

Donna McCartney, Chair of the National Association of Veterans' Research and Education Foundations and Executive Director of the Palo Alto Institute for Research and Education

Testimony
of the
National Association of Veterans'
Research and Education Foundations
Before the
Senate Committee on Veterans Affairs
Regarding
S. 2926
The "Veterans Nonprofit Research and Education Corporations
Enhancement Act of 2008"
Presented by
Donna McCartney
Chair of the National Association of Veterans'
Research and Education Foundations
and
Executive Director of the Palo Alto Institute for
Research and Education
May 21, 2008

Chairman Akaka and members of the Committee, thank you for the opportunity to testify on behalf of the National Association of Veterans' Research and Education Foundations (NAVREF) in regard to S. 2926, the "Veterans Nonprofit Research and Education Corporations Enhancement Act of 2008."

NAVREF is the membership organization of the 85 VA-affiliated nonprofit research and education corporations (NPCs) originally authorized by Congress under Public Law 100-322, and currently codified at sections 7361 through 7368 of the United States Code. NAVREF's mission is to promote high quality management of the NPCs and to pursue issues at the federal level that are of interest to its members. NAVREF accomplishes this mission through educational activities for its members and interactions and advocacy with agency and congressional officials. Additional information about NAVREF is available on its web site at www.navref.org.

I am Donna McCartney, the chair of the NAVREF Board of Directors and the executive director of the Palo Alto Institute for Research and Education (PAIRE). I worked for VA for over 28 years in various administrative capacities, and it is my privilege to continue my service to veterans in my current position. I mention this because the fundamental purpose of the nonprofits that are the subject of S. 2926 is to serve veterans by supporting VA research and education to improve the quality of care that veterans receive.

Background about the NPCs

In 1988, Congress allowed the secretary of the Department of Veterans Affairs to authorize "the establishment at any Department medical center of a nonprofit corporation to provide a flexible funding mechanism for the conduct of approved research and education at the medical center." [38 U.S.C. §7361(a)] At this time, 85 NPCs provide their affiliated VA Health Care Systems and medical centers with a highly valued means of administering non-VA federal research grants and private sector funds in support of VA research and education.

Last year, the NPCs collectively administered \$230 million with expenditures that supported nearly 5,000 VA-approved research and education programs. These nonprofits are dedicated solely to supporting VA and veterans. This includes providing VA with the services of nearly 2,500 without compensation (WOC) research employees who work side-by-side with VA-salaried employees, all in conformance with the VA background, security and training requirements such appointments entail.

For example, at the Palo Alto NPC, the nonprofit for which I am the executive director, we have 130 research employees and support 170 projects. Of these, approximately one third are federal awards. During fiscal year 2007 we expended \$10.4 million in support of VA research and education activities and expect our fiscal year 2008 expenditures to approach \$16 million. We provide a full range of on-site support services to VA researchers, including assistance preparing and submitting their research proposals; publishing the results; hiring lab technicians, study coordinators and other dedicated staff to work on the projects; procuring supplies, services and equipment; monitoring the required VA approvals; facilitating travel to scientific conferences, and providing a host of other services that enable investigators to focus on their research and veteran patients.

Beyond administering research projects and education activities these nonprofits support a variety of VA research infrastructure and administrative expenses. They have provided seed and bridge funding for investigators; staffed animal care facilities; funded recruitment of clinician researchers; paid for research administrative and compliance personnel; supported staff and training for institutional review boards (IRBs); and much more.

At my own institution, a seed grant PAIRE provided several years ago to a gastroenterology clinician-investigator resulted in his finding that an easily overlooked type of abnormality in the colon is the most likely type to turn cancerous, and is more common in this country than previously thought. This finding, reported on the front page of the March 5, 2008, New York Times and in the Journal of the American Medical Association, will change colonoscopy practices and may well lead to widespread earlier detection of a cancer that is preventable or curable through surgery. This year alone we have been able to make nine similar awards to VA Palo Alto investigators, in the hope of equally significant research success down the road.

S. 2926 Enhances and Clarifies NPC Authorities

Chairman Akaka, I am so pleased that you introduced this bill. There is a rapidly growing NPC affiliated with the Honolulu VA that just accepted a \$3.353 million Department of Defense (DoD) award to conduct research on telemental health and cognitive processing therapy for rural combat veterans with post-traumatic stress disorder (PTSD). That nonprofit and all the other NPCs -- and ultimately veterans - will benefit from S. 2926.

The bill heading correctly states that the purpose is to "modify and update" the 1988 statute, but we also view this as an opportunity to modernize and clarify the statute after nearly 20 years of experience under its current terms. The NPCs have already proven themselves to be valued and effective "flexible funding mechanisms for the conduct of approved research," and this bill will further enhance their value to VA.

The objectives of S. 2926 are consistent with the findings in the recently released VA Office of Inspector General (OIG) review of five NPCs and VHA's oversight of them. I know that VHA is working hard to address the shortcomings in oversight that the OIG identified. And we on the nonprofit side are working equally hard to ensure that we have appropriate controls over funds and equipment (including supporting documentation for all transactions), and that all NPC

officers, directors and employees are certifying their awareness of the applicable federal conflict of interest regulations. While we firmly believe that NPC boards and administrative employees strive to be conscientious stewards of NPC funds, we thank the OIG for its thorough review of those five NPCs and for bringing to light these areas in need of improvement.

It is noteworthy for the Committee that the OIG report cited no actual misuse of funds or instances of conflicts of interest, dual compensation of federal employees or fraud. However, we take very seriously the OIG finding that these NPCs nonetheless did not have adequate controls over some of the funds they manage. We believe that two major provisions in S. 2926 directly address this finding.

First, section 2 of S. 2926 allows formation of "multi-medical center research corporations" (MMCRCs). That is, two or more VA medical centers may share one NPC, subject to board and VA approval, while preserving their fundamental nature as medical center-based organizations. This will allow interested VA facilities with small research programs to join with larger ones. Or several smaller facilities may pool their resources to support management of one NPC with funds and staffing adequate to ensure an appropriate level of internal controls, including segregation of financial duties.

Second, the last item in section 5(a) of S. 2926 addresses the OIG criticism by broadening VA's ability to guide NPC expenditures. The only constraint on VA is that such guidance must be consistent with other federal and state requirements as specified in laws, regulations, executive orders, circulars and directives - of which there are many - applicable to other 501(c)(3) organizations. The purpose of this limitation is to avoid the possibility of imposing on NPCs conflicting requirements and reducing their ability to remain "flexible funding mechanisms." S. 2926 provides a number of other welcome enhancements to the NPC authorizing statute.

- Section 4(b)(2) of the bill broadens the qualifications for the two mandatory non-VA board members beyond familiarity with medical research and education. This will allow NPCs to use these board positions to acquire the legal and financial expertise needed to ensure sound governance and financial management.
- Section 4(c) of the bill also deletes the overly broad stipulation in the current statute that these non-VA board members may not have "any financial relationship" with any for-profit entity that is a source of funding for VA research or education. This absolute prohibition conflicts with regulations applicable to federal employees with respect to conflicts of interest, which are invoked for all NPC directors and employees in section 7366(c)(1) of title 38, United States Code. Unlike the deleted provision, federal conflict of interest regulations provide means of recusal as well as de minimus exceptions. Additionally, the prohibition has been interpreted to apply to any individual who has ever accepted compensation or reimbursement from a for profit sponsor of VA research for purposes unrelated to VA research, thereby eliminating many otherwise desirable and qualified individuals from serving on NPC boards.
- Section 5(a) of the bill provides NPCs with authority to reimburse the Office of General Counsel (OGC) for legal services related to review and approval of Cooperative Research and Development Agreements (CRADAs), the form of agreement used to establish terms and conditions for industry-funded studies performed at VA medical centers and administered by NPCs. The funds generated under this provision will help OGC to staff Regional Counsel offices to accommodate the workload these agreements entail and to provide training in CRADA requirements and related VA policies.

- Section 5(a) also increases the efficiency of NPC administration of funds generated by educational activities. This clause allows NPCs to charge registration fees for the education and training programs they administer, and to retain such funds to offset program expenses or for future educational purposes. However, it also explicitly sustains the existing prohibition against NPCs accepting fees derived from VA appropriations.
- Additionally, section 5(a) of the bill includes authority for VA to reimburse NPCs for the salary and benefits of NPC employees loaned to VA under Intergovernmental Personnel Act (IPA) assignments conducted in accordance with section 3371 of title 5, United States Code. This provision responds to recent OIG questions asking whether such reimbursements are allowable and permits VA to continue to benefit from this efficient and cost-effective mechanism to acquire the temporary services of skilled research personnel.

S. 2926 also contains a number of useful clarifications of NPC status and purposes.

- Section 2(c) codifies - without changing -- the legal status of the NPCs as state-chartered, independent organizations exempt from taxation under section 501(c)(3) of the Internal Revenue Service (IRS) code and subject to VA oversight and regulation. This clause of the bill codifies the congressional intent, previously expressed in the House report that accompanied the original NPC authorizing statute (H. Rept. 100-373), that nonprofits established under this authority would not be corporations controlled or owned by the government. As a result, S. 2926 resolves longstanding differences of opinion among stakeholders, overseers and funding sources about the legal status of NPCs.
- Section 3(a)(1) of the bill establishes that in addition to administering research projects and education activities, NPCs may support "functions related to the conduct of research and education." This resolves differences of opinion about the allowability of NPC expenditures that support VA research and education generally, such as purchase of core research equipment used by many researchers for many projects, and enhances the value of NPCs to VA facilities.
- Section 5(a) ascertains that all NPC-administered research projects must undergo "scientific" rather than "peer" review. This change recognizes that peer review is not necessary or appropriate for all research projects administered by NPCs. However, the bill leaves in place the overarching requirement for VA approval and the medical center's Research and Development Committee remains in a position to determine on a case-by-case basis whether a project also requires peer review as a condition of approval for NPC administration.

In addition to these enhancements and clarifications, S. 2926 reorganizes the NPC authorizing statute to put all provisions regarding their establishment and status in one section; describes their purposes in another; and gathers in one section the clauses enumerating their powers. Many other revisions are largely technical and conforming amendments.

S. 2926 Preserves Measures Providing Oversight of NPCs

Thus far my testimony has focused on the substantive changes that S. 2926 will implement. Before I conclude, I want to emphasize that this statute makes no changes in VA's power to regulate and oversee the NPCs. Further, NPC records remain fully available to the Secretary and his designees; to the Inspector General; and to the Government Accountability Office (GAO). Likewise, NPCs are still required to undergo an annual audit by an independent auditor in accordance with the sources - federal or private - and amount of its prior year revenues, and they

must submit to VA the resulting audit report along with detailed financial information and descriptions of accomplishments.

In the wake of the Sarbanes-Oxley Act and new Federal Accounting Standards Board (FASB) requirements and auditing standards, even the most basic form of nonprofit audit has become an effective means for assessing an organization's financial controls. Additionally, as more NPCs assume responsibility for federal grants, a higher percentage of NPC funds are subject to Generally Accepted Government Accounting Standards (GALAS) and OMB Circular A-133, the most rigorous and comprehensive level of auditing standards. Before the last independent financial audit of the Palo Alto nonprofit, my accounting staff had to respond to 40 pages of questions about our controls over funds and program compliance, and the auditors were on-site examining and testing our records for several weeks. I can assure you from personal experience that these audits are comprehensive and provide a sound framework for examining an organization's controls over funds as well as compliance with program requirements.

Conclusion

In conclusion, on behalf of NAVREF and the NPCs, I urge the Committee to report S. 2926 to the Senate for enactment at the earliest possible opportunity. The NPCs are already a highly efficient means to maximize the benefits to VA of externally-funded research conducted in VA facilities, ably serving to facilitate research and education that benefit veterans. Additionally, they foster vibrant research environments at VA medical centers, enhancing VA's ability to recruit and retain clinician-investigators and other talented staff who in turn apply their knowledge to state-of-the-art care for veterans.

Twenty years after the VA-NPC public-private partnership was first authorized by Congress, and co-incident with expiration of authority to establish new NPCs, this is a timely opportunity to update and clarify the NPCs' enabling legislation. This bill will accomplish those objectives. Experience working within the statute has brought to light its many strengths, but also areas that will benefit from modification, enhancement and updating, particularly in light of the increasing complexity of both research and nonprofit compliance. We believe enactment of S. 2926 will allow NPCs to better achieve their potential to support VA research and education while ensuring VA and congressional confidence in their management.

Chairman Akaka, thank you again for introducing this legislation and for the opportunity to testify on behalf of NAVREF during this hearing. We look forward to working with you, the members of the Committee and your House counterparts toward enactment of S. 2926. I would be pleased to answer any questions you