

**Testimony
Before the
Subcommittee on Health
Of the
Committee on Veterans Affairs**

**Regarding the
VA-Affiliated Nonprofit Research and
Education Corporations**

April 10, 2003

**Presented by
Eileen Lennon, Ph.D.**

Chair

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

Good afternoon, Mr. Chairman and members of the Subcommittee on Health of the Committee on Veterans Affairs. Thank you for the opportunity to present testimony on the VA-affiliated nonprofit research and education corporations. I am Eileen Lennon, Ph.D., executive director of the Seattle Institute for Biomedical and Clinical Research (SIBCR) and chair of the National Association of Veterans' Research and Education Foundations (NAVREF). NAVREF is the membership association of the VA-affiliated nonprofit research and education corporations. Its mission is to promote the interests of the VA nonprofits, and it does so through programs of education and advocacy. SIBCR is a member of NAVREF.

Background about the VA-Affiliated Nonprofits

Since 1988 when Congress passed the authorizing legislation, eighty-eight VA medical centers have established nonprofit research and education corporations. The statutory purpose of the nonprofits is to provide a flexible funding mechanism for the conduct of VA-approved research and education at the medical center. Each one is an independent, state-chartered 501(c)(3) organization. As mandated by Congress, senior facility executives serve on the board, and their officers, directors and employees are subject to federal regulations pertaining to conflicts of interest. Records of the nonprofits are available to the DVA Secretary, the Inspector General and the Comptroller General at any time. All research administered by the nonprofits must be VA approved and is subject to VA oversight and regulation.

While maintaining a close relationship with VA, Congress clearly intended for the nonprofits to be private sector organizations that are separate and different from VA. The nonprofits are a vehicle to accomplish objectives over and above what the VA can do itself, such as accepting and administering private sector and non-VA federal funds in support of research. The nonprofits can respond rapidly to the changing needs of research programs. However, the most important advantages of the nonprofits are that they bring additional resources to the VA research program, their expenditures benefit the research programs at their affiliated medical centers and they are flexible.

In reports submitted to VA in June 2002, the nonprofits reported total revenues of nearly \$180 million supporting 4,700 research projects. While most of this funding was derived from private sector grants from pharmaceutical companies and other nonprofits, \$57 million came from other federal agencies, including NIH, CDC and DOD. Federal funding is the fastest growing component of nonprofit revenues as more nonprofits begin assuming responsibility for administering NIH and other federal grants on behalf of VA investigators. Revenues from indirect cost rates associated with these federal grants benefit VA to an extent not possible when the grants are provided to affiliated universities, who generally do not provide resources from these funds to their affiliated VA.

In testimony presented before the Subcommittee on Oversight and Investigations last year, NAVREF discussed specific examples of how nonprofit expenditures benefit facility research programs. Appendix A of this statement provides current examples of nonprofit support for facility compliance programs to demonstrate the nonprofits' commitment to this important aspect of research. Because time is short, I will only discuss what SIBCR does to support the VA Puget Sound Health Care System in Seattle.

SIBCR administers funds related to about 20% of the 476 active projects at VA Puget Sound. These projects are funded by other nonprofit and voluntary health organizations as well as industry sources. SIBCR provides significant support to the projects it administers. This support includes hiring staff, payroll and benefits administration, negotiations with sponsors, preparing grant submissions, accounting and financial reporting, buying supplies and equipment and paying for the direct costs of the research, including clinical study services provided by the VA.

In addition to these functions, the SIBCR Board has approved support to the VA Puget Sound Health Care System Research and Development program including:

- Up to \$50,000 per year to provide bridge and development funding to VA investigators who are between grants. As a result of the SIBCR funding, investigators are better able to submit competitive research proposals to VA or other funding sources.

- At an annual cost of over \$100,000, provides 2.5 FTE for support of the research and development program including research administration and compliance management.
- With VA, co-funded the start up of a unit to support clinical research. This clinical research unit has 2.4 FTEs, including a nurse practitioner, a nurse and a research associate, to provide support to clinical research projects. The costs are defrayed from direct project charges, but SIBCR still covers over \$50,000 a year in salary support.
- Annually, provides each VA funded investigator with a \$500 allotment for travel. In view of the scarcity of VA travel funding, these small grants allow investigators to stay current in research in their fields by attending scientific meetings and presenting results of VA and non-profit funded research, all of which is approved by VA and relevant to veterans.

The pharmaceutical studies that SIBCR administers provide important benefits to veterans. For example, SIBCR is administering studies involving an approved new antibiotic known to be effective against antibiotic-resistant organisms. This drug costs \$85-95 per day and is not on the VA formulary. But by participating in studies, our clinician-investigators obtain it for their patients at no charge to VA. Our studies are showing that the drug is an effective treatment for catheter infections, pneumonia and limb-threatening diabetic foot infections, all problems among the veteran population. Further, the drug can be taken orally so there is no need for hospitalization or complex IV therapy. As a result of these studies, veterans get an expensive drug at no cost, cutting edge treatment for their condition, and they benefit from the extra care provided by the nurse who was hired by SIBCR to help the physician run the study.

A second example was supported in part by SIBCR funds. A physician who works closely with a group of African-American Vietnam Veterans was drawn into the serious problem of Post Traumatic Stress Disorder (PTSD) nightmares and sleep disturbance. Many of the veterans had not slept through the night in years with a negative impact on their ability to hold a job and interact socially. The physician speculated that if he reduced the excess brain adrenaline response, it might prevent the PTSD nightmares. He obtained VA approval and tried a generic drug that has been used for years to treat high blood pressure and costs only \$1 for 3 months treatment. It is safe and effective, and best of all, he found that it stopped the PTSD nightmares so the veterans slept better and improved their quality of life. SIBCR funds helped fund this pilot

research and now this project is funded with a VA merit award. This continues to be an exciting research endeavor applicable to all veterans suffering from PTSD as well as the many civilians who have had a traumatizing event precipitating PTSD.

2002 Oversight Hearings and GAO and IG Site Visits

Last year the VA-affiliated nonprofits were the subject of two hearings conducted by the Subcommittee on Oversight and Investigations. The first was a routine oversight hearing in May. I wish to emphasize that there was no precipitating event for this hearing. Unfortunately, misunderstandings about the functions of the nonprofits and their required reporting to VHA resulted in the subcommittee concluding that VA was not collecting sufficient information about the nonprofits. The subcommittee also determined that no one in VA was routinely looking critically at the information that was available. As a result, the IG and GAO were asked to investigate the nonprofits and to report their findings at a subsequent hearing.

During the summer of 2002, the GAO and IG audited 7 of the nonprofits and presented testimony before the Subcommittee on Oversight in September. Overall, the findings by both the IG and the GAO were supportive of the nonprofits. The GAO recognized that the nonprofits are integral to the VA research mission and that the growth of the nonprofits is directly related to a significant benefit to veterans. The GAO reported that "...expenditures were related to research or to running the nonprofit corporations and were consistent with its internal control procedures." The IG stated that "nothing came to our attention indicating that controls over expenditure and fund usage at these facilities were inadequate." Both acknowledged that the nonprofits provide significant benefit to VA research and validated that the nonprofits were fulfilling their intended statutory mission.

Response to GAO and IG Recommendations

In their testimony, both the IG and GAO recommended ways to increase collection of data about the nonprofits and to improve accountability. I will use the remainder of my time to address measures that are being taken to meet these objectives, and to provide our own

recommendations. NAVREF is committed to promoting the highest standards of fiscal and operational management of the nonprofit research and education corporations, and has participated fully in the development of these measures.

1. **Consistent with one of the IG's recommendations, NAVREF supported establishment of a new VA Nonprofit Program Office within VHA and the Office of Research and Development (ORD).** At ORD's invitation, NAVREF participated in discussions that helped shape the role and staffing of this office. We anticipate that the office will provide a degree of routine oversight by VHA that has been absent to date. We hope that this office also will work with NAVREF to be proactive in ensuring that VHA policies incorporate the nonprofits when appropriate, in communicating essential information that may not otherwise reach the executive directors, in assisting individual nonprofits in dealings with ORD, and in developing national solutions to common problems.

2. **Consistent with IG and GAO recommendations, and the objective of legislation that ultimately was not enacted by the 107th Congress, NAVREF supports improved accountability by the nonprofits.** While we had concerns about many of the specific IG recommendations and some provisions of this bill, last year we worked diligently with staff of this subcommittee and the Office of Research and Development to develop alternatives that would provide both VA and Congress with more meaningful information and an appreciable improvement in oversight. At the same time, our aim was to ensure that new requirements do not duplicate or conflict with standards already imposed on nonprofits by the Internal Revenue Service, the Federal Accounting Standards Board, the Office of Management and Budget and other federal, state and local oversight organizations. It is our understanding that new legislation will be introduced by this subcommittee next month that will contain mutually agreeable improvements in accountability including:
 - Requiring all nonprofits with revenues over \$300,000 to undergo an annual audit in accordance with Generally Accepted Government Auditing Standards (GAGAS).
Although this may double the cost of some nonprofits' audits, in our view the increased

scrutiny provided by a GAGAS audit, particularly in reviewing internal controls, justifies the additional expense.

- Developing a more meaningful annual report to VA and Congress. While the current report provides standardized financial information largely drawn from the IRS Form 990 each nonprofit must submit, it does not provide sufficient detail about nonprofit operations, and particularly fails to capture the many ways the nonprofits support facility research programs.
- Requiring the Inspector General to review annually 10% of the nonprofits' annual reports to VA.

That said, we will continue to recommend against imposing on the VA- affiliated nonprofits management and accounting practices not required of other US nonprofits. For example, VA nonprofits must retain the right to select their own fiscal year, methods of accounting (cash or accrual), accounting software and chart of accounts. In our view, efforts to make the nonprofits more like the government will undermine their statutory purpose as flexible funding mechanisms and the clear intent of Congress that they should be different and separate from the government. As stated in the authorizing legislation, the VA-affiliated nonprofits are “required to comply only with those Federal laws, regulations and executive orders and directives which apply generally to private nonprofit corporations” [38 USC 7361(a)].

3. **Also consistent with the recommendations of the *IG and GAO*, NAVREF supports improved reporting by the nonprofits and increased data collection by VA.** Current reporting is largely financial and fails to capture a true picture of the nonprofits and their value to VA. We have suggested that a more meaningful annual report is needed and have offered to work with the VA Nonprofit Program Office to develop a template. In addition, we have encouraged VA to collect from the IRS Form 990s submitted by the nonprofits the wealth of information that is not captured currently. At the same time, we recommend keeping the statutory reporting requirements to a minimum. Section 7366(a)(1)(A) of the nonprofit authorizing statute specifies that the records of a nonprofit shall be available to the Secretary. Consequently, additional statutory requirements for specific financial information

do not seem to be needed. The nonprofits are prepared to respond promptly to virtually any inquiry about their finances, if provided with reasonable response time to accumulate the data and assuming that the request does not entail undue cost and time commitments.

4. **Consistent with the IG’s recommendation, NAVREF supports improved guidance to define research expenditures.** Although we were unaware of any confusion in this regard, we have no objection to clear guidance and have provided ORD with draft text that we suggest incorporating in the next version of Handbook 1200.17, the VA policy manual for the nonprofits. Our suggested wording goes further than the IG recommendation in that it also includes specific guidance on documenting the research relatedness of nonprofit expenditures.

NAVREF’s Training and Standards Setting Initiatives

At the next meeting of the board of directors, NAVREF will continue its ongoing review of our mission as a forum for promoting the highest nonprofit management standards and ensuring that we provide outstanding educational programs to our members. The programs currently include:

- An annual conference that provides two days of training in nonprofit management that is specifically tailored for the staff of the VA-affiliated nonprofits;
- A second conference with two days devoted to a single operational topic such as human resource management or accounting;
- Best Practices Consultations designed to promote peer-to-peer sharing of “best practices” in nonprofit management conducted on site by experienced executive directors and NAVREF staff; and
- A new web based Best Practices Program that when complete, will provide comprehensive guidance on virtually all aspects on nonprofit management, with particular emphasis on compliance with VA policies.

During this same meeting, the board will also explore new educational initiatives, possibly involving “distance learning” opportunities over the Internet or during moderated conference

calls. And we look forward to re-scheduling the board training session we had planned to hold for hospital directors and chiefs of staff in conjunction with the VA Senior Management Conference.

Conclusion

I would like to conclude with three final NAVREF recommendations.

1. **We respectfully encourage this subcommittee to move forward on two legislative requests submitted by NAVREF.** The first would encode VA's intent that nonprofit employees with VA without compensation appointments shall be provided with protection against personal liability under the Federal Tort Claims Act. Due to a ruling by the Department of Justice such coverage is uncertain so a statutory clarification is required. The second would improve the effectiveness of the nonprofits by providing VA with a mechanism to use VA-appropriated funds to pay for services provided by nonprofits in support of VA research and education. NAVREF has no preference as to whether the solution is "contract" or "reimbursement" authority. We ask only that it serve the intended purpose and involve rigorous VA review and approval of all transactions. It has been our pleasure to work with subcommittee staff to develop these initiatives, and we request enactment this year.

2. **In our view, the Nonprofit Program Office staff should be strengthened by the addition of a full time VA attorney dedicated to nonprofit matters.** It is our understanding that ORD supports this step and has agreed to fund the necessary FTE.

3. **We encourage ORD and the Office of Academic Affiliations (OAA) to explore consolidating their respective data collection responsibilities within the VA Nonprofit Program Office.** In our view, it would be more efficient to make a single office responsible for collecting both research and education information and compiling a single, consistent report to Congress.

During the fifteen years since their inception, the nonprofits have become an integral and increasingly significant component of the VA research program. Many field personnel view the nonprofits as the best thing that ever happened to VA research, and we thank Congress for its foresight in authorizing them. However, as the GAO pointed out in spoken testimony last September, with growth comes increased potential for risk. While we fully appreciate the importance of accountability and oversight, we want to ensure that the nonprofits retain the flexibility necessary to perform the mission for which you established them. We appreciate that both this subcommittee and the VA have included individual nonprofits and NAVREF in deliberations over improvements and we look forward to continuing this working relationship.

Thank you for considering our views. I would be pleased to answer your questions.

Selected Examples of NPC Support for VA Research Compliance

Following are selected examples of NPC funds used in support of VA research compliance programs including support for VA R&D Committees and Institutional Review Boards (IRBs) as well as bio-safety and animal oversight programs. In many cases, these contributions are just a portion of total dollars donated in support of research at affiliated VA medical centers. Additional examples of NPC support for facility research programs include, but are not limited to salary support for research or animal staff, research and office equipment and maintenance costs, travel and meeting costs for research principal investigators and staff, publications, educational seminars, renovation of out-of date VA laboratory space, bridge funding, security, and young investigator grants.

Bronx Veterans' Medical Foundation, Inc. (NY): Provides salary support for two compliance officers, the IRB chair, and a secretary for the ACOS for Research and Development. Total Support: \$167,000

McGuire Research Institute, Inc. (VA): Provides salary support for Human Research Protections Program (HRPP) staff, IRB members and Investigational Pharmacy. MRI also provides support for HRPP training, equipment, renovations, supplies, vendor costs and other miscellaneous expenses. Total Support: \$697,100

Veterans Research Foundation of Pittsburgh (PA): Provides salary support for IRB staff and supports cost of IRB member honorariums. VRFP also provides support to HRPP through training, conference registration and education materials. Total Support: \$67,100

The Bay Pines Foundation, Inc. (FL): Supported an IRB regulatory requirements seminar and HRPP training by paying for registrations and travel expenses. Total Support: \$70,500

Brentwood Biomedical Research Institute (CA): Provides salary support for IRB staff and pharmacists. BBRI also supports VA research compliance by paying for travel, tuition and stipends for IRB and IACUC staff; volunteer and community members of the IRB and animal committees as well as salary for one full-time Clinical Research Center (CRC) coordinator. Total Support: \$422,500

Tuscaloosa Research and Education Advancement Corporation (AL): Provided salary support to the VA IRB and R&D programs. In addition, TREAC recognizes the importance of current compliance information and therefore supported IRB staff and the committee chairman to attend the VA Day at the Public Responsibility in Medicine & Research and the Applied Research Ethics National Association conferences. Total Support: \$43,600.

East Bay Institute for Research and Education, Inc. (CA): Paid HRPP salary expenses and loaned EBIRE employees to meet the immediate needs of the R&D office. EBIRE also contributes to the VA research program by absorbing administrative costs for employees. Total Support: \$122,000.

Palo Alto Institute for Research and Education, Inc. (CA): Over the past two years PAIRE has contributed more than \$150,000 for the development of a web based research application and management system to assist the R&D committee and subcommittees.

Baltimore Research and Education Foundation (MD): Provided funding for compliance costs for clinical studies and animal studies through support of IRB and IACUC expenses, consent form scanning into electronic media record and salary support for a quality assurance nurse. Total Support \$153,900