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FOUNDATION OF CARE: EXAMINING RESEARCH AT THE DEPARTMENT OF VETERANS AFFAIRS

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS UNITED STATES SENATE

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FOUNDATION OF CARE: EXAMINING RESEARCH AT THE DEPARTMENT OF VETERANS AFFAIRS

WEDNESDAY, NOVEMBER 1, 2023

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

The Committee met, pursuant to notice, at 3:42 p.m., in Room SR–418, Russell Senate Office Building, Hon. Jon Tester, Chairman of the Committee, presiding.

Present: Senators Tester, Brown, Blumenthal, Hirono, Manchin, Sinema, Hassan, King, Cassidy, Blackburn, and Tuberville.

OPENING STATEMENT OF CHAIRMAN JON TESTER

Chairman TESTER. I'll call this hearing to order. Good afternoon everybody. This hearing is on research activities of the VA. While veteran oriented research is an integral part of veteran specific care, the product of VA's research clearly impacts each and every one of us. For decades, VA has been at the forefront of our Nation's research efforts. Because of their work, we have access to new and innovative cancer treatments, life-saving vaccines, the pacemaker, and others.

VA remains in a unique position to spear breakthroughs in our medical and scientific knowledge, with access to data from the Nation's largest integrated healthcare system. We know countless lives depend on expanding our understanding of and treatment options for mental health conditions. That is why mental health treatment must always be a top priority of VA research. It has been three years since the passage of Commander John Scott Hannon, Veterans Mental Health Improvement Act, and just last year research provisions in the STRONG Act were signed into law.

These legislative accomplishments have a direct impact on research projects and funding, including in my home State and Matt Kuntz's home State of Montana. And in that regard, I want to welcome Matt Kuntz, who is a friend of Scott Hannon, the person that the John Scott Hannon Veterans Mental Health Care Improvement Act was named after. Matt Kuntz is the head of NAMI Montana. He has incredible knowledge of what goes on the ground, both from a VA perspective and a civilian perspective. He's also on the National VA Research Advisory Committee. Thanks for being here, Matt.

It's been over a year since we passed the Sergeant First Class Heath Robinson Honoring our PACT Act. This law sets up a frame-

work to better understand the illness, treatments, and connections between military service and toxic exposures. Now, while the PACT Act outlines specific research requirements, it also creates an interagency toxic exposure research working group.

This working group must guide future research efforts, such as the effect of toxic exposure on the descendants of veterans. Research must translate to real world improvements in veteran care. Veterans must have access to the newest and most current treatment options for conditions they're more likely to experience through clinical trials offered through VA.

And the VA needs to do more to ensure that our rural veterans, like those in Montana, are not left behind. This also requires the VA to prioritize research as a whole, ensuring that clinician researchers get an ample opportunity to expand our medical and scientific knowledge. I look forward to hearing from everyone here on how to best accomplish this critical mission. And if you'll just help me pause for a second.

[Pause.]

Chairman TESTER. Senator Moran is on his way. As you guys know, the reason I was late, and I think many of the others were late, is they were voting, and the ones that are here on time are voting now.

Senator TUBERVILLE. So we voted earlier.

Senator TESTER. It's exactly right. So I want to welcome our witnesses. We've got Dr. Rachel Ramoni. Doctor, good to have you here. You're the Chief Research and Development Officer for VA's Office of Research and Development. She is accompanied by Dr. Patricia Hastings. Patricia is the Chief Consultant of the Health Outcomes for Military Exposures Office and Sumitra Muralidhar. Sorry about that. I butchered it up pretty bad. She is the Program Director for the Million Veteran Project.

As I mentioned in my opener, we're also joined by Matt Kuntz, who's the Executive Director of the National Alliance on Mental Illness for the Treasure State. Dr. Ramoni, you may begin. You have 5 minutes, and please know that your entire written testimony will be made a part of the record.

STATEMENT OF RACHEL RAMONI ACCOMPANIED BY PATRICIA HASTINGS AND SUMITRA MURALIDHAR

Dr. RAMONI. Thank you so much, and good afternoon, Chairman Tester. On behalf of my colleagues, Dr. Patricia Hastings and Dr. Sumitra Muralidhar, I want to express our gratitude for the opportunity to discuss how VA's research programs improve the health of those who served, and express my gratitude for the wind that you put in our sails through the Hannon Act, and through the STRONG Act, and through the PACT Act.

VA's Office of Research and Development, which I am so privileged to lead, has the primary responsibility for managing the department's research appropriation and sets policy for department research activities. For nearly a century, VA has had a research program dedicated to enhancing the well-being of veterans through scientific discovery. We are embedded within the VA healthcare system, both operationally as well as culturally.

As an intermural program that exclusively funds eligible VA employees qualified to do research, the science we support is firmly grounded in the experience of clinicians and researchers working directly with veterans in 104 of our 170 medical centers nationwide. It is truly, truly an extraordinary system in which to conduct biomedical research. Our greatest distinction and honor, of course, is our mission to serve veterans.

Over 9 million former service members are enrolled in VA healthcare. Caring for these individuals and those who preceeded them has resulted in one of the richest healthcare data sets in the entire world. The VA informatics and computing infrastructure, also called Vinci, houses billions of records for over 25 million patients. Moreover, the Million Veteran Program Genomic Database is poised to achieve 1 million veteran contributors under Dr. Muralidhar's stewardship.

When our data powerhouse is paired with skilled researchers, modern scientific computing and analytic tools, and now the potential of AI, the opportunities for veteran centric discovery are vast. The Office of Research and Development's capacity to do good extends well, well beyond data science. We support the full range of research approaches, from basic science to rehabilitation research.

Today, VA researchers are fulfilling our mission through a range of impactful research, including shedding light on the impacts of military exposures, refining the diagnosis and treatment of brain and mental health conditions, and advancing precision cancer care.

VA research also plays an essential role in interagency efforts. We are deeply involved in the Cancer Moonshot, including co-leadership of working groups on decentralized clinical trials, that bring trials to veterans wherever they live, data and data safeguards.

In addition, as specified in the PACT Act, we have formed and are leading, as Chairman Tester mentioned, an interagency toxic exposures research working group under the Office of Science and Technology Policy. Every year, VA researchers make tremendous contributions to expanding our body of knowledge.

In fiscal year 2022, for example, our scientists authored nearly 14,000 research articles. Their work fuels the continuous cycle of research, evidence-based policymaking, clinical care and evaluation, which steadily improves veterans care. In the realm of military environmental exposures, Dr. Hastings' health outcomes and military exposures team is also integral to the process of using scientific evidence to inform policy and healthcare.

We thank you for your support with the PACT Act, which dramatically accelerated this work. The President's fiscal year '24 budget requests $938 million in appropriations for VA medical and prosthetic research to continue the investment in VA's capabilities as a national research enterprise sustaining your investments from prior years.

Research flourishes in the context of steady funding rather than in a setting of fluctuations between increasing and decreasing investment. Our research is conducted by highly specialized teams that can take years for a medical center to assemble. With the exception of the clinician researchers who lead research teams, most of the staff who conduct this research are hired on term or temporary basis rather than by permanent appointments.

This means that when funding contracts, those teams must be disbanded and their expertise is lost to the system. Your sustained investment is critical to ensuring that our vital research can continue as we address the physical, mental, and social needs of those who have borne the battle. We are so grateful for your enduring dedication and support.

In conclusion, I want to reiterate that at the heart of VA research lies our unwavering commitment to our veterans. Every discovery, every innovation, every advancement is a tribute to their sacrifices and a step toward fulfilling our mission to improve veterans' lives. I look forward to answering your questions.

[The prepared statement of Dr. Ramoni appears on page 25 of the Appendix.]

Chairman TESTER. Doctor, thank you for your testimony. Next we'll have Matt Kuntz from Montana. Matt, 5 minutes. Your entire statement will be part of the record.

STATEMENT OF MATTHEW J. KUNTZ

Mr. KUNTZ. Chairman Tester, Ranking Member Moran, and distinguished Members of the Senate Veterans Affairs Committee, on behalf of NAMI Montana, the National Alliance on Mental Illness for Montana, I would like to extend our gratitude for the opportunity to share with you our views and recommendations regarding veterans' healthcare research.

The entire NAMI community applauds the Committee's dedication, addressing the critical issues around mental health and veterans' suicide. I also express gratitude for the Committee's rescue of the VA's Research Program in the Cleland-Dole Act last year. Without the Committee's decisive action to prevent the bureaucratic conflict of interest implosion, VA research around the country would've shut down, and we would be having a much different hearing today.

As NAMI Montana's executive director, I serve on the NRAC Commission and have also served on the COVER Commission. I'm not speaking on behalf of NRAC or the COVER Commission today. Based upon that background and experience, I believe it's time for Congress to step in and give ORD clear legislative purposes, and realign its granting process to improve veterans' healthcare outcomes.

Specifically, I'm respectfully asking for two purposes and three funding categories, and I invite you to check my work. It's really easy to find the NRAC reports and ORD annual reports. It's about 60 pages annually a year. Some of the staff can read through 20 years in no time. And hopefully they'll see that I'm right.

The VAs ORD's current purposes are muddled by a variety of missions, objectives, and priorities. This lack of focus makes it difficult to determine what outcomes VHA, VA, ORD or its congressional funders are looking for.

So the purposes that I'm suggesting are, one, to serve veterans through large scale research and commercialization support in veteran specific healthcare areas such as toxic exposure, spinal cord injuries, prosthetics, and brain health, including mental health, suicide prevention, substance use disorders, and geriatric issues.

Two, to support implementation research and quality improvement throughout the Veterans' Healthcare Administration. Those purposes require a prioritization that I believe is necessary, and it leads to three categories of funding.

The first is large healthcare studies of veterans' issues, like the Million Veteran Program, the Hannon Initiative, and precision oncology. This is what VA research does best. We need to double down on these programs.

The second one is new. It's commercialization matching grants. We need to help the VA research insights find commercial partners to bring them through the FDA process. Well-designed matching grants of VA search resources can further the transition to real world care, while keeping the funds inside the VA healthcare system. We need to explore this.

And then finally, the third category, implementation and quality improvement grants. Making sure VA healthcare is scientifically adopting the best currently available methods and operations. These categories take the best of what the VA is currently doing and expands upon it.

These categories feed into each other to create a true learning system within VA healthcare. These categories honor the value of intramural research without single-mindedly being shackled to it.

In conclusion, ORD has taken clear steps to move to become an outcome-oriented organization, but it needs Congress to clarify its purpose, and strategic funding methodologies. Thank you again for the opportunity to testify in front of this honorable Committee. Your attention to this issue means a lot to NAMI Montana, and the people that we serve. We look forward to working with you in continuing to improve veterans' healthcare in the future. Thank you.

[The prepared statement of Mr. Kuntz appears on page 32 of the Appendix.]

Chairman TESTER. Matt, we appreciate you being here. We appreciate your comments to this Committee. We'll do 5-minute rounds of questions. Dr. Ramoni, could you tell me what the VA's current research priorities are?

Dr. RAMONI. Yes, sir. I can tell you what our current research priorities are. We have five strategic priorities. One is to increase veterans' access to high quality clinical trials. The second is to increase the substantial real-world impact of VA research. The third is to put VA data to work for veterans. The fourth is to proactively promote diversity, equity, and inclusion within our sphere of influence. And the fifth is to promote community using VA research. And that is community with our veterans, as well as other agencies, and internally to VA.

Those are our strategic priorities. We also have priorities that are focused on health conditions. And those health conditions include military exposures and toxic exposures including Gulf War illness, precision oncology, mental health and suicide prevention, and pain and opioid use disorder.

Chairman TESTER. You heard when it comes to community which is one of your priorities, you heard Matt Kuntz talk about quality improvement grants and matching grants for commercialization.

Two questions. Are there any available, number one, and number two, are they being utilized?

Dr. RAMONI. So sir, to the first point regarding quality improvement and implementation grant I would first point out that there is a research appropriation and a clinical care appropriation. The research appropriation cannot itself be used for implementation, but this is why we work closely with clinical partners such as the oncology program office to collaboratively implement research findings into practice.

We do have within our office a group called the Quality Enhancement Research initiative or QUERY that does have clinical dollars, and they work to implement evidence-based findings across VA. And in fact, our driving force in the Evidence Act within our entire organization. So those are a couple of the ways in which we promote implementation.

On top of that, the funding though is also infrastructure that promotes implementation. So our prototype for this is the precision oncology program under the Lung Precision Oncology Program. We have over 100 sites across the country. And by interacting with these medical center by medical center, we find that we can more proactively implement. We don't just publish and hope people implement, but we work closely with them to implement.

Chairman TESTER. Let me come back to this in the second round, but I want to ask Matt Kuntz a question before my time runs out. And that is, how can we best improve access to research projects for veterans in Montana?

Mr. KUNTZ. Senator Tester, I think it's by doubling down on those big projects, Million Veteran Program. I got an email as a Montana veteran's last week asking me to sign up. We're not going to have all of the fancy research infrastructure that the VA wants or needs to come to our State. I've given up on that after a decade of trying.

But I do believe that those big studies, like the Hannon Initiative, the Million Veteran Program, need to be able to be decentralized enough where you can demand that they be available to your veterans. That it is not the VA's choice whether or not to come to our State. It's just a matter of when and how.

Chairman TESTER. So I'm going to go back to—and I don't want to get a fight on the panel. You guys don't have to punch it out or nothing. But the truth is, when it comes to research as per mental health, as per the Hannon Act, rural America tends to rise to the top when it comes to suicides. Whether you're in Alaska or Montana or any other rural State, they tend to be higher there. Are you guys doing research in rural areas on that?

Dr. RAMONI. So our ability Senator Tester, honestly, to do research in rural areas, in particular clinical trials, is limited by the absence of academic affiliates there. But we are working as previously mentioned, on decentralized approaches, including the regulatory changes necessary to facilitate outreach to those areas. In addition to leveraging teleclinical trials and our pharmacy unit.

Chairman TESTER. Thank you. I'll come back to this, but there's got to be a way. I mean, we've got internet, we've got broadband, we've got the university system in Montana that's pretty damn

good that has everything from PA to nurse programs that are pretty doggone good.

I think it's a big mistake to say you guys don't have the big university. We don't have the, you know, we don't have the Ivy League schools and all that stuff when, especially when it comes to mental health, rural America's afflicted by it more. I believe more than anywhere else on a per capita basis. Senator King.

SENATOR ANGUS S. KING, JR.

Senator KING. I just want to follow up on that, Senator. I think it's very important because, you may well have different typologies and different pathologies in rural areas than you have in urban areas, and if the standard is a major research university, you're going to be missing a lot of the issues.

So I would agree. There's a university in Montana that's, I think you said pretty damn good. There's also one in, in the State of Maine that's pretty damn good. And we also have some important research institutions in Maine, the Jackson Laboratory, Maine Medical Center.

So the point is, I hope you'll rethink where these clinical trials take place, because if you're not doing them in rural areas, you may be missing some important information that could be informative because that's where a lot of veterans are.

Dr. RAMONI. Yes, Mr. King, I absolutely agree. I want to bring these trials to where the veterans are. Nothing gladdens my heart like when we learn that our research has saved a life. It is going to take some extra work, and I think it's worthwhile work.

And as I was talking to my colleague here, Dr. Muralidhar, I come here to learn. And what I'm hearing today is that we need to do better at getting clinical trials into our rural areas. And we'll have to do that by working with the medical center directors in those areas.

While I oversee the research program here from Washington, DC, it is the medical center directors who can really work with us and help to foster the research in those areas. In addition to steps that we're taking to allow for remote trials and leveraging the broadband that Chairman Tester raised.

Senator KING. Terrific resources. Thank you for that. You may be the first person that ever came here to learn something.

[Laughter.]

Senator KING. I appreciate that. Sorry, Mr. Chairman. We had a hearing several months ago on suicide prevention, and I talked to Dr. Miller. And it turns out that there are a number of sort of nonclinical factors affecting veteran suicide. One high on the list was financial insecurity, another was food insecurity.

I hope that this can be a focus. That this isn't only about mental health problems, but about those nonclinical items, because we need to know what's causing this, and therefore we can hopefully start to deal with it. Will you pursue that issue?

Dr. RAMONI. Yes, sir, on two fronts. One, I can get back to you with a list of what we are doing in that area. And then second we can certainly look to expand the work that we're doing. That takes a more holistic view. And I think it really is a strength of VA because we are, as a unified organization, we include benefits, and

we include healthcare. So we perhaps are uniquely able not only to understand, but also to intervene on those factors. Whereas other healthcare systems are not.

Senator KING. You have a national scope. You have urban, rural. You have a tremendous opportunity. I should have begun with a mention. We've got VA researchers in Maine working on 17 different projects from opioid use to workforce burnout. So I appreciate the work that you're sponsoring.

Geriatric research, education, and clinical centers. It certainly makes sense as our veterans age that you're looking at those geriatric issues. My only concern here is to be sure that ORD and GRECC are also coordinating with NIH and other agencies, so that we're not duplicating. We're spending a lot of money here. And if NIH is leading an enormous effort on Alzheimer's, for example, let's not duplicate it. Let's work with them. Add your expertise, and knowledge, and database to what they're doing.

Dr. RAMONI. Yes, you are really speaking to my heart there. We work extremely closely with the National Institute on Aging, and I think it serves as paradigm for how we should work with other institutes. At NIH, we meet at least twice yearly. Dr. Richard Hodes, who leads that institute and I are in regular communication. We collaborate——

Senator KING. Let's make it more than twice yearly.

Dr. RAMONI. Yes.

Senator KING. Can you accelerate that a little bit?

Dr. RAMONI. Yes. Well, yes. I'm one person and there are a lot of NIH institutes, so I'm going to have to open up my calendar. But yes, I would love to meet with them more regularly. We certainly have the senior program manager within our office who is the liaison, speaks with them much more regularly than that. But the two leadership teams come together twice yearly and we collaborate.

They are, let me tell you, most interested in our capabilities at having a clinical research infrastructure to both conduct clinical trials and data——

Senator KING. And the nationwide database.

Dr. RAMONI. Yes. And MVP is working very closely with a National Institute on Aging.

Senator KING. Now, Mr. Chairman, may I be indulged for an extra minute? If you learned of a disease that affected one out of four elderly veterans, an epidemic that caused significant harm, hospitalization costs, and often death, would you consider that worthy of research?

Dr. RAMONI. Yes, sir.

Senator KING. What I'm referring to is falls.

Dr. RAMONI. Yes.

Senator KING. And it is an epidemic among seniors in our country, and certainly among veterans. And my concern is that A, we don't know enough about it. And B, once we learn more that we learn how to prevent falls, it's a preventable epidemic, at least to some extent. And my frustration is that Medicare, for example, will pay for a hip replacement, but they won't pay for grab bars in your shower.

So I hope that this is an area that GRECC can focus upon, because this is an epidemic just like any other disease because it's killing people. I hope you'll put some emphasis on that.

Dr. RAMONI. Yes, sir. My own mother passed away following a fall. And a dear friend of mine lost her father following a fall. I think it is certainly worthy of study. And again, we will get back to you with the work we're currently doing, and then would love to have discussions about where we could do more.

Senator KING. And prevention is where we should be headed.

Dr. RAMONI. Absolutely. Absolutely. Because once you've fallen——

Senator KING. It's too late.

Dr. RAMONI. The damage is done.

Senator KING. That's right. Thank you, Mr. Chairman.

Chairman TESTER. The man from WVU Center Mansion.

SENATOR JOE MANCHIN III

Senator MANCHIN. Thank you very much Mr. Chairman. It's pleasure to be with you as always. And so Dr. Ramoni, I'd like to focus on the VA's National Artificial Intelligence Institute. There's no reason that the VA shouldn't be the world leader in adopting AI into healthcare practices.

If implemented properly, it could be revolutionary. Easing our staffing issues, monitoring our patient's safety, predicting diseases, mental illness, all the things that go with that, creating novel treatments, and thousands of other applications we know. So how is the work at the VA's AI Institute being prioritized by the VA? How far along are you?

Dr. RAMONI. Yes, so thank you, Senator. We started up the National AI Institute a few years ago, not knowing that the generative AI revolution was just around the corner. But we are fortunate to have as our leader of that AI Institute, Gil Alterovitz, and a team of people around the country in different medical centers doing that work.

Because we were able to lay that foundation, we have been able to participate in a number of national efforts, including in the most recent Executive order, ensuring that VA is on the map for AI. And to ensure that trustworthy AI principles——

Senator MANCHIN. Have you all basically briefed Secretary McDonough and Deputy Secretary Bradsher?

Dr. RAMONI. Have we briefed them?

Senator MANCHIN. Are they briefed?

Dr. RAMONI. Oh yes, they certainly are.

Senator MANCHIN. They're on top of it?

Dr. RAMONI. Yes. Yes, they are certainly read into the AI——

Senator MANCHIN. Let me just say this, through my AI work on my other committees, and Armed Services is one where I'm chairman of the Subcommittee on Cyber, I learned that AI is useless and truly useless without accurate, massive database.

So does the VA own all its own data? Are you including what is created by contractors? And do you own that access to all contractors' data that will go into your database? And who is that managed by? Who is managing that for you?

Dr. RAMONI. Well sir, for a complete answer we will have to get back to you, but I can tell you speaking as researchers who love nothing more than access to data, I can tell you that because of the work that our corporate data warehouse team has done on both the clinical and research sides, we have access to quite a bit of data.

Senator MANCHIN. Okay.

VA Response: All data generated within the VA for the purpose of research is owned by the VA. Aside from VA investigators, only VA contractors can conduct VA studies. Any data from these studies also belong to VA. The VA manages its own research data through on premise storage solutions and cloud storage. The stored data are subject to all applicable VA information security and privacy controls.

Dr. RAMONI. But I can tell you that there are some challenges in getting data back. For instance, in the case where genetic testing is sent to outside laboratories, that data is not specified in the contract always to come back to the VA.

Senator MANCHIN. So, I mean, have you looked at your contracts to make sure that they, basically, you need this to do the accurate work you need with AI for it to be effective? Have you started recommending those changes be made, so when you have outside contractors, you do own that, or you have rights to that database?

Dr. RAMONI. I know that in the conversations I've been privy to, which are in the context of oncology, that those are active discussions about ensuring that we get data back from those data providers.

Senator MANCHIN. Thank you. Mr. Kuntz, if I could talk to you because it's just a horrible situation. I know and I thank you for your work you're doing in mental illness and all the suicide——

Mr. KUNTZ. Thank you.

Senator MANCHIN [continuing]. And all the problems that we're having with our veterans. I was always interested, when someone is basically retiring out, coming back from either service, coming back from combat, and they're basically been diagnosed with some challenges. Is that forwarded on to you if they come back to Montana, in Montana? Are you made aware of all the medical conditions and records upon discharge that that soldier may have?

Mr. KUNTZ. Sir, I don't work for the Veterans' Administration, but I know that that's been something that we've been working with——

Senator MANCHIN. I mean, do you know if there's a problem there? Because it seems like to me, they're coming back home in West Virginia, we should have been notified that there was some serious problems we could have intervened and helped them with. And we're not seeing that until it's almost too late.

Mr. KUNTZ. Sir, I agree with you. I mean, it feels like it's something that's always talked about and it feels like from the DoD side, if you could lean on those folks and make sure——

Senator MANCHIN. Let me ask you this. Do you all, any of you all from the Department of Veterans, VA know anything about this? Are we able to access those records? Is my four hospitals in West Virginia going to have access to the medical records coming out and discharge records of a soldier coming out of service?

Dr. RAMONI. So sir, I am going to have to take that question back, but I want to make sure that I understand. Are you asking whether the VA receives the records from all discharged military?

Senator MANCHIN. I would say that if I'm coming out of the military and I'm discharged, okay. So you checked me out and I've had some problems. I've had some conditions.

Dr. RAMONI. Yes, sir.

Senator MANCHIN. And you all have treated me while I've been in service, while I was fully deployed. Now I'm discharged and you would ask me, what hospital do I want to go to? And I'd say, I want to go to the Woody Williams VA Center in Huntington, West Virginia. And would they be aware, would you make them aware of all of the conditions and all the prior treatments I've received, so they know that I might have some substance abuse problems?

Dr. RAMONI. Thank you, sir. We will take that question.

Senator MANCHIN. I don't, but I want to say I'm just hypothetically. Okay. And we're just——

Dr. RAMONI. Yes. We will take that question and get back to you because now I have a sense of——

Senator MANCHIN. What I'm trying to get to?

Dr. RAMONI [continuing]. Of what you're asking, yes.

VA Response: The Department of Veterans Affairs (VA) has a long-standing partnership with the Department of Defense (DoD) to coordinate the transition of care for service members leaving the military and needing ongoing care from the Veterans Health Administration (VHA). VHA has 43 VA Liaisons for Healthcare, advanced practice social workers and registered nurses, stationed at 21 Military Treatment Facilities (MTFs) and DoD installations, as well as five (5) Regional VA Liaisons for Healthcare to provide virtual transition assistance at DoD installations that do not currently have VA Liaisons located onsite. VA Liaisons for Healthcare provide direct access and coordinate individualized VA health care for service members from DoD to VA prior to discharge from the military. VA Liaisons for Healthcare collaborate with MTF treatment teams to identify ongoing health care needs then communicate those health care needs to the Post-9/11 Military2VA (M2VA) Case Management team at the VA health care facility closest to the service member's home or most appropriate location for the specialized services the medical condition requires. This includes information about substance abuse problems if applicable to the individual transitioning service member/Veteran. This formal transition process between the VA Liaisons for Healthcare and the Post-9/11 M2VA Case Management teams bridges the gap during the vulnerable time of transition. This specialized part of the military-to-civilian transition, namely the transition of health care from DoD to VHA, is accomplished by assessing individualized needs, expediting the transitioning service member's/Veteran's initial registration/enrollment for VA health care, scheduling initial VHA appointments, and ensuring screening for ongoing case management.

Post-9/11 M2VA Case Management teams are located at every VA health care facility and provide comprehensive transition assistance and longitudinal case management for Post-9/11-era wounded, ill, and injured service members and Post-9/11 era Veterans. The Post-9/11 M2VA Case Management team at the transitioning service member's/Veteran's home VA health care facility (such as the Woody Williams VA Center in Huntington, West Virginia) would receive the information provided by the VA Liaison for Healthcare and also has access to view DoD medical records through the Joint Longitudinal Viewer to gain a complete picture of the new Veteran's DoD health history. Post-9/11 M2VA Case Managers are social workers and nurses who provide case management to meet the clinical and non-clinical needs of the transitioning service member/Veteran and coordinate with the other members of the Veteran's VHA treatment team to ensure responsive, synchronized, and integrated care benefits and services.

Senator MANCHIN. I'm saying we can——

UNIDENTIFIED SPEAKER. Do you know when you can get the medical records from the VA?

Dr. RAMONI. Well, I know that once somebody is enrolled in the VA, that the VA does have access to DoD records. I'm not certain if prior to the enrollment those data are available. I'm also aware that there are a number of transition activities that occur upon discharge from the DoD to facilitate enrollment in VA.

But again, I'm not certain then whether if somebody doesn't enroll, then does VA have access to those records? And I think furthermore, Mr. Manchin, if I understand your question, then is there some proactive way to identify——

Senator MANCHIN. I'm just saying if we can intervene and——

Chairman TESTER. Gentlemen, I've got to get to Senator Cassidy. We're over quite a bit. But these are the researchers. I think we need to be talking to the clinicians to get that information. Okay. And she will, she'll get them.

Senator MANCHIN. I saw you had the gentleman from Montana.

Chairman TESTER. Kuntz is top flight, but he's in the private sector. Right on. So it's good. Senator Cassidy.

SENATOR BILL CASSIDY

Senator CASSIDY. Hey, hello. I'm going to ask just some basic questions. Perhaps Dr. Ramoni, you're the one who would answer. How much of the funding that you put out there is for basic research versus clinical research?

Dr. RAMONI. Yes, sir. I'm going to have to get back to you on that question. I know that among our—we have four major research services, basic science, clinical science, health service research, and rehab. That among the four, basic science is the largest.

VA Response: ORD funds research through four major research service areas: basic biomedical science, clinical science, health services research, and rehabilitation. Our funding for basic biomedical research constitutes approximately 39% of our total funding portfolio across all four services. The table below provides are actual funding amounts for FY2022 and 2023, and our requested budget for 2024.

Obligations by Service (Dollars in thousands)	2022 Actuals	2023 Actuals	2024 Request
Biomedical Laboratory R&D (821)	208,492	216,339	212,012
Rehabilitation R&D (822)	116,567	116,782	120,924
Health Services R&D (824)	123,604	120,743	125,691
Clinical Science R&D (829)	90,898	94,627	104,021
Service Obligations Totals	**539,561**	**548,491**	**562,648**

Senator CASSIDY. And is that money extramural or is it by researchers who are on a VA campus? Or are you contracting with somebody who is at a med school someplace, or?

Dr. RAMONI. These all are individuals who are at least five-eighths VA. And the work can be done either on the VA campus or through agreement or lease with academic affiliates or other lease space.

Senator CASSIDY. Now, do you have a sense of the percent that you're leasing off the campus versus on, and is there any difference in the productivity of the researcher who is physically situated on a VA campus versus one who is not?

Dr. RAMONI. I do not have that information at present.

Senator CASSIDY. How do you measure productivity of the people who receive these grants? Because I come from academic medicine and it's publish or perish, or you have to get a certain number of grants, or you've got to have, you know, you name it.

Dr. RAMONI. Yes.

Senator CASSIDY. How do you measure the productivity of the people whom you are funding?

Senator CASSIDY. So, to me, the ultimate part of what drew me to the VA and is different from where I was in academic medicine, is that I ultimately view the productivity of our researchers as making their way back to the veterans. So for instance, in the Lung Precision Oncology Program, it's, do we update the lung cancer screening guidelines on the military exposure.

Senator CASSIDY. I accept that. I have limited time. I accept that. But nonetheless, if it's really high quality work, it's going to be copied by others.

Dr. RAMONI. Yes. And so we do publish, we had 14,000 publications back in fiscal year '22. In addition to——

Senator CASSIDY. That must include abstracts too, right? Not peer reviewed.

Dr. RAMONI. I will have to go back and check for the record, but there are a large number of VA researchers.

VA Response: The 14,000 publications Dr. Ramoni reported are all peer-reviewed, scholarly publications. It does not include news coverage nor reports of the studies; abstracts and summaries may be provided as part of an article and are not counted as distinct articles. Abstracts and summaries are not counted as stand-alone items.

Senator CASSIDY. So let me go back to—because we're interested in how do you know that somebody's going to work? So publications is one way. Getting something licensed is another. Doing a clinical trial, enrolling 5,000 people is a third. Do you have kind of metrics that if we wanted to look at, we could say, "Whoa, this is really working," or, "Hmm, is anybody doing anything there?" You see what I'm saying? We need to have that, sort of, kind of——

Dr. RAMONI. Yes. And so what I would say is, prior to us implementing this effort to treat VA as a research enterprise, each center has its own way of tracking things. Each of the 107 medical centers that conducted research. We are now instituting systems across all of those systems that allow us to better understand what research is happening, what funding are they bringing in from outside sources, how many people are they enrolling in clinical trials, whether they're funded by VA or not. For VA funded research, we get progress reports, of course, on a yearly basis.

Senator CASSIDY. Now are you all funding researchers or are you funding a research proposition?

Dr. RAMONI. We fund proposals.

Senator CASSIDY. I see. So Dr. Jon Tester might bring you a proposal to do something on traumatic brain injury and you would look at it and see if it's good.

Dr. RAMONI. We conduct peer review, like NIH does.

Senator CASSIDY. Got you. Okay. And the clinical work that you are doing, do you have a sense of how many veterans are enrolled in clinical trials sponsored by your research?

Dr. RAMONI. For our research, we can gather information about how many people are enrolled in the trials. For trials that are sponsored by outside parties, we do not yet have that information at our fingertips.

Senator CASSIDY. So I think you're telling me that if a pharmaceutical company has a new treatment, they may be enrolling patients at a VA, but that would not necessarily be VA sponsored research. It would just be going through your institutional review board, enrolling VA patients.

Dr. RAMONI. Not necessarily going through our institutional review board, going through a review board——

Senator CASSIDY. Someplace?

Dr. RAMONI [continuing]. On which we rely, yes.

Senator CASSIDY. Now, in terms of though, going back to my question, do you have a number of veterans who are enrolled in clinical research that the VA sponsors?

Dr. RAMONI. Yes. We can get that number to you.

VA Response: For VA Office of Research and Development funded clinical trials, it is estimated that about 932,000 Veterans are enrolled or will be enrolled in studies that are currently recruiting, completed recruitment but active, or enrolling by invitation. Over 40,500 more Veterans are expected to be recruited for clinical trials that have not yet begun recruitment.

Senator CASSIDY. Okay. I'm almost out of time, but let me just say this. I'm going to put it plugin, Mr. Chair. We've been working on something called a VetPAC idea, modeled after MedPAC and MACPAC from Medicaid and Medicare analysis to give us a tool by which to evaluate these programs.

And we are not there yet, but I'd like to eventually bring it to the Committee and hopefully on a bipartisan basis, it'll give us a way to have more insights into what we're trying to learn.

Chairman TESTER. I look forward to that, Senator Cassidy, and I appreciate the work in that effort, because accountability is really important. We want to make sure the dollars that are spent, actually people are utilizing them in a way that provides benefits one way or the other. Thank you. Senator Hirono.

SENATOR MAZIE K. HIRONO

Senator HIRONO. So I'm curious about this, the Million Veteran Program. So is this Dr. Muralidhar? I think I'm mispronouncing somebody's name. Your name. Okay. So I'm curious about this MVP Program, soon approaching the goal of collecting genetic information of 1 million veterans. So how did you get this information from 1 million Veterans? When they access VA services? Do they somehow get tested for genetic information? How is this working?

Dr. MURALIDHAR. So, thank you for that question, Senator. So Million Veteran Program is really a voluntary research program that we actively consent veterans. So we reach out to them and invite them to participate in the program, and if they're interested, then they would consent to it.

And it's generally a 20-minute visit at the VA hospital. If they're coming in person, they provide a sample of blood, 10 ml for genetics

and other molecular data. And they complete surveys on health and lifestyle, military experience, and exposures. And they also give us access to their health records for research and agree to be recontacted.

That's the general premise of the participation. They can also enroll online. In 2019, we actually launched an online portal. So they can either come into a VA hospital where we have a site for enrollment, or they can enroll online.

Senator HIRONO. So what is the hope and expectation of having a million people's genetic information? What is it that the VA hopes to do with all of this? And is this the largest collection of this kind of voluntary genetic information?

Dr. MURALIDHAR. Yes, it is the world's largest cohort. Right now, we are just under 8,000 more to go to get to a million veterans. This is a partnership that we actually established with veterans right from the beginning. And the goal was really to understand how genetics, lifestyle, and military experiences and exposures, impact health and well-being.

And so we clean and curate the data, both from the electronic health record and the surveys. We curate all the molecular data, the genetic data that we generate from the biospecimen, and these are provided in a secure way to researchers within the VA at this point.

And now we have over a hundred projects doing work with this data set. We have over 350 publications and very high impact journals so far.

Senator HIRONO. And so with these hundred projects that you have, such as? Because the whole idea is to provide, I take it, better healthcare for veterans?

Dr. MURALIDHAR. Yes. So the ultimate goal is really to take these research findings and bring it back into the healthcare system. And so initially we focused several years on the recruitment and enrollment piece, and then we cleaned the data and started providing them for research. And now we are starting to see some initial projects that are bearing fruit in terms of clinical translation.

For example, we have one project where a polygenic risk score was identified for increasing risk in men to metastatic prostate cancer in African Americans. So that polygenic risk score is now being tested in a clinical trial to see if it improves when compared to standard of care to predict the risk for metastatic prostate cancer better.

Senator HIRONO. I don't imagine that you have a lot of Asian Native Hawaiian cohorts in this 1 million population.

Dr. MURALIDHAR. So we do have quite a bit of diversity. So we have about 18 percent African American, that's over 175,000 African Americans in the cohort. The largest in the world of its kind right now. We have 8 percent Hispanic ethnicity represented. We do have very low Asians, and you know Native Americans, and Pacific Islanders, about 1 percent or so.

So our goal is after we get to the million, beyond that, we will start diversifying the cohort more. We will have focused campaigns to recruit more of the underrepresented populations in this program.

Senator HIRONO. So you were asked—someone was asked the question of how many veterans are enrolled in clinical trials? And I don't know that we got the answer to that. We don't have that answer?

Dr. RAMONI. No, I will get that answer for you in response. I will be able to get that answer for VA funded trials. We will not have the information at this point for non-VA funded trials.

VA Response: For clinical trials funded through the VA Office of Research and Development, it is estimated that about 932,000 Veterans are enrolled or will be enrolled in studies that are currently recruiting, completed recruitment but active, or enrolling by invitation. Over 40,500 more Veterans are expected to be recruited for clinical trials that have not yet begun recruitment.

Senator HIRONO. So when you say the VA funded clinical trials, how many VA funded clinical trials are there? Because there aren't a lot of the clinical trials done in a hospital, regular hospital setting.

Dr. RAMONI. So if I am to look—I'm sorry, I'm looking for the numbers of clinical trials that we fund. I may have to take that question also for the record.

VA Response: As of November 21, 2023, the VA Office of Research and Development is funding 591 trials that are at various stages of activity (e.g., not yet recruiting, recruiting, active but not recruiting). The VA Office of Research and Development has also funded over 1,433 clinical trials that have been completed since it started to require clinical trials to be registered in Clinicaltrials.gov since 2007.

Senator HIRONO. I would be very interested in knowing how many, because it seems to me that clinical trials is one of the ways that people sign up for these trials. You can really make some determinations as to whether a particular protocol is working or not, depending on whatever the factors are. And it's not always a genetic kind of an identifier——

Dr. RAMONI. That's right. There are——

Senator HIRONO [continuing]. That is at play.

Dr. RAMONI. I apologize.

Senator HIRONO. So I'm curious to know the figures, because I do think that clinical trials is one of the very specific ways that we can make some determinations as to best treatments.

Dr. RAMONI. Yes, ma'am. And I was able to find the number. There are 2,029 clinical trials that are active across VA that we have a record of. And 617 of those are funded by us.

Senator HIRONO. Okay. And are these mainly cancer trials?

Dr. RAMONI. No. They cover a full range of conditions. So for instance, one of the largest trials that we're conducting is a comparison of fecal immunohistochemical testing. Like a Cologuard type test versus colonoscopy of 50,000 people followed for 10 years to see which is more effective in preventing death.

Senator HIRONO. Okay. Well, thank you.

Chairman TESTER. Rachel, could you send us the research projects that are being asked. Send it to me and I'll distribute to the Committee?

Dr. RAMONI. Yes.

VA Response: A current list of research projects funded by the VA Office of Research and Development (except for those funded by VA's Cooperative Studies Program) can be found on the National Institutes of Health RePORTER website (https://reporter.nih.gov/search/f4fehWMR-0Kj75mk2ik5MA/projects). A list of active Cooperative Studies Program projects can be found at: https://www.research.va.gov/programs/csp/studies.cfm.

Chairman TESTER. So that the Committee has an idea, at least on those 617 that are VA funded, what they're about. Okay? Senator Blackburn.

SENATOR MARSHA BLACKBURN

Senator BLACKBURN. Thank you. I appreciate that, Mr. Chairman. And as I told you all before the hearing started, I appreciate so much that you all are here today and to work with us on this. Dr. Ramoni, we talked a little bit about the CB program there at Vanderbilt, and the research work that is being done there. I had a question, as we were working on the hearing, the R and D office is embedded within the VA health system. So that means that the funds for research are available only to VA employees. Is that correct?

Dr. RAMONI. Yes, ma'am. That is correct.

Senator BLACKBURN. Okay. Now we know that the VA in Nashville is on the campus of Vanderbilt University, and the VA is right across from the hospital there, which is a research hospital, which has done some pretty amazing work.

So why would we not allow those funds to be used with some of the researchers that are really right across the street there at Vanderbilt and expand the opportunities for getting to an answer on CB and how that is going to be treated?

Dr. RAMONI. So thank you for the question, ma'am, which as I understand it, it's about why are we an intramural funding organization instead of sending funding extramurally, like let's say NIH or others?

So there are a few responses to that question. One is that A, given the amount of funding that we have we want part of our work in funding research within VA is it serves as both a recruitment and retention tool for clinicians. So research is one of the reasons why people come to work in VA. The second point is that the ideas then bubble up directly from the people who work with veterans on a day-to-day basis. The third is, of course, we encourage people to come and get a VA appointment. Meaning you can apply for funding with a promise of getting a VA appointment. It's not a sort of catch-22, where you have to have a VA appointment in order to apply for funding. But you need funding to sort of get an appointment.

And the third is that we actively collaborate, as I was mentioning previously with the primary extramural funding agencies like NIH, DoD, and others.

Senator BLACKBURN. Okay. Let me stop you at that. We've had a lot of success with our military service with the Pathfinder Program. Senator Rosen and I did a lot of work on this, and it allowed active duty to actually partner with engineers in our research institutions. We have had that program on campus at Vanderbilt, and it has been very successful.

And when you talk about the constricted bronchiolitis and Dr. Hastings was talking about how invasive the surgery is, the biopsy process is, it just seems that when you're doing this, you would have a portion of that funding that would allow you to partner with research institutions in hopes of getting to a faster resolution on this.

We've put so much work into dealing with toxic exposure. A big part of that is what happens with the respiratory system. So if we need to look at that allowance, we should do that, Mr. Chairman, and allow them to use some of those funds.

Before my time runs out, I do want to ask you about the data security efforts for the Million Veteran Program. And we want our veterans to feel safe knowing that their data, their information, their medical history, all of their PII is going to be safe. And we've seen the VA go through cyberattacks and information being leaked.

And the concern on this is not just cybersecurity, physical security is also a part of this. And I would like to know what you're doing to enhance that physical and that cybersecurity, so that veterans that are in that Million Veteran Program are going to be protected.

Dr. MURALIDHAR. Thank you for that very important question, Senator. So protecting the privacy and security of our veterans' data is paramount for us. It's our highest priority. So right from the time we collect the data from veterans, till the point that the data is used for research, we've put in place number of mechanisms to protect the data.

First and foremost, we code the data. There is no direct identifier like name, or date of birth, or social security number.

Senator BLACKBURN. So you're anonymizing——

Dr. MURALIDHAR. Yes.

Senator BLACKBURN [continuing]. All of that? Okay.

Dr. MURALIDHAR. Yes. And second of all, the environment, the computing environment in which we store the data and make it available to researchers is isolated from the VA network, for example. So if there are perturbations, even to the VA network, it will not impact this structure where the data is stored and used.

We don't send out data to researchers. We bring them to the data in a central secure scientific computing environment, and we provide the tools for them to do their analysis, and they're only able to take away the results. They cannot take any level data out.

And the last thing is, when you provide data to researchers, again, we code them and anonymize them. So researchers can't tell who it belongs to.

Senator BLACKBURN. Okay. That's helpful. Thank you.

Chairman TESTER. If you'll just bear with me a little bit, Senator Blumenthal. I want you to enlighten me because we started out this hearing and you talked about research has to be done in areas where there are major universities. Senator Blackburn just talked about Vanderbilt, which is a major university, and how did the VA funded projects were solely for VA and didn't utilize the university.

So, enlighten me why more of this isn't done in rural America, because what you just told her is that you don't need the universities. And what you told us earlier, if I heard this correctly, is that you need to do research where there is major universities.

Dr. RAMONI. Yes, Chairman Tester. Thank you for that question. Most of our researchers have dual appointments. They both are like Dr. Miller, Bob Miller, is both a Vanderbilt professor and a VA researcher. And that is true for the vast majority of our researchers. So it really is that academic affiliation that——

Chairman TESTER. So in fact, you are bringing in the information that the universities have because they have two jobs, one with the university and one with the VA.

Dr. RAMONI. That's the same for many of our clinicians as for our researchers, yes.

Chairman TESTER. Okay, thank you. Senator Blumenthal.

SENATOR RICHARD BLUMENTHAL

Senator BLUMENTHAL. Thanks, Mr. Chairman, and thank you for holding this hearing, which quite honestly is one of the more enlightening of our hearings. I'm learning a lot about stuff I never knew, like the MVP program, which as you observe in your testimony, is "The largest database of genetic information on African Americans in the world."

Seems to me there's probably a wealth of information in the MVP that you have already. You observe here that you've, "Identified 12 DNA variants associated with the risk of suicide and highlights the genetic link between suicide and factors such as impulsivity, chronic pain, attention deficit hyperactivity disorder, and heart disease."

Those conditions are associated with certain genetic makeups, and you have evidence as to the statistical links, and the potential for treating them. When will this information be, in a sense, weaponized into treatment that's available to the thousands, maybe millions of veterans who could benefit?

Dr. MURALIDHAR. So thank you for the question, Senator. So the paper just came out recently, and so we've identified associations, meaning that a genetic change is associated with certain conditions. So there are several steps that need to happen before it actually becomes a biomarker or a new drug is discovered because of it, or a drug can be repurposed because of that.

So we have to validate these results and then see if there is a way—if there's already a drug that's approved by FDA, that could be used for any of these conditions that can be repurposed you know, for preventing suicide. And so that's a longer step working with FDA and others to get to that point. But there are a few steps from the initial discovery to making it available.

Senator BLUMENTHAL. Well, how soon? You know, veterans are committing suicide every day, there's a real potential to save lives. We talk about this issue probably, I don't know how often at our meetings here, but as recently as this morning, we had a meeting with some of the Veterans Service Organizations. The Chairman was there, raised this issue. A number of us raised this issue right off the bat. And never once was this study mentioned.

I don't know whether you can tell us whether this process can be accelerated, whether there can be a priority on it. You note also that "Researchers are looking at numerous health conditions such as PTSD, depression, diabetes, and heart disease that are also associated with certain genetic factors."

So I think there's a potential here that is very important. I've been on this Committee for 12 years. I'm learning about it for the first time. Shame on me. But what more can we do to publicize it, and also to enable more veterans or persuade more veterans to be a part of it?

Because self-selection, I would guess the voluntary aspect of it may skew it somewhat. A veteran who is depressed on the verge of suicide, probably isn't going to enlist in the MVP program. So again, I just want to throw that question out there.

Dr. MURALIDHAR. Yes, thank you, Senator. So any veteran in the country can enroll in the program, either at a VA hospital or through our online portal. It is mvp.va.gov. It's simple to go there and learn more about it and enroll. We also recently launched a sub cohort within MVP, and this is really a very in-depth mental health survey that's sent out to veterans who are in the program to, to learn more about these conditions, the serious mental illness and substance use disorders.

And we launched about six sites this year. And roughly about 500 veterans have actually joined MVP and completed that survey. And so that's going to go on over the next few years so we can learn more and validate the findings that we get from one observation.

Senator BLUMENTHAL. I don't think I'm making myself clear. I'd like to know in a month, 3 months, 5 months, so we can help people, what you're finding and how to actualize it in treatment. If you're talking about years away, I think that's good, if your only objective is research. But we want practical solutions. I know I'm sounding oversimplistic, highly unscientific, but that's the instinct that will drive people like Matthew Kuntz, and he's nodding, anyone who is dealing with clinical depression that could cause suicide next week.

Dr. MURALIDHAR. Yes, and I completely agree with you. And I think that is our goal. The whole purpose of this program is to not just do research and discover something, but then to find ways to take it back to our veterans. And so we will work hard to take anything, any discovery that comes out of this program, to take it in toward the clinic.

Senator BLUMENTHAL. Thank you. My time has expired, but obviously my interest in this topic has not. And thank you, Mr. Chairman for having this hearing.

Chairman TESTER. Thank you, Senator Blumenthal. There was a vote call. It may last 15 minutes, it may last an hour and a half, who knows? But we're going to close this meeting out. And I want to thank you Dr. Ramoni, for being here and your two supporters, and Matt Kuntz. It's always good to see you, man. Keep up the good work. We appreciate you holding the fort down in Montana.

For those folks who want to put questions in for the record, I would ask that you would answer them in a timely way. Thank you for participation. The record will be kept open for a week and we are adjourned.

[Whereupon, at 4:43 p.m., the hearing was adjourned.]

A P P E N D I X

Prepared Statements

STATEMENT OF RACHEL RAMONI, DMD, ScD
CHIEF RESEARCH AND DEVELOPMENT OFFICER
OFFICE OF RESEARCH AND DEVELOPMENT (ORD)
VETERANS HEALTH ADMINISTRATION (VHA)
DEPARTMENT OF VETERANS AFFAIRS (VA)
BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE

"FOUNDATION OF CARE:
EXAMINING RESEARCH AT THE DEPARTMENT OF VETERANS AFFAIRS"

NOVEMBER 1, 2023

Good afternoon, Chairman Tester, Ranking Member Moran and members of the committee. I appreciate the opportunity to discuss VA efforts to ensure our research programs improve the health and well-being of the Nation's Veterans. I am accompanied today by Dr. Patricia Hastings, Chief Consultant, Health Outcomes Military Exposures (HOME) within VHA Patient Care Services, and Dr. Sumitra Muralidhar, Director of the Million Veteran Program.

Office of Research and Development (ORD) Overview

For nearly 100 years, VA's research program has focused on enhancing the well-being of Veterans and the Nation through scientific discovery. VA research has proudly contributed to major medical advances that serve as the foundation for much of American medicine, including the first implantable pacemaker; the first liver transplant; new prosthetics; the first ever clinical trials in the United States that formed the ability to later produce evidence leading to the approval of the shingles vaccine; and findings that support the use of therapies for posttraumatic stress disorder (PTSD) within VA. More recently, via access to national electronic health record data, VA researchers have made significant contributions to the Nation's understanding of and response to COVID-19. VA has produced several key findings related to diabetes, cardiovascular health, kidney disease and in an area referred to as post-acute sequelae of COVID-19 also known as long-COVID.

Because we are embedded within the VA health care system as an intramural research program that exclusively funds eligible VA employees qualified to do research, the research we fund is firmly grounded in the experience of clinicians and researchers working directly with Veterans in VA medical centers. Most of our researchers are faculty members at academic medical centers, and we can draw upon the best and the brightest researchers across the country. In fact, the ability to conduct research is one of the features that allows VA to attract and retain talented clinicians.

VA is indeed an extraordinary system to conduct biomedical research. Chief among its features is our mission to serve Veterans. In fact, 9.2 million of these extraordinary former Service members are enrolled in VA health care. Caring for these individuals and those who preceded them has resulted in one of the richest health care datasets in the world. When paired with skilled researchers and modern scientific computing, the opportunities for discovery that benefit Veterans and the Nation are vast. The capacity for VA research to do good goes well beyond the data: we support a full range of research approaches, including basic, translational, clinical, epidemiological, health services and rehabilitation research.

The President's Fiscal Year (FY) 2024 Budget requests $938 million in discretionary appropriations for VA's Medical and Prosthetic Research account to continue the investment in VA's capabilities as a national research enterprise, including research in support of American Pandemic Preparedness plan goals. This request builds upon the historic investment from the President's FY 2023 Budget to continue to increase funding to advance VA's research missions in areas such as military environmental exposures; traumatic brain injury; cancer and precision oncology; and mental health.

Given previous investments in VA to support broader efforts in advancing precision oncology research, VA is positioned to be an active leader and partner in the second Cancer Moonshot initiative through clinical trials and cutting-edge analyses of human tissues and tumors. This research has significantly contributed to advancements in health care for Veterans and Americans from every walk of life.

As an enterprise, VA is a tremendous source of biomedical evidence and research capability for Veterans and the Nation. We are building on that critical work to better link VA research efforts into an integrated enterprise. We intend to focus this actively coalescing enterprise on work that will fulfill our mission of improving Veterans' lives through research.

As a system, we are working on increasing all Veterans' access to high-quality clinical trials; enhancing the substantial real-world impact of VA research; putting VA data to work for Veterans; actively promoting diversity, equity and inclusion within our sphere of influence; and building community through VA research. Our research focuses on several cross-cutting clinical research priorities that reflect VA's unique opportunity and special responsibility to improve the health and quality of life of Veterans. These priorities include military environmental exposures; suicide prevention; PTSD; pain and opioid use; cancer; traumatic brain injury; and COVID-19. In addition, we are continuing important research on the prosthetic needs of women Veterans with limb loss; have made significant progress in implementing our plan to reduce, refine and replace sensitive animal species in VA research; and are advancing the use of artificial intelligence in biomedical research. VA efforts have prioritized Veterans' access to high-quality clinical trials and have increased the substantial real-world impact of our research. Consequently, we have increased opportunities to engage a broader community of investigators, funders and other stakeholders with shared interests to enable more robust research on how we care for Veterans.

Setting priorities is an essential part of stewarding the research appropriations given to us. ORD follows an iterative, multi-stakeholder process, outlined in the Government Accountability Office report "Efforts to Prioritize and Translate Research into Clinical Practice," completed in January 2020. These priorities factor into funding decisions and underpin enhanced central coordination of research. In addition, ORD responds to timely priorities identified by VA, VHA, Congress, Veterans Service Organizations and other key stakeholders.

Accordingly, ORD's current priorities correlate with our overall mission of improving Veterans' health and well-being via basic, translational, clinical, health services and rehabilitation research; applying scientific knowledge to develop effective individualized care solutions for Veterans; attracting, training and retaining the highest-caliber investigators and nurturing their development as leaders in their fields; and ensuring a culture of professionalism, collaboration, accountability and the highest regard for research volunteers' safety and privacy.

Research Related to Military Environmental Exposures

A tremendous amount is yet to be learned about the impacts of military exposures on Veterans' health. VA has completed 4.3 million toxic exposure screenings, with approximately 42.5% reporting a concern of exposure. To make rapid progress requires coordination across the Federal Government. ORD is leading the interagency Toxic Exposures Research Working Group (TERWG), mandated by section 501 of the Sergeant First Class Heath Robinson Honoring our Promise to Address Comprehensive Toxics Act of 2022 (the PACT Act). The TERWG includes 35 representatives from eight Federal departments and several agencies. As required by the PACT Act, the TERWG will deliver a strategic plan for coordinating efforts to deliver meaningful results to Veterans.

VA also is conducting research with an emphasis on advancing military exposure assessments and understanding effects on Veterans' health outcomes. For example, ORD recently began funding a study at the Nashville VA Medical Center on new technology for non-invasive detection of constrictive bronchiolitis (CB). This condition is a concern to Veterans and is difficult to diagnose. Non-invasive methods to diagnose and monitor Veterans with CB would dramatically improve the ability of VA to safely identify and provide care to Veterans with this condition.

Understanding the effect of military environmental exposures is a critical research focus for VA. We are committed to lead and partner in growing a high-quality evidence base and enhancing capabilities for state-of-the art research on military exposures so that VA can provide care and benefits to Veterans based on the best available evidence. Military environmental exposures can lead to short-term acute health outcomes and acute or delayed onset of diseases. We committed to urgently and proactively addressing the potential health effects of military environmental exposures of Veterans.

VA's overarching approach for addressing military environmental exposures includes the interrelated tenets of policy; research; communication, education and operations. These activities complement the research, review of presumption, education, risk, communication and clinical care already implemented through HOME; the War Related Illness and Injury Study Center (WRIISC) at three sites; the Airborne Hazards Open Burn Pit Center of Excellence; the Women's Operational Military Exposure Network to meet the unique concerns of women Veterans; the Complex Exposure Threats Center that studies and provides care for new or novel exposures such as directed energy; and the Metal Exposures Depleted Uranium Center.

Approximately 3.5 million U.S. Service members have deployed to Iraq, Afghanistan, Kuwait, Qatar, Djibouti, United Arab Emirates, Syria, Kyrgyzstan and surrounding areas since February 24, 1991. Prior cohorts of Veterans such as Vietnam and Atomic Veterans have had unique exposures depending on the circumstances of their military service. Defining health outcomes from all types of military exposures as well as emerging environmental threats is one of our top priorities.

VA uses a repeating cycle through which scientific evidence, policy and clinical programs continuously inform and improve through subsequent iterations, leading to improvements in Veterans' care. Science forms the foundation of policy decisions regarding the provision of evidence-based clinical care. In turn, the evaluation of clinical programs, trends in health care utilization and trends identified through health surveillance help identify knowledge gaps and determine priority areas for further research. To best understand and serve the needs of Veterans, VA must identify knowledge gaps and emerging threats, conduct research and use data to make evidence-based decisions about policy, care and benefits.

VA has expanded its portfolio of military environmental exposures research efforts to inform care and policy. VA is making this research investment in a complementary and parallel fashion with clinical programs and policies. This research investment is enabled through strategic planning at a national level and executed by clinician researchers, many of whom perform clinical and research duties at their local VA medical center.

One of the major challenges in the field of military environmental exposures is a lack of exposure assessment at the individual level. Improved exposure monitoring during military service may help make more precise determinations of the types and amounts of specific exposures incurred by Service members and will address a key gap in the field. Other critical areas of focus include developing clinical diagnostic tests to identify health conditions as early as possible and translating research findings into care that will make a difference in Veterans' lives.

HOME also conducts population-based epidemiological research to help answer questions about the associations of certain health outcomes and military environmental exposures. The WRIISCs and specialty centers also conduct military environmental exposures research to include clinical best practices. Education of Veterans and healthcare providers is an important part of these efforts. The Airborne Hazards and

Burn Pits Center of Excellence in New Jersey has completed the case definition for Deployment Related Respiratory Disease, which is part of a continuum of illness that may include CB. HOME works closely with the Department of Defense (DoD) on the Individual Longitudinal Exposure Record—a VA-DoD collaboration to track in-service exposures—to improve clinical care, research and Veteran disability claims processing.

Because military environmental exposure data frequently is unavailable, it can be difficult for VA to link health outcomes to a specific exposure. To address this gap in the science and data, ORD is designing new experiments to generate that data. One example of our efforts regarding environmental hazards is VA Cooperative Studies Program #595, the Service and Health Among Deployed Veterans study. We are actively enrolling over 6,000 Veterans across six VA recruitment sites to better understand the respiratory health of Southwest Asia-deployed Veterans. The study's primary objective is to assess the impact of fine particulate matter air pollution on pulmonary function. Investigators are using National Aeronautics and Space Administration (NASA) satellite data to quantify and provide an objective measure of exposure that has thus far eluded prior and current research efforts. Through a VA-led study, VA is partnering with DoD, NASA and academia to ensure its success.

Every Veteran's story matters, and that is why we are so focused on research and connecting it to health outcomes. "Put VA data to work for Veterans" is VA's broad strategic research priority. Our integrated health system means we are leveraging rich health datasets to accelerate discoveries and drive better outcomes. VA publishes its findings in peer-reviewed journals, which informs not only VA but also the Nation to improve many areas of care for Americans and indeed has global impacts.

VA research is very focused on Veteran health and needs, and it is core to VA's mission. Through research on military environmental exposures and in many other areas of importance to Veterans' health, VA will continue to provide and lead the way to serve the Nation's Veterans.

Million Veteran Program (MVP)

The signature example of our partnership with Veterans and the associated data assets held by VHA is the Million Veteran Program (MVP). MVP is a national, voluntary research program to study how genes affect health. MVP partners with Veterans who primarily receive their care in the VA health care system. Each Veteran agrees to contribute their blood samples and health information. Over 985,000 Veterans have enrolled so far with hopes to reach the million enrollee milestone by Veterans Day 2023.

Protecting the privacy and confidentiality of MVP participant data is the program's highest priority. Data from MVP participants is protected throughout the life cycle from the point of collection through data use. Tubes used for collecting blood samples as well as survey data and data from the electronic health record are marked with a code and do not contain personally identifiable information such as name, social security number or date of birth. Only a few authorized MVP staff have access to the participant's identity and can link the various data to an individual Veteran. Data is stored on secure servers

within the VA firewall, and the servers are in a secure, isolated architecture from the VA network so that any perturbations to the network do not affect MVP data.

Furthermore, before providing data access to researchers, a new code is assigned to the dataset. Approved researchers access data in this secure server architecture and conduct their analysis. Only summary results of the analyses can be downloaded from the servers. No individual-level data leave the servers. With the goal of making MVP data accessible to the broader research community outside VA in the future, data storage and access currently are being beta-tested by a small group of VA researchers in the VA Data Commons at the University of Chicago. Here, MVP data are completely deidentified and researchers do not access the data directly. Instead, they select the cases and controls needed for their analysis, and the analysis is completed by an automated tool with results returned to the researchers. Researchers use MVP data to study diseases such as diabetes, cancer and other service-related conditions. The amount and types of data generated by MVP and curated for researchers are expanding and will in the future include whole genome sequence data, methylation, metabolomes and proteomes.

MVP is the largest database of genetic information on African Americans in the world with over 170,000 participants enrolled thus far. In the cohort overall, 25% of enrollees are from minority racial and ethnic backgrounds. The program has completed the largest genome-phenome analysis (large scale analysis of the association between genetic variations and health conditions) in history by partnering with the Department of Energy on their supercomputer, SUMMIT, and provisioned summary results to all VA researchers. A manuscript describing this analysis is currently under a revise-and-resubmit request by the journal *Science*. Once published, the summary results also will be made available to the broader research community through the National Institutes of Health's portal, *Database of Genotypes and Phenotypes*.

By providing genotype data to MVP researchers, over 350 peer-reviewed papers in high-impact journals have been published since 2018, with over 50 papers published in 2023 alone. Because so many Veterans have volunteered to participate, MVP is able to shed unprecedented light on conditions that affect Veterans from all backgrounds. For example, the *American Journal of Psychiatry* recently published a study that identified 12 DNA variants associated with risk of suicide and highlights the genetic link between suicide and factors such as impulsivity, chronic pain, attention deficit hyperactivity disorder and heart disease. The findings suggest that suicide risk shares some genetic similarities for risk for these conditions and could help identify new prevention and treatment strategies. MVP contributed the largest dataset from Veterans for this study, with 14,089 cases and 395,064 controls. The study included data from 22 cohorts for 43,871 included cases and 915,025 matched controls.

Researchers are using MVP data to learn about the genes that may affect whether combat Veterans develop PTSD. The team hopes to gain new insight into the effects of PTSD on the brain so that new and improved treatments can be explored. This genomic research project on PTSD is one of the largest ever done.

MVP researchers also are examining how differences in a person's genes affect gene expression or how the information in DNA is translated into actual physiological changes within the body. Studying changes in gene expression will help researchers understand the genetic risk factors of different diseases. Researchers are looking at numerous health conditions such as PTSD, depression, diabetes and heart disease. Researchers will use the results to improve treatments and develop precision medicine, which is treatment customized to individual patients.

Conclusion

VA research is very focused on Veteran health and needs, and it is core to VA's mission. Through research on military environmental exposures and in many other areas of importance to Veterans' health, VA will continue to provide and lead the way to serve the Nation's Veterans. VA consistently has produced scientific findings across a range of diseases and conditions that enable VA to make real differences in the lives of Veterans and all Americans. This public benefit is due to the dedicated efforts of countless VA scientists and research staff over a long history and to those Veterans who selflessly served their Nation in the Armed Forces and continue their service through participation in research.

Mr. Chairman, this concludes my testimony. Thank you for the opportunity to testify today and for your continued support of our mission. I am happy to respond to any questions you or the Committee may have.

STATEMENT of

NAMI Montana

for the Record

U.S. Senate Committee on Veterans' Affairs

"Foundation of Care: Examining Research at the Department of Veterans Affairs"

Written Testimony Submitted by:

Matt Kuntz, J.D.

Executive Director

NAMI Montana

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Statement of Matt Kuntz, J.D., M.H.A.

Executive Director of NAMI Montana

United States Senate Committee on Veterans Affairs

"Foundation of Care: Examining Research at the Department of Veterans Affairs"

I. Introduction

Chairman Tester, Ranking Member Mo and distinguished members of the Senate Veterans Affairs Committee (SVAC), on behalf of NAMI Montana, the National Alliance on Mental Illness for Montana, I would like to extend our gratitude for the opportunity to share with you our views and recommendations regarding "Foundation of Care: Examining Research at the Department of Veterans Affairs." The entire NAMI community applauds the Committee's dedication in addressing the critical issues around veterans' suicide. NAMI is the nation's largest grassroots mental health organization dedicated to building better lives for the millions of Americans affected by mental illness. NAMI advocates for access to services, treatment, support and research, and is steadfast in its commitment to raising awareness and building a community of hope for all of those in need.

As NAMI Montana's Executive Director, I serve on the Secretary of Veterans Affairs National Research Advisory Council. I also recently completed my service as a member of the Creating Options for Veterans Expedited Recovery Commission (COVER Commission). I am not speaking on behalf of either NRAC, or the COVER Commission.

My view is a little unique because of my combination of on-the ground service in a rural state; my COVER Commission work in which we found glaring gaps in VA's research and application of research; and coming onto NRAC at the beginning of the pandemic in which the VA research ecosystem partnered with pharmaceutical companies to test the safety and efficacy of vaccines that were critical to the health of veterans and our entire population.

I also helped craft the Hannon Precision Brain Health Initiative. In that effort, I was able to see the power of Congressional strategic realignment of ORD's work to achieve critical transdiagnostic research tasks. I also advocated for SVAC to save ORD from imploding last year due to its byzantine Conflict of Interest rules. If SVAC hadn't saved ORD last year in the Cleland-Dole Act, we would be having a much different hearing today.

Based upon that background and experiences, I believe it's time for Congress to step in to give ORD clear legislative purposes and to realign its granting process along the lines of those purposes to improve veterans healthcare outcomes.

II. Recommended strategic realignment.

a. Background

The Veterans Administration's Office of Research and Development (VA ORD) is in need of a sustainable strategic position to best serve the health of America's veterans. The lack of a long-term strategic position can most clearly be seen when VA medical research was left out of the 21st Century Cures Act. Within the VA, this exclusion was seen as a failure of VA research to identify and publicize its successful and noteworthy outcomes. (NRAC Meeting Minutes, June of 2019) A harder analysis would suggest that the VA ORD is not strategically positioned to have healthcare outcomes that truly improve veterans healthcare.

Dr. Rachel Ramoni, VA ORD's Chief Research and Development Officer, is working to transition the organization "[I]into an integrated VA Research Enterprise to more efficiently and effectively achieve our mission to improve Veterans' well-being through research (Ramoni, 2023, p.2). Dr. Ramoni's transition is built on the idea of trade-offs and a fit between activities. The major trade off is moving away from the current model of roughly 100 VA Medical Centers (VAMCs) independently conducting research towards an integrated whole that functions as a research enterprise (Ramoni, 2023). The improvement in fit between activities should come in "[S]hifting from distributing funding by discipline (i.e., basic, clinical, health services, and rehabilitation) to distributing funding via integrated portfolios (e.g., precision oncology)" (Ramoni, 2023).

This is a necessary transition and it speaks to the leadership of Dr. Ramoni and her team. Yet, this transition does not go far enough in putting the VA ORD in a sustainable strategic position for long-term success. A sustainable strategy requires operational trade-offs and a fit between activities (Porter, 1996). A true transformation of this bogged-down program requires bigger trade-offs and better fit between activities.

b. VA ORD needs clear purposes to pursue and outcomes to measure.

VA ORD's current purposes are muddled by a variety of missions, objectives, and priorities. This lack of focus makes it difficult to determine what outcomes VHA, VA ORD, or its Congressional funders are seeking.

The clearest statement of VA ORD's mission is from Dr. Rachel Ramoni presentation on the VA Research Enterprise Transformation to the VA's National Research Advisory Council. Dr. Ramoni said that VA ORD mission was to "Improve Veterans' well-being through research" (Ramoni, 2023, p. 2). The Office of Research and Development's FY 2022 Report to the National Research Advisory Council (2023, p. 3) describes a more expansive mission:

- To improve Veterans' health and well-being via basic, translational, clinical, health services, and rehabilitative research;
- To apply scientific knowledge to develop effective individualized care solutions for Veterans;

- To attract, train, and retain the highest-caliber investigators and nurture their development as leaders in their fields; and
- To assure a culture of professionalism, collaboration, accountability, and the highest regard for research volunteers' safety and privacy.

Further muddying the strategic waters, the Office of Research and Development's FY 2022 Report to the National Research Advisory Council (2023, p. 3) described the the ORD's research investments as being built around five overarching strategic priorities:

- Increasing Veterans' access to high-quality clinical trials
- Increasing the real-world impact of VA research
- Putting VA data to work for Veterans
- Actively promoting inclusion, diversity, equity, and access
- Building community through VA research

One would expect that the ORD integration would provide clarity, but that is not the case. The Office of Research and Development's FY 2022 Report to the National Research Advisory Council (2023, p. 11) described the VA ORD research enterprise after the transformation as having:

- A Unique Value Proposition: VA Research uniquely contributes to the biomedical research ecosystem by focusing on the needs of Veterans and the Veterans Health Administration, as well as being embedded in the largest integrated health care system in the country.
- Real-world Outcomes: The VA Research enterprise improves Veterans' well-being by efficiently solving specific, real-world problems.
- Engaged People: The VA Research enterprise involves and relies upon diverse staff, researchers, and communities who feel a sense of belonging and empowerment and who share the purpose to improve Veterans' well-being.
- Integration: The VA Research enterprise is an integral part of the VA enterprise and the nation's biomedical and health ecosystem, strategically leveraging its relationships and partnerships.
- Operational Excellence: The VA Research enterprise is efficient and flexible in its operations. It offers streamlined processes, effective communication and collaboration, high-quality customer service, and the right tools and resources to support staff, researchers, and communities as they work to improve the well-being of Veterans.

This combination of mission, purposes, and strengths leads to a lack of strategic focus to VA ORD's efforts that frustrates its ability to serve veterans healthcare. ***It is time for Congress to clarify the purposes of VA ORD to***

- ***To serve veterans through large-scale research and commercialization support in veteran-specific healthcare areas such as toxic exposures, spinal cord injuries, prosthetics and brain health, to include suicide prevention, substance use disorders, and geriatric issues, and***
- ***To support quality improvement and implementation research throughout the Veterans Health Administration of the Department of Veterans Affairs.***

VA ORD's success under these purposes can then be measured using two of the goals laid out in VA ORD's FY 2022 Report to the National Research Advisory Council (2022, p.2) states that "Success of the VA research program should encompass several goals:

- ***The program should push the science in Veteran-specific areas such as traumatic brain injury, posttraumatic stress disorder, military exposures, and suicide to unlock new treatments and help speed those scientific advances through the translation pipeline to get these treatments into practice more quickly;***
- ***Success should be demonstrated through improvements to how care is organized and delivered in VA so that new advances are implemented effectively and widely to ensure that we are delivering the best available care consistently to all Veterans.***

c. Large-scale studies on veteran-specific healthcare issues is VA ORD's ultimate strength and should guide all trade-off decisions.

VA ORD has an internal budget of roughly $923 million dollars annually (Department of Veterans Affairs, 2023). While this is a significant amount of funding, it is not enough funding for VA ORD to succeed in moving whatever research it chooses from basic discovery to improved patient care. The challenge and cost of bringing new therapeutic agents to market is highly contentious, but there is little argument that the cost is expensive and increasing. Recent estimates range from $314 million to $2.8 billion to go from initial research through FDA approval (Wouters, 2020).

With the costs required to get research outcomes to veterans at that scale, VA ORD's budget has to be very strategic in order to be successful in improving veterans' lives. "[A]s a matter of comparison, in 2004, research spending by the National Institutes of Health reached $28.5 billion, whereas the members of the Pharmaceutical Research and Manufacturers of America report R&D spending of about $40 billion[.]" (Dubois, 2015, p. 846). The NIH budget increased from $28.5 billion in 2004 to President Biden's FY 2024 budget which proposed $51.1 billion for NIH (NIH Office of Budget, n.d.)

VA ORD's failure to marshall its resources into a coherent research enterprise may have been part of the reason it was excluded from the 21st Century Cures Act. When discussing that exclusion in June of 2019, an NRAC member suggested that VA ORD must focus on what VA research can do that no one else can (NRAC Meeting Minutes, 2019, p. 10). The specific quote from the NRAC member was "What has VA done that no one else has done, and that wouldn't have been done elsewhere" (NRAC Meeting Minutes, 2019, p. 10)?

VA ORD must focus its efforts on research that best serves its purposes and research that it is uniquely suited to provide for our nation's veterans. That focus is described in purpose one to serve veterans through large-scale, veteran-centric healthcare research and commercialization support in specific areas including toxic exposures, prosthetics and brain

health and suicide prevention, to include suicide prevention, substance use disorders, and geriatric issues.

VA ORD is in the best position of any medical research entity to deliver large-scale, big-data, veteran-centric healthcare research. This is already one of ORD's strengths as demonstrated through the Million Veteran Program, National Precision Oncology Program, and Hannon Precision Brain Health Initiative. It is time to move more heavily into this key strength of veteran health research with multiple research sites and a minimum of 200 participants.

d. All other research efforts should be focused directly on moving insights into veterans healthcare through grants for commercialization, implementation, and quality-improvement.

VA ORD's efforts only succeed if the research insights are able to actually improve veterans' health. Some insights can be harnessed through academic publication alone. Others may be shared with other researchers through large-scale VA data commons like those for Precision Oncology and the Hannon Precision Brain Health Initiative. Many will need additional support to be able to make it all of the way to veterans being served in clinical settings. This additional support by VA ORD will be granted for commercialization, implementation, and quality improvement.

This grant structure works together to build both on successful research while addressing new veterans health research needs that arise. These challenges were described by Dr. Ramoni when presenting on Proposed Priorities for the 2021 ORD Budget. "There has been a tendency to look at things backward. There needs to be a way to align funding with areas where there have been successes. For example, an evaluation of the portfolio should help with investing in those things that have been going well based on outcomes, while also turning toward forward-looking projects" (NRAC Meeting Minutes, June, 2019, p. 10).

(1) Commercialization Grants

VA ORD Commercialization Grants would be a new type of grants for VA ORD that address the basic reality that many veteran healthcare research innovations need to be approved by the Food and Drug Administration (FDA) before they are available for veterans care. The VA is not in position to move forward expensive FDA approval processes on its own, so it must support private partners efforts.

An example of how effective commercial funding efforts can be seen through the Defense Advanced Research Projects Agency's (DARPA) Revolutionizing Prosthetics program in which VA Rehabilitation, Research and Development was a clinical partner. DARPA funded a private partner to develop an advanced prosthetic and move it through the FDA process. This project was highlighted as one of VA ORD's main accomplishments in NRAC's letter to Secretary Schulkin in February 2017 (NRAC, 2018). This is exactly the kind of project that VA ORD needs to be able to fund on its own. VA ORD has powerful insights into what healthcare

treatments and technologies the nation's veterans need to have commercialized. It should not have to wait for DARPA or another agency to act. ORD should be able to put its own insights into action through matching commercialization grants.

Many of these commercialization grants should come out of insights generated in the large-scale veterans studies described above. For example, the Precision Oncology and Million Veterans programs will likely be considered failures if they do not generate scientific insights that will lead to treatment methodologies that require approval by the FDA. Those insights will be tailor-made for improving veterans care and the companies supporting them should be in a great position to obtain commercialization grants to move towards FDA approval.

Similarly, plugging the VA's quality improvement research into VA ORD's larger system data tools should help identify issues with veterans healthcare that need new FDA-approved interventions to address. VA ORD will have the critical roles of identifying pressing clinical needs in veterans healthcare that require new treatment or modalities, identifying the most suitable private sector partner to bring that treatment or modality to market through a competitive process, and providing matching funds for that partner to push the treatment or modality towards FDA approval.

(2) Implementation and Quality Improvement Grants

VA ORD Implementation and Quality Improvement Grants will support the implementation of evidence-based practices in veterans healthcare and to promote continuous quality improvement. These grants should support initiatives that apply research findings into practical settings, enhance the delivery of healthcare services, improve healthcare outcomes, and foster a culture of continual learning and improvement within the Veterans Administration. The overarching goal of these grants is to bridge the gap between research and practice, ensuring that the latest discoveries are efficiently and effectively integrated into the healthcare system to benefit veterans.

Implementation grants will help the VA adopt evidence-based practices in a scientific manner. The abysmal state of treatment-resistant depression care in the VHA system is an example of how badly these grants are needed.. The COVER Commission found that the VA had effectively refused to adopt evidence-based care methodologies for treatment-resistant depression despite those care types being recommended by the VA's own depression clinical practice guidelines (COVER, 2020). The lack of implementation methodologies for treatment-resistant depression was further highlighted by when President Trump was pushing for the VHA to adopt Esketamine for veterans' suicidality and the VHA appeared to have no idea how to assess or implement this medication despite it having been in the private clinical pipeline for years in one of the VA's primary clinical priorities (Thielking, 2020).

Another implementation example is the Suicide Prevention in the Emergency Department (SPED) methodology. This is research-proven method for preventing suicide in a patient group that is at extremely high risk of suicide. Congress pushed the VA to speed up the

implementation of this program that was stuck in a research environment through Section 507 of the Hannon Act (S.785, 2020). Congressional action was necessary in order to create a more direct path to implementation studies and quality improvement. The VA's research timelines were much too slow under the current system. Implementation was completed in Boudreaux (2020) and process improvement in Boudreaux (2023). The transition needed to happen faster for this high priority clinical population at high risk of mortality.

The majority of the quality improvement study concepts will come directly from VHA clinical care and administrative services. These small quality improvement studies have been emphasized for years in the VA as a way of improving care, such as the efforts in 2018 to use quality improvement to strengthen weaker clinical care systems. (HealthITAnalytics (2019). This is also consistent with the COVER Commission's (2020) recommendation for renewed focus on quality improvement with the VHA.

III. Conclusion:

It is time for VA ORD to transform into an outcome-oriented organization. ORD has taken clear steps to move this effort forward, but it needs Congress to clarify its mission and strategic funding priorities. Thank you again for the opportunity to testify in front of this honorable Committee. Your attention to this issue means a lot to me, NAMI Montana, and the people we serve. We look forward to working with you to improve the healthcare of America's heroes.

Sincerely,

Matt Kuntz, J.D., M.H.A.

Executive Director

NAMI Montana

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Questions for the Record

Department of Veterans Affairs (VA)
Answers to Questions for the Record
Committee on Veterans' Affairs
United States Senate
"Foundation of Care: Examining Research at the Department of Veterans Affairs"

November 1, 2023

Questions for the Record from Senator Mazie K. Hirono:

Question 1: In the hearing, you acknowledged that Asian American Veterans are underrepresented in the Million Veteran Program (MVP) and shared that once the MVP reached its one million-Veteran milestone, the project will prioritize outreach to underrepresented subpopulations like Asian Americans and Native Americans. How do you plan on conducting culturally appropriate outreach to Asian American Veterans to augment their representation in MVP?

VA Response: The Million Veteran Program (MVP) is currently planning a multipronged and phased approach to increase participation among subpopulations that are traditionally under-represented by age, race, ethnicity, sex, gender identity, religion, sexual orientation, geography (rural Veterans), or medical conditions of interest. Part of our strategy is to 'take MVP to the Veterans' by engaging in collaborations with relevant community organizations to educate and increase awareness of the program. To increase the Asian American involvement in MVP, the following approaches will be used:

- Map out the distribution of the Asian American Veteran population across the country by proximity to VA medical centers (VAMC) and/or community–based outpatient clinics.
- Identify where new MVP recruitment sites can be launched.
- Conduct focus groups with Asian American Veterans, both those who are and are not already enrolled in MVP, to identify what resonates with them about the program, what platforms they prefer, and what are their concerns.
- Develop materials to share with the Asian American Veteran community through existing direct mail/email campaigns, as well as engage our partners at the VA Center for Minority Veterans, Veterans Service Organizations (VSO), and other culturally relevant community organizations to increase awareness of MVP.
- Partner with Readjustment Counseling Services Mobile Vet Centers to conduct relevant community events that inform Asian Veterans of the importance of being represented in the cohort and enroll MVP volunteers on site.

Question 1a: Does the program need additional support or funding to achieve/obtain, at a minimum, a proportionate database of underrepresented groups?

VA Response: No additional funding is needed. MVP will use its current funding to accommodate focused recruitment strategies for the underrepresented populations.

Question 2: You said that, for Veterans participating in the MVP, they generally go to a VA hospital for a 20-minute appointment where they provide a blood sample, or they can enroll in the program online. What proportion of Veterans participated in the MVP database by providing an at-home blood sample?

VA Response: Since the 2019 launch of our web-based portal, more than 63,000 Veterans have joined MVP using the online program, representing 28% of MVP enrollments since the online launch. When they join online, they have the option to request an at-home blood collection kit or schedule an appointment at the nearest MVP enrollment site to provide a blood specimen. Since the launch of the home-collection kits in November 2021, more than 32,000 Veterans have requested the kits with to date, approximately 18,500 Veterans returning blood specimens for analysis, representing 37% of online participants since the at-home collection kit launch (approximately 2% of the entire MVP cohort). Veterans may choose to go into a VA medical center even after requesting an at-home collection kit.

It is important to note that the home collection kit yields about 0.5 milliliter (ml) of blood, while the in-person collection yields about 10ml. Therefore, only limited amount of DNA and data can be generated from the home-collection kit. On the other hand, the in-person collection at a VA hospital yields larger amounts of DNA for multiple analyses, including whole genome sequencing, as well as metabolites and proteins. The value of the home-collection kit is its ability to get DNA samples from volunteers who may live too far away or are unable to easily get to a collection facility. Veterans who live close to collection facilities are encouraged to provide blood in person if possible. For Veterans who opt to go in person for blood collection, every effort is made to tie the visit to a scheduled VA clinical appointment.

Questions for the Record from Senator Marsha Blackburn:

Question 1: Dr. Ramoni can you please expand more on the relationship between the Office of Research and Development and Vanderbilt University? Can you please share specific examples of research that your office conducts with Vanderbilt University or other Tennessee universities.

VA Response: The Research Service at Tennessee Valley Healthcare System (TVHS) has a very close relationship with our academic affiliates, Vanderbilt University Medical Center (VUMC) and Meharry Medical College. Principal Investigators (PI) at TVHS have academic appointments at either VUMC or Meharry. The relationship between TVHS' Research Service and VUMC is particularly strong, dating back to the early 1960s when the current VA was built on land obtained from Vanderbilt so that the two institutions could be near one another. Currently, there are 70 VUMC faculty who are funded by the Office of Research and Development (ORD) to perform Veteran-related research. Examples of the types of studies being conducted include:

- Dr. Eric Grogan is studying unnecessary invasive lung cancer diagnostic procedures using the VA-TVHS data base, and patient data from VUMC Lung Nodule Cohort and the University of Virginia Lung Nodule Cohort.
- Dr. Jennifer Lewis and biostatisticians from VUMC are studying the practice of, knowledge of, and attitudes of VA-TVHS providers towards lung cancer screening with low-dose computed tomography screening in high-risk patient populations.
- Dr. Matthew Freiberg is leading an observational study to analyze clinical and administrative data available through the Veterans Aging Cohort Study. Partnering with VA-TVHS, the West Haven VA, and VUMC, this study looks at the clinical and genetic determinants of peripheral artery disease, microvascular disease, and major adverse limb outcomes.
- Dr. Christianne Roumie is working with VA-TVHS providers and Hematology/Oncology fellows at UVMC to conduct a new quality assessment of colorectal cancer care to determine how well VA-TVHS meets overall National Cancer Care Network quality metrics.

TVHS is currently involved in an Honoring our Promise to Address Comprehensive Toxics (PACT) Act of 2022 project led by Dr. Bradley Richmond, a Pulmonary/Critical Care physician at TVHS, who is investigating environmental exposures and their effects on lung disease in Veterans.

Regarding other universities, VA has several collaborative efforts with the University of Memphis and the University of Tennessee Health Science Center (UTHSC) College of Medicine. For example, there is a Memorandum of Understanding for establishing a Center of Excellence for Veterans Health involving the University of Memphis Institute for Intelligent Systems. This effort will focus on better transparency and access to health data to expedite novel treatments for Veterans' health care. With UTHSC, there is research into post-traumatic osteoarthritis arising from joint injury. The Memphis VAMC is also a part of VA's lung cancer precision oncology program, which enables partnerships with its academic affiliates.

VA investigators are also collaborating with East Tennessee State University on multiple activities. Similar to other VAMCs, VA investigators have dual appointments at East Tennessee State University and are doing work in chronic viral infections, contributing to the VA national research biorepository, the Science and Health Initiative to Combat Infectious and Emerging Life-Threatening Diseases (VA SHIELD), and also mentoring and training future investigators. Additionally, some of these investigators also receive funding from the Department of Defense (DOD) for their work.

Question 2: I appreciate Dr. Muralidhar discussing the broad security measures in place for the Million Veteran Program. Can you please elaborate on the broader physical and cybersecurity measures your office takes to protect all projects and programs under its umbrella?

VA Response: VA's research program operates within VA's Office of Information and Technology (OIT) data security requirements and system access controls, including

all applicable Federal statutes, regulations, VA and Veterans Health Administration (VHA) policies that govern privacy, storage, and security of data. Additional committee reviews and regulatory controls to ensure appropriateness of data access and transparency of data storage are required for all research projects.

Every VA research project must undergo a review by a VA Information Security Officer, and all data must be retained or stored in accordance with applicable Privacy Act System of Records notice, Records Control Schedule 10-1, and VA policy. All VA researchers are required to complete annual cybersecurity and privacy training. Each research protocol that involves human subjects (including identifiable and coded human data) contains a section of how the investigator will protect the privacy and confidentiality of the patients and their data.

In addition to the security measures in place for MVP that were described during the hearing, there are other programs with similar program-specific physical and cybersecurity controls. For example, VA's Informatics and Computing Infrastructure (VINCI) program serves as a platform to manage and provide secure access to research data for thousands of VA investigators. VINCI maintains an "Authority to Operate" certification covering hundreds of aspects of security controls, including encryption, types of data stored, connections with other systems, types of users allowed, and firewalls.

Questions for the Record from Senator John Boozman:

Question 1: Recently, the FDA has labeled multiple alternative therapies, like MDMA, as "breakthrough therapies," and we anticipate approvals in the near future. However, many Veterans are not waiting for that. This highlights the urgency to expand the research around these therapies meaningfully. We owe it to Veterans to determine whether these compounds are safe and effective, and I believe the VA should be a part of this. Dr. Ramoni, what steps are the VA taking to scale up clinical research in the VA system related to alternative therapies like MDMA?

VA Response: Our Department is not only focused on finding the most innovative treatments but in doing so safely. ORD and the Office of Mental Health and Suicide Prevention (OMHSP) continually work together on proactive approaches to determine potential benefits of emerging therapeutics, including psychedelic assisted therapy, for Veterans. In September 2023, ORD and OMHSP co-hosted a State-of-the-Art Conference to address two major objectives: (1) to better understand the current state of scientific evidence and to identify a strategic framework to conduct future psychedelic assisted treatment research for select mental health conditions; and (2) to determine the necessary steps for potential VA system-wide clinical implementation for agents where Food and Drug Administration (FDA) approval may be anticipated. Furthermore, there are currently several studies underway at VA facilities that are funded by external sources.

FDA has approved Esketamine as an alternative therapy treatment for major depressive disorder. Early research suggests it may also be effective for substance use disorders (SUD), posttraumatic stress disorder (PTSD), treatment-resistant depression, and other severe brain health conditions. This is encouraging, but each compound-indication approval requires rigorous research to determine its safety and efficacy. It is imperative that we ensure we base future treatment recommendations on sound science.

Question 2: Dr. Ramoni, can you talk to me about what we have learned from this treatment, and how the VA will apply those lessons learned to future research related to alternative therapies?

VA Response: VA is funding several clinical trials using Ketamine (intravenous) and Esketamine (intranasal) to treat major depression and alcohol use disorder, and as an adjunctive therapy to prolonged exposure PTSD treatment, including treatment-resistant late-life depression, antidepressant-resistant PTSD, and treatment-resistant depression. The results of these studies are mixed, and most are yet to be published, but they provide robust evidence for the effect of ketamine on depression, specifically treatment-resistant depression. However, the results of a large multi-center clinical trial co-sponsored by VA and DOD and published in 2022 found no significant effects of Ketamine in the treatment of PTSD in active-duty Service members and Veterans.[1] The lessons learned from Ketamine will be carefully applied to the research on and clinical implementation of other novel alternative therapies for mental health conditions.

Question 3: In 2020, the National Influenza Vaccine Task Force, co-led by the Department of Health and Human Services and the Department of Defense, published the National Influenza Vaccine Modernization Strategy. The strategy outlines a vision for the United States' influenza vaccine enterprise to be highly responsive, flexible, resilient, scalable, and more effective at reducing the impact of influenza viruses. DOD has initiated research efforts to further this strategy, and HHS continues to push forward with broad implementation efforts. Dr. Ramoni, is the VA currently conducting any research efforts related to influenza vaccine modernization? If not, does the VA plan to begin any such efforts?

VA Response: VA researchers frequently study influenza virus characteristics, including whole genome characterization of influenza viruses and influenza virus effects on the human immune system, especially in aging. Additionally, VA conducts internal surveillance within the Veteran patient population on influenza diagnosis, treatment, safety, and efficacy. A VA collaboration with FDA and the Biomedical Advanced Research and Development Authority (BARDA) originally founded to study the Coronavirus Disease 2019 (COVID-19) has expanded to include treatment and vaccine effectiveness studies for respiratory syncytial virus (RSV) and influenza. The results of these studies inform vaccine modernization and are noted in VA's 2023 Actions Report to the 2020 National Influenza Vaccine Modernization Strategy.

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[1] Dose-related effects of ketamine for antidepressant-resistant symptoms of posttraumatic stress disorder in veterans and active-duty military: a double-blind, randomized, placebo-controlled multi-center clinical trial. Abdallah et al. *Neuropsychopharmacol.* 47, 1574–1581 (2022).

Questions for the Record from Senator Maggie Hassan:

Question 1: Last year's groundbreaking PACT Act recognized the impact that exposure to toxic substances has had on Service members' health while deployed overseas. It also set up a framework for reviewing new research into toxic exposures going forward. Toward that end, constituents in New Hampshire continue to be concerned with the impacts of toxic exposure on Service members here at home—not just overseas. What is the VA doing to ensure that we are studying whether military bases or operations inside the United States are exposing our Service members to toxic substances and any resulting health impacts?

VA Response: When DOD recognizes a potential hazard, they work with VA to study health outcomes from military environmental exposures both stateside and abroad. In particular, VA works in close collaboration with DOD through the Deployment Health Working Group to address environmental exposure health on Veterans. Additionally, Veterans can also provide feedback directly to VA or through the network of VSOs that meet regularly with VA leadership. The PACT Act also provided new mechanisms to directly solicit input from Veterans through Federal Register Notices and annual listening sessions with Veterans, VSOs, and others.

Questions for the Record from Senator Mazie K. Hirono:

Question 1: VISN 21, which includes Hawaii, Philippines, Guam, and American Samoa, does not have VA precision oncology programs (POPs) like the Lung Precision Oncology Program (LPOP) or Precision Oncology Program for Cancer of the Prostate (POPCaP). Veterans' limited access to VA's cutting-edge oncology research in Hawaii is further concerning because, in 2022, Hawaii was ranked last in the nation for early-stage diagnosis of lung cancer and sixth in the nation for rate of new cancer cases. How does the VA encourage veteran participation in its precision oncology research programs in VISNs that do not have POP sites?

VA Response: In Veterans Integrated Service Network (VISN) 21 the precision oncology hub for both Lung Precision Oncology Program and Precision Oncology Program for Cancer of the Prostate is the San Francisco VAMC. Expanding precision oncology to other VA facilities in the VISN requires sites to have the supporting infrastructure and clinical and research experts to do the work. ORD partners with the National Oncology Program (NOP) to support the use of VA National Tele-Oncology (NTO) services, which involves 71 VA facilities, to provide specialized expertise in oncology and enhance Veterans' access to the most advanced oncology care. This service includes access to expert oncology consultations (including rare malignancies) and delivers cancer diagnosis treatment, care coordination, palliative care for Veterans, and recruitment and enrollment into clinical trials via telemedicine. ORD is currently working with NOP to leverage the NTO platform and bring oncology care, trials, and research to Veterans across VISN 21.

Question 2: The Department's POPs often require a VA hospital or rely on the research sites' surrounding clinical research ecosystem such as a nearby National Cancer Institute comprehensive cancer centers or medical academic research center, preventing areas that do not have such resources from participating. Has the VA explored establishing a POP research site in VISN 21? What are the limitations for VISN 21 from establishing a POP research site?

VA Response: The hub Precision Oncology Program research site for VISN 21 is the San Francisco VAMC, with affiliated spoke sites located in Reno, Sacramento, and Fresno. VA is actively looking to recruit medical oncologists to support further expansion and delivery of precision oncology care and research, but currently offers NTO services across 71 VA facilities.

It is important to note that Veterans in the Pacific Islands VA Healthcare System (PIVAHCS) receive comprehensive cancer care, including precision oncology, primarily through community care. In Hawaii (Matsunaga VAMC), the initial work-up may be obtained through primary care with support from some VA specialists, but otherwise patients are sent to community care specialists to obtain biopsies. Patients with new cancer diagnoses are sent out on community care to Queens Medical Center, Kuakini Medical Center, or Tripler Army Medical Center. Veterans in Samoa, Guam, and the Philippines are sent out to community care for cancer work-up and treatment. Any precision oncology efforts, such as somatic mutation testing of tumor tissue, are coordinated by community care physicians. Currently, PIVAHCS has two registered nurses in Specialty Care who function as cancer navigators, but discussions are actively ongoing to build capacity to support PIVAHCS. Additionally, facilities are always available to assist with triage and the transfer of complex cancer patients to the mainland, as is clinically appropriate.

Question 3: I asked you during the hearing for the number of Veterans that have participated in VA research. Please provide the number of Veterans that have participated in VA research, and include a breakdown by demographics, including but not limited to, gender, racial and ethnic identity, age, service period.

VA Response: VHA does not maintain a central database tracking how many Veterans participate in all clinical research studies. Currently, ORD is funding more than 460 active clinical trials at various stages, with information maintained by each of its respective PIs. As an example of a typical demographic breakdown, the Cooperative Studies Program (CSP) enrolled 67,658 Veterans across 15 active clinical trials in fiscal year (FY) 2023. Of this figure, 93.4% were males and 6.4% were females; 90.5% were non-Hispanic/Latinos and 9.3% were Hispanic/Latino; and 74.6% were Caucasian and 19.6% were African American. These ratios have generally been consistent over previous years/reports within CSP surveying. Service period is only a collected data element when specifically relevant to the study protocol.

Questions for the Record from Senator Angus S. King Jr:

Question 1: Firearm Safety Suicide & Prevention Research – Among adults who died by suicide in 2020, firearms were ~20% more commonly involved among Veterans (71%) than non-Veterans (50.3%). Moreover, although non-Veteran firearm-involved suicide deaths decreased from 2001 to 2019, firearm-involved suicide deaths rose 3 percent among male Veterans and 13 percent among female Veterans. And for Veterans in VHA care who died from suicide and had been identified in the lower 50% risk tier, the prevalence of firearm involvement was 79.4%.

The data shows that Veterans who are clinically considered less at risk of suicide are more likely to kill themselves with a firearm. What research is ORD doing regarding the nexus between firearm safety and suicide prevention? Right now there are only 5 projects regarding lethal means and firearms safety research, totally less than $800,000. Why so little? Can more be done?

VA Response: ORD-funded research has focused on developing strategies that promote safe firearm storage for those at risk. One ORD-funded project used community-based, participatory research strategies to involve firearm retailers in developing and implementing a safe storage program. The original research project involved 3 firearm retailers, but with continued support from OMHSP, the investigators have expanded the program to 12 sites in 1 state with planned expansion into a second state. Two additional projects specifically concern developing counseling approaches that can be used in VA health care facilities. Three other lethal means safety (LMS) projects have been funded by VA entities other than ORD including OMHSP, Rocky Mountain Mental Illness Research, Education, and Clinical Center, and VISN 1. The Suicide Prevention Research Impact NeTwork (SPRINT), an ORD-funded research center dedicated to suicide prevention research, included LMS as a suicide prevention research priority in 2023. SPRINT has funded several research planning awards to projects focused on LMS, including:

- Implementation of lethal means counseling among Veterans with problematic substance use.
- Development of a brief, motivational interviewing intervention manual for LMS counseling for implementation within Primary Care and Primary Care Mental Health Integration.
- Project Life Force- Rural Veterans, Suicide-Specific Safety Planning Group Intervention over Telehealth for Rural Veterans and Veterans who do not seek VA Care: Pilot Implementation.
- Study to Assess Risk and Resilience in Service members (STARRS) – Longitudinal Study Researcher-in-Residence Program.
- Coaching Into Care (CIC) Suicide Prevention intervention: A promising LMS intervention for family members of Veterans at risk for suicide.

Additionally, ORD is restructuring to develop a Suicide Prevention Actively Managed Portfolio that will promote rapid advancement of more research projects and improved

alignment of research with operational priorities including LMS. We anticipate LMS research will be prioritized, leading to dedicated opportunities for LMS projects.

VA's Suicide Prevention Program (SPP) also funds innovative best practice pilots identified by the research to test feasibility and acceptability for field implementation. Recent demonstration projects addressing LMS include:

- Using Artificial Intelligence (AI) to identify firearms access in Veterans with SUDs.
- CIC LMS discussions with families/concerned others at inpatient psychiatric discharge.
- LMS with Older Veterans – Veteran and caregiver training videos curriculum.
- Safe firearm storage training for concerned/significant others.
- The Armory Project - Partnering with firearm retailers to promote and provide Out-of-Home Storage.
- SPP Now Plan is an annual effort to focus attention and support on high impact strategies to mitigate Veteran suicide. SPP Now Plan efforts have identified metrics and targets to assess progress and impacts of the effort toward accomplishing priorities and goals. The following are FY 2023 and FY 2024 Now Plan strategies with lethal means and firearm focus:
    - Law Enforcement Work Group to advance LMS across Federal agencies with focus on Veterans in law enforcement roles.
    - Gun lock distribution and LMS training to Community Care Network providers caring for Veterans at high risk for suicide.
    - Gun safes offered through VA Department of Prosthetics.
    - LMS video series development and dissemination in partnership with the National Shooting Sports Foundation.
    - LMS enhanced training, website and toolkit updates for the VA Caregiver Support Program.

In addition, VA's Office of Rural Health (ORH) funds and supports research to test interventions to reach Veterans living in rural settings. LMS focused projects include:

- Mitigating Firearm Suicide Risk for Rural Reserve/Guard Women Veterans: Online and Telephone/Telehealth-Implemented Shared Decision-Making Interventions.
- Facilitating LMS Conversations with Rural Caregivers.
- Firearm Injury Prevention among Rural Veterans in the U.S.: Database of Individual Patient Experiences: Pre-Implementation Study.
- Implementation and Evaluation of Firearm Injury Prevention Program Strategies at Two Rural VA Facilities: A Pilot Study.

VA's Women's Health Research Network Consortium (WHRN) has significantly expanded research in suicide prevention bringing national attention and resources to accelerate research into women Veterans' unique risks and resiliencies and gender differences that may inform gender-tailoring of suicide prevention interventions.

The Women Veterans Suicide Prevention Research Work Group provides technical support for researchers, promotes collaboration with national VA program offices, and increases dissemination and translation of research into clinical practice, public health strategies and policies.

In February 2021, the work group spearheaded a special journal supplement of Medical Care focused on "Advancing Knowledge of Suicide Risk and Prevention among Adult Women." This special supplement published new research addressing suicide risk, resilience, surveillance, and prevention among adult women, with a special emphasis on women Veterans and women on active duty. In less than a year, the supplement has been read/downloaded over 9,000 times, cited 32 times in other published peer-reviewed journal articles, and mentioned over 250 times in traditional news media and social media.

In May 2022, the work group convened a national research meeting presenting findings from 14 funded research studies designed to advance the understanding of gender differences in suicide risk and treatment needs to inform clinical and operational objectives. The next research meeting is planned for May 2024.

In January 2023, VA's Reproductive Health Research Work Group published a commentary in Women's Health Issues, "Research Priorities to Support Women Veterans' Reproductive Health and Health Care Within a Learning Health Care System," summarizing the research findings presented at the National VA Reproductive Health Research Conference and describes research priorities in reproductive health.

In September 2023, WHRN held a conference, "Accelerating Impacts Through Partnered Research," in Arlington, VA, focused on women Veteran research, bringing together subject matter experts, researchers, clinical, and program office leaders for advancing research with women Veterans by identifying the state of the science, current research, gaps and research needs, and alignment with operational priorities for 'partnered research.'

Question 2: Non-clinical Suicide Risk Factors – During the SVAC hearing on MH and Suicide Prevention, Dr. Miller, Director of Suicide Prevention, and I discussed how non-clinical, circumstantial factors like financial strain or food insecurity increase risk of suicide among Veterans. A recent study showed that there was a 400% greater likelihood of suicidal ideation among food insecure veterans compared to non-food-insecure veterans and a 900% increase for Veterans who are both food insecure and have a mental health disorder. Can you expand on the type of work ORD is doing to understand circumstantial risk factors to Veterans' suicide? How are you working within VA and cross-agencies to implement lessons learned from those studies?

VA Response: The study cited was partially funded by ORD. Dr. Elbogen, the lead author, is Director of the National Veterans Financial Resource Center at VA. ORD is also funding a project led by Dr. Nathan Kimbrel at the Durham VAMC that is using a wide range of geospatial and social determinants of health, along with electronic health

record (EHR) data, to predict suicide risk. Measures of food insecurity are included in their modeling efforts for this project. This work is particularly concerned with understanding how social-economic deprivation interacts with rurality to increase suicide risk.

Additionally, the Birmingham VAMC has been funded by ORD to examine how VHA services tailored to Veterans with social determinants of health (i.e., housing instability, justice involvement, unemployment) can protect against suicide mortality and morbidity. This project will potentially lead to actionable implementation projects, including increased recommendations to services.

VA is also working across agencies to implement the lessons learned from recent studies. For example, ORD has established a Suicide Prevention Research Executive Steering Committee. The purpose of the committee is to establish priorities for the portfolio, identify research gaps or needs, and review products from the portfolio. The committee includes representatives from OMHSP, SPP's Executive Director, and representatives from ORH. Agencies outside of VA that have representation on this committee include the National Institute of Mental Health and DOD. The Senior Manager for SPP meets with OMHSP's Research and Program Evaluation lead twice a month to discuss research products and lessons learned. ORD coordinates with OMHSP and provides support for demonstration projects that are intended to build on ORD-funded investigations and help determine feasibility of broad programming and expansion.

In addition, OMHSP is coordinating with staff in the Veterans Benefits Administration (VBA) to examine financial-related factors associated with suicide risk among VBA beneficiaries. As required by section 102 of the Commander John Scott Hannon Veterans Mental Health Care Improvement Act of 2019, VA and DOD are jointly reviewing suicide risk factors in DOD records for former Service members who died from suicide within a year of separation, including financial risk factors.

Question 3: GRECC – The Geriatric Research, Education, and Clinical Centers (GRECCs) are VA geriatric centers of excellence focused on aging. They were established by Congress in 1975 in order to improve the health and health care of older Veterans. They are located at 20 medical centers across the country and each is connected with a major research university. *The one for New England is based in Massachusetts.* Can you expand on how ORD and GRECC's are working with other government agencies to ensure there is no duplication and increased collaboration, particularly as it comes to geriatric diseases like Alzheimer's, Parkinson's ALS, Arthritis, and dementia?

VA Response: Within VA, ORD is actively engaged with the Geriatric Research, Education, and Clinical Centers (GRECC) as well as other clinical partners such as the Parkinson's Disease Research, Education and Clinical Centers. In addition, ORD has a long-standing partnership with the National Institute on Aging (NIA) with leadership meeting regularly to discuss collaborative opportunities.

Some of our most recent efforts include:

- Harmonizing MVP data with data being collected via the NIA-led Alzheimer's Disease Sequencing Project to improve statistical power of genetic studies of Alzheimer's and related dementias, including those prioritizing the inclusion of underrepresented populations.
- Several VA investigators at GRECCs also serve as site investigators for the PREVENTABLE trial, one of the largest ever clinical trials of adults 75 years and older. Funded by NIA and the National Heart Lung and Blood Institute, this trial seeks to determine if statins can help prevent dementia, disability, and heart disease.
- Increasing Veterans' enrollment in NIA-funded clinical studies of dementia via a collaborative pilot program that takes advantage of co-location with NIA's Alzheimer's Disease Research Centers and GRECC at five pilot sites. NIA provided supplemental funds to these sites to support activities, such as developing pragmatic solutions and share best practices and materials to increase Veteran outreach and sustain enrollment.
- Helping VA researchers, including early-career physicians and clinical psychologist scientists, with an interest in Alzheimer's and related dementias gain mentored research experience with established VA- and NIA-funded investigators through a career development award from VA and an administrative supplement from NIA.

ORD and GRECC will continue to identify potential collaboration opportunities with the National Institutes of Health (NIH) and other funding entities to enhance understanding of and treatment to geriatric diseases and to ensure that there are not duplicative efforts across the different agencies.

Question 4: Falls Prevention – About1 in 4 older Americans report falling every year. With Veterans generally being more clinically complex than the general population. Can you discuss the work that ORD is engaging on to prevent falls among Veterans? Has ORD considered designating "Falls" as its own research topic to engage on, and what, if anything, would ORD need from Congress in order to conduct more work on falls prevention?

VA Response: Falls research is part of a larger priority related to patient safety. ORD continues to provide VA investigators the opportunity to conduct research into fall prevention, patient safety, and risk factors for Veterans. VA investigators are evaluating the efficacy and effectiveness of several types of interventions (e.g., physical activity engagement, exercise, neuromodulation, balance training and perturbation, prosthetic fit and function) to reduce falls and/or reduce or eliminate risk factors and promote lasting behavior changes. Also, fall prevention strategies and interventions vary by setting, including community, hospital, and nursing homes. ORD studies have shown that Veterans who are forewarned of the health risks from a fall are less likely to have a fall, which proves the need to disseminate and translate the latest findings of research into the best clinical practices. Future research includes studies focused on evidence-based innovations in fall prevention appropriate to setting and consideration of multi-level

factors and differences, as well as implementing best practices, such as those documented and studied under the Agency for Healthcare Research and Quality (See: https://www.ahrq.gov/topics/falls.html) and recommended by the U.S. Preventive Services Task Force (https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/falls-prevention-in-older-adults-interventions).

Question 5: Remote clinical trials – Clinical trial studies involving novel medications and procedures are required to be conducted at VA research sites, which hinders access for rural Veterans and those with limited mobility. Patient safety is the top priority in all studies. However, access to low-risk trials could be expanded by expanding remote options. What barriers stand in the way of wide spread use of remote clinical trials for remote disabled and rural veterans?

VA Response: There are four types of barriers to remote clinical trials:

1) Regulatory barriers include concerns about the quality and validity of data collection in a decentralized clinical trial (DCT) and whether it can meet FDA's high standards. The DCT model changes the kind of control an Investigator has over providers in other organizations who are providing fee-for-service within the scope of their practice. Variable state and international laws/licensures need to be accounted for, and even FDA's published draft guidance is being interpreted differently by members of the research community.
2) Educational barriers stem from a lack of comprehensive understanding of DCT methods and how to leverage them in clinical trial design and implementation. Formal training programs often lack DCT topics and are only emerging at institutional training and national meetings. This demonstrates the need for educational resources that support DCT implementation, which will require education of diverse groups—including government and public sector sponsors—with oversight from regulatory agencies, designers of clinical trials, and other ancillary groups.
3) Infrastructure requirements for DCTs include development of pharmacies with national, or possibly international, scope of practice to allow the shipment of test equipment across state lines either to patients themselves, or to providers who would administer and monitor those tests to patients as part of their normal scope of practice. In addition, technologies need to be used to collect clinical trial data from distinct electronic health records, ensuring access to safety data and validity of clinical trial data for a successful DCT. Toolkits, including publicly shared models for workflow and standard operating procedures, need to be developed to show pathways for cross-agency and public private efforts to implement DCTs. Finally, institutions engaging in DCTs should consider possible funding models that address health care provider requirements when those providers are not part of the traditional study team.
4) DCT sponsors face additional financial barriers to ensure clinical trials manage per patient costs as well as an adequate number of sites for activating and managing these trials. Models for trial monitoring must also address geographically dispersed participants and providers. Disbursement of funds will

need to be allowed across Federal agencies and from public to private institutions and individuals.

VA is committed to reaching underrepresented populations affected by cancer and reducing cancer health disparities and ORD is currently piloting efforts to enroll more rural Veterans in its clinical trials. The VA cancer clinical research enterprise includes CSP managed network which provide a broad set of recruitment and infrastructure capabilities to enroll Veterans in clinical trials. This network includes NAVIGATE, a partnership between VA and NCI, Network of Dedicated Enrollment Sites (NODES), Lung Cancer Precision Oncology Program (LPOP), Precision Oncology Program for Cancer of the Prostate (POPCaP), a VA/Prostate Cancer Foundation Partnership, genitourinary sites (GU) and Advancing Capacity for Clinical Research through Engagement and Strategic Sites (ACCESS), a focused effort aimed at engaging rural Veterans and rural VA facilities interested in enrolling Veterans, strengthening or building out their local clinical research infrastructure. VA's efforts to reach rural Veterans takes advantage of CSP network, which have been used to enroll thousands of participants in VA into CSP studies and other definitive clinical trials. This capability is what launched VA's partnership with the National Cancer Institute to be able to offer more clinical trials to Veterans (through NAVIGATE). In general, the network uses a hub and spoke model that allow multiple clinical trials to be opened or brought to large, medium, and smaller facilities in both urban and rural VA facilities thereby democratizing clinical trial access. To further maximize the network in rural Veteran enrollment in clinical trials, the network is piloting the use of virtual coordinators located in different regions of the country to help facilitate clinical trial startup and recruit and enroll Veterans into investigator-initiated and industry trials.

Question 6: Infectious Diseases – ORD plays a notable role in U.S. government research operations around infectious diseases, given the risk of infection that Veterans broadly face. Vector-borne disease patterns are changing in troubling ways; for example, the first domestically contracted cases of malaria in decades were confirmed this past summer and a newly discovered day-biting mosquito species may drastically alter malaria control initiatives. Recognizing the risk that Veterans face to infectious diseases contracted through vectors like mosquitos, can you talk about how ORD has adjusted their infectious disease research portfolio in the face of these new challenges?

VA Response: VA clinicians are always ready to treat vector borne infections including malaria, liver parasites, and leishmaniasis as part of their routine patient care. ORD also recognizes the increasing threat of vector borne infections, which were once uncommon in the United States, and has established an Emerging Infectious Diseases Research Steering Committee that meets monthly to discuss and review infection epidemiology and ideas for research. Recently, the committee discussed a research collaboration with the Centers for Disease Control and Prevention (CDC) on the relatively new finding of *Pseudomonas mallei* in southern U.S. soils, a type of bacteria once thought to be present only in tropical regions in other parts of the world. Also,

ORD's biorepository system, VA SHIELD, has established a working group on vector borne infections, with an aim to collect samples and clinical data from Veterans.

Questions for the Record from Senator Joe Manchin:

Question 1: National Artificial Intelligence Institute (NAII): Dr. Ramoni, I would like to focus on the VA's National Artificial Intelligence Institute. There is no reason that the VA shouldn't be the world leader in adopting AI into healthcare practices. If implemented properly, AI could be revolutionary in easing staffing issues, monitoring patient safety, predicting disease, creating novel treatments, and thousands of other applications. How is the work at the VA's AI Institute being prioritized by the VA? Has Secretary McDonough, Deputy Secretary Bradsher, and Under Secretaries Elnahal and Jacobs been briefed on its work? Through my AI work on my other committees, I've learned that AI is useless without accurate massive datasets. Does the VA own all its data, including what is created by contractors, and who is that data managed by? How is the work at VA's AI Institute being prioritized by VA?

VA Response: AI certainly is a priority within VA, and the National Artificial Intelligence Institute (NAII) has played a critical role in several agency-level initiatives, including the fulfillment of the agency's obligations under Executive Order 14110: *Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence*, supporting upskilling of the AI workforce, developing trustworthy AI solutions and guidance, and building AI's VA's AI R&D capacity.

VA is focused on bringing viable AI research into operations for improve health care and benefits delivery to Veterans, working collaboratively across the enterprise. VA uses mechanisms such as the AI Tech Sprint, a primary requirement of EO 14110, to accelerate the development of AI solutions through a time limited competition that engages innovators nationwide. Promising AI solutions may be selected to be piloted after the conclusion of the competition. The current AI Tech Sprint is focused on reducing health care worker burnout, ultimately improving Veteran experience and care delivery.

Additionally, NAII contributes to agency AI guidance, including the VA Trustworthy AI Framework to provide guidance tailored to the agency's mission on the use and development of trustworthy AI.

Throughout this year, NAII has continually briefed Secretary McDonough and Under Secretary for Health Dr. Elnahal, providing regular updates on progress, especially regarding the AI Tech Sprints.

In accordance with Office of Management and Budget Circular A-130, anything that VA creates, collects, processes, maintains, disseminates, or disposes of by or for the Federal Government is considered Federal information, which means all the products

and data stemming from VA research are retained by VA. Any VA research data created by a VA contractor or affiliate pursuant to an agreement is VA data. There are situations where data are created for the purposes of research, and exists on information systems outside of VA, but when the data are transmitted into VA, it becomes VA data. All individually identifiable research data are part of a Privacy Act system of records.

Question 2: AI to Identify Healthcare Providers: Recently the VA's AI Institute completed a program focused on more accurately identifying healthcare providers. It is my understanding that the project had support from HHS, CMS, and DoD; and that it demonstrated the ability to increase the accuracy of provider directories to over 90%. It's been well-documented that inaccurate provider directories lead to both access to care and patient safety issues, especially for those seeking mental health services. It's also my understanding that the technology used as part of this project could provide a path forward for the VA to get clinical data back from Community Care Network providers to update Veterans' health records within the VA healthcare system. What is the current status of this project and what, if any, plans does the VA have to continue this very important work? What is the current status of this project?

VA Response: ORD's NAII led the first phase of this project as an AI tech sprint, which benefits from the ability to rapidly evaluate potential solutions to VA functional needs. Speaking generally, tech sprints are short term competitive engagements that encourage VA, industry, academia, and other partners to come together to solve challenges. In this case, the project aimed to align systems of records, with a primary focus on VA and Centers for Medicare and Medicaid Services, to enhance provider directory accuracy. Phase 1 was completed and showcased improved real-time data alignment with potential impacts on access to care and patient safety. Once a tech sprint is complete, the relevant program office(s) is/are armed with information to help them consider potential next steps. In this case, the relevant program office is VA's Office of Healthcare Informatics.

The current AI tech sprint is focused on improving clinical workflows to reduce health care worker burnout through speech-to-text solutions for medical appointments and accelerating document processing with AI to increase continuity of care for Veterans.

Question 3: How is NAII Accomplishing VA Priorities: In the VA's budget request for FY2024, the Department lays out their priorities to prevent homelessness among Veterans, support caregivers of Veterans, furthering research into Women Veteran's health to name a few. Although the NAII is still new, how has the NAII tried to use their program to advance some of the VA's biggest priorities? Can you provide any specifics into the research they're doing? What are the obstacles they are currently facing, if any?

VA Response: ORD NAII, along with other VHA and VA stakeholders, is an important contributor to foundational efforts in establishing AI governance and enhancing AI workforce development. VA researchers are advancing a wide range of

research projects that intersect with AI, which are being funded both by ORD and other sources. Examples of NAII's specific efforts include:

- NAII worked with the Center for Women Veterans to facilitate a project that leveraged AI to analyze hundreds of thousands of words across various meetings/reports to identify themes, trends, and recommendations on how to improve women's care at VA.
- An AI tech sprint winner created a mobile application that addresses the practical challenges caregivers face in managing Veterans' health care. The AI-driven platform creates personalized care plans for Veterans based on their specific medical history. The goal is to reduce administrative tasks for caregivers, allowing them to focus on caregiving.
- Collaborating with ORD's Health Services R&D to conduct research on an improved Veterans Affairs Surgical Quality Improvement Program.

VA's ongoing ability to conduct AI research will depend upon continued access to adequate computing infrastructure. Congress' approval of the $60 million investment of American Rescue Plan (P.L. 117-2) funds into research computing, for example, was a substantial boost to VA's capabilities and will drive discoveries in projects like MVP.

Infrastructure is useful to the extent that we have experts who are poised to make use of it. Recruitment of top tier AI talent is an industrywide obstacle due to the high demand of this extremely skilled human capital resource. ORD NAII is working with other offices to address this challenge, including efforts to upskill the existing Federal workforce.

Question 4: NAII Collaborative Efforts: The National Artificial Intelligence Institute outlines in their strategic plan that their fourth strategy is to collaborate with existing partners across agencies and the private industry to further their work. Which agencies and industry partners is the NAII working most closely with and what are some of the main goals you hope to achieve through these partnerships?

VA Response: Facilitating partnerships is one of ORD NAII's primary areas of focus, with the intent being that these partnerships and mechanisms for partnership will be broadly enabling for VA. ORD and, more specifically, ORD NAII is actively engaged in collaborative AI efforts with various agencies, including the Department of Health and Human Services, the Defense Health Agency, DOD, and the Department of Energy (DOE), among others. Collaborations with industry partners occurs through several mechanisms, each with a distinct goal. For example:

- MVP has a longstanding collaboration with DOE via an interagency agreement. VA and Veterans have benefited greatly from both the expertise and the computing infrastructure available there.
- Collaboration with the University of California San Diego and other academic institutions fosters advancements in radiology research and applications.
- The National Artificial Intelligence Research Resource Task Force aims to stand up a national research infrastructure that will broaden access to resources

essential for AI research and development. This effort is led by the National Science Foundation in coordination with the White House Office of Science and Technology Policy.

- Collaborative efforts identify and develop practical AI use cases that address critical challenges within the health care system and beyond. These partnerships aim to drive discovery that benefits Veterans and facilitate access to diverse data sets, ensuring the inclusivity and relevance of AI applications, promoting knowledge exchange, and spreading and reinforcing trustworthy AI principles across various initiatives and projects.

Questions for the Record from Senator Kyrsten Sinema:

Question 1: Ms. Ramoni, just yesterday the VA Inspector General released a report that told the devastating story of three VA patients in Phoenix. The I.G. identified deficiencies in processes and communication which actively harmed these patients. The Phoenix VA is a level one facility based on patient population, clinical services offered, and educational and research missions. Arizona Veterans deserve to receive timely, world class healthcare. How do we ensure that the burden of research doesn't detract from the day to day of serving Veterans?

VA Response: We are always concerned when any deficiencies in clinical processes and communications could harm VA patients. The events outlined in the Inspector General report occurred during the COVID-19 pandemic, a time in which ORD took specific steps to address demands on clinicians' time, including stopping all non-essential therapeutic studies in medical centers. This allowed facility staff to focus on COVID-19 clinical trials (vaccine and treatments) and clinical care and ensured our research staff were not unnecessarily exposed in the hospital environment.

Within VA, research is integrated into many of our clinical services and many of our researchers are primarily active clinicians. Clinical research enhances the clinical experience of most research participants because it results in additional observations and closer follow-up results of laboratory and physical findings due to the presence of a clinical trials coordination team. In some areas, especially oncology, clinical trials are the standard of care for those patients and can offer treatments that otherwise may not be available through any other means. VA also has regulatory requirements, quality assurance processes, and various other mechanisms to oversee research to ensure that protection standards are met. VA also has the only known Federal clinical research program that has met International Organization for Standardization 9001 registration requirements. Regardless of the area of research, clinician-investigators must have the approval of their supervisors to conduct their research responsibilities. Applications for VA research funding include statements of "protected time" for these individuals. These requirements apply even if clinicians specialize in non-clinical research (e.g., preclinical, health services, etc.).

Question 2: Ms. Ramoni, in your opening statement you discussed the VA's collaboration on research with outside organizations. Since 2015, ASU's Veteran's Wellness Research Center has conducted extensive research on the well-being of veterans and their families, examining questions relating to biomarkers of brain injuries, enhancing brain performance through cognitive training, and using smartphone training to improve sleep and physical activity, amongst many others. What plans does the VA have to expand partnerships with leading research universities?

VA Response: VA has a long history of collaborating with leading research universities. Most VA research programs affiliate with a university that conducts research and in some cases the affiliations extend to multiple schools. VA will continue to work with academic institutions such as Arizona State University and the University of Arizona to engage in research activities that will improve the health of Veterans.

Question 3: Ms. Ramoni, last year Congress passed the bipartisan PACT Act into law to improve the care our veterans receive in response to toxic exposure. As you mentioned, the law tasked the Office of Research and Development with leading an interagency working group to extensively research toxic exposure to enhance the speed and quality of individual exposure assessments and grow our understanding of how toxic exposure shapes Veteran health outcomes. Early detection can be critical for treatment. How else could the VA ensure that adverse health effects of toxic exposure are detected as early as possible and ensure our Veterans start on a treatment plan as soon as possible?

VA Response: As the Senator noted, "early detection can be critical for treatment." The major components of early detection are screening and education. This allows early recognitions of symptoms and promotes earlier diagnosis.

Important considerations are:

1) What is the earliest point that education and screening can begin for Veterans?
2) What are the best communications strategies to impart knowledge to Veterans?
3) Is there sufficient evidence to recommend screening for a particular condition?
4) Are there barriers to implementation of evidence-based screening policies?
5) How can the effectiveness of screening programs can be optimized?
6) How do screening and surveillance provide synergy for improving Veterans health?
7) Are there sufficient biobanked specimens and FDA-approved diagnostic tests to support screening and surveillance?

Additionally, it is important to support research that looks for new biomarkers that may enhance screening and value of biobanked repositories.

Question 4: Ms. Ramoni, Veterans across the country struggle with trauma, depression, and anxiety, and, unfortunately, many of them resort to substance abuse when they do not receive, or are unable to access, adequate care.

Currently, I am working with my fellow senators from both parties to pass the COMFORT Act and permit licensed counselors to serve military patients and their families in all fifty states, not just the ones they are licensed in. Has the VA conducted any research concerning linkages between Veterans' current mental health and the care they received while serving?

VA Response: While research has not been undertaken to specifically assess how a Veteran's current mental health status may have been impacted by past experiences with mental health services in the military, VA has had a keen interest in mental health research tracking Veterans as soon as possible in their transition from the military. This allows us to collect as much information as possible regarding Veterans' mental health status when leaving the military.

Many investigators depend on self-report of previous mental health services and do not have direct access to military mental health records. This is an area in which we anticipate the new VA EHR, which is compatible with both DOD and VA's systems, can help reduce the barriers VA researchers encounter.

There are potential opportunities to study these linkages through ongoing longitudinal studies where Service members are being followed when they are discharged from the military. The Millennium Cohort Study was established by an Act of Congress in 1999, and has enrolled over 250,000 Service members, of whom almost 75% are now Veterans. Data for this study primarily comes from DOD and VA as it involves investigators and key personnel databases from both agencies. It is possible that data from the Millennium Cohort Study could be used to address questions about the impact of treatment during military service on mental health following service.

Army STARRS was designed to comprehensively investigate risk and protective factors for suicide, suicide-related behavior, non-suicidal self-injury, and other mental/behavioral health issues in Army Soldiers. It is the largest research study of mental health risk and resilience ever conducted among Army personnel. STARRS-LS extends the original Army STARRS effort through follow-up of Soldiers during their careers in the Army as well as during their transition from the Army to civilian life, and this study includes access to EHR of Army personnel. To date, approximately 60% of the STARRS-LS cohort have transitioned to Veterans status, and therefore, data collected in this research study has significant relevance for examining longitudinal predictors of suicide in Veterans. VA, a partner in the study along with NIH, now has investigators training on using the incredibly rich data set, which includes the ability to link DOD health records with VA health records for a subset of consented participants. After training is completed, we can work with these investigators to use this data to better understand the relationship between mental health status and prior mental health services while in the military.

Questions for the Record from Senator Thom Tillis:

Question 1: In 2020, the National Influenza Vaccine Task Force, co-led by the Department of Health and Human Services and the Department of Defense, published the National Influenza Vaccine Modernization Strategy. The strategy outlines a vision for the United States' influenza vaccine enterprise to be highly responsive, flexible, resilient, scalable, and more effective at reducing the impact of influenza viruses. In particular, the strategy calls for the United States to strengthen and diversify the domestic influenza vaccine supply chain and to promote the development and domestic production of non-egg-based influenza vaccines. DOD has initiated research efforts to further this strategy and HHS continues to push forward with broad implementation efforts. Is the VA currently conducting any research efforts related to influenza vaccine modernization? If not, does the VA plan to begin any such efforts?

VA Response: VA researchers study influenza virus characteristics, including whole genome characterization of influenza viruses and influenza virus effects on the human immune system, especially as related to aging. VA conducts internal surveillance within the Veteran patient population on influenza diagnosis, treatment, and illness severity. Key studies examine why influenza illness is often more dangerous in cigarette smokers, a prevalent risk among Veterans. Influenza vaccine safety and efficacy is monitored within the Veteran population. A VA collaboration with FDA and BARDA is underway that was founded to study COVID-19 and is being expanded to include treatment and vaccine effectiveness studies for RSV and influenza. All this work contributes to the overall understanding of influenza that informs vaccine modernization and is noted in VA's 2023 actions report to the 2020 National Influenza Vaccine Modernization Strategy.

Question 2: The quarterly SAIL report, a publicly disclosed publication since 2015 by VA, evaluates an array of 25 quality metrics along with two efficiency and productivity metrics across various domains, encompassing mortality rates, complications, patient contentment, overall operational efficiency, and physician capabilities from146 VA medical centers. However, VA research remains absent from this assessment. This prompts the question of how VA can assert the success of research in the absence of quantifiable measures, and whether it is feasible to establish a set of metrics capable of gauging the effectiveness and impact of the VA's research program?

VA Response: VA Research already has a metric framework, developed by the Quality Enhancement Research Initiative (QUERI). The QUERI framework of Alignment, Commitment, Tailoring, Informing the field, Observing health care changes, and generating New questions/projects (ACTION) provides measures of, impact, scientific implementation, and policy initiatives. Our ACTION framework is based on comprehensive review of other key impact frameworks, such as the National Academy of Medicine Degrees of Impact, CDC Science Impact Framework, RAND Corporation, and the results from a recent national evaluation of QUERI. The measures include not only scientific productivity but degrees of research-operations partnership,

communication of impacts, number of providers/patients using effective treatments generated from studies, and whether this work led to or shaped new programs or policies.

Key impact metrics, such as the number of implementation facilities, number of providers/staff trained, and number of patients served were derived directly from health system performance plan goals. Other examples of ACTION metrics include the number of research innovations implemented in routine care, number of sites adopting innovations, the number of providers trained to use the innovations, and whether the innovations led to patient health improvements and/or improved provider experience. QUERI-funded centers/projects submit reports every 6 months describing their key activities and impacts, based on the QUERI ACTION Impact Framework.

As further background, VA has developed a substantial infrastructure to support VA research studies regarding suicide and other causes of mortality. For example, the VA / DOD Mortality Data Repository has supported over 285 VA studies regarding cause-specific mortality, across the continuum of causes of death categories. VA's investment in ongoing suicide surveillance has also substantially informed the general scientific research literature. For example, a preliminary analysis indicates that among the most recent 20 papers published in 2023 that included "Veteran" and "suicide" in the title or abstract, 65% cited one of the 8 published National Veteran Suicide Prevention Annual Reports to date.

Questions for the Record from Senator Tommy Tuberville:

Question 1: Dr. Ramoni, the VA has neither the statutory, nor regulatory authority, to facilitate gender-affirming surgeries for Veterans; however, I understand that the VA is conducting a study on the needs, preferences, and perceived barriers for gender-affirming surgeries for transgender Veterans at the VA. Given the VA's vast authorities and countless needs for research in other areas, why was it decided to put time and resources toward this topic?

VA Response: Transgender individuals are between two or three times more likely to serve in the military. (Gates, G. J., & Herman, J. L. (2014). Transgender Military Service in the United States. The Williams Institute at UCLA School of Law. http://www.jstor.org/stable/resrep35579.) Moreover, transgender Veterans die by suicide at twice the rate of other Veterans. Research indicates that access to comprehensive health care for transgender individuals can improve mental health outcomes. VA is taking steps towards addressing this inequity. In preparing to do so, it is critical to understand the needs of these Veterans and the barriers they face to accessing this life-saving care.

Question 2: Another study the VA research office is facilitating is that on the clinical care needs of LGBT Veteran patients with spinal cord injuries. Why would LGBT Veteran patients have any different needs related to spinal cord injuries

than non-LGBT Veteran patients? What information triggered such a study be conducted?

VA Response: SCIs are estimated to affect between 249,000 and 363,000 Americans, with about 17,730 new injuries occurring each year. About 80% of people with new injuries are males, and roughly 42,000 people with SCIs are Veterans. Nearly half of all SCIs occur in people between the ages of 16 and 30, so many patients live with the effects of these injuries for decades. There is also considerable variation in SCI treatment outcomes across racial and socioeconomic groups.

VA is one of the largest single providers for people identifying as LGBTQ+ who also have a spinal cord injury. Minimal information is available on the health care experiences and needs of Veterans with spinal cord injury or disorders (SCI/D) who identify as LGBTQ+. Veterans with SCI/D have access to a large comprehensive system of specialty care within VA's health care system for physical and mental health care across their lifetime, but VA providers may lack the experience, sensitivity, and/or knowledge to manage the specific needs of those Veterans. Studies that focus on subpopulations enable more opportunity to understand the experiences of individual Veterans and enable a more effective, personalized health care experience.

The overarching goal is to open the door to improving VA health care for vulnerable and understudied populations. The study will provide essential information from both Veteran and provider perspectives to begin to fill this gap and contribute invaluable data towards developing solutions.

Department of Veterans Affairs
April 2024

Statements for the Record

Senator Sinema
Statement for the Record
Senate Veterans' Affairs Committee
Foundation of Care:
Examining Research at the Department of Veterans Affairs
11/01/2023

Senator Sinema Statement

Thank you, Chairman Tester, for holding this hearing and thank you to our witnesses for being here today.

In Arizona, where roughly 10 percent of our state's population is serving or has previously served as a member of our armed forces, the challenges facing our veterans are varied. Our provider facilities can be hard to reach for those residing in our rural communities. Additionally, staffing shortages coupled with onerous wait times have made accessing care even more difficult.

Enhancing access to care is crucial, but so too is discovering new and innovative treatments for our citizens struggling against diseases and disabilities while ensuring care is tailored to the diverse needs of every patient. Our veterans in particular are faced with mental health challenges that are often compounded by the harmful effects of toxic exposure. I applaud the V.A.'s research efforts in these areas, and I am proud to work alongside my colleagues from both sides of the aisle to tackle these challenges.

NAVREF
National Association of Veterans' Research and Education Foundations
1717 K ST NW Suite 900 Washington, DC 20006
202.951.7701 | info@navref.org | www.navref.org

Statement for the Record Submitted by the
National Association of Veterans' Research and Education Foundations
to the Senate Committee on Veterans' Affairs
United States Senate

Hearing on "Foundation of Care: Examining Research at the Department of Veterans Affairs"
November 1, 2023

The National Association of Veterans' Research and Education Foundations is a 501(c)(3) nonprofit membership organization of research and education foundations affiliated with Department of Veterans Affairs (VA) medical centers. These nonprofits, also known as the VA-affiliated nonprofit research and education corporations (NPCs), were authorized by Congress over thirty years ago to provide flexible funding mechanisms for the conduct of research and education at VA facilities nationwide (38 USC §§7361-7366). Currently, NAVREF represents over 75 NPCs supporting research and education activities at over 100 VA medical centers.

NAVREF's mission is simple— we exist to build a stronger veteran research and innovation community through support and collaboration. We make it easier for VA medical centers to work with external partners on initiatives that will improve Veteran health care. And, we uplift an infrastructure that WORKS.

Over the last thirty years, NAVREF members have launched and sustained partnerships that have expanded the availability of clinical trials for Veterans, bolstered the research capabilities of local VA medical centers, and provided more training opportunities for VA staff, Veterans, and their families. In FY22 alone, NAVREF members facilitated more than $310 million in research and education investments across the VA. This $310M is in addition to VA appropriated funding, and represents the investments by non-VA federal partners, private industry, and other academic and nonprofit institutions across the country to improve the lives of Veterans and their families. Congress intentionally allowed each NPC to develop their own unique policies and procedures tailored to the needs of their local VAMC, and the local community of Veterans that they serve.

Today, approximately 70% of NPC revenues are derived from non-VA federal agencies, such as the National Institutes for Health (NIH) and Department of Defense (DOD). Our NPCs are known for maintaining lower-than-average management expenses, thanks to efficient management practices and minimal overhead costs. Our members take pride in offering rapid personnel hiring, streamlined compliance paperwork processing, and dedicated administrative support for grant submissions. To that end, we commend the Senate Veterans Affairs Committee (SVAC) for championing efforts to streamline aspects of VA research operations, such as the provisions from the former VIPER Act. This will ensure that VA continues to attract the most promising researchers and investigators across the country to improve care and delivery for Veterans and their families.

Beyond cost-effective stewardship of funds, NAVREF members also play a crucial role in identifying research sponsors and potential grant-making organizations, oftentimes initiating initial contact on behalf of VA investigators with potential partners to support VA research and education projects. As a result, Veterans and their families have benefitted from access to the latest medications and health care treatments, in a closely supervised setting at no cost to the VA.

NAVREF
National Association of Veterans' Research and Education Foundations
1717 K ST NW Suite 900 Washington, DC 20006
202.951.7701 | info@navref.org | www.navref.org

Our members are actively engaged in research projects that will transform what we know about the long-term health needs of our Veterans. Below, we have provided a few illustrative examples of active research and education projects that our members are facilitating to improve care for Veterans and their families.

Project VALOR, Boston VA Research Institute
Funded by the DoD, the Boston VA Research Institute is currently pursuing a project called Long-Term Psychological and Physical Health Outcomes Following Military Deployment: The Veterans After-Discharge Longitudinal Registry (Project VALOR). This project focuses on new data collections from a cohort of 1,649 men and women who were deployed to Afghanistan or Iraq, post-9/11.

The study aims to gain a deeper understanding of the long-term effects of:

- deployment on psychosocial outcomes (such as PTSD, employment, marriage quality, suicidal ideation, etc.);
- the long-term impact of deployment on physical health outcomes (including coronary heart disease and cardiometabolic risk factors); and
- a more accurate comprehension of how factors like pre-deployment experiences (e.g., childhood abuse), peri-deployment events (e.g., traumatic brain injury), post-deployment reintegration experiences, and biological factors (e.g., polygenic risk scores) interrelate to provide a more precise understanding of the impact of risk and resilience factors.

Additionally, the research aims to shed light on the experiences related to reporting sexual assault and harassment, as well as identifying the barriers and facilitators to reporting these incidents.

With funding provided by DOD, the Boston VA Research Institute facilitates and supports the work of the grant with researchers at VA Boston Healthcare System.

Strength at Home, Boston VA Research Institute
Another noteworthy project facilitated by the Boston VA Research Institute is the Strength at Home Project, also funded by the DOD. This project addresses intimate partner aggression (IPA), a national public health issue and a major concern across military and veteran communities.

The Strength at Home Couples (SAH-C) program was designed to prevent IPA in at-risk couples, particularly among military personnel and their partners. Multiple studies have shown the program's effectiveness in VA settings and communities. This research initiative seeks to test the effectiveness of SAH-C for military couples on an installation and explore any potential obstacles or support systems needed for a successful program implementation. Given the significance of the IPA issue and the absence of a specific prevention intervention on military bases, this research is both timely and crucial. It has the potential to alleviate the suffering of military families and enhance our understanding of preventing violence within military relationships.

Support for New Therapies for PTSD, San Diego Veterans Medical Research Foundation
NPCs are often engaged in research for emerging therapies, most recently those efforts to better understand the use of psychedelics in treating PTSD. The Veterans Medical Research Foundation in San Diego, California, is leading two pilot studies focused on the feasibility, safety, and clinical benefits of incorporating MDMA into evidence-based treatments for PTSD. The first study explores MDMA-assisted brief couples PTSD therapy (bCBCT) in an open-label setting. The second study investigates the use of MDMA in massed Prolonged Exposure Therapy (PE) for PTSD, comparing it to low-dose MDMA-assisted

NAVREF
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1717 K ST NW Suite 900 Washington, DC 20006
202.951.7701 | info@navref.org | www.navref.org

massed PE in a double-blind manner. Funded by a nonprofit organization (Healing Breakthrough), these studies will vastly expand the knowledge base for MDMA-assisted therapies for Veterans with PTSD.

* * *

As we look to the future of health care delivery across the VA, NAVREF is eager to work with Congress and the VA to support emerging health care needs for Veterans and their families. Health care delivery is evolving at a rapid pace, and we look forward to exploring ways to leverage this infrastructure to advance opportunities to support health care innovation, quality improvement, and quality assurance. Incorporating QA and QI practices is crucial for ensuring that the research conducted within the VA system meets the highest standards of excellence, and NAVREF can help the VA research program continually evolve and maintain its commitment to excellence.

Thank you for your attention to these matters. We express our gratitude for your continued support for the VA research program and the VA-affiliated nonprofit corporations. We look forward to working with you to achieve our vision of a nation in which our nations' heroes receive the finest care based on innovation, research, and education.

NEUROFLOW®

1601 Market St., Suite 1500
Philadelphia, PA 19103
www.neuroflow.com

The Honorable Jon Tester
Chairman
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building, Washington, D.C. 20510-6050

The Honorable Jerry Moran
Ranking Member
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building, Washington, D.C. 20510-6050

Letter for the Record: U.S. Senate Committee on Veterans' Affairs' Hearing titled: "Foundation of Care: Examining Research at the Department of Veterans Affairs."

Dear Chairman Tester, Ranking Member Moran,

I hope this finds you all well. I am writing to you to discuss the importance of, and progress I have observed related to, translating research into meaningful impacts in Veterans' lives, specifically around using better data to improve mental health and reduce risk of suicide. I am writing to you as an Army Combat Veteran, patient of the VA, and CEO of NeuroFlow, a technology company that works with the VA.

To that end, I believe there has been significant progress to date in driving impact, but we must and can do more. We left last week's Hearing inspired by the collective voices and calls to action to achieve real-world impact. That said, we want to share examples for the record of how the VA and industry are translating funded research into impact.

In 2003, Dr. David Oslin at the Veterans Integrated Services Network (VISN) 4 Mental Illness Research and Clinical Center (MIRECC) sought to improve how Primary Care Providers (PCPs) manage Veteran behavioral health needs in primary care. He established the Behavioral Health Laboratory (BHL) program at the Corporal Michael J. Crescenz VA Medical Center (Philadelphia) and associated Community-Based Outpatient Clinics (CBOCs) to improve evidence-based mental health care on a population level. Since inception, the Philadelphia BHL has improved depression, anxiety, and alcohol misuse outcomes, reduced patient wait times and increased engagement rates.

In 2004, Dr. Oslin entrusted Capital Solution Design, a wholly-owned subsidiary of

NeuroFlow, with developing a measurement-based care software tool called BHL and BHL Touch (referred to as “BHL” hereafter). Since the inception, the BHL software has scaled to 150+ VA facilities, specifically those in rural areas in Montana, Maine, and Kansas. As a VA partner for the past 15 years, we applaud VISN 4 MIRECC and Dr. David Oslin (referred to as “VA” hereafter) for paving the way for what an innovative partnership between the VA and industry should look like.

To date, the VA and BHL have delivered the following:

- 17,000+ registered VA users (VA clinical team staff)
- 700,000+ registered VA patients
- 2.6M+ assessments completed
- 4.73/5 average VA provider rating (based on ease of use, efficiency, etc.)
- 50%+ of all depression and anxiety screenings making BHL the primary software tool used nationally by the VA for these assessments

As we look to the future, we are prioritizing other critical initiatives - this time, we seek to reduce clinician hours spent on administrative assessments during patient visits and wait times for patient visits. There are currently 80+ assessments, also known as clinical reminders, that screen for conditions (e.g., depression, anxiety, toxic exposures) during patient visits. We have identified the following challenges:

- The administrative burden, with assessments taking 10 minutes of a 30-minute patient appointment
- Limited visibility for providers into completion or what data is highlighted
- Minimal options for patient to complete assessments prior to visit

With a similar innovative spirit as in 2003, we seek to digitize (text and email) and automate clinical reminders at scale. We have already tested the efficacy through beta testing at Southern Nevada, Philadelphia, and Puget Sound VA Medical Centers (VAMCs). In the near-term, we are evaluating efficacy of BHL and eScreening (a VA solution) through an official 60-day research pilot at Minneapolis and Butler VAMCs.

Should 80+ clinical reminders be digitized, automated and adopted nationally, we anticipate significant outcomes for VA:

- Roughly 20 million clinician hours or $2 billion saved (assuming standard Primary Care Provider Visits)
- Reduced Veteran appointment wait times (and uniformity of times across VAMCs)
- Reduced administrative burden and clinician burnout

- Improved patient experience and satisfaction
- Alignment with critical Veteran legislation
- Simplified data capture and analysis (and triage to appropriate level of care)

This is yet another example of how VA leaders are driving research and innovation for our Veterans, from ideation to real-world impact. We would be delighted to share research pilot results at a future hearing or other relevant meetings early next year. On behalf of the NeuroFlow team, and more importantly, on behalf of the VA partners we work with, we thank the committee for considering our perspective and for convening this important hearing.

Sincerely,

Christopher Molaro

Christopher Molaro
CEO & Chairman
NeuroFlow, Inc
BHL, a NeuroFlow Platform

Testimony *of*

Foundation of Care: Examining Research at the Department of Veterans Affairs

Presented by

Jack McManus
National President

Before the

Senate Veterans Affairs Committee

November 1, 2023

Chairman Tester, Ranking Member Moran, and members of the committee, on behalf of the membership of Vietnam Veterans of America (VVA), thank you for the opportunity to provide our remarks on the *Toxic Exposure Research Act* (*TERA*) before this committee.

The Toxic Exposure Research Act, P.L. 114-315 §§ 114-315 lays the groundwork for research into the health of the children and grandchildren of generations of veterans who have been impacted by toxic exposures during their military service. Epigenetic effects are a known risk of toxic exposure, whether such exposure involves Agent Orange, organophosphates, burn pits, or other sources. The impact has been most clearly evidenced by the children of Vietnam veterans suffering from structural and functional birth defects, but the full impact of toxic exposure on our descendants must be investigated, and that responsibility lies with the Department of Veterans Affairs (DVA).

It should be stated in no uncertain terms: **The Department of Veterans Affairs did not follow the legislative intent of the Toxic Exposure Research Act.**

Background

The *Jeff Miller and Richard Blumenthal Veterans Health Care and Benefits Improvement Act of 2016* required the Secretary of Veterans Affairs to "seek to enter into an agreement with the National Academy of Medicine under which the National Academy of Medicine conducts an assessment on scientific research relating to the descendants of individuals with toxic exposure."[1] In other words, the National Academy of Medicine would be tasked with conducting the assessment, which would include a review of scientific literature on descendants of individuals exposed to toxins, an assessment of areas that require additional study, "an assessment of the scope and methodology required to conduct *adequate scientific research*" on the impact of this exposure, the establishment of categories to be used for evidentiary classification of exposure, and the "*identification of a research entity or entities*" that possess subject matter expertise and the ability to research toxic exposure issues. [Emphasis added].[2] Then, according to § 632(d)(1):

> Not later than 90 days after receiving the results of the assessment and determination under subsection (c), the Secretary shall submit to the Committee on Veterans' Affairs of the House of Representatives a certification of the understanding of the Secretary, based on such results and determination, regarding the feasibility of conducting further research regarding health conditions of descendants of veterans with toxic exposure that is expressed by such results and determination.[3]

The VA secretary certified that the establishment of a Health Monitoring Research Program (HMRP) to study the generational health effects of serving in the Gulf War is not feasible.[4] In certifying infeasibility, Secretary McDonough cited a report from the VA Working Group tasked

[1] Pub. L. 114-315 § 632(a)(1).
[2] Id. at §632(b).
[3] Id. at § 632(d)(1).
[4] Letter to Senator Moran from VA Secretary McDonough, dated July 21, 2021 (hereinafter Letter to Sen. Moran)

with assessing the viability of conducting the HMRP.[5] The Working Group first convened on January 31, 2020, and its report relied on a 2018 report from the National Academies of Science, Engineering and Medicine (NASEM).[6] The Working Group only met on 13 occasions, adjourning for the last time on October 14, 2020 – seven months before finally publishing its report.[7] It is important to note that the assessment conducted by the VA Working Group could not be sanctioned under §§632(a)(1) or (a)(2), as only the National Academy of Medicine or an organization that is not part of the federal government were authorized to conduct the assessment; i.e. the Working Group report cannot be used to supplant the conclusions and recommendations of the NASEM report. Irrespective of this fact, the VA Secretary was delinquent in the submission of his certification following the publication of the 2018 NASEM Report.[8] Instead, the VA Secretary chose to paraphrase conclusions from the Working Group's report, and in his certification, Secretary McDonough stated that barriers to the successful operation of an HMRP:

> [I]nclude lack of a national health record and a national birth defects database from which to draw data, inability to meet administrative and infrastructure requirements and scientific evidence that does not support a link between in-service toxic exposures and adverse intergenerational health outcomes.[9]

Specifically, the Working Group report justifications given for disapproving the HMRP are as follows:

> 1) Scientific evidence suggests that toxic exposure-induced generational effects have not occurred in military service members who deployed to the Southeast and Southwest Asia theaters of operation; although some could argue limitations in methodology for some of the published studies; 2) multiple short-and long-term achievability barriers in epidemiological studies, clinical requirements, and research; 3) feasibility and scalability concerns with administrative and infrastructure availability and needs; 4) no federal agency able to perform the HMRP for birth defects without access to a national birth defects database and national health records; 5) prior efforts for comprehensive implementation of environmental health monitoring and birth defects studies have failed and were deemed not feasible after significant effort.[10]

The dissenting opinion on the VA Working Group was as follows:

> The lack of strong evidence, considered alongside the strength of suggestive findings and biological plausibility, justifies the formation of an HMRP. Service members and their offspring, and the U.S. at large, deserve to know the risks associated with military service. A carefully conducted HMRP would provide that

[5] Id; *see Report of the Intergenerational Effects of Military Exposures Work Group to the Secretary of Veterans Affairs In response to Public Law 114-315, sec. 632 (d)* (May 2021) (hereinafter Working Group report).
[6] NASEM, Gulf War and Health, Vol. 11: Generational Health Effects of Serving in the Gulf War (Nov. 2018) (hereinafter "NASEM report")
[7] Supra, footnote 5.
[8] Supra, footnote 3.
[9] Letter to Sen. Moran
[10] Working Group Report, at 2.

> evidence. If an HMRP identifies reproductive and developmental harms associated with toxic exposures occurring during military service, it would provide the scientific, medical, and epidemiologic infrastructure to determine who is at greatest risk, for what, for how long, and what types of interventions should be pursued to mitigate it. Because of its complexity, an HMRP could not be created overnight. It would need to be carefully built from the ground up leveraging existing scientific and data infrastructures, with future scalability linked to feasibility studies at each stage of its development. A successful HMRP has the potential to directly benefit service members and the U.S. at large.[11]

The following sections are divided based on the VA Working Group's assertions and demonstrate that the HMRP is, in fact, feasible.[12]

Supposed Lack of Scientific Evidence

The Working Group Report concludes that there is an insufficient link between exposure to toxins and birth defects, relying on a 2018 report from the National Academies of Science, Engineering and Medicine (NASEM).[13] The 2018 NASEM Report relies on its prior reports from 2006, 2008, 2010, and 2016 to come to this conclusion; only two additional studies appear to have been considered, and the NASEM Report states in bold lettering **"The Volume 11 committee concludes that there is inadequate/insufficient evidence to determine whether an association exists between deployment and developmental effects**."[14]

The following is a non-exhaustive list of toxins to which service members were exposed when deployed in Southwest Asia that have been linked to generational effects:

Toxin Class	Toxins
Chemical Warfare Agents	Sarin & Cyclosarin[15] Sulfur Mustard[16]
Deployment-Related Exposures	Anthrax Vaccines[17]

[11] Id., at 9.
[12] *But see* P.L. 114-315 § 633(a):

> **Unless the Secretary of Veterans Affairs certifies under section 632(d) that the results of the assessment and determination under section 632(c) indicate that it is not feasible to conduct further research regarding health conditions of descendants of veterans with toxic exposure,** not later than 180 days after receiving such results and determination, the Secretary shall establish an advisory board (in this section referred to as the ``Advisory Board") to advise the Secretary in the selection of a research entity or entities under section 634, advise such entity or entities in conducting research under such section, and advise the Secretary with respect to the activities of such entity or entities under such section. (Emphasis added).

[13] Supra, footnote 6.
[14] NASEM Report, at 64-67.
[15] Omar Hakeem, *Adverse Outcomes in Women Exposed to Syrian Chemical Attack*, THE LANCET (Feb. 23, 2015).
[16] Abolghasemi, et al., *Childhood Physical Abnormalities Following Paternal Exposure to Sulfur Mustard Gas in Iran: a Case-Control Study*, CONFLICT AND HEALTH (July 2010).
[17] Ryan, et al., *Birth Defects Among Infants Born to Women Who Received Anthrax Vaccine in Pregnancy*, AM. J. EPIDEMIOLOGY (15 August 2008).

	Hexavalent Chromium[18]
Pesticides	Carbaryl[19] Chlorpyrifos[20] Propoxur[21]
Combustibles	Polycyclic Aromatic Hydrocarbons (PAHs)[22] Polychlorinated Dibenzo-P-Dioxins (PCCDs)[23] Polychlorinated Dibenzofurans (PCDFs)[24]
Solvents	Trichloroethylene[25] & Tetrachloroethylene[26] Glycols & Glycol Ethers Toluene[27] Xylenes[28]

As indicated by the sources cited in the above chart, some as recent as last year, research continues to emerge linking these toxins to birth and other generational effects on the descendants of exposed individuals. Therefore, the Working Group's claim that there is inadequate or insufficient evidence regarding the association between deployment exposure and developmental effects is dubious. At a minimum, the Working Group report indicates that the scientific literature review, if ever properly conducted, was last properly conducted in 2018, and is thus invalid by the time of the Working Group's publication in 2021.

Alleged Barriers to Study, Clinical Requirements, and Research Constraints

The Working Group provides two reasons for opposing HMRP feasibility: epidemiological and clinical challenges and barriers, and research challenges and barriers. The group first asserts that recruiting and maintaining "sufficient numbers of veterans, their partners, and their offspring" would be difficult.[29] As seen concerning the study of individuals exposed to PFOAs, this barrier

[18] Marlissa A. Campbell, *Evidence on the Developmental and Reproductive Toxicity of Chromium (Hexavalent Compounds)*, CAL. ENV. PROTECTION AGENCY (August 2009).
[19] *Hazardous Substance Fact Sheet: Carbaryl*, NJ DEPT. OF HEALTH AND SENIOR SERVICES (last visited Nov. 23, 2021) ("Carbaryl may be a teratogen").
[20] J D Sherman, *Chloripyrifos (Dursban) – Associated Birth Defects: Report of Four Cases*, ARCH. ENV. HEALTH (Jan. – Feb. 1996).
[21] Beranger, et al., *Multiple Pesticides in Mothers' Hair Samples and Children's Measurements at Birth: Results From the French National Birth Cohort (ELFE)*, 223 INT. J. HYGIENE & ENV. HEALTH 1, 22-33 (Jan. 2020).
[22] O'Brien, et al., *Maternal Occupational Exposure to Polycyclic Aromatic Hydrocarbons and Craniosynostosis Among Offspring in the National Birth Defects Prevention Study*, BIRTH DEFECTS RESEARCH PART A| 106 CLINICAL AND MOLECULAR TERATOLOGY 1, 55-60 (Jan. 2006).
[23] K. Srogi, *Levels and Congener Distributions of PCDDs, PCDFs and Dioxin-Like PCBs in Environmental and Human Samples: A Review*, ENV. CHEM. LETTERS 6, 1-28 (2008).
[24] Id.
[25] Makrin, et al., *A Systematic Evaluation of the Potential Effects of Trichloroethylene Exposure on Cardiac Development* (last visited Nov. 29, 2021).
[26] Aschengrau, et al., *Modeled Exposure to Tetrachloroethylene-Contaminated Drinking Water and the Occurrence of Birth Defects: A Case-Control Study From Massachusetts and Rhode Island*, 17 J. ENV. HEALTH 75 (2018).
[27] OSHA, *Toluene*, U.S. DEPT. OF LABOR (last visited Nov. 23, 2021).
[28] Taskinen, et al., *Laboratory Work and Pregnancy Outcome*, 36 J. OCCUPATIONAL MED. 3, 311-19 (Mar. 1994).
[29] Working Group Report, at 7-8.

may be overcome.[30] While the Working Group complains of the lack and use of registries for data collection and population tracking, it runs several registries of its own.[31] Likewise, the CDC also funds 10 state-based birth defect registries,[32] so while there may not be a particular national registry, it is feasible that a national registry may be established, or at a minimum, existing registries[33] may be used to identify and classify suspect classes.

The second justification for finding the HMRP infeasible is that the Working Group claims that the lack of available data makes it difficult to determine what, if any impact toxic exposures have or will have on veterans' descendants, while also objecting to the establishment of the HMRP. This argument is entirely circular, as the purpose of the HMRP is to determine whether exposure to these toxins have or will induce generational effects. Only one member of the Working Group considered this.[34]

Feasibility and Scalability Concerns re: Administration and Infrastructure

The VA Working Group claims that to "enable competent management and coordination of an HMRP, a dedicated Administrative and Research Infrastructure Core (ARIC) would be required."[35] The Working Group also emphasizes that an HMRP will need both a Quality Management System (QMS) and a Quality Management Program (QMP) to be "put in place by the lead agency [VA]."[36] The Working Group also asserts that a biorepository/biobank will be necessary to conduct an HMRP and that "collection of bio specimens for subsequent analysis will place a significant burden of need on a biorepository or bio banking system[.]"[37] To accomplish this goal the Working Group also asserts that "[t]he data analysis will require linking databases and statistical software, particularly VA and DoD electronic health records and other records, and potentially other databases (such as those of the Centers for Medicare and Medicaid Services and state cancer registries).[38]

What the Working Group report leaves out is that the NASEM Report does not appear to establish a definite need for a biobank/biorepository. The Working Group also fails to consider whether it is possible to record analyses of biological samples for electronic retention and then destroy the material post-analysis, as opposed to the "costly" proposal from the Working Group: the Research-Ready VA Biorepository (RRVAB), which would be capable of sending samples for long-term storage at a biobank.[39] Ultimately, the Working Group makes another circular argument, noting that it is "challenging at this time to envision an HMRP being viewed as both feasible and scalable without the necessary agreed governance and administrative resources and tools in place to include

[30] *Advisories issued for C8 Medical Monitoring Program*, PARKERSBURG NEWS & SENTINEL (Mar. 28, 2017).
[31] *See Environmental Health Registry Evaluation for Veterans*, DEPT. OF VET. AFFAIRS (last visited Nov. 29, 2021).
[32] CDC, State-Based Birth Defects Tracking Systems (last visited Nov. 23, 2021) (The CDC funds 10 state-based birth defect registries).
[33] *See also, e.g. Birth Defect Research for Children*, NATIONAL BIRTH DEFECT REGISTRY (last visited Nov. 23, 2021).
[34] *See supra,* footnote 11.
[35] Working Group Report, at 27.
[36] Id. at 28.
[37] Id. at 29.
[38] Id. at 29.
[39] Id. at 33.

agreed-upon funding streams and budgets, none of which are currently agreed on or operational[;]"[40] the group came to this conclusion presumably knowing that the Secretary would certify the HMRP as unfeasible, which would prevent cost analysis from occurring anyway. Moreover, the Working Group contends that the system necessary for conducting an HMRP would also require the integration of electronic health records without acknowledging the VA's current push toward the development of its own EHR system.[41]

No Assignable Federal Agency to Perform HMRP

The Working Group asserts that "[t]here is no federal agency able to perform the HMRP for birth defects without access to a national birth defects database and national health records …. The aims of the HMRP are not achievable without vested participation of many agencies," and that "VA does not have pediatric research expertise."[42] The report also implies that the program would be primarily reliant on DoD records, as it emphasizes that "[o]ther than self-reported data, DoD research programs have limited access to longitudinal data of veteran populations beyond DoD collected longitudinal administrative and health information," concluding that "a national health records and a national birth defects database is imperative to address data gaps."[43] State-run, federally subsidized birth-defect databases already exist,[44] and the Working Group conceded the following in their report:

> The NASEM committee further stated that "the committee finds that it may be possible to implement parts of the proposed HMRP and hypothesis-driven studies by leveraging ongoing programs. The committee examined a number of ongoing research programs, including the VA-sponsored Million Veteran Program (MVP) and the DoD sponsored Millennium Cohort (MilCo) and MilCo Family Study as well as the DoD Birth and Infant Health Registry and the DoD Serum Repository. Building on and coordinating among these existing health monitoring and epidemiologic research programs can reduce costs, expedite data collection, and provide access to already engaged study populations."[45]

While the scale of the program may not be national in its infancy, an HMRP could grow using self-reporting and by integrating existing infrastructures. Moreover, veterans' participation and their respective health data are likely to contribute to data-set development as the result of the *Sergeant First Class Heath Robinson Honoring our Promise to Address Comprehensive Toxics Act of 2022* (PACT).[46]

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[40] Id. at 32.
[41] *See EHR Modernization*, Dept. of Veterans Affairs (last visited Dec. 2, 2021) https://www.ehrm.va.gov/ ("VA is transitioning to a new electronic health record (EHR) system — *the software that stores health information and tracks all aspects of patient care* [by 2028]. The new system *connects VA medical facilities with the Department of Defense* . . . and participating community care providers, allowing clinicians to easily access a Veteran's full medical history in one location.")
[42] Working Group Report, at 8.
[43] Id.
[44] *See infra*, **Barriers to Study, Clinical Requirements, and Research Constraints**, at 3-4.
[45] Working Group Report, at 20.
[46] Pub. L. 117-168 (2022); see also VA PACT Act Performance Dashboard, Issue 18 (Oct. 13, 2023) https://www.accesstocare.va.gov/pdf/VA_PACTActDashboard_Issue18_101323_508.pdf (as of this date, 567,724 veterans and survivors have completed PACT Act claims).

A Prior Failure Is Insufficient Indication of Infeasibility

The VA Working Group's final justification for denying the feasibility of the HMRP relates to failed prior efforts. Specifically, the Working Group only provides two examples: the National Children's Study and the Committee to Study the Need for and Feasibility of Epidemiologic Studies of Adverse Reproductive Outcomes in Families of Atomic Veterans, Institute of Medicine, 1995.[47] The National Children's Study was similar to the proposed HMRP but was terminated after only seven years of funding. The Working Group mentions that $1.6 billion was allocated and that "the final report concluded that the overall goals of examining how environmental factors influence child health and development were not feasible and the program was terminated."[48] The Working Group Report's cost statement was incorrect – the cost was 25% lower – and it failed to mention that a health study called the Environmental Influences on Child Health Outcomes (ECHO) program arose from the defunded National Children's Study.[49] The ECHO program serves as an example of how a successful HMRP may be rolled out to study the generational effects of toxic exposure in veterans.[50] The second example cited by the Working Group can largely be disregarded, as the point of referencing it was to show that the committee was concerned about "insurmountable difficulties in finding and contacting a sufficiently large number of study subjects (offspring of Atomic Veterans)."[51] Considering the probable lack of sufficient documentation and the definite lack of internet access for most Americans in the year 1995, the committee's concern is irrelevant to studies that would be conducted in 2021.

Conclusion

None of the VA Working Group's justifications for opposing the establishment of an HMRP to determine the generational impact of toxic exposure hold water.

The VA Working Group's insistence that there is no assignable federal agency available to administer an HMRP is in bad faith. Studies exist linking exposure to generational effects. Programs monitoring toxic exposure impact also exist; there are 10 statewide, birth-defect registries, a non-governmental birth defect registry, and there are studies currently being run by the VA itself (see, e.g., the Million Veteran Program, Millennium Cohort, and MilCo Family Study).

The VA Working Group failed to demonstrate that a biobank is necessary, and the Group's insistence that it would be cost-prohibitive is entirely speculative as they failed to conduct even a rudimentary cost assessment.

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[47] Id., at 8.
[48] Id., at 8-9.
[49] Rachel Cernansky, *US Child-Health Study Rises From Ashes of High-Profile Failure*, NATURE 542 (2017).
[50] Kaja Z. LeWinn, et al., *SPR Perspectives: Environmental Influences on Child Health Outcomes (ECHO) Program: Overcoming Challenges to Generate Engaged, Multidisciplinary Science*, PEDIATRIC RESEARCH (Jun. 15, 2021).
[51] Supra, footnote 47.

Lastly, the Working Group's reliance on a failed study and dated committee conclusion is invalid as the study was (apparently) successfully rebooted and the study existed before the widespread adoption of the internet in the United States.

If a nation is to send its men and women to war, it has an obligation to address the visible and invisible wounds resulting from conflict. The VA Secretary insists that toxic exposure is a key issue. Congress enacted the *PACT Act* to treat illnesses arising from the same. While veterans are beginning to receive the assistance they so desperately need, their descendants continue to be overlooked. For this reason, on behalf of the membership of Vietnam Veterans of America (VVA), I demand revisitation and implementation of the requirements outlined in the *Toxic Exposure Research Act*.

Jack McManus

Jack McManus was elected to serve as VVA National President at VVA's 20th National convention, held in November 2021, in Greensboro, North Carolina. First elected VVA national treasurer in 1995, he was re-elected to the position in 1997, and again in 2019. He previously served as the VVA Michigan State Council president from 1989 to 1996, overseeing the largest state program in VVA. In 1997, he was awarded VVA's highest honor, the VVA Commendation Medal, for his extraordinary service to the organization, to all veterans, and to the community at large. The VVA New York State Council has also recognized him with its own Commendation Medal.

During his career as a private businessman, McManus's company employed approximately 3,500 in two service-sector businesses, with $150 million annually in sales. In 1978, his company was recognized as the first drug-free workplace in the building service contracting industry. The company also emphasizes special hiring programs for handicapped individuals, ex-offenders, and rehabilitated substance abusers for its internal rehabilitation programs. From 1978 to 1985, McManus was the program manager for his company's contract with the Kennedy Space Center space shuttle program in Florida.

Originally from New York City, Jack McManus joined the Air Force in 1965, where he served until 1969. Between 1967 and 1968, he was assigned to Operation Ranch Hand in Vietnam.

Jack received his B.A. in Business Management from New York University in 1973. He resides in North Carolina with his wife, Jackie. He is a recipient of numerous business and community awards.

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