

**Statement for the Record
of the
Hearing Held by the
Health Subcommittee of the
House Committee on Veterans Affairs
on June 18, 2009**

In regard to

H.R. 2770

***The Veterans Research and Education Corporations
Enhancement Act of 2009***

**Legislation to Update and Clarify Provisions of the
Law Authorizing the
VA-Affiliated Nonprofit Research and
Education Corporations
38 U.S.C. §§ 7361-7366**

**Submitted by the
National Association of Veterans' Research and
Education Foundations (NAVREF)**

June 18, 2009

The National Association of Veterans' Research and Education Foundations (NAVREF) thanks Veterans Affairs Committee Chairman Bob Filner for introducing H.R. 2770, the *Veterans Research and Education Corporations Enhancement Act of 2009*, on June 9. We also thank Ranking Member Steve Buyer for collaborating with Mr. Filner to finalize and co-sponsor this legislation. We are grateful to Chairman Mike Michaud, Ranking Member Henry Brown and the members and staff of the Health Subcommittee for holding a hearing on this and other important health-related legislation.

Upon enactment, H.R. 2770 will update and clarify provisions of the law authorizing the VA-affiliated nonprofit research and education corporations. The Senate counterpart of H.R. 2770 is title VI of S. 252 which was introduced by Chairman Daniel Akaka on January 15, 2009. Subsequently, it was the subject of a Senate Committee on Veterans Affairs hearing on April 22 and was marked up by the Senate Committee on Veterans Affairs on May 21. The substantive provisions of S. 252 and H.R. 2770 are identical. The only differences between the two bills are in the clause numbering and in a few provisions, the lead-in phrasing.

NAVREF is the membership organization of the 82 VA-affiliated nonprofit research and education corporations (NPCs) originally authorized by Congress under Public Law 100-322, and currently codified at sections 7361 through 7366 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 as well as interactions and advocacy with agency and congressional officials. Additional information about NAVREF is available on its web site at www.navref.org.

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)] Currently, 82 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.

The fundamental purpose of the nonprofits is to serve veterans by supporting VA research and medical education to improve the quality of care that veterans receive. For example, a seed grant provided by the Palo Alto Institute for Research and Education (PAIRE) 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, is changing colonoscopy practices and may well lead to widespread earlier detection of a cancer that is preventable or curable through surgery. During 2008 PAIRE made nine similar awards to VA Palo Alto investigators in the hope of equally significant research success down the road. Similarly, a few years ago funds administered by the Seattle Institute for Biomedical and Clinical Research (SIBCR) allowed a psychiatry clinician-investigator to test use of Prazosin, an inexpensive, already approved drug, for treatment of veterans with debilitating post-traumatic stress-related nightmares. The SIBCR funding allowed the investigator to accumulate positive preliminary data that then led to DOD and NIH awards to further test this promising treatment.

Last year, the NPCs collectively administered more than \$250 million with expenditures that supported approximately 4,000 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.

Beyond administering VA-approved research projects and education activities, these nonprofits support a variety of VA research infrastructure and administrative expenses. As described above, 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.

Legislation Would Enhance and Clarify NPC Authorities

The purpose of H.R. 2770 is to modernize and clarify the 1988 statute after 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” [38. U.S.C. § 7361(a)]. VA’s most recent annual report to Congress regarding the NPCs stated, “The VA-

affiliated NPCs continue to make a substantial contribution to the VA research and education missions.” This legislation will further enhance their value to VA.

The objectives of this legislation are consistent with the findings in the May 2008 VA Office of Inspector General (OIG) review of five NPCs and VHA’s oversight of them. VHA is working hard to address the shortcomings in oversight that the OIG identified. NAVREF and the NPCs are working equally hard to ensure that NPCs have appropriate controls over funds and equipment (including strengthening the 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 NAVREF firmly believes that NPC boards and administrative employees strive to be conscientious stewards of NPC funds, NAVREF thanks the OIG for its thorough review of those five NPCs and for bringing to light these areas in need of improvement.

It is noteworthy that the OIG report cited no misuse of funds or instances of conflicts of interest, no dual compensation of federal employees and no fraud. However, we take very seriously the OIG finding that these NPCs nonetheless may not have had adequate controls over some of the funds they manage. Two major provisions in H.R. 2770 directly address this finding:

First, section 2(a) allows voluntary formation of “multi-medical center research corporations.” 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 provision – the centerpiece of the legislation – will allow interested VA facilities with small research programs to join voluntarily 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) – “(f) Policies and Procedures” - 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 prevent the possibility of imposing on NPCs conflicting requirements and to ensure that they remain independent “flexible funding mechanisms.”

H.R. 2770 provides a number of other welcome enhancements to the NPC authorizing statute.

- Section 4(b) 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) 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 standard currently applied to NPC board members, federal conflict of interest regulations provide means of recusal as well as *de minimus* exceptions. Additionally, the current prohibition may be applied to any individual who has 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) “(b) “(1) “(C) 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.
- Section 5(a) “(b) “(1) “(D) 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. Although OGC is already obligated to review these agreements without reimbursement, the funds generated under this provision would help OGC to staff Regional Counsel offices to accommodate the substantial workload these agreements entail and to provide training for VA attorneys in CRADA requirements and related VA policies. The NPCs support making these reimbursements.

- Section 5(a) “(b) “(2) of the legislation provides VA with authority 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.
- Section 5(a) “(c) “(3) establishes explicit authority for VAMCs to accept funds provided by NPCs that may fall outside of VA’s gift acceptance authority. It also allows VAMCs to retain such funds locally and to deposit them in the appropriate VA account without having to route them through the Treasury, necessitating cumbersome steps to get the funds to the right VA account. Finally, this provision makes these reimbursements “no year” money to give VAMCs needed flexibility in timing for use of the funds.

Although VA has broad authority to accept gifts (38 USC §8301), many NPC payments to VAMCs are more accurately described as reimbursements to the VAMC or payments for services and may not be consistent with VA’s gift acceptance authority. For example, NPCs typically reimburse VAMCs for the cost of clinical services provided exclusively for research purposes; VA employees’ time spent on NPC-administered programs; and animal per diems. This clause also will allow VA to resolve longstanding VAMC uncertainty about how to treat such reimbursements and will let the VAMC that incurred the cost retain the amounts reimbursed. Currently, VAMCs must send such reimbursements to the Treasury and then the Fiscal Office must use a cumbersome process to bring the funds back to the VAMC.

H.R. 2770 also contains a number of useful clarifications of NPC status and purposes.

- Sections 2(b), (c) and (d) codify – 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. Clause (c) of this section 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, this legislation resolves longstanding differences of opinion among stakeholders, overseers and funding sources about the legal status of NPCs.

- Section 3(a)(1) of the legislation 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 appropriateness of NPC expenditures that support VA research and education generally, such as purchase of core research equipment used by many researchers for multiple projects, and enhances the value of NPCs to VA facilities.
- Section 5(a) “(d) 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 legislation 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 VA approval.

In addition to these enhancements and clarifications, H.R. 2770 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. Other revisions are largely technical and conforming amendments.

Proposed Legislation Preserves Measures Providing Oversight of NPCs

H.R. 2770 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 the amount of their prior year revenues, and they must submit to VA an annual report that includes the resulting audit report along with detailed financial information and descriptions of accomplishments.

In the wake of the Sarbanes-Oxley Act and changing Federal Accounting Standards Board (FASB) auditing standards, even the most basic form of nonprofit audit has become an effective means for assessing an organization’s financial controls. Additionally, the percentage of NPC funds subject to audits conducted in accordance with OMB Circular A-133, the most rigorous level of applicable auditing standards, will continue to increase as more NPCs assume responsibility for non-VA federal grants. According to reports submitted to VA in June 2008,

nearly 80% of prior year NPC expenditures were subject to an A-133 audit and overall, 99.7% of NPC expenditures were subject to an audit of one type or another. 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, NAVREF urges the Congress to pass H.R. 2770 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, this is a timely opportunity to update and clarify the NPCs' enabling legislation. This legislation will accomplish those objectives. Experience working within the current 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 H.R. 2770 will allow NPCs to better achieve their potential to support VA research and education while ensuring VA and congressional confidence in their management.

NAVREF thanks the Health Subcommittee of the House Committee on Veterans Affairs and its staff members, as well as the full committee staff, for their work on H.R. 2770. We look forward to working with the members of the Committee toward enactment of this bill. Please direct any questions you may have to NAVREF Executive Director Barbara West at 301-656-5005 or bwest@navref.org.