

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”**

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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]nto 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 marshal 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,



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