



Testimony

Before the Subcommittee on Oversight and
Investigations, Committee on Veterans' Affairs, House
of Representatives

For Release on Delivery
Expected at 11:00 a.m.
Thursday, September 19, 2002

VA HEALTH CARE

Nonprofit Corporations Enhance VA Research, but Would Benefit from Increased Oversight

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Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the Department of Veterans Affairs' (VA) nonprofit research corporations, which receive funds primarily from non-VA sources to conduct medical research at VA facilities. In fiscal year 2000, these corporations administered funds amounting to \$174 million, or about 15 percent of VA's total medical research dollars. The authority to establish private nonprofit research corporations, contained in the Veterans' Benefits and Services Act of 1988,¹ provides a flexible funding mechanism for, among other things, hiring and contracting for goods and services for certain medical center research.

Since VA's nonprofit corporations were first established, there has been limited oversight of their operations and contributions to VA research. For example, the VA Inspector General's last major review of the program occurred in 1994, when VA was cited for failing to provide adequate policies and guidance relating to budgeting, accounting, and oversight of these corporations. On May 16, 2002, this subcommittee, along with the Subcommittee on Health, conducted a hearing on VA's nonprofit research corporations. In following up on that hearing, you asked that we provide additional information on the corporations. My testimony today will focus on (1) the benefits nonprofit research corporations provide to VA, (2) processes to detect individual and institutional conflicts of interest within nonprofit research corporations, and (3) nonprofit research corporations' financial activities and how they are monitored by VA.

To conduct our work, we visited 5 of the 88 nonprofit corporations based on their dollar revenues for 2000.² We compared and analyzed data from each of the five nonprofit research corporations' audited financial statements to their Internal Revenue Service (IRS) tax forms for 2000 and 2001, along with general ledger account balances and supporting documentation for revenues and expenses. We also reviewed VA's annual reports on nonprofit research corporations' activities for fiscal years 1998

¹Pub. L. No. 100-322 § 204, 102 Stat. 487, 510-512 (1988). Provisions pertaining to nonprofit corporations are codified at 38 U.S.C. §§ 7361 *et seq.*

²Three were large nonprofit corporations with revenues greater than \$5 million, one was a medium corporation with revenue of about \$3 million, and one was a small corporation with revenue less than \$1 million.

through 2000,³ and relevant legislation and regulations. We visited each of the nonprofit corporations' affiliated VA medical centers and interviewed officials from VA's Offices of Research and Development, General Counsel, and Financial Management. We also spoke with principal investigators, who are usually either part- or full-time VA employees. They design and control research projects and frequently have dual appointments with the VA medical centers' affiliated universities.⁴ We also interviewed officials from federal agencies that provide funds to VA nonprofit research corporations, including the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS), and the Department of Defense (DOD). Our work was conducted from June 2002 through September 2002 in accordance with generally accepted government auditing standards.

In summary, we found the following:

- Nonprofit corporations support VA's research environment by funding a portion of the department's research needs, such as laboratory equipment and improvements to infrastructure, and by providing flexible personnel and contracting arrangements to respond to investigators' needs.
- To detect conflicts of interest, investigators on research projects administered by VA nonprofit corporations are subject to federal statutes and regulations applicable to federal employees concerning conduct and conflicts of interest and may be required to disclose their financial interests. Institutional conflicts of interest are unlikely to occur in VA's nonprofit research corporations because they cannot own stock, have an equity interest in private companies, or obtain intellectual property rights.
- VA has delegated responsibility for monitoring and overseeing the activities of nonprofit corporations to the directors of VA medical centers, however, VA headquarters does not oversee and monitor corporations' financial activities and ensure that identified deficiencies are corrected.

Background

In carrying out its mission, VA conducts medical research to find new treatments for diseases and disabilities that affect veterans and the nation's population as a whole. VA researchers have been involved in a

³VA's annual report for 2001 will not be available until after October 1, 2002.

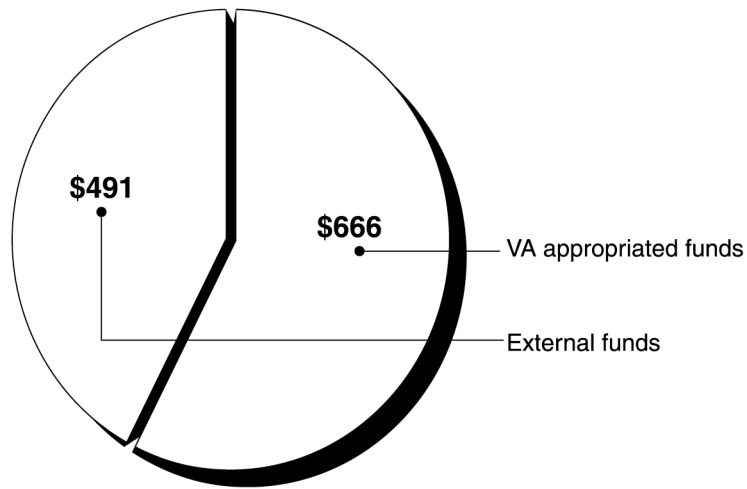
⁴For the past 50 years, many VA medical centers have been affiliated with medical schools for patient care, medical education, research, and sharing of staff and other resources.

variety of important advances in medical research, including development of the cardiac pacemaker, kidney transplant technology, prosthetic devices, and drug treatments for high blood pressure and schizophrenia. VA's research programs include nine high-priority areas: acute and traumatic injuries, military and environmental exposures, special high-risk or underserved populations, sensory disorders and loss, aging, mental illness, substance abuse, chronic diseases, and health services and outcomes research.

In fiscal year 2000, funding for VA research totaled almost \$1.2 billion, supporting research projects conducted by more than 3,800 scientists at 115 VA medical centers across the country. These funds finance research projects and their supporting infrastructure, including capital expenditures for buildings, animal laboratories, and equipment. Funding made available for medical research through annual appropriations provided \$666 million of VA's fiscal year 2000 research dollars; the other \$491 million was provided by other federal and nonfederal sources (see fig. 1).⁵ Federal funding comes from such sources as NIH and DOD, while nonfederal funding sources include private organizations, such as drug or biotechnology companies, or organizations such as the American Lung Association, the American Heart Association, and the American Diabetes Association. Of the \$491 million, \$174 million was administered by the nonprofit corporations, and the remaining \$317 million was administered by VA medical centers or their affiliated universities.

⁵Research grants and awards usually provide funds for direct and indirect costs. Direct costs include expenses that can be specifically linked to a project, such as the salaries of technicians who conduct research. Indirect costs include overhead expenses for the administration of projects, such as grant application preparation, as well as for expenses incurred for shared resources that are not readily allocated to the multiple projects using them, for example, digital microscopes.

Figure 1: VA Research Funding for Fiscal Year 2000 (in millions)



Source: VA's Office of Research and Development 2000 Annual Report: *Serving Veterans: Better Health Care Through Research*.

Nonprofit research corporations exist solely to support VA research and education, using their funds to support local VA medical centers' research environments.⁶ They are collocated with VA facilities and usually do not pay VA for services such as rent, utilities, local telephone services, and janitorial services. Currently, there are 88 chartered nonprofit research corporations, of which 85 are actively conducting research.

In 2000, the most recent year for which revenue data are available, VA's nonprofit research corporations received about \$174 million in revenues—almost a 140-percent increase over the last 5 years—and administered 4,651 VA-approved research projects. The largest source of funding for VA's nonprofit research corporations has been private organizations, averaging more than 40 percent from fiscal years 1996 through 2000 (see table 1). NIH has been the largest government source of funding for the corporations.

⁶The Congress expanded the authority of nonprofit research corporations in 1999 to include funding for education to improve VA employees' job performance and veterans' overall health care knowledge in addition to research (Veterans Millennium Health Care and Benefits Act, Pub. L. No. 106-117 § 204, 113 Stat. 1545, 1562 (1999)(codified at 38 U.S.C. §7361)). In 2000, revenue for educational purposes accounted for 1 percent of nonprofit corporations' total revenue.

Table 1: Funds Administered by VA Nonprofit Research Corporation by Source Types, 1996 to 2000 (in thousands)

Sources	1996	1997	1998	1999	2000
Private	\$36,685	\$46,321	\$57,903	\$63,413	\$64,492
NIH	4,553	13,147	14,961	15,513	28,081
University ^a	3,398	2,939	4,063	5,392	7,958
VA ^b	3,789	5,556	6,214	4,714	6,694
DOD	780	473	697	1,628	3,449
VA/DOD ^c	0	6,291	457	1,358	1,734
CDC	1,151	1,567	3,597	5,521	229
Other government	578	995	1,474	3,340	3,532
Other ^d	22,356	21,205	32,498	47,739	57,564
Total	\$73,290	\$98,494	\$121,864	\$148,618	\$173,733

^aThese funds include reimbursement for services that the nonprofit corporation provided to the university. For example, the nonprofit corporation charges the university a fee for running a test on a piece of equipment the corporation owns.

^bThese funds are for intergovernmental personnel agreements, which allow temporary reassignment of employees between VA and the nonprofit corporations.

^cIncludes initiatives such as VA/DOD research on post traumatic stress disorder.

^dThis includes interest from nonprofit corporations' investments and donors who gave less than \$25,000 to a nonprofit corporation in that year. Donors can include private companies, other nonprofit organizations, and individual donors.

Source: 2000 VA Non-Profit Research and Education Corporation Annual Report.

VA treats all funds administered by VA medical centers as appropriated funds, and medical centers are generally required to comply with statutory and other restrictions on the use of those funds, as well as with federal regulations governing procurement and the hiring of employees. Prior to the establishment of nonprofit corporations, VA administered research funding from external sources through special accounts at local medical centers—known as general post funds—or through its affiliated universities.

Flexibility Allows Nonprofit Corporations to Enhance VA Research

Nonprofit corporations provide a flexible funding mechanism to support the indirect cost of VA's research environment. For example, nonprofit corporations' funds can be used to renovate laboratory space and support start-up research to develop grant proposals. Nonprofit research corporations also have more flexibility with respect to personnel and procurement issues than VA medical centers because, as private corporations, they are not subject to federal personnel or procurement regulations.

The five nonprofit corporations we visited typically obtained donated and grant funds of between 10 and 20 percent of direct project costs to apply to indirect costs.⁷ According to the nonprofit corporations' executive directors we interviewed, these indirect cost rates are generally based on what other nonprofit organizations normally charge and not based on their actual indirect costs. These indirect costs include the costs for running the corporation, equipment purchases, facility upgrades, subscriptions to scientific journals, travel to research conferences, maintaining VA research libraries, and renovating and maintaining VA animal laboratories. Further, nonprofit corporations can use the funds they obtain for indirect costs to support research. For example, at one VA medical center, the nonprofit research corporation incurred \$8,451,000 in expenses in 2001, with \$7,693,000 spent on the direct costs of research projects; \$413,000 spent on corporation operating expenses, such as grant administration and payroll processing for research staff; and \$345,000 spent on activities and improvements to the medical center's research environment. Some of these activities and improvements included maintaining a clinical studies center, paying the salaries of a research science officer and assistant, and providing the "seed" or project start-up money for scientists to perform initial research to generate data necessary to apply for research grants.

According to VA's Office of Research and Development, the funds used by the nonprofit corporations to purchase equipment and maintain and upgrade VA's facilities allow VA to use more of its appropriated funds for conducting research. For example, at one facility we visited, the nonprofit corporation is renovating laboratory space necessary to conduct a VA-funded research project. While grants to affiliated universities can also be used to cover indirect costs of research conducted at VA facilities, VA officials told us that universities generally do not provide funding to help pay for VA's indirect costs; instead, they use it to support the indirect costs of the universities and their own research facilities. At another medical center, VA's Office of Inspector General suggested security improvements be made in research laboratories containing hazardous materials. About \$56,000 was needed from either VA's Office of Research and Development or the medical center to make these improvements. Instead, the nonprofit corporation provided the funding. This preserved the Office of Research

⁷One nonprofit corporation we visited, which administers grants from NIH, had negotiated about a 40-percent indirect cost rate with HHS and was reimbursed at this rate. These grants typically have higher indirect cost rates to help the grantee meet additional reporting requirements. Universities' indirect cost rates for these grants are typically over 50 percent.

and Development's funds for research and the medical center's funds for patient care.

In addition to the improvements in equipment, facilities, and research-related services, nonprofit corporations bring other benefits to VA's research environment. Because private nonprofit corporations are not subject to the regulations that govern federal agency hiring practices, they can hire and release employees more quickly than VA, which, according to researchers, can be more responsive to their individual project personnel and contracting needs. For example, at some of the VA nonprofit corporations we visited, the principal investigators stated that because funding for research is dependent on the number, length, and timing of grants received, they prefer to quickly hire research technicians and support staff after project funds are awarded and release them from the projects as soon as their work is completed. The principal investigators noted that if nonprofit corporations did not exist, it would take longer to begin the research because they would have to hire staff through VA. A medical center official reported that it usually took 6 weeks or more to hire a research employee through VA compared to less than a week through the nonprofit corporation.

Nonprofit corporations can also contract for goods and services more quickly than VA can because they do not have to follow the federal acquisition process. For example, two of the nonprofit corporations we visited were able to quickly order highly specialized digital, computerized microscopes needed by several research teams. Officials told us that based on their past experiences, if those microscopes had been purchased through VA's competitive process, it could have taken months to award a contract.

Finally, VA's research environment is key to attracting and retaining highly qualified physicians, according to officials at some of the medical centers we visited and in VA's Office of Research and Development. Investigators we interviewed said their research directly related to and benefited the care they provided to their patients, such as administering experimental research drugs for cancer. Some of the researchers we interviewed also noted that the nonprofit corporation's contribution to the local VA research facility was one of the main reasons they came to or remained at the facility. For example, at one nonprofit corporation we visited, the corporation renovated laboratory space needed to attract an investigator, who is also a physician.

VA Has Processes in Place to Help Detect Conflicts of Interest

Conflicts of interest can occur in connection with medical research when an individual or an institution has financial interests in the research. Conflicts of interest impair the conduct of objective, unbiased research and create the risk that an investigator will compromise a study's integrity to gain financial rewards or recognition. Investigators may establish financial relationships with donors—for example as employees, consultants, board members, or stockholders—as long as these relationships do not compromise, or appear to compromise, their professional judgment and the independence of the research.⁸ For example, an investigator's financial relationships must not bias or appear to bias the development of the study to ensure certain outcomes. A conflict of interest would also result if investigators reported only favorable research results or withheld certain study findings to maintain a competitive edge for the entities in which they have financial interests. Conflicts of interest have the potential to put study subjects and the general population at risk.

Investigators on research projects administered by VA nonprofit corporations must follow federal statutes and regulations applicable to federal employees concerning conduct and conflicts of interest. They cover, for example, restrictions on gifts from outside sources, the use of non-public information, and employees' financial interests.⁹ Because investigators design and control the research, they may also be subject to additional federal conflict of interest regulations. For example, principal investigators conducting research under NIH grants are subject to Public Health Service¹⁰ regulations, and investigators conducting pharmaceutical trials are subject to Food and Drug Administration regulations. These regulations require investigators to disclose their financial interests.

There are other conflict of interest procedures that investigators in some locations must follow. For example, investigators at three of the five VA nonprofit corporations we visited were required by the VA medical center or its affiliated university to disclose their financial interests related to each research project they conducted. At one of these locations, the corporation, the university, and VA formed a conflicts of interest

⁸U.S. General Accounting Office, *Biomedical Research: HHS Direction Needed to Address Financial Conflicts of Interest*, [GAO-02-89](#) (Washington, D.C.; Nov. 26, 2001).

⁹Applicable statutes and regulations include 18 USC §§ 202-209; 5 C.F.R. §§ 2634-2635.

¹⁰The Public Health Service, an operating division within HHS, includes agencies such as NIH, the CDC, and the Food and Drug Administration.

committee to review financial disclosures and identify and manage conflicts of interest. The results of these reviews are documented in the committee's meeting minutes and forwarded for review to the VA medical center's institutional review board (IRB).¹¹

Additionally, to guard against potential conflicts of interest, nonprofit corporation board members, officers, and employees must sign a certification that they comply with federal statutes and regulations on conflicts of interest; however, they are not required to file financial disclosure forms. Certain nonprofit corporation board members and officers are required to file financial disclosure forms because of their positions at the medical center. For example, a VA medical center's director and chief of staff, who also serve on the nonprofit corporation's board of directors, are required to file financial disclosure statements because of the positions they hold at the medical center. A VA official told us that there is no routine comparison of these financial disclosure forms and ongoing research projects at a particular facility.

While federal regulations govern the financial interests of individuals, no similar regulations apply to the financial interests of an institution. Institutional conflicts of interest occur when an entity's financial interests conflict with its goals of conducting and fostering objective, unbiased research. Financial interests may color an entity's review, approval, or monitoring of research conducted under its auspices or its allocation of equipment, facilities, and staff for research. Some institutions, such as universities, may obtain financial benefits from owning stock in a company that sponsors research or from owning patents that result from research. In contrast, VA nonprofit research corporations cannot own stock, have an equity interest in private companies, or own patents. Consequently, these types of institutional conflicts are unlikely to occur. VA nonprofit corporations may only invest in government-backed securities such as certificates of deposit or U.S. Treasury bonds. VA, not the nonprofit corporations, controls the rights to patents arising from research administered by nonprofit corporations. In addition, nonprofit corporations cannot accept funds to administer a research project unless the local VA medical center approves it.

¹¹IRBs are established to protect the rights and welfare of human research subjects. As part of its responsibilities, the IRB takes steps to manage, reduce, or eliminate potential or real individual and institutional conflicts of interest.

VA Headquarters Does Not Monitor or Oversee Nonprofit Corporations' Financial Activities

The Secretary of VA has delegated responsibility for overseeing and evaluating nonprofit corporations to the directors at local medical centers. This responsibility includes ensuring that deficiencies noted in audited financial statements¹² and management letters¹³ are corrected. VA requires that nonprofit corporations submit their audited financial statements and management letters; tax forms; and supplemental information on donors, payees, and research projects to the medical center's chief financial officer and the nonprofit corporation's board of directors—which must, by statute, include the medical center's director, chief of staff, and assistant chief of staff for research—for review prior to the issuance of VA's annual report to the Congress. At all five sites we visited, the nonprofit corporations provided their 2000 and 2001 audited financial statements as required, and all five received unqualified opinions on their financial statements, indicating that none contained material misstatements.¹⁴

We also reviewed a sample of the five nonprofit corporations' expenditures from their most recent annual financial statements—including those for travel, meetings, conferences, professional dues and memberships, publications, and office supplies—and generally found that the expenditures were related to research or to running the nonprofit corporation and were consistent with its internal control procedures. However, no standard body of rules exists that governs the type and amount of expenditures made by nonprofit corporations, although specific requirements may be established by the source of the funds. For example, if the nonprofit corporations receive funds from a federal agency, then the Office of Management and Budget Circular A-122¹⁵ applies, which does not allow certain expenses, such as for entertainment or alcohol. Other donors may place specific restrictions on the use of their funds.

¹²By statute, nonprofit corporations with more than \$300,000 in revenue in any year are required to obtain an independent audit of their financial statements. Nonprofits with annual revenues between \$10,000 and \$300,000 must obtain an independent audit at least once every 3 years. In addition, audits of nonprofits that expend \$300,000 or more in federal funding must follow generally accepted government auditing standards, which include reports on internal controls and compliance with applicable laws and regulations.

¹³Management letters identify needed improvements in internal controls, even though these control weaknesses do not have a material impact on the financial statements.

¹⁴The five nonprofit corporations' annual financial statements for 2000 and 2001 covered different time periods. Four used a calendar year cycle and one used a fiscal year cycle.

¹⁵Office of Management and Budget Circular A-122: *Cost Principles for Non-Profit Organizations*, June 1, 1998.

We reviewed a sample of travel expenditures—including the travel of members of the board of directors and executive directors—and found that while nonprofit corporations are not eligible for government rates, the rates they paid were comparable to the federal government’s rates for meals and lodging. Of the 66 travel vouchers we reviewed, only one first-class airline rate was charged and for only one segment of the trip because no economy seats were available.

In addition, we reviewed expenses related to meetings. They generally covered food and beverages provided at staff meetings, team building sessions, and dinners with potential recruits. The dollar amounts were typically a small portion of the nonprofit corporation’s total expenditures. For example, one nonprofit corporation with annual expenditures of almost \$8.5 million spent \$16,171 on these expenses. Another nonprofit corporation with expenditures of about \$25 million spent \$66,469 on these expenses.

Two of the five locations we visited received management letters from their independent auditors in 2000 and 2001, citing areas for improvement in internal controls. We found that these nonprofit corporations had either corrected or were in the process of correcting problems cited in the previous years’ management letters. For example, at one nonprofit corporation, the external audit of its year 2000 financial records found that it did not reconcile its general ledgers at month end in accordance with generally accepted accounting practices. Although the nonprofit corporation’s 2001 management letter still identified some problems with month-end reconciliations, the auditor noted that improvements had been made. While each nonprofit corporation submits its financial statements and management letters to VA, VA headquarters does not use this information to oversee and monitor the nonprofits’ financial activities and ensure that identified deficiencies are corrected.

According to VA, it relies in part on the VA Inspector General, IRS, GAO, and state and local authorities to identify fraud, waste, and abuse. However, officials at the five nonprofit corporations we visited stated that, for the last 5 years, their corporations have not been the subject of systematic review, although the VA Inspector General is currently investigating specific matters related to nonprofit corporations reported through its fraud hotline. The two largest corporations we visited stated that their state labor departments conducted reviews, but these reviews were limited to their personnel practices and records.

Concluding Observations

Nonprofit research corporations have become an integral component of VA's research agenda. From 1996 through 2000, research funding through the corporations at VA facilities increased by almost 140 percent and in 2000 stood at almost \$174 million. Because research administered by the nonprofit corporations can only support veteran-related research, such funding growth can significantly benefit veterans. Furthermore, the corporations have flexibility to use funding to initiate or continue VA-approved research and for enhancing infrastructure and making other improvements at VA medical centers. The ability to use funds this way provides seed money for new research ideas and attracts researchers who are also physicians involved in providing patient care to veterans.

Because of the large amount of funding that now flows through the nonprofit corporations, the absence of central VA oversight is not inconsequential. While the nonprofit corporations' financial statements are audited by independent auditors, they have not been subject to routine national oversight—such as through VA's Office of Research and Development—to identify areas for improvement and to ensure that the nonprofit corporations corrected the problems identified by independent auditors. Moreover, VA headquarters has not evaluated nonprofit corporations to measure their effectiveness or compare their operations. This type of high-level oversight and evaluation is a critical element of success. While medical center directors provide an essential and important overview function locally, they are not at arm's length from the nonprofits because of their close working relationships with them. As a result, VA headquarters could provide additional review, for example, by comparing financial disclosure forms and research projects at medical centers. VA headquarters could consider other oversight to better ensure that the benefits of nonprofit corporations are achieved in ways that safeguard VA's interests.

Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions you or other members of the subcommittee may have.

Contact and Acknowledgments

For further information, please contact Cynthia A. Bascetta at (202) 512-7101. Individuals making key contributions to this testimony include Michael T. Blair, Jr., Cherie' M. Starck, William R. Simerl, Michael Tropauer, Mary W. Reich, and Karen M. Sloan.