and burn pits, including through the study of the data included in the Burn Pit Registry. When the registry is up-to-date and everyone is registered, this Center will truly be equipped to help us tackle this enormous problem.

A definitive scientific link between exposure and specific illnesses has not yet been made. While many scientists agree that the evidence points to a direct link, more research is needed to develop treatments and to solidify the connection to these illnesses. We need more veterans registered so we can improve this important research.

Until this point, the Department of Defense (DOD) has not taken formal accountability of toxic exposures for deployed servicemembers. IAVA helped develop new legislation to tackle this problem. In May 2018, Reps. Tulsi Gabbard and Brian Mast introduced the Burn Pits Accountability Act (H.R. 663), and the Senate version (S. 191) was subsequently introduced by Sens. Amy Klobuchar and Dan Sullivan. The legislation directs DOD to include an evaluation of whether a servicemember has been exposed to open burn pits or toxic airborne chemicals in servicemembers' periodic health assessments and during military separations. If they report being exposed, they will be enrolled in the Burn Pit Registry unless they opt-out.

This legislation is bipartisan and commonsense. It simply does what should have been done long ago: it compels DOD to record exposures before the servicemember leaves the military.

Through the efforts of our sponsors, IAVA, and our many partner VSOs, the legislation has been included in both the House and Senate-passed versions of the National Defense Authorization Act (NDAA) for Fiscal Year 2020. The original bill is backed by 42 Senators and 197 House Members from both parties. IAVA calls on conferees to ensure the legislation remains in the final NDAA.

IMPORTANT ADDITIONAL STEPS WE CAN TAKE RIGHT NOW

IAVA has supported and continues to support other VA-focused toxic exposure legislation, and has joined with other leading VSOs in a Wounded Warrior Project-led coalition—the Toxic Exposure in the American Military (TEAM)—to better understand the risks and effects of toxic exposure in order to ensure servicemembers, veterans, and survivors have access to the care and benefits they need. Through the TEAM, each member VSO increases its capacity to effectively advocate for affected personnel and our members.

An important next step forward for those who have been exposed (and their families) is the joint VA/DOD development of the Individual Longitudinal Exposure Record (ILER) database. The ILER will record potential and known exposures throughout a servicemember's time in uniform in order to provide DOD and VA clinicians, claims adjudicators, and benefits advisors actionable data needed to improve the care provided to servicemembers and veterans. Data from those receiving treatment for illnesses through DOD and VA should be fed back into the ILER, ultimately increasing VA's ability to develop a presumptive illness database off of evolving illnesses.

If this system is done right, it will provide servicemembers and veterans significant transparency into their exposures that many have been saying has been lacking by DOD and VA. However, while this system has tremendous potential in allowing servicemembers, veterans, and their medical providers access to critical exposure information, ILER is not available currently to personnel outside of the DOD or VA. IAVA recommends that Congress require DOD and VA to develop a user-friendly online tool that allows individuals easy access information and the ability to download their ILER data.

IAVA is also concerned that the ILER will be available to VA claims adjudicators without sufficient guidelines for how they will interpret the information. We are concerned that VA claims adjudicators will use ILER to deny claims if there is no information in the system regarding the veterans' possible exposure. VBA must train their claims adjudicators appropriately on how it interprets and uses the information. Congress should establish clear guidelines on how VA can use the ILER database when processing a claim for possible exposure at VA.

Further, while we understand how important it is that the Airborne Hazards and Open Burn Pit Registry data is studied and used by the new aforementioned VA Center of Excellence, it is unclear what has resulted from analysis to date. We recommend the Center of Excellence establish a yearly report to Congress on information that is being captured and any trends that have been identified.

IAVA appreciates recent efforts by DOD and VA to demonstrate the ILER to military and veterans service organizations, and encourages those efforts to continue and increase.

Again, I thank the Chairman and Members of the Committee for inviting IAVA to express our members' views on this critical issue. It's important, with a widespread impact, and those that have been exposed during their time in uniform need the attention and treatment they are due.

PREPARED STATEMENT OF TRAGEDY ASSISTANCE PROGRAM FOR SURVIVORS

CHAIRMAN ISAKSON, RANKING MEMBER TESTER AND DISTINGUISHED MEMBERS OF THE SENATE COMMITTEE ON VETERANS AFFAIRS: The Tragedy Assistance Program for Survivors (TAPS) thanks you for the opportunity to make you aware of issues and concerns of importance to the families we serve, the families of the fallen.

While the mission of TAPS is to offer comfort and support for surviving families, we are also committed to improving support provided by the Federal Government through the Department of Defense (DOD), the Department of Veterans Affairs (VA), Department of Education (DoED), Department of Labor, state governments, government contractors, and local communities for the families of the fallen—those who fall in combat, those who fall from invisible wounds and those who die from accidents, illness or disease.

TAPS was honored to enter into a new and expanded Memorandum of Agreement with the Department of Veterans Affairs in 2017. This agreement formalizes what has been a long-standing, informal working relationship between TAPS and the VA. The services provided by TAPS and VA are complementary, and in this public-private partnership each will continue to provide extraordinary services through closer collaboration.

Under this agreement, TAPS continues to work with surviving families to identify resources available to them both within the VA and through private sources. TAPS will also collaborate with the VA in the areas of education, burial, benefits and entitlements, grief counseling and other areas of interest.

UNDERSTANDING ILLNESSES THAT MAY RESULT FROM TOXIC EXPOSURE

According to the Department of Veterans Affairs, veterans who served after 9/11 may have been exposed to a dozen different wide-ranging environmental and chemical hazards, some of which carry very real risks. Whether from burn pits, depleted uranium, or toxic fragments, they are getting sick and dying young from uncommon illnesses and early onset disease.

The Tragedy Assistance Program for Survivors (TAPS) interest in understanding illnesses that may result from toxic exposure stems from our desire to ensure surviving families have access to all available survivor benefits earned through the service of their loved one. The information that can be gathered from our survivor histories is also invaluable in establishing patterns and baselines that can be applied to the veteran community, save lives, and prevent this now and in the future.

Over the past five years, survivors of a military death due to illness seeking TAPS services increased by 51.37 percent. In 2018, more than 26 percent of family members who came to TAPS had experienced a loss due to illness. This is second only to suicide, at nearly 31 percent, and far surpasses all other circumstances of death, including hostile action.

Since 2017, TAPS and Vietnam Veterans of America (VVA) have been privileged to partner with the Wounded Warrior Project (WWP) to advocate for warriors suffering from illnesses caused by toxic exposure and surviving family members whose loved one died after experiencing symptoms of that exposure.

TAPS and other partners are working together to share lessons learned, gather data, and advocate for Post-9/11 veterans, their families, and survivors. Through this partnership, we have made great strides over the past two years to create a growing awareness of the issue of toxic exposure by enlisting support from other organizations, such as members of The Military Coalition (TMC).

TAPS is also a founding member of a new veteran and military toxic exposure working group called the Toxic Exposure in the American Military (TEAM) coalition. The TEAM coalition includes 15 Veteran Service Organizations (VSO) and Military Service Organizations (MSO) all addressing toxic exposure issues.

ILLNESS LOSS SURVIVOR TESTIMONIALS

Since 2008, TAPS has been contacted by over 11,000 surviving family members whose loved ones died due to illness. While we know there's a significant number

of veterans who die of common illnesses, we have become deeply concerned that like the Vietnam era, post-9/11 veterans have been exposed to toxins that are known to cause cancer. TAPS is working to gather survivor stories and aggregate data to better understand the scope and types of illness loss.

Here are a few of the many stories we have collected from our surviving families:

Coleen Bowman, Widow of SGM Robert Bowman

“In June 2011 after two deployments, Rob was diagnosed with an extremely rare cancer, Cholangiocarcinoma (bile duct cancer). During deployments, Rob was in close proximity to an open air burn pit that burned around the clock. His vehicle was struck at least 10 times by IEDs. Rob passed away on January 13, 2013, at the age of 44. Several of the men that Rob served with have many different illnesses, to include cancer, and several have passed away since at very young ages.”

Robyn Thompson, Widow of LTC Todd Thomson

“His cancer was far advanced, and was spreading rapidly, and genetic testing indicated it was one of the rarest forms of colon cancer diagnosed in our country.”

Kris Marbutt, Widow of Sgt. John Marbutt

“He worked very closely to the burn pits. In 2010 he was diagnosed with a brain tumor and told it was benign. He was initially denied a CT scan. He was diagnosed with a second ‘huge tumor’ glioblastoma. He died on October 21, 2016, he was 34 years old.”

Jennifer Moser, Widow of LTC Gregory Moser

“In June, 2016 he was diagnosed with stage 4 lung cancer (alk mutation, a non smokers lung cancer). His doctor signed a letter stating that his cancer was likely due to toxic exposure.”

Laura Forshey, Widow of Sgt. Curtis Forshey

“Three months into his deployment, he began to experience bloody noses that would go on for hours at a time. He went to the doctor there on the FOB where they ran bloodwork. The results showed his white blood count was way off. They flew him to Landstuhl, Germany. His wife, Laura, and their 3 month-old son Ben, along with Curtis parents flew to be with him in Germany. While they were in flight, Curt passed away. His cause of death was a brain aneurysm, caused from the cancer they discovered. Acute Promyelocytic Leukemia. Curt was 22 years old. He died on March 27, 2007. With proper diagnosis and treatment it is curable in 80–90% of patients.”

June Heston, Widow of BG Michael Heston

“Mike was active duty in the Vermont National guard. Mike deployed to Afghanistan three times. First in 2003 for 7 months, then 2006–2008 for 15 months, and last 2011–2012 for one year. In April 2016 Mike had gone into the doctor not feeling well. For 10 months doctors couldn’t figure out what was wrong with him. Finally in January 2017 Mike was diagnosed with a very rare form of pancreatic cancer, stage 4. Mike passed away shortly after that on November 14, 2018.”

EXPOSURE-RELATED ILLNESSES

Sadly, there are millions of servicemembers and veterans who were potentially exposed to burn pits and other toxins while serving, and many will die from exposure-related illnesses. Their loved ones will make up a large portion of the next generation of TAPS survivors.

While the government has created a self-report registry, they admit it’s a flawed and limited system that covers only exposures to burn pits. There are many other instances of exposure that are not tracked, and only a small number of those exposed to burn pits have actually registered. Sadly most young veterans who have died of rare cancers never knew to register.

By the year 2021, TAPS believes that deaths due to illness will surpass all combat deaths, non-combat deaths, accidents, and suicides combined. It’s time to take action and learn more about which toxins are causing rare cancers in our young people. Research must be done in and outside of government. We don’t have time on our side, we already know a number of toxins our troops were exposed to are carcino-

gens. We must get that information into the hands of veterans and their medical providers so they can plan for early screening and make connections for accurate diagnosis and effective early treatments.

The Departments of Defense and Veterans Affairs are working hard to mine data to match exposures to veterans but we must work harder and faster. The Individual Longitudinal Exposure Record (ILER) may be groundbreaking but we must make sure this critical information will be available to servicemembers, veterans, families, and survivors.

WHAT TAPS IS DOING

In the case of our TAPS families, we must provide answers to our survivors. So many are left wondering how their loved one survived deployments and returned home safely, only to succumb to illnesses years after returning home.

Like we did when we saw increasing trends and deaths by suicide, TAPS is developing a program to specifically address the needs of our survivors who grieve the death of their loved one to an illness. Many are left wondering how their physically fit military member could succumb to such an aggressive and rare illness that ended their life. We must all move forward together.

CONCLUSION

TAPS believes it is time to legislate funding for research, treatment, education, programs and awareness campaigns so we can save lives. Those who volunteer their lives to protect the freedom of our Nation and the families who stand beside them are ready to know America's priority is to protect and provide for all those who are ready to make the ultimate sacrifice.

The Tragedy Assistance Program for Survivors thanks the Senate Committee on Veterans Affairs and its distinguished Members for holding this important hearing on toxic exposure, and providing TAPS the opportunity to submit a statement for the record.

PREPARED STATEMENT OF RICHARD F. WEIDMAN, EXECUTIVE DIRECTOR FOR POLICY AND GOVERNMENT AFFAIRS, VIETNAM VETERANS OF AMERICA

CHAIRMAN ISAKSON, RANKING MEMBER TESTER, AND MEMBERS OF THE SENATE VETERANS' AFFAIRS COMMITTEE: Vietnam Veterans of America sincerely appreciates your concerns that have moved you to for hold this hearing on an issue of critical importance to all veterans, their families and survivors: the VA's inconsistent and incomprehensible Presumptive Disability Decision-Making Process.

Vietnam Veterans are well-versed in the delays and denials, obfuscations and other impediments in the VA's "presumptive disability decisionmaking process." We have long maintained that this process, and the pervasive attitude that underlies it, runs counter to the spirit and rationale in the very foundation of VA's mission, the promise made by President Abraham Lincoln: *To care for him who shall have borne the battle, and for his widow, and his orphan.*

Exposures to toxic chemicals, of course, are among the hazards of the work place for members of the military, both here in CONUS and in deployments across the globe, in times of war and eras of peace. Ever since the war in Vietnam, such exposures, for the most part invisible, are now considered to be, in many instances, just as lethal as wounds inflicted by shrapnel and bullets. But, while a bullet hole or traumatic amputation are observable results of hostile actions of combat with the enemy, the long-term effects of exposure to toxic agents most often are not. Making a case, and a claim, for infliction of a toxic wound can be, and most often is, a daunting proposition.

Such wounds, however, are real. Very real. They can wreck a life, or end a life, and potentially impact the health and well-being of the offspring of servicemembers who were only working their mission, doing their job. They are hurting when they go to the VA for help. And they hurt even more when they are told there is no nexus between a health condition afflicting them and what they were exposed to while in the service of our Nation.

To illustrate the problem with how the Veterans Benefits Administration in essence flaunts the needs of veterans and the will of Congress, consider, if you will, the difficulties faced by veterans of the 1990-91 Gulf War.

According to the VA, "During the period of August through December 2015, Compensation Service [the VA's Quality Review staff] conducted a special focus review (SFR) of Gulf War cases . . . A total of 311 cases from the first two quarters of Fiscal Year 2015 were reviewed. Although some of these cases included claims for other

disabilities that were not related to the Gulf War, this review was restricted to the Gulf War-related illnesses on each claim ... The VBA's findings: of the 311 cases reviewed, 291 were properly denied, and 20 were improperly denied. This corresponds to a 94 percent accuracy rate within our sample."

VBA officials testified as to the SFR findings during a 2016 hearing in the House of Representatives dubbed "Persian Gulf War: An Assessment of VA's Disability Claim Process with Respect to Gulf War Illness." It seems, however, that the SFR did not cover what it was supposed to cover—claims from FY 2011 through FY15.

Even after former Secretary Bob McDonald had instructed the VBA to do a second, and proper, SFR of claims from FY 2011–2015, the VBA still bollixed it up. They managed to draw 112 fewer claims. Of 199 cases reviewed in each of four fiscal years, the SFR concluded that 178 decisions were correct and 21 decisions had been "prematurely denied." Of particular note was this statement by the VA's Compensation Service: "It is imperative that the reviewer fully review the narrative in these decisions to ascertain whether service connection was properly considered under 38 CFR § 3.317."

In the wake of these findings, and considering evidence presented by Gulf War activists, Secretary McDonald instructed the VBA to set up a review lane to be used to overturn wrongfully denied Gulf War Illness-related claims, one claim at a time. To date, nearly 400 wrongfully denied presumptive Medically Unexplained Chronic Multi-Symptom Illness, or MUCMI, claims, have been overturned—one claim at a time. The VBA is supposedly using these overturned claims as training aids for their adjudicators.

These data suggested that the VBA adjudicators had failed to follow statutory and regulatory provisions and the VA's own procedures (in its M21-1 manual's Notice to Examiners in Southwest Asia Claims). Thus, there was a systemic problem with presumptive Gulf War Illness-related claims.

It is instructive to note that the 2017 GAO report, *Persian Gulf War: An Assessment of VA's Disability Claims Process with Respect to Gulf War Illness* found that the VA's ability to accurately process Gulf War Illness-related claims was hampered by:

- Inadequate training for both VBA adjudicators and Compensation and Pension (C&P) examiners.
- The failure of adjudicators to recognize that the examiner has provided an unnecessary medical opinion concerning service connection (nexus), thus wrongfully denying veterans' claims.
- The abysmal number of C&P examiners—only 10 percent of them—who had taken an optional online 90-minute training course.
- The failure of VBA decision letters that often do not communicate key information as to why a veteran's claim was denied.

Since the 2016 GAO report, there has been no significant improvement in regard to the issues Gulf War veterans face in having claims properly adjudicated, despite years of advocacy efforts, two hearings in the House (March 15, 2016 and July 13, 2017), and numerous promises by the VA. Still today, according to data furnished by the VBA, Undiagnosed Illness claims (UDX) are denied at a 95 percent rate, and Medically Unexplained Chronic Multi-Symptom Illness (MUCMI) claims at a 73 percent rate.

Another recent problem in Gulf War Illness-related disability claims is that the examiner, usually a nurse practitioner, will often:

- State that the veteran doesn't have a current diagnosed disability, when in fact the examiner failed to view non-VA medical records.
- Lump several illnesses into one condition, effectively denying the other conditions.
- Overrule and alter the diagnosis, or challenge the qualifications of the veteran's treating physician, resulting in a denial.

To us, this is déjà vu all over again. Today, 45 years after the last U.S. combat troops exited South Vietnam, we're still fighting to ensure that Vietnam veterans receive the benefits that we've earned for having served our country in a war half-way around the globe.

What should the VA, the VBA, do to do right by the veterans it serves? What can Congress do to ensure that the VA uses the tools provided by statute, in regulations, and in the VA's own processes and procedures? Inasmuch as acronyms are coin of the realm here in the Nation's capital, let us offer TOAT:

Training: The VBA must ensure that adjudicators and Compensation and Pension (C&P) examiners are adequately trained and updated with changes in the law, with scientific and epidemiological advances, with alterations in policy—and that they are in fact using the tools and references available to them. Also, for instance, the

VA's "optional" 90-minute training module for Gulf War Illness claims should be required.

Oversight: Congress must insist that the VA provide quarterly statistics on how its adjudicators handle particular conditions, the problems and issues they perceive, the complaints they receive.

Accountability: Whenever and wherever possible, claims for a particular condition—PTSD or Military Sexual Trauma or Gulf War Illness, for example—ought to be steered to adjudicators who "specialize" in such claims in order to increase consistency in ratings throughout the system. Just as important, because it has been our experience that adjudicators routinely deny presumptive, service-connected maladies, to hold their supervisors accountable, which is not done at present.

Transparency: The VA ought to hold quarterly briefings for Congress, the media, and the veterans' community based on their quarterly reports. Officials ought to unshackle themselves from a bunker mentality, defend what they do yet acknowledge their mistakes, and make public what they will transmit to Congress what they feel they need to improve their own processes and procedures. And this can't simply be, We need more money.

Vietnam Veterans of America thanks you for this opportunity to submit our Statement for the Record, and will reply to any questions regarding this testimony that you may have.

PREPARED STATEMENT OF WOUNDED WARRIOR PROJECT

CHAIRMAN ISAKSON, RANKING MEMBER TESTER AND DISTINGUISHED MEMBERS OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS, Thank you for inviting Wounded Warrior Project (WWP) to submit the following testimony on "Toxic Exposure: Examining the VA's Presumptive Disability Decision-Making Process."

Wounded Warrior Project is transforming the way America's injured veterans are empowered, employed, and engaged in our communities. Since our inception in 2003, we have grown from a small group of friends and volunteers to an organization of nearly 700 employees spread across the country and overseas delivering over a dozen direct-service programs to warriors and families in need.

While we are primarily an organization that assists post-9/11 wounded, ill, and injured servicemembers (and their families), the issue of toxic exposure is a cross-generational problem, and we are proud to advocate for all veterans affected. We understand that for thousands of men and women who served, environmental and chemical hazards have carried real and potential health risks. Accordingly, WWP has a strong interest in Congress' work on studying and addressing any harm to veterans that may have been caused by toxic exposure illnesses related to service.

A significant number of post-9/11 servicemembers and veterans (like their Vietnam era counterparts), seem to be suffering from uncommon illnesses or unusually early onset of more familiar diseases like cancer. It appears that exposure to contaminants such as burn pits, toxic fragments, or other hazards typically seen on overseas deployments, are emerging as common threads among veterans who are sick, dying, or already deceased. We believe there is likely causation between deployments of the last 18 years and illnesses as noted above. While we are currently focused on deployment exposures, we are also aware of the challenges servicemembers face regarding possible exposures stateside. Debates in scientific and medical communities have not reached consensus on the relationships between certain toxic exposures and presumed health outcomes which is why the issue must be further researched.

These concerns were the impetus behind recent WWP partnerships with the Tragedy Assistance Program for Survivors (TAPS), Burn Pits 360, and Vietnam Veterans of America (VVA) to bring forth public awareness and investigate the harmful effects of toxic exposures in the military. To date, WWP has invested \$620,000 in these partnerships to address the needs associated with toxic exposure. These funds help drive the mission to bring awareness and advocacy to servicemembers, veterans, and survivors seeking access to the care they need and benefits they deserve.

To further raise awareness and improve collaboration across the community, WWP has led the formation of a new veteran and military toxic exposure working group called the Toxic Exposure in the American Military (TEAM) coalition. The TEAM coalition includes 15 Veteran Service Organizations (VSO) and Military Service Organizations (MSO) all addressing toxic exposure issues. Members of TEAM include, WWP, Burn Pits 360, Cease Fire Campaign, Hunter Seven, Iraq and Afghanistan Veterans of America, Military Officers Association of America, The American Legion, Tragedy Assistance Program for Survivors, Veteran Warriors, Vietnam Veterans of America, Enlisted Association of the National Guard of the United States,

California Communities Against Toxics, National Veterans Legal Services Program, Vets First, and the Dixon Center. Additional organizations attend the monthly coalition meetings for broader input.

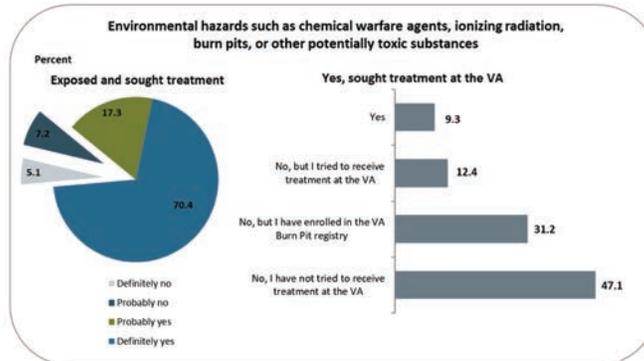
With the legacy of a decades-long struggle to deliver care and benefits to those who have or continue to suffer from the effects of Agent Orange, we strive to ensure that today's veterans struggling to receive health care are not fighting for treatment years from now. If we do not act, we may look back wondering if we should have done more sooner. Accordingly, our mission is focused on treating servicemembers and veterans before they become critically ill through early identification and better research, which can be utilized to develop new forms of treatment.

Through our testimony, we hope to highlight a host of issues we have seen regarding toxic exposure, and while the issues are broad—and the challenges great—we will be focusing on five key topic areas for this testimony that WWP considers to be the appropriate first steps needed to address the needs of the community. Additionally, our recommendations are informed by daily interaction with the young veterans we serve, guided through the work from the TEAM coalition, and from data captured using our Annual Wounded Warrior Alumni Survey, which is the largest and longest longitudinal survey of the post-9/11 veteran population with over 35,000 respondents and in its tenth iteration. The full results of this year's data will be released on October 29, in the Kennedy Caucus Room, but we are able to share data regarding toxic exposure for this testimony.

2019 WWP WARRIOR SURVEY RESULTS ON TOXIC EXPOSURE:

A new question in the 2019 Annual Wounded Warrior Alumni Survey asked post-9/11 wounded, ill, and injured servicemembers about exposure to environmental hazards such as chemical warfare agents, ionizing radiation, burn pits, or other potentially toxic substances during their military service. A majority (70.4%) of Warriors reported certain exposure to hazardous chemicals or substances; however, only 9.3% said they had received treatment for their exposure at the VA. Slightly more than thirty percent (31.2%) are enrolled in VA's Airborne Hazards and Burn Pit Registry. Slightly more than thirty percent (31.2%) are enrolled in VA's Airborne Hazards and Burn Pit Registry. Warriors who reported exposures were more likely to indicate poorer health. Additionally, 89.8 % of Warriors who reported their health as "Poor" or "Fair" indicated "Probably Yes" or "Definitely Yes" to exposure of an environmental hazard during military service versus 81.9 % of Warriors who rated their health as "Very good" or "Excellent" indicated "Probably Yes" or "Definitely Yes" to exposure of an environmental hazard during military service.

Of those that indicated that they were exposed to environmental hazards such as chemical warfare agents, ionizing radiation, burn pits, or other potentially toxic substances during service, 9.3% stated they sought treatment at VA, 12.4% said that they did not receive treatment at VA for toxic exposure illnesses but tried, and 31.2% indicated that they have not tried to receive treatment at VA but have enrolled in VA's Airborne Hazards and Burn Pit Registry. Although we do not clearly know why so few veterans seem to be receiving treatment at VA, our assumption is that access issues are driven by a lack of communication with veterans on this topic and the difficulty of establishing service connection for illnesses believed to be caused by toxic exposure. Whether successful in receiving VA treatment or not, it is noteworthy that nearly 22% of surveyed Warriors reported seeking such treatment.



As the conversation regarding prevention and treatment moves forward, it is important to look at the populations that legislative changes affect the most. We recommend reaching out to organizations who have original data on these populations to better understand how veterans might be affected and where lapses in care currently exist. *Please see the appendix for additional data on Toxic Exposure from our 2019 Warrior Alumni Survey.*

Below are Wounded Warrior Project's recommendations for the Committee as it addresses the presumptive disability decisionmaking process.

1. Establish Entitlement to Care for Veterans Suffering from Toxic Exposure Illnesses

While burn pit exposure numbers are alarming in their own right, these numbers pale in comparison to the population of servicemembers who were exposed to other toxins for which there is no registry. Health outcome studies such as those performed by the National Academy of Medicine and the Committee on the Assessment of VA's Airborne Hazards and Open Burn Pit Registry have shown that "not only are the emissions released by burn pits a complex mixture of various chemicals and particulates that depend on factors such as the composition of the trash burned, accelerant used, temperature, ventilation, and the burn rate, but the composition and magnitude of air pollutants on military bases in theaters of operation are also affected by a variety of other anthropogenic and natural toxicants."¹

This is why we believe that post-service preventative health checks and treatment for those suffering from toxic exposure illnesses are a priority. As with any large scale health concern, prevention and treatment go hand in hand. While the Department of Defense (DOD) is best suited to develop prevention measures to stop exposures to toxic substances, VA is best equipped to identify illnesses and the development of treatments related to those exposures. WWP recommends VA work with DOD using the Individual Longitudinal Exposure Record (ILER), and other evidence, to develop a "High Risk" database. This database should allow identified "High Risk" veterans the ability to receive a presumptive zero percent disability rating for toxic exposure. This zero percent rating would allow veterans access to needed healthcare within the VA medical system. We ask that VA start with treatment in conjunction with a study and data collection on those who are receiving treatment for illnesses. This study and data collection, in conjunction with ILER and VA's Airborne Hazards and Burn Pit Registry, should provide researchers the data needed to develop a list of illnesses that could be presumed to be related to toxic exposures. In doing so, this addresses two of WWP's primary concerns regarding toxic exposure: (1) early identification of toxic exposure illnesses and (2) life-saving treatment for those affected.

The difficulty in developing a "High Risk" database is defining those who could be considered "High Risk." We recommend by starting with deployed servicemembers and veterans that have rare forms of cancer or other medical conditions that fall outside the norm for their age and background. The ILER system has the ability to pull clusters of individuals based off of common exposures and units. If a unit has an unusual amount of cancer rates, this would be an indication that the entire unit is at a higher than normal rate of risk. Once these clusters are identified, notification should be sent out by DOD and VA to inform the servicemembers and veterans that they are considered to be at "High Risk." For those who receive treatment for illnesses through DOD and VA treatment centers, it is imperative that this data is fed back into the ILER system for tracking and research. By identifying "High Risk" cohorts, compiling data on their illnesses, and administering treatment, it may help compiling the data necessary to develop a list of presumptive illnesses.

2. Allow Veterans and VSOs Access the ILER System

The Individual Longitudinal Exposure Record (ILER) is a web-based application developed over the past eight years between DOD and VA that can assist in determining the linkage between individuals and possible toxic exposures while serving in the military. DOD has been proactive in reaching out to the veteran and military communities to answer questions and identify concerns from VA and key stakeholders. The system is impressive and we sincerely appreciate the work that DOD has done to demonstrate the system to the community.

ILER can create a comprehensive exposure record for individual veterans by cross-referencing available DOD data. The system links individuals with known exposure events and incidents to compile a servicemember's possible exposure history. This system will be accessible to DOD clinicians, VA clinicians, VA claims adjudica-

¹ <https://www.ncbi.nlm.nih.gov/books/NBK436096/>

tors, and researchers. In theory, anyone with access to the database will have the ability to download a pdf file that contains a servicemembers historical exposure, a possible connection between exposures and different medical complications, possible illnesses attributed to these exposures, high-risk indicators, and cross-reference other servicemembers from a unit that might also be exposed. This system is useful to researchers attempting to find and isolate specific control groups and to servicemembers and veterans undergoing treatment.

While this system has the potential to be life-saving, it is currently unavailable for use by anyone outside the DOD or VA. Allowing servicemembers, veterans, and their health care providers the ability to identify possible exposure risk factors before or during treatment could mean the difference between life and death. We recommend that Congress consider directing DOD and VA develop an easy to use portal that allows individuals to download their ILER information. Currently, the process for a veteran to obtain his or her record is to file a Freedom of Information Act (FOIA) request with DOD. Alternatively, it is possible for a veteran to obtain permission from VA to release the information to a private health care provider, but not directly to the veteran. We find this unnecessary and counterproductive when this could be the difference between proving service connection or not receiving health care from VA. Additionally, while VA claims adjudicators have access to the system, Veteran Service Organization (VSO) claims representatives do not have access and are limited in their ability appropriately represent veterans.

We are also concerned that this system will be available to VA claims adjudicators with little understanding of how information will be interpreted. When individuals access the ILER database, there is a small disclaimer that states that lack of information found in the system does not indicate that a veteran was not exposed. It is our understanding that each military branch collects toxic exposure information differently. We would not want differences in data collection to lead to denial of benefits and healthcare. We must be careful to ensure that VA claims adjudicators do not inadvertently use the ILER system to deny claims if sufficient information does not exist within ILER regarding the veterans possible exposure. We would recommend Congress set clear guidelines on how VA can use the ILER system when processing a VA claim for possible exposure. Additionally, we look forward to working with the Veteran Benefits Administration (VBA) on learning how claims adjudicators are being trained to access the system and interpret the information.

Last, while DOD has done a great job reaching out to the community, it has been difficult to understand how VA will use the ILER system and whether VA has worked with VSOs regarding their implementation and usage plan. We encourage Congress to continue oversight of the ILER system and how VA is able to utilize this system.

3. Order Additional Research into Treatment and Causation

While working collaboratively with the TEAM coalition, WWP was able to identify common trends in existing research and delineate paths for future studies. The need for research can be broken down into two separate issue areas: (1) research into treatments and (2) research into causation. It is important to note the difference between research for treatment versus research for connection between exposure and illnesses. Research into treatment should encourage greater focus on genomics studies in order to ascertain the best treatments and expand predictive medicine for veterans. Research into causation should be focused on how different exposures relate to different illnesses.

Research for Treatment:

We recommend that VA perform a study on how to develop better treatment options for those affected by toxic exposure. Specifically, we would like VA to implement a national screening, treatment and research program within a Center of Excellence, preferably VA's Airborne Hazards and Burn Center of Excellence (AHPCE), under the direction of the Deputy Under Secretary of Health for Policy and Services. One area of focus we would recommend looking into would be lung cancer screening and how to expand VA's ability to identify lung cancers. The incidence rate of lung cancer among veterans (137 per 100,000) is more than double that of civilian rates (54.9 per 100,000)² due primarily to higher smoking rates and exposure to known and suspected carcinogens during service.

² https://seer.cancer.gov/csr/1975_2016/browse_csr.php?sectionSEL=15&pageSEL=sect_15_table.05

Lung cancer develops slowly and rarely exhibits obvious symptoms until the late stages when survival rates drop to 5%.³ Screening those at high risk with CT scans before symptoms appear can shift diagnosis to early stage. Since the National Cancer Institute's 50,000-person National Lung Screening Trial in 2010, multiple international screening randomized controlled trials—including the Belgian-Dutch NELSON trial,⁴ the MILD trial in Italy,⁵ decades of population screening in Japan,⁶ and the 20-year International Early Lung Cancer Action Program (I-ELCAP)⁷ study, all show that between 50% and 80% of those diagnosed at early stage by CT screening will have long-term, recurrence-free survival.

Therefore, WWP recommends legislation authorizing the Deputy Under Secretary for Health for Policy and Services to develop and validate protocols and quality controls for simultaneous screening and management of other findings, including, specifically, baseline and follow up CT scans to document and validate cohort and case-controlled studies of those exposed to burn pit emissions and other known and suspected carcinogens.

Research for connection between exposure and illnesses:

Wounded Warrior Project realizes that a barrier to care at VA, for health issues believed to be from toxic exposures, is proving an illness is related to service and as a result of toxic exposure. In order to fill gaps in research about the relationships between burn pits and other toxic exposures and specific illnesses, WWP recommends establishing a study by the National Academy of Medicine on burn pits and other contaminants that might have affected servicemembers deployed Outside Continental United States (OCONUS). While the National Academy of Medicine has performed reports in the past, new conclusions can likely be drawn using the new ILER data. In the past, the National Academy of Medicine listed "Limited statistical power—Small sample size in many of the studies prevents the detection of associations"⁸ as a reason for not being able to connect exposure and illness. Access to the ILER data should help address this problem. We recommend this report cover current ongoing research, identification of the negative effects of exposure from burn pits and other contaminants, an estimate of how many servicemembers might have been affected, possible ways to develop a "High Risk" list using the ILER system, and what Congress, the Federal Government, and the VSO/MSO community can do to assist these servicemembers and veterans.

Additionally, new epidemiological data on the entire Post-9/11 cohort should be collected to understand exposures and current short and long-term health problems related to their military service. Wounded Warrior Project would also like to see an in-depth report on the DOD Periodic Occupational and Environmental Monitoring Summary (POEMS). These reports have a vast amount of data regarding environmental exposures in Afghanistan and Iraq. Conducting a report that can capture this data in a way that promotes informed legislative action is critical for future progress on this issue.

4. Update the Airborne Hazards and Burn Pit Registry

There are more than 165,000 veterans enrolled in VA's Airborne Hazards and Burn Pit Registry—all of whom served on or after 9/11, during operations Desert Shield and Desert Storm, or in the Southwest Asia theater of operations after August 2, 1990, and were deployed to a base or station where open burn pits were used or where possible exposures to toxic substances occurred. While VA's Airborne Hazards and Burn Pit Registry asks questions regarding exposures not related to burn pits, it can be unclear to veterans if exposure to other relevant contaminants is recorded in the registry due to the name. Our first recommendation would be to update the name to include or convey the idea that all forms of toxic exposures during deployments are captured.

While VA's Airborne Hazards and Burn Pit Registry is important, we are unaware of any analysis of the information being performed other than the 2016 study titled *Burn Pit Emissions Exposure and Respiratory and Cardiovascular Conditions Among Airborne Hazards and Open Burn Pit Registry Participants*.⁹ We recommend VA's Airborne Hazards and Burn Pits Center of Excellence conduct a comprehensive

³ <https://seer.cancer.gov/statfacts/html/lungb.html>

⁴ <https://www.ascopost.com/issues/october-25-2018/nelson-trial/>

⁵ <https://doi.org/10.1093/annonc/mdz117>

⁶ <https://www.auntminnie.com/index.aspx?sec=sup&sub=cto&pag=dis&ItemID=124046>

⁷ <https://www.ncbi.nlm.nih.gov/pubmed/30511179>

⁸ <https://www.nap.edu/download/13209>

⁹ <https://www.ncbi.nlm.nih.gov/pubmed/27218278>

report on information that is being captured and any trends that have been identified.

Last, WWP recommends Congress pass H.R. 1001, the Family Member Access to Burn Pit Registry Act, which will direct the Secretary of Veterans Affairs to provide a process by which a family member of a deceased individual who is eligible for the Department of Veterans Affairs burn pit registry may register for such registry on behalf of the deceased individual. While we support H.R. 1001, we understand that it is important to keep datasets clean; however, we feel that it is still important to track this information. Therefore, allowing family members to add information to a file while keeping the original data safe from alteration still allows researchers to identify trends, and expands the data to include those who are deceased. We feel this additional language should be considered if H.R. 1001 were to be addressed in the Senate. We also feel that feeding this information back into the ILER system and developing "High Risk" cohorts could save lives in the long run. A proactive approach VA and DOD can take is to track which veterans have passed away, from what type of illness, identifying clusters, and reaching out to other members of that unit.

5. Provide Training for Clinicians

Recently, WWP had a post-9/11 wounded warrior attend a medical examination for difficulty breathing, with the examination conducted by a VA contractor. During the medical assessment, the veteran reported that he was never asked about possible exposures to burn pits or other contaminants. Proper training and identification of possible "High Risk" veterans go hand in hand. WWP recommends VA develop a training module on questions VA providers and VA contractors should ask veterans at the beginning of an exam to help identify a possible "High Risk" veteran. This would include adding questions to the exam questionnaire, training to probe for additional information regarding types of exposures, and training to inform veterans of resources available to them. For instance, research has shown that there is a possible connection between chemicals that were inhaled by servicemembers while deployed and a higher risk of chronic bronchitis or chronic obstructive pulmonary disease.¹⁰ If VA clinicians are not trained on the types of symptoms that may be common to different toxic exposures, then there is a risk of misdiagnosis. Sometimes it can be as simple as asking "were you ever stationed near a burn pit?" to get both patient and provider to think more critically about toxic exposures.

CONCLUSION

Wounded Warrior Project's mission is to honor and empower wounded, ill, and injured veterans, servicemembers, and their families. We have seen increased health complications for a young population that should be generally healthy. We cannot ignore obvious correlation between certain toxic exposures and illnesses with no reasonable explanation for onset. We do not have the resources to adequately answer these questions alone and rely on our partners, both in and out of Congress, to help understand why we have seen an increase in rare cancers and other illnesses. We believe it is in large part to toxic exposure. This is not only related to those deployed overseas but also encompass Per- and Polyfluoroalkyl Substances (PFAS) contaminants, Camp Lejeune water contamination, burn pits, and many other exposures. We will continue to advocate for all generations of Warriors who are dealing with medical complications due to toxic exposures and urge Congress to take action as each day that veterans are denied proper medical diagnosis and treatment is another day that could mean life or death.

Wounded Warrior Project thanks the Senate Committee on Veterans' Affairs, its distinguished members, and all who have contributed to the discussions surrounding today's hearing. We share a sacred obligation to serve our Nation's veterans, and WWP appreciates the Committee's effort to identify and address the issues that challenge our ability to carry out that obligation as effectively as possible. We are grateful for the invitation to submit this statement for the record and stand ready to assist when needed on these issues and any others that may arise.

¹⁰ <https://www.ncbi.nlm.nih.gov/pubmed/27218278>

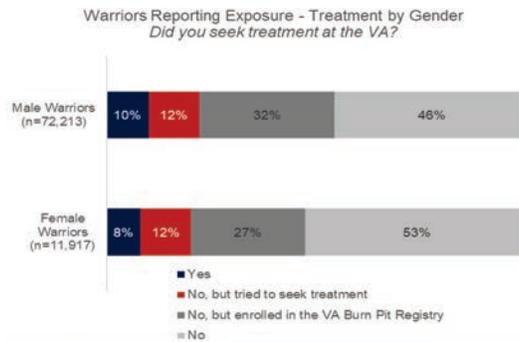
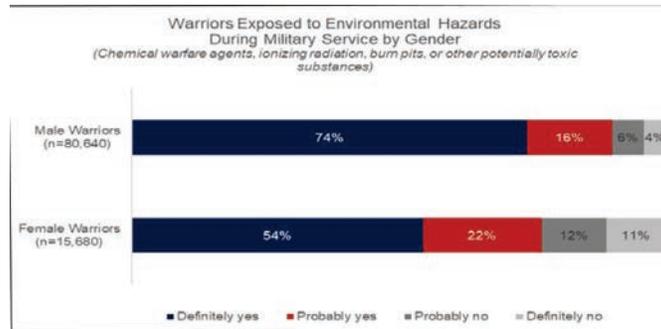
Appendix:

2019 ANNUAL WARRIOR SURVEY

TOXIC EXPOSURE INFORMATION BY DEMOGRAPHIC VARIABLES

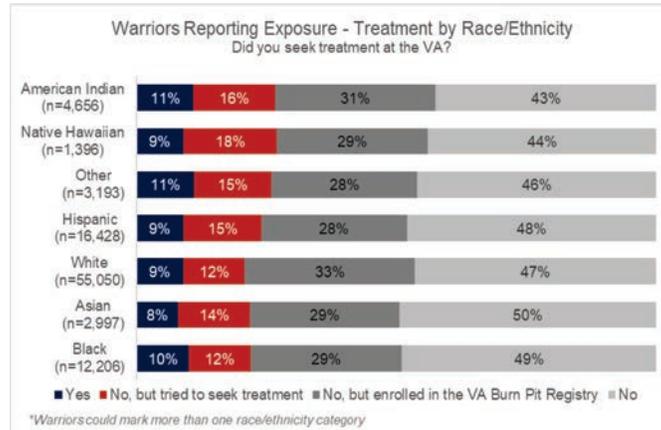
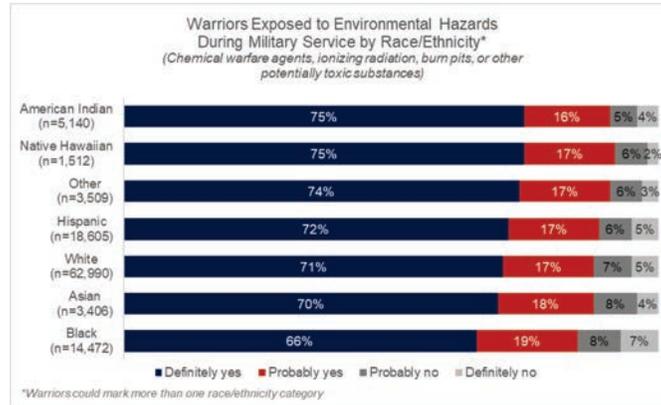
A higher rate of male warriors indicated they had some exposure to environmental hazards such as chemical warfare agents, ionizing radiation, burn pits, or other potentially toxic substances during their military service, with 90% of male warriors reporting they were definitely or probably exposed versus 76% of female warriors.

The treatment rates between male and female warriors were similar. Of those who indicated some exposure, 46% of male warriors had not received treatment or enrolled in the VA's Airborne Hazards and Burn Pit Registry, while 53% of female warriors had not received treatment or enrolled in the VA's Airborne Hazards and Burn Pit Registry.



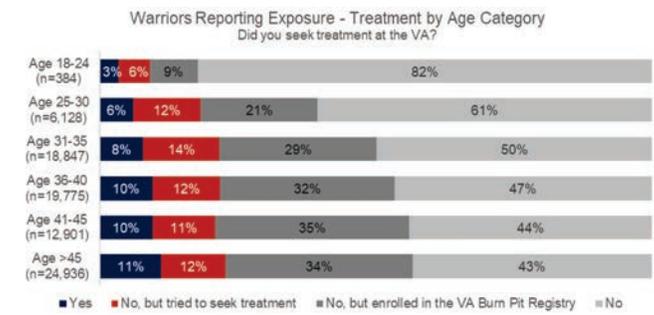
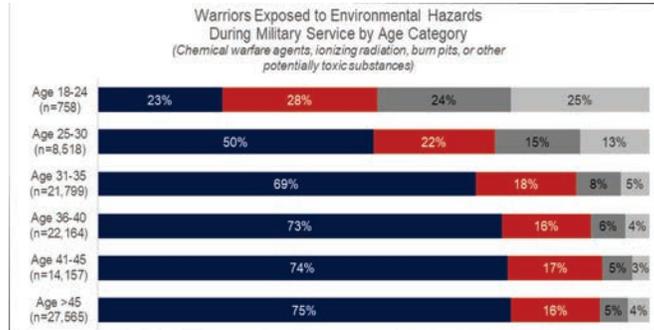
There was little variation among race or ethnicity for warriors reporting exposure to environmental hazards such as chemical warfare agents, ionizing radiation, burn pits, or other potentially toxic substances during their military service.

- The treatment rates among race or ethnicity were also similar.
- In the future, we will do significance testing to see if there are true differences.



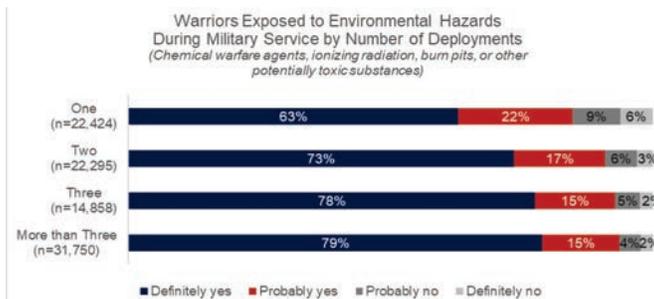
Older Warriors report higher rates of exposure to environmental hazards such as chemical warfare agents, ionizing radiation, burn pits, or other potentially toxic substances during their military service, with 92 percent of Warriors age 41–45 indicating definitely or probably yes, and 91 percent of Warriors age 45 and older indicating the same. For comparison, 51 percent of warriors age 18–24 indicated definitely or probably yes, and 72 percent of Warriors age 25–30 indicated the same.

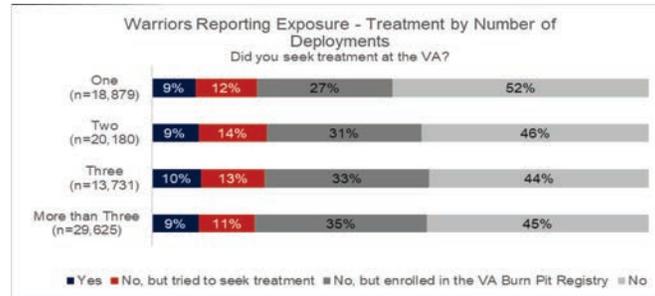
- The treatment rates among age groups followed a similar trend. Of those who indicated some exposure, Older warriors had higher rates reporting treatment or enrollment in the VA’s Airborne Hazards and Burn Pit Registry.



Perhaps not surprisingly, Warriors who reported being deployed 3 or more times reported higher rates of exposure to environmental hazards such as chemical warfare agents, ionizing radiation, burn pits, or other potentially toxic substances during their military service, with 93% of Warriors deployed three times indicating definitely or probably yes, and 94% of Warriors deployed more than three times indicating the same. For comparison, 85% of warriors deployed once indicated definitely or probably yes and 91% of Warriors deployed twice indicated the same.

- Despite the high rates of reported exposure among Warriors who deployed multiple times, these Warriors do not report high rates of treatment. A little over a third of Warriors within each deployment category have enrolled in the VA's Airborne Hazards and Burn Pit Registry (35% of Warriors deployed more than three times, 33% of Warriors deployed three times, 31% of Warriors deployed two times).





PREPARED STATEMENT OF SUSAN M. ZEIER, VETERAN ADVOCATE, BURN PITS 360-OHIO, AND MOTHER-IN-LAW OF A BURN PIT VETERAN

SEPTEMBER 25, 2019

Soldiers are the epitome of excellent health before being deployed to war zones like Iraq and Afghanistan yet thousands have returned home safely from war only to realize a battle for their lives are just beginning. These returning soldiers are dying at alarming rates and fighting for their lives now in their 20s, 30s, and 40s and it's a disgrace that our country is not helping many who need desperate tests, surgeries, biopsies, and treatment.

As the mother-in-law, of an Iraq War Veteran, on March 21, 2017, the agony of realizing that thousands of our servicemembers returning from Iraq and Afghanistan and have experienced a constellation of debilitating chronic ailments including terminal diseases hit my family like a rock. Around noon on that fateful March day, my phone rang with the caller ID telling me it was my daughter. I knew she was with her active duty military husband and where they were, at a local cancer center meeting with an oncologist who was to deliver them news on the type of cancer my son-in-law had, having had test results show days earlier that he indeed was suffering from some form of cancer.

Anxiously waiting for this phone call, I already knew that my son-in-law been diagnosed with a rare autoimmune disease called mucous membrane pemphigoid which is known mainly to strike elderly women and not 35 year old men. Diagnosing him took bouncing around to about 10 different doctors after the first nine couldn't figure out the health condition causing his chronic daily nosebleeds and eventual bleeding from his ears but we were hopeful after being told the disease was manageable and possibly curable. But having cancer was another story, thus my anxiety awaiting his test and scan results, I answered the phone like I always do when I know it's her, "Hi Sweetie." Before I could barely get "Hi" out, the most terrifying unintelligible hysterically distressed shrieks were blasting in my ear. Not one word could I understand but I knew it was bad... very, very bad. This was a distraught wail no mother ever wants to hear from their child and especially, as was soon substantiated that I'm not going to be able to do anything to take away hers or her husband's excruciating pain. I won't be able to fix this.

Finally about 15 minutes later after calming my daughter down enough to speak coherently but still somewhat hysterically screaming at me. She was able express that the doctor walked into the room and the first words out of his mouth were, WHAT THE HELL HAVE YOU BEEN EXPOSED TO???? While he went on to explain that my grand-daughter's daddy has contracted an extremely rare form of cancer, non-small cell adenocarcinoma lung cancer with no primary tumor and the cancer is stage IV. 20 highly respected oncologists were consulted with to hopefully figure out the best treatment that would possibly extend his life past the life expectancy prognosis of two weeks to a few months if the aggressive cancer could not be brought under control. The oncologists agreed that his form of cancer could've only been caused by long term toxic exposure, but none of the 20 consults had answers other than experimenting with a variety of treatments and pray that one works. The physician's dilemma occurred because seeing patients with this rare form of lung cancer never happens so there just aren't any statistics on prognosis and treatments that work the best. The doctor told the young couple that people just aren't exposed to the type of toxins he apparently was. To complicate matters, not having a primary tumor there's nothing to direct chemotherapy or radiation to. He already had mets (metastases) to his bone and pericardium and if initial treatments didn't slow

down the cancer's progression the oncologist told them he only has at most a couple months to live as his bronchioles and airway was being compromised.

Cancer has taken over his membranes, his lungs, thoracic wall, heart, and all of the chest and neck lymph nodes. My kids were told on that day to get his affairs in order and complete any paperwork pertaining for the end of life. The doctor cried and had to excuse himself from the room while giving them time to fall apart. As my daughter described it to me, her husband agonizingly pounded on the wall before leaning against it and started crying almost collapsing until she held him up to prevent him from falling.

Our entire family was in total shock, walking around in a daze for a few days speculating where the toxic exposure took place and what were we going to do to help. How are we going to explain to his 3-1/2 year old daughter that her daddy will be going away and never coming back? Our family was devastated and confused as we tried to grasp what was happening. My husband and I were asked by our son-in-law to make sure his girls are OK. Make sure his daughter uses his GI Bill and goes to college. Make sure we are with her for all of her milestones growing up: starting kindergarten, Sweet 16, homecomings, proms, father-daughter dances, boyfriends, learning to drive, graduating high school and college and getting married. He was so distressed telling me that he won't get to see his baby girl grow up and witness all those parts of her life.

I sat with him the day his former Captain who is now a Sergeant Major stopped by to visit. The officer was about to be deployed to Kuwait for a year and was struggling to say "good-bye." I listened as both men were in tears talking about their time together in the military and the close bond they developed. It was gut wrenching to hear my daughter's husband ask his former commander that if he passes away while the Sergeant Major is still in Kuwait, will he be able to come back for his funeral. He went on to say, wiping tears on his sleeve, that there is no other person that he wants to speak at his funeral than the man who was his first captain upon joining the military. With tears pouring from his eyes, Sergeant Major explained that he already made arrangements just in case.

That was 2-1/2 years ago. With immunotherapy keeping my beloved son-in-law alive for now, those two have had more time together as well, but more on that later.

I soon learned the horrifying meaning of two simple words: "Burn Pits." The only thing, which even remotely explains his type of Cancer and his extremely rare autoimmune disorder is the burn pits he was near when he was in Iraq on guard duty near one of Saddam's palaces for a period of 3 months. He is an army medic and was stationed at a clinic on Camp Liberty, but at some point during his time there and he wrote me letters and emails explaining as much. He was pulled from medic duties and given orders to stand guard near one of Saddam's palaces located on Camp Victory and near military headquarters. While Camp Liberty was nicknamed "Camp Trashcan" in honor of their notorious burn pits, Camp Victory was also well known for huge infernos of burning trash. Most days for a period of 3 months, this soldier was forced to stand in an area very close to the edge of a burn pit. If the smoke blew his way, he couldn't leave. His duty was to watch out for and protect the defense contractors working the pits. Learning the hows and whys, he was exposed to a plethora of toxins every day for 3 months was mind boggling to me and quite frankly, pissed me off. It's unconscionable that our military commanders would turn a blind eye and ignore the fact that my family member was being poisoned. Believing that our country learned a tough lesson after the Agent Orange disgrace, man was I wrong. In the months moving forward I felt as if I was a zombie walking around in a science fiction movie where for some whacked out reason our government leader's unleashed chemical weapons on our own troops in Iraq. Watching this hypothetical movie, one would be relieved, thinking, "This could never happen because it's so stupid." But it did happen and it's worse than stupid. It's horrifying and criminally negligent and there are no words enough to describe the anger, heartbreak and disgust at how our country could perpetrate actions so deadly onto our war heroes. And in turn, not do everything humanly possible to take care of them after they return home. I've never seen an ounce of shame or remorse from anyone associated with the military other than Lt. Col Dan Brewer, a military environmental engineer who was tasked with testing the air quality at just about every burn pit in the Middle East. Brewer's warnings were brushed aside. So they KNEW! They KNEW soldiers were being poisoned, the proof was there. Any intelligent individual would say, "This is good! They know!! Now they will stop the practice of open burning all trash." But they DIDN'T!!! As a taxpayer who helped fund the poisoning of American soldiers I feel so much shame that America did this. A country I love and has so many things to be proud of, but not everything we do is good; and the bad things need desperately to be acknowledged before that shame can be fixed.

Eventually, the oncologist was able to get the cancer under control with chemo and radiation before starting immunotherapy treatments that he still undergoes to this day. However, we know immunotherapy is not a cure, but if he continues responding to it, it does shrink the cancer and slows down the progression. It will not be gone though. It will buy him time and quality of life. And it surely has. There are good days and there are bad days. My son-in-law never has a completely comfortable day and I wish he could. He puts up with more than a person should have to, but he is blessed to have more time on this earth with his family and friends and most importantly, his 6 year old daughter, Brielle. The anger, the depression, the worry, the fear, having faith, praying, the roller coaster ride is like nothing I can imagine anyone having to experience. Surgeries, ER visits, countless treatments, countless imaging, countless meds, everyday nose bleeds, the hair loss, the throwing up, the shortness of breath, the fatigue, the extensive sleeping, the insomnia, the gaining weight, the heart racing, the headaches, the blisters, the skin reactions, the bad news, the good news, the lack of feeling like you are a person or even the lack of feeling you are in your body at all. This is the whirlwind of a nightmare my children have been living for the past 2-1/2 years. And this is not a person who was dealt a bad hand and got cancer. THIS WAS DONE TO HIM!!! He should be looking forward to taking his daughter to school and gymnastics classes and planning vacations with his wife and daughter, but instead, he must spend most of this time and energy fighting for his life.

On top of that I learned that the VA and Dept. of Defense refuse to acknowledge that the toxic infernos in Iraq caused his and thousands of other veterans' diseases and that absolutely made my blood boil. Because my loved one was still active duty, his care has been phenomenal and first rate most of the time, however, once I heard of and met other veterans who have been denied benefits even though they are seriously ill was just mind boggling to me. Why on earth would we not take care of our soldiers and sailors who willingly volunteered to fight for all of us? It is all of our responsibility to take care of every single war hero suffering and dying from war wounds, be they physical, invisible or toxic wounds making them "delayed" casualties.

Reading the stance on the Veterans' Administrations website over 2 years ago infuriated me so much so it was making me sick: "At this time, research does not show evidence of long-term health problems from exposure to burn pits. VA continues to study the health of deployed Veterans." I knew in an instant that this was a slap in the face to all Middle East war veterans who lived on bases with burn pits. You don't have to be a genius to KNOW that burning the vast array of toxic causing substances and waste such as: Asbestos, medical waste, human remains, animal remains, plastics, rubber, military vehicles, munitions, explosives, chemical weapons, pesticides, gasoline, lp tanks, batteries, Styrofoam, aerosol cans, expired medications, human waste, mattresses, 50 gallon metal drums, oil, adhesives and containers, paint cans, and coated electrical wire... that anyone exposed to and inhaled the smoke daily, for weeks, months and even years is highly likely to become seriously ill and die. This remains the VA's stance despite numerous other studies and information that prove burn pits, were in at least some cases positioned so all smoke traveled downwind toward soldiers' living areas, some being as close as one quarter of a mile. This remains the VA's stance even though there's evidence that burn pit emissions contain particulate matter, sulfur oxides, carbon monoxide, volatile organic compounds and various irritant gases, and according to the American Lung Association, even short exposures can kill for vulnerable persons and long term exposures are dangerous for everyone. Inhalation of particulate matter air pollution can lead to premature death from respiratory and cardiovascular causes, including strokes. Burning materials that the military disposed of in the burn pits produces chemicals associated with immune dysfunction, IQ deficit, reproductive abnormalities, nose and throat cancer liver and kidney disease and leukemia. This remains the VA's stance even though there's evidence of what kinds of trash was incinerated in open air toxic infernos including chemical weapons.

What I would like to know is, "Is there any evidence that definitively shows burn pit exposure DOES NOT cause long-term health problems?"

My stomach hurt every day and the nausea wouldn't quit. For about a month the pain felt as if someone kicked me in the gut and then turned around and denied they did it until I found the only way to ease my pain was to become active in fighting for Burn Pits Veterans. My son-in-law and daughter have been reluctant and scared to speak out on their own behalf because he is active duty. The separation process has begun and fortunately his current Captain has been fighting for him to get the benefits he deserves even though the chain of command on the other side is trying to force him to accept retiring with the least amount of benefits... a regular military retirement with much less benefits than a medical and disabled due

to combat injuries retirement. Fortunately, for the Sergeant Major mentioned earlier, he copied and saved all of my son-in-law's deployment records. It's outrageous that we just learned in this retirement battle that shortly after his lung cancer diagnosis, some of his deployment records disappeared. I had heard that from my Congresswoman's veteran affairs staff member as he told me early on to make sure we had copies of his records, but as far as we knew, his stayed intact when actually they hadn't.

It's a disgrace that a dying active duty soldier can't even speak out on his own behalf because he fears retaliation and will be denied the compensation and benefits he's earned. Even though he has followed the letter of "military law," they are still trying to screw him over. It's outrageous and my anger is such that I've become consumed by burn pits. My granddaughter's daddy will be officially retired very soon and he will at that time speak to anyone who is truly interested in hearing his story. In my opinion he is a cut and dried case with absolutely no doubt of proof that burn pits have given him a death sentence.

The anger has caused me to become consumed with burn pits so two years ago I began searches to educate myself and learn everything I could about them. My research began on the obvious place, the internet, everything burn pits and here is what my research has showed and some of what I've learned along the way:

Burn Pits 360 Veterans Organization is the only veterans group solely focused on burn pits issues and I am fortunate to have them be one of my first discoveries on my initial burn pits internet search, reaching out to them and joining their cause. I am now the Ohio Advocate for Burn Pits 360 and it was through them that I first learned that thousands of our servicemembers have come back from Iraq and Afghanistan and have experienced a constellation of debilitating, chronic ailments. Many of them served around open air burn pits where thousands of pounds of trash was burned daily. Much of this trash was known to be toxic such as: plastics, batteries, paints and solvents, and much more. Despite the connection we feel research does support between our servicemembers' illnesses and the burn pits, they are being denied specialized healthcare, disability claims and death benefits at an extraordinarily high rate.

For these reasons Burn Pits 360 has for over a decade been lobbying Congress to pass legislation that would force the VA to acknowledge that there is a connection between burn pits and many serious, chronic and terminal diseases. The research is there. We don't need more research. In fact, Burn pits 360 was a force behind Congress forcing the VA to construct the Burn pits Registry, which does nothing, by the way, but list potential burn pit victims. The VA registry alone does not assist anyone and not all Iraq and Afghanistan Veterans can be on it, mainly because their deaths occurred before 2014.

Burn pits 360 started their own registry and has over 6,000 veterans signed on. Our data has been used several times for credible research and their results are astounding. What we need is for the DOD to acknowledge results from years of research from brilliant doctors and researchers like Dr. Anthony Szema and Dr. Robert Miller. Even air quality studies by military bioenvironmental engineers like Lt. Col Darrin Curtis and Lt. Col. Dan Brewer are being ignored by military and VA officials. **THE RESEARCH IS THERE. NO MORE RESEARCH IS NECESSARY TO START HELPING THE VETERANS NOW.**

It is imperative that Congress moves to solve this problem so that servicemembers, veterans, and their family members get the support they need and are entitled to. Supporting and writing a Senate Companion Bill to proposed legislation proposed earlier this year is a first step toward making sure that happens. Let's end the policy of "delay, deny and wait till they die." Those House Bills are:

1. Family Member Access to Burn Pits Registry Act (H.R. 1001) This Act would allow family members of deceased Servicemembers who suspect the death was a result of a burn pit exposure caused illness to participate in the Airborne Hazards and Open Burn pit Registry on their behalf with new registry entries. Current rules don't allow family members access, therefore many soldiers who passed away prior to the 2014 enactment of the registry are not included.

2. Burn Pits Revision Act (H.R. 1005) This Act would require the Department of Veterans Affairs to establish a diagnostic code and evaluation criteria for Constrictive Bronchiolitis.

There are a few doctors out there doing lung biopsies on sick soldiers and are finding titanium and copper elements in the soldiers lungs, which they have been able to tie it back to burn pits in Iraq and Afghanistan but military officials refuse to accept those studies.

3. In 2006, Air Force Lt Col Darrin Curtis commissioned a study at a Balad burn pit which was done by the US Army Center for Health Promotion and Preventative Medicine showing results as being labeled by an assessment team member as “the worst environmental site I have personally visited.” Curtis wrote in his memo: “It is amazing that the burn pit has been able to operate without restrictions over the past few years without significant engineering controls being put in place. I would hope in the future that issues such as burn pits are identified early on and engineering controls such as incinerators would be used to mitigate these hazards. It seems that money has been the issue of why engineering controls are not currently in place.” And: “In my professional opinion, there is an acute health hazard for individuals. There is also the possibility for chronic health hazards associated with the smoke. It is my recommendation that engineering controls, such as the anticipated incinerators, should be expedited to solve this problem. In my professional opinion, the known carcinogens and respiratory sensitizers released into the atmosphere by the burn pit present both an acute and a chronic health hazard to our troops and the local population.”

While everything burn pits is horrifying and incredibly disturbing to me, this is one of the studies that really hurts because it was completed right before my son-in-law landed in Iraq. It is my understanding that this memo warning of health risks from inhaling burn pits smoke was immediately classified and no action was taken to protect soldiers and Iraqis from the danger.

4. Thousands of our servicemembers have come back from Iraq and Afghanistan and have experienced a constellation of debilitating, chronic ailments and rare, terminal cancers. Many of them served around open air burn pits where thousands of pounds of trash was burned daily. Much of this trash was known to be toxic such as: plastics, batteries, paints and solvents, human remains and much more. Despite the connection between our servicemember’s illnesses and the burn pits, they are being denied specialized healthcare, disability claims and death benefits at an extraordinarily high rate.

I realize there has been toxic exposure legislation passed and also more pending but none of it is moving fast enough to help veterans being denied healthcare.

5. From the Atlanta Journal Constitution, April 25, 2019

This quote infuriates me because I know there’s plenty of SCIENCE and research out there to give credence to a long list of burn pit presumptive illnesses—“We continually look at the research and follow trends since some diseases, such as a cancer, have a long latency period,” VA spokesman Terrence Hayes said in an email. “At this time, science does not support making burn pit exposure a presumptive condition for any illness.”

Seriously, is this acceptable? 1/5th ??? And many veterans I’ve conversed with feel that the VA will grant one condition but give only a small percentage disability rating if any in efforts to pacify the veteran and make them give up appealing the decisions. Still, the agency has approved some disability compensation claims that had at least one condition related to burn pit exposure. From June 2007 through March of this year, the VA processed 12,378 of them. Of those, 2,425—or a fifth—had at least one burn pit condition granted, according to the VA.

6. The VA is doing a serious injustice to war veterans by not facilitating benefits and services that they are entitled to and rightly deserve by keeping a burn pits registry that disallows changes and updates in health conditions. Once the veteran is registered even a death entry cannot be made if he or she dies.

7. I couldn’t believe and was stunned to learn that no environmental laws were being practiced overseas. It seemed like the manuals for disposing of waste whether they be EPA guidelines or from another entity evidently were just tossed in the burn pits unread.

8. And even more unsettling was realizing there is that there is seems to be a repetitive expression of insensitivity and neglect by the government when it comes to caring for soldiers harmed by actions approved by top military commanders. This happened to Vietnam Veterans and now is continuing throughout the wars in Iraq and Afghanistan. Though the DOD does admit that soldiers were constantly exposed to heavy smoke and ash from the burn pits in those war zones, it continues to deny that this massive exposure in any way harmful to the men and women serving on those bases as stated in a pamphlet made available to military personnel back in July 2008. The brochure gave assurances that “Under most conditions, breathing smoke from burning trash and human waste does not result in any significant risk to short—or long-term health issues.” The pamphlet went on to say that “smoke from burning trash or human waste” was usually made up of relatively harmless “heated gases including carbon monoxide and dioxide, water vapor, and fine particulate matter and hydrocarbons.”

A year later, the U.S. Government Accountability Office (GAO) published its burn pits report detailing what was burned at the Balad base burn pit in Iraq which pretty much was anything and everything imaginable that we know not to burn like, rubber, batteries, medical waste, human remains, plastics and so much more. The Balad pits burned about 147 tons of trash a day, seven days a week for seven straight years and no regulations at all. What's even more alarming about the Balad pits is that they were built on and around a mustard gas facility yet contamination in the soil was never tested after the U.S. bombed the site.

9. The fact that the British military hired Iraqis to install incinerators on their bases, but what I don't know is if anyone has "researched" the health on soldiers living on those bases. If the claims by the DOD that the sand/dust storms and other uncontrollable pollution is the cause of so many deaths and chronic diseases then why hasn't anyone suggested finding out about the health of soldiers who weren't exposed to toxic burn pits but were exposed to the other elements suggested by the U.S. DOD? If the Brit veterans aren't as sick, wouldn't that be another check in the box that burn pits are responsible for many of our soldiers' rare and terminal chronic diseases?

That brings me to another outrage: How does the wealthiest, greatest, most powerful military in the world decide that installing incinerators would not be cost effective? What price do we put on keeping our men and women in uniform safe and healthy even AFTER they leave the other obvious dangers of a warzone?

I'd like to add that the cost of installing incinerators should pale in comparison to what healthcare costs for thousands upon thousands of seriously and terminally ill veterans will be. But then again, maybe not because most of the war heroes aren't being taken care of by the VA.

10. Several studies and leaked memos that the Pentagon has tried to hide have surfaced. Attached are a few of them.

1: Leaked Memo: Afghan Burn Pit Could Wreck Troops' Hearts, Lungs

2: Lt. Col. Darrin Curtis memo, i.e., Balad Air Base Iraq

3: Dr. Anthony Szema's statement to the Senate Democratic Policy Committee Hearing, "Are Burn Pits in Iraq and Afghanistan Making Our Soldiers Sick?" on Friday, Nov. 6. 2009

11. I know that there are over 3600 Ohio veterans registered on the VA's Burn Pit Registry and that there should be many more.

12. It is terribly unjust and sad for the soldiers that they aren't awarded Purple Hearts for suffering from toxic wounds of war. It's sad to know that one day when the Iraq War Memorial is constructed in our Nation's Capital that my grand-daughter's daddy's name won't be on it. It's a disgrace that Burn Pits Veterans are not counted as the casualties of combat and war as they should be.

In conclusion, I don't think anybody in Washington would be comfortable if there was a 10-acre pit in their backyard where they were burning blown-up Humvees, car paint cans, unused pharmaceuticals, human remains, pesticide containers, plastics, chemical weapons and rubber. I beg you to don't let open air burn pits continue on any overseas or homeland bases. Give our soldiers clean water. Follow all EPA/OSHA regulations just as civilians would! They aren't animals, this isn't a Third World country! Take care of our own!!! If you aren't going to expose yourselves to it than don't expose our loved ones to it!!! If I came and burned all of these things a few yards from your home every day I would be arrested. Don't do it to our military!!! Just STOP POISONING OUR SOLDIERS!!!

The military is still utilizing burn pits overseas!!! Who is next to be stricken with a debilitating disease because of this toxic exposure? You grandchildren, your nieces, your nephews, a friend, a neighbor, or someone else you know who could have their life put in jeopardy for what reason? To save money? Veterans and we family members and caregivers need our voices heard. We need, you, our senators to step up and let our voices be heard, but not only do our voices need to be heard, but you have to have an open heart to feel what we are going through in order to not allow this to happen to our own any more. You need to take care of our soldiers who have fought so unselfishly for our lives and this includes all of you in Congress. You all need to hear our voices!

Our military volunteer to go into war and enter in to a special Brotherhood/Sisterhood, so that civilians don't have to in order to continue our independence and freedoms. They know they may die from being shot or blown up, but they certainly don't sign up to be poisoned by their own commanders. They don't expect that when they come home from war they may battle a whole different monster and end up fighting for their lives on our own turf after the war is done!!!

Now, take care of them and don't let open air burn pits continue on any overseas or homeland bases. Give them clean water. Follow all EPNOSHA regulations just

as civilian would! They aren't animals, this isn't a Third World country! Take care of our own!!! If you aren't going to expose yourselves to it than don't expose our loved ones to it!!! If I came and burned all of these things a few yards from you every day I would be arrested. Don't do it to our military!!!

And yes this is 2019!!! This should have been taken care of a long time ago!!! We know what cancer causing agents are and that it is unsafe to smoke cigarettes and be next to a fire with everything you can think of being burned in it! There is no excuse in the entire world for not installing incinerators and properly disposing of waste.

There needs to be a bill for those affected by the burn pits, so that you can sue the DOD and contractors for negligence in exposure to burn pits.

There needs to be a law not allowing a monopoly for contractors to be hired to complete jobs with the DOD resulting in politicians benefiting and profiting from their companies receiving the contracts.

This problem is just beginning. The illnesses are just now starting to manifest themselves. We don't need any more damn research. The research that supports the dangers of inhaling toxins and its effects on the human body are already well documented and accepted science. We already have the Agent Orange debacle. We already know the rate of cancers among fire fighters is tremendous, and they wear PPE and suffer high exposures for limited amounts of time. Those who were exposed to the Burn Pits suffered heavy to moderate exposures for months, sometimes even years with multiple deployments. The items burned in the Burn Pits you would find in your home and then some. We don't burn waste here in the States because we already know breathing toxins produce long term negative health effects, cancers, respiratory ailments and so on. We require incinerators for that reason. This is simply outrageous what they are doing to all of them.

American and other countries soldiers were knowingly, willingly and unnecessarily exposed to the toxins from the Burn pits. The evidence of this negligence is overwhelming with what we already knew, and with the air quality samples taken, the memos written since around 2003 warning of the long term health effects of this. This is a national disgrace to treat people who willingly signed up to serve and went down range like this.

Pass This Bill:

- Any American Citizen who was exposed to the toxins from the Burn Pits and been diagnosed with an illness related to them will get any and all medical they need.
- Any American Citizen who was exposed to the toxins from the Burn Pits should receive immediate compensation for their injuries.
- Any American Citizen who was exposed to the Burn Pits should receive a monthly pension in addition to the compensation. The pension should be equal to or greater than the amount of the livelihood they had lost due to the illness inflicted on them.

My husband and I were honored to receive an America flag that was flown in our honor over the military headquarters on Camp Victory in Iraq and was presented to us from our son-in-law as a thank you for the support we gave him while he was deployed to Iraq. Not wanting the flag to be weathered or tattered we decided we would fly it on our front porch on strictly military holidays, like Memorial Day, 4th of July, Veterans' Day, etc. As Memorial Day approached in 2017, my husband asked me, "Should I get out the Iraq flag?" and his words hit me like a ton of bricks.

You see when our son-in-law explained to us his close proximity to the burn pits for those 3 months, he mentioned that it was something he emailed me about back then, because he wasn't happy to be pulled from medic duties. So, I asked him if Saddam's Palace was the military headquarters where our flag flew in our honor and he replied, "Yes."

My heart sunk as I realized I was holding in my hand a now symbol and reminder of the EXACT LOCATION my son-in-law was severely poisoned and that symbol had flown there in my honor. I was devastated and we haven't flown that particular flag yet. It's been a war in my head as to what to do with it. Have it destroyed, put it in the attic and forget about it. I feel like my support while he served our country is tainted now so I tried to come up with ways that I could feel good about that flag again and do it in his honor: I would fight to get a congressional hearing where veterans impacted by burn pits could have their voices heard and if I accomplish that goal I will gladly fly that flag again in his and all other burn pit victims' honor.

My heart is broken that my goal was not accomplished today and my flag will remain in a box and out of sight.

Thank you for taking the time to read my statement and for hosting this very important hearing. What our veterans need now is action to get them help ASAP. They don't have years to wait on more research. They are dying now with many already dead. Please work on Senate bills to correspond with H.R. 100 I and H.R. 1005. Schedule more hearings and bring in veterans who are afflicted and affected by burn pits. These are the men and women who you should be listening to. You can't pass legislation that takes care of their needs without giving them a seat at the table to express those needs. Not one burn pit bill already in effect or pending does anything to get burn pits veterans the healthcare they need right now. You must act NOW!!! Not tomorrow!!! Now!!!!

Sincerely,

SUSAN M. ZEIER,
SANDUSKY, OHIO.

Attachments (3)

ATTACHMENT #1

DEPARTMENT OF THE AIR FORCE
332D AIR EXPEDITIONARY WING
Balad Airbase, Iraq, 20 December 2006.

MEMORANDUM FOR 332 EAMDS/SGP FROM: 332 EAMDS/SGPB

SUBJECT: Burn Pit Health Hazards

1. The burn pit at Balad AB (Logistics Support Area Anaconda) has been identified as a health concern for several years in numerous after action reports, Standard Form 600s (Environmental/Occupational Health Workplace Exposure Data (EOHWED), attached) in addition to other Bioenvironmental Engineering continuity documentation. During the Environmental Health Site Assessments ducted January-April 2006 by the US Army Center for Health Promotion and Preventive Medicine (USACHPPM), open burning of solid waste was identified as the number two most common environmental health finding. Balad's burn pit was quoted as being "the worst environmental site I have personally visited, and that includes 10 years working RCRA/CERCLA clean-up for the Anny and DLA," by one of the assessment team members.

2. We have not yet been able to quantify contaminants that exceed the Military Exposure Guides (MEG) for most of the chemicals of concern. This data gap is a result of our inability to collect "worst case" data due to the dynamic nature of the burn pit's plume. Contributing to the difficulty of conducting a thorough scientific investigation are ongoing ground and air combat operations and the remoteness of the base. Army Technical Guide (TG) 230 specifically states that the guidance in TG 230 is not a "substitute for having trained preventive medicine personnel onsite or in theater."

3. The Air Force documents exposure to the burn pit for those stationed at Balad AB as an environmental health hazard by placing detailed information in each Airman's medical record during their post-deployment medical outprocessing. This is a permanent part of their medical record and is a mandatory document that assists the Air Force in complying with Presidential Review Directive 5. It is amazing that the burn pit has been able to operate without restrictions over the past few years without significant engineering controls being put in place. I would hope in the future that issues such as burn pits are identified early on and engineering controls such as incinerators would be used to mitigate these hazards. It seems that money has been the issue of why engineering controls are not currently in place.

4. The smoke hazards are associated with burning plastics, Styrofoam, paper, wood, rubber, POL products, non-medical waste, some metals, some chemicals (paints, solvents, etc.), and incomplete combustion by-products. A list of possible contaminants includes: acetaldehyde, acrolein, arsenic, benzene, carbon dioxide, carbon monoxide, dichlorofluoromethane, ethylbenzene, formaldehyde, hydrogen cyanide, hydrogen chloride, hydrogen fluoride, various metals, nitrogen dioxide, phosgene, sulfuric acid, sulfur dioxide, toluene, trichloroethane, trichloropropane, and xylene. Many of these chemical compounds have been found during past air sampling. Burn pits may have been an acceptable practice in the past, however today's solid waste contain materials that were not present in the past that can create hazardous compounds such as those listed above. Open pit burning may only be practical when it is the only available option and should only be used in the interim until other ways of disposal can be found. This interim fix should not be years, but more in the order of months.

5. In my professional opinion, there is an acute health hazard for individuals. There is also the possibility for chronic health hazards associated with the smoke; thus the information is being made a permanent part of each Airman's medical record. I base this assessment on the data that I have reviewed and on-site smoke plume assessments (boots on the ground). My background includes a Doctor of Philosophy in Engineering (Environmental), registered and licensed as a Professional Engineer in Arkansas and Utah, respectively, and seventeen years of conducting health risk assessments.

I am writing this memo to translate what I see is an operational health risk to those that have been, are now and will be deployed to Balad AB (LSAA). It is my recommendation that engineering controls, such as the anticipated incinerators, should be expedited to solve this.

DARRIN L. CURTIS, LT COL, USAF, BSC,
Bioenvironmental Engineering Flight Commander.

cc: 332 EAMDS/CC

20 Dec 06

1st Ind., 332 EMDG/SGP

MEMORANDUM FOR 332 EMDG/CC

I concur with Lt Col Curtis' risk assessment. In my professional opinion, the known carcinogens and respiratory sensitizers released into the atmosphere by the burn pit present both an acute and a chronic health hazard to our troops and the local population.

JAMES R. ELLIOTT, LT COL, USAF, MC, SFS,
Chief, Aeromedical Services.

cc: CENTAF(F)/SG Bioenvironmental Engineer

ATTACHMENT #2



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
COMBINED JOINT INTERAGENCY TASK FORCE (CJIATF)-435
TASK FORCE PEACEKEEPER
BAGRAM AIRFIELD, AFGHANISTAN
APO AE 09354-0998

CJIATF-435-TFPK-MED

15 April 2011

MEMORANDUM FOR RECORD

SUBJECT: Air Quality Summary on Bagram Air Field (BAF)

1. The purpose of this memorandum is to summarize the results of air samples taken here on BAF, which includes Camp Sabahu-Harrison, and the potential long term effects that the air quality here may have on Service Members. Results of air samples taken over approximately the last eight years indicate that there may be an increased risk of long term adverse health conditions as a result of the poor air quality here on BAF.
2. Preventive Medicine (PM) teams take weekly air samples of Particulate Matter 10 and 2.5 micrometers in size (PM₁₀ and PM_{2.5}). U.S. Army Public Health Command analyzes the air samples and summarizes them in the *Periodic Occupational Exposure Monitoring Summary* (POEMS). The draft POEMS for Bagram Air Field (BAF), Afghanistan covers the 2002-2010 time period. According to the draft POEMS, the average air quality for PM₁₀ and PM_{2.5} was 302 µg/m³ and 110 µg/m³ respectively. The National Ambient Air Quality Standard set by the Federal Government for PM₁₀ and PM_{2.5} is 150 µg/m³ and 35 µg/m³ respectively. The Air Quality Index associated with the levels summarized for the average concentration here on BAF during the time period in the draft POEMS for PM₁₀ and PM_{2.5} is 174 and 177 respectively. Per U.S. Environmental Protection Agency standards, air quality indexes in the range of 151-200 are considered "Unhealthy".
3. The primary contributor to the elevated PM₁₀ and PM_{2.5} was a burn pit which services the trash generated on BAF with a population of up to 40,000 Service Members and contractors. Throughout the deployment the burn pit smoke plume drifted over the LSA exposing Service Members to increased air contaminants.
4. The long term health risk associated with air conditions on BAF from PM_{2.5} and PM₁₀ indicates there is a potential that long-term exposure at these levels may increase the risk for developing chronic health conditions such as reduced lung function or exacerbated chronic bronchitis, chronic obstructive pulmonary disease (COPD), asthma, atherosclerosis, or other cardiopulmonary diseases. This does not mean that service members that served on BAF will acquire adverse long term pulmonary or heart conditions but that the risk for such is increased.
5. If service members feel they have developed adverse health conditions due to something they were exposed to during their deployment, they should seek medical advice from the Veteran's Administration health care facilities in their local area. The medical providers at these facilities will have access to the data compiled by Public Health Command and will be able to make a determination if the adverse health condition that the service member is concerned about is a result of the exposure they received during their time on BAF.
6. The point of contact for this memorandum is the undersigned and can be reached at 318-481-9063 or gerold.m.pratt@afghan.swa.army.mil or mike.pratt@us.army.mil.


G. MICHAEL PRATT
CPT, MS
Environmental Science Engineering Officer
Preventive Medicine OIC

ATTACHMENT #3

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SENATE DEMOCRATIC POLICY COMMITTEE

“ARE BURN PITS IN IRAQ AND AFGHANISTAN MAKING OUR SOLDIERS SICK?”

Good morning. My name is Dr. Anthony Szema. Thank you, Senator Dorgan, for the opportunity to testify. I am the Head of the Allergy Diagnostic Unit at Stony Brook University Medical Center in New York. I also serve as an Assistant Professor of Medicine and Surgery at SUNY Stony Brook School of Medicine and the Chief of the Allergy Section at the Veterans Affairs Medical Center in Northport, New York. I received my undergraduate degree in Industrial and Management Engineering from Rensselaer Polytechnic Institute in Troy, NY, and my medical degree from Albany Medical College in Albany, New York. I completed three fellowships at Columbia University in pulmonary diseases, critical care medicine, and clinical and adult and pediatric allergy/immunology.

I am testifying today in my personal capacity and do not in any way represent the interests, beliefs or opinions of my employers.

It is common sense and widely known that smoke from any fire can affect health. There is an extensive body of research on the dangers of smoke inhalation. Trash should not be burned because it can cause harmful air pollution. The contents of smoke depend on the trash, temperature and oxygen available. There are short- and long-term health consequences associated with exposure to fire, smoke and fumes. The synergistic impact from the combination of burning chemicals is unknown. Soldiers acutely exposed near the burn pits may have burning eyes and nose, nausea, headaches and asthma-like symptoms.

Incinerators may provide a healthier alternative to burn pits in Iraq and Afghanistan because they burn trash at higher temperatures, which create less harmful smoke than the burn pits. Ten pounds a day of trash from a household burn barrel may produce as much pollution as a modern, well-controlled incinerator burning 400,000 pounds of trash a day. Harmful smoke may also be reduced by recycling plastic, paper, metal, glass, ink cartridges and by installing EPA-compliant bio-hazard waste measures for medical waste.

Burning anything leads to particulate matter (PM) which is inhaled and toxic to the lungs and heart. The size of particulate matter is important to consider because the particles act as a carrier of various harmful chemicals in the air. The smaller the particulate matter, the deeper the particles are able to travel into the lungs. PM 10 are larger particles which can be trapped in the nose, whereas PM 2.5 and ultrafine PM are able to enter the lung alveoli or air sacs. PM 2.5 and ultra-fine PM are particularly harmful to human health. Not only is there a risk of asthma, bronchitis, and emphysema with ultrafine PM, but there is also an association with respiratory and cardiovascular mortality—death—from inhalation of ultrafine particulate matter. Particulate matter levels are especially bad if they are high, but particulate matter may even be worrisome if levels are low. The toxicity depends on the composition of the particulate matter itself. For example, is the particulate matter acting as a carrier of black carbon or arsenic? Particulate matter levels should always be considered when performing air sampling to measure air quality.

The US Army Center for Health Promotion and Preventive Medicine (CHPPM) did not include data about particulate matter PM 10, PM 2.5 or ultra-fine PM levels in their May 2008 analysis of the air quality at Balad Air Base in Iraq. PM 2.5 and ultra-fine PM should have been a large component of CHPPM's analysis. CHPPM also failed to conduct comprehensive testing at any other bases using burn pits in Iraq and Afghanistan, so we do not have information about air quality at those bases.

When I think of air pollution, the first issue I think of is the level of PM 2.5 and the potential toxins these could be carrying. Inhalation of PM air pollution can lead to premature death from respiratory and cardiovascular causes, including strokes. Inflammation and reduced lung function may even be seen in lung tissue from healthy adults. Year-round exposure to PM has been associated with small airway disease and increased risk of dying from lung cancer and cardiovascular disease. Reduction in PM 2.5 by 10 $\mu\text{g}/\text{m}^3$ is associated with reduced mortality risk.

Individuals have reported uncontrolled burning of waste in the burn pits in Iraq. The chemicals generated from slow, low-heat burning present a variety of health risks. The type of plastic (PVC) used to make plastic bottles produces dioxin and hydrochloric acid when burned. These chemicals are associated with immune dys-

function, IQ deficit, and reproductive abnormalities. Polystyrene foam cups can be a source of carcinogens including dioxin, benzene, styrene and furans when burned. Chromated copper arsenate (CCA)-treated wood contains pro-carcinogenic arsenic. Bleached or colored paper contains harmful chemicals. Bleached paper contains halogenated hydrocarbons and furans associated with leukemia and liver disease. Colored paper contains heavy metals like lead and cadmium associated with blood, liver and kidney disease. Particle board and plywood release formaldehyde when burned; this is associated with nose and throat cancer, as well as liver and kidney disease and airway inflammation. Cardboard used for packaging of foodstuffs may contain fungicides which are associated with neurological disorders. The variety of materials burned at the burn pits in Iraq produces an enormous array of chemicals which may plausibly combine when burned to produce unknown dangers.

The location and time during which air sampling occurs can largely impact the results and reliability of those tests. I think of this as garbage in, garbage out. If the sampling equipment, location of testing and timing are not performed properly, one will not gather accurate information and will not be able to provide a confident analysis of the results. The May 2008 CHPPM report included analyses based only on testing conducted from January to April 2007. This was partly conducted during Iraq's rainy season and did not include any measurements from the summer. The results could not reflect a year-long exposure to the smoke from the burn pit because of the changing weather conditions. This would be like testing for snow in Albany, NY, during the summer. Testing will not detect any snow, but this does not mean that it does not snow in Albany.

With regard to location, if the wind typically blows the fumes away to the north, this does not mean that a lack of detection in monitors placed to the south means that the air is safe to breathe. The timing of the testing is also relevant because numerous materials were burned in the pits. If you tested during a time when medical trash was not burned, then you would not detect the toxins emitted from this type of burning, including lead, mercury, and furans. The testing does not tell us anything about the air quality before or after the burning occurred. Individuals exposed to burn pit fumes in 2004 may have experienced worse conditions than those in 2007. It is also important to analyze the ashes and dust in a burn pit pile after materials have been burned. This dust may contain toxins which are not detectable by airborne collection methods.

In my practice as an allergist and pulmonologist at the Veterans Affairs Medical Center in Northport, NY, the demographics of the patients I typically see have changed since 1997. Until 2004, I mostly saw 80-year-old veterans. However, from 2004 to the present, I have begun seeing young women and men who were previously healthy athletes capable of passing basic training and performing combat duty. Now these individuals suffer from a variety of respiratory illnesses, including asthma and difficulty breathing during exertion, and are not fit for continued military duty. This is an alarming trend.

In 2008, I presented data at the American Thoracic Society International Conference showing high new-onset asthma diagnosis rates among soldiers deployed to Iraq. I performed a study of veterans who served in Iraq and were treated at the Veterans Affairs Medical Center in Northport, NY, from March 2004 to May 2007. Our study was prompted by the fact that 13 percent of U.S. Army Medic visits in Iraq are for new-onset acute respiratory illness. We compared veterans who served in Iraq with those who served in the United States. After studying more than 6,000 veterans, we found that deployment to Iraq is associated with new-onset asthma. Individuals who have asthma are not allowed to serve in the military, but our data of soldiers returning from Iraq indicates new-onset adult asthma is diagnosed at twice the rate (10%) compared to stateside-based troops (5%). Even when stratified by age groups, the higher risk for asthma still holds. Our findings are not surprising given that a survey of 15,000 military personnel deployed to Iraq and Afghanistan found that nearly 70 percent reported experiencing respiratory illness during their service. Of these, 17 percent required medical care.

It is important to understand that occupational asthma from phthalates is subtle and is not detected with PM monitors. It may be assessed by known exposure, clinical symptoms, and physical examination of patients, physiology and skin testing. Also, many of the tests typically given to determine respiratory illness, such as spirometry, a pulmonary function test, are insensitive and may not detect the true nature of the illness. Dr. Robert Miller, a doctor at—Vanderbilt University, has performed a study of individuals exposed to a fire in Iraq in 2003. These individuals had normal CT scans and pulmonary function tests. Only by performing a lung biopsy was he able to properly diagnose most of his patients with constrictive bronchiolitis, likely from exposure to toxic smoke fumes.

Additional funded research is needed to fully understand the health implications for soldiers breathing the fumes from burn pit smoke, such as: 1) a university-based health research network, utilizing more sophisticated tertiary-care testing; and 2) basic research institutes at these health research sites to study the mechanisms of these new diseases in animal models and develop novel drugs to treat new, deployment-related diseases. These efforts may lead to health benefits for not only our military personnel but also for the general population.

In summary, you should not bum trash or inhale burning trash. There are short- and long-term health consequences associated with exposure to fire, smoke and fumes.

