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Hearing on

The VA-Affiliated Nonprofit Research and

Education Corporations

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Presented by

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Good morning, Mr. Chairman and members of the Committee on Veterans Affairs Subcommittees on Health, and Oversight and Investigations. Thank you for the opportunity to present testimony on 1) the management of the VA-affiliated nonprofit research and education corporations and 2) the effectiveness of the partnership between the corporations and the Veterans Health Administration. I am Antonio Laracuente, executive director of the Atlanta Research and Education Foundation (AREF) and chairman of the National Association of Veterans' Research and Education Foundations (NAVREF). NAVREF is the membership association of the eighty-five VA-affiliated nonprofits.

First, I will address corporation management. I am the first to acknowledge that managing a VA-affiliated nonprofit is challenging — difficult, but rewarding. Like all state-chartered tax-exempt corporations, the VA nonprofits must comply with local, state and federal requirements. In addition, management must comply with 38 U.S.C. 7361 and the VA implementing guidance in Handbook 1200.17. Further, the corporations operate in the VA environment so they must ensure that their employees comply with a broad spectrum of VA regulations.

All together, these add up to many layers of compliance regulations and oversight including, but not limited to:

- Congress
- Internal Revenue Service
- Department of Labor
- State and local government agencies
- VA Inspector General
- VA Comptroller General
- VA Office of General Counsel
- Federal agencies and regulations governing research and education
- VA handbooks specific to the nonprofits as well as research and education, human resource management, safety, conduct and ethics, etc.
- Board of directors including the medical center director, chief of staff and associate chiefs of staff for research and education.
- Certified public accountant (CPA) and guidance promulgated by the American Institute of Certified Public Accountants

- CPA Auditor and regulations of the Federal Accounting Standards Board
- Office of Management and Budget (OMB) and regulations contained in various OMB Circulars

When Congress authorized VA medical centers to establish nonprofits in 1988, a new dimension was added to the roles of the Associate Chiefs of Staff for Research and Development and the R&D Administrative Officers who took the initiative in setting up the nonprofits. Nonprofit operational and financial management systems had to be created from scratch. A lot of effort went into developing templates and web sites to assist in the dissemination of operating policies and information. Overall, research personnel, the boards and the medical center management quickly recognized the value of the nonprofits and worked hard to manage them successfully.

I encourage you to visit some nonprofit web sites — www.sibcr.org and my own, www.atlaref.org — to see the level of management maturity that the corporations have achieved during the last 14 years. You'll find employee handbooks, forms for ordering supplies and equipment, policies and procedures for expenditures, steps required to obtain R&D Committee approval for projects, and much more.

Is there room for improvement? Of course. As in any business, we cannot become complacent. The corporations are at different points in their business life cycles, but we feel strongly that the trend is in the right direction. We attribute this to four major factors:

1. Over time, executive directors have gained experience in managing nonprofits.
2. As the original executive directors retire, they are being replaced by executive directors with substantial nonprofit experience.
3. The audit requirement imposed by Congress in 1996 has raised awareness of financial accountability and internal controls.
4. Boards better understand their oversight and fiduciary responsibilities and are learning to exercise them rigorously.

Everyone associated with the nonprofits is acutely sensitive to the possibility that poor management of one corporation has the potential to reflect badly on all the nonprofits. This is the main reason that 14 corporations established NAVREF in 1992. NAVREF is a 501(c)(3) education organization whose primary purpose is to provide a forum for guidance on managing a VA nonprofit. As

chairman, I am particularly proud of the spirit of cooperation and sharing that is characteristic of everyone involved in NAVREF.

- On a daily basis, corporation staff and board members access the NAVREF web site, bulletin board and newsletters to obtain information that fosters high standards of management.
- Members regularly ask questions of NAVREF Executive Director Barbara West who researches the answers and generally responds in less than a day.
- Sixteen foundations have taken advantage of NAVREF's Best Practices Consultations program and we are beginning development of a new comprehensive self-assessment and improvement program that will provide members with the tools to ensure that they are following "best practices."
- Annually, about 130 corporation executive directors, senior staff and board members attend NAVREF's two-day conference offering networking opportunities and educational sessions tailored for our members.
- Members take advantage of insurance products tailored specifically for their needs and discounts on equipment and supplies that NAVREF has negotiated using the collective purchasing power of the nonprofits.
- Under arrangements made by NAVREF, experienced executive directors mentor new ones leading to on-site visits and on-going exchanges of information.
- Members regularly consult members of the Office of General Counsel Corporations Panel through a collaborative program negotiated by NAVREF that allows corporations to reimburse VA for assistance in making sure that VA interests are not compromised in clinical research agreements.

We are also sensitive to the fact that with growth, the corporations become more prominent in supporting VA's research and education programs and therefore have a responsibility to constantly strive to meet the highest standards of nonprofit management. And I believe we are meeting that challenge.

Turning to the second topic of this panel, I am confident that the nonprofit – Veterans Health Administration (VHA) partnership is highly effective. The corporations are an integral and essential component of facility research programs. Funds permitting, they fill in the gaps when VA resources fall short and more recently, they are helping facilities meet increasingly complex and stringent human research requirements by hiring research compliance and institutional review board (IRB) staff. VA-appropriated funds are woefully inadequate for these needs.

The corporations are extremely lean organizations. On average, ninety cents of every dollar expended by the corporations supports VA research and education. Only 10% of their expenditures support foundation administration — salaries, insurance, office equipment, accounting, etc. — far below the industry norm of 25%. This is in part because the corporations are housed in VA facilities. But it is due largely to a concerted effort by the boards and executive directors to allocate their resources to support for VA research and education. In reports submitted in June 2001, the corporations reported research expenditures of $141 million and administration of more than 4,600 research programs.

Generally, these expenditures are for research equipment and supplies; space renovations; travel to scientific conferences; and salaries for research personnel including technicians, nurses, research coordinators, animal care takers, data clerks and investigators.

The following are just a few of the specific ways just three medium-sized corporations support VA research:

Salt Lake City – Western Institute for Biomedical Research (WIBR):

- Since 1994, WIBR has awarded young VA investigators $300,000 in seed grants. So far, half of these awardees have gone on to obtain VA, NIH and other peer reviewed funding in excess of $1.8 million.
- Private sector contributions of $325,000 have allowed WIBR to purchase a scanning electron microscope and donate it for VA investigators' use.
- For two years, WIBR has hired and donated to VA a full-time Research Compliance Officer and a part-time support clerk to run a Risk Management Office dedicated to protection of human and animal subjects, safety/biosafety and ensuring scientific integrity.

Long Beach – Southern California Institute for Research and Education (SCIRE)

- Each year, SCIRE provides three $5,000 bridge funding grants that allow established VA investigators with lapsed funding to maintain their laboratories and/or develop data and proposals for submission for VA merit review awards as well as NIH and other grants.
- Student stipends enable local undergraduate university students to work in the VA laboratories to assist researchers, but also to develop an interest in research under the direct supervision of a funded VA principal investigator.

- SCIRE donates to VA the services of an Information Technology Support computer specialist to assist in the selection and installation of hardware and software for research personnel, repair computers and provide a variety of research technology support services.
- SCIRE publishes a monthly clinical coordinator newsletter to disseminate information to SCIRE, VA and university funded clinical coordinators based at the VA. In addition, it holds a monthly training session for all the coordinators to introduce new regulations, practice guidelines, etc.

Atlanta – Atlanta Research and Education Foundation (AREF)

The Atlanta Foundation is closely affiliated with the VA. Our board meetings have hefty agendas that include proposed ways to assist the VA research program and fill funding gaps where needed. Recent and on-going contributions include the following:

- AREF has funded numerous small, but essential renovation projects that include design and remodeling of laboratories, and patching and painting. Over the last three years, the costs have totaled over $70,000.
- At a cost of $355,000, AREF covered the cost of converting and expanding unused medical center space in order to provide the research program with much needed new laboratory space.
- AREF partnered with the VA to purchase a $120,000 high tech microscope by allocating $9,000 to renovate a room to house it.
- AREF has a young investigator award program that funds up to three $25,000 grants per year so that young investigators who hold VA clinical appointments may collect preliminary data and compete for grants at the national level.
- Finally, AREF has partnered with the medical center to develop a clinical studies center. While VA pays a clinician director, AREF annually invests over $200,000 to staff the center and pay for training in human studies compliance.

Attachment 1 in my written testimony provides more ways corporations are helping their facilities. In addition to these tangible benefits that corporations confer on facility research programs, there are significant intangible benefits:

1. The corporations assist VA in recruiting clinician investigators who in turn provide high quality care for veterans. They support recruitment travel costs and often pay to upgrade a laboratory to suit a new investigator's particular needs.

2. Efficient services provided by the corporations increase principal investigator satisfaction and productivity and help VA retention rates. Prompt personnel hiring, quick turnaround on travel reimbursements, and efficient procurement are just a few of the benefits.
3. Veterans have access to the latest drugs and the extra care that goes along with participation in clinical research, saving VA millions of dollars in pharmaceutical costs and improving patient outcomes.
4. The corporations help make up for inadequate VA travel funding by supporting the costs of attending scientific meetings.

The corporations are gradually implementing the 1999 authority to support VA's education mission. Two facilities have established corporations specifically to administer educational activities, but more commonly, the research corporations are evolving into research **and** education corporations. This is a gradual process because we have to develop new policies and procedures and inform VA education personnel of the advantages — and limitations — of partnering with the corporations. In a few years, we anticipate that the corporations will be providing VA with access to educational opportunities for staff and patients that currently are not possible due to the lack of VA funding for education. Examples of recent corporation education activities:

- Pursuant to a $30,000 grant, the **Biomedical Research Institute of New Mexico** sponsored a conference on infectious diseases that was attended by 78 VA, university and community physicians.

- The **East Bay Institute for Research and Education** administered a state-of-the-art training session in endoscopic retrograde cholangiography and papillotomy. Procedures were performed live at the VA and transmitted to large screens at a nearby hotel conference room where 215 registrants watched and listened. Many VA nurses, physicians and trainees attended free while a small registration fee was charged to community and university attendees.

- The **Boston VA Research Institute** (BVARI) assisted VA in managing the 2001 Information Technology Conference that over 3,000 VA employees attended. BVARI also supports research fellowship training grants for VA physicians.

I believe that all of these illustrate that the VHA – nonprofit partnership is far more effective that anyone had expected it to be in 1988. **The corporations cannot replace a robust federal appropriation for the VA research program and medical center support. However, they can help leverage VA-**

appropriated dollars in ways that benefit the research program, VA facilities, VA staff and VA patients.

Research facilities across the nation appreciate the leap of faith Congress took in authorizing the nonprofits, but as you may be aware, we have asked Congress to make modifications in the authorizing statute.

On April 16, legislation was introduced in the Senate that will accomplish two objectives:

1) Confer federal employee status on certain corporation employees for purposes of Federal Tort Claims Act (FTCA) coverage; and
2) Clarify that VA medical centers (VAMCs) and NPCs may enter into VA-approved contracts and other forms of agreements for the purpose of facilitating VA research and education.

As yet, there is no House equivalent to these provisions which are included in S. 2132. We ask you to either incorporate them in legislation that is under development by the House Committee on Veterans Affairs, or to accept the Senate language in conference.

The VA Office of General Counsel (OGC) has long maintained that NPC employees who have VA without compensation (WOC) appointments and work on VA-approved research projects under the supervision of VA employees are afforded protection against medical malpractice liability under the Federal Tort Claims Act and 38 U.S.C. §7316, subject to certification by the Attorney General that the employee's work is within the scope of government work. However, in an opinion issued in 2000, the Department of Justice (DOJ) cast an unacceptable degree of doubt on the OGC position by stating that NPC employees are not federal employees for purposes of the FTCA.

Congress has conferred federal employment status for purposes of FTCA coverage on certain non-federal employees of such organizations as the Thrift Investment Fund, the Arctic Research Commission, the Peace Corps, the Postal Service, the Public Health Service and the Atomic Energy Commission. Similarly, Section 3 of S. 2132 would confer FTCA coverage on certain NPC employees, and we ask you to support this provision.

In my testimony, I have described some of the donated goods and services the corporations provide to their VAMCs. At the same time, when it is cost-effective and efficient, VAMC research and education

programs would benefit from agreements that would allow the corporations to provide additional services over and above what they can afford to donate. However, to date, OGC has considered a VA payment for a service provided by a corporation to be a prohibited transfer of VA-appropriated funds. As a result of this interpretation of §7361(a), the NPCs' ability to facilitate VA research and education has been curtailed.

Section 2 of S. 2132 has been carefully crafted to permit VAMCs to make payments to NPCs pursuant to VA-approved contracts — or other forms of agreements — for services provided by the NPCs to facilitate VA research and education. Please note that an integral feature of Section 2 is that all such agreements would be subject to VA review and approval. NAVREF and its members welcome this requirement to provide mutual assurance that the agreements will withstand rigorous scrutiny. Such services would be provided by organizations that are motivated by VA needs — not profit — and that exist solely to serve VA's research and education missions. With your permission, I would like to enter the record our recent statement on these provisions. We would appreciate your approval of them so the corporations may better fulfill their mission of facilitating VA research and education.

Finally, the authority to establish new corporations expires December 21, 2003. Now that the corporations have proven their value to VA, we encourage Congress to eliminate the sunset clause entirely.

1. Over the next decade and beyond, facility consolidations and changes resulting from the CARES process may result in altered dynamics that make a corporation necessary where there is no current need.
2. As facilities become more aware of the advantages of corporation education activities, those that do not conduct significant research may want to establish education corporations.

Thank you for your consideration of our requests. This concludes my prepared remarks, and I would be pleased to answer your questions.

Attachment 1

Selected Additional Examples of Research Corporation

Contributions to VA Facilities

Palo Alto Institute for Research and Education (PAIRE):

- Provides seed grants ranging from $15,000 to $100,000 to new VA appointees, junior faculty and persons appointed to significant VA research positions such as the GRECC director. Grants enable investigators to start new research programs, hire laboratory technicians to work on projects that result in grant submissions or to acquire supplies and equipment.
- Donated over $100,000 for the development of a web site that permits electronic processing of research projects.
- Cost shares with VA the salary and fringe benefits for a Research Compliance Officer, IRB Coordinator, Database Manager and R&D Project Coordinator.

Middle Tennessee Research Institute:

- Donated software that enhances the VA research office's ability to comply with new and existing human subject oversight requirements.
- Donates to VA the services of a Research Pharmacist.
- Supported travel and training costs for a new Research Compliance Officer.

Missouri Foundation for Medical Research: Contributed $45,000 to partner with the university to purchase a $192,000 MicroCat scanner and a $229,000 Gammacell Irradiator and to install them in the VA animal facility.

Durham Research Institute:

- Spent $24,000 on research laboratory improvements during the last two years.
- Since 1999, has provided $232,000 in seed grant funding.

Indiana Institute for Medical Research: Provided $52,000 to purchase a confocal microscope and set aside $87,000 to purchase equipment for a newly renovated wet laboratory which will include a new biosafety level 3 lab.

Collaborative Medical Research Corporation (White River Junction):

- Committed $34,000 to partner with the VA research program to acquire three state-of-the-art pieces of laboratory equipment.
- Sponsors bi-weekly research seminars, bringing nationally prominent speakers to the VA facility to share results and build collaborations in order to help grow the White River Junction research program.
- Will soon begin funding a nurse research coordinator to facilitate studies in cardiology, gastroenterology and pulmonary disease as well as a Research Compliance Officer.

New England Medical Research Institute: Assisted in the recruitment of a highly sought after research scientist by donating $5,000 to pack and move over $100,000 worth of research equipment that is now available to the new researcher as well as others in the facility.

Biomedical Research Foundation (Little Rock):

- To date, provided VA investigators with nearly $1 million in funding for pilot studies, equipment purchases and bridge grants.
- During the last two years, purchased three sets of animal cages at a cost of $75,000 and donated them to VA.
- Pays the salary for a full-time Research Compliance Officer and a half-time Safety Officer for a total cost of $81,000.

Veterans Education and Research Association of Michigan (VERAM): So far during 2002, VERAM has provided three research grants of $25,000 each and contributed .25 FTEE for a human studies coordinator.

Cleveland VA Medical Research and Education Foundation: Awarded $46,000 worth of bridge funding to VA investigators and provided salary support for IRB clerical staff.

Buffalo Institute for Medical Research (BIMR):
- Recently collaborated with the medical center to open a clinical research center (CRC) in a former in-patient ward. The CRC is used by investigators conducting both in-patient and out-patient studies. BIMR provided $7,000 to convert the ward and provides on-going salary support for staff.
- Supports two part-time animal care workers at a cost of $3,000 per year.
- Annually, spends about $17,000 to cover the cost of service contracts on VA research equipment.

Research Corporation of Long Island: Donated $40,000 to the medical center for a Research Pharmacy Technician.

Salem Research Institute:
- Donates a .5 FTEE secretary to the research office.
- Supports the cost of training for personnel responsible for human subject oversight.
- Coordinates meetings between Salem investigators and their collaborators from around the country.
- Subscribes to a variety of professional journals and purchases reference materials on research issues.

Midwest Biomedical Research Foundation:
- Provided five seed grants of $10,000 each to young investigators that has allowed them to go on to achieve NIH, VA merit and other funding.
- Supported 40% of the salaries for a physician and a scientist for the facility's Neurobiology Laboratory.
- Hires clerical workers to help principal investigators complete all the paperwork required for research study approvals.

Minneapolis Veterans Research Institute (MVRI) regularly purchases core equipment and donates it to VA. So far, this has included a cell sorter, freezer and industrial copier. MVRI also provides $10,000 a year to cover equipment repairs and miscellaneous emergency expenses.

Bronx Veterans' Medical Research Foundation (BVMRF): Donates the cost of salaries for the IRB chairman and the Research Compliance Officer. BVMRF also makes up the chronic deficit in the cost of running the animal facility.